

ECHA Programming Document 2017 - 2019

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ECHA Programming Document 2017-2019

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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, Biocidal Products 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 Johannesburg World Summit on sustainable development (WSSD) in 2002.

ECHA's first Single Programing Document 2017-2019, which to a large extent is based on ECHA's Multi-Annual Work Programme 2014-2018, comprises the multiannual and annual section (Work Programme 2017) 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 2016 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 2017 will be adjusted accordingly.

The resource allocation for all activities under the BPR and PIC Regulations as described under the relevant sections of the Work Programme 2017 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 both 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
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
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

(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. Introduction

The multi-annual period of this Programming Document coincides with the timeframe in which the REACH regulatory processes, and with them the European Chemicals Agency, will have reached their full maturity. The coming three years will be shaped by intense activities mainly driven by the last REACH registration deadline in 2018 when a high number of low tonnage substances will need to be registered. As described below, many of ECHA's preparatory initiatives will be linked to this deadline.

Within this programming period, 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. At the same time, the Agency 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 its expertise, services and data towards other regulatory areas. As an underlying driver, the better regulation agenda of the Juncker Commission will be an important source of inspiration and ECHA will contribute where relevant. A good example will be the circular economy package adopted by the Commission in December 2015. An important highlight in the coming years will also be the evaluation of the REACH, CLP and BPR regulations under the REFIT programme of the Commission. Here, ECHA will provide its full support in order to ensure a further optimisation of this comprehensive chemicals management legislation.

2. 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 document all the information on the substance they manufacture or import in a registration dossier and submit it to ECHA. In order to promote the harmonised interpretations of data, and reduce registration costs and unnecessary 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.

2. Evaluation

ECHA and the Member States evaluate the information submitted by companies. 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.

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 and that the hazards are clearly communicated to workers and consumers in the European Union. ECHA manages the process with regard to harmonised classifications not only for industrial chemicals, but also for pesticides and biocides. By providing opinions of its Committee for Risk Assessment (RAC) on the proposals submitted by Member States and industry. In addition, it provides information on the classification and labelling of all registered and notified substances which can be used by industry, workers and the public at large. ECHA also 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, and after the opinion of the Committees for Socio-economic Analysis and Risk Assessment as well as 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 (Art 69(2)), 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 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 reguest, 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 impact 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, firstly to confirm if risk management processes need to be initiated, and secondly, to check which process is the most suitable. The process can also lead the conclusion that a substance is currently of no, or low concern.

ECHA's ambition is by the end of 2018, to gradually map 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.

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

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 evaluation processes or other means and, where concerns are confirmed, identify the most suitable regulatory instrument through the risk management option analysis (RMOA);
- 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.

3. 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, Biocides 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 backstop 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 the 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 judgements 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

Whilst the EU has the most ambitious chemicals legislation in the world, it is nevertheless not alone in seeking to reduce risk and have chemicals used more safely. 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 Rotterdam Convention, as well as SAICM².

4. ECHA's drivers

ECHA's work will be driven by many ambitions and regulatory obligations during the period 2017-2019. One of the most important drivers will be the successful completion of the phase-in period for registering substances under REACH and to manage the last registration deadline in 2018. Therefore, the Agency will reinforce its supporting activities in particular raising SMEs' awareness of the REACH obligations and helping SMEs in taking up their regulatory responsibilities by building on numerous information products and novel IT tools rolled out already in 2016. The main challenge for the Agency is to promulgate this support as widely as possible, also including reaching companies that are not fully aware of their obligations as manufacturers or importers of substances or as downstream users. In addition, ECHA will keep exerting its powers to raise the level of quality of the REACH registration dossiers via a revised completeness check process and the implementation of its compliance check strategy. At the same time the growth of the already extensive information on the properties of chemicals will intensify dissemination and data screening/analysis work.

While gaining more experience in identifying substances of concern, ECHA will step up its actions towards identifying relevant substances of very high concern (SVHCs) as part of the 2020 roadmap. As a result, REACH as well as BPR authorisations will provide for a continuous workload that will also be reflected in challenges to provide advice and assistance, which will evolve according to regulatory peak activities. In order to address the relevant substances of concern ECHA will focus on integrating the various REACH processes to ensure that ultimately human and environmental health are safeguarded from potential adverse impacts of chemical substances. In a similar manner, ECHA's communications will expand beyond specialised audiences to address

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.

the general public, consumers and end users while the work on the harmonised enforcement of the chemical regulations can be expected to intensify.

Within this programming period, ECHA will further contribute significantly to the EU commitment in relation to the "World Summit of Sustainable Development (WSSD) 2020" goals. Indeed, in 2002, the European Union and its Member States, made a commitment to the sound management of chemicals throughout their life cycle, "aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment." Achieving this "WSSD 2020 goal" will be an important driving force for the Agency when implementing its chemical regulations.

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 and through providing further support to companies in substituting hazardous substances with safer alternatives. 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 Commissioner Juncker'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 parallel aims, namely to increase innovation and competitiveness within the EU's chemical sector and to ensure a level playing field in the EU and EEA.

Furthermore, within the next programming period, the European Commission will assess the 5-years operation of REACH and publish its findings in 2017, building upon ECHA's own 5-year report on REACH and CLP implementation, published in May 2016. Within this context, the REACH regulation and the bundle of other EU legislation on chemicals will undergo an evaluation as part of the Regulatory Fitness and Performance (REFIT) programme. This will be followed by the Commission's review of the REACH legislation with a parallel assessment of the performance of ECHA.

In the years to come ECHA will also be taking on new regulatory tasks. The Agency will for instance provide tools, guidance and support to notifiers of information relating to emergency health response to the national poison centres who 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). In addition, ECHA will also anticipate and prepare for its future beyond the 2020 horizon. Focussing on its core strengths (Regulatory expertise, Good governance, IT and chemical information intelligence), it will ensure it can deliver "value for money" service to more harmonised and fit-for-purpose regulatory tasks.

These drivers, together with ECHA's experience gained thus far, are reflected in the four strategic objectives as described in the following section. At the same time, ECHA has started a process together with its Management Board to define a new strategic plan for years 2019-2023.

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 2017 - 2019

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 - specific indicator under development ⁴	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 High quality information for safe manufacture and use

REACH shifted the responsibility for establishing the safe use of chemicals to companies manufacturing and importing them. The information they provide needs to be compliant with the REACH information requirements, and fit-for purpose, 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 in a transparent way into adequate and reliable conditions of safe use. Also under the BPR, good quality data is a success factor as it facilitates the evaluation carried

⁴ Until 2016 the achievement of this strategic objective was monitored using an aggregated indicator focusing on data provided with respect to substance identity, uses as intermediates, hazards and classification. With the new 'Regulatory strategy' and changes introduced by IUCLID 6 the previous methodology and algorithms to quantify data availability and quality are no longer appropriate and hence have to be redeveloped for future use.

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 fundamentals 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 relating to compliance with the legal requirements. 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 of companies in their territory and will continue to support the coordination of enforcement across the EU/EEA through the work of the Forum.

The Agency provides advice and assistance to duty holders via guidance and helpdesk. Emphasis for these support activities will be 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 feasibilities 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 areas of operation:

- 1. Improving the quality of information in dossiers;
- 2. Maximising the impact of the communication of risk management advice in the supply chain; and
- 3. Improving the dissemination of information.

2.1.1 Improving the quality of information in dossiers

Preparation of dossiers

ECHA will further strengthen its efforts, in collaboration with its stakeholders, to support companies to meet their needs for submitting good quality dossiers towards the 2018 REACH registration deadline. This is to prevent, to the extent possible, compliance shortcomings that were found in dossiers submitted for the two previous registration deadlines and now require a lot of effort and time to bring the dossiers up to the required compliance. This will trigger a peak of enquiries reaching both ECHA and the national helpdesks. ECHA will support the national helpdesks via HelpNet and reinforce its training of the national helpdesks to further develop and increase their capacity to provide advice, and will continue to clarify the supporting documents and improve their accessibility. After the 2018 registration deadline, the level of advice and assistance needed will remain relatively high, with the focus shifting to proactive advice on dossier quality.

During 2017, ECHA will publish the remaining updates of the guidance on Information Requirements and Chemical Safety Assessment, in support of the 2018 registration deadline. Similarly, new guidance will continue to be developed addressing where appropriate changes in the regulations for which ECHA is in charge, for instance on information requirements for nanomaterials, including exposure assessment, as well as new or updated guidance on alternative methods and on substance identification.

In 2017, ECHA intends to further facilitate SMEs in fulfilling their obligations. The accessibility and sustainability of the ECHA IT services for registration will be enhanced by launching an online secure service called ECHA Cloud Services for SMEs. The Cloud Services will be offered free of charge to SMEs only; through stepwise implementation it will offer to SMEs the functionalities needed for preparation of a registration dossier. This service will undergo an ex-post evaluation in 2019; in that context the future roadmap for the IUCLID tool and the Cloud Services model will be subject to a reflection for a possible convergence. In addition, ECHA will continue to support the OECD in the promotion of IUCLID as an international tool. This is particularly relevant for enabling better data exchange and sharing data analysis methods and experience across regulatory bodies worldwide, hereby increasing the efficiency of all parties, companies submitting data and authorities.

ECHA will also support industry in fulfilling their obligations under the CLP Regulation and stimulate relevant updates within the Classification and Labelling Inventory. Also for the Biocidal Products Regulation, the Agency will keep developing and improving its guidance documents, submission IT tools and manuals for the submission of biocidal dossiers and support the many SMEs that operate in this sector.

Submission of dossiers

The quality of dossiers is also tackled at the point of submission of dossiers. In its preparations for the 2018 registration deadline, ECHA will have made its IT systems through which registration processes are initiated (e.g. REACH-IT) more user-friendly, allowing a more flexible interface and communication channel with registrants.

The completeness check that ECHA performs is an important step in enforcing conformity of the registrations. In addition to the revised automated completeness check, ECHA will verify manually the completeness of certain data elements, in particular the identification of the substance and justifications for deviating from standard information requirements. This work is expected to reach a major peak in 2018, but will remain at a high level post 2018 to also address the updated dossiers. In addition, further to the clarification brought by the Board of Appeal decision⁵, similar verifications will be done retroactively on dossiers in the database that are not updated, verifying also that the registrants registered jointly for the same substance. Registrations that are not completed within the deadline will be revoked. These enhancements of the completeness check are expected to have an important positive impact on the quality of the information. To help registrants, ECHA will continue to maintain its Validation Assistant tool that enables companies to verify that frequently occurring shortcomings are appropriately addressed.

Post submission, ECHA will continue to screen and analyse the registration information for different regulatory purposes. The selection and priority setting will need to be adapted to the information available for substances registered in low tonnages so that the prioritisation work can start swiftly in 2019. Where relevant, targeted campaigns (for example to specific sectors) will continue to be used to stimulate dossier updates for substances that are short-listed for dossier evaluation or present clear deficiencies. Substances registered for intermediate use only will continue to be screened systematically. These data analysis and screening activities are expected to grow post 2018 as the volume of information contained in ECHA databases will have significantly increased.

Evaluation of dossiers

Evaluating the content of dossiers is the main way in which ECHA can ensure that information gaps are filled and provide confidence in the compliance of registrations with the legal requirements. The resulting decisions requesting further information will significantly contribute to the improvement of the overall information quality.

⁵ BoA decision of 15 March 2016 relating to case number A-022-2013: http://echa.europa.eu/documents/10162/13575/a-022-2013_decision_en.pdf

ECHA will continue to examine the compliance of dossiers - based on a selection using concern-based criteria as established in the compliance check strategy and target selected elements in the dossiers that are particularly important for the safe use of a substance. This concern-driven approach will further increase the proportion of examinations of high volume chemicals far above the regulatory minimum of five percent of dossiers per tonnage band.

The Agency will be using increasingly sophisticated scientific IT tools to systematically screen all higher tier hazard endpoints in the registration dossiers in order to implement its concern-driven compliance check strategy. Ultimately, the outcome of this strategy will ensure that the intrinsic properties of substances that matter have been adequately documented. ECHA will continue to inform and engage with both the Member State competent authorities and the Member State Committee on a regular basis so that the evaluation decision-making will work in the best possible way. Dossier evaluation will not hesitate to address scientifically challenging issues, including evaluation of dossiers on substances in nanoforms.

In addition to issuing formal and legally binding decisions, ECHA wants companies to update and improve their dossier quality proactively. To this end, ECHA will communicate actively dossier evaluation findings for example via its annual Evaluation report (Art 54 of REACH).

ECHA will assess registrants' updates after an evaluation decision as quickly as possible after the deadline set in the decision. ECHA will notify the Commission and the Member States of the information obtained and on its conclusions regarding the need for any risk management measures and communicate promptly with the national authorities in order to ensure maximum efficiency in enforcing decisions. Ultimately, ECHA will consider declaring a registration invalid if compliance with REACH information requirements cannot otherwise be implemented.

ECHA will also share experiences from REACH dossier evaluation processes with the national authorities and the Biocidal Products Committee when analysing alternative options for more speedy processing of active substances and biocidal products.

Strategic action area 1.1 Improving quality of information in dossiers			
Priority area	2017	2018	2019
Preparation of dossiers	Communication activities to reach out to companies who are unaware of their responsibilities, or are inexperienced in REACH. Training (update) of national helpdesk correspondents on dossier preparation Webinars and workshops for 2018 registrants Third Article 117(3) report published Launch of ECHA Cloud Services for SMEs. Adaptation of the inquiry process following closure of the pre-registration possibility	Cloud services are delivered to SMEs	OSAR Toolbox enhanced version published, extending its applicability to other types of substances (e.g. inorganics and nanomaterials) and higher-tier endpoints. ECHA Cloud Services undergoes an ex-post evaluation and a roadmap for the service and the IUCLID tool is defined
Submission of dossiers	Outreach campaign in preparation of the 2018 deadline REACH-IT: Further simplified online functions for submitting dossiers (DCM) Annual letter campaign on short-listed priority substances. First experiences with the retroactive check of the completeness of the registrations over 100 tonnes analysed and work initiated for checking	Successful management of the 2018 registration deadline Annual letter campaign on short-listed priority substances.	Priority setting methods adapted to information available for substances registered in low tonnages, especially 1-10 tonnes Systematic screening of 1-10 tn and 10-100 tn dossiers initiated to support priority setting for evaluation. Manifestly incomplete dossiers for the key human health and

⁶ Where relevant ECHA will also verify reliability and integrity of toxicological and ecotoxicological data in line with the principles of Good Laboratory Practice (GLP)

Strategic action	Strategic action area 1.1 Improving quality of information in dossiers			
Priority area	2017	2018	2019	
	all dossiers for the key human health and environment endpoints Retroactively address multiple registrations for the same substance Training (update) of national helpdesk correspondents on dossier submission First experiences of sector pilot approaches that started in 2016 analysed and work with next sectors initiated.		environment endpoints addressed	
Evaluation of dossiers	At least 100 priority substances of concern addressed under CCH, in accordance with the set priorities. Testing proposals re-submitted in 2016 on reproduction toxicity concluded (DDs issued). Review of the CCH strategy and priorities.	At least 100 priority substances of concern addressed under complementary measures or CCH, in accordance with the refined priorities set in 2017. More than 10% of the priority substances (over 100 tn) checked for compliance for the key human health and environment endpoints 7. Plan for compliance checks 2019-2020 established.	At least 100 priority substances of concern addressed under complementary measures or CCH, in accordance with the priorities set in the CCH plan 2019-2020.	

2.1.2 Maximising the impact of the communication of risk management advice in the supply chain

The focus of ECHA's action will be 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. This will include dialogues between ECHA and sector organisations and further actions to stimulate a demand for good quality information on safe use in the market.

Exposure scenarios and safety data sheets

It is essential that the exposure scenarios included in the chemical safety reports (CSR) are transferred into good quality exposure scenarios for communication in Safety Data Sheets (SDSs). Downstream end-users of substances (and mixtures) should receive information relevant to them in a more consistent and useable form. Therefore, as part of the CSR/ES Roadmap (updated in 2016) ECHA will keep supporting registrants and downstream users to adopt the methods, tools and standardised formats developed under the roadmap. ECHA will also continue to promote the development of use-map tools and information for downstream user sector organisations, and their uptake by REACH registrants. Given the important role of mixtures in the supply chain, special attention will be paid to the implementation of a scientifically sound methodology for converting exposure scenarios for substances into information on the safe use of mixtures that can be easily understood.

Based on an evaluation of the CSR/ES Roadmap conducted in 2016, ECHA will further stimulate and broaden the information exchange system with specific focus on downstream industry (including article producers). Ultimately these downstream users will experience the benefits of the information exchange for their risk management measures (i.e. related to product safety and site-specific measures) and their regulatory obligations towards other chemicals-related legislations. ECHA will also continue to work to promote the communication and sharing of

⁷ 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

information among industry and between industry and authorities on the effective implementation of exposure scenarios as a novel communication vehicle (e.g. via the ENES⁸ platform or the downstream users communication campaign). Discussions with the enforcement authorities will take place to address specific sectors where problems with the implementation of the exposure scenario concepts have been identified (e.g. in the context of the REF-5 project focusing on extended safety data sheets).

Substances in articles

Article producers can benefit from the information generated for REACH to comply with other legal requirements (e.g. the construction product directive or the toys directive). ECHA will examine, together with the Commission, national authorities and sector organisations, ways in which the practical implementation of these legal requirements can be brought together. ECHA will raise the awareness of article importers on the potential risks of substances in articles, on the existing restrictions and on the communication and notification obligations on the Candidate List substances. Specific work with sector organisations will help article importers to identify the substances present in their articles. Finally, ECHA will explore ways of improving the overall knowledge on the presence of and risks related to substances in articles and how this knowledge can be made available to the relevant actors, including the general public. The involvement of enforcement authorities as well as the customs authorities is crucial in order to assure that substances in imported articles fulfil the REACH requirements. To enhance this, the Forum will start a pilot project on substances in articles in 2017.

The BPR contains new and extensive requirements for treated articles. According to the regulation, articles can only be treated with biocidal products containing active substances approved in the EU. There is also a new requirement concerning the labelling of treated articles. The implementation of these provisions needs to be supported by regulatory advice, guidance and awareness raising activities in cooperation with the Commission and the Member States.

Strategic action area 1.2 - Maximising the impact of communication of risk management advice in the supply chain			
Priority area	2017	2018	2019
Exposure scenarios and safety data sheets	Based on the evaluation of CSR/ES Roadmap in 2016 adapt the outreach activities to downstream users in key sectors and prepare the next stage the CSR/ES Roadmap	Perform activities in line with the 2016 review of the CSR/ES Roadmap	Perform activities in line with the 2016 review of the CSR/ES Roadmap
Substances in articles	Review of the SiA notification support tools, including information on SVHCs in materials Outreach activities to importers and manufacturers in key sectors Implement enforcement pilot project on substances in articles.	Forum pilot project focusing on substances of concern in articles	

2.1.3 Improving the dissemination of information

Dissemination of substance information

Transparency provides an important incentive for companies to provide reliable, scientifically sound and understandable data that will uphold their reputation of being compliant with the EU chemicals safety regime. Industry and civil society themselves can scrutinise the information and

⁸ Exchange Network on Exposure Scenarios: http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

draw attention to any incoherence or inadequacies. ECHA is committed to making the best use of the unique data generated by companies in response to the EU chemicals legislation.

ECHA publishes and updates information on all registered substances and notified substances to the classification and labelling inventory on its website. This information is complemented by other types of data resulting from ECHA's regulatory activities, such as the Community Rolling Action Plan, the Candidate List of substances of very high concern, the list of authorisations and restrictions. To give predictability to registrants, the Agency maintains on its website the Public Activities Coordination Tool (PACT) that provides advance notice of the substances that are on an authority's radar for exploring the potential need for regulatory risk management.

The focus in 2018-2019 will be on publishing the information from the 2018 registration deadline, including the assessment of confidentiality requests. This goes a long way to fulfilling one objective of REACH, namely granting EU citizens "free and easy access to basic data on chemicals" in order to "allow them to make informed decisions about their uses of chemicals". As this information is scientific and technical in nature, ECHA has revamped its dissemination platform in 2016 to make it more easily accessible for wider audiences. ECHA will further strive to integrate the information on substances arising from different legislations and regulatory processes (e.g. informing on ongoing dossier evaluation running on specific substances) so that users can easily obtain an overview of the available data for that substance.

ECHA anticipates that dissemination activities, data delivery in general and synchronisation with external services and sources will increase over the planning period with many demands arising from authorities, third parties and from companies themselves. In this context, ECHA will prepare in 2018 and 2019 the provision of registration data for registration purposes as the data protection starts gradually expiring from 2020 onwards.

Over the years, ECHA's website has become a focal point for information on chemical properties as well as a major hub demonstrating how they are regulated under the Agency's four main legislations. ECHA will further expand this central data management and dissemination role by exploring integration and synergies to other EU legislations in the period post 2018. The ultimate aim is to increase consistency and transparency in chemicals management, hereby increasing the safe handling of chemicals. For this purpose ECHA will conduct, in cooperation with the European Commission, a feasibility study in 2016-2017 to assess whether further services can be developed leveraging the data management and dissemination capabilities of ECHA.

Strategic action area 1.3 – Improving the dissemination information			
Priority area	2017	2018	2019
Dissemination of substance information	Feasibility study on extending the dissemination website with an "EU chemicals legislation finder", i.e. giving overview on how a substance is regulated at EU level Explore the possibilities of linking with websites providing information on products – or incentivise the production of a new site - to maximise the use of ECHA's data for citizens	Dossiers from 2018 registration deadline published and linked to eChemportal for maximising public availability of information on chemicals	Pending the outcome of the feasibility study on the "EU chemicals legislation finder", gradual extension of the Dissemination website

2.2 Using information intelligently to identify and address chemicals of concern

Under REACH and CLP, it is the individual Member States and the Commission who 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 proportionate and 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 will be 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 be contributing significantly to the promotion of the substitution of the most dangerous substances in the EU. Via the common screening approach, ECHA will keep involving Member States in identifying the substances of potential concern that deserve dossier or substance evaluation to clarify the concern and relevant regulatory action after a risk management option analysis.

The Biocidal Products Regulation 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 Biocidal Products Regulation 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 areas of operation:

- 1. Mobilising authorities and aligning views;
- 2. Identification of substances for regulatory risk management; and
- 3. Addressing identified concerns through REACH, CLP and other legislation.

2.2.1 Mobilising authorities and aligning views

Member States not only play a central role as initiators of the risk management processes under REACH and CLP, they also provide experts to the ECHA Committees and are key players when the outcome of the process is put forward for regulatory decision-making and for enforcing the existing and new requirements. Quick, efficient and successful implementation only works if the understanding and views on priorities for regulatory risk management actions are aligned to the greatest extent possible.

The cooperation and coordination among Member States, ECHA and the Commission which has substantially increased over the last years through the establishment of expert 9 and coordination 10 groups to support the implementation of the SVHC Roadmap. These expert and coordination groups facilitate discussion and enhance consensus among MSCAs on which substances matter most and help avoiding overlapping work and gaps. Moreover, through this work the pool of Member States actively contributing to risk management processes is expected to increase further.

By integrating and streamlining the common screening, evaluation and risk management processes, ECHA in cooperation with Member States and the Commission aims to shorten the time between the identification of concern and the adoption of the most appropriate EU-wide regulatory risk management measure. A policy agreement of suitable substances for the authorisation list would also streamline the process and orient it to a workable substitution drive

⁹ PBT and ED expert groups

¹⁰ CMR and Sensitisers and other equivalent level of concern coordination groups, petroleum & coal stream substances coordination group

of SVHCs. By encouraging the applicants to focus their applications for authorisation on the analysis of alternatives the process will give a concrete boost to innovation and the competitiveness of European industry.

All of ECHA's Committees under REACH and CLP (MSC, RAC, SEAC) are involved in the risk management processes according to their respective competences. Therefore, the ECHA Secretariat will continue to inform the Committees on the relevant policy developments and choices made. In addition, Member States will need to provide scientific and technical support to the members of the Committees.

The intelligent use of information also comes into play with enforcement. In the coming years, ECHA will intensify its support to the national enforcement authorities dealing with REACH, CLP, PIC and BPR, including developing a common understanding on enforcement needs and priorities.

Strategic action	Strategic action area 2.1 – Mobilising authorities and aligning their views			
Priority area	2017	2018	2019	
Mobilising authorities and aligning views	Review of the co-operation supporting the SVHC roadmap implementation Results of the second enforcement pilot project on authorisation and implement the pilot project on CLP addressing internet sales of chemicals. Enforcement Projects (implement REF-5 and prepare REF-6) Reinforce institutional interlinks between ECHA and national enforcement authorities	Progress review on the SVHC roadmap and reaching the WSSD 2020 goals Enforcement Projects (implement REF-6 and prepare REF-7) Results of the enforcement pilot project on substances in articles.	Review workshop(s) on the SVHC roadmap and reaching the WSSD 2020 goals Enforcement Projects (implement REF-7 and prepare REF-8)	

2.2.2 Identification of substances for regulatory risk management

ECHA has set up the common screening approach to support the identification of substances for inclusion in the Candidate List and for further work under other REACH and CLP processes and to find the best combination and order of the follow up actions.

In the coming years the Agency will continue to focus on newly identified substances that may give cause for concern and for which there are no (or limited) regulatory risk management measures in place. It will use the information included in the current registration and classification databases, which are already the largest in the world. It will furthermore strive to bring in information from other sources, including those from other regulatory bodies, to enhance the knowledge on the potential uses that may lead to substantial exposure of workers and consumers or the environment. In addition, further action will be taken to ensure that when substances that might need regulatory intervention are identified during 'regular' evaluation processes this knowledge is efficiently fed back to common screening activities and shared with the Member States.

In line with the SVHC roadmap 2020 implementation plan ECHA will, with the help of scientific experts groups, continue to focus on identifying substances of equivalent level of concern to CMRs and PBT/vPvBs¹¹ and such as endocrine disruptors. The Agency will also strive to identify and understand if there are technically and economically suitable substitutes that the EU industry could adopt in a pro-active manner.

¹¹ Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative.

The screening activities will be automated where possible and ECHA will further intensify the development of a solid and integrated IT database and flexible IT screening tools to ensure that the MSCAs and ECHA can fully benefit from the information provided.

Overall, addressing information gaps and improving quality of information in dossiers based on the REACH compliance check and substance evaluation is essential for effective regulatory risk management decisions. Such decisions may also result in additional operating conditions or risk management measures at company level, or in decisions to substitute with alternatives. Substance evaluation allows requesting information which goes beyond the standard information requirements, to clarify a potential concern for human health or the environment. Substance evaluation will include evaluation of substances in nanoforms and thereby contribute to advancing the information and understanding of hazards and risks posed by nanomaterials.

Strategic action area 2.2 Identification of substances for regulatory risk management			
Priority area	2017	2018	2019
Screening	Revision of the screening scenarios to identify substances that matter most to take into account the changed IUCLID 6 and 2018 registrations	Start screening substances registered by 2018 deadline 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	
Criteria, approaches and tools	Annual report on 2020 SVHC roadmap implementation	Annual report on 2020 SVHC roadmap implementation	Annual report on 2020 SVHC roadmap implementation
Filling information gaps	Implementation of the recommendations of the first review of the Substance evaluation process	Second review of the substance evaluation process (2015-2017)	Implementation of the recommendations from the second review

2.2.3 Addressing identified concerns through REACH, CLP and other legislation

Based on the results of the screening and subsequent activities, authorities should be able to conclude on the best risk management option to address the identified concerns. In the context of the SVHC 2020 Roadmap 12 developed by the Commission together with ECHA and the Member States, the RMO analysis framework will be regularly reviewed allowing authorities to efficiently make informed choices. In addition to continuing with its own efforts in developing RMO analyses as well as SVHC and restrictions dossiers, ECHA will continue to play an active role in coordinating the actions foreseen under this roadmap to ensure that all relevant substances of concern are identified and addressed via the most appropriate risk management route. At the same time ECHA will keep on developing recommendations for adding substances to the authorisation list. The actual number of dossiers with proposals for identification as SVHCs, harmonised classifications or restrictions that ultimately will need to be managed depends on the conclusions of the more than 400 RMO analyses that are foreseen to be carried out until 2020.

ECHA will work together with the Member State authorities to reach agreement on the general principles for selecting substances for which the process of harmonising their classification and labelling at EU level should be initiated. In general, efforts will be made to substantially reduce the overall processing time for dossiers proposing harmonised classification. In addition, the information in the C&L Inventory will be analysed to identify priorities for efforts by industry to agree on their self-classification.

¹² Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020

ECHA will continue to work with the Commission, Member States and stakeholder organisations to ensure further streamlining and focusing of the application for authorisation process taking account of the experience gained in the first years. In addition, ECHA will further explore its options for providing more extensive and specific support to companies in substituting SVHCs substances with safer alternatives. In relation to the work of its committees, the Agency continues to operate in a transparent manner while aiming to further increase the efficiency of the submission process for applications for authorisations and the opinion forming of RAC and SEAC. At the same time, it will endeavour to increase the availability of high quality information to allow potential applicants to analyse alternatives to substances of very high concern and thus make an informed decision on whether to substitute or to apply for an authorisation. This information will allow ECHA's scientific committees to conclude on applications efficiently.

ECHA will continue to actively use its website during the public consultation on the substance and its alternatives to ensure that, to the extent possible, all relevant information on suitable alternatives is available to support the opinion forming process. Where feasible, active participation of those companies producing the alternatives will be encouraged. In a similar manner, ECHA will further support applicants, in particular downstream users, so that good quality and fit-for purpose applications can be submitted in a cost-effective manner. ECHA also will work with its stakeholders to ensure that fit-for-purpose information on alternatives is available to potential applicants and effectively fed into the opinion forming process.

Successful implementation of the 2020 SVHC Roadmap will most likely lead to an increase in the number of restrictions. This will also oblige Member States to become more efficient and develop more targeted approaches and follow up on the recommendations developed by the restrictions efficiency task force. ECHA expects that in this period the first proposals to restrict the use of substances in imported articles after the sunset date, will be decided upon and new proposals will be put forward.

When considering regulatory action it may be the case that REACH is not the most effective solution to address concerns about the impact of a substance through a specific use. In those cases, ECHA will liaise with the European Commission and other relevant authorities about the need to use legislative or other regulatory action. In the same way, it is possible to use REACH to manage environmental or health concerns identified during the implementation of other EU legislation. This could lead to requests for information on registered substances or even requests for ECHA to prepare Annex XV restrictions or SVHC dossiers, or to suggest that MSCAs take action in the context of REACH (e.g. substance evaluation or classification).

ECHA will work together with the European Commission to increase the understanding of how REACH could support other EU legislative processes (e.g. for carrying out the workers risk assessment under the Occupational Health and Safety Legislation) and contribute to developing effective communication between the relevant parties. Where relevant and appropriate, ECHA will explore ways of enhancing the coherent implementation of the different pieces of Union legislation related to chemicals.

ECHA will start developing an effective and pragmatic approach to prepare the support to the Biocidal Products Committee and its working groups for the Union authorisation process. In this context, ECHA will look at the experiences gained in mutual recognition of national authorisations.

Strategic action area 2.3 Addressing identified concerns through REACH, CLP and other legislation			
Priority area	2017	2018	2019
Through REACH & CLP	Analysis of the possibilities to improve the C&L inventory, joint communication campaign with stakeholders, MSCAs and COM Conference on lessons learned of the applications for authorisation	Report on the identification of technically feasible and affordable substitutes	

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
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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 holds 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 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. 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:

- 1. Expertise and capacity building;
- 2. Serving as a hub for excellence in regulatory science; and
- 3. ECHA's Regulatory Science Strategy.

2.3.1 Expertise and capacity building

ECHA has a competence management framework to identify the needs for sustained capacity-building and support their implementation as an integral part of the overall strategic and day-to-day management. This framework ensures that ECHA remains proactive in adapting its scientific and regulatory capacity through training and development to meet the new competence challenges it will be facing in the near future. Examples of areas where science is rapidly moving forward include alternative testing methods, including in vitro techniques, read across and QSARs, and nanomaterials. Due to the dynamic nature of the progress in science and in the regulatory field a regularly reviewed competence mapping will provide a basis for the framework.

Competence mapping enables the identification and prioritisation of the needs for development in the medium term. This enables the Agency to prepare for its operational needs and foreseen medium and longer-term challenges in its regulatory activities (e.g. the update of work plans for nanomaterials or test methods, development of approaches for addressing endocrine disruptors, or guidance development in relevant areas). Both the mapping and the implementation plan for

capacity building will be revised on a regular basis in support of the continuous professional development of skills of ECHA's staff. This will encompasses training and development, including active participation on scientific and professional meetings and workshops, co-authoring scientific papers, lectures by invited experts and professional accreditation schemes.

ECHA's Scientific Committees are producing a major part of its scientific output via Committee opinions and agreements. The Committee members also hold an invaluable amount of scientific knowledge and expertise that is already part of the shared competence asset supporting ECHA. In its competence development activities ECHA also takes into account Member State authorities and other key partners to enable efficient coordination and optimal use of resources of all relevant actors.

The expected benefits of this activity include ECHA having the capacity to rapidly transfer the latest scientific knowledge in emerging areas into its guidance, advice, and tools for industry, into its regulatory opinions and decisions, and in the advice and support given to the EU institutions.

Strategic action area 3.1 – Expertise and capacity building			
Priority area	2017	2018	2019
Expertise and capacity building	Review of the competence management framework Action plan prepared to ensure adequate scientific and regulatory capacity relevant for circular economy. Annual training programme for inspectors delivered to a group of national trainers	Improvement actions completed to ensure ECHA's staff capacity to assess alternative methods and approaches. Annual training programme for inspectors delivered to a group of national trainers	Action plan prepared to ensure adequate scientific and regulatory capacity for ECHA post-2020, including for potential new tasks. Annual training programme for inspectors delivered to a group of national trainers

2.3.2 Serving as a hub for excellence in regulatory science

A strong element of the third strategic objective is ECHA's aspiration to become a hub for the scientific and regulatory capacity-building of Member States, European institutions and other actors. This also involves a strengthened interface with the scientific community, international organisations involved in chemicals assessment such as OECD and WHO, and ECHA's international partners. This external orientation is justified as the scientific and regulatory issues that the Agency faces are in most cases similar to those faced by its external partners and stakeholders. The competence management framework, as described above, is considered to be a prerequisite of the external dimension of ECHA's capacity-building.

Within the "hub concept" ECHA will continue to provide a platform and network of expertise for where its experts can convene with peers from Member States, the European Commission, other Agencies, international organisations and academia to address relevant topics. ECHA's scientific activities will be strongly need-oriented and serving the regulatory decision-making and scientific opinion-forming of the Agency. This also includes the scientific advice provided to the European Commission (e.g. in the development of internationally accepted test guidelines). ECHA has multiple elements and structures in place that are exemplifying the "hub concept" such as for example the various expert groups (e.g. PBT, nanomaterials) and its topical scientific workshops. Similarly, ECHA is contributing to, and benefiting from activities hosted by other actors; examples include Commission work on endocrine disruptors and combination effects, IATAs (Integrated Approaches to Testing and Assessment) and OECD work on adverse outcome pathways.

In addition, this approach means strengthening and developing activities already in place under the agreements or memoranda of understanding with other relevant EU and international partners. In particular, ECHA will continue to invest in further developing the partnership and cooperation with the Commission's JRC, to maximise the synergies of combining R&D and regulatory activities in the areas of alternative test methods, computational toxicology and other non-testing approaches, integrated testing strategies, as well as nanomaterials.

Applications for authorisation and restrictions require up-to-date knowledge and skills on regulatory impact assessment, including socio-economic analysis. Therefore, ECHA has been upgrading systematically the skills of the members of its scientific committees, in particular, SEAC and its own staff, as well as the staff of Member States. It plans to continue to do so and will also continue to work together with organisations outside the EU both bilaterally and through international bodies such as the OECD. ECHA will continue to have research projects on the technical and economic consequences of using alternative substances and technologies, the values that would be used to estimate human health or environmental impacts of chemicals regulation and to learn lessons from different impact assessments of the management of risks related to chemicals in the EU and elsewhere. ECHA will also continue to collaborate with academic networks and associations in risk management, analysis of alternatives and economic analysis, including the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP). NeRSAP meetings are intended to be held about once a year hosted by an industry stakeholder, Member State and ECHA in a rotating manner.

To facilitate a closer dialogue between academia and regulatory science, ECHA will continue organising topical scientific workshops, e.g. with a view to assess the regulatory impact of the latest scientific developments on a specific area and how they could be transferred to methodologies applied and guidance and tools developed by ECHA. The workshops will have a strong regulatory perspective and high visibility. In the same way, ECHA will also keep on participating and contributing to equivalent initiatives from other relevant actors.

Topics in regulatory science of high priority, in the future, include endocrine disruptors, combination effects, read-across/grouping of substances, integrated testing strategies, non-standard methods for information for the 2018 registrations and dealing with uncertainty in predicted properties for risk assessment and classification. Also with regard to nanomaterials, while noting that the legal text should be clarified, ECHA will further aim to ensure that the regulatory requirements of REACH, CLP, and BPR can be implemented to address the hazards and risks of substances in nanoform and keep extending its capacities where relevant. Special attention will be given to scientific and regulatory activities, including guidance, at the EU and OECD level in the field of safe use of nanomaterials.

Overall, the expected benefits of this area of operation include:

- optimisation of capacity building between key players, avoiding gaps and unnecessary overlaps;
- more focused cooperation between ECHA, other relevant EU agencies, international organisations, and ECHA's international partner organisations;
- more rapid integration of scientific development into regulatory decision-making, including accelerating the regulatory acceptance of alternative testing and assessment methods, and integrated testing strategies especially with a view of the 2018 registration deadline.

Strategic action area 3.2 – A hub for excellence in regulatory science							
Priority area	Priority area 2017 2018 2019						
Hub for excellence in regulatory science	1 regulatory science workshop Actions resulting from the 2016 ECHA report under Art 117.2 of REACH 3rd Report on use of alternatives under Art 117.3 published. Report on the regulatory applicability of alternative and non-animal approaches published.	1 regulatory science workshop Overall plan to update ECHA guidance to latest scientific developments.	1 regulatory science workshop Regulatory science cooperation with international partners reviewed.				
Socio- economic analysis	Launch of collaborative research on the valuation of human health impacts of chemical exposure.		Results of the research on values available published and disseminated				

2.3.3 ECHA's Regulatory Science Strategy

The scientific credibility of ECHA requires the active involvement of its staff in the new developments in regulatory science areas of hazard / risk assessment and risk management. Based on its Regulatory Science Strategy, ECHA will aim for clear and consistent prioritisation of contributions to research activities, such as those under the Framework Programme projects and Horizon 2020. As ECHA cannot use its resources to carry out research itself, the participation is normally foreseen in the form of membership in steering boards, and contributing to project plans and research programmes to ensure regulatory relevance of these activities. In addition, publication and dissemination of scientific assessments arising from ECHA regulatory work will be further stimulated. Furthermore, based on its strategy, ECHA will strive to facilitate research projects to benefit from ECHA's databases and information assets and will further support the current ECHA graduate scheme to promote career development of young regulatory scientists.

The expected benefits of this area of operation include:

- more coherent and visible priority setting and approaches for contributing to scientific developments, including cooperation with key scientific societies and associations;
- increased awareness among the scientific community about the regulatory relevance of various research activities, and a shift towards problem formulation and research funding for regulatory work.

Strategic action area 3.3 – ECHA's Regulatory Science Strategy					
Priority area	2017	2018	2019		
ECHA's Regulatory Science Strategy	Review of the Science Strategy taking into account the 2016 ECHA report under Art 117.2 of REACH and the 2020 "REACH" goals	Updated communication from ECHA towards research community on R&D needs serving ECHA's priorities.			

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 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.

With the experience and expertise gained since its foundation in 2007, the Agency 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. ECHA will further strengthen its capabilities and expertise in the area of chemicals management. Activities such as supporting the European Poison centres, where ECHA will in addition to maintaining tools, formats and a European Product Category system for the notification of information on mixtures classified as hazardous for the purposes of emergency health responses, further offer its know-how and IT infrastructure to the benefit of all parties dealing with these notifications, is one example how ECHA can offer leverage towards optimising and reinforcing other regulatory support activities within the EU (in this case the forthcoming amendment of the CLP regulation). Under this strategic objective ECHA anticipate to address such future opportunities for example via Management Board workshops and feasibility studies.

The overall implementation approach is divided into the following action areas of operation:

1. Maximising the effectiveness and efficiency of existing and new work processes;

- 2. Delivering integrated and re-usable IT systems and services; and
- 3. HR policies and initiatives for maximising the potential of staff members and coping with decreasing staff levels.

2.4.1 Maximising the effectiveness and efficiency of existing and new work processes

ECHA will keep working on improving the efficiency and effectiveness of all its four pieces of legislation (REACH, CLP, Biocides and PIC). Where possible, relevant improvements in particular processes and tools will be expanded to fertilise across the various regulatory domains and to ensure overall improvement across sectors. In a similar manner, further efficiencies will be pursued through linking information and databases on chemicals overall. Within its continuous strive for improvement, refinement and/or re-engineering of many processes is foreseen. The aim will be to make any necessary changes well before the run up to the 2018 REACH deadline. Especially, in light of this milestone, ECHA will continue improving its customer experience with specific attention to the needs of SMEs.

In the area of biocides ECHA will continue working to improve the efficiency within the review programme of active biocidal substances in cooperation with the Member States. These efficiencies remain crucial both from the point of view of achieving the desired impact of the BPR, and also has a direct impact on future fee income for ECHA arising from subsequent product authorisation. While gaining experience with the first applications for Union authorisation, the Agency will focus to refine and improve these processes. This is important in anticipation of the foreseen increase in applications and workload both for ECHA and for Member States.

ECHA will also review the overall effectiveness and efficiency of the work processes that involve the other European regulatory actors: the European Commission and the Member State competent authorities. For all stakeholders involved (e.g. enforcement, ECHA's committees) it will remain important to share lessons learnt and strive for efficiency gains in order to cope with the increasing workload.

Based on the Commission review of REACH, to be published in 2017, and on the external review of the Agency, ECHA will implement the relevant recommendations to improve its work and the relevant operations. Considerable contribution from ECHA is to be expected towards the fitness check of the REACH regulation under the REFIT program.

Strategic action area 4.1 – Maximising the effectiveness and efficiency of existing and new work processes					
Priority area	2017	2018	2019		
Quality system	Renewal of ISO9001 certification and possible extension of its scope to biocides processes				
Process re- engineering	Efficiency improvements through re- engineering of REACH and CLP processes	First round of efficiency improvements through re-engineering of REACH and CLP processes completed			
Biocides	Preparedness for the first extension of the scope of Union Authorisation	Review the Union Authorisation process on the basis of experience gained with first years of implementation.			
PIC	Three-year report on operations				
CLP	Maintenance of tools and guidance for the notification to the poison centres.	Maintenance of tools and guidance for the notification to the poison centres Development of 'one-stop notification' system for notifications to the poison	Support to notifiers for the 1 st deadline of notifications to the poison centres		

Feasibility study for 'one-stop notification' system for notifications to the poison centres	centres subject to outcome of the feasibility study	
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2.4.2 Delivering integrated and re-usable IT systems and services

IT has a fundamental role to play in maximising efficiency, especially where processes can be automated and data mining can be developed to support the Agency's scientific and regulatory work. All four pieces of legislation remain very heavily dependent on the use of automated IT systems. ECHA will keep on exploring tools and expertise to improve and integrate its services towards stakeholders. Internally, IT systems will keep on focussing on harmonising and consolidating shared solutions to improve efficiency and facilitate future maintenance work.

After having achieved a first foundations milestone in 2016 with the release of renewed IT tools for all parties (Industry and Authorities) and after having completed the first roadmap of its Enterprise Content Management Programme, ECHA will define and pursue the new target architecture suitable to support the new phase of ECHA, notably after the last registration deadline. ECHA will also roll out its special Cloud Services for SMEs based on centrally hosted and operated IUCLID functionalities for preparing registration dossiers online and store data at ECHA.

Specific attention will be paid to those processes where the MSCAs play particular roles in order to better support integration, consolidation and usability, ultimately better enabling the strategic objective on mobilising all the actors involved in the successful implementation of the legislations. ECHA will seek to consolidate the interface for Authorities and Committees to interact with all ECHA processes under REACH, CLP, and BPR.

To help foster efficiency and consistency in the authorities' work, ECHA will facilitate MSCAs cooperation and coordination of activities on specific substances. These will include information exchange platforms and easy-to-use overviews of the regulatory status of different groups of substances.

A major driver of the IT activities in general will be enhancing the usability and searchability of ECHA's information and integrating with other relevant data sources. Internally IT developments during the period will further automate and streamline important elements of the management processes, planning and reporting.

The increased reliance on IT requires an assurance that it is resilient enough to withstand major incidents or disruptions. Therefore, ECHA will continue its investment in making its ICT infrastructure more resilient, easy to operate and flexible; easy to expand and more redundant to withstanding incidents. Finally, given the fast-paced evolution of technology and the natural lifecycle of IT systems, there will be one major technological and architectural revision of the broad landscape of IT solutions and services within the period.

Strategic action area 4.2 Delivering integrated and re-usable IT systems and services								
Priority area	2017 2018 2019							
Deliver IT support for regulatory processes	Readiness of the performance and resilience of the IT systems and services for the last REACH deadline Target architecture 2017-2020 defined Initiate a roadmap for IT solutions for Authorities and Committees to further integrate and streamline processes and mutual interactions (ECHAinteract). Update of the ECM roadmap, achieving the completion of the objectives on historical archiving	Target architecture 2017-2020 pursued Further implement the ECHAinteract roadmap Design the ECM historical archiving solution	Target architecture 2017-2020 pursued Consolidation of ECHAinteract roadmap Deploy ECM historical archiving solution					

Strategic action area 4.2 Delivering integrated and re-usable IT systems and services					
Priority area	2017	2018	2019		
	New version of the EUSES tool for biocides				
Deliver IT support for administrative processes	Implementation of an enhanced planning and reporting solution	Consolidation of the planning and reporting solution			
Ensure adequacy of ICT infrastructure	Readiness for last REACH deadline Support for cloud services for SMEs secured; Future Infrastructure Services model designed Replace the expiring framework contracts for outsourced services Workplace IT facilities upgrade completed Upgrade of the Security Models for remote access Upgrade key technologies (e.g. Documentum, Sharepoint) in line with an established technology roadmap.	Transition to new sourcing channels 80 % of the technical services are outsourced Upgrade of the Security Models for cloud provisioning	Infrastructure Services upgraded Workplace IT facilities upgrade started		

2.4.3 HR policies and initiatives for maximising the potential of human resources and cope with decreasing staff levels

ECHA has staff with high levels of professional expertise - even where the available pool of expertise is limited – for example the field of regulatory science. However, the skills and knowledge of staff need to be continually developed.

ECHA's human resources policies and practices must cater for the current demands (through the short-term cycle of objective setting, performance appraisal, training, etc.), but must also be flexible enough to deliver on new areas of work and in situations of decreasing staff levels (through the long-term cycle of organisation development and flexibility, priority setting, culture and leadership).

The retention of performing staff is central to ECHA's continued success. Key issues to be addressed during the period include effective performance management; identification, development and reward of key people; assignment of posts to priority areas and strategic human resource development. Moreover, it will be a major management challenge in this respect to proactively influence, motivate and empower staff in the achievement of our priorities.

Strategic action area 4.3 HR policies and initiatives						
Priority area 2017 2018 2019						
HR Policies and Initiatives	Decision on ECHA's future physical workplace	Review of competency mapping framework				

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, as planned for 2016-2019

ECHA's main activity drivers	2016	2017	2018	2019
Dossiers arriving REACH and CLP				
Registration dossiers (including updates)	10000	13000	59500	19500
Testing proposals	220	220 ¹³	240	70
Confidentiality requests	390	540	3290	450
Access to data older than 12 years	320	350	390	320
PPORD notifications (incl. requests for prolongation)	300	300	300	300
Inquiries concluded	1600	1700 ¹⁴	1900	2000
Data sharing disputes	20	80	170	20
Restriction proposals submitted by MS and ECHA (REACH Annex XV)	10	6	8	8
Restriction proposals (or reports) developed by ECHA on behalf of the Commission	2	5	4	4
Restrictions proposals (or reports) developed under Article 69(2).	2	1	1	1
Proposals for harmonised classification and labelling (CLP Annex VI)	60	70	75	85
Proposals for identification as SVHC (REACH Annex XV) 15	20	15	20	25
Authorisation applications	60	5	15	15
Alternative name requests	100	50	50	50
Substances on the CoRAP to be evaluated by MSs	39	25	40	50
ECHA decisions REACH and CLP				
Evaluation decisions				
- Testing proposal	250	150	105	165

¹³ Includes delayed testing proposals resulting from the 216 pending Commission decisions on testing proposals related to extended one-generation reproduction toxicity study (EOGRTS) originally included in the estimate for 2016

¹⁴ 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 in 2017

¹⁵ The actual number of SVHC dossiers arriving will depend on the outcome of the RMO analyses.

- Compliance Check	ECHA's main activity drivers	2016	2017	2018	2019
Decisions on data sharing 20 70 140 15 Decisions on PPORD 50 50 50 50 Decisions on completeness check (negative) 16 Decisions on confidentiality requests 50 65 340 150 Recoil Repairs Submitted 26 27 36 30 Cases closed 15 25 25 25 Chters Updates of the CoRAP for substances subject to substance evaluation 11 Recommendations to the European Commission for the Authorisation List 11 Received helpdesk questions on REACH and CLP Resolved general enquiries 600 1200 1200 600 Press enquiries and interviews 500 550 600 400 SME checks 500 330 400 400 Management Board meetings 4 4 4 4 4 4 MSC meetings 6 6 6 6 6 6 RAC meetings 6 5 4 4 Forum meetings 7 6 5 500 Biocides Received helpdesk questions on Biocides 7 76 5000 Applications for new active substance 23 8 28 8 Received helpdesk questions on Biocides 7 76 5 6 76 6 76 76 76 76 76 76 76 76 76 76 76	- Compliance Check	180	180	180	180
Decisions on PPORD 50 50 50 50 Decisions on completeness check (negative) ¹⁶ Decisions on confidentiality requests (negative) ¹⁷ 50 65 340 150 Appeals Appeals submitted 26 27 36 30 Cases closed 15 25 25 25 Others Updates of the CoRAP for substances subject to substance evaluation 1	- Substance evaluation	30	30	30	22
Decisions on completeness check (negative) 16 Decisions on confidentiality requests (negative) 17 South Properties (negative) 18 South Properties (negative) 19 South Properties (negative)	Decisions on data sharing	20	70	140	15
(negative) 16 100 280 1200 400 Decisions on confidentiality requests (negative) 17 50 65 340 150 Appeals Appeals submitted 26 27 36 30 Cases closed 15 25 25 25 Others Updates of the CoRAP for substances subject to substance evaluation 1 2	Decisions on PPORD	50	50	50	50
Appeals Appeals Appeals Appeals Appeals Appeals Submitted 26 27 36 30		100	260	1200	400
Appeals submitted 26 27 36 30 Cases closed 15 25 25 25 Others Updates of the CoRAP for substances subject to substance evaluation 1		50	65	340	150
Cases closed 15 25 25 25 Others Updates of the CoRAP for substances subject to substance evaluation 1 2 2 2	Appeals				
Others Updates of the CoRAP for substances subject to substance evaluation 1 2 2 1 2	Appeals submitted	26	27	36	30
Updates of the CoRAP for substances subject to substance evaluation 1 2 2 2 0	Cases closed	15	25	25	25
to substance evaluation 1 2 1 1 1	Others				
Commission for the Authorisation List 1 0 1 1 Received helpdesk questions on REACH and CLP n/a 8000 10000 2650 Resolved general enquiries 600 1200 1200 600 Press enquiries and interviews 500 550 600 400 SME checks 500 330 400 400 Management Board meetings 4 4 4 4 MSC meetings 6 6 6 6 RAC meetings 8 7 6 6 SEAC meetings 6 5 4 4 Forum meetings 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance approval 23 8 28 8 Applications for renewal or review of active substances 0 2 11 5		1	1	1	1
CLP IVA 8000 10000 2850 Resolved general enquiries 600 1200 1200 600 Press enquiries and interviews 500 550 600 400 SME checks 500 330 400 400 Management Board meetings 4 4 4 4 MSC meetings 6 6 6 6 RAC meetings 8 7 6 6 SEAC meetings 6 5 4 4 Forum meetings 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance approval 23 8 28 8 Applications for renewal or review of active substances 0 2 11 5		1	0	1	1
Press enquiries and interviews 500 550 600 400 SME checks 500 330 400 400 Management Board meetings 4 4 4 4 MSC meetings 6 6 6 6 RAC meetings 8 7 6 6 SEAC meetings 6 5 4 4 Forum meetings 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance approval 23 8 28 8 Applications for renewal or review of active substances 0 2 11 5		n/a	8000	10000	2650
SME checks SME ch	Resolved general enquiries	600	1200	1200	600
Management Board meetings 4 4 4 4 4 4 4 MSC meetings 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	Press enquiries and interviews	500	550	600	400
MSC meetings 6 6 6 6 6 RAC meetings 8 7 6 6 SEAC meetings 6 5 4 4 Forum meetings 3 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance approval Applications for renewal or review of active substances Outside Search Sear	SME checks	500	330	400	400
RAC meetings 8 7 6 6 SEAC meetings 6 5 4 4 Forum meetings 3 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance approval Applications for renewal or review of active substances On the second state of	Management Board meetings	4	4	4	4
SEAC meetings 6 5 4 4 Forum meetings 3 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance 23 8 28 8 approval Applications for renewal or review of active substances On the contraction of the c	MSC meetings	6	6	6	6
Forum meetings 3 3 3 3 3 Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance 23 8 28 8 approval Applications for renewal or review of active 0 2 11 5	RAC meetings	8	7	6	6
Biocides Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance 23 8 28 8 approval Applications for renewal or review of active 0 2 11 5	SEAC meetings	6	5	4	4
Received helpdesk questions on Biocides n/a 3000 5000 5000 Applications for new active substance 23 8 28 8 approval Applications for renewal or review of active 0 2 11 5	Forum meetings	3	3	3	3
Applications for new active substance 23 8 28 8 approval Applications for renewal or review of active 0 2 11 5 substances	Biocides				
Applications for renewal or review of active 0 2 11 5 substances	Received helpdesk questions on Biocides	n/a	3000	5000	5000
substances		23	8	28	8
Opinions on active substances in the Review 50 50 50 50		0	2	11	5
Programme		50	50	50	50

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
 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	2016	2017	2018	2019
Applications for Union authorisation	8	37	30	40
Assessment of technical equivalence	30	37	45	45
BPC meetings	5	6	6	6
Biocides appeals	1	3	1	1
PIC				
Notifications	6300	8900	10700	12900
Received helpdesk questions on PIC	n/a	650	1200	900
New TA posts to be filled for PIC	0	0	1	0

3. Human and financial resource outlook for 2017-2019

3.1 Overview of the past and current situation.

Staff population overview (detailed data provided in Table 1 in Annex II)

ECHA clearly recognises the present economic and budgetary circumstances and their impact on its operating environment and steps have been, and will continue to be, taken to gradually further improve the efficiency of the operational and administrative processes. While ECHA's workload will remain high, and in certain areas will continue to increase, the Agency has to adapt to an overall reduction in staff resources during the period of 2017-2019.

In 2015, ECHA achieved a vacancy rate of 2% for REACH/CLP posts which it wishes to maintain as low as possible. ECHA achieved its recruitment target for PIC posts, attaining a vacancy rate of 0%. For Biocides posts, the vacancy rate is higher, due to the uncertainty of the number of posts for 2016.

For the period 2017–2019, ECHA will follow the Commission Communication COM(2013)519 with respect to the number of TA posts for REACH/CLP and PIC tasks, and a slightly lower number of TA posts for 2017 and 2018 for Biocides. For 2019, the Biocides TA posts are also aligned with the 2013 Commission Communication on the multiannual financial framework (MFF).

Staff-related expenditure in 2015 (detailed data provided in Table 1 in Annex II)

For REACH/CLP staff related expenditure, it is to be noted that, contrary to July 2013 to June 2015 period when the salaries were frozen, we expect an approximate 2.4 % salary increase as of July 2015 and an estimated 1% each year thereafter; as well, we should note that the calculation of 2017 has been made on the full Establishment Plan instead of 95 % in 2016 (to adjust to the latest low vacancy rate and turnover statistics at ECHA).

For a fourth consecutive year, the European Schooling expenses are included in the budget and they amount to approximately € 987,185 for REACH (1,103,000 for REACH, Biocides and PIC altogether).

3.2 Resource programming for the years 2017-2019

3.2.1 Financial Resources (detailed data provided in Tables in Annex II)

3.2.1.1 REVENUES

REACH /CLP

The REACH/CLP income is comprised of collected fees and charges as well as the EU subsidy. The forecasted fee income and, consequently, the required subsidy vary significantly over the years covered by the planning period. This is mostly due to the fee income uncertainty and the final registration deadline under the REACH regulation, which falls in 2018, causing a significant peak in the revenues.

In 2017, the fees and charges are estimated to total c. € 26 million and the required balancing EU subsidy is c. € 69 million.

BIOCIDES

Similarly to REACH/CLP, the Biocides activities are financed with both fee income and EU subsidy. The high uncertainty continues with respect to the budgeted revenue from fees and charges, which are based on dossier application volumes.

In 2017, the fees and charges are estimated to total c. \in 5.8 million and the required balancing EU subsidy is c. \in 4.5 million.

Following the growing number of applications and the consequent additional staff needs to handle

these, the subsidy required for the year 2017 exceeds the amount foreseen in the MFF.

PIC

ECHA's PIC activities will be fully funded from an EU subsidy over the planning period with the amounts foreseen in the MFF. So far the reduction in expenditure has been absorbed by Title 5, but ECHA will examine whether a higher subsidy for 2018-2019 would be needed to compensate part of the increase, considering that the number of substances on the Annex I is increasing faster than anticipated and also that ECHA receives an extra post in 2018.

3.2.1.2 EXPENDITURE

Title 1

REACH /CLP

For 2017, the needs for staff-related expenditure (Title 1) amount to c. € 62 million, which is c. € 1 million more than in the 2016 budget. Salaries represent 92% of the total Title 1 budget, while other staff-related expenditure accounts for 8% of the total.

BIOCIDES

The total amount for staff-related expenditure in Biocides in 2017 is estimated at c. \in 6.9 million, representing an increase of 21%. This increase is stemming from the additional 7 posts for 2017. Of the total staff related expenditure, direct salary costs are \in 6.1 million (88%) and other personnel costs \in 0.8 million (12%).

PIC

Total amount for staff-related expenditure in PIC is estimated at c. \in 0.7 million. Of this amount, direct salaries represent c. \in 0.5 million and other personnel costs c. \in 0.2 million.

Title 2

The overall Title 2 (infrastructure and operating) expenditure for 2017 amounts to c. € 15 million, which corresponds to the 2016 level.

The chapter 20 (Rental of buildings and associated costs) increases slightly from 2016 and totals € 7.5 million.

The administrative IT expenditure in Title 2 (chapter 21 and 22) encompasses the purchase of software, hardware and their respective maintenance as well as any related IT services needed for the smooth running and administration of the Agency.

An amount of \in 3.6 million is allocated to the Outsourced IT managed services that include i.a. the so called Infrastructure as a Service and that are necessary to operate the ICT infrastructure of the Agency.

Operational Titles

Title 3 (REACH / CLP)

The year 2017 is crucial in ECHA's preparation for the last registration deadline of phase-in substances in 2018.

In light of the final REACH registration deadline in 2018, the number of companies having to comply with REACH requirements becomes larger and many of those companies will be SMEs and inexperienced with the legislation. That brings increased demands on the communication function to reach out, particularly to SMEs, with more support and, where possible, provide them with simplified and shorter information, thereby making it understandable and easier to use. At the

same time, the awareness-raising activities for general audiences (particularly consumers) on the safe use of chemicals and "right to ask" will continue.

Substance evaluation is expected to continue at a slightly lower level in 2017-18, with 35-40 substances per year, and again increase in 2019. The evaluation work is done 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 expected high number of authorisation applications that arrived at the end of 2015, and early 2016, will be challenging for the Secretariat, as well as for the Risk Assessment and Socio-Economic Analysis Committees also in 2017, from both scientific and workload perspectives. The anticipated budget for the rapporteurs foresees payment appropriations necessary to cover contractual obligations from previous years, as well as for contracts signed in 2016. An increase in expenditure is furthermore foreseen to support an increase in risk management related activities such as support to the development of restriction dossiers as well as for activities in relation to substances in articles.

The IT costs in Title 3 are intended to cover all the costs for developing and maintaining IT tools such as REACH-IT, IUCLID, ECHA Cloud Services for SMEs, CHESAR, RIPE, Dynamic Case, Portal Dashboard, ODYSSEY and other ECM Programme tools quality assurance services for the aforementioned applications and other services. Also the costs related to Data Management and Dissemination of REACH data fall under Title 3.

Preparing REACH-IT for 2018 registration deadline is ongoing and in 2017 enhancements are planned for improving ECHA internal efficiency. After that, the application will be adapted to the post - 2018 needs, considering cost effective maintainability.

The ECM Programme will complete the objectives on archiving. Funds are reserved for the implementation of the new ECHAinteract roadmap pursuing a single interface for Competent Authorities and Committees with easy access to all case and substance information, and standardised interactions with ECHA Processes.

In relation to the IT tools for Authorities, it is expected that in 2017 ECHA will take over the development of EUSES.

The estimates for the year 2017 also include the running recurrent costs for operating the ECHA Cloud Services for SMEs totalling € 217 thousand.

Finally, in 2018 an extraordinary high number of interims is going to be needed to support the staff to handle the workload stemming from processing the incoming registration dossiers and providing support to the registrants and thus the expenditure foreseen for that year is significantly higher than in the other years of the planning period.

Title 4 (BIOCIDES)

The main expenditure item in 2017 for Biocides is related to the IT tools. In relation to the IT tools for Authorities, it is expected that in 2017 ECHA will take over the development of EUSES and support the enforcement in the BPR with Biocides funds. The expenditure foreseen for R4BP service are kept to the financial fiche. However, for the R4BP project, provided that funds are made available in 2016, the development part can be completed during 2017 and the application is expected to go into maintenance mode after that.

Another significant expenditure item relates to the Biocidal Products Committee, through which 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.

Title 5 (PIC)

The largest part of the PIC budget for 2017 is foreseen for the maintenance of the IT tools related to the support of the export notifications and the import consents. Other main parts are used for Communications, particularly for translating materials into 22 languages.

Information on budget outturn and cancellation of appropriations provided in Table 3 of Annex II.

3.2.2 Human resources

Resource outlook over the years 2017 to 2019 (detailed data provided in table 2 in Annex III)

New tasks:

At present, the foreseeable new tasks for the period of 2017-2019, are those requested by the Commission to support the renewal of authorisations of biocidal products containing anticoagulant rodenticide active substances.

It is also proposed, that from 2016 onwards ECHA would become responsible for some new tasks in relation to the notification of emergency health response to the poison centres, in accordance with the amendment to the CLP regulation. This may include – further to a feasibility study carried out in 2017 - the development in 2018 of a new portal ('one-stop notification' system) for receiving notifications to the poison centres and dispatching them to the relevant bodies. This last activity is a new task not included in the Commission proposal and impact assessment, which will require appropriate funding and potentially additional human resources, especially in 2018 as the the initial development of the system and the setting up of the operations may need to happen at a time where many resources will be dedicated to handling of the 2018 registration deadline.

The European Commission will delegate to ECHA the task to host the EU Nanomaterials Observatory. The Observatory will analyse, evaluate and disseminate information on nanomaterials present on the EU market. While implementation may already start in 2016, the years 2017-2019 would be the period when this new function becomes fully operational.

Finally, it is expected that the Commission will request ECHA in the near future to carry out some administrative, technical and scientific tasks for the implementation of the Regulation (EC) No 850/2004 on Persistent Organic Pollutants (POPs). The details of the activities foreseen and the related budget and staff consequences will be further clarified during the recast of that Regulation which the Commission is currently working on.

Growth of existing tasks:

Resource outlook for REACH/CLP-related tasks

This section quantifies the required overall number of staff required by ECHA for REACH/CLP-related tasks for the period 2017-2019, taking into account the anticipated workload inherent in existing tasks and in the growth of such existing tasks.

As outlined in the section on operational activities, ECHA's registration activity will undergo significant growth from mid-2016 until mid-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 is anticipated to be at least 45,000 (and could be up to 70,000), which represents a 15-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, in the fields of assessment of the confidentiality requests in the dossiers and publication of information on ECHA website. In addition, ECHA started implementing in 2016 a manual verification of certain data requirements, such as substance identity, as part of the submission process, including a retroactive verification that existing registrations contain meaningful information and that the registrants registered jointly for the same substance. ECHA also expects to receive an increased number of appeals due to these developments. The above will consequently also increase the Agency's human resource needs, including interim personnel. Our current estimations indicate that this could require approx. 30 interim staff, or contract agents, in 2017 and approx. 100 interim staff, or contract agents, in 2018. The level of industry activity, combined with survey work that we are undertaking, will give ECHA an even clearer picture of the workload as we approach 2018 and, thus, we may be able to revise the estimations.

ECHA is also anticipating a steady increase related to handling data sharing disputes as well as providing adequate support to the substance information exchange forums (SIEFs), commencing in 2016 and, with a potential significant increase in inquiries for getting in contact with other registrants due to the termination of the pre-registration option in May 2017. This will have an important impact on the human resources requirements from mid-2017 onwards.

In addition, the activity related to data analysis and demands from EU Authorities is expected to grow steadily until May 2018 and then increase with the sheer volume of dossiers which will be stored in ECHA databases. ECHA will enhance screening and prioritisation for subsequent evaluation and risk management work. As this will require additional IT-related support, ECHA continues to develop user friendly and simplified IT solutions and services.

In 2015-2016, ECHA's IT staff resources have been decreasing while facing an increase in activity in all areas. After 2016, given the number of systems and services in operation and maintenance, the resources required would only slightly reduce. In this context, to meet the target cuts and still sustain its portfolio, ECHA is progressing with the outsourcing of IT services.

While ECHA's evaluation activity is expected to remain relatively stable, certain existing tasks are expected to grow. The Compliance Check Strategy requires a more comprehensive evaluation of registrations in growing numbers. The follow-up of decisions will, in many cases, become more complex and also higher in numbers. Following the recent developments ECHA needs to intensify its role in assessing that the vertebrate animal testing is indeed used only as a last resort which is also increasing the workload.

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

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

For applications for authorisations, a peak in workload is taking place in 2016 and will continue until mid-2017. This has created additional demands to provide the adequate scientific, technical and administrative support to enable the Committees to deliver opinions while maintaining the scientific and regulatory validity and respecting the legally binding deadlines. The workload is expected to reduce in 2018, facilitating some temporary resource reallocation before returning to capacity from 2019.

There is an envisaged requirement for the CA positions (within the financial capacity of the Agency) that takes account of the expected high increase in workload for the 2018 registration deadline and the growth of the existing tasks outlined above. Although ECHA will also engage interim staff to process the registrations coming in for the 2018 deadline, the related guidance and regulatory advice, the invoicing process can only be handled by the statutory staff (that is,

CAs). It is to be noted that the additional CA posts for 2017 and 2018 will only be used if the volume of registrations and applications go beyond the current (conservative) estimated levels. ECHA expects that it will be requested by the Commission to carry out further work in support of the implementation of the circular economy package and the development of the strategy for a non-toxic environment as announced in the 7th Environment Action Programme. Furthermore, ECHA plans to increase its efforts in the area of encouraging and providing support to industry in their efforts in substituting SVHCs and other substances of concern, based on a strategy that will be developed in 2017.

Resource outlook for Biocides regulation

ECHA is in a difficult situation that stems from the fact that the Commission's original financial model assumed that all ECHA's activities on biocides would, in the medium term, be fully covered by fees. This fee income would then be used to cover the fee-related as well as the non-fee related work, where the latter now accounts for approximately 80% of our work. The EU subsidy was planned for the initial set-up period but would be reduced quickly assuming quickly rising fee income.

It is anticipated that the foreseen increase of the workload in 2017, and beyond, requires additional resources. This increase results from the combination of a significantly higher number of applications to ECHA, and a large scale IT development project to complement the implementation of the legislation and additional activities requested by the Commission in relation to the renewal of the anticoagulant rodenticide active substances and the corresponding product authorisations.

In the context of the development of criteria for endocrine-disrupting properties under the BPR the Commission has requested ECHA to start preparations for the (re)evaluation of the approvals of certain active substances vis-à-vis these new criteria, once they are adopted. Further discussion will be initiated on the additional resources that are necessary to ensure a successful execution of these important evaluations.

Resource outlook for Prior Informed Consent (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. However, it is to be noted that the number of notifications is 25% higher than initially estimated and, by end 2015, has already exceeded the estimated number for 2017. This requires additional interim support for handling the peak of notifications in Q4 of each year.

Efficiency gains and negative priorities

Starting from 2014, ECHA embarked on a process – ECHA 2020 – to take the existing and future resource and policy challenges as an opportunity to start shaping ECHA for the future. In considering this strategy, a number of activities have been identified as potentially decreasing in resource requirements over the planning period.

For 2017, the changes in resource forecasts are reflected in Annex I.

The overarching vision for ECHA is summarised as follows:

- ECHA should function as a lean organisation focussed on delivering operational and impactful regulatory work within its mandate,
- ECHA should demonstrate (even more than before) its added value to the European citizen, and
- ECHA should be agile and ready to take on new tasks (should this be requested of the Agency).

The two guiding principles, from a resource allocation perspective, are as follows:

- Proportionally more resources to be allocated to leaner, more efficient and better integrated operational activities based on clear priorities to achieve high and powerful impact
- Horizontal support activities to operate in a leaner manner, delivering fit-for-purpose services.

In practice, major process improvement opportunities are managed through Efficiency Projects which aim to address all major regulatory and support processes by 2018. Examples of such gains are the fast-tracking of the processing of testing proposals, the simplification of administrative processes such as payments and speaking requests and the re-organisaton of procurement into competence centres with the corresponding simplification of process steps. In addition to direct gains, the programme is supporting the growing need for more lean operations (including management practices) so that improvement will continue at operational, horizontal support and administrative level.

It should also be noted that, in 2014, Lloyd's Register Quality Assurance awarded ECHA the ISO 9001:2008 certificate. The scope of the current ISO 9001:2015 certification covers ECHA's scientific, technical and administrative tasks under the REACH, CLP, and PIC regulations and the development of supporting IT applications. The certification confirms that ECHA's management system conforms to internationally recognised good practice and it is anticipated that, through using the established quality management framework, ECHA will continue improving its work and working methods.

Opportunities for redeployment

ECHA will maintain its proactive approach to human resources management through internal redeployment, competency development and simplification of delivery modes. The waves of peaks in demand for certain activities, such as Registration and Authorisation, will be seen as opportunities to continue to actively promote redeployment, leveraging internal skills and increasing overall flexibility.

ECHA will continue to carefully monitor the establishment plan and ensure good forward planning with respect to recruitment, mobility and promotions, including consideration of potential strategic conversions of posts (that is, a limited number of higher grades to lower grades after retirements or unplanned departures of experts) 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.

In particular, the retention of performing staff will be 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 assignment of posts to priority areas. The appropriateness of ECHA's organisation will also be reviewed, as needed. In addition, it is recognised that it will be a significant management challenge to proactively motivate staff in the achievement of our priorities in the face of increasing workload and decreasing resources.

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

ECHA is fully in line with the Commission Communication as regards the REACH and PIC posts. For Biocides posts, ECHA is slightly below the Commission Communication allocation of posts for 2017, and is aligned for 2018 and 2019.

III WORK PROGRAMME 2017

Executive summary

The fourth 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 complemented with specific support to SMEs as a growing proportion of these companies have imminent obligations under the four regulations managed by ECHA.

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

The year 2017 is crucial for the last registration deadline of phase-in substances in 2018. First-time registrants will be encouraged to register their dossiers by using the new generation of ECHA's IT tools for dossier preparation or submission and the updated guidance, presented in a step-wise approach under the REACH 2018 webpages, and where necessary using the support provided by ECHA or national helpdesks. For that purpose they will have had to share data in existing or newly created substance information exchange forums (SIEFs) or even taken the role of lead registrant, taking benefit of specific training courses to that effect, with emphasis on avoidance of unnecessary animal tests. Downstream users will be encouraged to contact their suppliers to ascertain their registration intentions and provide them with information on specific uses in harmonised formats. Companies will also be made aware of the deadline of 31 of May 2017 for pre-registration for companies having joined the market in recent years and having to meet the 2018 registration deadline. As ECHA's automated and manual screening of incoming dossiers may lead to rejection, ECHA will also be ready to support the affected registrants in clarifying the reasons for the rejection and in advising on how to complete the dossier comprehensively.

Based on the updated Chemical Safety Report/Exposure Scenario (CSR/ES) Roadmap, ECHA will together with national authorities and industry stakeholders investigate how to stimulate the development and use of state-of-the-art Safety Data Sheets (SDSs) in the supply chains up to the production of articles. Attention will also be given to the compliance of notification obligations of importers of mixtures and articles as they may contain substances of very high concern. These efforts will contribute to the safer use of chemicals.

After the release of the new dissemination platform early 2016 and the further improvements made over that year, ECHA will promote its use by industry, consumers, workers and researchers and set the framework for further extending its dissemination pages.

In order to improve the safety information in registration dossiers and to facilitate identification of candidate substances for regulatory risk management measures, ECHA conducts compliance checks on the highest priority substances. In line with the strategy endorsed in 2014, the focus is on higher tier human health and environment endpoints in lead and individual dossiers for the tonnage bands over 100 tonnes. In addition, other measures, such as targeted letter campaigns to registrants whose dossiers show minor defects will contribute to better quality of the registration database. At the same time, ECHA will continue the examination of testing proposals, making sure that the testing is tailored to the real information needs and that registrants are able to justify eventual animal test as a last resort.

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

The integrated screening activities will identify substances of potential concern, which should either be addressed under compliance check, placed on the Community Rolling Action Plan

(CoRAP) for substance evaluation or addressed through specific assessment discussions, for instance with respect to their potential PBT or endocrine disrupting properties. When concerns are subsequently confirmed and the most appropriate option is identified through a risk management option analysis (RMOA), it is expected that the Member State concerned or the Commission will initiate the appropriate risk management measure. Thereby, the number of substances put forward for the Candidate List, or proposals for harmonised classification or restrictions would increase. It is also expected that a growing number of Member States will participate in these efforts.

The high number of authorisation applications that arrived at the end of 2015 or in 2016 will continue to occupy the Secretariat as well as the Risk Assessment and Socio-economic Analysis Committees in 2017. The Commission's Implementing Regulation introducing simplified rules for special cases as well as the changes to the fees for authorisation application should help in reducing the burden and costs for companies. Further efforts will be undertaken to promote the participation in the process of providers of alternative substances and techniques in order to stimulate substitution and innovation.

ECHA will furthermore work on implementing the improvement actions in the application for authorisation (AfA) process following the discussion in the March 2016 meeting of the Management Board.

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 stimulate the adequate use of the scientific methods to justifiably replace the standard information requirements and in particular by drawing registrants' attention to the Read-Across Assessment Framework (RAAF). ECHA will also publish a report on the regulatory applicability of alternative methods and approaches to promote an up to date assessment on the opportunities and limitations of alternatives to animal testing.

After having updated its guidance on the REACH information requirements to better take into account the specific aspects of nanomaterials, ECHA will continue its activities to improve the quality of registration data for nanomaterials. As and when the Commission will modify the REACH annexes for the same purpose, further improvement of guidance will be unavoidable.

On the basis of the criteria for identifying endocrine disrupters adopted by the Commission, ECHA will also need to develop relevant guidance, especially for biocides. ECHA will also more generally start to review its extensive guidance document package to identify needs for scientific updates.

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 while at the same time decreasing staff resources, ECHA will continue to improve its efficiency and effectiveness. In 2017, the Agency will re-examine the architecture of its IT systems in order to further improve integration, serve both the industry and Member States better but also to reduce manual work in its internal processes. In the meantime, the current IT tools and systems require still additional investment so that the regulatory processes can be adequately supported. ECHA will also roll out new Cloud Services to the benefit of SMEs.

Regarding implementation of the Biocidal Products Regulation (BPR), ECHA will create efficiencies to support the preparation of decisions related to the review programme of active substances or applications that benefit from more appropriate fee levels following the Commission's review of the fee regulation. Thanks to the extra staff ECHA is receiving in 2017, ECHA should ultimately be able to meet the heavy workload of the fee- and non-fee-based activities of the BPR while constantly improving the IT tools that support industry and all involved authorities.

Finally, ECHA will actively support the Commission in the review of the REACH and CLP regulations and the development of instruments that stimulate the circular economy.

5. Provide specific support to SMEs

Whilst ECHA's communication, advice and assistance are relevant to all duty holders, the delivery of its services in 2017 will continue to have particularly SMEs in mind:

- Implementation of the 2018 REACH Registration Roadmap will be providing support particularly to SME registrants.
- Deliverables provided by ECHA and its partners in 2017 under the CSR/ES Roadmap will particularly support SMEs further down the supply chains.
- The further improvement of the dissemination web section will be designed to benefit SMEs to allow them to find information on the properties and state of regulatory oversight over chemical substances for which they may have obligations.
- ECHA will pay specific attention to help SMEs that plan to submit applications for authorisation under REACH. This help will be given through examples, as well as in the workshops and Pre-Submission Information Sessions to ensure that SMEs know what information is required to apply for authorisations in a "fit-for-purpose" manner.
- ECHA's communications' activities on BPR, REACH and CLP obligations will particularly have SMEs and downstream users in mind both in terms of content and format.
- ECHA will continue its efforts to provide translations of guidance and other relevant documents for SMEs in official EU languages, where appropriate.

1. Operational activities

1.1 REACH 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.

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. It also decides on data-sharing disputes submitted to ECHA and gives access to data when appropriate.

ECHA also 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	2015 actual	2016 estimate	2017 estimate
Helpdesk questions received ¹⁸	NA ¹⁹	1 000	2 800
Inquiries concluded	1 368	1 600	1 700 ²⁰
Access to data older than 12 years	394	320	350
Data-sharing disputes	6	20	80
Decisions on data-sharing disputes	4	20	70
Appeals on data-sharing decisions	0	1	1

Key objective

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

Main actions and outputs of 2017

- Implement ECHA's REACH 2018 roadmap, which outlines ECHA's plans for improving registration process, tools and support for the last registration deadline of phase-in substances, in dialogue with industry stakeholders, Commission and national authorities and specifically:
 - Monitor, via the various stakeholder networks, the need for specific support for SME registrants, and based on assessed demand arrange e.g. webinars, best practices or workshops on specific issues.
 - Provide advice to industry sectors that may face specific difficulties and develop registration guidelines suitable to their sector (similar to the essential oils sector in 2015-2016) with the aim of also improving data quality and compliance.
 - Provide support to registrants and downstream users via the Agency's SME Ambassador, in view of the expectation that companies will take their business decisions on continuing placing specific phase-in substances due for registration in 2018 onto the market only during 2017.
 - To further facilitate dossier preparation for SMEs that have comparatively less technical resources than the large companies do, ECHA intends to launch a centrally hosted and managed Cloud platform that will be accessible on-line, without any need for local installation and local data storage. According to this delivery model, companies will manage

¹⁹ Not available for 2015 due to the change in the WP structure introduced from 2016 onwards. The total amount of questions received in 2015 for REACH, CLP, BPR and PIC (as well as respective IT tools) was 7 770.

¹⁸ Regulatory and non-regulatory questions related to dossier preparation only.

²⁰ 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.

their data and prepare their registration dossiers online, on an ECHA hosted and supported service. It is estimated that using this option the SMEs segment of the chemical Industry could save approximately 5.4 Million Euros per year.

- Improve the usability of IT tools for dossier preparation through releases of IUCLID and Chesar.
- Revise ECHA's model for servicing users, to rely more on the national helpdesks as first
 point of contact particularly for SMEs to better cope with the presumably very high level of
 requests for end users' support on the IT tools. Special training, second level support and
 dedicated IT environments for the national helpdesk will be considered in order to enable
 local support to the use of the IT tools.
- Intensify coordinated communication activities via various networks (such as the REACH Communicators' network), and using multiple communication channels (online, audiovisual, documentation, events and social media) in order to raise awareness among registrants.
- Support the fulfilment of information requirements
 - Maintain the list of substances for which there is evidence that one or more Annex III
 criteria might be met and in which case all information requirements according to Article
 12(1)(a) should be provided, unless evidence to the contrary is included in the registration
 dossier; provide support to registrants to make use of this list as needed.
 - Encourage downstream users, via awareness actions, to benefit from the harmonised means to communicate uses for registration purposes, and registrants to document the results of their chemical safety assessments in harmonised formats.
 - Maintain and improve tools for generating and communicating use and exposure information from downstream users to registrants, and promote the uptake of use map packages by registrants for their 2018 registrations and updates.
 - Promote the use of newly released QSAR Toolbox 4.0 for filling data gaps in 2018 registrations by giving trainings and publishing examples. Initiate the second part of the Phase III implementation of the QSAR Toolbox which includes both scientific and technical improvements.
 - Keep the amendments of published guidance on information requirements for REACH, to a
 minimum, in line with the Guidance Moratorium of 2016, and limit them to those necessary
 to accommodate legal developments, to ensure as much guidance stability as possible in
 the two years ahead of the 2018 REACH registration deadline. At the same time start
 reviewing the potential need for updating the guidance to scientific developments post
 2018.
 - Promote Chesar and provide training to increase the number of users. Support to sectors for developing assessment inputs to registrants in Chesar format. Further development of the tool.
- ECHA will develop a strategy on the future development of exposure estimation tools and their relation to Chesar, as the quality of the CSA/CSR are to some extent dependent on them. The role of ECHA regarding these tools should be clarified. Future activities will depend on the decision on ECHA's role. Continue communicating about correct use of alternative methods and approaches to replace animal testing. Increase transparency of ECHA's criteria and judgements in accepting or rejecting justifications for adapting standard information requirements and the use of weight of evidence.

- Report on the alternatives to testing on animals for the REACH Regulation (Article 117(3) report). ECHA will also publish a report on regulatory applicability of alternative and non-animal approaches.
- Continue activities of the Nanomaterials Working Group including the organisation of two workshops.
- Pre-registration and SIEF management
 - In order to optimise data sharing after closure of the possibility to pre-register mid 2017, adapt the inquiry process to be able to handle a large number of inquiries and ensure that potential new registrants of phase-in substances (newcomers on the European market) are put in contact with SIEF members of the last deadline.
 - Manage the increasing number of data-sharing disputes arising from the reinforcement of the OSOR principle in REACH-IT.

Performance indicators ²¹	2015 actual	2016 estimate	2017 target
Percentage of inquiries concluded within the target timeframe (20 working days)	92%	80%	80%
(NEW)Effective working time of ECHA staff used per inquiry concluded	NA	NA	1.8 – 2 person days
(NEW)Percentage of received data sharing disputes handled within relevant timeframes ²²	NA	NA	100%
(NEW)Effective working time of ECHA staff used per data sharing decision	NA	NA	16 – 18 person days
(NEW)Percentage of ECHA Helpdesk questions related to dossier preparation, answered within established timeframe (15 working days)	NA	NA	90%

Resources	2015 actual ²³	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	11 736 098	12 330 283
Human resources (FTE)	NA	48	49

1.1.2 Registration and dossier submission

²¹ For new proposed indicators the values for 2015 and 2016 are not available (NA);

²² 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)

²³ Work Programme 2015 followed a different activity structure to the one introduced for 2016 and followed throughout this programming document. Resources split according to the WP2015 activities is presented in the General Report 2015.

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. 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 the REACH-IT system which also provides a secure communication channel between all involved parties.

The ECHA Secretariat supports the Forum to further strengthen and harmonise the effective enforcement of the registration obligations in the EU/EEA Member States.

Workload driver estimates	2015 actual	2016 estimate	2017 estimate
Registration dossiers received (including updates)	8 243	10 000	13 000
Confidentiality requests processed	173	390	540
PPORD notifications received (including requests for extension)	247	300	300
Helpdesk questions received ²⁴	NA	3 500	2 000
Decisions on completeness check (negative)	41	100	260
Decisions on confidentiality requests (negative)	28	50	65
Decisions on PPORD notifications	40	50	50
Appeals submitted ²⁵	1	2	2

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 2017

Process an increasing number of registrations (preliminary estimates up to ca. 7000 new

²⁴ Regulatory and non-regulatory questions related to dossier submission only.

²⁵ 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

registrations and 6000 updates). This may have an impact on the follow-up activities such as assessment of confidentiality requests and SME status verification. A majority of the new registrations are expected to be submitted for the 2018 deadline.

- Further develop the process and support for manual verification of completeness of information based on experience gathered in 2016, also targeting retroactively existing registrations to verify that the information provided is meaningful.
- Ensure that all legacy cases of registrations submitted outside of the joint registration are addressed in 2017.
- Ensure the internal readiness of the IT tools and related IT services for handling the incoming
 peak of registration dossiers for the 2018 registration deadline; in particular those necessary
 for users access management, for processing dossiers, inquiries and confidentiality claims,
 for invoicing and for reporting.
- As part of implementing ECHA's regulatory strategy, continue to stimulate dossier updates
 through the publication of the list of substances to be potentially addressed under compliance
 check, targeted letter campaigns e.g. to inform registrants that their dossiers may be targeted
 for dossier evaluation, verify the intermediate status of substances of very high concern, and
 other measures so that the quality of registration information is further enhanced.

Performance indicators ²⁶ ²⁷		2015 actual	l	2016 estimate	•	2017 target
Level of satisfaction of interested parties with submission and dissemination activities of ECHA	dossier	High		High		High
(NEW)Unplanned IT system downtime prosubmission within service hours (average of resystems, per month)	eventing lated IT	NA		NA		2%
(NEW)Average time (working days) to manually perfirst completeness check of a registration dossier	form the	NA		NA		15 days
(NEW)Effective working time of ECHA staff used per processed registration dossier (incl. updates)		NA		NA		0.6 - 0.65 person days
(NEW)Percentage of ECHA Helpdesk questions red dossier submission and substance identity, answere established timeframe (15 working days).				NA		90%
Resources	2015 a	actual 2016 estin				017 stimate

²⁶ 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

²⁷ For new proposed indicators the values for 2015 and 2016 are not available (NA);

Financial resources (costs, euros)	NA	9 256 352	9 564 452
Human resources (FTE)	NA	43	42

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. 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.

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	2015 actual	2016 estimate	2017 estimate
Draft decisions on testing proposals	139	300	70
Final decisions on testing proposals	194	250	150
Compliance checks concluded	183	200	220
Final decisions on compliance checks	144	180	180
Follow-up evaluations on dossier evaluation decisions concluded	268	350	330
Number of substances on the CoRAP list to be evaluated by the MSs ²⁸	48	39	24

²⁸ The declining trend in the number of substances under substance evaluation is mainly due to the refined interplay between substance evaluation and compliance check, i.e. more substances are first addressed under compliance check also for the endpoints relevant for the substance evaluation. This temporary trend is expected to turn in 2018.

Final decisions on substance evaluation	29	30	30
Appeals submitted	21	23	23
Helpdesk questions received ²⁹	NA	150	750

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.

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

²⁹ Regulatory and non-regulatory questions related to evaluation only.

in 2016.

Performance indicators ³⁰	2015 actual	2016 estimate	2017 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	NA ³¹	80%	80%
(NEW)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	NA	NA	≥75%
(NEW)Effective working time of ECHA staff used per final dossier evaluation output	NA	NA	25 – 28 person days
(NEW)Percentage of Follow-up evaluations performed within 6 months from the deadline set in a Decision (TPE and CCH)	NA	NA	90%
(NEW)Percentage of substance evaluation decisions adopted within 60 days from the MSCA/MSC agreement	NA	NA	90%
(NEW)Percentage of ECHA Helpdesk questions related to evaluation, answered within established timeframe (15 working days)	NA	NA	90%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	18 947 311	17 874 662
Human resources (FTE)	NA	106	106

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 particularly provided through regulatory advice, HelpNet, communications and guidance activities as well as the Exchange Network on

³⁰ For new proposed indicators the values for 2015 and 2016 are not available (NA);

³¹ Not available for 2015 due to the change in the WP structure introduced from 2016 onward.

Exposure Scenarios (ENES). This activity corresponds to the commitments of ECHA under the Chemical safety report / Exposure scenarios Roadmap (CSR/ES Roadmap³²). It is also linked 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	2015 actual	2016 estimate	2017 estimate
Number of events organised with industry to improve the uptake of Roadmap products	NA	NA	5
Helpdesk questions received ³³	NA	100	200

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 2017

- Subject to the outcome of the evaluation of the CSR/SE Roadmap and ENES activities carried out in 2016, support downstream user industry's utilisation of tools, formats and methodologies developed under the CSR/ES Roadmap. Specifically, promote development of use maps in new downstream user sectors.
- Provide targeted support for downstream users to support their adoption and uptake of the risk reduction measures in REACH exposure scenarios.
- Support to enforcement authorities, including support to the operational phase of the Forum's fifth harmonised enforcement project (REF-5) on extended safety data sheets, exposure scenarios, risk management measures and operational conditions.
- Continue to broaden the exemplification of REACH information useful/needed to comply with other legislation, and the benefits of REACH.
- Further promote companies' awareness of their obligations for sharing information in the supply chain through communication activities based on a set of downstream user-oriented information material published on the ECHA website in 2016. This may trigger a certain increase also in questions to the ECHA and national helpdesks during the subsequent year that the HelpNet will need to address.

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

³² CSR/ES Roadmap link

³⁴ For new proposed indicators the values for 2015 and 2016 are not available (NA)

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	NA	90%	

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	2 996 515	3 036 807
Human resources (FTE)	NA	17	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.

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 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	2015 actual	2016 estimate	2017 estimate
Upon request by the Commission, support provided for the development of RMO analyses and/or SVHC dossiers	4	5	5
Number of expert and coordination meetings (incl RiME)	9	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.

- Adapt common screening methods to address newly registered substances with lower information levels, including complementary approaches, using other than REACH/CLP data as its basis.
- Ensure maturity of the common screening approach for all REACH/CLP processes with the focus on enhancing its use (e.g. initiating the CLH process for substances that matter) and improving the system based on lessons learned.
- Use the RMOA approach to identify appropriate risk management needs based on the information generated through CCH and SEv and their respective follow-up, leading up to development of a 'common follow-up approach'.
- Continue preparation of RMOA's, upon request by the Commission, and providing coordination and support to Member States in their preparation. Ensure well-functioning informal assessment of PBT and ED properties. Adapt as needed guidance and advice on ED identification based on the criteria set out by the Commission.
- Continue developing article service-life exposure assessment approaches based on the gap
 analysis done in 2016 and supporting industry in improving service-life parts of their
 CSA/ESs thus using REACH data to contribute to the implementation of circular economy.
 Moreover, explore further how CSAs and ESs can cover the waste stage.
- Maintain high level of efforts for co-operation and co-ordination with all authorities of the
 work on SVHC roadmap implementation and beyond. Effective use of a combination of
 meetings, including RiME and concern related expert and co-ordination groups, and IT tools.
 The implementation of the approach used for the petroleum and coal stream sector is
 integrated to the extent necessary into the other co-operation work.
- Continue the review of the SVHC roadmap implementation initiated in 2016 and report as part of the annual report on the first elements of this review (relevance of impurities, sensitisers). Progress the review of other elements together with Member States Competent Authorities.

- Develop the third SVHC roadmap progress report and identify actions for further improvement.
- Continue updating the information on ECHA's website on screening and assessments thus providing industry with better predictability on which substances will be under authorities' attention and consequently allowing more time to plan for substitution and improving safety.

Performance indicators ³⁵	2015 actual	2016 estimate	2017 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	NA	38 – 47 person days

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	2 961 639	3 143 386
Human resources (FTE)	NA	17	16

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.

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	2015	2016	2017
	actual	estimate	estimate

³⁵ For new proposed indicators the values for 2015 and 2016 are not available (NA);

Number of proposals for identifying SVHCs ³⁶	9	20	15
Recommendation for inclusion of substances in the authorisation list.	1	1	O ³⁷
Number of received Applications for authorisation	7	60	5
RAC & SEAC opinions ¹⁾ on applications for authorisation	25	60	40
Helpdesk questions received ³⁸	NA	300	650

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 2017

- Handle the increased workload on SVHC dossiers, in particular those pertaining to PBTs, EDs and other substances of equivalent concern by ensuring involvement of the relevant expert groups, and sufficient capacity of the MSC.
- Continue to raise awareness of and support the implementation of obligations to communicate in the supply chains and to notify to ECHA SVHCs in articles. This work will in particular consider the update of the Guidance on requirements for substances in articles launched in 2016, which will be based on the court judgement on the 0,1 % limit and experiences so far.
- Implement a further streamlined and focussed application process taking account of the experience gained, including the "Lessons Learnt" conference and "Streamlined Applications" workshop held in 2015, as well as the recommendations of the "Task Force on Applications for Authorisation", possibly indicating good examples of applications.
- Establish the "reference" DNELs and dose-response relationships for substances that have been placed on the Authorisation List in 2016.
- Continue to improve and adapt communication through ECHA's website to facilitate the preparation of "fit-for-purpose" applications for authorisation.
- Conclude the work related to applications, mostly relating to the use of chromium compounds, submitted in the end of 2015 and early 2016, including the opinion forming by ECHA's Committees for Risk Assessment and Socio-economic Analysis and the support to the Commission in finalising the commission implementing decisions.

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³⁶ 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

³⁷ 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.

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

- Organise with the Commission a second "Lessons Learnt" conference based on the experience gained in particular with the applications on the use of chromium compounds and based on its outcome establish the necessary follow-up actions.
- Ensure full availability of information about notifications of companies covered by the authorisation decisions to enforcement authorities in the Portal Dashboard NEA.
- Publish the report from Forum's second pilot project on authorisation-related obligations.
- Develop a strategy on how to further encourage and support industry in their efforts in substituting SVHCs and other substances of concern.
- Contribute to a feasibility study on the different systems in place for tracking of chemicals from article production and import through the service-life until waste and recovery.
- First draft developed of a framework to carry out Socio-economic assessments of recycling and waste recovery practices
- Initiate and prepare a Forum pilot project on substances in articles

Performance indicators ³⁹	2015 actual	2016 estimate	2017 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 an application for authorisation	NA	NA	13 months
(NEW)Effective working time of ECHA staff used per authorisation opinion	NA	NA	38 – 46 person days

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	5 830 893	5 544 310
Human resources (FTE)	NA	33	31

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

 $^{^{39}}$ For new proposed indicators the values for 2015 and 2016 are not available (NA);

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	2015 actual	2016 estimate	2017 estimate
Restriction proposals submitted by MS and ECHA (Annex XV)	4	10	6
Annex XV restriction dossiers (or preparatory reports) prepared on request by the Commission	2	2 ⁴⁰	5 ⁴¹
Restriction proposals or reports developed under Article 69(2)	2	2	1
RAC & SEAC opinions ¹⁾ on restriction proposals	6	7	4
Helpdesk questions received ⁴²	NA	100	600

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 2017

- Provide support to the Member States during their preparation of restriction dossiers, e.g. in the Pre-Restriction Information Meetings and continue to improve the efficiency of the process.
- Initiate further development of methodologies (including valuation) for carrying out socioeconomic analysis.
- Further develop and implement a capacity building programme for Member States and members of the SEA Committee on regulatory impact assessment, in particular on methods used in socio-economic analysis.
- Report from the Forum's fourth coordinated enforcement project on restrictions (REF-4)

Performance indicators ⁴³	2015 actual	2016 estimate	2017 target
	i		

Commission request to prepare an Annex XV restriction dossier on lead stabilisers used in PVC and in addition prepare preliminary reports on formaldehyde and formaldehyde releasers.

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Commission request to prepare an Annex XV restriction dossier on i) lead in shot in wetlands, ii) chemicals used in tattoo inks and in addition prepare preliminary reports on a) substances in recycled rubber granules, b) Bisphenol S in thermal paper and c) cadmium in recycled plastics (preparation for a review). More details in http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions/current-activites-on-restrictions. Additional requests are possible for 2017.

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

⁴³ For new proposed indicators the values for 2015 and 2016 are not available (NA);

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	NA	15 months
(NEW)Effective working time of ECHA staff used per restrictions opinion	NA	NA	200 – 255 person days

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 274 879	3 454 427
Human resources (FTE)	NA	17	16

1.2.4 Classification and Labelling

Overview

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.

Workload driver estimates	2015 actual	2016 estimate	2017 estimate
Proposals for harmonised classification and labelling	56	60	70
RAC opinions on proposals for harmonised classification and labelling	38	55	40
Alternative name requests	38	100	50
Helpdesk questions received ⁴⁴	360	250	250

Key objective

 $^{\rm 44}$ Regulatory and non-regulatory questions related to classification and labelling only.

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.

- Aim to reduce the overlapping work for the CLH process with the assessment processes for
 pesticides and biocides in MSCAs, committees and agencies by further development and
 support to the use of integrated assessment templates to reduce the workload of dossier
 submitters and increase efficiency of the processes.
- Efficiently manage the development of CLH opinions for biocides and pesticides, which are expected to increase in number in the coming years. The selection of industrial chemicals is based, to an increasing extent, on common screening.
- Publish updates to the guidance on the application of the CLP criteria and on labelling and packaging in accordance with CLP to take into account the 8th Adaptation to Progress (ATP) of the CLP Regulation during 2017.
- Update CLP guidance, as necessary, to reflect changes in information requirement. Depending
 on the further clarification of the applicability and development of the test methods, ECHA
 will work on the use of bioelution in C&L, with the aim of publication of new guidance during
 2018.
- Develop support on the use of read-across in CLP based on work done in 2016.
- Continue monitoring the convergence of self-classifications and where appropriate carry out focussed actions encouraging industry to agree on classifications and to update notifications accordingly.
- Provide scientific and technical support to the European Commission in the context of the further development of the United Nations Global Harmonised System of classification and labelling of chemicals (UNGHS). Continue to raise awareness amongst the public of the CLP pictograms. The European Commission intends to include questions on the use and recognition of CLP pictograms and understanding cautionary statements into a Eurobarometer study to be launched in late 2016, and the Agency will adapt its communication to the public on these matters in accordance with the survey's results.
- ECHA's HelpNet Secretariat will again organise a HelpNet CLP workshop which will, inter alia, address typical industry questions on practical labelling challenges.
- Support the implementation and collection of results from the Forum's pilot project on CLP addressing internet sales of chemicals

Performance indicators ⁴⁵	2015 actual	2016 estimate	2017 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	NA	10 months

⁴⁵ For new proposed indicators the values for 2015 and 2016 are not available (NA);

(NEW)Effective working time of ECHA staff used per CLH opinion	NA	NA	45 – 55 person days
(NEW)Percentage of ECHA Helpdesk question related to C&L, answered within the established timeframe (15 working days)	NA	NA	90%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	4 071 679	4 446 081
Human resources (FTE)	NA	23	23

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, 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 working groups in 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 for technical equivalence.

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

ECHA performs the evaluations and 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	2015 actual	2016 estimate	2017 estimate
Opinions on active substances approval (under the Review programme)	49	50	50
Biocides Inquiries received	152	50	50
Biocides Data sharing disputes	9	5	5
Applications for new active substance approval	9	23	8
Applications for renewal or review of active substances	7	0	2
Applications for Union authorisation for biocidal products	11	8	37
Applications for active substance suppliers (Article 95)	197	35	25
Assessment of technical equivalence	26	30	37
Submissions to Member States	3 631	3 000	3 000
Appeals submitted	4	1	3
Helpdesk questions received ⁴⁶	922	750	3 000

Key objective

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

- Implement further measures to increase the efficiency of the active substance approval process and the Review Programme based on the outcome of the workshop with Member States that took place in 2015 and subsequent discussions in 2016.
- Support the Member States Competent Authorities for the preparation of BPC opinions on active substances.
- Start preparations for the (re)evaluation of the approvals of certain active substances vis-àvis the new criteria for endrocrine disruptors, once they are adopted.
- Support the preparation of the first BPC opinions on Union authorisation of biocidal products with a special emphasis on the efficiency of the opinion forming process and the coordination between Member States Competent Authorities dealing with related applications.

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

- Evaluate the new applications for inclusion in the Article 95 list.
- Further develop the Register for Biocidal Products (R4BP 3),) and the SPC editor, in order to progress towards the comprehensive implementation of the biocides legislation.
- Publish updates to the Guidance on the Biocidal Products Regulation: new guidance on Volumes I, II, III & IV, Part C, Evaluation.
- Continue and finalise the European comparative assessment of biocidal products containing anticoagulant rodenticides active substances).
- Initiate the development of a new version of EUSES for biocides with the aim to cover new emission estimation models for all product types.
- Support the BPR enforcement by preparing the development of an IT tool for BPR inspectors and, if so desired by the Member States, by establishing and supporting a Forum subgroup to harmonise approaches to enforcing the BPR.

Performance indicators ⁴⁷	2015 actual	2016 estimate	2017 target
Level of satisfaction of the members of the BPC (inc. 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)Unplanned IT system downtime preventing submission within service hours (average of related IT systems, per month)	NA	NA	2%
(NEW)Percentage of BPR inquiries concluded within the target timeframe (20 working days)	NA	NA	80%
(NEW)Percentage of received BPR data sharing disputes handled within 60 days	NA	NA	100%
(NEW)Average time to process an active substance dossier (from competent authority evaluation report to BPC opinion)	NA	NA	9 months
(NEW)Effective working time of ECHA staff used per active substance opinion	NA	NA	27 – 33 person days
(NEW)Percentage of ECHA Helpdesk questions related to Biocides, answered within established timeframe (15 working days)	NA	NA	80%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	7 865 000	10 358 000
Human resources (FTE)	NA	53	59

 $^{^{47}}$ For new proposed indicators the values for 2015 and 2016 are not available (NA);

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.

Workload driver estimates	2015 actual	2016 estimate	2017 estimate
Export notifications	5 951	6 300	8 900
Helpdesk questions received ⁴⁸	209	150	650
Scientific and technical requests from the Commission, EU and non-EU DNAs	1 500	1 800	2 200

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.

- Process a continuously increasing number of notifications.
- Produce the three-year report on operation of the PIC Regulation, together with the routine annual report.
- Attend, in support of the Commission, the 8th Conference of the Parties to the Rotterdam Convention, provide scientific input and participate in the preparation of the Chemical Review Committee

Performance indicators ⁴⁹	2015	2016	2017
renormance mulcators	actual	estimate	target

⁴⁸ Regulatory and non-regulatory questions related to PIC only.

⁴⁹ For new proposed indicators the values for 2015 and 2016 are not available (NA)

Percentage of export notifications processed within the legal timeframe	99%	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	NA	<15 days

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	1 151 000	1 183 000
Human resources (FTE)	NA	7	7

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 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
- 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	2015 actual	2016 estimate	2017 estimate
Number of dossiers to be disseminated	12 200	10 000	13 000
Number of external requests for data	60	60	60

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.

- Consolidate different interfaces provided to the Authorities and Committees pursuing a secure single interface whereby different services (e.g. access to information on the progress of ECHA processes) are accessible. This will be supported by the Enterprise Data Model and into the Data Integration Platform.
- Implement the basis for recording information on substances and their related deficiencies and concerns across the different processes according to an Enterprise Data Model. Thus supporting the distribution of information to Authorities and reporting on actions and decisions taken across the regulatory processes on a substance or a dossier, supporting the sharing of information on the regulatory activities lifecycle and integrated views on multiple regulatory processes.
- Enrich the dissemination of biocides information with the automated publication of data extracted from biocides dossiers such as Summary Product Characteristics and Product Assessment Reports.
- Upgrade the common Data Integration Platform in terms of technology to replace obsolete components and architecture to further align with the enterprise data model
- Upgrade the enterprise content management (ECM) platforms
 - o EMC Documentum used to implement the ECHA solution for case management in the internal processes due to the end-of-life of the current version in use.
 - Microsoft Sharepoint used to implement the ECHA solution for case, process and document management related to the non-regulatory processes due to end-of-life of the current version in use.

- Prepare feasibility studies and implementation roadmaps for initiatives relevant to ECHA's stakeholders. For example, deliver data or access to data as a service to third parties when coherent with ECHA's mission; develop support for collection and dissemination of substances in articles data.
- Further develop tools and support to facilitate data provision by companies to national poison centres under Article 45 of the CLP Regulation.
 - o Integrate latest legislative changes into the tools and formats developed by the Commission in 2016, i.e. XML, PC Editor, Product Category System and UFI generator.
 - o Undertake, in collaboration with the Commission and Member States, a feasibility study into providing a 'one-stop notification' system that would enable participating Member States to receive notifications in the new format and facilitate companies notifications to multiple countries simultaneously.
- Continue to promote the data on chemicals to the general public, in collaboration with the media and accredited stakeholders.

Performance indicators ⁵⁰	2015 actual	2016 estimate	2017 target
Level of Member States' and Commissions user satisfaction with data management services	NA	High	High
Level of satisfaction of stakeholders with dissemination activities of ECHA.	NA	High	High
(NEW)Maximum continuous downtime (% non-availability) of the website, Portal Dashboard, S-CIRCA and Dynamic Case	NA	NA	2%
(NEW)Percentage of registered dossiers published on the Dissemination Portal within 20 working days from completing the registration process	NA	NA	90%

Resources	2015 actual		2017 estimate
Financial resources (costs, euros)	NA	10 097 385	10 104 257
Human resources (FTE)	NA	37	39

1.6 Delegated tasks – for information only

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 Regulation⁵¹ the tasks entrusted should be referred to in the annual work programme of the Agency

⁵⁰ For new proposed indicators the values for 2015 and 2016 are not available (NA)

⁵¹ MB/WP/03/2014, Article 8

for information purposes only, and the Executive Director shall consult the Management Board before signing the delegation agreement.

1.6.1 Nanomaterials Observatory

Based on a delegation agreement between the European Commission and ECHA the Agency is hosting the EU Observatory for Nanomaterials. The objective of the observatory is to provide publicly available information on nanomaterials in the EU market, their safety aspects, and related research activities. The Nanomaterials Observatory also aggregates, evaluates and interprets the data, and communicates the results to decision-makers, authorities and the general public in a user-friendly and easily understandable way. The observatory is a response by the Commission 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, thus hampering effective risk assessment, management, and enforcement.

Overview

Nanomaterials observatory is collecting available information on nanomaterials with a specific focus on their safety aspects, including how they are regulated, their hazards and risks, ongoing nanosafety research activities and their main results, and information about how they are marketed and used in the EU.

ECHA is using 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 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 that are planned to be released in 2017, 2018, and 2019.

Key objective⁵²

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

- Publish the first version of the observatory by June⁵³ 2017 based on readily available data and information sources.
- Start preparations for the second version to be published in 2018. The second version is planned to cover new information on sectoral legislation (e.g. food and cosmetics), further information on products and articles where nanomaterials are present, updated information on nanomaterials in EU market, and wider information on relevant research activities.

⁵² Performance indicator(s) to measure the achievement of Nano-Observatory's key objective will be developed within the first 6 month of its operation

⁵³ Six months from the signature of the delegation agreement

- Increase the focus on consumer oriented information,
- Complete the first step of an IT analysis to see what opportunities there are for creating e.g. search functionalities or interoperability between various data bases. Depending on the result initiate the development of them.

Resources	2015 actual		2017 estimate
Financial resources (costs, euros)	NA	800 000	600 000
Human resources (FTE)	NA	0,5	3

1.6.2 EU Chemical Legislation Finder

The Commission entrusted ECHA at the end of 2016 with performing a feasibility study with a view to set up an 'EU Chemical Legislation Finder' that aims at providing easy access to information on regulation applicable to a given chemical substance. 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 Chemical 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 action to be implemented consists of a feasibility study prior to the definition and implementation of a project, in particular with regard to the scope of the EU legislation to be covered, the potential market needs, the interoperability of data sources, the service level to be considered, the organisation aspects, the financial needs for the set-up and the update of IT solution and related services. ECHA received at the end of 2016 an amount of 100.000 EUR to undertake the feasibility study.

Key objective

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. In longer-term perspective, help identifying opportunities for streamlining legislations or addressing overlaps as well as gaps in the legislative landscape.

- Feasibility study as described above
- Depending on the outcome of the feasibility study, start preparations for the definition and implementation of the project.

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, and PIC 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	2015 actual	2016 estimate	2017 estimate
MSC meetings	6	6	6
RAC meetings	6	8	7
SEAC meetings	4	6	5
BPC meetings	4	5	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 2017

- Manage memberships of each Committee (renewals and new appointments/nominations), with specific focus on ensuring adequate capacity of RAC and SEAC. Review experiences gained with co-opted members.
- Implement efficiency improvements continuously in all Committees resulting from the completion and integration of IT tools.
- Prepare, run and follow-up the plenary meetings for the MSC (6), BPC (6), RAC (7) and SEAC (5).

Performance indicators ⁵⁴	2015 actual	2016 estimate	2017 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	NA	>60%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 705 446	3 358 212
Human resources (FTE)	NA	17	17

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	2015 actual	2016 estimate	2017 estimate
Number of REF projects (at any stage of project life cycle)	3	3	4
Number of pilot projects (at any stage of project life cycle)	4	6	4
Forum meetings	3	3	3
Active working groups	14	11	12

⁵⁴ For new proposed indicators the values for 2015 and 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 and the PIC regulations efficiently and effectively.

- Support via the Forum Secretariat, the harmonisation of national enforcement authorities' approaches to enforcement through three Forum plenary meetings, continued development through methodological tools, best practice and sharing of information.
- Continue preparing, executing and reporting from Forum coordinated enforcement projects. In addition, prepare the manual for the sixth Forum project (REF-6) and select the subject of seventh Forum project (REF-7).
- Continue establishing best practice in enforcement and testing enforcement approaches by running Forum pilot projects,
- Continue to examine enforcement proposals and deliver advice on enforceability of restrictions.
- Continue to promote intelligent use of information by maintaining institutional interlinks between ECHA and national enforcement authorities intended for enforcement of ECHA decisions by inspectors and provision of intelligence to the national authorities.
- Continue to support enforcement authorities by developing and delivering an annual training programme for inspectors to a group of national trainers.
- Continue to support enforcement by the national enforcement authorities via on-going improvement and modernisation of the IT-tools available to inspectors such as Portal Dashboard for national enforcement authorities

Performance indicators ⁵⁵	2015 actual	2016 estimate	2017 target
Level of satisfaction of the members and other participants with the functioning of the Forum Secretariat	High	High	High
(NEW)Portion of Member States (EU or EEA) participating in REF projects	NA	NA	100%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	1 702 050	1 551 735
Human resources (FTE) ⁵⁶	NA	8	8

⁵⁵ For new proposed indicators the values for 2015 and 2016 are not available (NA);

⁵⁶ Biocides resources are not included in this estimate but under the Biocide Activity in section 1.3 (p. 68)

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

Workload driver estimates	2015 actual	2016 estimate	2017 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.

- Organise 1 HelpNet Steering Group meeting and 6 HelpNet workshops on BPR, CLP and REACH
- Continue preparing questions and answers sets (FAQs) on BPR, CLP and REACH
- Complete the review of the Security Model applied to remote access for MSCAs to take into account new technological possibilities and new working practices
- Keep the national REACH helpdesks informed on developments related to the 2018 registration deadline to allow them to provide advice and assistance to potential registrants, in particular to SMEs that may be struggling with the preparation of their dossiers
- Organize a training (update) for national helpdesk correspondents on dossier submission

Performance indicators ⁵⁷	2015	2016	2017
	actual	estimate	target
Level of satisfaction of HelpNet members with the HelpNet Secretariat support	High	High	High

⁵⁷ For new proposed indicators the values for 2015 and 2016 are not available (NA)

(NEW)Quality of the advice provided by SON as perceived by the Management Board members	NA	NA	High

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	300 561	311 233
Human resources (FTE)	NA	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 Board itself, acts entirely independent from the ECHA Secretariat.

Workload driver estimates	2015 actual		2016 estimate		2017 estimate	
Workload arreit estimates	REACH	BPR	REACH	BPR	REACH	BPR
Appeals submitted	22	4	25	1	24	3
Procedural decisions	16	4	15	2	15	2
Cases closed	12	3	14	1	22	3

Key objective

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

- Process and decide on incoming appeals which are expected to include an increased number
 of registration and data sharing related cases due to the manual completeness check and the
 reinforcement of the OSOR principle in the REACH-IT as well as a steady influx of cases in
 relation to substance evaluation and compliance check decisions.
- Adopt up to 25 final appeal decisions, closing an appeal.
- 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 ⁵⁸	2015 actual	2016 estimate	2017 target
Percentage of final Board of Appeal decisions made within 90 working days of the closure of the written or oral procedure	93%	90%	90%
(NEW)Average time to process an appeal	NA	NA	15 months
(NEW)Effective working time of Board of Appeal and its Registry to conclude an appeal case against ECHA's decision	NA	NA	85 – 90 person days

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	1 680 880	1 696 662
Human resources (FTE)	NA	11	11

2.2 Management

ECHA is governed by a 36-member Management Board. The Executive Director is in charge of the management and administration of the Agency. He is the legal representative of the European Chemicals Agency and reports to ECHA's Management Board. Together with the Directors, he manages and supervises all activities of the Agency.

Overview

The Agency strives to ensure a modern corporate identity and management that complies with the highest EU 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 ISO9001:2015 certified, to organise its operations in a hierarchical or matrix structure. 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 an Archiving Strategy This includes reducing the need for paper in general and exploring the needs and opportunities of digitising current and legacy paper archives of the Agency.

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. 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 ECHA Secretariat supports the work of the Management Board and its working groups in its role as the governing body of the Agency.

⁵⁸ For new proposed indicators the values for 2015 and 2016 are not available (NA);

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.

ECHA will celebrate its 10th anniversary in 2017. To mark this milestone, the Agency will prepare suitable communication products and high-level events, also in cooperation with the City of Helsinki within the framework of the Helsinki Chemicals Forum and the 100 years anniversary of the Republic of Finland.

Workload driver estimates	2015 actual	2016 estimate	2017 estimate
Number of general questions	607	600	1 200
Management Board meetings	4	4	4
Number of audits to take place in a year ⁵⁹	13	17	17

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 outputs.

Main actions and outputs of 2017

Corporate governance and support activities will continue as foreseen in the standard planning, reporting and monitoring cycles, ensuring continuity and efficiency of the Agency's work. Specific activities in 2017 are:

- Coordinate and organize meetings and consultations with the Management Board, including its Working Groups
- Prepare and coordinate directors meetings including management decisions, delegations and policies
- Manage the Agency's reputation by: gathering feedback on the Agency's performance from stakeholders though surveys and by daily media and social media monitoring; and acting on the feedback received
- In recognition of both the need to communicate more effectively with consumers and workers, and the unsuitability of ECHA's website for these two target audiences, the Agency will build a separate website for them. This will retain ECHA branding and editorial content, but will have a different look and feel so as to make it more appealing to the general public. It will contain content on all aspects of chemicals in our life, including information on nanomaterials, as part of the remit of the EU Nanomaterials Observatory. The site will be developed in consultation with accredited stakeholders.

⁵⁹ This includes the internal audits and their follow-up performed by the European Commission's Internal Audit Sevice (IAS) and ECHA's Internal Audit Capability (IAC) as well as ECHA's Integrated Quality Management System audits

- Prepare suitable communication products and organise events to celebrate 10th anniversary of ECHA's establishment
- Contribute to the Commission's REACH review studies, communication and support documents, as well as to the implementation and follow-up of the exercise
- Perform audit activities in line with the annual audit plan.
- Optimise further the Integrated Quality Management and Internal Control Systems towards the 2017 surveillance audits
- Implement the Agency's environmental programme aiming at improving its environmental performance
- Implement the Archiving Strategy
- Respond to enquiries (ca. 500) from general public about ECHA and its activities.
- Support corporate planning and reporting on ECHA's activities
- Start implementing identified solution(s) to streamline planning and reporting activities
- 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.
- Implement the corporate-wide efficiency development programme with new projects, competency development, communication and performance management

Performance indicators ⁶⁰	2015 actual	2016 estimate	2017 target
Percentage of very important audit recommendations implemented within the deadline (IAS).	NA ⁶¹	100%	100%
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	1.5% increase	2% increase	2% increase
Level of satisfaction of MB Members with ECHA Secretariat's support to their governing role	High	High	High
(NEW)Number of critical recommendations from any auditor	NA	NA	0
(NEW)Proportion of work programme indicators for which the set targets were achieved	NA	NA	98%

Resources	2015 actual	2016 estimate	2017 estimate

⁶⁰ For new proposed indicators the values for 2015 and 2016 are not available (NA);

⁶¹ There were no very important audit recommendations in 2015.

Financial resources (costs, euros)	NA	7 711 311	7 138 594
Human resources (FTE)	NA	42	42

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	2015 actual	2016 estimate	2017 estimate
Number of amending budgets in a year	3	2	2
Number of subsidy requests (incl. cash-flow forecast requirements)	4	7	7
Number of outgoing payments in a year (incl. commercial invoices)	12 918	13 000	13 000
Number of fee receipts in a year	4 234	4 500	6 000
Number of contracts (incl. procurements and purchase orders)	739	700	700
SME status checks for REACH/CLP	423	500	330

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.

- Prepare and manage the implementation of budget, including amendments and transfers, revenue collection and cash management, procurement and contracting, financial reporting including annual accounts.
- Continue regular exchange with Commission partner services on revenue estimates for the future, the needs to review the fee regulations and discuss ways of handling any shortfall or surplus during the calendar year

- Monitor and report on reimbursements to Member States and prepare eventual reviews of the Management Board rules on this matter
- Continue extending the IT support for ECHA financial processes, following the needs and gaps identified during the analysis performed in 2016.
- Continuously ensure correctness of the SME fee reductions claimed by registrants with focus on examining registrations from the 2013 deadline.
- Implement further efficiency measures, including automation and streamlining of financial processes as part of the corporate efficiency development programme.

Performance indicators	2015 actual	2016 estimate	2017 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).	88%	80%	80%
Carryover rate (% of committed funds carried over into the next year)	11%	<20%	<20%
Cancelled carryover payment appropriations.	5%	≤5%	≤5%
Percentage of payments made within the legal/contractual deadlines	96%	≥95%	≥95%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 959 909	4 005 230
Human resources (FTE)	NA	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.

Workload driver estimates	2015 actual	2016 estimate	2017 estimate
Number of statutory staff selections completed	11	10	10
Number of recruitments completed	42	35	35
Number of trainings organised	265	250	275
Number of contract renewals	119	100	100
Number of statutory staff subject to annual appraisal	538	520	520
Number of staff in the payroll	563	550	550
Number of decisions related to entitlements	NA ⁶²	500	500

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.

- Conduct the annual objective setting, performance appraisal and reclassification exercises
- · Provide all HR services with high quality to the staff
- Maintain good relations and dialogue with the staff committee and European School of Helsinki and other major stakeholders
- Conduct the Job Screening Exercise as part of a wider inter-Agency benchmarking exercise initiated by the European Commission.
- Provide relevant training activities to ensure continuous capacity-building of staff
- Ensure the integration of the general competencies in all HR processes
- Ensure availability of necessary interim workforce especially for the upcoming registration deadline

Performance indicators 63	2015 actual	2016 estimate	2017 target
Percentage of establishment plan posts filled	98%	95%	98%
Turnover of TAs.	4%	< 5%	< 5%
Turnover of CAs (excluding short-term CAs).	12%	< 10%	< 10%

 $^{^{62}}$ Not available for 2015 as this is a new workload driver

⁶³ For new proposed indicators the values for 2015 and 2016 are not available (NA)

Level of satisfaction of all staff with the HR services	High	High	High
Percentage improvement in the Job Screening Exercise	1%	1%	1%
(NEW)Percentage of days that staff are absent from work due to sickness	NA	NA	≤5%

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 645 030	3 667 413
Human resources (FTE)	NA	27	25

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 in 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, but other vehicles are also used to increase the outreach to new audiences – for example, social media. 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	2015 actual	2016 estimate	2017 estimate
Number of work stations to maintain	650	700	700
Number of meetings held at ECHA Conference Centre (including internal meetings)	1 500	1 500	1 600
Number of facilities related incidents	820	1 400	1 400
Number of new publications produced	43	100	50
Number of pages translated into 22 languages	1 050	1 300	1 100

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.

- Implement an event management IT tool, according to the vision document prepared in 2016, to improve the efficiency of the process and better cope with the significantly increasing number of events per year
- Provide all corporate services at high quality to staff
- Maintain and enhance the use of the audio-visual equipment and facilities to reduce travel requirements of the members of ECHA bodies and its staff
- Prepare and submit to the European Parliament/Council a request for approval of the building project
- Final decision regarding the new long term lease in the same or a new building
- Maintain and further improve stakeholder relations via dedicated accredited stakeholder organisation communication activities, joint projects and events; interactions with Member States and EU partners in order to ensure efficient communication with a wide range of audiences throughout Europe.
- Maintain and improve all the internal and external communication vehicles of the Agency website, newsletters, press materials, publications, audio-visual products, social media and intranet
- Continue to translate materials that are important for small companies and the general public into 23 languages

Performance indicators ⁶⁴	2015 actual	2016 estimate	2017 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.	High	High	High
Level of reader satisfaction with ECHA's written output, including language availability measured in terms of timeliness, content and usability	High	High	High
Level of satisfaction of the staff with the corporate services	High	High	High
(NEW)Average time to resolve an internal, facility related request	NA	NA	<8h

⁶⁴ For new proposed indicators the values for 2015 and 2016 are not available (NA); estimation of 2017 targets will be provided in the final draft (tbc)

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 308 612	3 080 627
Human resources (FTE)	NA	23	21

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 competent and enforcement 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 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.

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 estimates	2015 actual	2016 estimate	2017 estimate
Number of IT related incidents	7 390	5 600	5 600
Number of IT contracts to be managed in a year ⁶⁵	105	111	111
Number of Agency- wide IT applications in operation	35	45	41

Key objective

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

- Revise and strengthen the relevant IT services and the IT support for business continuity to be prepared for the 2018 deadline
- Complete the roll-out of the new IT facilities for the workplace initiated in 2016
- Establish new outsourcing framework contracts for ICT services and software and application

⁶⁵ 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)

management services;

- Support the new model of delivering ECHA Cloud Services to SMEs users
- Consolidate integration management after the achievement in 2016 of the target information systems architecture (as mostly defined in 2011)
- Define and pursue a new target architecture for the IT landscape post 2018 deadline; in this context analyse in particular:
 - the operational and administrative needs associated with delivering software as a service e.g. cloud services for SMEs
 - the needs for a mobile IT strategy to assess the opportunity of adapting some of the ECHA's IT tools (e.g. the Portal Dashboard for Enforcement field work) to mobile devices
 - the needs and opportunities which can be met by leveraging the data management capabilities, services and platforms established in the previous years
 - The identification of new candidates for common components and services in ECHA's IT landscape (e.g. mass mailing solution)
- Maintain the Technology roadmap and ensure an adequate technology update index to prevent risks of security, obsolescence, loss of efficiency;

Performance indicators ⁶⁶	2015 actual	2016 estimate	2017 target
Availability of mission-critical systems for externally used IT systems (i.e. uptime during service hours).	98.5%	99% (average 98 %)	99% (average 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	NA	<8h

Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 164 759	3 374 020
Human resources (FTE)	NA	22	22

⁶⁶ For new proposed indicators the values for 2015 and 2016 are not available (NA)

Annexes

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Annex I: Resource allocation per Activity of the Work Programme 2017

Activity	Staff allocation – 2016 final estimate	Staff allocation - 2017 estimate	Draft Budget 2016	Budget estimate 2017
1.1. 1 Registration dossier preparation	48	49	11 736 098	12 330 283
1.1.2 Registration and dossier submission	43	42	9 256 352	9 564 452
1.1.3 Evaluation	106	106	18 947 311	17 874 662
1.1.4 Communication of risk management advice through the supply chain	17	16	2 996 515	3 036 807
1.2.1 Identifying needs for Regulatory Risk Management	17	16	2 961 639	3 143 386
1.2.2 Authorisation	33	31	5 830 893	5 544 310
1.2.3 Restrictions	17	16	3 274 879	3 454 427
1.2.4 Classification and Labelling	23	23	4 071 679	4 446 081
1.3 Biocides	53	59	7 865 000	10 358 000
1.4 PIC	7	7	1 151 000	1 183 000
1.5 Data management and dissemination	37	39	10 097 385	10 104 257
1.6 Delegated tasks	-	3	-	600 000
2.1.1 Committees	17	17	3 705 446	3 358 212
2.1.2 Forum	8	8	1 702 050	1 551 735
2.1.3 HelpNet and Security Officers Network	2	2	300 561	311 233
2.1.4 Board of Appeal	11	11	1 680 880	1 696 662
2.2 Management	42	42	7 711 311	7 138 594
2.3.1 Financial resources	27	26	3 959 909	4 005 230
2.3.2 Human resources	27	25	3 645 030	3 667 413
2.3.3 Corporate Services	23	21	3 308 612	3 080 627
2.3.4 ICT	22	22	3 164 759	3 374 020
Totals	580	581	107 367 309	109 823 390

Annex II: Human and Financial Resources

Table 1: Revenue

Title Chapter Article Item	Heading		Budget 2015	Budget 2016	Budget 2017
1	REVENUE FROM FEES AND CHARGES				
10	Revenue from fees and charges				
100	Fees and charges collected from registrations	REACH	21 720 585	23 210 566	24 795 753
101	Fees and charges collected from authorisations	REACH	728 239	5 961 449	523 418
102	Fees and charges from appeals	REACH	28 276	14 244	p.m.
103	Fees and charges from CLP	REACH	134 147	144 000	148 613
104	Other fees and charges	REACH	1 174 227	1 750 000	1 008 716
	Chapter 10 - Tota	al .	23 785 474	31 080 259	26 476 500
11	Revenue from fees and charges				
110	Fees relating to active substances	BIOCIDE	1 003 000	3 644 200	1 170 000
111	Fees for Union authorisation of biocidal products	BIOCIDE	1 654 000	2 203 000	2 881 300
112	Miscellaneous fees	BIOCIDE	2 761 667	1 600 000	1 720 000
113	Fees and charges from appeals	BIOCIDE	5 000	p.m.	p.m.
	Chapter 11 - Tota	al	5 423 667	7 447 200	5 771 300
19	Balancing fee income				
199	Balancing fee income	REACH	87 189 693	8 839 383	0
	Chapter 19 - Tota	al	87 189 693	8 839 383	0
	Title 1 - TOTA	L	116 398 833	47 366 842	32 247 800
2	CONTRIBUTIONS FROM THE GENERAL BUDGET OF TH	E EUROPEAN	UNION		
20	Contributions from the General Budget of the European Union				
200	Contributions from the General Budget of the European Union	REACH	0	58 936 000	69 489 500
		BIOCIDE	5 789 000	519 628	1 450 000

		PIC	1 222 001	1 039 880	1 139 537
	Contributions from the General Budget of the				
201	European Union - Assigned Revenue	REACH	0	0	0
		BIOCIDE	0	330 372	3 050 000
		PIC	0	111 120	43 463
202	IPA programs (earmarked)	REACH	0	p.m.	p.m.
203	Biocides programme(earmarked)	BIOCIDE	0	p.m.	p.m.
204	Other	REACH	0	p.m.	p.m.
		BIOCIDE	0	p.m.	p.m.
		PIC	0	p.m.	p.m.
	Chapter 20	0 - Total	7 011 001	60 937 000	75 172 500
	Title 2	- TOTAL	7 011 001	60 937 000	75 172 500
3	PARTICIPATION BY THIRD COUNTRIES IN THE ACTIVITIES	AGENCY'S			
30	Participation by third countries in the Agency's activ	ities			
300	EFTA contributions	REACH	0	1 626 630	1 716 390
		BIOCIDE	307 791	130 800	86 700
		PIC	0	p.m.	p.m.
	Chapter 30	0 - Total	307 791	1 757 430	1 803 090
	Title 3	- TOTAL	307 791	1 757 430	1 803 090
4	OTHER CONTRIBUTIONS				
40	Other contributions				
400	Other contributions	BIOCIDE	0	p.m.	p.m.
	Chapter 40	0 - Total	0	0	0
	Title 4	- TOTAL	0	0	0
5	ADMINISTRATIVE OPERATIONS				
Ε0					

50 Administrative operations

	Title 6 - TOTAL		300 000	0	0
	Chapter 60 - Total	1	300 000	0	0
603	Revenue from Delegation Agreements	REACH			600 000
602	Balancing of non-materialised fee income	BIOCIDE	0	p.m.	p.m.
		PIC	0	p.m.	p.m.
		BIOCIDE	0	p.m.	p.m.
601	Voluntary contributions from Member States	REACH	0	p.m.	p.m.
600	IPA programme	REACH	300 000	p.m.	p.m.
60	Contributions under specific agreements				
6	CONTRIBUTIONS UNDER SPECIFIC AGREEMENTS				
	Title 5 - TOTAL		757 651	4 584	0
	Chapter 50 - Total	<u> </u>	757 651	4 584	. 0
		PIC	0	p.m.	p.m.
- •		BIOCIDE	0	p.m.	p.m.
504	Administrative revenue from institutions and bodies	REACH	0	p.m.	p.m.
		PIC	0	p.m. p.m.	p.m. p.m.
503	Proceeds from the sale of goods and services	REACH BIOCIDE	0 0	p.m.	p.m.
503	Draggeds from the cale of goods and comiless	PIC REACH	0	p.m.	p.m.
		BIOCIDE	0	p.m.	p.m.
502	Revenue from investments and bank interest	REACH	317 787	4 584	p.m.
		PIC	924	p.m.	p.m.
		BIOCIDE	16 258	p.m.	p.m.
501	Reimbursement of miscellaneous expenditure	REACH	422 682	p.m.	p.m.
		PIC	0	p.m.	p.m.
500	Revenue from the sale of publications	REACH BIOCIDE	0	p.m. p.m.	p.m. p.m.

9	ADMINISTRATIVE OPERATIONS				
90	Administrative operations				_
900	Administrative operations	ECHA	0	p.m.	p.m.
		Chapter 90 - Total	0	0	0
		Title 9 - TOTAL	0	0	0
		TOTAL REVENUE	124 775 276	110 065 856	109 223 390

Annex II: Table 2 – Expenditure

Title Chapter Article I tem	Heading		Appropriations 2015	Appropriations 2016	Appropriations 2017
1	STAFF				
11	STAFF IN ACTIVE EMPLOYMENT				
110	Staff holding a post provided for in the establis	hment plan			
1100	Basic salaries	REACH	30 795 421	31 450 000	31 680 457
		BIOCIDE	2 563 506	2 519 200	3 030 000
		PIC	273 680	314 300	316 000
1101	Family allowances	REACH	3 229 671	3 324 000	3 465 500
		BIOCIDE	283 652	282 500	310 000
		PIC	21 655	29 200	31 100
1102	Expatriation and foreign residence allowances	REACH	3 713 847	3 834 000	3 791 700
		BIOCIDE	365 948	345 100	430 000
		PIC	31 294	37 600	38 000
	Article 110 -	Total	41 278 675	42 135 900	43 092 757
111	Other staff				
1112	Contract agents	REACH	4 823 743	5 006 500	5 381 600
		BIOCIDE	539 477	695 000	935 000

		PIC	45 906	41 000	45 000
1113	Seconded national experts	REACH	588 395	523 000	755 000
		BIOCIDE	86 056	83 500	85 000
		PIC	0	p.m.	p.m.
1114	Trainees	REACH	173 988	180 000	192 000
		BIOCIDE	0	6 400	18 000
		PIC	0	p.m.	p.m.
	Article 111 - Tota	al	6 257 564	6 535 400	7 411 600
113	Employer's social security contributions				
1130	Insurance against sickness	REACH	1 089 012	1 113 000	1 051 000
		BIOCIDE	89 603	93 800	105 000
		PIC	9 305	10 500	11 000
1131	Insurance against accidents and occupational disease	REACH	160 327	164 000	156 000
		BIOCIDE	13 204	14 000	16 000
		PIC	1 379	1 600	2 000
1132	Unemployment insurance	REACH	415 402	427 000	402 000
		BIOCIDE	33 312	35 100	40 000
		PIC	3 086	3 600	4 000
1133	Constitution or maintenance of pension rights	REACH	7 004 634	2 165 000	1 926 400
		BIOCIDE	0	309 300	395 000
		PIC	0	p.m.	p.m.
	Article 113 - Tota	al	8 819 265	4 336 900	4 108 400
114	Miscellaneous allowances and grants				
1140	Childbirth grants and death allowances	REACH	2 975	4 000	4 000
		BIOCIDE	1 388	1 000	1 000
		PIC	0	200	200
1141	Travel expenses for annual leave	REACH	779 937	805 000	800 000
		BIOCIDE	74 775	72 000	85 000

		PIC	9 347	12 852	15 000
1142	Other allowances and grants	REACH	61 782	29 444	20 000
		BIOCIDE	0	p.m.	p.m.
		PIC	0	p.m.	p.m.
1147	Shiftwork and standby duty	REACH	6 313	15 000	15 000
		BIOCIDE	0	p.m.	p.m.
		PIC	0	p.m.	p.m.
	Article 114 - 1	otal	936 516	939 496	940 200
115	Overtime				
1150	Overtime	REACH	1 141	3 000	3 000
		BIOCIDE	0	200	p.m.
		PIC	0	100	p.m.
	Article 115 - 1	otal	1 141	3 300	3 000
119	Weightings				
1190	Weightings	REACH	7 095 347	6 816 000	6 966 800
		BIOCIDE	611 461	546 000	658 000
		PIC	61 430	69 000	69 000
	Article 119 - 1	otal	7 768 239	7 431 000	7 693 800
	CHAPTER 11 - TO	TAL	65 061 399	61 381 996	63 249 757
12	MISCELLANEOUS EXPENDITURE ON STAFF RECRUITMENT AND TRANSFER				
120	Miscellaneous expenditure on staff recruitment	and transfer			
1200	Recruitment expenses	REACH	107 338	203 400	179 631
		BIOCIDE	7 124	12 994	23 236
		PIC	1 554	290	9 934
1201	Installation, resettlement, and daily subsistence allowances and removal and travel expenses	REACH	432 096	258 456	350 000
		BIOCIDE	78 817	70 000	96 000
		PIC	9 938	10 000	30 000

	Article 120 - Tota	I	636 866	555 140	688 801
	CHAPTER 12 - TOTAL	-	636 866	555 140	688 801
13	MISSIONS AND DUTY TRAVEL				
130	Missions expenses, duty travel expenses and ancill	ary expenditure			
1300	Missions expenses, duty travel expenses and ancillary expenditure	REACH	35 418	40 030	53 160
		BIOCIDE	3 713	3 480	6 120
		PIC	446	530	720
	Article 130 - Tota	I	39 577	44 040	60 000
	CHAPTER 13 - TOTAL	-	39 577	44 040	60 000
14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE				
140	Restaurants and canteens				
1400	Restaurants and canteens	REACH	58 236	22 810	23 036
		BIOCIDE	6 558	1 984	2 652
		PIC	787	301	312
	Article 140 - Tota	I	65 581	25 095	26 000
141	Medical service				
1410	Medical service	REACH	360 760	402 737	457 176
		BIOCIDE	40 447	34 947	52 632
		PIC	4 858	5 314	6 192
	Article 141 - Tota	I	406 066	442 998	516 000
142	Social welfare				
1420	Special allowances and assistance grants	REACH	0	p.m.	p.m.
		BIOCIDE	0	p.m.	p.m.
		PIC	0	p.m.	p.m.
1421	Special allowance for handicapped	REACH	11 638	33 506	30 124
		BIOCIDE	1 311	2 912	3 468
		PIC	157	442	408

1423	Social contacts between staff	REACH	54 146	55 638	122 268
1425	Social contacts between stair	BIOCIDE	6 098	4 848	14 076
		PIC	732	764	1 656
	Article 142 - To		74 081	98 110	172 000
144	Early childhood centres and schooling		7, 66.	70 1.0	.,,,
1441	Early childhood centres and schooling	REACH	1 133 553	999 796	1 069 106
	3	BIOCIDE	95 057	89 493	123 081
		PIC	467	1 082	14 480
	Article 144 - To	otal	1 229 077	1 090 371	1 206 667
	CHAPTER 14 - TOI	ΓAL	1 774 805	1 656 574	1 920 667
15	TRAINING				
150	Further training and language courses				
1500	Further training and language courses for staff	REACH	1 020 834	972 031	1 016 400
		BIOCIDE	88 665	84 100	119 227
		PIC	10 695	14 172	14 705
	Article 150 - To	otal	1 120 194	1 070 303	1 150 332
	CHAPTER 15 - TOI	ΓAL	1 120 194	1 070 303	1 150 332
16	EXTERNAL SERVICES				
160	External services				
1601	Administrative assistance from Union institutions	REACH	502 062	494 361	476 668
		BIOCIDE	56 538	40 141	54 876
		PIC	6 785	6 148	6 456
1602	Interim services	REACH	875 027	1 109 000	1 100 000
		BIOCIDE	216 510	376 000	326 000
		PIC	49 735	54 700	51 733
	Article 160 - To	otal	1 706 656	2 080 350	2 015 733
	CHAPTER 16 - TOI	ΓAL	1 706 656	2 080 350	2 015 733
7	ENTERTAINMENT AND REPRESENTATION EXPENSES				

170	Entertainment and representation expenses				
1700	Entertainment and representation expenses	REACH	3 844	7 672	17 940
		BIOCIDE	429	680	2 060
		PIC	0	p.m.	p.m.
	Article 170 -	- Total	4 274	8 352	20 000
	CHAPTER 17 - TOTAL		4 274	8 352	20 000
	Title 1 -	Total	70 343 772	66 796 755	69 105 290

Title Chapter Article Item	Heading		Appropriatio ns 2015	Appropriatio ns 2016	Appropriatio ns 2017
2	BUILDING, EQUIPMENT AND MISCE	LLANEOUS OPERATING EXPEN	DITURE		
20	RENTAL OF BUILDINGS AND ASSOCIATE	ED COSTS			
200	Rental costs				
2000	Rental costs	REACH	5 962 026	5 564 487	5 289 924
		BIOCIDE	317 520	298 155	616 956
		PIC	64 032	59 955	72 583
	Д	Article 200 - Total	6 343 578	5 922 597	5 979 463
201	Insurance				
2010	Insurance	REACH	33 302	7 170	8 370
		BIOCIDE	1 771	390	540
		PIC	354	80	90
	Д	Article 201 - Total	35 428	7 640	9 000
202	Water, gas, electricity, heating				
2020	Water, gas, electricity, heating	REACH	264 377	p.m.	267 840
		BIOCIDE	14 063	2 978	17 280
		PIC	2 813	1 504	2 880
	A	Article 202 - Total	281 252	4 482	288 000

203	Cleaning and maintenance				
2030	Cleaning and maintenance	REACH	265 247	292 302	309 062
		BIOCIDE	14 109	15 629	19 940
		PIC	2 822	3 146	3 324
	Article 203 -	Total	282 178	311 077	332 326
204	Fitting out of premises				
2040	Fitting out of premises	REACH	50 166	193 970	26 040
		BIOCIDE	2 675	10 575	1 680
		PIC	534	2 115	280
	Article 204 -	Total	53 375	206 660	28 000
205	Security and surveillance of the building				
2050	Security and surveillance of the building	REACH	552 949	663 532	649 152
		BIOCIDE	29 433	35 382	41 401
		PIC	5 870	7 076	6 901
	Article 205 -	Total	588 251	705 990	697 454
206	Preliminary expenditure to construction, acqui	isition or rental of imr	novable property		
2060	Preliminary expenditure to construction, acquisition or rental of immovable property	REACH	16 892	186 299	116 250
		BIOCIDE	899	9 910	7 500
		PIC	179	1 982	1 250
	Article 206 -	Total	0	198 190	125 000
	CHAPTER 20 - T	OTAL	7 584 061	7 356 636	7 459 243
21	INFORMATION AND COMMUNICATION TECHNOLOG	Υ			
210	ICT equipment, software and external services	s			
2100	ICT Equipment - Hardware and software	REACH	1 268 872	1 066 737	579 816
		BIOCIDE	67 493	56 475	66 752
		PIC	13 499	11 296	7 854
2101	ICT Maintenance	REACH	1 027 848	361 832	210 726
		BIOCIDE	54 677	19 246	24 260

		PIC	10 935	3 849	2 855
2103	Analysis, programming, technical assistance and other external services for the administration of the Agency	REACH	2 763 616	4 445 782	4 900 240
		BIOCIDE	212 504	249 616	548 842
		PIC	28 290	47 295	66 373
2106	Telecommunications equipment	REACH	43 778	p.m.	p.m.
		BIOCIDE	1 550	p.m.	p.m.
		PIC	81	p.m.	p.m.
2107	Telecommunication charges	REACH	135 431	265 754	498 021
		BIOCIDE	15 249	23 360	57 335
		PIC	1 819	3 420	6 746
	Article 210 - Tota	I	5 645 641	6 554 662	6 969 820
	CHAPTER 21 - TOTAL	-	5 645 641	6 554 662	6 969 820
22	MOVABLE PROPERTY AND ASSOCIATED COSTS				
220	Technical equipment and installations				
2200	Technical equipment and installations	REACH	78 197	219 058	177 200
		BIOCIDE	8 782	19 038	20 400
		PIC	1 056	2 892	2 400
	Article 220 - Tota	I	88 036	240 988	200 000
221	Furniture				
2210	Furniture	REACH	50 995	172 087	113 408
		BIOCIDE	5 743	14 993	13 056
		PIC	689	2 290	1 536
	Article 221 - Tota	I	57 428	189 370	128 000
223	Vehicles				
2230	Vehicles	REACH	1 334	3 318	3 101
		BIOCIDE	150	289	357
		PIC	18	44	42
	Article 223 - Tota	1	1 503	3 651	3 500

225	Documentation and library expenditure				
2250	Documentation and library expenditure	REACH	28 805	42 856	37 585
		BIOCIDE	3 241	3 725	1 778
		PIC	394	566	210
	Article 22	5 - Total	32 440	47 147	39 573
	CHAPTER 22	- TOTAL	179 407	481 155	371 073
23	CURRENT ADMINISTRATIVE EXPENDITURE				
230	Stationary and office supplies				
2300	Stationary and office supplies	REACH	103 201	92 292	89 486
		BIOCIDE	11 585	8 090	10 302
		PIC	1 394	1 218	1 212
	Article 23	0 - Total	116 181	101 600	101 000
232	Financial Charges				
2320	Bank and other financial charges	REACH	122	800	886
		BIOCIDE	0	p.m.	102
		PIC	0	p.m.	12
	Article 23	2 - Total	122	800	1 000
233	Legal expenses				
2330	Legal expenses	REACH	0	5 000	25 000
		BIOCIDE	0	p.m.	p.m.
		PIC	0	p.m.	p.m.
	Article 23	3 - Total	0	5 000	25 000
235	Other administrative expenditure				
2350	Miscellaneous insurance	REACH	1 934	6 363	6 645
		BIOCIDE	218	553	765
		PIC	26	84	90
2351	Transportation and removal services	REACH	358	5 909	2 658
		BIOCIDE	40	514	306

	Title 2 - Tot	al	13 613 516	14 644 061	15 085 831
	CHAPTER 25 - TOT.	AL	8 271	11 000	6 000
	Article 250 - To	tal	8 271	11 000	6 000
		PIC	99	132	72
		BIOCIDE	827	869	612
2500	Administrative meeting expenditures	REACH	7 345	9 999	5 316
250	General meeting expenditures				
25	MEETINGS EXPENDITURE				
	CHAPTER 23 - TOT.	AL	196 135	240 608	279 695
	Article 235 - To	tal	79 832	133 208	152 695
		PIC	0	p.m.	24
		BIOCIDE	0	p.m.	204
2357	Publications	REACH	549	2 000	1 772
		PIC	0	p.m.	p.m.
		BIOCIDE	0	p.m.	p.m.
2356	Administrative translation and interpretation costs	REACH	0	p.m.	p.m.
		PIC	288	426	648
		BIOCIDE	2 400	2 411	5 513
2355	Business Consultancy	REACH	51 692	77 725	99 889
		PIC	268	445	410
		BIOCIDE	2 226	2 935	3 483
2354	Postage and delivery charges	REACH	19 828	33 765	30 252
		PIC	0	p.m.	p.m.
		BIOCIDE	0	p.m.	p.m.
2353	Other operating expenditure	REACH	0	p.m.	p.m.
		PIC	5	78	36

Title Chapter Article Item	Heading	Executed Commitment Appropriations 2015	Executed Payment Appropriations 2015	Commitment Appropriations 2016	Payment Appropriations 2016	Commitment Appropriations 2017	Payment Appropriations 2017
3	OPERATING EXPENDITURE - REACH						
30	REACH						
300	OPERATIONAL ACTIVITIES - IMPLEMENTATION OF T	HE REACH PROCE	ESSES				
3003	Registration, datasharing and dissemination	562 988	196 122	572 000	572 000	1 097 000	1 097 000
3004	Evaluation	1 654 669	218 614	1 302 450	1 302 450	260 000	260 000
3005	Risk Management	536 198	272 285	460 000	460 000	900 000	900 000
3006	Classification and labelling	0	0	20 000	20 000	170 000	170 000
3007	Advice and assistance through guidance and helpdesk	154 965	146 092	173 900	173 900	223 000	223 000
3008	Scientific IT tools	13 704 528	9 858 509	15 138 000	15 138 000	10 951 836	10 951 836
3009	Scientific and technical advice to EU institutions and bodies	188 689	100 469	114 000	114 000	551 000	551 000
	Article 300 - Total	16 802 036	10 792 092	17 780 350	17 780 350	14 152 836	14 152 836
301	ECHA'S BODIES AND CROSS-CUTTING ACTIVITIES						
3011	Committees and Forum	1 371 659	1 062 472	2 252 100	2 252 100	1 442 500	1 442 500
3012	Board of Appeal	58 793	24 487	84 500	84 500	83 000	83 000
3013	Communications including Translations	2 852 905	2 179 962	4 088 490	4 088 490	3 886 140	3 886 140
3014	International cooperation	0	0	p.m.	p.m.	p.m.	p.m.
	Article 301 - Total	4 283 357	3 266 921	6 425 090	6 425 090	5 411 640	5 411 640
302	MANAGEMENT, ORGANISATION AND RESOURCES						
3022	Management Board and management of the Agency	1 032 474	817 990	862 900	862 900	1 132 826	1 132 826
	Article 302 - Total	1 032 474	817 990	862 900	862 900	1 132 826	1 132 826
303	HORIZONTAL ACTIVITIES						
3030	Missions	534 517	512 374	582 000	582 000	594 100	594 100
3031	External training	0	0	p.m.	p.m.	p.m.	p.m.
	Article 303 - Total	534 517	512 374	582 000	582 000	594 100	594 100
309	REFUNDS REACH/CLP						
3090	Refunds REACH/CLP	0	0	0	0	0	0

	Title 3 - Total	22 844 674	15 933 378	27 084 540	26 309 440	23 380 002	23 327 785
	CHAPTER 39 - TOTAL	0	0	0	0	600 000	600 000
	Article 391 - Total	0	0	0	0	600 000	600 000
3911	Delegated tasks					600 000	600 000
391	Delegated tasks						
	Article 390 - Total	0	0	0	0	0	0
3903	IPA programme according to agreement 2015/361-049	0	0	p.m.	p.m.	p.m.	p.m.
3902	IPA programme according to agreement 2012/291-934	0	0	p.m.	p.m.	0	0
390	IPA EXPENSES RELATED TO EARMARKED REVENUE						
39	EARMARKED OPERATIONS						
	CHAPTER 38 - TOTAL	154 900	337 707	1 140 000	645 100	300 000	1 100 140
	Article 380 - Total	154 900	337 707	1 140 000	645 100	300 000	1 100 140
3801	Cooperation with international organisations for IT programmes	154 900	337 707	1 140 000	645 100	300 000	1 100 140
380	Cooperation with OECD and other international actors						
38	INTERNATIONAL ACTIVITIES						
	CHAPTER 31 - TOTAL	37 390	206 294	294 200	14 000	1 188 600	336 243
	Article 311 - Total	37 390	206 294	294 200	14 000	1 188 600	336 243
3111	Substance evaluation and Rapporteurs	37 390	206 294	294 200	14 000	1 188 600	336 243
311	SUBSTANCE EVALUATION AND RAPPORTEURS (MULTI	ANNUAL)					
31	MULTIANNUAL ACTIVITIES						
	CHAPTER 30 - TOTAL	22 652 384	15 389 376	25 650 340	25 650 340	21 291 402	21 291 402
	Article 309 - Total	0	0	0	0	0	0

Title Chapter Article I tem	Heading	Appropriations 2015	Appropriations 2016	Appropriations 2017
4	OPERATING EXPENDITURE - BIOCIDES			_
40	BIOCIDES			

400	OPERATIONAL ACTIVITIES - IMPLEMENTATION OF THE	BIOCIDES PRO	CESSES	
4000	Substances, products and technical equivalence	0	p.m.	50 00
4001	Refunds pursuant to Article 13 of the Regulation (EU) 564/2013	0	p.m.	p.m
4003	Submissions, datasharing and dissemination	0	p.m.	p.m
4007	Advice and assistance through guidance and helpdesk	27 057	30 125	31 65
4008	Scientific IT tools	1 470 733	1 374 470	1 095 95
4009	Scientific and technical advice to EU institutions and bodies	0	p.m.	p.n
	Article 400 - Total	1 497 790	1 404 595	1 177 60
401	ECHA'S BODIES AND CROSS-CUTTING ACTIVITIES			
4011	Biocidal products Committee and Forum	293 162	287 000	489 20
4012	Board of Appeal	3 658	12 000	15 50
4013	Communications including Translations	162 591	80 020	99 71
	Article 401 - Total	459 411	379 020	604 41
402	MANAGEMENT, ORGANISATION AND RESOURCES			
4022	Management Board and management of the Agency	126 483	70 773	118 59
	Article 402 - Total	126 483	70 773	118 59
403	HORIZONTAL ACTIVITIES			
4030	Missions	30 293	73 800	66 60
4031	External training	0	p.m.	p.n
	Article 403 - Total	30 293	73 800	66 60
	CHAPTER 40 - TOTAL	2 113 977	1 928 188	1 967 20
48	INTERNATIONAL ACTIVITIES			
480	Cooperation with OECD and other international actors			
4801	Cooperation with international organisations for IT programs	0	p.m.	p.r
	Article 480 - Total	0	0	
	CHAPTER 48 - TOTAL	0	0	

49

490	BIOCIDES EXPENSES RELATED TO EARMARKED REVEN	NUE		
4900	BIOCIDES programme according to the service contract ENV.D.3/SER/2011/552228	0	p.m.	p.m.
4901	Preparatory work for the implementation of the BPR, as 4901 per letter 13/3938 of 13/12/2013 by the Royal Norwegian Ministry of Environment		p.m.	p.m.
	Article 490 - Total	0	0	0
	CHAPTER 49 - TOTAL	0	0	0
	Title 4 - Total	2 113 977	1 928 188	1 967 208

Title Chapter Article Item	Heading	Appropriations 2015	Appropriations 2016	Appropriations 2017
5	OPERATING EXPENDITURE - PIC			
50	PIC			
500	OPERATIONAL ACTIVITIES - IMPLEMENTATION OF T	HE PIC PROCESS	ES	
5000	Studies and consultants	0	p.m.	p.m.
5007	Advice and assistance through guidance and helpdesk	0	p.m.	p.m.
5008	Scientific IT tools	225 853	362 472	305 974
	Article 500 - Total	225 853	362 472	305 974
501	ECHA'S BODIES AND CROSS-CUTTING ACTIVITIES			
5011	Meetings with the DNAs and expert groups on PIC implementation	0	p.m.	p.m.
5013	Communications including Translations	208 689	5 740	17 402
	Article 501 - Total	208 689	5 740	17 402
503	HORIZONTAL ACTIVITIES			
5030	Missions	12 855	19 200	13 900
5031	External training	0	p.m.	p.m.
	Article 503 - Total	12 855	19 200	13 900
	CHAPTER 50 - TOTAL	447 397	387 412	337 276
	Title 5 - Total	447 397	387 412	337 276

Annex II: Table 3 - Budget outturn and cancellation of appropriations Calculation budget outturn

REACH / CLP

Budget outturn	2013	2014	2015
Reserve from the previous years' surplus (+)	171 892 360	160 044 885	87 189 692
Revenue actually received (+)	89 183 277	27 817 012	24 825 943
Payments made (-)	-87 417 947	-90 826 274	-93 301 724
Carry-over of appropriations (-)	-10 288 735	-10 333 258	-10 460 492
Cancellation of appropriations carried over (+)	1 451 030	490 200	546 332
Adjustment for carry over of assigned revenue appropriations from previous year (+)			51 427
Exchange rate differences (+/-)	-2 645	-2 873	-11 794
Adjustment for negative balance from previous year (-)			
Total	164 817 340	87 189 692	8 839 384

The amount of € 1 058 576 remained uncommitted.

BIOCIDES

Budget outturn	2013	2014	2015
Revenue actually received (+)	7 484 948	7 728 121	11 536 716
Payments made (-)	-5 105 036	-7 089 216	-6 653 783

Budget outturn	2013	2014	2015
Carry-over of appropriations (-)	-2 243 829	-543 110	-2 037 505
Cancellation of appropriations carried over (+)	178 792	234 577	26 444
Adjustment for carry over of assigned revenue appropriations from previous year (+)			178 581
Exchange rate differences (+/-)			0
Adjustment for negative balance from previous year (-)			0
Total	314 875	330 372	3 050 453

The amount of € 636 341 remained uncommitted and is cancelled.

PIC

Budget outturn	2013	2014	2015
Revenue actually received (+)	1 561 500	1 297 391	1 222 925
Payments made (-)	-461 657	-1 003 063	-1 015 317
Carry-over of appropriations (-)	-1 048 839	-192 017	-164 310
Cancellation of appropriations carried over (+)	40 762	8 810	2 769
Adjustment for carry over of assigned revenue appropriations from previous year (+)			166
Exchange rate differences (+/-)			
Adjustment for negative balance from previous year (-)			

Budget outturn	2013	2014	2015
Total	91 766	111 121	46 233

The amount of € 43 463 remained uncommitted and is cancelled.

Annex III. Staff population and its evolution

Table 1 – Overview of all categories of staff

Staff pop		a	populati ctually fi 31.12.20	lled ir	1	EL	opulatio J budget	2019	5	2	populati ctually f 31.12.20	lled i 015×	n		pulation budget	2016			budg	jet 20					get 2	018×				2019		
		REACH/ CLP	Sio ci des	PIC	TOTAL	REACH/ CLP	Siccides	PIC		RE ACH/ CLP	Biocid es	PIC	TOTAL	REACH/	Siocide s	PIC	TOTAL	REACH/ CLP	Siocid	PIC	Deleg sted tooks		REACH / CLP	Siocid es	PIC	De leg a te d taaka	TOTAL	REACH/ CLP	Siocid es	PIC	Deleg sted tesks	TOTAL
Officials	AD	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	\vdash	-	-	-	-		-
OHCES	AST	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		•	-	-	-		-	-	-	-		-
	AD	307	31	1	339	308	39	1	348	304	31	1	336	303	30	1	334	301	35	1		337	298	38	1		337	298	43	1		342
TA	AST	126	9	5	140	122	9	- 5	136	117	9	5	131	117	9	5	131	109	9	5		123	106	9	6		121	106	10	- 6		127
	AST/SC																															
Total AD	+AST	433	40	6	479	430	48	6	484	421	40	6	467	420	39	6	465	410	44	6		460	404	47	7		458	404	53	7		464
																			•					•								
CA FG IV		17	3	0	20	18	3	1	22	14	- 4		18	20	4	1	25	19	- 6	1	2	28	18	10	- 1	2	31		10	1	2	30
CA FG III		55	5	0	60	62	5		67	53	- 6		59	64	8		72	65	7		- 1	73	66	- 6		1	73	62	- 6		1	69
CA FG II		21	2	1	24	15	2		17	23	0	1	24	18	2		20	18	2			20	24	2			26	18	2			20
CA FG I		2	0	0	2	3	0		3	2			2				0					0					0					(
TOTAL CA	As in place	95	10	1	106					92	10	1	103																			
Total CA	(FTE)	89.8	8,49	1	99	98	10	1	109	85	9.08	1	95	102	14	1	117	102	15	1	3	121	108	18	1	3	130	97	18	1	3	119
SNE		11	1	0	12	13	2	0	15	7	1		8	13	2	0	15		1	0		14	_	2	0	0	17		2	0	0	17
Structura providers*		45			45					40			40																	_		
Total		584	51	7	642	541	60	7	608	560	51	7	618	535	55	7	597	525	60	7	3	595	527	67	8	3	605	516	73	8	3	600
External s occasiona e placeme	d	34	7	2	43					34	9	3	46																			
		^ 9 TAs (ınder reeru	Oment						^ 3 TAs u	nder reer	ilmeni	t					* finel nu	mber d	posts	will be		* final n	umber of	posts (will be						
		* 1 CA u	nder reeru	Oment						* 3 CAs o	inder reer	ulimen	E .					determin	ed by th	ic budg	ctary		determin	ed by th	c budg	dary						

authority

authority

Table 2	– Mu	ılti-anr	านส	al staf	f policy plan 2017-2019																			
Category	Esta	blishmer	nt pl	an in	Modifie	cations e	envis	saged in	Establ	ishment	plar	n in the	Establi	ishment	pla	n in the	Establ	ishment	t pla	n 2018	Establ	ishmen	t pla	n 2019
and grade	vote	d EU Bud	get	2015	establi	ishment	plan	2015 in	vote	d EU bud	get	2016	draf	t EU buc	lget	2017								
					applica	ition of f	lexib	ility rule																
		TA				TA	ı			TA			TA					TA				TA		
	REACH/				REACH/				REACH/				REACH/				REACH/				REACH/			
	CLP	Biocides	PIC	TOTAL	CLP	Biocides	PIC	TOTAL	CLP	Biocides	PIC	TOTAL	CLP	Biocides	PIC	TOTAL	CLP	Biocides	PIC	TOTAL	CLP	Biocides	PIC	TOTAL
AD 16	0	0	0	0					0		0	0	0		0	0	0		0	0	0		0	0
AD 15	1	0	0	1					1		0	1	1		0	1	1		0	1	1		0	1
AD 14	4	0	0						4		0		5		0				0				0	7
AD 13	14	1	0	15					15		0		15		0	15	15		0				0	16
AD 12	23	2	0						20	2	0		18		0		18		_				0	21
AD 11	29	3	0						31	3	0		31	3	<u> </u>		31		_		31		_	34
AD 10	31	4	0						33	3	0		36	3	0	39	38		0					44
AD 9	48	7	0	•					48	6	0		48	6		• •	49		•					60
AD 8	48	12	1	61					50	9	1	60	49			62	48				50			63
AD 7	48	6	0	•					52	5	0		59		0	• •	61	5	_				0	63
AD 6	53	4	0	57					41	4	0		31	4	0	35			_		21		_	27
AD 5	9	0	0	9					8		0	8	8		0	8	6		0	6	5	1	0	6
Total AD	308	39	1	348					303	32	1	336	301	35	1	337	298	38	1	337	298	43	1	342
AST 11	0	0	0	0					0		0	0	0		0	0	0		0	0	0		0	0
AST 10	1	0	0	1					0		0	0	0		0	0	1		0	1	1		0	1
AST 9	7	0	0	7					6		0	6	5		0	5	4		0	4	5		0	5
AST 8	8	0	0	•					9		0		7		0	7	6		0	_			0	8
AST 7	12	1	2						12	1	2	15	11	1	2	14	11		2	14			2	15
AST 6	16	0	0						16		0		15		0				0				0	19
AST 5	29	3							31	3	0		31	3	_	34	27		-				_	34
AST 4	16	2							12	2	0		19			22	23							23
AST 3	18	3	3						19	1	3		13	3	=	18			_		13		2	16
AST 2	10	0	0						7		0	_	5		0	5	3		0				0	1
AST 1	5	0	0	5					5		0	5	3		0	3	0		0	0	0		0	0
Total AST	122	9	5	136					117	7	5	129	109	9	5	123	106	9	6	121	106	10	6	122
AST/SC 6				0								0				0				0				0
AST/SC 5				0								0				0				0				0
AST/SC 4				0								0				0				0				0
AST/SC 3				0								0				0				0				0
AST/SC 2				0								0				0				0				0
AST/SC 1				0								0				0				0				0
TOTAL																								
AD+AST	430	48	6	484					420	39	6	465	410	44	6	460	404	47	7	458	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 ten 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 2014, ECHA did not recruit secretaries at AST level and, for the period 2016-2018, 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 registration deadline, ECHA is planning on using specific shorter term CA contracts as well.

d. Seconded national experts⁶⁷

⁶⁷ SNEs are not employed by the agency

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.

e. Structural service providers68

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 replacement⁶⁹

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.

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 2017–2019, ECHA estimates the following intake of graduate trainees:

Year	2016	2017	2018	2019
Trainees	25	30	30	30

⁶⁸ Structural service providers are not employed by the agency

⁶⁹ 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 at 1.0°	activity 1.2014	How ma membe prom reclass 20	Average number of years in grade of reclassified/pro moted staff members in 2015	
	officials	TA	officials	TA	
AD 16		0	0	0	N/A
AD 15		1	0	0	N/A
AD 14		1	0	0	N/A
AD 13		6	0	0	N/A
AD 12		16	0	1	5.38
AD 11		17	0	0	N/A
AD 10		26	0	2	5.15
AD 9		44	0	2	4.96
AD 8		42	0	1	5.00
AD 7		57	0	15	4.51
AD 6		63	0	20	4.10
AD 5		57	0	7	4.25
Total AD		330	0	48	4.76
AST 11		0	0	0	N/A
AST 10		0	0	0	N/A

AST 9	2	0	0	N/A
AST 8	1	0	0	N/A
AST 7	6	0	0	N/A
AST 6	11	0	0	N/A
AST 5	18	0	1	4.75
AST 4	27	0	10	4.13
AST 3	41	0	7	4.32
AST 2	15	0	3	4.45
AST 1	14	0	5	3.99
Total AST	135	0	26	4.33
Total	465	0	74	4.54

Table 2 - Reclassification of contract staff

Function Group	Grade	Staff in activity at 1.01.2014	How many staff members were reclassified in 2015	Average number of years in grade of reclassified staff members in 2015
CAIV	18	0	0	N/A
	17	0	0	N/A

	16	2	0	N/A
	15	0	0	N/A
	14	9	1	3.63
	13	6	2	3.81
CAIII	12	0	0	N/A
	11	0	0	N/A
	10	11	1	5.46
	9	27	1	4.75
	8	13	2	4.94
CAII	7	0	0	N/A
	6	0	0	N/A
	5	9	0	N/A
	4	7	0	N/A
CA I	3	0	0	N/A
	2	0	0	N/A
	1	3	2	3.12
Total		87	9	4.28

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/74/2010) on the policy and procedure for the reclassification of Temporary Agents dated 17 December 2010 (implementing Article 10 of the Staff Regulations and Article 10 of the CEOS).

ECHA is actively engaging with the Inter-Agency Standing Working Group with respect to adapting its reclassification systems, in accordance with the requirements of the new Staff Regulations.

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.

Annex IV. C. Mobility policy

Mobility within ECHA

ECHA revised its internal mobility policy in 2014, in collaboration with the Staff Committee, with the objective of encouraging mobility within the organisation and attracting candidates with profiles that can be used in ECHA's various Directorates. In 2015, eight (8) staff members availed of internal mobility opportunities within ECHA.

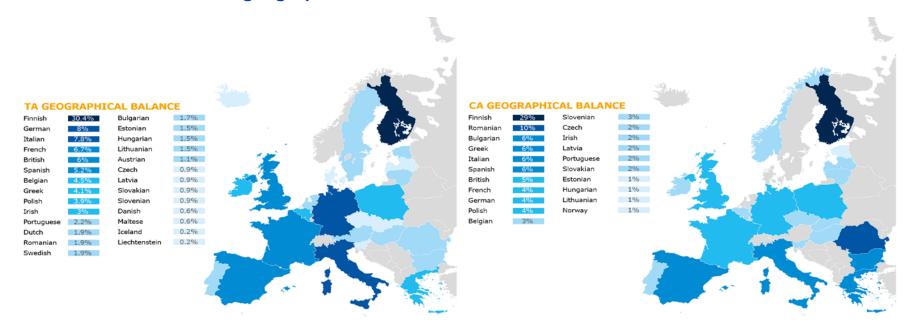
Mobility between Agencies (Inter-Agency Job Market)

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. In 2015, there were no Inter Agency Mobility calls published by ECHA.

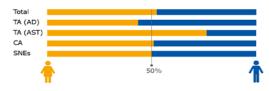
Mobility between the Agencies and the Institutions

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



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 40 % 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 2015-2016 are the following: nursery: 17, primary: 83 and secondary: 46. The total number of ECHA related children is therefore 146, 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 2014/2015, ECHA has to pay the subsidy out of its own budget, which amounts to €1.2 Million.

The ESH has 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 joined 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
Information to be provided per building:	Annankatu 18 (AK18) Lonnrotinkatu 12 (LK) Bulevardi (BL)	
Surface area (in square metres) - Of which office space - Of which non-office space	24 809 m2 15 823 m2 8 986 m2	
Annual rent (in EUR)	6 048 048 €	
Type and duration of rental contract	Leas contract until 31.12.2019 (with a purchase option until 30.06.2019)	
Host country grant or support	No	
Present value of the building	building/A	

ECHA has negotiated with the building's landlord to reduce the rented surface by terminating the rental contract for Lönnrotinkatu 12 with effect from 1 January 2016. This reduced the rental surface by 1.718m2 (or an estimated reduction in rent of 24.941€/month - that is 4,75% of the total rent). From January 2017 only the office space in Lönnrotinkatu building will be rented.

Building projects in planning phase

Following the expiration of the current lease contract of ECHA's office building by 31.12.2019, a preparatory assessment on ECHA workplace environment has been completed. In addition a market survey has been launched preceding the market prospect that will be included in the negotiation procedure foreseen to start in Q2 2016. Negotiations are foreseen to conclude between the end of 2016 and beginning of 2017.

Building projects submitted to the European Parliament and the Council

The current planning foresees the submittal of a proposed building project to the Budgetary Authority at the earliest mid-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.

	Privileges granted	l to staff
Agency privileges	Protocol of privileges and immunities / diplomatic status	Education / day care
Inviolability	Immunity from jurisdiction regarding official capacity	Same access to daycare organised by municipalities as Finnish nationals
Facilitations for Communications	Exemption from registration requirements	Access to Finnish school system

	Duty free import of goods upon taking up services	
	Reimbursement of VAT between 1 June 2007 and 31 May 2009 (no longer in place)	
	Right to free export when leaving the service	
	Exemption from taxes on EU salaries	
	Exemption from national car tax once every three years	
	Executive Director and Directors join diplomatic status	
	Temporary residence permits to family members who are not EU / EEA nationals	
	Issuance of personal cards through the Foreign Ministry	
	Issuance of Finnish identity numbers	
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 will be 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 pilot ex-ante and ex-post evaluation performed by an external contractor.

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. Working groups (WGs) on the individual evaluations will be established on a case-by-case basis.

Draft multi-annual and annual rolling evaluation plan

Indicative start time period	Project	Prepared by:	Progress reporting to:	Comments
Q4/2015	Assess the results of the Enterprise content management (ECM) programme based on the outcome of the Benefits realisation management exercise (outsourced analysis covering the ECM programme retrospectively and the future ECM strategy)	ECF	DCM	 Assess the coverage of the 5 evaluation criteria in the ex-post evaluation and the cost-benefit-risk analysis in the ex-ante evaluation Collect lessons learnt and the relevant elements from the BRM for the purpose of future evaluations

	retrospectively and the future ECM strategy)			
Q2/2016	Perform an evaluation of the Chemical Safety Assessment (CSA) programme and the Roadmap of the Chemical Safety Report/Exchange Network of Exposure Scenarios to contribute to the future of this work	ECF and WG	DCM	 Evaluate the coverage of the 5 criteria in the CSA programme with own resources and CSR/ES Roadmap and ENES via outsourcing Decide on the future of the CSA programme and CSR/ES RoadmapENES strategy following the results of the evaluation
Q2/2016	Perform an ex-ante evaluation of the future options of ECHA building strategy and project	ECF and WG	DCM	Evaluate different management arrangements and options from cost-benefit perspective, e.g. ranging from renting the current premises to renting new premises (built or still to be built) over the design, construction and management of a proper premise.
Q3/2016	Assess the feasibility of using / expanding Article 117(2) report as an ex-post evaluation of all Work programme activities of ECHA	ECF and WG	DCM	Consider covering the 5 criteria in Article 117 (2) report thus enabling the Commission to perform their own ex-post evaluation
Q1/2017	Perform an evaluation of all IT projects having relation to the registration deadline for 2018 (e.g. REACH-IT 3.1 and IUCLID 6.1)	ECF and WG	DCM	Evaluate the coverage of the 5 criteria with own resources or via outsourcing (fitness check)
Q3/2017	Perform an ex-post evaluation of ECHA Efficiency programme	ECF and WG	DCM	Evaluate the coverage of the 5 criteria including the benefits of the programme vs its cumulative cost (fitness check)

Annex VIII. Risks 2017

ECHA conducts an annual risk management exercise. The aim is to identify, assess and manage the potential events that could put the achievement of objectives defined in the Work Programme 2017 (WP 2017) at risk. As a result of this exercise a number of risks were identified, assessed and considered in the preparation of the WP 2017.

ECHA's management identified seven main risks. These are the most sensitive with regard to their likelihood of occurrence and potential impact on the implementation of the WP 2017. For these seven main risks, mitigation measures have been defined whose effectiveness will be closely monitored throughout the year.

Three of the selected risks were classified as 'Reduce'. For these risks an action plan is detailed in the table below, to ensure that the risk response is effectively carried out and to reduce the likelihood of these risks impacting the implementation of the WP 2017.

The remaining identified risks were classified as 'Accept', meaning that ECHA's management accepts the risk. Nevertheless, there will be continuous monitoring of these risks throughout 2017, and re-evaluation if necessary to ensure that they are kept under control.

More details on the risks and action plans in the table here below

	ECHA CORPORATE RISK REGISTER 2017									
	RISK IDENTIFICATION				RISK ASSESSMENT		RISK RESPONSE AND TREATMENT			
Activity affected	SPD Objective	Risk cause	Risk description	Risk consequence	Risk type	Risk level	Risk Response	Proposed Actions		
1.1 REACH dossier management and assessment	Processing registration dossiers for the	Complexity and scale of enhanced TCC and OSOR implementation in combination with high volumes of dossier submission of insufficient quality	The OSOR and enhanced TCC projects are important developments which improve the impact but also complexity of registration processing and will sometimes require expert input from other units. During 2017 ECHA needs to develop its capacity not only in terms of volume but also in terms of profiles who can administer these more complex cases		SYSTEMS	HIGH	Reduce	Aim to make the process "routine" in 2017 by: - Cross-unit team with clear responsibilities created - Training and capacity building - Close monitoring - Setting up a "team" helping on manual TCC as needed	Owner Dir. C	continuous follow up
2.1 Management of ECHA bodies	RAC & SEAC AfA opinions	As the number of AfA opinions to be adopted will be very high, the quality of AfA opinions might not meet the expected level	In case of a peak, ECHA may not be able to process applications with the expected level of quality, due to limited staff resources and Committees' overload	Resulting in reputational damage and negative impact on quality	3. PEOPLE AND ORGANISATION	MEDIUM	Accept	Monitor during 2017	Dir. B and D	continuous follow up
All regulatory objectives	Integrated regulatory strategy	Insufficient resources available in ECHA for initiating and following up new proactive action by industry; high complexity of priority CCH cases; system for tracing and tracking of screening and evaluation outcomes not ready in time; insufficient resources and support from MSs to initiate RMOAs and RRMMs	We do not make expected progress in the characterisation of the substances and regulatory actions around substances that matter	Unsuccessful strategy and reputational risk	2. PLANNING, PROCESSES AND SYSTEMS	MEDIUM	Reduce	Clear annual and multi-annual plan for triggering action by industry developed and agreed between the Directorates, together with allocation of adequate resources; close monitoring of the implementation by all Directorates Temporary measures for tracing and tracking on outcomes with the current tools; prioritisation of development of an adequate system, including necessary IT-tools with the aim of having a proper system in place by end of 2017 Informal interaction with certain priority category cases well ahead starting the formal process; streamlining of drafting of CCH decisions on read-across and category cases and implementation of MSCA/MSC agreements on the new cases to reduce the proportion of cases requiring MSC involvement; close monitoring and continual efficiency improvements of the evaluation process Close monitoring and communication to MSCAs of SVHC roadmap activities, in particular to ensure that cases where SEV or DEV have concluded the need for further regulatory measures receive the necessary follow-up	Dir. E,D and C	continuous follow up
2.3 Resources	All objectives affected	Lack of financial balancing mechanism in presence of volatile REACH and Biocide revenues	Under the current financial regulation, ECHA may not be able to balance its volatile income and expenditure under REACH and Biocides without some form of balancing mechanism (such as a reserve)		4. LEGALITY AND REGULARITY ASPECTS	MEDIUM	Accept	Monitor during 2017	Dir. R	continuous follow up
1.1 REACH dossier management and assessment	Processing registration dossiers for the 2018 deadline	Potential delay in the implementation of 'ECHA efficiencies' in REACH-IT software	The REACH-IT backlog includes a number of functionalities which together would significantly improve the efficiency of the registration process. Additionally, a more holistic implementation of non-registration dossier types (AfA, CLP24 etc.) would allow more focus on registration processing.	Additional resource needs for the 2018 deadline, more complex training/induction needed.	3. PEOPLE AND ORGANISATION	MEDIUM	Reduce	- Immediate overall planning of next versions to tackle the cascading effect on timelines and 2017 budget, adaptation during 2017 depending on progress - Review of project organisation with adequate business analysis support from the Contractor - Scope management: deprioritisation of non-critical improvements so that ECHA's development addressing efficiency can progress; corresponding reduction of the scope of the release if critical resources not available - Go-live planning with emphasis on integration points - Extensive training of ECHA staff dealing with REACH-IT	Dir. C	Throughout 2017 during planning and development phases
1.3 Biocides	Achievement of Review Programme target (i.e. 50 opinions per year)	Due to resource issues in the Members 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	Future income of ECHA negatively impacted	1. EXTERNAL ENVIRONMENT	MEDIUM	Accept	Monitor during 2017	Dir. D	continuous follow up
2.3 Resources	All objectives affected	Due to the fact that ECHA's present building is relatively old requiring refurbishment	ECHA's present building is seriously damaged due to services failures	Disturbance to ECHA staff functioning and consequent impact on ECHA's Work Programme objectives and potential environmental impact	6. ENVIRONMENTAL MANAGEMENT	MEDIUM	Accept	Monitor during 2017	Dir. R	continuous follow up
1.1 REACH dossier management and assessment - 2.3.4 ICT	Not achieving ECHA Cloud Service objectives	New technical solution, ECHA has not provided Cloud Service before. Availability of resources to deliver all the planned IT changes and enhancements well before the registration deadline	Due to technical complexities the development takes more time than anticipated and the solution is not available for SME in the planned timetable	SMEs would not be able to benefit from the simplification planned in the Cloud Service during their preparation for the 2018 deadline	2. PLANNING, PROCESSES AND SYSTEMS	MEDIUM	Accept	Pre-study is being conducted, Q&A on the implementation, gradual implementation of the project, additional resources are being onboarded	Dir.I	continuous follow up

Annex IX. Procurement plan 2017

Contract subject	Estimated budget (€)	Budget line	Procurement channel	Foreseen launch	Foreseen signature
IT support and maintenance services for the text analytics application	60 000	3003	FWC ECHA/2011/103.Lot 3	Q2	Q3
Services to support SID (Substance Identity) assessment: scientific reports from experts on "rare" substance types coming up to 2018 (low volume substances) Expert training on e.g. IUPAC nomenclature for coordination complexes	60 000	3003	FWC ECHA/2015/50 Lot 2	Q3	Q4
Support to SMEs, 2nd round 2018 roadmap	30 000	3003	FWC ECHA 2015/50 Lot 1	Q3	Q4
Specialised scientific services in chemical safety assessment to support the development of the Chemical Safety Assessment (CHESAR) tool	134 500	3003	Negotiated procedures with at least three/five candidates FR 104/RAP 137(1)	Q3	Q4
Scientific services targeting challenging topics from Dossier Evaluation (one or more contracts)	50 000	3004	FWC ECHA/2015/50 Lot 1	Q2/Q3	Q3/Q4
Several contracts for risk management identification services: services to develop an approach for assessing potential (socioeconomic) impact of potential future regulatory measures at Risk Management Option Analysis stage	120 000	3005	FWC ECHA/2015/50 Lot 1 and FWC/2015/256	Q2/Q3	Q3/Q4

Enhancing the understanding and interactions of ECHA with the supply chains of substances	50 000	3005	FWC ECHA/2015/50	Q3	Q4
Scientific services on challenging issues raised by Applications for Authorisation (two specific contracts: Dose-response (25 000), Meta-analysis (30 000).	55 000	3005	FWC ECHA/2015/50	Q2/Q3	Q3/Q4
Several contracts for implementation of substitution activities: capacity building, analysis of alternatives - Evaluation studies	100 000	3005	FWC ECHA/2015/50 Lot 1 and FWC/2016/130	Q3	Q4
One or more contracts for services to prepare Annex XV restriction dossiers on selected substances	150 000	3005	FWC ECHA/2015/50 Lot 1	Q2/Q3	Q3/Q4
Services to improve the methodologies of socio- economic analysis carried out for risk management of chemicals: Follow-up to the willingness to pay survey (preparation of the survey instrument with OECD, US EPA and Env &Health Canada) and other SEA related activities. (Several contracts)	100 000	3005	FWC ECHA/2015/50 Lot 1 and FWC/2015/256	Q3	Q4
Studies, consultancy, experts related to Act. Classification and Labelling	15 000	3006	Negotiated procedure with at least one candidate > € 15 000 FR 104/RAP 137(2)	Q2/Q3	Q3/Q4
Several contracts for PROGRAMME ECM & ECHA Interacts: IT business services, helpdesk, change management, service desk for Dynamic Case, Portal Dashboard, ODYSSEY	1 360 700	3008	FWC/2014/86, FWC/2015/321	Q4-2016- Q1/Q2-2017	Q1-Q4

Updating the XML format and potentially the PC editor	30 000	3008	DI-7360 SIDE	Q1	Q1
Several contracts for PROGRAMME ECM & ECHA Interacts: IT business services, helpdesk, change management, service desk for Dynamic Case, Portal Dashboard, ODYSSEY	1 360 700	3008	FWC/2014/86, FWC/2015/321	Q4-2016- Q1/Q2-2017	Q1-Q4
Several contracts for PROGRAMME IT Services for Industry: ECHA Cloud for SMEs, REACH-IT, Chesar, EUSES, new initiatives	1 959 113	3008, 4008	ECHA/2010/95N, FWC/2011/103/Lot 1 and 3, HANSEL	Q4-2016- Q1/Q2-2017	Q1-Q4
Several contracts for PROGRAMME IT Services for Industry: Chesar, IUCLID, Reach_IT, EUSES, R4BP, ePIC	933 434	3008, 4008 and 5008	FWC/2011/103/Lot 1 and 3	Q4-2016- Q1/Q2-2017	Q1-Q4
PROGRAMME Management Information Systems: Remedy licences and services	302 000	3008	DI-7360 SIDE	Q4-2016- Q1/Q2-2017	Q2
Several contracts for PROGRAMME Data Management Services: BIDI, Dissemination	490 000	3008	ECHA/2014/86	Q2	Q2/Q3
Several contracts for PROGRAMME Data Management Services: BIDI, ClassLab, Deficiencies and concerns, Dissemination	1 910 000	3008	ECHA/2014/86, ECHA/2011/103- lot 1 and Lot 3	Q4-2016- Q1/Q2-2017	Q1/Q3
Several contracts for PROGRAMME iTex Service Desk: Interim services, Reach-IT and R4BP ECHA service desk	451 320	3008, 4008	ECHA/2014/344 ECHA/2011/103/Lot 1	Q4-2016- Q1/2017	Q1/Q2
Several contracts for PROGRAMME ICT Procurement: MAINTENANCE: HARDWARE and SOFTWARE	866 925	3008	DG DIGIT FWCs	Q4-2016- Q3/2017	Q1-Q4

PROGRAMME ICT Procurement: Programme management services	50 000	3008	ECHA/2014/86	Q4-2016	Q1
PROGRAMME ICT Security: MEETING: 1 SON meeting	40 000	3008	Catering and travel FWCs	Q3	Q3
Horizontal activities: IT Programme management activities	110 000	3008	FWC ECHA/2011/103/Lot 1 and 3	Q4-2016	Q1
PROGRAMME IT services for industry: Project new initiatives (Poison Centres System)	40 000	3008	FWC ECHA/2011/103/Lot 3	Q1	Q1
Topical Scientific Workhop 2017 (New Approach Methods)	30 000	3009	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q2	Q3
Relationship & potential use of ToxCast /Tox21 data (project 2)	50 000	3009	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q3	Q4
Applicability of in vitro/in silico toxicokinetic (TK) information to enhance read-across (project 1)	50 000	3009	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q3	Q4
Testing strategy for endocrine disruptors.	50 000	3009	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q3	Q4
Non-extractable residues (NERs).	30 000	3009	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q3	Q4
Orders for Printing and design services	32 000	3013	FWC ECHA/2016/30	Q1 - Q4	Q1-Q4

Services for Website development and maintenance	375 000	3013, 4013	FWC ECHA/2014/110	Q1	Q1
Media and social media monitoring services	95 000	3013	FWC ECHA/2016/53	Q1	Q3
Audiovisual services (2 videos related e.g. to the launch of the nano/consumer micro site and REACH benefits)	80 000	3013	SLA with Office for Publications, which will be responsible for the procurement	Q1	Q2
Corporate Identity revision	54 000	3013	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q3	Q4
Restructuring of ECHA human health data "restructuring ECHA data project"	100 000	3801	FWC ECHA/2016/71	Q3	Q3
Development and maintenance in 2016 of ECHEM Portal (the Global Portal to Information on Chemical Substances)	200 000	3801	FWC ECHA/2014/86	Q3	Q4
Strategic policy stakeholder interaction (studies)	200 000	3022	Negotiated procedures with at least one/three/five candidates FR 104/RAP 137(1)	Q2/Q3	Q3/Q4
Certification ISO 9001: follow-up audit. Certification ISO 14001: follow-up audit , other quality related costs	60 000	3022	FWC ECHA/2013/483	Q2	Q3
Legal and court cases, ad-hoc legal advice (several contracts)	255 000	3022, 4022	Exceptional negotiated procedure under Art. 134.1.i) RAP or low-value negotiated procedures	Q1-Q4	Q1-Q4
Advice on IPR	90 000	3022	FWC JRC	Q2	Q3

Consulting services on corporate Planning and Monitoring	55 000	3022	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q2	Q3
IT audit consultancy to support the Internal Audit Capability	40 000	3022	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q1	Q2
IT audit consultancy to support Evaluations of ICT systems	40 000	3022	Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q2	Q3
Streamlining of processes under efficiency programme	100 000	3022	Extension of Service Contract ECHA 2016/193	Q1	Q1
Streamlining of processes under efficiency programme (tools, assessments, analysis, audits, etc. based on assessed needs)	65 000	3022	HANSEL or negotiated procedures with at least five candidates FR 104/RAP 137 (1)	Q2	Q3
FWC for Cloud and managed IT services	0	3008	Open or competitive procedure with negotiation (FWC for 7 years, value TBD)	Q1	Q4
FWC for IT services related to Biocides and PIC regulations and other IT Systems	600 000	4008, 5008	Open procedure (FWC for 4 years, value TBD)	Q1	Q3
FWC for IT services for IT solutions for industry under REACH	0	3008	Open procedure (FWC for 4 years, value TBD)	Q3	Q3-2018
FWC for data management services and application management services	0	3008, 4008 and 5008	Open procedure (FWC for 4 years, value TBD)	Q2	Q4-2017
PROGRAMME ICT Helpdesk: IdMCC maintenance	24 000	3008	ECHA/2011/103/Lot 1	Q2	Q3

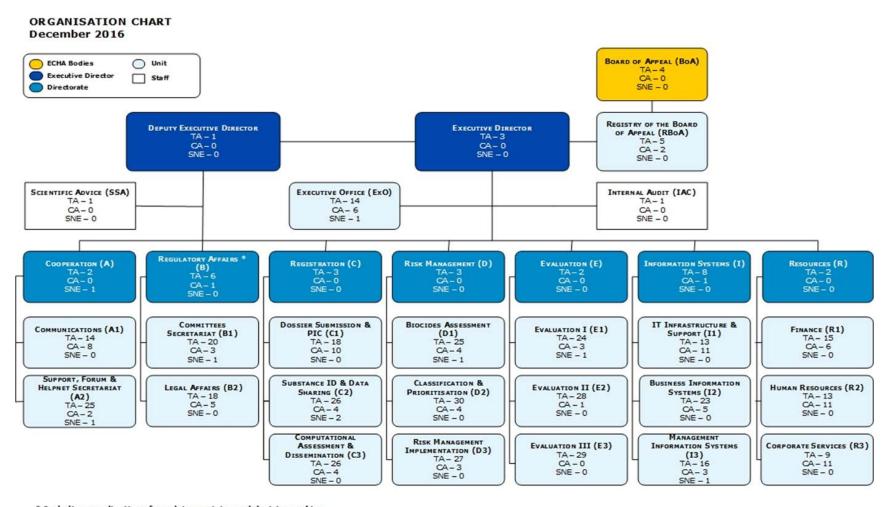
Several contracts for PROGRAMME ADSM & Release management: application management services for Reach-IT/IDM/R4BP/ePIC, Diss, eChemPortal, Portal Dashboard, Website, Documentum; Oracle and Unix operating systems services	1 438 679	3008, 4008 and 5008	FWC/2010/95N, FWC/2014/86, FWC/2015/321, DG DIGIT FWC	Q4-2016- Q1/Q2-2017	Q1-Q4
Several contracts for PROGRAMME ECM & ECHA Interacts: Documentum Platform & Software Upgrade, Governance support, IT Technical Services: CIRCA-BC (IT Infra hosting and operations)	693 428	3008	ECHA/2015/321, MoU DG DIGIT	Q4-2016- Q1/Q2-2017	Q1-Q4
Services for Biocides activities	50 000	4000	FWC ECHA/2015/50 Lot 1 or Negotiated procedure with at least three candidates FR 104/RAP 137(1)	Q3	Q4
FWC for travel services (4 years, overall value of 8 MEUR)	2 000 000	Several	HANSEL	Q4/2016	Q1/2017
Multiple FWC (cascade) for Interim staff for ECHA	2 000 000	Several	Open procedure (the overall estimated value of the FWC for 4 years is 8 000 000)	Q4/2016	Q1/2017

TOTAL SUM:

19 909 263

The Plan includes operational procurement of ECHA in 2017 ≥15000 €

Annex X. Organisation chart 2017



^{*} Including coordination of regulatory opinion and decision-making

Annex XI. IT resources

ECHA IT RESOURCES	ECHA IT RESOURCES							
IT tool	Main description	Activities served by tool						
IUCLID	Main tool for technical dossier preparation for Industry in REACH, CLP and BPR. 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. Tool for preparation of applications for authorisation.	 1.1.1 Registration dossier preparation 1.1.2 Registration and dossier submission 1.1.3 Evaluation 1.2.1 Identifying needs for Regulatory Risk Management 1.2.2 Authorisation 1.2.3 Restrictions 1.2.4 Classification and Labelling 1.3 Biocides 						
CHESAR	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.	1.1.1 Registration dossier preparation 1.1.4 Communication of risk management advice through the supply chain						
QSAR Toolbox	Software application intended to be used by OECD member countries, chemical industry and other stakeholders in filling gaps in data needed for assessing the hazards of chemicals.	1.1.1 Registration dossier preparation 1.5 Data management and dissemination						
REACH-IT	The tool for inquiry submission and processing. Submission web application for REACH and CLP, as well as the tool for automated processing of submission, granting a	1.1.1 Registration dossier preparation 1.1.2 Registration and dossier submission						

ECHA IT RESOURCES		
IT tool	Main description	Activities served by tool
	registration number or PPORD notification number, once technical completeness and other relevant rules are met. Invoicing tool for fee based submissions. 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). Submission tool for the applications for authorisation.	1.2.2 Authorisation 1.2.4 Classification and labelling
Odyssey	Guides the scientific decision-making process and ensures consistency & traceability.	1.1.3 Evaluation
	ECHA's website is the primary communication vehicle of the Agency. It is the fundamental source of information and guidance for companies seeking to comply with the legislation on chemicals. It is essential reading for dossier preparation, registration and dossier submission and evaluation. It informs and is the vehicle for public consultation in the different steps of the Authorisation process, on Restrictions, on CLP and on Biocides. It is the source of information for notifiers and DNAs on PIC and for companies wishing to appeal decisions.	1.1.1 Registration dossier preparation 1.1.2 Registration and dossier submission 1.1.3 Evaluation 1.1.4 Communication of risk management advice through the supply chain 1.2.1 Identifying needs for regulatory risk management 1.2.2 Authorisation 1.2.3 Restrictions 1.2.4 Classification and Labelling
Website	ECHA's website is the source of information on procurement exercises.	1.3 Biocides

ECHA IT RESOURCES		
IT tool	Main description	Activities served by tool
	It is the channel through which ECHA communicates its vacancies. It is the channel through which ECHA demonstrates who we are, what we do, how we are structured, how we make decisions and how stakeholders can engage with us.	1.4 PIC1.5 Data management and dissemination2.1.4 Board of Appeal2.3.1 Financial resources2.3.2 Human resourcesManagement
Remedy 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 ECHA services.	 1.1.1 Registration dossier preparation 1.1.2 Registration and dossier submission 1.1.3 Evaluation 1.1.4 Communication of risk management advice through the supply chain 1.2.2 Authorisation 1.2.3 Restrictions 1.2.4 Classification and Labelling 1.3 Biocides 1.4 PIC 2.1.3 HelpNet and Security Officers Network
Dynamic Case	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	1.1.2 Registration and dossier submission 1.1.3 Evaluation

ECHA IT RESOURCES		
IT tool	Main description	Activities served by tool
	steps also for auditing and other legal aspects (e.g. access to data, appeals).	1.2.1 Identifying needs for Regulatory Risk Management
		1.2.2 Authorisation
		1.2.3 Restrictions
		1.2.4 Classification and Labelling
		1.3 Biocides
		1.5 Data management and dissemination
		2.1.1 Committees
		2.1.2 Forum
		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
	External collaboration tool used to exchange documents with	2.1.4 Board of Appeal
Secure CIRCA-BC	MSCAs.	2.2 Management

ECHA IT RESOURCES		
IT tool	Main description	Activities served by tool
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).	1.1.2 Registration and dossier submission1.1.3 Evaluation1.2.4 Classification and Labelling
IT for Screening	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 Evaluation1.2.1 Identifying needs for Regulatory Risk Management1.5 Data management and dissemination
Portal Dashboard for MSCAs/ NEAs	Portals for Competent Authorities and National Enforcement Authorities (NEAs) under REACH and CLP to access integrated data around 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 2.1.2 Forum
Dissemination Portal	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.	1.2.4 Classification and Labelling1.1.2 Registration and dossier submission1.3 Biocides1.4 PIC

ECHA IT RESOURCES		
IT tool	Main description	Activities served by tool
		1.5 Data management and dissemination
C&L Platform	Web-based discussion forum to support Industry fulfilling their legal obligation to agree on the classification and labelling for substances which appear to be the same but have been differently classified by different companies.	1.2.4 Classification and Labelling
R4BP	Used by Industry for submitting applications under the Biocidal Products Regulation to ECHA and by ECHA/MSCAs for providing applicants with the related decisions. R4BP represents the implementation of the register for Biocidal products foreseen in the legislation.	1.3 Biocides
SPC Editor	Tool for Industry and MSCAs to process the Summary of Product Characteristics as foreseen in the BPR	1.3 Biocides
ePIC	Web application used by Industry for submitting PIC notifications to ECHA. Central IT tool for all the actors involved in PIC: Industry, ECHA, Designated National Authorities, Customs, European Commission: all the actors interact using the tool.	1.4 PIC
MSCAs IUCLID central database for REACH&CLP	Two large central databases of scientific data in IUCLID format opening direct access and full IUCLID functionalities to MSCAs.	1.5 Data management and dissemination

ECHA IT RESOURCES		
IT tool	Main description	Activities served by tool
MSCAs IUCLID central database for Biocides		
	The Data Integration Platform is the data management system to provide data integration and aggregation, business intelligence and reporting on business data; It provides integrated data to consuming systems, notably the	
	Dissemination Portal, the Portal dashboard for MSCAs and for the Enforcement Authorities.	
Data Integration Platform	It enables the re-use of data without duplication, advanced searches, data intelligence; capabilities which make the data usable and meaningful for consumption.	1.5 Data management and dissemination
сома	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 Committees2.1.2 Forum2.1.3 HelpNet and Security Officers Network2.2 Management
Planning and reporting integrated IT solution	A set of solutions serving planning, monitoring and reporting on corporate work, human resources and financial resources	2.2 Management2.3.1 Financial resources2.3.2 Human resources
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 IT RESOURCES		
IT tool	Main description	Activities served by tool
ECHAnet	Intranet of ECHA – the Agency's primary internal communication and collaboration tool.	2.2 Management
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 and on classification and handling of information.	2.2 Management
Mail registry		2.2 Management
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
ABAC	Budget, Accounting and Asset management system provided by the European Commission.	2.3.1 Financial resources
EasySign	Electronic workflow supporting some financial workflows.	2.3.1 Financial resources
Dynamic Case for SME verification		2.3.1 Financial resources
Integrated Human Resource Management System	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 IT RESOURCES		
IT tool	Main description	Activities served by tool
Mission management tool	Tool used to create mission orders and process mission claims and reimbursements.	2.3.2 Human resources 2.3.3 Corporate services
Webex	A platform for videoconferencing.	2.3.3 Corporate services
Hardware and software licences		2.3.4 ICT
Workplace ICT facilities and services		2.3.4 ICT
Telecommunication equipment and services		2.3.4 ICT
Integrated Access Management:	IT solution to provision/de-provision user accounts and grant access to IT systems for internal and external users	2.3.4 ICT
Remedy Ticketing system	System facilitating mainly the Incident management of IT and business services	2.3.4 ICT
Automation and administrative tools to support IT operations.		2.3.4 ICT