



# ECHA Programming Document 2017 - 2019

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***ECHA Programming Document 2017-2019***

Bratislava, 29 September 2016

Doc: MB/32/2016 final

**Reference:****ISBN-13:****ISSN:****Publ.date:****Language:** EN

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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 Programming 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 request, with technical and scientific input and assistance.

### **COMBINING THE REACH AND CLP PROCESSES INTO AN INTEGRATED REGULATORY STRATEGY**

Based on the first years of experience in implementing REACH and CLP regulatory processes, ECHA developed an integrated regulatory strategy which coherently brings all the processes together to achieve the aims of these Regulations, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development<sup>1</sup>.

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.

<sup>1</sup> Outcome of the World Summit on Sustainable Development, Johannesburg 2002: [http://www.unesco.org/education/tlsf/mods/theme\\_a/img/02\\_WSSDOutcomes.pdf](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 back-stop for the implementation of the EU chemicals safety regime and of ECHA's regulatory decisions.

#### **Duty holders**

Chemicals legislation places many duties on companies. Risk assessment, the safe use of substances, classification and labelling and communication down the supply chain are the responsibility of individual companies. ECHA's support to the industry aims to ensure that 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 nanofoms 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 SAICM<sup>2</sup>.

## **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

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<sup>2</sup> 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 Development<sup>3</sup>, 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.

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<sup>3</sup> 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 <sup>4</sup>	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

<sup>4</sup> 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 feasibility studies are anticipated in order to explore and assess the benefits, added-value and opportunities of ECHA's unique databases for dedicated areas related to chemicals management.

Overall this strategic objective will be achieved via the following 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 decision<sup>5</sup>, 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.

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<sup>5</sup> 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](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.<sup>6</sup> 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.

<b>Strategic action area 1.1 Improving quality of information in dossiers</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Preparation of dossiers</b>	<ul style="list-style-type: none"> <li>Communication activities to reach out to companies who are unaware of their responsibilities, or are inexperienced in REACH.</li> <li>Training (update) of national helpdesk correspondents on dossier preparation</li> <li>Webinars and workshops for 2018 registrants</li> <li>Third Article 117(3) report published</li> <li>Launch of ECHA Cloud Services for SMEs.</li> <li>Adaptation of the inquiry process following closure of the pre-registration possibility</li> </ul>	<ul style="list-style-type: none"> <li>Cloud services are delivered to SMEs</li> </ul>	<ul style="list-style-type: none"> <li>QSAR Toolbox enhanced version published, extending its applicability to other types of substances (e.g. inorganics and nanomaterials) and higher-tier endpoints.</li> <li>ECHA Cloud Services undergoes an ex-post evaluation and a roadmap for the service and the IUCLID tool is defined</li> </ul>
<b>Submission of dossiers</b>	<ul style="list-style-type: none"> <li>Outreach campaign in preparation of the 2018 deadline</li> <li>REACH-IT: Further simplified online functions for submitting dossiers (DCM)</li> <li>Annual letter campaign on short-listed priority substances.</li> <li>First experiences with the retroactive check of the completeness of the registrations over 100 tonnes analysed and work initiated for checking</li> </ul>	<ul style="list-style-type: none"> <li>Successful management of the 2018 registration deadline</li> <li>Annual letter campaign on short-listed priority substances.</li> </ul>	<ul style="list-style-type: none"> <li>Priority setting methods adapted to information available for substances registered in low tonnages, especially 1-10 tonnes</li> <li>Systematic screening of 1-10 tn and 10-100 tn dossiers initiated to support priority setting for evaluation.</li> <li>Manifestly incomplete dossiers for the key human health and</li> </ul>

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

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

<sup>7</sup> 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 ENES<sup>8</sup> 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.

<b>Strategic action area 1.2 - Maximising the impact of communication of risk management advice in the supply chain</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Exposure scenarios and safety data sheets</b>	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
<b>Substances in articles</b>	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

<sup>8</sup> 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.

<b>Strategic action area 1.3 – Improving the dissemination information</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Dissemination of substance information</b>	<p>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</p> <p>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</p>	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<sup>9</sup> and coordination<sup>10</sup> 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

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<sup>9</sup> PBT and ED expert groups

<sup>10</sup> 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.

<b>Strategic action area 2.1 – Mobilising authorities and aligning their views</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Mobilising authorities and aligning views</b>	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/vPvBs<sup>11</sup> 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.

<sup>11</sup> 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.

<b>Strategic action area 2.2 Identification of substances for regulatory risk management</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Screening</b>	Revision of the screening scenarios to identify substances that matter most to take into account the changed IUCID 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	
<b>Criteria, approaches and tools</b>	Annual report on 2020 SVHC roadmap implementation	Annual report on 2020 SVHC roadmap implementation	Annual report on 2020 SVHC roadmap implementation
<b>Filling information gaps</b>	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<sup>12</sup> 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.

<sup>12</sup> 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.

<b>Strategic action area 2.3 Addressing identified concerns through REACH, CLP and other legislation</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Through REACH &amp; CLP</b>	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	

<b>Other legislation</b>		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 encompass 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.

<b>Strategic action area 3.1 – Expertise and capacity building</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Expertise and capacity building</b>	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.

<b>Strategic action area 3.2 – A hub for excellence in regulatory science</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Hub for excellence in regulatory science</b>	1 regulatory science workshop Actions resulting from the 2016 ECHA report under Art 117.2 of REACH 3 <sup>rd</sup> 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.
<b>Socio-economic analysis</b>	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.

<b>Strategic action area 4.1 – Maximising the effectiveness and efficiency of existing and new work processes</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Quality system</b>	Renewal of ISO9001 certification and possible extension of its scope to biocides processes		
<b>Process re-engineering</b>	Efficiency improvements through re-engineering of REACH and CLP processes	First round of efficiency improvements through re-engineering of REACH and CLP processes completed	
<b>Biocides</b>	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.	
<b>PIC</b>	Three-year report on operations		
<b>CLP</b>	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 <sup>st</sup> 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 life-cycle 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
<b>Deliver IT support for regulatory processes</b>	<p>Readiness of the performance and resilience of the IT systems and services for the last REACH deadline</p> <p>Target architecture 2017-2020 defined</p> <p>Initiate a roadmap for IT solutions for Authorities and Committees to further integrate and streamline processes and mutual interactions (ECHAinteract).</p> <p>Update of the ECM roadmap, achieving the completion of the objectives on historical archiving</p>	<p>Target architecture 2017-2020 pursued</p> <p>Further implement the ECHAinteract roadmap</p> <p>Design the ECM historical archiving solution</p>	<p>Target architecture 2017-2020 pursued</p> <p>Consolidation of ECHAinteract roadmap</p> <p>Deploy ECM historical archiving solution</p>



<b>Strategic action area 4.2 Delivering integrated and re-usable IT systems and services</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
	New version of the EUSES tool for biocides		
<b>Deliver IT support for administrative processes</b>	Implementation of an enhanced planning and reporting solution	Consolidation of the planning and reporting solution	
<b>Ensure adequacy of ICT infrastructure</b>	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.

<b>Strategic action area 4.3 HR policies and initiatives</b>			
<b>Priority area</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>HR Policies and Initiatives</b>	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
<b>Dossiers arriving REACH and CLP</b>				
Registration dossiers (including updates)	10000	13000	59500	19500
Testing proposals	220	220 <sup>13</sup>	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 <sup>14</sup>	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) <sup>15</sup>	20	15	20	25
Authorisation applications	60	5	10	20
Alternative name requests	100	50	50	50
Substances on the CoRAP to be evaluated by MSs	39	35	40	50
<b>ECHA decisions REACH and CLP</b>				
Evaluation decisions				
- Testing proposal	250	150	250	140

<sup>13</sup> 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

<sup>14</sup> 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

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

<b>ECHA's main activity drivers</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
- Compliance Check	180	180	180	180
- Substance evaluation	30	30	30	32
Decisions on data sharing	20	70	140	20
Decisions on PPORD	50	50	50	50
Decisions on completeness check (negative) <sup>16</sup>	100	130	690	120
Decisions on confidentiality requests (negative) <sup>17</sup>	50	65	340	150
<b>Appeals</b>				
Appeals submitted	26	27	45	30
Cases closed	15	25	25	25
<b>Others</b>				
Updates of the CoRAP for substances subject to substance evaluation	1	1	1	1
Recommendations to the European 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	330	330
Management Board meetings	4	4	4	4
MSC meetings	6	6	6	6
RAC meetings	8	7	6	5
SEAC meetings	6	5	4	4
Forum meetings	3	3	3	3
<b>Biocides</b>				
Received helpdesk questions on Biocides	n/a	3000	7000	5000
Applications for new active substance approval	23	8	28	8
Applications for renewal or review of active substances	0	2	11	5

<sup>16</sup> 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

<sup>17</sup> 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

<b>ECHA's main activity drivers</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Opinions on active substances in the Review Programme	50	50	50	50
Applications for Union authorisation	8	37	40	50
Assessment of technical equivalence	30	37	45	45
BPC meetings	5	6	6	6
Biocide appeals	1	1	1	1
<b>PIC</b>				
Notifications	6300	7200	8300	9600
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.

Considering the high uncertainty related to the fee income, the Agency's actual dossier based estimates have been reduced by 5% for prudence for the years 2018 and 2019.

The overall required subsidy for the planning period is within the current MFF ceilings. As regards 2017, ECHA's foreseen subsidy need is c. € 2 million below the MFF ceiling. The year 2018 will be characterised by high workload stemming from the registration deadline and there will be extra expenditure required to support companies, in particular SMEs, for this last registration deadline. It is being verified whether the estimated income derived from fees and charges together with the EU subsidy foreseen in the MFF will be sufficient to cover this additional expenditure in 2018.

## **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. € 5.6 million and the required balancing EU subsidy is c. € 4.5 million.

Following the growing number of applications and the consequent additional staff needs to handle these, the subsidy required for the years 2017 and 2019 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. € 60 million, which is in line with the 2016 budget. Salaries represent 91% of the total Title 1 budget, while other staff-related expenditure accounts for 9% of the total.

##### **BIOCIDES**

The total amount for staff-related expenditure in Biocides in 2017 is estimated at c. € 7 million, representing an increase of 17%. This increase is stemming from the additional 7 posts for 2017. Of the total staff related expenditure, direct salary costs are € 6.3 million (90%) and other personnel costs € 0.7 million (10%).

##### **PIC**

Total amount for staff-related expenditure in PIC is estimated at c. € 0.7 million. Of this amount, direct salaries represent c. € 0.5 million and other personnel costs c. € 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) decreases 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 € 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 7<sup>th</sup> 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-organisation 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.



<b>Workload driver estimates</b>	2015 actual	2016 estimate	2017 estimate
Helpdesk questions received <sup>18</sup>	NA <sup>19</sup>	1000	2800
Inquiries concluded	1368	1600	1700 <sup>20</sup>
Access to data older than 12 years	394	320	350
Data-sharing disputes	6	20	80
Decisions on data-sharing disputes	4	16	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

<sup>18</sup> Regulatory and non-regulatory questions related to dossier preparation only.

<sup>19</sup> 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.

<sup>20</sup> 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.

installation and local data storage. According to this delivery model, companies will manage their data and prepare their registration dossiers online, on an ECHA hosted and supported service. It is estimated that using this option the SMEs segment of the chemical Industry could save approximately 5.4 Million Euros per year.

- 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, audio-visual, 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.

<b>Performance indicators<sup>21</sup></b>	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 <sup>22</sup>	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%

<b>Resources</b>	2015 actual <sup>23</sup>	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	11 736 098	tbd
Human resources (FTE)	NA	48	tbd

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

<sup>22</sup> 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)

<sup>23</sup> 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.

## 1.1.2 Registration and dossier submission

### Overview

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

Before assigning the registration number, the Agency verifies the completeness of the information and the payment of the registration fee in order to ensure that all the elements required are included in the dossier and are meaningful. 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.

<b>Workload driver estimates</b>	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 <sup>24</sup>	NA	3500	2000
Decisions on completeness check (negative)	41	100	130
Decisions on confidentiality requests (negative)	28	50	65
Decisions on PPORD notifications	40	50	50
Appeals submitted <sup>25</sup>	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").

<sup>24</sup> Regulatory and non-regulatory questions related to dossier submission only.

<sup>25</sup> 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

## Main actions and outputs of 2017

- Process an increasing number of registrations (preliminary estimates up to ca. 7000 new registrations and 6000 updates). This may have an impact on the follow-up activities such as assessment of confidentiality requests and SME status verification. A majority of the new registrations are expected to be submitted for the 2018 deadline.
- 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.

<b>Performance indicators<sup>26 27</sup></b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 target</b>
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA	High	High	High
(NEW)Unplanned IT system downtime preventing submission within service hours (average of related IT systems, per month)	NA	NA	2%
(NEW)Average time (working days) to manually perform the first completeness check of a registration dossier	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 related to dossier submission and substance identity, answered within established timeframe (15 working days).	NA	NA	90%

<sup>26</sup> 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

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

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	9 256 352	tbd
Human resources (FTE)	NA	43	tbd

### 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.

<b>Workload driver estimates</b>	2015 actual	2016 estimate	2017 estimate
Draft decisions on testing proposals	139	300	250
Final decisions on testing proposals	194	250	150
Compliance checks concluded	183	200	200
Final decisions on compliance checks	144	180	180
Follow-up evaluations on dossier evaluation decisions concluded	268	350	300

Number of substances on the CoRAP list to be evaluated by the MSs <sup>28</sup>	48	39	35
Final decisions on substance evaluation	29	30	30
Appeals submitted	21	23	23
Helpdesk questions received <sup>29</sup>	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.

### Main actions and outputs of 2017

- 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

<sup>28</sup> 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.

<sup>29</sup> Regulatory and non-regulatory questions related to evaluation only.

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 in 2016.

<b>Performance indicators<sup>30</sup></b>	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 <sup>31</sup>	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/MS agreement	NA	NA	90%
(NEW)Percentage of ECHA Helpdesk questions related to evaluation, answered within established timeframe (15 working days)	NA	NA	90%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	18 947 311	tbd
Human resources (FTE)	NA	106	tbd

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

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



### 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 Exposure Scenarios (ENES). This activity corresponds to the commitments of ECHA under the Chemical safety report / Exposure scenarios Roadmap (CSR/ES Roadmap<sup>32</sup>). 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.

<b>Workload driver estimates</b>	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 <sup>33</sup>	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

<sup>32</sup> [CSR/ES Roadmap](#) link

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

increase also in questions to the ECHA and national helpdesks during the subsequent year that the HelpNet will need to address.

<b>Performance indicators<sup>34</sup></b>	2015 actual	2016 estimate	2017 target
Level of satisfaction of the interested parties with the quality of the support provided by the ECHA secretariat in the area of supply chain communication	High	High	High
(NEW)Percentage of ECHA Helpdesk questions related to communication of risk management advice through the supply chain, answered within established timeframe (15 working days)	NA	NA	90%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	2 996 515	tbd
Human resources (FTE)	NA	17	tbd

## 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

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

## 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.

<b>Workload driver estimates</b>	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.

## Main actions and outputs of 2017

- 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.

<b>Performance indicators<sup>35</sup></b>	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

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	2 961 639	tbd
Human resources (FTE)	NA	17	tbd

## 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.

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

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

<b>Workload driver estimates</b>	2015 actual	2016 estimate	2017 estimate
Number of proposals for identifying SVHCs <sup>36</sup>	9	20	15
Recommendation for inclusion of substances in the authorisation list.	1	1	0 <sup>37</sup>
Number of received Applications for authorisation	7	60	5
RAC & SEAC opinions <sup>1)</sup> on applications for authorisation	25	60	40
Helpdesk questions received <sup>38</sup>	NA	300	650

<sup>1)</sup> 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

<sup>36</sup> 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

<sup>37</sup> Due to the 15-16 months planning cycle for the development of the Annex XIV recommendation the 8<sup>th</sup> 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.

<sup>38</sup> Regulatory and non-regulatory questions related to authorisation only.

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.
- 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

<b>Performance indicators<sup>39</sup></b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 target</b>
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

<b>Resources</b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 estimate</b>
Financial resources (costs, euros)	NA	5 830 893	tbd
Human resources (FTE)	NA	33	tbd

### 1.2.3 Restrictions

<sup>39</sup> For new proposed indicators the values for 2015 and 2016 are not available (NA);

## Overview

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

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

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

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

<b>Workload driver estimates</b>	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 <sup>40</sup>	5 <sup>41</sup>
Restriction proposals or reports developed under Article 69(2)	2	2	1
RAC & SEAC opinions <sup>1)</sup> on restriction proposals	6	7	4
Helpdesk questions received <sup>42</sup>	NA	100	600

<sup>1)</sup> 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 socio-economic analysis.

<sup>40</sup> 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.

<sup>41</sup> 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-activities-on-restrictions>. Additional requests are possible for 2017.

<sup>42</sup> Regulatory and non-regulatory questions related to restrictions only.

- 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)

<b>Performance indicators<sup>43</sup></b>	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 Restriction proposal	NA	NA	15 months
(NEW)Effective working time of ECHA staff used per restrictions opinion	NA	NA	200 – 255 person days

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 274 879	tbd
Human resources (FTE)	NA	17	tbd

## 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.

<b>Workload driver estimates</b>	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

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



Alternative name requests	38	100	50
Helpdesk questions received <sup>44</sup>	360	250	250

### Key objective

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

### Main actions and outputs of 2017

- 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 8<sup>th</sup> 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

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<sup>44</sup> Regulatory and non-regulatory questions related to classification and labelling only.

<b>Performance indicators<sup>45</sup></b>	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
(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%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	4 071 679	tbd
Human resources (FTE)	NA	23	tbd

### 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.

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

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.

<b>Workload driver estimates</b>	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	3000
Appeals submitted	4	1	1
Helpdesk questions received <sup>46</sup>	922	750	3000

### **Key objective**

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

### **Main actions and outputs of 2017**

<sup>46</sup> Regulatory and non-regulatory questions related to Biocides only.

- 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-à-vis the new criteria for endocrine 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.
- 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.

<b>Performance indicators<sup>47</sup></b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 target</b>
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

<sup>47</sup> For new proposed indicators the values for 2015 and 2016 are not available (NA);

(NEW)Percentage of ECHA Helpdesk questions related to Biocides, answered within established timeframe (15 working days)	NA	NA	80%
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<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	7 865 000	tbd
Human resources (FTE)	NA	53	tbd

## 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.

<b>Workload driver estimates</b>	2015 actual	2016 estimate	2017 estimate
Export notifications	5 951	6300	7200
Helpdesk questions received <sup>48</sup>	209	150	600
Scientific and technical requests from the Commission, EU and non-EU DNAs	1500	1800	2200

### 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.

<sup>48</sup> Regulatory and non-regulatory questions related to PIC only.

## Main actions and outputs of 2017

- 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 8<sup>th</sup> Conference of the Parties to the Rotterdam Convention, provide scientific input and participate in the preparation of the Chemical Review Committee

Performance indicators <sup>49</sup>	2015 actual	2016 estimate	2017 target
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	tbd
Human resources (FTE)	NA	7	tbd

## 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

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

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

<b>Workload driver estimates</b>	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.

### **Main actions and outputs of 2017**

- 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
  - 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, the initiatives explored could include: extend the ECHA website with an “EU chemical legislation finder”, based on the outcome of the feasibility study launched in 2016, in order to provide a comprehensive overview on how a chemical substance is regulated across various legislations in Europe; 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.
  - 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.
  - 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.

<b>Performance indicators<sup>50</sup></b>	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%

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



<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	10 097 385	tbd
Human resources (FTE)	NA	37	tbd

## 1.6 Delegated tasks: Nano Observatory

Based on a delegation agreement between the European Commission and ECHA the Agency is hosting the EU Nanomaterials Observatory. 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 nano-safety 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 objective<sup>51</sup>

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.

### Main actions and outputs of 2017

- Publish the first version of the observatory by spring<sup>52</sup> 2017 based on readily available data and information sources.

<sup>51</sup> Performance indicator(s) to measure the achievement of Nano-Observatory's key objective will be developed within the first 6 month of its operation

<sup>52</sup> Six months from the signature of the delegation agreement

- 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.
- 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.

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	800 000	tbd
Human resources (FTE)	NA	0,5	tbd

## 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.

<b>Workload driver estimates</b>	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).

<b>Performance indicators<sup>53</sup></b>	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%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 705 446	tbd
Human resources (FTE)	NA	17	tbd

## 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.

<b>Workload driver estimates</b>	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

<sup>53</sup> 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.

## Main actions and outputs of 2017

- 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

<b>Performance indicators<sup>54</sup></b>	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%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	1 702 050	tbd
Human resources (FTE) <sup>55</sup>	NA	8	tbd

<sup>54</sup> For new proposed indicators the values for 2015 and 2016 are not available (NA);

<sup>55</sup> 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.

<b>Workload driver estimates</b>	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.

#### Main actions and outputs of 2017

- 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

<b>Performance indicators<sup>56</sup></b>	2015 actual	2016 estimate	2017 target
Level of satisfaction of HelpNet members with the HelpNet Secretariat support	High	High	High

<sup>56</sup> 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
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Resources	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	300 561	tbd
Human resources (FTE)	NA	2	tbd

## 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	
	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.

### Main actions and outputs of 2017

- 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.

<b>Performance indicators<sup>57</sup></b>	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

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	1 680 880	tbd
Human resources (FTE)	NA	11	tbd

## 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.

<sup>57</sup> 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.

<b>Workload driver estimates</b>	2015 actual	2016 estimate	2017 estimate
Number of general questions	607	600	1200
Management Board meetings	4	4	4
Number of audits to take place in a year <sup>58</sup>	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 through 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.

<sup>58</sup> This includes the internal audits and their follow-up performed by the European Commission's Internal Audit Service (IAS) and ECHA's Internal Audit Capability (IAC) as well as ECHA's Integrated Quality Management System audits

- Prepare suitable communication products and organise events to celebrate 10<sup>th</sup> 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

<b>Performance indicators<sup>59</sup></b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 target</b>
Percentage of very important audit recommendations implemented within the deadline (IAS).	NA <sup>60</sup>	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%

<b>Resources</b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 estimate</b>

<sup>59</sup> For new proposed indicators the values for 2015 and 2016 are not available (NA);

<sup>60</sup> There were no very important audit recommendations in 2015.

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

## 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.

#### Main actions and outputs of 2017

- 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.

<b>Performance indicators</b>	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%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 959 909	tbd
Human resources (FTE)	NA	27	tbd

### 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.

<b>Workload driver estimates</b>	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 <sup>61</sup>	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.

### Main actions and outputs of 2017

- 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

<b>Performance indicators<sup>62</sup></b>	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%

<sup>61</sup> Not available for 2015 as this is a new workload driver

<sup>62</sup> 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%

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 645 030	tbd
Human resources (FTE)	NA	27	tbd

### 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.

<b>Workload driver estimates</b>	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)	1500	1500	1600
Number of facilities related incidents	820	1400	1400
Number of new publications produced	43	100	50
Number of pages translated into 22 languages	1050	1300	700

## Key objective

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

## Main actions and outputs of 2017

- 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

<b>Performance indicators<sup>63</sup></b>	<b>2015 actual</b>	<b>2016 estimate</b>	<b>2017 target</b>
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

<sup>63</sup> 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)

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 308 612	tbd
Human resources (FTE)	NA	23	tbd

### 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.

<b>Workload driver estimates</b>	2015 actual	2016 estimate	2017 estimate
Number of IT related incidents	7 390	5600	5600
Number of IT contracts to be managed in a year <sup>64</sup>	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.

#### Main actions and outputs of 2017

- 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

<sup>64</sup> 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;

<b>Performance indicators<sup>65</sup></b>	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

<b>Resources</b>	2015 actual	2016 estimate	2017 estimate
Financial resources (costs, euros)	NA	3 164 759	tbd
Human resources (FTE)	NA	22	tbd

<sup>65</sup> 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

*As sent to the European Commission on 31.1.2016; to be revised and updated in December 2016 after adoption of Union budget*

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	12 139 720
1.1.2 Registration and dossier submission	43	46	9 256 352	9 814 750
1.1.3 Evaluation	106	106	18 947 311	18 715 020
1.1.4 Communication of risk management advice through the supply chain	17	16	2 996 515	2 818 620
1.2.1 Identifying needs for Regulatory Risk Management	17	17	2 961 639	3 225 010
1.2.2 Authorisation	33	32	5 830 893	5 567 320
1.2.3 Restrictions	17	17	3 274 879	3 354 070
1.2.4 Classification and Labelling	23	23	4 071 679	4 080 250
1.3 Biocides	53	60	7 865 000	10 343 300
1.4 PIC	7	7	1 151 000	1 183 000
1.5 Data management and dissemination	37	36	10 097 385	9 970 000
2.1.1 Committees	17	16	3 705 446	3 311 800
2.1.2 Forum	8	8	1 702 050	1 593 370
2.1.3 HelpNet and Security Officers Network	2	2	300 561	307 760
2.1.4 Board of Appeal	11	11	1 680 880	1 685 080
2.2 Management	42	41	7 711 311	7 546 280
2.3.1 Financial resources	27	26	3 959 909	3 829 810
2.3.2 Human resources	27	26	3 645 030	3 756 020
2.3.3 Corporate Services	23	23	3 308 612	3 322 630
2.3.4 ICT	22	21	3 164 759	3 033 710
<b>Totals</b>	<b>580</b>	<b>583</b>	<b>107 367 309</b>	<b>109 597 520</b>

## Annex II: Human and Financial Resources

*As sent to the European Commission on 31.1.2016; to be revised and updated in December 2016 after adoption of Union budget*

**Table 1: Expenditure**

### ECHA

Expenditure	2016		2017	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
<b>Title 1</b>	66 894 409	66 894 409	67 804 800	67 804 800
<b>Title 2</b>	15 323 600	15 323 600	15 558 380	15 558 380
<b>Titles 3-5</b>	25 589 000	25 149 300	25 535 500	26 234 340
<b>Total expenditure</b>	<b>107 807 009</b>	<b>107 367 309</b>	<b>108 898 680</b>	<b>109 597 520</b>

EXPENDITURE	Commitment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>71 185 445</b>	<b>66 894 409</b>	<b>67 804 800</b>		<b>1%</b>	<b>71 523 260</b>	<b>69 613 490</b>
<b>11 Salaries &amp; allowances</b>	65 061 591	60 620 000	61 656 500		2%	65 550 820	63 679 180
- of which establishment plan posts	58 803 834	53 767 300	54 532 500		1%	58 107 580	56 567 507
- of which external personnel	6 257 757	6 852 700	7 124 000		4%	7 443 240	7 111 672
<b>12 Expenditure relating to Staff recruitment</b>	644 689	880 600	770 820		-12%	767 500	757 970
<b>13 Mission expenses</b>	39 577	60 200	60 000		0%	60 000	60 000
<b>14 Socio-medical infrastructure</b>	1 915 542	2 095 800	2 071 840		-1%	2 011 880	2 011 940
<b>15 Training</b>	1 463 790	1 134 909	1 296 630		14%	1 184 050	1 155 390
<b>16 External Services</b>	2 055 568	2 082 800	1 929 000		-7%	1 929 000	1 929 000
<b>17 Receptions and events</b>	4 689	20 100	20 010		0%	20 010	20 010
<b>Title 2</b>					-		

<b>Infrastructure and operating expenditure</b>	<b>16 082 969</b>	<b>15 323 600</b>	<b>15 558 380</b>		<b>2%</b>	<b>15 513 830</b>	<b>18 354 100</b>
<b>20 Rental of buildings and associated costs</b>	7 895 237	7 604 100	7 492 490		-1%	7 499 970	10 357 030
<b>21 Information and communication technology</b>	7 045 686	7 066 200	7 236 730		2%	7 202 100	7 166 650
<b>22 Movable property and associated costs</b>	884 298	333 700	500 630		50%	500 920	501 190
<b>23 Current administrative expenditure</b>	248 967	310 900	318 510		2%	300 810	319 190
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	8 781	8 700	10 020		15%	10 030	10 040
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 3</b>						0	0
<b>Operational expenditure</b>	<b>22 871 917</b>	<b>24 226 600</b>	<b>22 829 860</b>		<b>-6%</b>	<b>22 710 330</b>	<b>18 851 080</b>
<b>30 REACH</b>	<b>22 652 384</b>	<b>22 993 900</b>	<b>22 397 160</b>		<b>-3%</b>	<b>22 356 130</b>	<b>18 296 880</b>
<b>3003 Registration, datasharing and dissemination</b>	562 988	562 000	1 177 000		<b>109%</b>	2 700 000	928 000
<b>3004 Evaluation</b>	1 654 669	1 736 500	1 580 000		<b>-9%</b>	1 511 000	1 511 000
<b>3005 Authorisations and restrictions</b>	536 198	735 000	1 235 000		<b>68%</b>	1 335 000	1 335 000
<b>3006 Classification and labelling</b>	0	40 000	50 000		<b>25%</b>	50 000	50 000
<b>3007 Advice and assistance through guidance and helpdesk</b>	154 965	160 700	235 500		<b>47%</b>	235 500	145 500
<b>3008 Scientific IT tools</b>	13 704 528	11 903 200	11 454 120		<b>-4%</b>	10 901 640	8 796 410
<b>3009 Scientific and technical advice to EU institutions and bodies</b>	188 689	260 000	260 000		<b>0%</b>	260 000	260 000
<b>3011 Committees and Forum</b>	1 371 659	2 505 900	1 969 400		<b>-21%</b>	1 544 500	1 474 500
<b>3012 Board of Appeal</b>	58 793	98 500	96 000		<b>-3%</b>	96 000	96 000
<b>3013 Communications including Translations</b>	2 852 905	3 057 000	2 458 550		<b>-20%</b>	1 808 550	1 786 240
<b>3014 International cooperation</b>	0	0	0		-	0	0

<b>3022 Management Board and management of the Agency</b>	1 032 474	1 400 100	1 351 590		<b>-3%</b>	1 383 940	1 384 230
<b>3030 Missions</b>	534 517	535 000	530 000		<b>-1%</b>	530 000	530 000
<b>3031 External training</b>	0	0	0		-	0	0
<b>3090 Refunds REACH/CLP</b>	0	0	0		-	0	0
<b>31 MULTIANNUAL ACTIVITIES</b>	<b>37 390</b>	<b>132 700</b>	<b>132 700</b>		<b>0%</b>	<b>54 200</b>	<b>54 200</b>
<b>3111 Committees and Forum (Multiannual)</b>	37 390	132 700	132 700		<b>0%</b>	54 200	54 200
<b>38 INTERNATIONAL ACTIVITIES</b>	<b>154 900</b>	<b>1 100 000</b>	<b>300 000</b>		<b>-73%</b>	<b>300 000</b>	<b>500 000</b>
<b>3801 Cooperation with international organisations for IT programmes</b>	154 900	1 100 000	300 000		<b>-73%</b>	300 000	500 000
<b>39 EARMARKED OPERATIONS</b>	<b>27 243</b>	<b>0</b>	<b>0</b>		-	<b>0</b>	<b>0</b>
<b>3901 IPA programme according to agreement 2009/214-524</b>	0	0	0		-	0	0
<b>3902 IPA programme according to agreement 2012/291-934</b>	0	0	0		-	0	0
<b>3903 IPA programme according to agreement 2015/361-049</b>	27 243	0	0		-	0	0
<b>3910 ENP programme</b>	0	0	0		-	0	0
<b>Title 4</b>						0	0
<b>Operational expenditure</b>	<b>2 291 034</b>	<b>1 070 200</b>	<b>2 351 950</b>		<b>120%</b>	<b>1 823 000</b>	<b>1 779 240</b>
<b>4000 Substances, products and technical equivalence</b>	0	100 000	50 000		<b>-50%</b>	50 000	50 000
<b>4003 Submissions, datasharing, dissemination</b>	0	0	0		-	0	0
<b>4007 Advice assistance through guidance and helpdesk</b>	27 057	22 800	52 000		<b>128%</b>	52 000	52 000
<b>4008 Scientific IT tools</b>	1 470 733	309 300	1 453 410		<b>370%</b>	963 980	896 710
<b>4009 Scientif technic advice to EU institut and bodies</b>	0	0	0		-	0	0
<b>4011 Biocidal products Committee and Rapporteurs</b>	293 162	356 300	511 000		<b>43%</b>	511 000	523 500
<b>4012 Board of Appeal</b>	3 658	15 500	17 000		<b>10%</b>	17 000	17 000

<b>4013 Communications including Translations</b>	162 591	108 800	99 050		<b>-9%</b>	66 580	77 560
<b>4022 Management Board and management of the Agency</b>	126 483	105 000	119 490		<b>14%</b>	112 440	112 470
<b>4030 Missions</b>	30 293	52 500	50 000		<b>-5%</b>	50 000	50 000
<b>4031 External training</b>	0	0	0		<b>-</b>	0	0
<b>4901 Preparatory work BPR 13/3938 Norwegian</b>	177 057	0	0		<b>-</b>	0	0
<b>Title 5 Operational expenditure</b>	<b>447 397</b>	<b>292 200</b>	<b>353 690</b>		<b>21%</b>	<b>251 070</b>	<b>226 470</b>
<b>5000 Studies and consultants</b>	0	0	0	0	<b>-</b>	0	0
<b>5007 Advice assistance through guidance and helpdesk</b>	0	0	0	0	<b>-</b>	0	0
<b>5008 Scientific IT tools</b>	225 853	219 800	230 230	0	<b>5%</b>	218 370	193 770
<b>5011 Meetings with the DNAs and experts on PIC implem</b>	0	0	0	0	<b>-</b>	0	0
<b>5013 Communications including Translations</b>	208 689	59 000	108 460	0	<b>84%</b>	17 700	17 700
<b>5030 Missions</b>	12 855	13 400	15 000	0	<b>12%</b>	15 000	15 000
<b>5031 External training</b>	0	0	0	0	<b>-</b>	0	0
<b>TOTAL EXPENDITURE</b>	<b>112 878 762</b>	<b>107 807 009</b>	<b>108 898 680</b>	<b>0</b>	<b>1%</b>	<b>111 821 490</b>	<b>108 824 380</b>

EXPENDITURE	Payment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>70 343 772</b>	<b>66 894 409</b>	<b>67 804 800</b>		<b>1%</b>	<b>71 523 260</b>	<b>69 613 490</b>
<b>11 Salaries &amp; allowances</b>	65 061 399	60 620 000	61 656 500		2%	65 550 820	63 679 180
<i>- of which establishment plan posts</i>	58 803 642	53 767 300	54 532 500		1%	58 107 572	56 567 502
<i>- of which external personnel</i>	6 257 757	6 852 700	7 124 000		4%	7 443 240	7 111 672
<b>12 Expenditure relating to Staff recruitment</b>	636 866	880 600	770 820		-12%	767 500	757 970

<b>13 Mission expenses</b>	39 577	60 200	60 000		0%	60 000	60 000
<b>14 Socio-medical infrastructure</b>	1 774 805	2 095 800	2 071 840		-1%	2 011 880	2 011 940
<b>15 Training</b>	1 120 194	1 134 909	1 296 630		14%	1 184 050	1 155 390
<b>16 External Services</b>	1 706 656	2 082 800	1 929 000		-7%	1 929 000	1 929 000
<b>17 Receptions and events</b>	4 274	20 100	20 010		0%	20 010	20 010
<b>Title 2</b>					-		
<b>Infrastructure and operating expenditure</b>	<b>13 631 486</b>	<b>15 323 600</b>	<b>15 558 380</b>		<b>2%</b>	<b>15 513 830</b>	<b>18 354 100</b>
<b>20 Rental of buildings and associated costs</b>	7 602 031	7 604 100	7 492 490		-1%	7 499 970	10 357 030
<b>21 Information and communication technology</b>	5 645 641	7 066 200	7 236 730		2%	7 202 100	7 166 650
<b>22 Movable property and associated costs</b>	179 407	333 700	500 630		50%	500 920	501 190
<b>23 Current administrative expenditure</b>	196 135	310 900	318 510		2%	300 810	319 190
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	8 271	8 700	10 020		15%	10 030	10 040
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 3</b>					-	0	0
<b>Operational expenditure</b>	<b>15 959 950</b>	<b>23 786 900</b>	<b>23 528 700</b>		<b>-1%</b>	<b>22 988 830</b>	<b>19 029 580</b>
<b>30 REACH</b>	<b>15 389 376</b>	<b>22 993 900</b>	<b>22 397 160</b>		<b>-3%</b>	<b>22 356 130</b>	<b>18 296 880</b>
<b>3003 Registration, datasharing and dissemination</b>	196 122	562 000	1 177 000	0	<b>109%</b>	2 700 000	928 000
<b>3004 Evaluation</b>	218 614	1 736 500	1 580 000	0	<b>-9%</b>	1 511 000	1 511 000
<b>3005 Authorisations and restrictions</b>	272 285	735 000	1 235 000	0	<b>68%</b>	1 335 000	1 335 000
<b>3006 Classification and labelling</b>	0	40 000	50 000	0	<b>25%</b>	50 000	50 000
<b>3007 Advice and assistance through guidance and helpdesk</b>	146 092	160 700	235 500	0	<b>47%</b>	235 500	145 500
<b>3008 Scientific IT tools</b>	9 858 509	11 903 200	11 454 120	0	<b>-4%</b>	10 901 640	8 796 410



<b>3009 Scientific and technical advice to EU institutions and bodies</b>	100 469	260 000	260 000	0	<b>0%</b>	260 000	260 000
<b>3011 Committees and Forum</b>	1 062 472	2 505 900	1 969 400	0	<b>-21%</b>	1 544 500	1 474 500
<b>3012 Board of Appeal</b>	24 487	98 500	96 000	0	<b>-3%</b>	96 000	96 000
<b>3013 Communications including Translations</b>	2 179 962	3 057 000	2 458 550	0	<b>-20%</b>	1 808 550	1 786 240
<b>3014 International cooperation</b>	0	0	0	0	-	0	0
<b>3022 Management Board and management of the Agency</b>	817 990	1 400 100	1 351 590	0	<b>-3%</b>	1 383 940	1 384 230
<b>3030 Missions</b>	512 374	535 000	530 000	0	<b>-1%</b>	530 000	530 000
<b>3031 External training</b>	0	0	0	0	-	0	0
<b>3090 Refunds REACH/CLP</b>	0	0	0	0	-	0	0
<b>31 MULTIANNUAL ACTIVITIES</b>	<b>206 294</b>	<b>14 000</b>	<b>31 400</b>		<b>124%</b>	<b>132 700</b>	<b>132 700</b>
<b>3111 Committees and Forum (Multiannual)</b>	206 294	14 000	31 400	0	<b>124%</b>	132 700	132 700
<b>38 INTERNATIONAL ACTIVITIES</b>	<b>337 707</b>	<b>779 000</b>	<b>1 100 140</b>		<b>41%</b>	<b>500 000</b>	<b>600 000</b>
<b>3801 Cooperation with international organisations for IT programmes</b>	337 707	779 000	1 100 140	0	<b>41%</b>	500 000	600 000
<b>39 EARMARKED OPERATIONS</b>	<b>26 573</b>	<b>0</b>	<b>0</b>		-	<b>0</b>	<b>0</b>
<b>3901 IPA programme according to agreement 2009/214-524</b>	0	0	0	0	-	0	0
<b>3902 IPA programme according to agreement 2012/291-934</b>	0	0	0	0	-	0	0
<b>3903 IPA programme according to agreement 2015/361-049</b>	26 573	0	0	0	-	0	0
<b>3910 ENP programme</b>	0	0	0	0	-	0	0
<b>Title 4</b>					-	0	0
<b>Operational expenditure</b>	<b>619 113</b>	<b>1 070 200</b>	<b>2 351 950</b>		<b>120%</b>	<b>1 823 000</b>	<b>1 779 240</b>
<b>4000 Substances, products and technical equivalence</b>	0	100 000	50 000		<b>-50%</b>	50 000	50 000
<b>4003 Submissions, datasharing, dissemination</b>	0	0	0		-	0	0
<b>4007 Advice assistance through guidance and helpdesk</b>	27 057	22 800	52 000		<b>128%</b>	52 000	52 000

<b>4008 Scientific IT tools</b>	123 952	309 300	1 453 410		<b>370%</b>	963 980	896 710
<b>4009 Scientif technic advice to EU institut and bodies</b>	0	0	0		-	0	0
<b>4011 Biocidal products Committee and Rapporteurs</b>	146 549	356 300	511 000		<b>43%</b>	511 000	523 500
<b>4012 Board of Appeal</b>	3 658	15 500	17 000		<b>10%</b>	17 000	17 000
<b>4013 Communications including Translations</b>	126 028	108 800	99 050		<b>-9%</b>	66 580	77 560
<b>4022 Management Board and management of the Agency</b>	108 000	105 000	119 490		<b>14%</b>	112 440	112 470
<b>4030 Missions</b>	28 793	52 500	50 000		<b>-5%</b>	50 000	50 000
<b>4031 External training</b>	0	0	0		-	0	0
<b>4901 Preparatory work BPR 13/3938 Norwegian</b>	55 076	0	0		-	0	0
<b>Title 5</b>					-	0	0
<b>Operational expenditure</b>	<b>336 451</b>	<b>292 200</b>	<b>353 690</b>		<b>21%</b>	<b>251 070</b>	<b>226 470</b>
<b>5000 Studies and consultants</b>	0	0	0	0	-	0	0
<b>5007 Advice assistance through guidance and helpdesk</b>	0	0	0	0	-	0	0
<b>5008 Scientific IT tools</b>	138 611	219 800	230 230	0	<b>5%</b>	218 370	193 770
<b>5011 Meetings with the DNAs and experts on PIC implem</b>	0	0	0	0	-	0	0
<b>5013 Communications including Translations</b>	184 986	59 000	108 460	0	<b>84%</b>	17 700	17 700
<b>5030 Missions</b>	12 855	13 400	15 000	0	<b>12%</b>	15 000	15 000
<b>5031 External training</b>	0	0	0	0	-	0	0
<b>TOTAL EXPENDITURE</b>	<b>100 890 772</b>	<b>107 367 309</b>	<b>109 597 520</b>	<b>0</b>	<b>2%</b>	<b>112 099 990</b>	<b>109 002 880</b>

**REACH/CLP**

Expenditure	2016		2017	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations

<b>Title 1</b>	60 186 009	60 186 009	60 115 230	60 115 230
<b>Title 2</b>	14 378 400	14 378 400	14 427 290	14 427 290
<b>Title 3</b>	24 226 600	23 786 900	22 829 860	23 528 700
<b>Total expenditure</b>	<b>98 791 009</b>	<b>98 351 309</b>	<b>97 372 380</b>	<b>98 071 220</b>

EXPENDITURE	Commitment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>65 188 712</b>	<b>60 186 009</b>	<b>60 115 230</b>		<b>0%</b>	<b>63 139 000</b>	<b>60 403 300</b>
<b>11 Salaries &amp; allowances</b>	59 942 126	54 835 000	54 801 000		0%	57 991 010	55 283 920
- of which establishment plan posts	54 355 808	48 928 000	48 699 000		0%	51 629 990	49 510 290
- of which external personnel	5 586 318	5 907 000	6 102 000		3%	6 361 020	5 773 630
<b>12 Expenditure relating to Staff recruitment</b>	545 187	725 100	611 890		-16%	611 890	611 890
<b>13 Mission expenses</b>	35 418	54 600	53 700		-2%	53 700	53 700
<b>14 Socio-medical infrastructure</b>	1 743 440	1 902 000	1 854 270		-3%	1 800 610	1 800 660
<b>15 Training</b>	1 328 577	1 022 809	1 155 210		13%	1 042 630	1 013 970
<b>16 External Services</b>	1 589 748	1 628 000	1 621 040		0%	1 621 040	1 621 040
<b>17 Receptions and events</b>	4 216	18 500	18 120		-2%	18 120	18 120
<b>Title 2 Infrastructure and operating expenditure</b>	<b>14 951 428</b>	<b>14 378 400</b>	<b>14 427 290</b>		<b>0%</b>	<b>14 386 620</b>	<b>17 032 670</b>
<b>20 Rental of buildings and associated costs</b>	7 420 586	7 147 600	6 968 010		-3%	6 974 970	9 637 300
<b>21 Information and communication technology</b>	6 512 771	6 626 500	6 706 190		1%	6 674 130	6 641 150
<b>22 Movable property and associated costs</b>	785 305	303 800	448 060		47%	448 310	448 560

<b>23 Current administrative expenditure</b>	224 969	292 700	296 070		1%	280 240	296 680
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	7 798	7 800	8 960		15%	8 970	8 980
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 3</b>					-	0	0
<b>Operational expenditure</b>	<b>22 871 917</b>	<b>24 226 600</b>	<b>22 829 860</b>		<b>-6%</b>	<b>22 710 330</b>	<b>18 851 080</b>
<b>30 REACH</b>	<b>22 652 384</b>	<b>22 993 900</b>	<b>22 397 160</b>		<b>-3%</b>	<b>22 356 130</b>	<b>18 296 880</b>
<b>3003 Registration, datasharing and dissemination</b>	562 988	562 000	1 177 000		109%	2 700 000	928 000
<b>3004 Evaluation</b>	1 654 669	1 736 500	1 580 000		-9%	1 511 000	1 511 000
<b>3005 Authorisations and restrictions</b>	536 198	735 000	1 235 000		68%	1 335 000	1 335 000
<b>3006 Classification and labelling</b>	0	40 000	50 000		25%	50 000	50 000
<b>3007 Advice and assistance through guidance and helpdesk</b>	154 965	160 700	235 500		47%	235 500	145 500
<b>3008 Scientific IT tools</b>	13 704 528	11 903 200	11 454 120		-4%	10 901 640	8 796 410
<b>3009 Scientific and technical advice to EU institutions and bodies</b>	188 689	260 000	260 000		0%	260 000	260 000
<b>3011 Committees and Forum</b>	1 371 659	2 505 900	1 969 400		-21%	1 544 500	1 474 500
<b>3012 Board of Appeal</b>	58 793	98 500	96 000		-3%	96 000	96 000
<b>3013 Communications including Translations</b>	2 852 905	3 057 000	2 458 550		-20%	1 808 550	1 786 240
<b>3014 International cooperation</b>	0	0	0		-	0	0
<b>3022 Management Board and management of the Agency</b>	1 032 474	1 400 100	1 351 590		-3%	1 383 940	1 384 230
<b>3030 Missions</b>	534 517	535 000	530 000		-1%	530 000	530 000
<b>3031 External training</b>	0	0	0		-	0	0
<b>3090 Refunds REACH/CLP</b>	0	0	0		-	0	0
<b>31 MULTIANNUAL ACTIVITIES</b>	<b>37 390</b>	<b>132 700</b>	<b>132 700</b>		<b>0%</b>	<b>54 200</b>	<b>54 200</b>
<b>3111 Committees and Forum (Multiannual)</b>	37 390	132 700	132 700		0%	54 200	54 200

<b>38 INTERNATIONAL ACTIVITIES</b>	<b>154 900</b>	<b>1 100 000</b>	<b>300 000</b>		<b>-73%</b>	<b>300 000</b>	<b>500 000</b>
<b>3801 Cooperation with international organisations for IT programmes</b>	154 900	1 100 000	300 000		-73%	300 000	500 000
<b>39 EARMARKED OPERATIONS</b>	<b>27 243</b>	<b>0</b>	<b>0</b>		<b>-</b>	<b>0</b>	<b>0</b>
<b>3901 IPA programme according to agreement 2009/214-524</b>	0	0	0		-	0	0
<b>3902 IPA programme according to agreement 2012/291-934</b>	0	0	0		-	0	0
<b>3903 IPA programme according to agreement 2015/361-049</b>	27 243	0	0		-	0	0
<b>3910 ENP programme</b>	0	0	0		-	0	0
<b>TOTAL EXPENDITURE</b>	<b>103 012 057</b>	<b>98 791 009</b>	<b>97 372 380</b>		<b>-1%</b>	<b>100 235 950</b>	<b>96 287 050</b>

EXPENDITURE	Payment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>64 536 888</b>	<b>60 186 009</b>	<b>60 115 230</b>		<b>0%</b>	<b>63 139 000</b>	<b>60 403 300</b>
<b>11 Salaries &amp; allowances</b>	59 941 934	54 835 000	54 801 000		0%	57 991 010	55 283 920
- of which establishment plan posts	54 355 616	48 928 000	48 699 000		0%	51 629 990	49 510 290
- of which external personnel	5 586 318	5 907 000	6 102 000		3%	6 361 020	5 773 630
<b>12 Expenditure relating to Staff recruitment</b>	539 434	725 100	611 890		-16%	611 890	611 890
<b>13 Mission expenses</b>	35 418	54 600	53 700		-2%	53 700	53 700
<b>14 Socio-medical infrastructure</b>	1 618 334	1 902 000	1 854 270		-3%	1 800 610	1 800 660
<b>15 Training</b>	1 020 834	1 022 809	1 155 210		13%	1 042 630	1 013 970
<b>16 External Services</b>	1 377 089	1 628 000	1 621 040		0%	1 621 040	1 621 040
<b>17 Receptions and events</b>	3 844	18 500	18 120		-2%	18 120	18 120
<b>Title 2 Infrastructure and operating expenditure</b>	<b>12 728 864</b>	<b>14 378 400</b>	<b>14 427 290</b>		<b>0%</b>	<b>14 386 620</b>	<b>17 032 670</b>

<b>20 Rental of buildings and associated costs</b>	7 144 958	7 147 600	6 968 010		-3%	6 974 970	9 637 300
<b>21 Information and communication technology</b>	5 239 544	6 626 500	6 706 190		1%	6 674 130	6 641 150
<b>22 Movable property and associated costs</b>	159 332	303 800	448 060		47%	448 310	448 560
<b>23 Current administrative expenditure</b>	177 685	292 700	296 070		1%	280 240	296 680
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	7 345	7 800	8 960		15%	8 970	8 980
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 3</b>					-	0	0
<b>Operational expenditure</b>	<b>15 959 950</b>	<b>23 786 900</b>	<b>23 528 700</b>		<b>-1%</b>	<b>22 988 830</b>	<b>19 029 580</b>
<b>30 REACH</b>	<b>15 389 376</b>	<b>22 993 900</b>	<b>22 397 160</b>		<b>-3%</b>	<b>22 356 130</b>	<b>18 296 880</b>
<b>3003 Registration, datasharing and dissemination</b>	196 122	562 000	1 177 000		109%	2 700 000	928 000
<b>3004 Evaluation</b>	218 614	1 736 500	1 580 000		-9%	1 511 000	1 511 000
<b>3005 Authorisations and restrictions</b>	272 285	735 000	1 235 000		68%	1 335 000	1 335 000
<b>3006 Classification and labelling</b>	0	40 000	50 000		25%	50 000	50 000
<b>3007 Advice and assistance through guidance and helpdesk</b>	146 092	160 700	235 500		47%	235 500	145 500
<b>3008 Scientific IT tools</b>	9 858 509	11 903 200	11 454 120		-4%	10 901 640	8 796 410
<b>3009 Scientific and technical advice to EU institutions and bodies</b>	100 469	260 000	260 000		0%	260 000	260 000
<b>3011 Committees and Forum</b>	1 062 472	2 505 900	1 969 400		-21%	1 544 500	1 474 500
<b>3012 Board of Appeal</b>	24 487	98 500	96 000		-3%	96 000	96 000
<b>3013 Communications including Translations</b>	2 179 962	3 057 000	2 458 550		-20%	1 808 550	1 786 240
<b>3014 International cooperation</b>	0	0	0		-	0	0
<b>3022 Management Board and management of the Agency</b>	817 990	1 400 100	1 351 590		-3%	1 383 940	1 384 230

<b>3030 Missions</b>	512 374	535 000	530 000		-1%	530 000	530 000
<b>3031 External training</b>	0	0	0		-	0	0
<b>3090 Refunds REACH/CLP</b>	0	0	0		-	0	0
<b>31 MULTIANNUAL ACTIVITIES</b>	<b>206 294</b>	<b>14 000</b>	<b>31 400</b>		<b>124%</b>	<b>132 700</b>	<b>132 700</b>
<b>3111 Committees and Forum (Multiannual)</b>	206 294	14 000	31 400		124%	132 700	132 700
<b>38 INTERNATIONAL ACTIVITIES</b>	<b>337 707</b>	<b>779 000</b>	<b>1 100 140</b>		<b>41%</b>	<b>500 000</b>	<b>600 000</b>
<b>3801 Cooperation with international organisations for IT programmes</b>	337 707	779 000	1 100 140		41%	500 000	600 000
<b>39 EARMARKED OPERATIONS</b>	<b>26 573</b>	<b>0</b>	<b>0</b>		<b>-</b>	<b>0</b>	<b>0</b>
<b>3901 IPA programme according to agreement 2009/214-524</b>	0	0	0		-	0	0
<b>3902 IPA programme according to agreement 2012/291-934</b>	0	0	0		-	0	0
<b>3903 IPA programme according to agreement 2015/361-049</b>	26 573	0	0		-	0	0
<b>3910 ENP programme</b>	0	0	0		-	0	0
<b>TOTAL EXPENDITURE</b>	<b>93 225 702</b>	<b>98 351 309</b>	<b>98 071 220</b>		<b>0%</b>	<b>100 514 450</b>	<b>96 465 550</b>

## BIOCIDES

Expenditure	2016		2017	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
<b>Title 1</b>	6 004 600	6 004 600	7 017 730	7 017 730
<b>Title 2</b>	790 200	790 200	973 620	973 620
<b>Title 3</b>	1 070 200	1 070 200	2 351 950	2 351 950
<b>Total expenditure</b>	<b>7 865 000</b>	<b>7 865 000</b>	<b>10 343 300</b>	<b>10 343 300</b>

EXPENDITURE	Commitment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>5 426 053</b>	<b>6 004 600</b>	<b>7 017 730</b>		<b>17%</b>	<b>7 650 320</b>	<b>8 479 790</b>
<b>11 Salaries &amp; allowances</b>	4 662 383	5 237 000	6 322 300		21%	6 960 470	7 789 930
- of which establishment plan posts	4 036 850	4 344 500	5 355 300		23%	5 933 800	6 507 992
- of which external personnel	625 533	892 500	967 000		8%	1 026 670	1 281 937
<b>12 Expenditure relating to Staff recruitment</b>	88 000	114 500	118 990		4%	118 990	118 990
<b>13 Mission expenses</b>	3 713	4 800	5 580		16%	5 580	5 580
<b>14 Socio-medical infrastructure</b>	163 426	177 400	192 690		9%	187 110	187 120
<b>15 Training</b>	120 676	91 000	124 960		37%	124 960	124 960
<b>16 External Services</b>	387 382	378 300	251 320		-34%	251 320	251 320
<b>17 Receptions and events</b>	473	1 600	1 890		18%	1 890	1 890
<b>Title 2 Infrastructure and operating expenditure</b>	<b>970 156</b>	<b>790 200</b>	<b>973 620</b>		<b>- 23%</b>	<b>970 220</b>	<b>1 136 300</b>
<b>20 Rental of buildings and associated costs</b>	395 102	380 300	449 550		18%	450 000	616 460
<b>21 Information and communication technology</b>	464 238	367 800	456 700		24%	454 470	452 360
<b>22 Movable property and associated costs</b>	88 407	25 800	46 560		80%	46 590	46 610
<b>23 Current administrative expenditure</b>	21 531	15 600	19 870		27%	18 220	19 930
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	878	700	940		34%	940	940
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0



<b>Title 4</b>					-		
<b>Operational expenditure</b>	<b>2 291 034</b>	<b>1 070 200</b>	<b>2 351 950</b>		<b>120%</b>	<b>1 823 000</b>	<b>1 779 240</b>
<b>4000 Substances, products and technical equivalence</b>	0	100 000	50 000		-50%	50 000	50 000
<b>4003 Submissions, datasharing, dissemination</b>	0	0	0		-	0	0
<b>4007 Advice assistance through guidance and helpdesk</b>	27 057	22 800	52 000		128%	52 000	52 000
<b>4008 Scientific IT tools</b>	1 470 733	309 300	1 453 410		370%	963 980	896 710
<b>4009 Scientific technic advice to EU institut and bodies</b>	0	0	0		-	0	0
<b>4011 Biocidal products Committee and Rapporteurs</b>	293 162	356 300	511 000		43%	511 000	523 500
<b>4012 Board of Appeal</b>	3 658	15 500	17 000		10%	17 000	17 000
<b>4013 Communications including Translations</b>	162 591	108 800	99 050		-9%	66 580	77 560
<b>4022 Management Board and management of the Agency</b>	126 483	105 000	119 490		14%	112 440	112 470
<b>4030 Missions</b>	30 293	52 500	50 000		-5%	50 000	50 000
<b>4031 External training</b>	0	0	0		-	0	0
<b>4901 Preparatory work BPR 13/3938 Norwegian</b>	177 057	0	0		-	0	0
<b>TOTAL EXPENDITURE</b>	<b>8 687 243</b>	<b>7 865 000</b>	<b>10 343 300</b>		<b>32%</b>	<b>10 443 540</b>	<b>11 395 330</b>

EXPENDITURE	Payment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>5 263 649</b>	<b>6 004 600</b>	<b>7 017 730</b>		<b>17%</b>	<b>7 650 320</b>	<b>8 479 790</b>
<b>11 Salaries &amp; allowances</b>	4 662 383	5 237 000	6 322 300		21%	6 960 470	7 789 930
<i>- of which establishment plan posts</i>	4 036 850	4 344 500	5 355 300		23%	5 933 800	6 507 992

- of which external personnel	625 533	892 500	967 000		8%	1 026 670	1 281 937
<b>12 Expenditure relating to Staff recruitment</b>	85 940	114 500	118 990		4%	118 990	118 990
<b>13 Mission expenses</b>	3 713	4 800	5 580		16%	5 580	5 580
<b>14 Socio-medical infrastructure</b>	149 470	177 400	192 690		9%	187 110	187 120
<b>15 Training</b>	88 665	91 000	124 960		37%	124 960	124 960
<b>16 External Services</b>	273 048	378 300	251 320		-34%	251 320	251 320
<b>17 Receptions and events</b>	429	1 600	1 890		18%	1 890	1 890
<b>Title 2 Infrastructure and operating expenditure</b>	<b>767 157</b>	<b>790 200</b>	<b>973 620</b>		<b>-</b>	<b>970 220</b>	<b>1 136 300</b>
<b>20 Rental of buildings and associated costs</b>	380 469	380 300	449 550		18%	450 000	616 460
<b>21 Information and communication technology</b>	351 474	367 800	456 700		24%	454 470	452 360
<b>22 Movable property and associated costs</b>	17 917	25 800	46 560		80%	46 590	46 610
<b>23 Current administrative expenditure</b>	16 469	15 600	19 870		27%	18 220	19 930
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	827	700	940		34%	940	940
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 4 Operational expenditure</b>	<b>619 113</b>	<b>1 070 200</b>	<b>2 351 950</b>		<b>-</b>	<b>1 823 000</b>	<b>1 779 240</b>
<b>4000 Substances, products and technical equivalence</b>	0	100 000	50 000		-50%	50 000	50 000
<b>4003 Submissions, datasharing, dissemination</b>	0	0	0		-	0	0
<b>4007 Advice assistance through guidance and helpdesk</b>	27 057	22 800	52 000		128%	52 000	52 000
<b>4008 Scientific IT tools</b>	123 952	309 300	1 453 410		370%	963 980	896 710



<b>Title 1 Staff Expenditure</b>	<b>570 680</b>	<b>703 800</b>	<b>671 840</b>		<b>-5%</b>	<b>733 940</b>	<b>730 400</b>
<b>11 Salaries &amp; allowances</b>	457 082	548 000	533 200		-3%	599 340	605 330
- of which establishment plan posts	411 176	494 800	478 200		-3%	543 790	549 225
- of which external personnel	45 906	53 200	55 000		3%	55 550	56 105
<b>12 Expenditure relating to Staff recruitment</b>	11 503	41 000	39 940		-3%	36 620	27 090
<b>13 Mission expenses</b>	446	800	720		-10%	720	720
<b>14 Socio-medical infrastructure</b>	8 676	16 400	24 880		52%	24 160	24 160
<b>15 Training</b>	14 537	21 100	16 460		-22%	16 460	16 460
<b>16 External Services</b>	78 437	76 500	56 640		-26%	56 640	56 640
<b>17 Receptions and events</b>	0	0	0		-	0	0
<b>Title 2</b>					-		
<b>Infrastructure and operating expenditure</b>	<b>161 384</b>	<b>155 000</b>	<b>157 470</b>		<b>2%</b>	<b>156 990</b>	<b>185 130</b>
<b>20 Rental of buildings and associated costs</b>	79 549	76 200	74 930		-2%	75 000	103 270
<b>21 Information and communication technology</b>	68 677	71 900	73 840		3%	73 500	73 140
<b>22 Movable property and associated costs</b>	10 587	4 100	6 010		47%	6 020	6 020
<b>23 Current administrative expenditure</b>	2 467	2 600	2 570		-1%	2 350	2 580
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	105	200	120		-40%	120	120
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 5</b>					-	0	0
<b>Operational expenditure</b>	<b>447 397</b>	<b>292 200</b>	<b>353 690</b>		<b>21%</b>	<b>251 070</b>	<b>226 470</b>
<b>5000 Studies and consultants</b>	0	0	0		-	0	0
<b>5007 Advice assistance through guidance and helpdesk</b>	0	0	0		-	0	0
<b>5008 Scientific IT tools</b>	225 853	219 800	230 230		5%	218 370	193 770

<b>5011 Meetings with the DNAs and experts on PIC implem</b>	0	0	0		-	0	0
<b>5013 Communications including Translations</b>	208 689	59 000	108 460		84%	17 700	17 700
<b>5030 Missions</b>	12 855	13 400	15 000		12%	15 000	15 000
<b>5031 External training</b>	0	0	0		-	0	0
<b>TOTAL EXPENDITURE</b>	<b>1 179 461</b>	<b>1 151 000</b>	<b>1 183 000</b>		<b>3%</b>	<b>1 142 000</b>	<b>1 142 000</b>

EXPENDITURE	Payment appropriations						
	Executed Budget 2015	Budget 2016	Draft Budget 2017		VAR 2017 / 2016	Envisaged 2018	Envisaged 2019
			Agency request	Budget Forecast			
<b>Title 1 Staff Expenditure</b>	<b>543 236</b>	<b>703 800</b>	<b>671 840</b>		<b>-5%</b>	<b>733 940</b>	<b>730 400</b>
<b>11 Salaries &amp; allowances</b>	457 082	548 000	533 200		-3%	599 340	605 330
<i>- of which establishment plan posts</i>	411 176	494 800	478 200		-3%	543 782	549 220
<i>- of which external personnel</i>	45 906	53 200	55 000		3%	55 550	56 106
<b>12 Expenditure relating to Staff recruitment</b>	11 492	41 000	39 940		-3%	36 620	27 090
<b>13 Mission expenses</b>	446	800	720		-10%	720	720
<b>14 Socio-medical infrastructure</b>	7 001	16 400	24 880		52%	24 160	24 160
<b>15 Training</b>	10 695	21 100	16 460		-22%	16 460	16 460
<b>16 External Services</b>	56 519	76 500	56 640		-26%	56 640	56 640
<b>17 Receptions and events</b>	0	0	0		-	0	0
<b>Title 2 Infrastructure and operating expenditure</b>	<b>135 465</b>	<b>155 000</b>	<b>157 470</b>		<b>2%</b>	<b>156 990</b>	<b>185 130</b>
<b>20 Rental of buildings and associated costs</b>	76 604	76 200	74 930		-2%	75 000	103 270
<b>21 Information and communication technology</b>	54 623	71 900	73 840		3%	73 500	73 140

<b>22 Movable property and associated costs</b>	2 158	4 100	6 010		47%	6 020	6 020
<b>23 Current administrative expenditure</b>	1 981	2 600	2 570		-1%	2 350	2 580
<b>24 Postage / Telecommunications</b>	0	0	0		-	0	0
<b>25 Meeting expenses</b>	99	200	120		-40%	120	120
<b>26 Running costs in connection with operational activities</b>	0	0	0		-	0	0
<b>27 Information and publishing</b>	0	0	0		-	0	0
<b>28 Studies</b>	0	0	0		-	0	0
<b>Title 5</b>						0	0
<b>Operational expenditure</b>	<b>336 451</b>	<b>292 200</b>	<b>353 690</b>		<b>21%</b>	<b>251 070</b>	<b>226 470</b>
<b>5000 Studies and consultants</b>	0	0	0		-	0	0
<b>5007 Advice assistance through guidance and helpdesk</b>	0	0	0		-	0	0
<b>5008 Scientific IT tools</b>	138 611	219 800	230 230		5%	218 370	193 770
<b>5011 Meetings with the DNAs and experts on PIC implem</b>	0	0	0		-	0	0
<b>5013 Communications including Translations</b>	184 986	59 000	108 460		84%	17 700	17 700
<b>5030 Missions</b>	12 855	13 400	15 000		12%	15 000	15 000
<b>5031 External training</b>	0	0	0		-	0	0
<b>TOTAL EXPENDITURE</b>	<b>1 015 152</b>	<b>1 151 000</b>	<b>1 183 000</b>		<b>3%</b>	<b>1 142 000</b>	<b>1 142 000</b>

**Annex II: Table 2 – Revenue****ECHA**

Revenues	2016	2017
	Revenues estimated by the agency	Budget Forecast
EU contribution	71 612 000	75 001 000
Other revenue	35 755 309	34 596 520
<b>Total revenues</b>	<b>107 367 309</b>	<b>109 597 520</b>

REVENUES	2015	2016	2017		VAR 2017 /2016	Envisaged 2018	Envisaged 2019
	Executed Budget	Revenues estimated by the agency	As requested by the agency	Budget Forecast			
<b>1 REVENUE FROM FEES AND CHARGES</b>	29 209 141	33 556 019	32 301 180	0	-4%	75 672 520	36 723 730
<b>2. EU CONTRIBUTION</b>	7 011 000	71 612 000	75 001 000	0	5%	35 385 000	70 166 000
of which Administrative (Title 1 and Title 2)	6 067 032	54 664 468	56 974 070	0	4%	27 341 471	56 397 329
of which Operational (Title 3)	943 968	16 947 532	18 026 930	0	6%	8 043 529	13 768 671
of which assigned revenues deriving from previous years' surpluses	0	0	0	0	-	0	0
<b>3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)</b>	307 791	2 199 290	2 295 340	0	4%	1 042 470	2 113 150
of which EFTA	307 791	2 199 290	2 295 340	0	4%	1 042 470	2 113 150
of which Candidate Countries	0	0	0	0	-	0	0
<b>4 OTHER CONTRIBUTIONS</b>	0	0	0	0	-	0	0

of which delegation agreement, ad hoc grants	0	0	0	0	-	0	0
<b>5 ADMINISTRATIVE OPERATIONS</b>	756 727	0	0	0	-	0	0
<b>6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT</b>	300 924	0	0	0	-	0	0
<b>7 CORRECTION OF BUDGETARY IMBALANCES</b>	0	0	0	0	-	0	0
<b>TOTAL REVENUES</b>	<b>37 585 583</b>	<b>107 367 309</b>	<b>109 597 520</b>	<b>0</b>	<b>2%</b>	<b>112 099 990</b>	<b>109 002 880</b>

**REACH / CLP**

Revenues	2016	2017
	Revenues estimated by the agency	Budget Forecast
<b>EU contribution</b>	<b>66 811 000</b>	<b>70 883 000</b>
<b>Other revenue</b>	<b>31 540 309</b>	<b>27 188 220</b>
<b>Total revenues</b>	<b>98 351 309</b>	<b>98 071 220</b>

REVENUES	2015	2016	2017		VAR 2017 /2016	Envisaged 2018	Envisaged 2019
	Executed Budget	Revenues estimated by the agency	As requested by the agency	Budget Forecast			
<b>1 REVENUE FROM FEES AND CHARGES</b>	23 785 474	29 556 019	25 083 000		-15%	66 002 000	27 245 000
<b>2. EU CONTRIBUTION</b>	0	66 811 000	70 883 000		6%	33 517 000	67 224 000
of which Administrative (Title 1 and Title 2)	0	50 652 328	53 877 146		6%	25 851 270	53 962 846
of which Operational (Title 3)	0	16 158 672	17 005 854		5%	7 665 730	13 261 154



of which assigned revenues deriving from previous years' surpluses					-		
<b>3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)</b>	0	1 984 290	2 105 220		6%	995 450	1 996 550
of which EFTA		1 984 290	2 105 220		6%	995 450	1 996 550
of which Candidate Countries					-		
<b>4 OTHER CONTRIBUTIONS</b>					-		
of which delegation agreement, ad hoc grants					-		
<b>5 ADMINISTRATIVE OPERATIONS</b>	740 469				-		
<b>6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT</b>	300 000				-		
<b>7 CORRECTION OF BUDGETARY IMBALANCES</b>					-		
<b>TOTAL REVENUES</b>	<b>24 825 943</b>	<b>98 351 309</b>	<b>98 071 220</b>	<b>0</b>	<b>0%</b>	<b>100 514 450</b>	<b>96 465 550</b>

**BIOCIDES**

Revenues	2016	2017
	Revenues estimated by the agency	Budget Forecast
EU contribution	3 650 000	2 935 000
Other revenue	4 215 000	7 408 300
<b>Total revenues</b>	<b>7 865 000</b>	<b>10 343 300</b>

REVENUES	2015	2016	2017		Envisaged 2018	Envisaged 2019
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	Executed Budget	Revenues estimated by the agency	As requested by the agency	Budget Forecast	VAR 2017 /2016		
<b>1 REVENUE FROM FEES AND CHARGES</b>	5 423 667	4 000 000	7 218 180		80%	9 670 520	9 478 730
<b>2. EU CONTRIBUTION</b>	5 789 000	3 650 000	2 935 000		-20%	726 000	1 800 000
of which Administrative (Title 1 and Title 2)	5 250 039	3 153 340	2 267 614		-28%	599 271	1 518 952
of which Operational (Title 3)	538 961	496 660	667 386		34%	126 729	281 048
of which assigned revenues deriving from previous years' surpluses					-		
<b>3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)</b>	307 791	215 000	190 120		-12%	47 020	116 600
of which EFTA	307 791	215 000	190 120		-12%	47 020	116 600
of which Candidate Countries					-		
<b>4 OTHER CONTRIBUTIONS</b>					-		
of which delegation agreement, ad hoc grants					-		
<b>5 ADMINISTRATIVE OPERATIONS</b>	16 258				-		
<b>6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT</b>					-		
<b>7 CORRECTION OF BUDGETARY IMBALANCES</b>					-		
<b>TOTAL REVENUES</b>	<b>11 536 716</b>	<b>7 865 000</b>	<b>10 343 300</b>		<b>32%</b>	<b>10 443 540</b>	<b>11 395 330</b>

**PIC**

Revenues	2016	2017
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	Revenues estimated by the agency	Budget Forecast
EU contribution	1 151 000	1 183 000
Other revenue	0	0
<b>Total revenues</b>	<b>1 151 000</b>	<b>1 183 000</b>

REVENUES	2015	2016	2017		VAR 2017 /2016	Envisaged 2018	Envisaged 2019
	Executed Budget	Revenues estimated by the agency	As requested by the agency	Budget Forecast			
<b>1 REVENUE FROM FEES AND CHARGES</b>	0	0	0		-	0	0
<b>2. EU CONTRIBUTION</b>	1 222 000	1 151 000	1 183 000		3%	1 142 000	1 142 000
of which Administrative (Title 1 and Title 2)	816 993	858 800	829 310		-3%	890 930	915 530
of which Operational (Title 5)	405 007	292 200	353 690		21%	251 070	226 470
of which assigned revenues deriving from previous years' surpluses					-		
<b>3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)</b>	0	0	0		-	0	0
of which EFTA	0	0	0		-	0	0
of which Candidate Countries					-		
<b>4 OTHER CONTRIBUTIONS</b>					-		
of which delegation agreement, ad hoc grants					-		
<b>5 ADMINISTRATIVE OPERATIONS</b>					-		

<b>6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT</b>	924				-		
<b>7 CORRECTION OF BUDGETARY IMBALANCES</b>					-		
<b>TOTAL REVENUES</b>	<b>1 222 924</b>	<b>1 151 000</b>	<b>1 183 000</b>	<b>0</b>	<b>3%</b>	<b>1 142 000</b>	<b>1 142 000</b>

## 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 (-)			
<b>Total</b>	<b>164 817 340</b>	<b>87 189 692</b>	<b>8 839 384</b>

The amount of € 1 058 576 remained uncommitted.

**BIOCIDES**

<b>Budget outturn</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
<b>Revenue actually received (+)</b>	7 484 948	7 728 121	11 536 716
<b>Payments made (-)</b>	-5 105 036	-7 089 216	-6 653 783
<b>Carry-over of appropriations (-)</b>	-2 243 829	-543 110	-2 037 505
<b>Cancellation of appropriations carried over (+)</b>	178 792	234 577	26 444
<b>Adjustment for carry over of assigned revenue appropriations from previous year (+)</b>			178 581
<b>Exchange rate differences (+/-)</b>			0
<b>Adjustment for negative balance from previous year (-)</b>			0
<b>Total</b>	314 875	330 372	3 050 453

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

**PIC**

<b>Budget outturn</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
<b>Revenue actually received (+)</b>	1 561 500	1 297 391	1 222 925
<b>Payments made (-)</b>	-461 657	-1 003 063	-1 015 317
<b>Carry-over of appropriations (-)</b>	-1 048 839	-192 017	-164 310
<b>Cancellation of appropriations carried over (+)</b>	40 762	8 810	2 769

<b>Budget outturn</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
<b>Adjustment for carry over of assigned revenue appropriations from previous year (+)</b>			166
<b>Exchange rate differences (+/-)</b>			
<b>Adjustment for negative balance from previous year (-)</b>			
<b>Total</b>	91 766	111 121	46 233

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

## Annex III. Staff population and its evolution

*As sent to the European Commission on 31.1.2016; to be revised and updated in December 2016 after adoption of Union budget*

**Table 1 – Overview of all categories of staff**

Staff population		Staff population - posts actually filled in 31.12.2014*				Staff population in voted EU budget 2015				Staff population - posts actually filled in 31.12.2015*				Staff population in voted EU budget 2016				Staff population in draft EU budget 2017*				Staff population envisaged in 2018				Staff population envisaged in 2019				
		REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides**	PIC	TOTAL	REACH/CLP	Biocides**	PIC	TOTAL	REACH/CLP	Biocides**	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	
Officials	AD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	AST	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TA	AD	307	31	1	339	308	39	1	348	304	31	1	336	303	32	1	336	298	35	1	334	296	38	1	335	296	43	1	340	
	AST	126	9	5	140	122	9	5	136	117	9	5	131	117	7	5	129	112	9	5	126	108	9	6	123	108	10	6	124	
	AST/SC																													
<b>Total AD+AST</b>		<b>433</b>	<b>40</b>	<b>6</b>	<b>479</b>	<b>430</b>	<b>48</b>	<b>6</b>	<b>484</b>	<b>421</b>	<b>40</b>	<b>6</b>	<b>467</b>	<b>420</b>	<b>39</b>	<b>6</b>	<b>465</b>	<b>410</b>	<b>44</b>	<b>6</b>	<b>460</b>	<b>404</b>	<b>47</b>	<b>7</b>	<b>458</b>	<b>404</b>	<b>53</b>	<b>7</b>	<b>464</b>	
CA FG IV		17	3	0	20	18	3	1	22	14	4		18	18	4	1	23	17	6	1	24	16	8	1	25	15	8	1	24	
CA FG III		55	5	0	60	62	5		67	53	6		59	64	8		72	71	8		79	72	8		80	62	8		70	
CA FG II		21	2	1	24	15	2		17	23	0	1	24	18	2		20	18	2		20	18	2		20	18	2		20	
CA FG I		2	0	0	2	3	0		3	2			2				0				0				0				0	
TOTAL CAs in place		<b>95</b>	<b>10</b>	<b>1</b>	<b>106</b>					<b>92</b>	<b>10</b>	<b>1</b>	<b>103</b>																	
<b>Total CA (FTE)</b>		<b>89.8</b>	<b>8.49</b>	<b>1</b>	<b>99</b>	<b>98</b>	<b>10</b>	<b>1</b>	<b>109</b>	<b>85</b>	<b>9.08</b>	<b>1</b>	<b>95</b>	<b>100</b>	<b>14</b>	<b>1</b>	<b>115</b>	<b>106</b>	<b>16</b>	<b>1</b>	<b>123</b>	<b>106</b>	<b>18</b>	<b>1</b>	<b>125</b>	<b>95</b>	<b>18</b>	<b>1</b>	<b>114</b>	
SNE		11	1	0	12	13	2	0	15	7	1		8	15	2	0	17	16	2	0	18	17	2	0	19	12	2	0	14	
Structural service providers**		45			45					40			40																	
<b>Total</b>		<b>584</b>	<b>51</b>	<b>7</b>	<b>642</b>	<b>541</b>	<b>60</b>	<b>7</b>	<b>608</b>	<b>560</b>	<b>51</b>	<b>7</b>	<b>618</b>	<b>535</b>	<b>55</b>	<b>7</b>	<b>597</b>	<b>532</b>	<b>62</b>	<b>7</b>	<b>601</b>	<b>527</b>	<b>67</b>	<b>8</b>	<b>602</b>	<b>511</b>	<b>73</b>	<b>8</b>	<b>592</b>	
External staff for occasional replacement**		34	7	2	43					34	9	3	46																	

\* 9 TAs under recruitment  
\* 1 CA under recruitment

\* 3 TAs under recruitment  
\* 3 CAs under recruitment

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

\*\*in line with the latest communication from August 2015      \*\*in line with the latest communication from August 2015

**Table 2 – Multi-annual staff policy plan 2017-2019**

Category and grade	Establishment plan in voted EU Budget 2015				Modifications envisaged in establishment plan 2015 in application of flexibility rule				Establishment plan in the voted EU budget 2016				Establishment plan in the draft EU budget 2017				Establishment plan 2018				Establishment plan 2019			
	TA				TA				TA				TA				TA							
	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL
AD 16	0	0	0	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	0	1	1	0	0	1	1	0	0	1
AD 14	4	0	0	4					4		0	4	5	0	0	6	6	0	0	6	6	0	0	6
AD 13	14	1	0	15					15		0	15	15	0	0	16	16	0	0	16	16	0	0	16
AD 12	23	2	0	25					20	2	0	22	18	2	0	20	17	2	0	19	17	2	0	19
AD 11	29	3	0	32					31	3	0	34	31	3	0	34	32	3	0	35	32	3	0	35
AD 10	31	4	0	35					33	3	0	36	36	3	0	39	39	3	0	42	39	4	0	43
AD 9	48	7	0	55					48	6	0	54	48	6	0	54	50	6	0	56	53	9	0	62
AD 8	48	12	1	61					50	9	1	60	47	12	1	60	46	12	1	59	46	13	1	60
AD 7	48	6	0	54					52	5	0	57	59	5	0	64	62	5	0	67	62	5	0	67
AD 6	53	4	0	57					41	4	0	45	30	4	0	34	19	7	0	26	16	7	0	23
AD 5	9	0	0	9					8		0	8	8		0	8	8		0	8	8		0	8
<b>Total AD</b>	<b>308</b>	<b>39</b>	<b>1</b>	<b>348</b>					<b>303</b>	<b>32</b>	<b>1</b>	<b>336</b>	<b>298</b>	<b>35</b>	<b>1</b>	<b>334</b>	<b>296</b>	<b>38</b>	<b>1</b>	<b>335</b>	<b>296</b>	<b>43</b>	<b>1</b>	<b>340</b>
AST 11	0	0	0	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	0	0	0	0	0	0	0	0	0
AST 9	7	0	0	7					6		0	6	5		0	5	4		0	4	4		0	4
AST 8	8	0	0	8					9		0	9	9		0	9	8		0	8	8		0	8
AST 7	12	1	2	15					12	1	2	15	11	1	2	14	11	1	2	14	11	1	2	14
AST 6	16	0	0	16					16		0	16	16		0	16	17		0	17	17		0	18
AST 5	29	3	0	32					31	3	0	34	31	3	0	34	33	3	0	36	35	3	0	38
AST 4	16	2	0	18					12	2	0	14	19	2	1	22	21	2	2	25	21	2	2	25
AST 3	18	3	3	24					19	1	3	23	13	3	2	18	7	3	2	12	7	3	2	12
AST 2	10	0	0	10					7		0	7	5		0	5	5		0	5	5		0	5
AST 1	5	0	0	5					5		0	5	3		0	3	2		0	2	0		0	0
<b>Total AST</b>	<b>122</b>	<b>9</b>	<b>5</b>	<b>136</b>					<b>117</b>	<b>7</b>	<b>5</b>	<b>129</b>	<b>112</b>	<b>9</b>	<b>5</b>	<b>126</b>	<b>108</b>	<b>9</b>	<b>6</b>	<b>123</b>	<b>108</b>	<b>10</b>	<b>6</b>	<b>124</b>
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
<b>TOTAL AD+AST</b>	<b>430</b>	<b>48</b>	<b>6</b>	<b>484</b>					<b>420</b>	<b>39</b>	<b>6</b>	<b>465</b>	<b>410</b>	<b>44</b>	<b>6</b>	<b>460</b>	<b>404</b>	<b>47</b>	<b>7</b>	<b>458</b>	<b>404</b>	<b>53</b>	<b>7</b>	<b>464</b>



## **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 experts<sup>66</sup>**

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<sup>66</sup> 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 providers<sup>67</sup>**

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 replacement<sup>68</sup>**

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:

<b>Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<b>Trainees</b>	<b>25</b>	<b>30</b>	<b>30</b>	<b>30</b>

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<sup>67</sup> Structural service providers are not employed by the agency

<sup>68</sup> External staff for occasional replacements is not employed by the agency

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

**Table 1 - Reclassification of temporary staff/promotion of officials**

Category and grade	Staff in activity at 1.01.2014		How many staff members were promoted / reclassified in 2015		Average number of years in grade of reclassified/promoted 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
<b>Total AD</b>		<b>330</b>	<b>0</b>	<b>48</b>	<b>4.76</b>
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
<b>Total AST</b>		<b>135</b>	<b>0</b>	<b>26</b>	<b>4.33</b>
<b>Total</b>		<b>465</b>	<b>0</b>	<b>74</b>	<b>4.54</b>

**Table 2 - Reclassification of contract staff**

<b>Function Group</b>	<b>Grade</b>	<b>Staff in activity at 1.01.2014</b>	<b>How many staff members were reclassified in 2015</b>	<b>Average number of years in grade of reclassified staff members in 2015</b>
<b>CA IV</b>	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
<b>CA III</b>	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
<b>CA II</b>	7	0	0	N/A
	6	0	0	N/A
	5	9	0	N/A
	4	7	0	N/A
<b>CA I</b>	3	0	0	N/A
	2	0	0	N/A
	1	3	2	3.12
<b>Total</b>		<b>87</b>	<b>9</b>	<b>4.28</b>

**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.

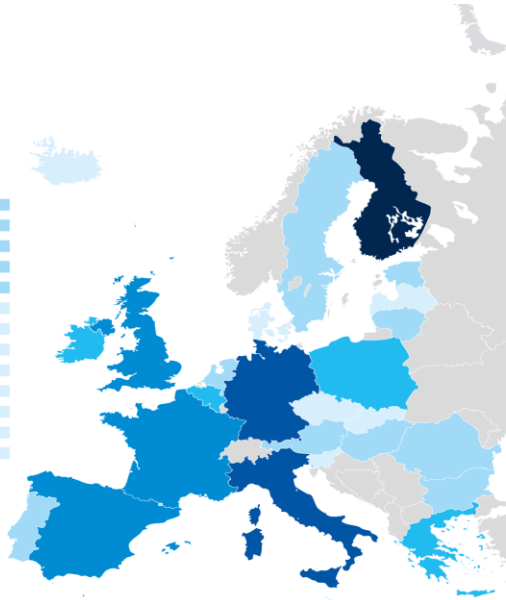
**Mobility between the Agencies and the Institutions**

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

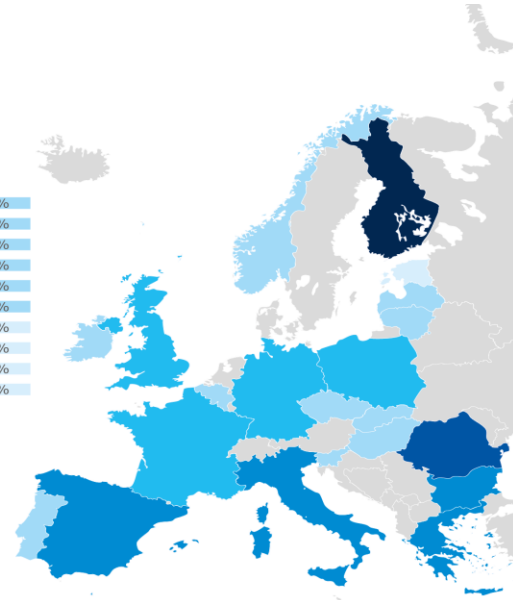
#### TA GEOGRAPHICAL BALANCE

Finnish	30.4%	Bulgarian	1.7%
German	8%	Estonian	1.5%
Italian	7.8%	Hungarian	1.5%
French	6.7%	Lithuanian	1.5%
British	6%	Austrian	1.1%
Spanish	5.2%	Czech	0.9%
Belgian	4.5%	Latvia	0.9%
Greek	4.1%	Slovakian	0.9%
Polish	3.9%	Slovenian	0.9%
Irish	3%	Danish	0.6%
Portuguese	2.2%	Maltese	0.6%
Dutch	1.9%	Iceland	0.2%
Romanian	1.9%	Liechtenstein	0.2%
Swedish	1.9%		

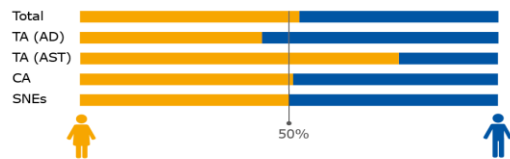


#### CA GEOGRAPHICAL BALANCE

Finnish	29%	Slovenian	3%
Romanian	10%	Czech	2%
Bulgarian	6%	Irish	2%
Greek	6%	Latvia	2%
Italian	6%	Portuguese	2%
Spanish	6%	Slovakian	2%
British	5%	Estonian	1%
French	4%	Hungarian	1%
German	4%	Lithuanian	1%
Polish	4%	Norway	1%
Belgian	3%		



#### 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<sup>[1]</sup>, 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.

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<sup>[1]</sup> 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.



<i>Annankatu 18</i>	Office	12 963					326 928
	Meeting Facilities		5 122				53 882
	Canteen + Lobby			1 329			35 728
	Storage				727		14 099
	Garage					1 808	11 115
<i>Lonnrotinkatu 12</i>	Office	438					4 380
<i>Bulevardi</i>	Office	2 422					57 872
Total (m2)	24371	15832	5122	1329	727	1808	<b>504 004</b>

ECHA has negotiated with the building's landlord to reduce the rented surface by terminating the rental contract for Lönrotinkatu 12 with effect from 1 January 2016. This reduced the rental surface by 1.718m<sup>2</sup> (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 Lönrotinkatu 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.

Agency privileges	Privileges granted to staff	
	Protocol of privileges and immunities / diplomatic status	Education / day care
Inviolability	Immunity from jurisdiction regarding official capacity	Same access to daycare organised by municipalities as Finnish nationals
Facilitations for Communications	Exemption from registration requirements Duty free import of goods upon taking up services Reimbursement of VAT between 1 June 2007 and 31 May 2009 (no longer in place) Right to free export when leaving the service Exemption from taxes on EU salaries Exemption from national car tax once every three years	Access to Finnish school system

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	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	<ul style="list-style-type: none"> <li>Assess the coverage of the 5 evaluation criteria in the ex-post evaluation and the cost-benefit-risk analysis in the ex-ante evaluation</li> <li>Collect lessons learnt and the relevant elements from the BRM for the purpose of future evaluations</li> </ul>

	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	<ul style="list-style-type: none"> <li>Evaluate the coverage of the 5 criteria in the CSA programme with own resources and CSR/ES Roadmap and ENES via outsourcing</li> <li>Decide on the future of the CSA programme and CSR/ES Roadmap/ENES strategy following the results of the evaluation</li> </ul>
Q2/2016	Perform an ex-ante evaluation of the future options of ECHA building strategy and project	ECF and WG	DCM	<ul style="list-style-type: none"> <li>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.</li> </ul>
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	<ul style="list-style-type: none"> <li>Consider covering the 5 criteria in Article 117 (2) report thus enabling the Commission to perform their own ex-post evaluation</li> </ul>
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	<ul style="list-style-type: none"> <li>Evaluate the coverage of the 5 criteria with own resources or via outsourcing (fitness check)</li> </ul>
Q3/2017	Perform an ex-post evaluation of ECHA Efficiency programme	ECF and WG	DCM	<ul style="list-style-type: none"> <li>Evaluate the coverage of the 5 criteria including the benefits of the programme vs its cumulative cost (fitness check)</li> </ul>



## **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 affected	Risk cause	Risk description	Risk consequence	Risk type	Risk level	Risk Response	Proposed Actions		
								Description	Owner	Deadline
1.1 REACH dossier management and assessment	Processing registration dossiers for the 2018 deadline	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	Insufficient resourcing (both in terms of scale and profile) could result in increased reliance on expertise from different units and potentially limit the success of the 2018 deadline. This type of work has a longer 'onboarding' period than has been needed for previous deadlines	2. PLANNING, PROCESSES AND 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	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 RMMs	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)	Disturbance in the long-term planning of ECHA; in case of shortfall, ECHA may not be able to achieve its budget implementation targets	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. Potential change in User Interface during the peak period resulting in need to re-train large number of staff	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: de-prioritisation 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 on-boarded	Dir. I	continuous follow up

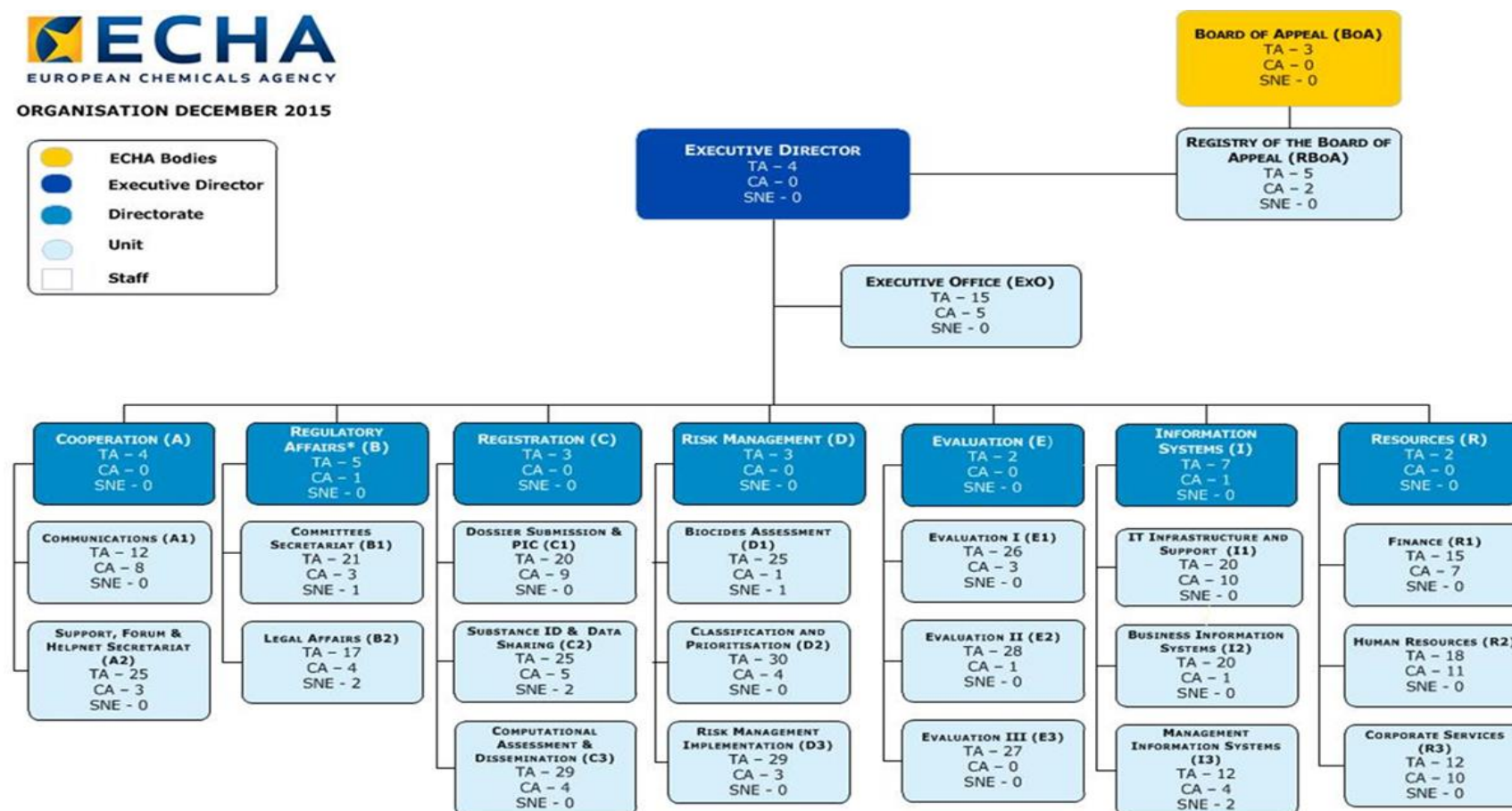
**Annex IX. Procurement plan 2017**

To be inserted in December 2016

## Annex X. Organisation chart 2017



ORGANISATION DECEMBER 2015



\* INCLUDING COORDINATION OF REGULATORY OPINION- AND DECISION-MAKING

## Annex XI. IT resources

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
<b>IUCLID</b>	<p>Main tool for technical dossier preparation for Industry in REACH, CLP and BPR.</p> <p>Used as the central database of dossiers for the regulatory work of ECHA and for the work of national Competent Authorities in REACH, CLP and BPR.</p> <p>Tool for preparation of applications for authorisation.</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.1.2 Registration and dossier submission</p> <p>1.1.3 Evaluation</p> <p>1.2.1 Identifying needs for Regulatory Risk Management</p> <p>1.2.2 Authorisation</p> <p>1.2.3 Restrictions</p> <p>1.2.4 Classification and Labelling</p> <p>1.3 Biocides</p>
<b>CHESAR</b>	<p>Supports registrants to carry out their safety assessments in a structured manner, prepare their chemical safety reports (CSRs) and generate their exposure scenarios for communication in the supply chain.</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.1.4 Communication of risk management advice through the supply chain</p>
<b>QSAR Toolbox</b>	<p>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.</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.5 Data management and dissemination</p>
<b>REACH-IT</b>	<p>The tool for inquiry submission and processing.</p> <p>Submission web application for REACH and CLP, as well as the tool for automated processing of submission, granting a</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.1.2 Registration and dossier submission</p>

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
	<p>registration number or PPORD notification number, once technical completeness and other relevant rules are met.</p> <p>Invoicing tool for fee based submissions.</p> <p>It offers a secure communication inbox used for all communication with registrants, used also by non-submission regulatory processes (e.g. communication of evaluation decisions).</p> <p>Submission tool for the applications for authorisation.</p>	<p>1.2.2 Authorisation</p> <p>1.2.4 Classification and labelling</p>
<b>Odyssey</b>	<p>Guides the scientific decision-making process and ensures consistency &amp; traceability.</p>	<p>1.1.3 Evaluation</p>
<b>Website</b>	<p>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.</p> <p>It informs and is the vehicle for public consultation in the different steps of the Authorisation process, on Restrictions, on CLP and on Biocides.</p> <p>It is the source of information for notifiers and DNAs on PIC and for companies wishing to appeal decisions.</p> <p>ECHA's website is the source of information on procurement exercises.</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.1.2 Registration and dossier submission</p> <p>1.1.3 Evaluation</p> <p>1.1.4 Communication of risk management advice through the supply chain</p> <p>1.2.1 Identifying needs for regulatory risk management</p> <p>1.2.2 Authorisation</p> <p>1.2.3 Restrictions</p> <p>1.2.4 Classification and Labelling</p> <p>1.3 Biocides</p>

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
	<p>It is the channel through which ECHA communicates its vacancies.</p> <p>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.</p>	<p>1.4 PIC</p> <p>1.5 Data management and dissemination</p> <p>2.1.4 Board of Appeal</p> <p>2.3.1 Financial resources</p> <p>2.3.2 Human resources Management</p>
<b>Remedy and its customisation Helpex</b>	<p>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.</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.1.2 Registration and dossier submission</p> <p>1.1.3 Evaluation</p> <p>1.1.4 Communication of risk management advice through the supply chain</p> <p>1.2.2 Authorisation</p> <p>1.2.3 Restrictions</p> <p>1.2.4 Classification and Labelling</p> <p>1.3 Biocides</p> <p>1.4 PIC</p> <p>2.1.3 HelpNet and Security Officers Network</p>
<b>Dynamic Case</b>	<p>Case management tool to support the creation and processing of business cases at the same time providing a repository for the documents generated. It ensures traceability of the process</p>	<p>1.1.2 Registration and dossier submission</p> <p>1.1.3 Evaluation</p>

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
	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
<b>Secure CIRCA-BC</b>	External collaboration tool used to exchange documents with MSCAs.	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 2.1.4 Board of Appeal 2.2 Management



<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
<b>Reporting</b>	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 submission 1.1.3 Evaluation 1.2.4 Classification and Labelling
<b>IT for Screening</b>	ECHA develops algorithms and uses powerful dedicated data mining tools to screen the high volume of dossiers submitted and identify candidates for compliance checks according to the compliance checks strategy.	1.1.3 Evaluation 1.2.1 Identifying needs for Regulatory Risk Management 1.5 Data management and dissemination
<b>Portal Dashboard for MSCAs/ NEAs</b>	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
<b>Dissemination Portal</b>	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 Labelling 1.1.2 Registration and dossier submission 1.3 Biocides 1.4 PIC

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
		1.5 Data management and dissemination
<b>C&amp;L Platform</b>	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
<b>R4BP</b>	Used by Industry for submitting applications under the Biocidal Products Regulation to ECHA and by ECHA/MSAs for providing applicants with the related decisions. R4BP represents the implementation of the register for Biocidal products foreseen in the legislation.	1.3 Biocides
<b>SPC Editor</b>	Tool for Industry and MSAs to process the Summary of Product Characteristics as foreseen in the BPR	1.3 Biocides
<b>ePIC</b>	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
<b>MSAs IUCLID central database for REACH&amp;CLP;</b>	Two large central databases of scientific data in IUCLID format opening direct access and full IUCLID functionalities to MSAs.	1.5 Data management and dissemination

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
<b>MSCAs IUCLID central database for Biocides</b>		
<b>Data Integration Platform</b>	<p>The Data Integration Platform is the data management system to provide data integration and aggregation, business intelligence and reporting on business data;</p> <p>It provides integrated data to consuming systems, notably the Dissemination Portal, the Portal dashboard for MSCAs and for the Enforcement Authorities.</p> <p>It enables the re-use of data without duplication, advanced searches, data intelligence; capabilities which make the data usable and meaningful for consumption.</p>	1.5 Data management and dissemination
<b>COMA</b>	Contact Management tool used to manage lists of contacts (as Management Board or Committees members, experts listed by expertise, legal contacts, etc.), to search and sort data.	2.1.1 Committees 2.1.2 Forum 2.1.3 HelpNet and Security Officers Network 2.2 Management
<b>Planning and reporting integrated IT solution</b>	A set of solutions serving planning, monitoring and reporting on corporate work, human resources and financial resources	2.2 Management 2.3.1 Financial resources 2.3.2 Human resources
<b>ECM - Records Management system</b>	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

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
<b>ECHANet</b>	Intranet of ECHA – the Agency’s primary internal communication and collaboration tool.	2.2 Management
<b>ECM-Document Management System</b>	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
<b>Mail registry</b>		2.2 Management
<b>Declarations of Interest management tool</b>	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
<b>ABAC</b>	Budget, Accounting and Asset management system provided by the European Commission.	2.3.1 Financial resources
<b>EasySign</b>	Electronic workflow supporting some financial workflows.	2.3.1 Financial resources
<b>Dynamic Case for SME verification</b>		2.3.1 Financial resources
<b>Integrated Human Resource Management System</b>	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

<b>ECHA IT RESOURCES</b>		
<b>IT tool</b>	<b>Main description</b>	<b>Activities served by tool</b>
<b>Mission management tool</b>	Tool used to create mission orders and process mission claims and reimbursements.	2.3.2 Human resources 2.3.3 Corporate services
<b>Webex</b>	A platform for videoconferencing.	2.3.3 Corporate services
<b>Hardware and software licences</b>		2.3.4 ICT
<b>Workplace ICT facilities and services</b>		2.3.4 ICT
<b>Telecommunication equipment and services</b>		2.3.4 ICT
<b>Integrated Access Management:</b>	IT solution to provision/de-provision user accounts and grant access to IT systems for internal and external users	2.3.4 ICT
<b>Remedy Ticketing system</b>	System facilitating mainly the Incident management of IT and business services	2.3.4 ICT
<b>Automation and administrative tools to support IT operations.</b>		2.3.4 ICT