ECHA
EUROPEAN CHEMICALS AGENCY

Work Programme 2016

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List of Acronyms

BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C & L	Classification and Labelling
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
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ES	Exposure scenario
EU	European Union
Forum	Forum for Exchange of Information on Enforcement
HelpNet	REACH and CLP Helpdesk Network
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
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
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
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
RMOA	Risk Management Option Analysis
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum
SDS	Safety Data Sheets
SME	Small and Medium-sized Enterprises
SON	Security Officers' Network

SPC	Summary of Product Characteristics
SVHC	Substance of Very High Concern
WP	Work Programme
WSSD	World Summit on Sustainable Development

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.

Introduction

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 to make sure that the operational aspects of the legislation function appropriately.

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 those agreed at Johannesburg World Summit on sustainable development (WSSD) in 2002.

The Draft ECHA Work Programme (WP) 2016, which is based on ECHA's Multi-Annual Work Programme 2014-2018, is prepared in connection with the preliminary draft budget submitted to the Commission and to ECHA Management Board. 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 2015 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 will be adjusted accordingly. This is particularly relevant for the Biocidal Products Regulation (BPR) activities as the Commission's budget proposal significantly deviates from the MB proposal.

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

Highlights 2016

The third 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 with a strong focus on further improving the efficiency and effectiveness of the Agency. Complementing these four strategic objectives specific actions supporting the SMEs are introduced as a fifth element below.

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

The year 2016 is crucial for ECHA's preparation for the last registration deadline of phase-in substances in 2018 in order to ensure stability in tools and guidance for the registrants, especially SMEs, well ahead of the deadline. In the first half of the year ECHA will roll-out the new generation of its IT tools for dossier preparation (IUCLID, Chemical Safety Assessment and Reporting tool CHESAR) and submission (REACH-IT); the new generation will – amongst other enhancements – improve user friendliness, taking stock of the experience gained and the feed-back received to date. ECHA will accompany this roll-out by providing practical guides and familiarising national helpdesks with the new tools. . This IT support as well as easy access to updated registration guidance will allow efficient formation of substance information exchange forums (SIEFs), fair and transparent SIEF operation and coordinated registration efforts in the coming years. Any update of guidance documents with a view to the next registration deadline, in particular in support of alternatives to animal testing, will normally be published by May 2016. This will allow ECHA to invite all registrants to start submitting their dossiers for the last deadline from mid-2016 onwards making full use of the new tools and guidance.

ECHA's tools for dossier preparation will be complemented by a suite of industry tools developed under the chemical safety report/exposure scenario (CSR/ES) Roadmap facilitating the transfer of information on use and conditions of use from downstream users to registrants, for submission to the authorities via the registrants' dossiers. These efforts will contribute to the safer use of chemicals and will also promote innovation.

In order to improve the safety information and thereby risk management of chemicals and to facilitate identification of candidates for regulatory risk management measures, ECHA conducts compliance checks on the highest priority substances. In line with the strategy endorsed in 2014, and in line with the Multi-Annual Work Programme, the focus is on higher tier human health and environment endpoints in lead and individual dossiers for the tonnage bands over 100 tn. In addition, other complementary measures, such as announcing in advance substances potentially selected for compliance check and targeted information campaigns, are used to encourage registrants to improve their dossiers. At the same time, ECHA will in 2016 finalise the examination of the testing proposals submitted for the 2013 registration deadline in the dossiers and start examining re-submitted proposals for testing on reproductive toxicity from the 2010 registration deadline which were suspended from decision-making awaiting a change of the relevant REACH Annexes.

After the release of the new dissemination platform at the end of 2015, ECHA will continue publishing information on substances in a new format. This will contain all essential information on substances' intrinsic properties, hazards, uses and regulatory status in an easily accessible layout.

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

An integrated screening approach will identify substances of potential concern, which should either be addressed under compliance check, put on the Community rolling action plan (CoRAP) list of substances scheduled for substance evaluation by Member States or on the Roadmap 2020 list of substances for a risk management option analysis. When the most appropriate option is identified, it is expected that the Member State concerned or the Commission decides to 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 larger number of Member States will participate in these efforts.

Following the review of the substance evaluation process in 2015, ECHA will together with the Member States make sure that substance evaluation supports and contributes to the regulatory risk management processes.

The authorisation system will face a peak due to applications expected at the end of 2015 or early 2016, marking its full maturity. Both the Secretariat as well as the Risk Assessment and Socio-economic Analysis Committees will therefore make use of their full capacity from scientific and workload perspectives. The modified rules, formats and procedures for submission and handling of authorisation applications for special cases should help in reducing the burden for companies and regulators. At the same time the participation of third parties in the consultation process for each application will be actively promoted to ensure that appropriate information on alternative substances or techniques, if available, will be fed into the opinion-forming process.

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 its scientific capacity in accordance with its science strategy defined in 2014, which outlined the areas that are most important from a regulatory decision-making perspective.

ECHA will publish its Read-Across Assessment Framework (RAAF) for environmental endpoints to increase transparency on how ECHA is assessing read-across cases developed by industry. This will also facilitate registrants in updating their dossiers and thereby help to further avoid unnecessary animal tests and related costs. ECHA will also continue contributing to and building its expert capacity in the new testing and assessment methods to ensure that they have received regulatory acceptance and can be used by the registrants for endpoints relevant for the 2018 registration deadline.

Following the anticipated update of the REACH Annexes to provide further clarity on how nanomaterials are addressed and how their safety should be demonstrated in registration dossiers, ECHA will increase its activities to improve the quality of registration data for nanomaterials. To improve transparency on nanomaterials on the market ECHA will also assess the information in relevant registration dossiers on nanomaterials, taking into account information from other relevant sources and prepare related documentation for specialists and the broad public.

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

To achieve the ambitious targets of the Multi-Annual Work Programme while at the same time decreasing staff resources, ECHA will continuously improve its efficiency. In 2016, the Agency will continue investing in developing the IT systems to serve primarily the

industry for the preparation of the 2018 registration deadline but also to streamline the internal administrative processes. In 2016 ECHA will continue to support harmonisation and standardisation of practices and templates in industry with regard to use, risk management and exposure information. Such standardisation is a key strategy for making REACH implementation more efficient. ECHA's role is considered crucial in this respect by implementing the EU Regulations in a way that allow chemical industries and small and medium-sized enterprises (SMEs) to enhance their innovation capacity and their competitiveness.

Based on experience gained in the first years of implementation ECHA will continue to take further measures and create efficiencies in supporting the Member States in their work under the review programme of active substances under the Biocidal Products Regulation (BPR) and for the preparation of the related opinions by the Biocidal Products Committee. ECHA will strive to implement an effective model for managing the authorisation of biocidal active substances and products. It is assumed that the foreseen revision of the fee regulation and the revision of the resource requirements of the Agency will lead to a stable financial basis for carrying out the fee-related as well as the non-fee related activities under the BPR. In addition to potential changes to the fee regime, the finalisation of the guidance work will in the coming years eliminate the long period of uncertainty and instability in the industry generated by the difficult transition from the old directive to the regulation introduced in 2012.

Due to the expected higher workload of the Secretariat and the scientific Committees continuous efficiency improvements are being developed and implemented. The measures agreed earlier with the Management Board and the Committees to deal with their extra workload will help to overcome the peak in activity expected for 2016.

Finally, ECHA will produce its second Article 117(2) report on the operation of the REACH and CLP regulations, which will focus on proposals on how to make the legislation work more efficiently and effectively in the future, in order to support the achievement of the objectives of these Regulations.

5. Provide specific support to SMEs

Whilst ECHA’s support, advice and assistance as well as communications are relevant to all duty holders, the design of several actions to be undertaken in 2016 will particularly have SMEs in mind:

- Implementation of the 2018 REACH Registration Roadmap will be providing support to registrants.
- Deliverables provided by ECHA and its partners in 2016 under the CSR/ES Roadmap will particularly support SMEs further down the supply chain.
- The new dissemination web-section will be further improved for the benefit to SMEs to be understandable and easier to use in order to allow them to find information on the properties and state of regulatory oversight over chemical substances for which they may have obligations.
- ECHA’s communications’ activities on BPR, CLP and REACH obligations will particularly have SMEs in mind – both in terms of the targetted content, but also in terms of the communications vehicles used – audio-visual, online, e-publications, events, social media, posters and other joint projects with stakeholders and the member states.
- ECHA will continue its efforts to provide translations of guidance and other relevant documents for SMEs in official EU languages, where appropriate.

1. Operations

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 helpdesk, guidance and communication activities. The Agency processes the dossiers and assigns registration numbers so that companies can manufacture, import or place their substances on the European market.

ECHA evaluates the substance identity, hazard, use and exposure information as well as testing proposals submitted by companies to 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 Member States however, the Forum for Exchange of Information on Enforcement hosted by ECHA, provides a network of Member State authorities responsible for the enforcement with the aim of harmonising their approach to enforcement of REACH registration and evaluation provisions.

1.1.1 Registration dossier preparation

Activity

ECHA provides advice and assistance to industry as well as support to competent authorities and to the helpdesks established by Member States. ECHA supports the exchange of information and best practice between national helpdesks, including through specific REACH Helpdesk Network (HelpNet) workshops.

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.

To support companies in fulfilling their information requirements, the Agency provides guidance and also contributes actively to the further development of test methods, including alternative test methods. 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.

To support the preparation of the dossiers, the Agency provides two systems: IUCLID, 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 OECD to ensure harmonisation and help companies to re-use their data for other regulatory regimes.

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

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

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.

Key objective

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

Main Actions and Outputs of 2016

- Implement ECHA's REACH 2018 Roadmap[1], 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:
    - Carry out the related 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);
    - Conclude the support to industry sectors developing specific registration guidance (e.g. inorganic pigments, essential oils). This may be complemented by further communication on the methodology for determining substance sameness;
    - To provide stability to duty holders preparing for the 2018 REACH registration deadline, the Agency will apply a "Guidance moratorium" from 31 May 2016 onwards. Apart from exceptional updates in response to, for instance, changes to the legal texts, ECHA will not publish registration-related guidance until the registration deadline of 1 June 2018.
    - Provide advice to SMEs for their negotiations in the SIEF to get access to data and the joint submission also taking into account the Commission's Implementing Regulation and ECHA's recommendations.
- Support the fulfilment of information requirements:
    - Develop CSR examples for a variety of typical assessment situations and provide training as well as webinars.
    - Amend the Read-across assessment framework (RAAF) in particular to include environmental effects. Organise a topical scientific workshop on use of new approach methodologies to generate human health hazard information.
    - Release a new version of the OECD QSAR Toolbox, which will include a streamlined approach to predict toxicity of endpoints related to low tonnage requirements, and further improve possibilities to build weight-of-evidence

[1] http://echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf.

approaches for other endpoints (including *in vitro* methods/models, adverse outcome pathways, AoP).

- Publish an indicative list of substances for which there is evidence that one or more Annex III criteria are met and hence all information requirements according to Article 12(1)(a) should be provided, unless evidence to the contrary is included in the dossier.

- Publish update of the elements of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) that relate to Chemical Safety Assessment and Exposure Scenarios.

- Publish updates to guidance documents with regard to nanomaterials to take also into account any revisions of the REACH Annexes.

- Publish updates to Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) e.g. relating to possible data waiving option for acute oral toxicity by weight of evidence, and for skin sensitisation by integrated approach for testing and assessment (IATA).

- Publish updated/new Chemical Safety Assessment (CSA) and Exposure Scenarios related advisory documents under the CSR/ES Roadmap[2] to reflect latest developments for gathering and documenting use and conditions of use information from downstream users.

- Release the new generation of tools, IUCLID 6 and Chesar 3 with a focus on improving the reporting possibilities in order to improve dossier quality and compliance and restructuring of the architecture for improved and more effective maintainability; simplification of IUCLID for the user will be pursued. Release the IUCLID Validation Assistant with enhanced and upgraded rules for verifying data completeness and quality prior to submission to ECHA. .

- Subject to the results of the feasibility study conducted in 2015, start the implementation of a centrally hosted IUCLID platform for industry to be made available on-line as a service; this new delivery model would ensure that the latest version of IUCLID and the IUCLID data sets created by users would be always and securely available on-line making the access to IUCLID simpler and more cost effective for industry, particularly SMEs.

- Provide specific support to duty holders and national helpdesks during the roll-out of the new generation of IT tools through workshops or webinars, as necessary.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate

[2] http://echa.europa.eu/csr-es-roadmap

Helpdesk questions	NA[3]	2000	3000[4]
HelpNet Steering Group meetings	1	1	1
Inquiries concluded	1300	1400	1600
Decisions on data sharing disputes	4	7	10
Access to data older than 12 years	265	350	320
Appeals on data sharing decisions	0	1	1

Resources

Financial resources (costs, euros)	Human resources (FTE)
11 577 304	47

1.1.2 Registration and dossier submission

Activity

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 in articles containing substances of very high concern 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.

[3] Due to the new structure of the WP, this figure is unavailable.

[4] Questions related to dossier preparation, only.

Key objective

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

Main Actions and Outputs of 2016

- Release the new generation of REACH-IT so that it is ready for the 2018 deadline. This includes the changes on the completeness check process and the reinforcement of the "One substance – One Registration" (OSOR) principle agreed in 2015as well as a revised technical architecture, a and a much improved user interface, especially for registrants submitting member dossiers, It also implements a higher level of multilingualism and the integration with the ECHA Identity and Access Management services which will allow better management of the companies legal entity data and simplified authentication for those who use more than one submission systems of ECHA. Duty holders and national helpdesks will be informed through workshops or webinars, as necessary.

- Process an increasing number of registrations with the likely arrival of the first wave of registrations submitted by the large companies for the 2018 deadline (preliminary estimates up to ca. 4000 new registrations and 6000 updates). ECHA will also start manual verification of certain key points of the dossiers. A registration peak may also occur in the months preceding the release of the new IT tools. This may have an impact on the follow-up activities such as assessment of confidentiality requests and SME status verification.

- As part of implementing ECHA's compliance check strategy agreed in 2014, continue to stimulate dossier updates through publication of a list of substances to be potentially addressed under compliance check, targeted letter campaigns and other complementary measures so that the quality of information registration is further enhanced.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Registration dossiers (including updates)	9001	5 700	10 000
Confidentiality requests	232	240	390
PPORD notifications (including requests for extension)	234	400	300
Helpdesk questions[5]	6	2000	3500
Decisions on completeness check (negative)	59	60	100
Decisions on confidentiality requests (negative)	67	30	50

[5] Questions related to dossier submission only.

[6] Due to the change in WP structure, not available.

Decisions on PPORD	48	50	50
Appeals submitted	3	3	2

Resources

Financial resources (costs, euros)	Human resources (FTE)
8 922 813	41

1.1.3 Evaluation

Activity

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.

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 2016

- Continue to address relevant higher tier hazard endpoints for substances of potential concern via compliance checks on over 1000 tn dossiers and 100-1000

tn dossiers, in line with the compliance check strategy set in 2014, and based on the implementing and priority setting approaches elaborated further in 2015The selection of dossiers for compliance check will be based on the common screening also serving regulatory risk management and further manual screening to focus on the priority dossiers over 100 tn.

- Start to provide more 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.

- Conclude up to a draft decision the remaining testing proposals from 2013 registration deadline before the set legal deadline, 1 June 2016. It also aims to finalise the decision making on 80% of all 2013 testing proposal cases processed by the end of 2015.

- Re-assess testing proposals, approximately 200, submitted by registrants on reproduction toxicity and referred to the Commission for decision in years 2011-2014, which are anticipated to be re-submitted to ECHA due to the amendment of the REACH standard information requirements. These will need to be re-examined and concluded with draft decisions; cases will be grouped and prioritised with the aim of efficient and effective handling of them. This includes consideration of application of Article 40(3)(c) of the REACH Regulation, based on which ECHA may request one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX-XI.

- Continue to ensure that based on the experience gained in 2015together with the Commission and the Member States, , in the most efficient and effective manner, registrants comply with their obligations to conduct vertebrate animal testing only as a last resort. ECHA will also continue reporting on its actions in this regard.

- Together with Member States, make sure that substance evaluation supports and contributes to the regulatory risk management processes in an effective and efficient manner based on the conclusions achieved in 2015. It will include effective interplay with dossier evaluation and risk management processes in the annual CoRAP updating and ECHA's seamless coordination of and support to substance evaluation, decision making and conclusion.

- Continue addressing the lack of information for the safe use of substances in nanoforms under both dossier and substance evaluation.

- Replace the IT-tools supporting dossier evaluation workflow (i.e. DEP by Dynamic Case) to harmonise case management throughout the REACH and CLP processes. Based on the outcome of the feasibility study mid-2015, the IT-tool supporting scientific assessment under dossier evaluation is integrated with other ECHA data / workflow systems.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Draft decisions on testing proposals	204	220	300

Final decisions on testing proposals	129	180	250
Compliance checks concluded, at least 75% of which addressing the relevant higher tier hazard endpoints	273	200	225
Final decisions on compliance checks	172	120	180
Follow-up evaluations on dossier evaluation decisions concluded	282	400	350
Final decisions or conclusions on substance evaluation	38	40	45
Appeals submitted	15	16	23
Helpdesk questions	NA[7]	100	150

Resources

Financial resources (costs, euros)	Human resources (FTE)
19 444 200	108

1.1.4 Communication of risk management advice through the supply chain

Activity

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 on safe use is communicated down the supply chain. Support is particularly provided through ECHA's Helpdesk, HelpNet, communications and guidance activities as well as the Exposure Scenarios Network (ENES). This activity corresponds to the commitments of ECHA under the Chemical safety report / Exposure scenarios Roadmap.

Key objective

ECHA facilitates the generation and communication of information on uses 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 2016

- Provide input to 2018 Roadmap actions to ensure that registrants have a solid information basis for their chemical safety assessment, in particular in relation to use description and potentially demonstrating negligible exposure.

[7] Due to the change in WP structure, this figure is unavailable.

- Hold targeted workshops with downstream user (DU) sectors to make use of the tools available for input to registrants (e.g. use maps) and biannual meetings of the Exposure Scenario Network (ENES).
- Develop further examples of exposure scenarios for communication (covering different kinds of hazards).
- Review the methodologies that have been used in different sectors for converging substance related exposure scenario information into advice on safe use of mixtures.
- Broaden the exemplification of REACH information useful/needed to comply with other legislation.
- Continue to support enforcement authorities through the annual training event for inspectors and trainers who train inspectors on the national level.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Helpdesk questions	NA[8]	NA	100

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
2 824 883	16

1.1.5 Performance indicators for REACH dossier management and assessment[9]

Indicator	**Latest result 2014**	**Target 2016**
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
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	NA	High
Level of satisfaction of users with the quality of external users support service ECHA Helpdesk services	High	High

[8] Due to the change in WP structure, this data is unavailable.

[9] All processes are managed in view of meeting the legal deadlines in 100% of the cases

Level of satisfaction of MSCAs with ECHA's coordination and support to substance evaluation.	NA	High
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA	High	High
Percentage of testing proposals from 2013 deadline concluded	45%	100%
Percentage of unanimous MSC agreements on evaluation decisions	60%	80%
Percentage of ECHA Helpdesk questions answered by the external users support service within the established timeframe (15 working days)	93%	90%

1.2 Risk management

The European Chemicals Agency 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 European Union 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 Helpdesk, communications and HelpNet as well as 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

Activity

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 highest concerns. To this end, ECHA implements common screening approaches for all REACH and CLP processes, including evaluation, to identify the substances and uses which matter the most.

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.

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 2016

- Further develop the common screening approach and in particular expand it to cover compliance check needs. This approach provides a basis for improved integration of further information generation via evaluation processes for the authorities to initiate, where relevant, further regulatory risk management under REACH and CLP.

- Continue preparation of RMOA's, upon request by the Commission, and providing coordination and support to Member States in their preparation. In general it is expected that the number of these RMOAs will rise as a result of the work done in previous years under the common screening approaches as well as through the assessment work under Persistent, Bioaccumulative and Toxic / Endocrine disruptor (PBT/ED) expert groups and substance evaluation.

- Maintain high level of efforts for co-operation and co-ordination with all authorities of the SVHC roadmap implementation work, including RiME and the Carcinogenic, Mutagenic or toxic to Reproduction (CMR) and sensitiser co-ordination groups. The work on petroleum and coal stream substances will reach the same implementation level as the other substances groups set up under the SVHC Roadmap.

- Develop the second SVHC roadmap progress report and identify actions for further improvement.

- Generate increased information on ECHA's website on screening and assessments providing industry better predictability on which substances will be under authorities' attention and consequently more time to plan for substitution and improving safety.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Upon request by the Commission, support provided for the development of RMO analyses and/or SVHC dossiers	5	5	5

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
2 928 730	17

1.2.2 Authorisation

Activity

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

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

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

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

ECHA provides support particularly to potential applicants through its Helpdesk and HelpNet services as well as its communications.

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 2016

- ECHA expects some increase in the number of SVHC dossiers. In addition, the overall workload will increase since most dossiers will relate to PBTs, EDs or other substances of equivalent concern and hence may require specific effort and involvement from the respective expert groups, including from the MSC.

- ECHA will have implemented a further streamlined and focussed application process taking account of the experience gained with the first applications, including the "Lessons Learned Conference" held in February 2015 as well as the recommendations of the "Task Force on Applications for Authorisation" that are planned to be delivered in mid-2015.

- ECHA will have made IT tools fully operational including the notification register for companies covered by the authorisation to notify their uses and for helping authorities to enforce authorisation.

- ECHA will further improve and adapt the communication through the web to facilitate the preparation of "fit for purpose" applications for authorisation.

- ECHA anticipates that some 100 applications, mostly relating to the use of chromium compounds, are likely to be submitted in the latter part of 2015 and early 2016. This increase in activity will provide a specific challenge for ECHA including its Committees for Risk Assessment and Socio-economic Analysis. To this end the ECHA Secretariat and MSCAs will need to make specific efforts to ensure adequate capacity of RAC and SEAC to appoint rapporteurs for all applications and implement further measures to improve the efficiency of RAC and SEAC.

- Organise specific awareness-raising activities related to substances in articles for one or more priority article or material types.

- Initiate the review of the Substances in Articles Guidance to adapt it to experiences obtained and the outcome of the court case on the 0.1% limit and, where possible, increase its practicability for industry.

- Support further method development to quantify the human health impacts through Willingness-to-Pay or Quality-Adjusted Life Years approaches.

- Support further development of methodology for carrying out socio-economic analysis for PBTs and PBT-like substances including both costs and benefits estimations.

- Publish the Forum's report on inspections and enforcement action undertaken under its first pilot project on authorisation-related obligations (regarding MDA and Musk Xylene) and first results of the second pilot project (substances with a sunset date in 2015).

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Number of proposals for identifying SVHCs	14	10	50[10]
Recommendation for inclusion of substances in the authorisation list.	1	1	1
Applications for authorisation	16	70	30
RAC & SEAC opinions on applications for authorisation	30	40	60
Helpdesk questions	NA[11]	225	300

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
5 961 474	34

1.2.3 Restrictions

Activity

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

[10] The expected number of proposals for identification of SVHCs for 2016 stems from the yearly consultation with the Member States Competent Authorities on their plans for developing such type of dossiers

[11] Due to the change in WP structure, this figure is unavailable.

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 of the restrictions.

Key objective

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

Main Actions and Outputs of 2016

- Implement the the recommendations of the Restriction Efficiency Task Force to improve the efficiency of the dossier preparation and opinion-forming processes. ECHA will provide support to the Member States during their preparation of restriction dossiers.

- Develop examples of the article service-life exposure assessment, identify the main gaps in approaches and further develop priority aspects of the assessment methods in order to serve development and evaluation of restriction dossiers.

- Forum will oversee the implementation of the operational phase of the fourth Forum coordinated enforcement project (REF-4) focused on the enforcement of restrictions.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Annex XV restriction dossiers prepared on request by the Commission	2	3	4
Restriction proposals (Annex XV)	7	9	10
RAC & SEAC opinions on restriction proposals	5/4	9	7
Helpdesk questions	NA[12]	75	100

[12] Due to the change in WP structure, this figure is unavailable.

Resources

Financial resources (costs, euros)	Human resources (FTE)
3 302 708	17

1.2.4 Classification and Labelling

Activity

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 communications, Helpdesk and HelpNet activities, including a CLP HelpNet workshop.

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 2016

- ECHA will further align the respective regulatory processes for harmonised classification and labelling (CLH) for active substances in biocides and pesticides. About two thirds of the CLH opinions will be concerning these substances, whereas the total number of RAC opinions is expected to remain at the same level as in the previous years.

- Continue screening in cooperation with Member States; industrial chemicals are preferably selected from priorities resulting from this common screening approach.

- Continued monitoring of convergence of self-classifications; where appropriate focussed actions encouraging industry to agree on classifications and update notifications accordingly.

- Publish an update to the Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008 (CLP).

- Support national helpdesks in their awareness-raising activities towards consumers in relation to the new CLP pictograms which will be in full use for substances and mixtures newly placed on the market.
- 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).
- Report of the Forum pilot project where national enforcement authorities follow up specific cases where ECHA has identified deficiencies in harmonised classification and labelling, focusing on substances with CMR or sensitising properties.
- Report of the Forum pilot project on child resistant fastenings.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Proposals for harmonised classification and labelling	44	60	70
RAC opinions on proposals for harmonised classification and labelling	51	50	55
Alternative name requests	28	150	150
Helpdesk questions	NA[13]	200	250

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
4 199 040	24

1.2.5 Performance indicators for Risk Management[14]

Indicator	**Latest result 2014**	**Target 2016**
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

[13] Due to the change in the WP structure, this figure is not available.

[14] All processes are managed in view of meeting the legal deadlines in 100% of the cases

Percentage of Committee opinions adopted by consensus	93%	80%

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.

Activity

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.

Support the Biocidal Products Committee and its working groups in the harmonisation of risk assessment approaches and preparation of emission scenario documents and guidance.

Process the applications for data sharing (inquiries and data sharing disputes) and for technical equivalence.

Support to duty holders via the ECHA Helpdesk as well as information and training for national BPR helpdesks via the HelpNet.

Perform the evaluations and public consultations defined in the biocides legislation and manage the participation to the Review Programme and the Article 95 list.

Development of the IT tools (in particular Register for Biocidal Products (R4BP) 3 and the Summary of Product Characteristics (SPC) editor) in order to progress towards the comprehensive implementation of the biocides legislation.

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 2016

- 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 ECHA

- Support to the Member States Competent Authorities for the preparation of BPC opinions on active substances.

- Support to the preparation of the first BPC opinions on Union authorisation of biocidal products is foreseen to take place with a special emphasis on the efficiency of the opinion forming process and the coordination between Member States Competent Authorities dealing with related applications.

- Continue the evaluation of new applications for inclusion in the Article 95 list beyond 1 September 2015 as later deadlines are applicable for products which were not considered as biocides under the former Directive and for products containing in situ generated active substances not covered by the current entries in the Review Programme.

- Further develop (pending availability of necessary additional financial and human resources) the Register for Biocidal Products (R4BP 3, including the migration from the previous system) and the SPC editor, in order to progress towards the comprehensive implementation of the biocides legislation and in particular to address the request of the Commission to implement the meta-SPC concept for the authorisations of Biocidal Product Families (BPF).

- Publish updates to the Guidance on the Biocidal Products Regulation: Volume IV Environment, Part B, Risk assessment and Volume V on micro-organisms as well as new guidance on Volumes I, II, III & IV, Part C, Evaluation (subject to available resource in 2015 and 2016).

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Number of active substance / product type combinations to be assessed under the Review Programme	34	50	50
Biocides Inquiries	90	50	50
Biocides Data sharing disputes	7	5	5
Applications for new active substance approval	10	2	2
Applications for renewal or review of active substances	2	3	0
Applications for Union authorisation for biocidal products	0	12	5
Applications for active substance suppliers (Article 95)	10	150	50
Applications for technical equivalence	6	20	20
Applications for chemical similarity	0	10	10
Submissions to Member States	2094	3 000	3 000
Appeals	0	3	1

Helpdesk questions to be answered	2000	750	400

Resources

Financial resources (costs, euros)	Human resources (FTE)
7 135 841	52[15]

Performance indicators

Indicator	Latest result 2014	Target 2016
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

[15] 52 FTE's is based on the 2016 budget proposal adopted by the MB; the actual figure may be lower depending on the incoming applications and fee income. The figure will be adjusted as necessary based on outcome of the 2016 budget negotiation.

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. The Agency is responsible for administrative and technical tasks and also provides technical and scientific guidance to industry, the designated national authorities (DNAs) both from the EU and from third countries, and the European Commission.

Activity

Administer the notifications and maintain the system for any legislative changes. Publish summary report on actual volumes of exports and imports at the Union level in 2015 for substances listed in Annex I of the PIC Regulation.

Provide 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).

Provide the secretariat for the Forum and supports it to further strengthen and harmonise the effective enforcement of the PIC regulation in the EU/EEA Member States.

Maintain the ePIC application.

Key objective

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

Main Actions and Outputs of 2016

- Process a continuously increasing number of export notifications.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Export notifications	4678	4 000	6000
Helpdesk questions	NA	100	150

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
1 151 000	7

Performance indicators

Indicator	Latest result 2014	Target 2016
Percentage of export notifications processed within the legal timeframe	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

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.

Activity

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.

- The integration of data across different sources and processes into a common Data Integration Platform is used to support Dissemination, the Portals for Authorities, reporting as well as the regulatory processes performed in ECHA.

- Automated data mining for dossiers and substance screening purposes in order to focus the evaluation and risk management processes.

- Automated 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 better 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.

- Providing case management tools to support the processing of regulatory or administrative files in the application of the legislations or the internal administrative practices.

- Dissemination of information on chemicals on the ECHA website.

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 2016

- Deploy and support the new Portal Dashboard for Enforcement developed in 2015 and replacing the RIPE system. The main focus for its further development will be the dissemination of biocidal information and authorisation notifications.

- Achieve integration of all REACH and CLP screening activities in support of working on substances that matter.

- Adapt the new Dissemination platform to the IUCLID 6 format. This platform will be extended to become the single source of disseminated content, either coming from Industry dossiers or produced by the Agency or MSCAs, notably the status of substances and dossiers under evaluation. External audiences will easily find relevant information on the chemical substances disseminated under REACH, CLP, BPR and PIC in the new ECHA Dissemination web pages on chemicals.

- Continue disseminating information on substance in nanoform, taking into account information from other relevant sources, and also taking into account different audiences, such as specialists and the general public.

- Consolidate the case management system used in all ECHA's REACH and CLP regulatory processes (Dynamic Case) to support further efficiency making and extend support to new use cases in the administrative and Biocides processes.

- Contribute to the European Commission's development of tools to facilitate data provision by companies to national poison centres under Article 45 of the CLP Regulation. Explore further options to support companies and Member States.

Resources

Financial resources (costs, euros)	Human resources (FTE)
9 651 463	34

Performance indicators for Data management

Indicator	Latest result 2014	Target 2016
Level of Member States' and Commissions user satisfaction with data management services	-	High
Level of satisfaction of stakeholders with dissemination activities of ECHA.	High	High

2. Governance and support

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.

The HelpNet is a network made up of ECHA and the national BPR, CLP and REACH helpdesks. The network was created to improve cooperation on issues of common interest. The HelpNet is governed by the HelpNet Steering Group composed of ECHA, the national helpdesks, the Commission and observers from candidate countries and/or 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 legal redress.

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

Activity

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 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.

Key objective

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

Main Actions and Outputs of 2016

- Manage memberships of each Committee (renewals and new appointments/nominations), with specific focus on ensuring adequate capacity of RAC and SEAC.

- Implement efficiency improvements continuously in all Committees by completing

on-going development and integration of IT tools.

- Prepare, run and follow-up of plenary meetings for the MSC (6), BPC (4), RAC (8) and SEAC (6).

Resources

Financial resources (costs, euros)	Human resources (FTE)
3 827 792	16

2.1.2 Forum

Activity

ECHA Secretariat organises the meetings and 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 stakeholder organisations. Therein, the Forum will also discuss and find harmonised solutions to practical challenges faced by inspectors which will be recorded in its manual of conclusions. The projects and support of the Forum to ECHA's operations is covered above under Section 1, "Operations", of this Work Programme.

Key objective

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

Main Actions and Outputs of 2016

- Support via the Forum Secretariat harmonisation of national enforcement authorities' approaches to enforcement through three Forum plenary meetings, through methodological tools and the sharing of information.

- Prepare the Manual for the fifth Forum-coordinated enforcement project (REF-5) focusing on obligations related to extended safety data sheets (e-SDSs), exposure scenarios, risk management measures and operational conditions, and select the subject of the sixth Forum project (REF-6). Continue establishing best practice in enforcement and testing enforcement approaches by running pilot enforcement projects.

Resources

Financial resources (costs, thousands euros)	Human resources (FTE)
1 674 659	7

2.1.3 HelpNet and Security Officers Network

Activity

The ECHA Secretariat will support the exchange of information and best practice between national helpdesks through HelpNet Steering Group meeting(s) as well as the use of HelpEx (the exchange tools used between HelpNet correspondents to harmonise responses to questions from industry).

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.

Key objective

ECHA Secretariat supports and facilitates the work of the networks efficiently and effectively by providing the necessary infrastructure and support for their functioning.

Main Actions and Outputs of 2016

- Draft and discuss Frequently Asked Questions (FAQs) and their respective answers via the HelpNet, including their publication on ECHA's website.
- Organise at least one HelpNet Steering Group meeting.
- Organise at least one SON meeting.

Resources

Financial resources (costs, euros)	Human resources (FTE)
298 322	2

2.1.4 Board of Appeal

Activity

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.

Key objective

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

Main Actions and Outputs of 2016

- Process incoming appeals which are expected in particular in relation to substance evaluation decisions and compliance checks.
- Adopt up to 15 final appeal decisions.
- Adopt procedural decisions, as needed.
- Publish a robust body of high-quality decisions online.
- Ensure effective (i.e. clear, accurate and timely) communication with the (potential) parties in relation to appeal proceedings.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
Appeals submitted	18	23	26

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
1 653 388	11

2.2 Management

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

Activity

The Agency strives to ensure a modern corporate identity and management that complies with the highest EU standards including engagement of its stakeholders. ECHA uses an activity and project-based management and quality system, which is ISO 9001 certified, to organise its operations in a hierarchical or matrix structure. The management of information is balanced between openness and security principles.

The core functions of the Management Board include the adoption of the budget 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.

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, access to documents. Complaints are effectively analysed from the legal perspective.

ECHA's internal communication activities play a fundamental role in both the efficient management of the Agency and its corporate identity. Effective internal communication remains key to informed and committed staff.

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 and security of assets and information, and provides an assurance of the conformity and quality of outputs.

Main Actions and Outputs of 2016

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 2016 are:

- 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.
- Prepare and publish ECHA's second report on REACH and CLP operations under Article 117.2 of REACH.
- 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.
- Implement the corporate wide efficiency development programme with new pilot projects, competency development, communication and performance management.
- Optimise further the existing Integrated Quality Management and Internal Control System towards the 2016 surveillance audits.
- Perform audit and consultancy activities in line with the annual audit plan.
- Respond to enquiries (ca. 500) from general public about ECHA and its activities.
- Develop ECHA's Electronic Content Management system (e.g. Dynamic Case) further in support of house-wide efficiency gains in regulatory and administrative processes.
- Continue streamlining of ECHA's planning and reporting activities with a leaner process and improved and integrated IT solution supporting multiple dimensions

of the planning cycle.

- 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.

- Benefit from an updated internal website and new internal communication tools.

Resources

Financial resources (costs, euros)	Human resources (FTE)[16]
7 880 939	45

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

Activity

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.

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 2016

- Progressively extend the support for standardised finance systems, following the architectural and functional choices made in 2015.

[16] This number includes Directors, their assistants and relevant corporate support services

- Continuously ensure correctness of the SME fee reductions claimed by registrants with focus on examining registrations from the 2013 deadline. Support the verification process with a case management system, including further measures to facilitate correct declaration of company size.
-
- Implement further efficiency measures, including automation and streamlining of financial processes.
- Progressively extend the use of European Commission's financial and accounting system used by ECHA (ABAC) for procurement and contract management workflows.

Workload indicators

Workload driver estimates	2014 actual	2015 estimate	2016 estimate
SME status checks for REACH/CLP[17]	276	400	250

Resources

Financial resources (costs, euros)	**Human resources (FTE)**
3 891 308	27

2.3.2 Human resources

Activity

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 key 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, 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.

[17] SME status checks for BPR will be performed on demand, according to the rules of BPR Regulation.

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 2016

- Conduct of the Job Screening exercise (as part of a wider inter-Agency benchmarking exercise initiated by the European Commission).
- Implement capacity-building actions identified under Strategic Objective No 3.
- Implement a general competency exercise for non-scientific staff.
- Complete implementation of the HR Management System (with the addition of the Recruitment site).
- Roll-out change management initiatives.

Resources

Financial resources (costs, euros)	Human resources (FTE)
3 964 262	28

2.3.3 Corporate services

Activity

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; work space 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.

Key objective

ECHA has secure and healthy office premises and adequate facilities for the staff and external visitors.

Main Actions and Outputs of 2016

- Develop a vision and implementation plan for the Agency's future workplace (including a market survey of the local real estate market to determine options for ECHA's decision on its future building).
- Complete the refurbishment plan of ECHA's present building

- Implement a meeting and event management tool, based on a common vision for stakeholder management, Committee meetings and event management at ECHA.
- Implement a new Framework Contract for security and reception services.
- Implement a new A/V signal distribution system in ECHA's Conference Centre

Resources

Financial resources (costs, euros)	Human resources (FTE)
3 397 938	24

2.3.4 ICT

Activity

This activity manages and provides the IT services for the agency. It is a core activity on which all other activities depend, ensuring that the staff have the appropriate IT tools at their disposal, and ensuring they are delivered to the required quality whilst complying to IT security standards. The activity also ensures the delivery of IT services to external stakeholders, and ensures delivery and maintenance of external facing IT applications. All services are assessed for business continuity requirements, and designed and maintained according to identified needs. This activity also facilitates the granting of access to authorised users to IT applications, while preventing access to non-authorised users. The sourcing of services has become more diversified over time, and requires significant effort to procure, manage assets and to manage external providers.

Key objective

The technical ICT infrastructure and the Management Information Systems of the Agency are operated at a high level of service, continuity and security.

Main Actions and Outputs of 2016

- Adequately support the delivery of the new generation of Business Information Systems to secure the Agency's upgrade milestones in 2016.
- Increasingly use the centralised Integrated Access Management service launched in 2015 by a significant additional number of IT systems.
- Ensure that maintenance releases of all the IT tools used for the Administration of the Agency are in production.
- Initiate the upgrade of the ICT facilities available at the workplace to align with the evolution of IT technology and enhance flexibility and mobility of the workforce.
- Carry out a major upgrade of the ICT infrastructure and services to support the performance of the data management IT solutions which are particularly demanding in terms of computational and storage capacity. In this context a new sourcing approach for ICT infrastructure capacity and for application management

services will become effective, also to optimise resources and control of costs. ECHA IT service providing will become even more a multi- provider environment whilst ECHA IT staff will focus on service management, service integration and capacity management. The internal processes are adapted accordingly.

Resources

Financial resources (costs, euros)	Human resources (FTE)
3 114 777	22

2. Performance indicators

Indicator	Latest result 2014	Target 2016
Commitment rate (of commitment appropriations at the end of the year).	97%	95%
Payment rate (of payment appropriations at the end of the year).	87%	80%
Carryover rate (% of committed funds carried over into 2016).	10%	< 20%
Level of satisfaction of the Committee, Forum and MB members with the functioning of the conference centre.	High	High
Percentage of establishment plan posts filled.	97%	95%
Turnover of TAs.	4.3%	< 5%
Turnover of CAs (excluding short-term CAs).	7,2%	< 10 %
Availability of mission-critical systems for externally used IT systems (i.e. uptime during service hours).	99%	On average 98 %
Percentage of very important audit recommendations implemented within the deadline (IAS).	100%	100%
Percentage of final Board of Appeal decisions made within 90 working days of the closure of the written or oral procedure.	90 %	Annual report of the BoA
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	55.6	2% increase over 2015 value

3. Agency risks

ECHA conducts an annual risk management exercise to identify, assess and manage the potential events that could put the achievement of the objectives defined in the Work Programme at risk. As a result of this exercise, a number of risks were identified, assessed and considered in the preparation of Work Programme 2016. ECHA's management ranked the following main risks as most important with regard to their likelihood of occurrence and impact on the implementation of Work Programme 2016, and defined risk mitigation measures whose effectiveness will be closely monitored during the year.

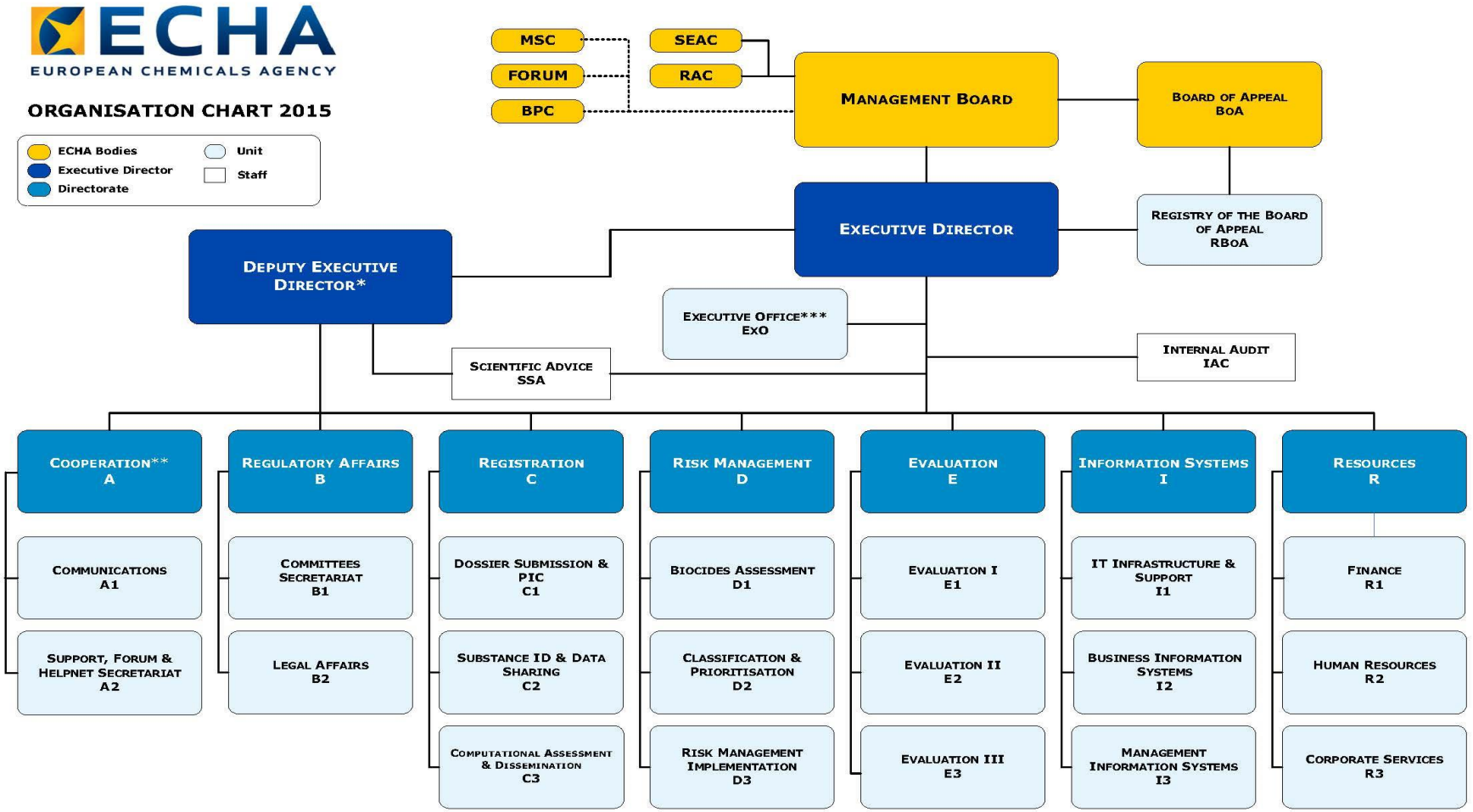
Under the current Financial Regulation, ECHA may not be able to balance its volatile income and expenditure without some form of balancing mechanism. ECHA considers that improved income forecasts with a number of scenarios and fall-back plans will allow for actions if there is a change in the budgetary circumstances, while a balancing mechanism could ensure control over this risk.

The Biocidal Products Regulation has brought new obligations and tasks to ECHA. Due to resource constraints at the Member states and ECHA level, as well as due to the difficulty to forecast the revenue from fees and the complexity of the different processes to be managed under the Regulation, the ability of ECHA to achieve the work programme objectives, and in particular the ability to cope with workload peaks in any area of biocides activity may be negatively impacted. As a result, ECHA and/or the MSCAs may not be able to process all applications under the BPR and deliver all reports in good quality and due time, which may negatively impact the targets in the Review Programme. ECHA considers that close cooperation with the MSCAs, including support with guidelines, templates and capacity building is very important to mitigate this risk. With regard to human resources, ECHA will need to be flexible in internal reallocation, should the fee income in the BPR not suffice for the resources recruited or if there is an unexpected peak of work in applications.

A risk with regard to the authorisation applications under REACH was identified in relation to two potential scenarios. A first one is that in case of a peak in the authorisation applications, which may impact both the staff ability to manage the volume and the opinion-forming process of the Committees, the Agency has foreseen a flexible internal reallocation and a potential involvement of more Committees members as rapporteurs. A second one is the risk of a significantly lower income than forecasted, which is tackled as part of the general financial risk the Agency is facing with regard to the income uncertainty for the coming years.

A number of work programme objectives are highly dependent on the IT governance system and the IT infrastructure and the foreseen developments in 2016. Prioritisation and careful management of the projects scope, together with reinforced controls in outsourcing will be a key in managing the ambitious IT portfolio in 2016.
The implementation of the efficiency development programme needs to be also carefully monitored in order to ensure that all foreseen objectives will be met. Since the programme is at a stage of an initial investment and requires resources to drive improvements, at a time when resource cuts are increasing the overall workload, there is a risk that not all highly ambitious objectives of the Programme are met in due time and/or quality. To mitigate that risk, Management's support is crucial, especially at the level of policies, rules, empowering staff to take decisions and de-prioritising other activities where possible.

ANNEX 1: ECHA Organisation



* Exercising also the function of Director of Regulatory Affairs
** Exercising also the function of SME Ambassador
*** The Quality Manager forms part of the Executive Office

Ver 2.0/2015

ANNEX 2: Estimated resources for 2016

ECHA RESOURCES 2016		
Activity	**Staff allocation[18] (FTEs)**	**Budget allocation[19] (euros)**
1. Operations		
1.1 REACH dossier management and assessment		
1.1.1 Registration dossier preparation	47	11 577 304
1.1.2 Registration and dossier submission	41	8 922 813
1.1.3 Evaluation	108	19 444 200
1.1.4 Communication of Risk Management advice through the supply chain	16	2 824 883
1.2 Risk Management		
1.2.1 Identifying needs for Regulatory Risk Management	17	2 928 730
1.2.2 Authorisation	34	5 961 474
1.2.3 Restrictions	17	3 302 708
1.2.4 Classification and Labelling	24	4 199 040
1.3 Biocides	52	7 135 841
1.4 PIC	7	1 151 000
1.5 Data management and dissemination	34	9 651 463
2. Governance and support		
2.1 Management of ECHA bodies and networks		
2.1.1 Committees	16	3 827 792
2.1.2 Forum	7	1 674 659
2.1.3 HelpNet and Security Officers' Network	2	298 322
2.1.4 Board of Appeal	11	1 653 388
2.2 Management	45	7 880 939
2.3 Resources		
2.3.1 Financial resources	27	3 891 308
2.3.2 Human resources	28	3 964 262
2.3.3 Corporate services	24	3 397 938
2.3.4 ICT	22	3 114 777
Total	**579**	**106 802 841**

[18] The staff allocation figure expresses the human resources needed at the Agency to implement its activities in 2016. The estimate indicates the needs in full time equivalent and includes the Temporary Agents and the Contract Agents

[19] The operational expenditure (Titles 3-5) is allocated directly to the Activities. The Staff and Infrastructure related expenditure (Titles 1 and 2) is allocated to the activities based on the FTEs with minor exceptions, where a direct link to Activities can be established, such as legal expenses under Title 2.

ANNEX 3: Procurement plan

[to be inserted in December 2015]

ANNEX 4: ECHA's public risk register

ECHA CORPORATE RISK REGISTER 2016										
RISK IDENTIFICATION						RISK ASSESSMENT	RISK RESPONSE AND TREATMENT			
Activity affected	WP Objective affected	Risk cause	Risk description	Risk consequence	Risk type	Risk level	Risk Response	Proposed Actions		
								Description	Owner	Deadline
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	Reduce/accept	1) Exchange solutions with the MSCAs on their resources needs 2) Support the quality of the assessment reports with guiding templates 3) Support the quality of the assessment reports through the involvement of the ECHA dossier manager 4) Improve the efficiency of active substance approval process and the Review Programme based on the outcome of the workshop with Member States that took place in 2015 ECHA	Dir D	continuous follow up
1.5 Data management and utilisation	Several objectives are affected	Due to: i) challenging new generation of IT tools to release and support, combined with the maintenance of the current systems; ii) reduction in IT resources; iii) increase in scope due to new users/responsibilities in the MSCAs, DNAs, EAs	ECHA may not be able to release all foreseen IT solutions and thus not meet all IT related objectives	Resulting in delayed delivery, negative impact on automation and process efficiency	2. PLANNING, PROCESSES AND SYSTEMS	MEDIUM	Reduce	1) Establish and reinforce programme management both at ECHA level and at contractor level. 2) Implement further automation in application delivery. 3) Ensure careful management of the scope of the projects and the IT portfolio using the IT governance in place. 4) Consider outsourcing some services to relieve time from ECHA IT staff.	Dir I	continuous follow up
1.3 Biocides	All Biocides objectives affected	Due to market uncertainty with regard to the fee income and higher complexity of the legislation than initially foreseen	ECHA may not be able to meet all Biocides objectives, e.g. process all applications within legal deadlines due to limited staff resources in case of a peak	Resulting in delays and possible complaints	1. EXTERNAL ENVIRONMENT	MEDIUM	Reduce/accept	In case of a significantly higher number of applications, further discussion with the Commission will be initiated to get agreement on higher recruitment levels. If this is unsuccesful and if the increased income would allow so, other ways of leveraging capacity will need to be sought. Depending on the income situation, the ambition level, e.g. in terms of support to the MSs and BPC members may need to be reduced.	Dir D/ Dir R	continuous follow up
1.2 Risk management	ECHA Secretariat supports RAC and SEAC, and in particular their rapporteurs, to develop high quality opinions on applications for authorisations in a transparent and efficient manner that can effectively support the Commission's decision making on granting or refusing an authorisation.	Due to market uncertainty with regard to the number of authorisation applications	2 scenarios: i) In case of a peak, ECHA may not be able to process applications due to limited staff resources and the Committees may not be able to give opinions within legal deadlines or ii) In case of a much lower number of applications, ECHA may be lacking fee income	i) Committees overloaded, potential impact on legal deadlines in case of a peak. ii) Financial risk in case of significantly lower number of applications.	1. EXTERNAL ENVIRONMENT	MEDIUM	Reduce/accept	1) In case of significantly higher number of applications (more than 40 and thus higher income), a flexible redeployment of REACH staff resources as well as the use of Seconded National Experts (if possible) would need to be initiated. RAC and SEAC may need to use all members as rapporteurs and consider using co-opted members. The use of interims and "intra muros" consultants may be considered as well. 2) In case of lower number of applications and thus lower income, budget savings and/or reallocation of the staff need to be considered	Dir B/ Dir D	continuous follow up
2.3 Resources	All objectives affected	Lack of financial balancing mechanism	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 be unable to honour its legal obligations; ECHA may not be able to achieve its budget implementation targets.	4. LEGALITY AND REGULARITY ASPECTS	MEDIUM	Reduce/accept	1) Exercise continuous monitoring of income and expenditure, improve income forecasting and create scenarios and fallback plans allowing for actions in case of changes in the circumstances 2) Communicate the income development and uncertainties to the Commission permitting them to seek for remedial action as needed 3) Continue negotiating for a balancing mechanism	Dir R	continuous follow up
2.2 Management	All objectives affected	Due to the fact that: i) The Efficiency programme is in a stage of an initial investment, thus requiring resources to drive changes and process improvements; ii) Efficiency gains at the moment are not sufficient to compensate for the resource reduction	ECHA may not be able to meet all objectives of the ambitious Efficiency Development Programme	Negatively impacting ECHA's reputation, as expectations are created both in the Comission and Management board	3. PEOPLE AND ORGANISATION	MEDIUM	Reduce	1) Ensure timely Management support at the level of policies/rules where changes are bringing efficiency gains. 2) Empower staff by delegating decision-making to lower levels where risk is assessed as low to speed up the process flow. 3) Raise more awareness among staff, get more volunteers in the Programme to speed up the projects' progress. 4) De-prioritise other activities where possible.	Dir R/ ExO	continuous follow up

Annex 5: ECHA IT resources

ECHA IT RESOURCES		
IT tool	**Main description**	**Activities served by tool**
IUCLID	Main tool for technical dossier preparation for Industry in REACH, CLP and BPR. Used as the central database of dossiers for the regulatory work of ECHA and for the work of national Competent Authorities in REACH, CLP and BPR. Tool for preparation of applications for authorisation.	1.1.1 Registration dossier preparation; 1.1.2 Registration and dossier submission; 1.1.3 Evaluation; 1.2.1 Identifying needs for Regulatory Risk Management; 1.2.2 Authorisation; 1.2.3 Restrictions; 1.2.4 Classification and Labelling; 1.3 Biocides
CHESAR	Supports registrants to carry out their safety assessments in a structured manner, prepare their chemical safety reports (CSRs) and generate their exposure scenarios for communication in the supply chain.	1.1.1 Registration dossier preparation; 1.1.4 Communication of risk management advice through the supply chain
QSAR Toolbox	Software application intended to be used by OECD member countries, chemical industry and other stakeholders in filling gaps in data needed for assessing the hazards of chemicals.	1.1.1 Registration dossier preparation
REACH-IT	The tool for inquiry submission and processing. Submission web application for REACH and CLP, as well as the tool for automated processing of submission, granting a registration number, once technical completeness and other relevant rules are met. Invoicing tool for fee based submissions. It offers a secure communication inbox used for all communication with registrants, used also by non-submission regulatory processes (e.g. communication of evaluation decisions). Submission tool for the applications for authorisation.	1.1.1 Registration dossier preparation; 1.1.2 Registration and dossier submission; 1.2.2 Authorisation
Odyssey	Guides the scientific decision making process and ensures consistency & traceability.	1.1.1 Registration dossier preparation; 1.1.3 Evaluation
Website	ECHA's website is the primary communication vehicle of the Agency. It is the fundamental source of information and guidance for companies seeking to comply with the legislation on chemicals. It is essential reading for dossier preparation, registration and dossier submission and evaluation. It informs and is the vehicle for public consultation in the different steps of the Authorisation process, on Restrictions, on CLP and on Biocides. It is the source of information for notifiers and DNAs on PIC and for companies wishing to appeal decisions.	1.1.1 Registration dossier preparation; 1.1.2 Registration and dossier submission; 1.1.3 Evaluation; 1.1.4 Communication of risk management advice through the supply chain; 1.2.2 Authorisation: 1.2.3 Restrictions; 1.2.4 Classification and Labelling; 1.3 Biocides; 1.4 PIC;

ECHA IT RESOURCES		
IT tool	**Main description**	**Activities served by tool**
	ECHA's website is the source of information on procurement exercises. It is the way in which ECHA communicates about vacancies. It is the way in which ECHA demonstrates who we are, what we do, how we are structured. How we make decisions and how stakeholders can engage with us.	2.1.4 Board of Appeal; 2.3.1 Financial resources; 2.3.2 Human resources Management
Remedy and its customisation Helpex	IT service management tool in which the enquiries, service requests and incidents are stored for processing and a database for regular reporting on the service level of the ECHA Helpdesk and other ECHA services.	1.1.1 Registration dossier preparation; 1.1.3 Evaluation; 1.1.4 Communication of risk management advice through the supply chain; 1.2.2 Authorisation; 1.2.3 Restrictions; 1.2.4 Classification and Labelling; 1.3 Biocides; 1.4 PIC; 2.1.3 HelpNet and Security Officers Network
SME verification tool	Tool used by ECHA to check the declared company status.	1.1.2 Registration and dossier submission
Dynamic Case	Case management tool to support the creation and processing of business cases at the same time providing a repository for the documents generated. It ensures traceability of the process steps also for auditing and other legal aspects (e.g. access to data, appeals).	1.1.2 Registration and dossier submission; 1.1.3 Evaluation; 1.2.1 Identifying needs for Regulatory Risk Management; 1.2.2 Authorisation; 1.2.3 Restrictions; 1.2.4 Classification and Labelling; 1.3 Biocides; 1.5 Data management and dissemination; 2.1.1 Committees; 2.1.2 Forum 2.1.4 Board of Appeal
Secure CIRCA-BC	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
Reporting	Automated reporting is a key instrument to monitor, manage and inform about submissions, fee income and related data; the status of cases opened for evaluation: it is a crucial tool for the regular reports on	1.1.2 Registration and dossier submission; 1.1.3 Evaluation; 1.2.4 Classification and Labelling

ECHA IT RESOURCES		
IT tool	**Main description**	**Activities served by tool**
	evaluation foreseen in the regulations (e.g. Article 117 (2) report).	
ECM-DEP	Workflow-oriented case management tool to support the creation and processing of business cases for dossier evaluation and at the same time providing a repository for the documents generated. It ensures traceability of the process steps also for auditing and other legal aspects (e.g. access to data, appeals).	1.1.3 Evaluation
IT for Screening	ECHA develops algorithms and uses powerful dedicated data mining tools to screen the high volume of dossiers submitted and identify candidates for compliance checks according to the compliance checks strategy.	1.1.3 Evaluation; 1.2.1 Identifying needs for Regulatory Risk Management
Portal Dashboard for MSCAs	Portal for Competent Authorities 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
Dissemination Portal	ECHA stores and integrates data in the C&L Inventory part of its Dissemination Portal. ECHA stores and integrates data on chemicals which represent one of the largest knowledge bases in the world on scientific and hazardous properties, experimental study data, safe use, risk management measures, classification and labelling. Complex and resource intensive IT support has been developed by ECHA to give facilitated access to the public to such knowledge base.	1.2.4 Classification and Labelling; 1.5 Data management and dissemination
C&L Platform	Web-based discussion forum to support Industry fulfilling their legal obligation to agree on the classification and labelling for substances which appear to be the same but have been differently classified by different companies.	1.2.4 Classification and Labelling
R4BP	Used by Industry for submitting applications under the Biocidal Products Regulation to ECHA and by ECHA/MSCAs for providing applicants with the related decisions. R4BP represents the implementation of the register for Biocidal products foreseen in the legislation.	1.3 Biocides
SPC Editor	Tool for Industry and MSCAs to process the Summary of Product Characteristics as foreseen in the BPR	1.3 Biocides
ePIC	Web application used by Industry for submitting PIC notifications to ECHA. Central IT tool for all the actors involved in PIC: Industry, ECHA, Designated National Authorities, Customs, European Commission: all the actors interact using the tool.	1.4 PIC

ECHA IT RESOURCES		
IT tool	**Main description**	**Activities served by tool**
MSCAs IUCLID central database for REACH&CLP; MSCAs IUCLID central database for Biocides	Two large central databases of scientific data in IUCLID format opening direct access and full IUCLID functionalities to MSCAs.	1.5 Data management and dissemination
Data Integration Platform	Data warehouses are the back-end to provide integration, aggregation, data intelligence, reporting for data consuming systems, notably the Dissemination Portal, the Portal dashboard for MSCAs and for the Enforcement Authorities, reporting. It does not offer direct functionalities to end-users, rather it enables the re-use of data without duplication, advanced searches, data intelligence; capabilities which make the data usable and meaningful for consumption.	1.5 Data management and dissemination
COMA	Contact Management tool used to manage lists of contacts (as Management Board or Committees members, experts listed by expertise, legal contacts, etc.), to search and sort data.	2.1.1 Committees; 2.1.2 Forum; 2.1.3 HelpNet and Security Officers Network; 2.2 Management
Planning and reporting integrated IT solution		2.2 Management; 2.3.1 Financial resources; 2.3.2 Human resources
ECM - Records Management system	System capable of storing and managing ECHA records according to ECHA filing plan, information security rules, retention rules, etc. making records immutable.	2.2 Management
ECM – Document management System	Document management and collaboration capabilities for all ECHA staff.	2.2 Management
ECHAnet	Intranet of ECHA – the Agency's primary internal communication and collaboration tool.	2.2 Management
ECM-Document Management System	Platform used by ECHA's personnel to store and collaborate on documents applying the internal policies and procedures on management of documents and records and on classification and handling of information.	2.2 Management
Mail registry		2.2 Management
Declarations of Interest management tool	Tool used to declare, and search Declarations of Interests by all ECHA's personnel. Used in the Conflict of Interests checks in all processes.	2.2 Management
ABAC	Budget, Accounting and Asset management system provided by the European Commission.	2.3.1 Financial resources
EasySign	Electronic workflow supporting some financial workflows.	2.3.1 Financial resources
Dynamic Case for SME verification		2.3.1 Financial resources

ECHA IT RESOURCES		
IT tool	**Main description**	**Activities served by tool**
Integrated Human Resource Management System	Supports the HR processes: Personnel and Payroll Administration, HR Financial management, Staff planning & reporting, Time management (and related time clocking devices), Recruitment, Performance & Career management, Training.	2.3.2 Human resources
Mission management tool	Tool used to create mission orders and process mission claims and reimbursements.	2.3.2 Human resources; 2.3.3 Corporate services
Meetings and events management tool		2.3.3 Corporate services
Webex	A platform for videoconferencing.	2.3.3 Corporate services
Outsourced ICT managed services, including hosting in external datacentres		2.3.4 ICT
Hardware and software licences		2.3.4 ICT
Workplace ICT facilities and services		2.3.4 ICT
Telecommunication equipment and services		2.3.4 ICT
Integrated Access Management: IT solution to provision/de-provision user accounts and grant access to IT systems for internal and external users		2.3.4 ICT
Remedy Ticketing system		2.3.4 ICT
Automation and administrative tools to support IT operations.		2.3.4 ICT