

# Multi-Annual Work Programme

2014-2018

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## ECHA's Legal Mandate

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

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

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

The recast of the so-called "PIC" Regulation (the Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals) also came into force in 2012. Certain tasks related to PIC will be transferred from the Joint Research Centre of the European Commission to ECHA in 2014.

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

## ECHA's Mission, Vision and Values

Mission	Values
<p>ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.</p> <p>ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.</p>	<p><b>Transparent</b> 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.</p> <p><b>Independent</b> 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.</p> <p><b>Trustworthy</b> Our decisions are science based and consistent. Accountability and the security of confidential information are cornerstones of all our actions.</p> <p><b>Efficient</b> We are goal-oriented, committed and we always seek to use resources wisely. We apply high quality standards and respect deadlines.</p>
<p><b>Vision</b></p>	<p><b>Committed to well-being</b></p>
<p>ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.</p>	<p>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.</p>

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**LIST OF ACRONYMS**

AOP	Adverse Outcome Pathways
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
CA	Contract Agent
C & L	Classification and Labelling
CHESAR	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
COM	European Commission
CSR	Chemical safety report
DU	Downstream user
ECHA	European Chemicals Agency
eChemPortal	Global Portal to Information on Chemical substances
EEA	European Economic Area
EEA	European Environment Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMAS	Eco-Management and Audit Scheme
EMA	European Medicines Agency
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HR	Human Resources
ICT	Information and Communication Technology
IPA	Instrument for Pre-Accession
IQMS	Integrated Quality Management System
ISO	International Organization for Standardisation
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre of the European Commission
MB	Management Board
MFF	Multi-annual Financial Framework
MS	(European Union) Member State
MSC	ECHA Member State Committee
MSCA	Member State competent authority
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, bioaccumulative and toxic
PIC	Prior Informed Consent procedure
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationships
RAC	ECHA Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	Central IT system providing support for REACH

RIPE	REACH Information Portal for Enforcement
RMO	Risk Management Options
SAICM	Strategic Approach to International Chemicals Management
SDS	Safety data sheet
SEAC	ECHA's Socio-economic Analysis Committee
SIEF	Data Sharing and Substance Information Exchange Forum
SME	Small and Medium-sized Enterprise
SVHC	Substance of very high concern
TA	Temporary Agent
TAIEX	Technical Assistance and Information Exchange instrument managed by the Directorate-General Enlargement of the European Commission
UN	United Nations
UN ECE	United Nations Economic Commission in Europe
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and very Bioaccumulative

## FOREWORD BY THE MANAGEMENT BOARD

Welcome to the European Chemicals Agency's Multi Annual Work Programme for the five years from 2014 to 2018. This is the first time that I am writing the foreword to such document since taking over the chairmanship of ECHA's Management Board in October 2012. It's a role that I am honoured to fulfil and which brings me in closer contact with the Executive Director and the management staff to ensure that ECHA delivers on the goals outlined in these pages.

I am particularly pleased to be introducing this 5-year strategic plan to you – it is the first of its kind, built around four strategic objectives chosen by the Board last year, rather than the activity-based Programme of the past. I find it a very satisfying document because it is setting out a high level, aspirational approach for achieving the important goals that REACH and the other EU's groundbreaking chemicals legislations have set for us.

The strategic direction is based on the Agency's experience over the first five years of its operations in implementing REACH and CLP – in managing the registration process and helping companies to comply by submitting quality data that ECHA makes available to the public; in addressing chemicals of concern; and in providing scientific advice. In these three key respects ECHA has identified in this plan intelligent steps in making considerable progress in cooperation with the European Commission and the Member States.

Of course, one issue will impact on the achievement of these objectives – the availability of resources. ECHA receives fees from industry for many of the services it provides as well as, when needed, a subsidy from the EU. ECHA, like all public bodies is looking very hard at its use of public money – indeed, one of the four strategic aims is about working more efficiently and effectively in particular when introducing the new legislation on biocides and export-import notifications.

At this point I would like to pay tribute to my predecessor, Thomas Jakl, who chaired the Board with great skill, diplomacy and commitment over four years, and whose guidance led the Agency to the point where it was able to develop these four strategic objectives. I hope that I am able to have a similarly positive impact on the implementation of the strategic plan so that it may bring tangible improvements to human health and the environment, while stimulating innovation and competitiveness.

I commend this document to you and hope that in reading it you will have a clear sense of the strategic direction in which the Agency will be travelling over the coming years.

Nina Cromnier  
Chairman of the Management Board

## **FOREWORD BY THE EXECUTIVE DIRECTOR**

Welcome to this Multi-Annual Work Programme for the European Chemicals Agency for 2014 to 2018. It is based around four strategic objectives for that five year period – improving the quality of information on chemicals; making best use of that information for risk management and control; addressing scientific challenges; and working ever more efficiently and effectively in our daily work and in the new tasks coming from the Biocides and PIC regulations. I am confident that we have focussed on the four objectives that are really fundamental to our mission and vision. By focussing on securing public trust in the safety information provided by industry, on reducing presence and exposure to chemicals of concern, on building capacity to provide reliable scientific advice and on becoming more efficient and effective, ECHA will become over time a respected agency.

I would like to play tribute to our Management Board, the Member States and our Accredited Stakeholders who each helped us to refine our thinking by challenging and questioning us, thereby enabling us to identify the necessary actions that should be undertaken under each of the four strategic objectives that you see described here.

Information is everything in a knowledge society – the perceived lack of information on commonly used chemicals led to REACH and the core requirement of that legislation is that companies shall submit in a registration quality information that assess the risks and provide safety instructions to manage those risks for all substances they manufacture or put on the market above 1 tonnes. That information can then be used to identify and address chemicals of concern and to meet the scientific challenges.

I very much look forward to hearing your views on this Programme and on our work – and if you are an organisation at EU level with a stake in one of the four EU chemicals regulations that we manage and would like to play a more active role in our work, then why not join us as an Accredited Stakeholder. You can find details of the criteria and how to apply on our website.

Thank you for taking the time to read our Programme.

Geert Dancet  
Executive Director



## 1 INTRODUCTION

Since its establishment in 2007, ECHA has grown from a few dozen staff members to an organisation of more than 500 people who have successfully achieved the demands placed on them by the legislation. A study<sup>1</sup> ordered by the Commission as part of its REACH review confirmed that ECHA has met most of its key objectives during the start-up phase and that its stakeholders were satisfied with its achievements. ECHA will take the report's recommendations into account when implementing this MAWP.

ECHA now has mature processes for REACH and CLP. A wealth of information has been accumulated on chemicals and significant progress has been made to assess their risks and make the information available to the public. The Commission's repeat of the REACH benchmark study<sup>2</sup> notes that REACH has already made a significant impact on the safe use of chemicals. At the same time, ECHA is embracing the new activities laid down in the Biocidal Products and PIC Regulations. This is challenging, but synergies can be found with REACH and CLP - not least on putting processes/IT in place, interacting with stakeholders, developing guidance and making information publicly available quickly.

This five-year strategy sets out how ECHA will contribute to the objectives of the REACH, CLP, Biocidal Products and PIC Regulations.<sup>3</sup> At the same time, the strategy will enable ECHA to reach its vision of becoming the world's leading regulatory authority on the safety of chemicals. The strategic approach was already presented in ECHA's MAWP for 2013-2015 and it has been further elaborated here. The Agency is working on measurements (baselines and targets) designed to monitor progress towards achieving the strategic objectives.

This MAWP is different from its predecessors. It is fixed for five years, instead of three on a rolling basis, and is based around four strategic objectives which are broken down into a few action areas. The Annual Work Programmes will then provide details on the individual actions planned, year by year. However, the main milestones are already highlighted in Annex 1 of this document. A review of the progress in the action areas and milestones will be conducted regularly during the lifetime of this programme and corrective action will be taken where necessary.

Close cooperation with the European Institutions, the Member States and their competent and enforcement authorities are key factors for the future success of the regulations. Equally, ECHA has to continue to interact with all stakeholders and develop the networks between industry, MSCAs, EU institutions and civil society further. The successful delivery of the Agency's strategic vision for the planning period is also dependent on the availability of the necessary resources. This is essential to ensure that the start-up phase of the Biocides and PIC activities can be effectively and smoothly handled while continuing to meeting the ambitious agenda of the REACH and CLP Regulations.

The planning in this Work Programme is founded on the availability of the staffing numbers presented in Annex 1 and upon the baseline figures presented in Annex 3, which are an update of the Commission estimates made at the time the REACH Regulation was prepared. Having passed two important deadlines for REACH registrations and CLP notifications respectively, in 2010/2011, ECHA can now base some of its predictions on real data. Some parts of the baseline numbers nevertheless remain subject to a significant degree of uncertainty, in particular with regard to authorisation applications under the REACH and Biocidal Products Regulations. At this point in time, the biggest uncertainty remains in the annual staffing numbers and revenue by either subsidy or industry fees. Without adequate resources, ECHA is unable to put its ambitious plans into effect. It therefore calls on the Commission and the Budgetary authority (Parliament and Council) to ensure sufficient resources for setting the size and distribution of the MFF.

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<sup>1</sup> Final Report on the Review of the European Chemicals Agency, Pwc, 14 March 2012.

<sup>2</sup> The REACH Baseline study, 5 years update, 2012 edition, Eurostat Methodologies and Working papers.

<sup>3</sup> While the strategy is well developed for REACH and CLP, based on 5 years' experience of operations, implementation of Biocidal Products and PIC Regulations is only starting up, and hence, cannot provide the same level of detail.

## 2 ECHA AND ITS ENVIRONMENT

ECHA operates in a complex environment. Implementing the legislation is a shared responsibility with many partners and REACH, CLP, Biocides and PIC are not the only pieces of legislation which impact on industry in the chemicals area. The range of companies impacted by the EU chemicals legislation is vast – right the way to companies who would never believe that the chemicals laws had anything to do with them.

### 2.1 The EU regulatory system for chemical safety

#### 2.1.1 REACH and CLP

The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. At the same time, the European Union can take additional measures on the most hazardous substances, where there is a need for complementary regulatory action at EU level.

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

##### 1. Registration

Companies are required to document all the information on the substance they manufacture or import in a registration dossier and submit it to ECHA. In order to promote the harmonised interpretations of data, and reduce registration costs and unnecessary testing on animals, registrants of the same substance have to share their data and submit their registration jointly. ECHA manages the registration process through its support to companies, facilitation of data sharing and arbitration of data sharing disputes. ECHA verifies the completeness of registration information before assigning a registration number.

##### 2. Evaluation

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

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

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

##### 3. Classification and Labelling

The CLP Regulation sets the rules for the classification and labelling of chemicals. It aims to determine whether a substance or mixture displays properties that lead to a classification as hazardous. 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.

##### 4. Authorisation

The authorisation procedure aims to assure that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the functioning of the EU's internal market. After a two-step regulatory process managed by ECHA, SVHCs may be included in the

Authorisation List and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Authorisation applications are submitted to ECHA, and after the opinion of the Committees for Socio-economic Analysis and Risk Assessment as well as public consultation, the European Commission decides to grant or refuse authorisation.

## 5. Restrictions

Restrictions are designed to manage risks that are not addressed by the other REACH processes or by other Community legislation. They limit or ban the manufacture, placing on the market or use of certain substances within the EU. A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Community-wide basis. After the opinions of the Committees for Socio-economic Analysis and Risk Assessment as well as public consultation, the European Commission, together with the Member States, takes the final decision.

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

### 2.1.2 Biocides

The Biocidal Products Regulation (BPR) concerns the placing on the market and use of biocidal products. These are typically used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, through the action of the active substances contained in the biocidal product. ECHA is not only coordinating the evaluation of active substances and the Union wide authorisation of biocidal products but is also the central hub for all applications, establishment of technical equivalence, assessment of applications for alternative suppliers, resolution of data sharing disputes, dissemination, preparation of guidance, communication.

### 2.1.3 PIC

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

## 2.2 Working with others

The successful implementation of the REACH, CLP, Biocidal Products and PIC Regulations requires the collaboration of many players. It depends on companies, ECHA's institutional partners at EU level, the Member States, and key stakeholders playing their parts. It also relies on scientific developments in the regulatory, scientific and academic world. It also implies that ECHA's communications work – by means of informing others via its website or dedicated publications and engaging them via awareness-raising and other campaigns – will constitute a main element in putting this MAWP into effect.

The information gathered through REACH is an invaluable asset and must be made full use of in a responsible manner – by other countries' legislators and authorities, international organisations, companies and citizens.

### 2.2.1 EU Partners (EU institutions, other EU agencies)

The EU chemicals legislation gives shared responsibility for its implementation. The Member States (in the form of competent authorities and enforcement authorities – which may or may not be the same) and the European Commission are ECHA's primary regulatory partners. Their tasks are outlined in the legislation and each of them requires a close interaction with ECHA.

At EU level, ECHA also has a number of related Agencies. These include EFSA and EMA – with whom a close cooperation on science and communication activities is of mutual advantage. This ensures that relevant decisions on chemicals at EU level are consistent and synergies found. ECHA and the Agencies have signed memoranda of understanding to guide their cooperation. ECHA will also need

to work with other EU bodies that handle related subjects relevant to chemicals safety management, such as those related to worker protection.

### **2.2.2 The Member States**

As mentioned earlier, the roles of Member States are outlined in the law. They play pivotal roles in decision making and they carry the primary responsibility for the enforcement of the law. The resources made available for REACH, CLP, Biocides and PIC responsibilities in Member States have a direct impact on the progress that can be made at EU level on each of the regulations and therefore on their ultimate success. With that in mind, ECHA will continue to seek to prioritise and prepare the activities with the Member States to maximise the efficiency and effectiveness of the legislation's implementation, including facilitation of the use of IT tools and access to IT-systems.

Effective, proportionate enforcement and dissuasive sanctions for non-compliance will need to provide the ultimate back-stop for the implementation of the EU chemicals safety regime and of ECHA's regulatory decisions. In particular via the Forum for the Exchange of Information on Enforcement, the Agency will further promote the operational follow-up of its decisions by national enforcement authorities.

### **2.2.3 Duty holders**

Chemicals legislation places many duties on companies. Risk assessment, the safe use of substances, classification and labelling and communication down the supply chain are the responsibility of individual companies. It follows that there was an appropriate collaboration between ECHA and industry particularly at the onset of the legislation, when guidance, tools and procedures were being developed in order to make the law work but also to make its successful implementation more likely.

ECHA's support to the industry aims to ensure that the companies understand how to comply with the legislation. This guarantees efficient use of resources both within ECHA and also in the companies in the long run as well as strengthening transparency and predictability as companies are aware of current requirements and upcoming changes.

### **2.2.4 Accredited stakeholder organisations (ASOs)**

ECHA also collaborates with many stakeholder organisations, in particular with organisations representing industry, NGOs and trade unions. Their involvement in ECHA's work provides transparency and valuable input into the regulatory decision making – for example through their participation as observers in ECHA's Committees. Given the potentially wide range and number of stakeholders interested in working with ECHA, the Agency has established a set of five criteria which an accredited stakeholder organisation must fulfil.

### **2.2.5 The scientific scene**

Developments in science and technology can have a big impact on ECHA's work, thus there is a need for an interface with the scientific community and academia. Technological developments like nanotechnology for example have raced ahead, and regulatory science has to respond to ensure that the potential risks of such substances can be adequately assessed: companies producing substances in nanoform have to explain the potentially different impact of their substance in its different forms within their registration dossier. ECHA in turn takes account of these scientific developments in making judgments about the adequacy of the information provided in dossiers.

By the same token, developments in assessing the properties of substances by using new test methods and prediction techniques such as read-across and computational methods also have a significant impact on the scientific justifications provided by companies and ECHA's examination of these.

ECHA encourages training for young professionals seeking to work in regulatory science.

### **2.2.6 The worldwide scene**

Whilst the EU has the most ambitious chemicals legislation in the world, it is nevertheless not alone in seeking to reduce risk and have chemicals used more safely. ECHA will share experience with the increasing number of countries adopting chemicals safety legislation akin to REACH.

ECHA will continue to work with international organisations, in particular with the OECD, on activities of mutual interest. The REACH Regulation requires that the Agency takes on the maintenance and further development of the IUCLID tool which was developed under the auspices of the OECD. But

the joint work with the OECD also includes methodologies for hazard and risk assessment and analysis, computational tools like the QSAR toolbox and database construction – thereby allowing industry to input data once and use it for many purposes in other jurisdictions and allowing the maximum of transparency for regulators and the public. It is greatly to the advantage of companies in terms of competition and innovation that the legislative regimes in place throughout the world have a common scientific base.

ECHA will continue to work with the regulatory authorities of countries with whom it has memoranda of understanding – Australia, Canada, Japan, and the USA – to share best practice, exchange information and to learn. The Agency will also continue to support EU policies in its dealings with the outside world, such as with EU accession or neighbouring countries, as well as supporting the European Commission in representing the EU in multilateral conventions on chemical safety, such as the Stockholm and Rotterdam Conventions as well as SAICM<sup>4</sup>.

This worldwide scene also requires ECHA to address audiences outside the EU, particularly manufacturers of substances regulated by REACH, CLP, BPR, or PIC and of other stakeholders who closely follow developments under the EU chemicals safety regimes.

## 2.3 ECHA's drivers

There are three key drivers for ECHA's work over the five year period of this Multi-Annual Work Programme. The first is related to the need of quality information on chemicals to enable their safe use, the second is economic and the third is the future of the EU's chemicals legislation.

Firstly, the increasing demand for reliable information on chemicals. The EU chemicals legislation requires companies to separately and/or jointly provide hazard and safety information on the chemicals they produce or import. Clear and reliable information is essential for all operators in the supply chain to protect their workers and customers as well as for regulators who need to decide on eventual EU-wide risk management measures on certain chemicals. It is also important for consumers and civil society who rightly demand it in order to hold companies and regulators to account and make personal choices about consumption. The driver is an ever increasing demand from all stakeholders for accessible quality information that is fit for purpose.

Secondly, the challenging economic environment through global competition underlines the equal importance of REACH's parallel aims, namely to increase innovation and competitiveness within the EU's chemical sector and to ensure a level playing field in the EU and EEA. In particular, by taking account of the special needs of SMEs; dealing swiftly and firmly with companies who do not meet their legal obligations; supporting coordinated enforcement throughout the EU; and facilitating innovation for example by supporting the faster substitution of the substances of highest concern or providing incentives for research-oriented companies to make use of the exemption from registration for the purpose of Product and Process Oriented Research and Development (PPORD).

By the same token, EU bodies are not immune from the very same economic constraints and ECHA has to cut its resources in the coming years. In ECHA's case, it is now more critical than ever that it focuses its energies to ensure that operations are impactful, streamlined, optimised and cost-effective. Any future reductions in manpower, fee income and EU subsidy will of course result in more limited ambitions and work programmes of a reduced scope than that outlined here.

The third driver is the EU chemicals legislation, any change to it, or indeed, new legal responsibilities being given to ECHA. They of course cannot be foreseen here. Nevertheless, ECHA is proud to have been given responsibility for such groundbreaking and important legislation and looks forward to making full use of its scientific and technical competence in the future.

These drivers, together with ECHA's experience over the first five years, have led it to develop four strategic objectives for the coming years:

1. Maximising the availability of high quality information to enable the safe manufacture and use of chemicals.
2. Mobilising authorities to use information intelligently to identify and address chemicals of concern.

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<sup>4</sup> Adopted by the International Conference on Chemicals Management (ICCM) on 6 February 2006 in Dubai, United Arab Emirates, the Strategic Approach to International Chemicals Management (SAICM) is a policy framework to foster the sound management of chemicals.

3. Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors.
4. Embracing current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.

### 3 HIGH QUALITY INFORMATION FOR SAFE MANUFACTURE AND USE

REACH shifted the responsibility for establishing the safe use of chemicals to the companies manufacturing and importing them. Companies have to gather and generate information on the properties and uses of their chemicals, assess potential risks and demonstrate safe use in the registration dossiers they submit to ECHA. They also have to provide corresponding safety advice to their customers.

Once generated, this information is used in many important ways to further the safe use of chemicals. It is the cornerstone for companies themselves to recommend risk management measures throughout their supply chain – right the way up to the products used by consumers. It is also the main source for authorities to identify substances or uses of substances that require EU-wide regulatory risk management. Scientific and academic organisations will use it for their research programmes, including those developing methods of analysis which would avoid the need to test substances on animals. Finally, the registration dossiers, the classification and labelling notifications and other data received via additional mechanisms, have resulted in a wealth of information on chemicals and their uses being available on ECHA's website. This will eventually be complemented by data on biocides in 2014. The information is there to be used, in a responsible manner, by everyone and anyone for the benefit of human health and the environment in Europe and throughout the world.

However, for all this to be achieved, the information provided needs to be of high quality, in other words, scientifically sound, understandable and reliable. The key word is quality. Unfortunately, the level of quality of the information provided by companies is not yet sufficient. ECHA has found that, whilst registrants successfully submitted their dossiers for the first REACH registration deadline, at least one third of the dossiers have quality deficiencies. The deficiencies relate to their compliance with the legal requirements and/or how the hazard, exposure and use information is converted into adequate and reliable safety instructions. The quality problems were expected, given that the obligations were new and extensive, but they are not acceptable and cannot be allowed to persist.

The deficiencies range from ambiguous substance identity; insufficiently documented or unclear study summaries; severe inconsistencies or gaps in hazard information and corresponding classification and labelling; imprecise chemical safety assessments to inadequate exposure scenarios. Long-term studies required to assess the risks to human health are often replaced by waivers or justifications which, in many cases, did not hold up to scrutiny. Formal ECHA reports give more details on these shortfalls: "The use of alternatives to testing on animals for REACH"<sup>5</sup>; and the annual evaluation reports<sup>6</sup>. These findings are of course based on the early implementation of REACH but it is not unreasonable to assume that similar challenges will be faced not only for the other registration deadlines but also in the implementation of the Biocidal Products Regulation because of the similarities with REACH on the approaches to the generation of hazard data and risk assessment.

For REACH to succeed, these deficiencies must be addressed and, as the provider of the information, industry needs to take its responsibility for that. However, ECHA and the national authorities have a role to play by ensuring clarity on the legal requirements, acting swiftly and decisively where companies are falling short of their obligations and communicating clearly and promptly when lessons have been learnt.

In conclusion, ECHA has a central role in the EU chemicals legislation, in increasing the reliability of its public database on chemicals and a mandate to issue legally binding decisions on chemical companies to provide information to redress deficiencies in registration dossiers. It is therefore in a key position to improve both the quality and the availability of information on chemicals in use in Europe today. The challenge for ECHA during the period 2014-2018 is to induce improvements in the quality of that information so that it can be used effectively to enable the safe manufacture and use of chemicals. At the same time, by taking prompt action against companies whose information falls short of the standard, ECHA will help to ensure a level playing field for all registrants.

ECHA will make use of both its regulatory powers and of incentives. The regulatory powers are clear - ECHA will issue legally binding decisions on companies and their compliance is followed up by the

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<sup>5</sup> Published on 29 June 2011.

<sup>6</sup> Available on the ECHA website.

Agency and the national enforcement authorities. It will ensure that Member States are aware of any concerns with companies in their territory and will continue to support the coordination of enforcement across the EU through the work of the Forum. It may also need to continue to recommend the levying of fees or charges on companies whose poor levels of compliance require a disproportionate amount of time on ECHA's part and for which they currently make no additional payment.

ECHA has a safety net for companies who feel the Agency has incorrectly applied its regulatory power. Companies can appeal against many of ECHA's decisions by taking their case to the Board of Appeal for their consideration and decision. The Board of Appeal is a 'quasi-judicial' body that takes its decisions independently and impartially. Decisions taken by the Board of Appeal may have a subsequent impact on the operation and implementation of REACH and the Biocidal Products Regulation.

The incentives are much more varied in nature and come through the support provided by ECHA: awareness raising and information campaigns to make sure that companies are aware of their responsibilities and what is expected of them; detailed guidance; IT and other tools to make the task easier and therefore success more likely; providing examples of good practice; and measures to facilitate the dialogue between the different actors in the supply chain.

Higher quality information also requires a further improvement and integration of ECHA's IT systems. This concerns both the tools provided to help registrants in meeting the quality requirements as well as the tools used by ECHA and the authorities for screening the registration information in a systematic manner, setting priorities, processing dossiers for regulatory action and then their efficient dissemination.

The overall implementation approach is therefore divided into three action areas:

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

## **3.1 Improving the quality of information in dossiers**

### **3.1.1 Preparation of dossiers**

Dossiers have to include all the information required by the legislation and in the expected format so that they can be further processed and disseminated efficiently both to authorities and to the public at large. Making a positive impact on the quality of information at dossier preparation stage is the ideal.

From 2014, ECHA will strengthen its efforts, in collaboration with its stakeholders, to meet the needs for the 2018 REACH registration deadline. This final deadline is expected to generate the highest number of registrations and there will also probably be far more inexperienced and sole registrants. In this respect, the advice provided by the national REACH and CLP helpdesks becomes even more important as they will be the first line helpers for companies in their own languages. ECHA will reinforce its training with the national helpdesks to further develop their capacity to provide advice.

ECHA will also actively review and adapt the guidance and training, based on the experience of the 2013 deadline and with SMEs specifically in mind. Four particular areas for which additional support will be provided are: substance identification; description of uses; chemical safety reports; and the harmonisation of classification and labelling by industry.

Inadequate or inconsistent substance identity information has been a weakness in dossiers received thus far. If the substance identity is unclear, then the validity of the entire dossier of information is called into question. This issue is therefore fundamental. Further guidance and support will be provided well ahead of the 2018 REACH registration deadline for complex substances such as UVCBs and substance sameness. ECHA will also reinforce the completeness check in this respect, where appropriate.

More clarification will also be provided on the use descriptor system which is vital for communication in the supply chain. The weaknesses to be addressed are a lack of understanding of how the system works and insufficient standardisation across industry sectors in distinguishing different uses that



lead to different levels of exposure. The weaknesses can lead to an underestimation of the exposure, thereby not assuring safety of all uses.

The third area for additional support is to ensure the development of high quality chemical safety reports (CSRs). ECHA will assess methods and tools for exposure assessment in those areas where major gaps exist and adapt the IT tool Chesar accordingly. Together with the other regulatory authorities, ECHA will also assess whether the Chesar format of the CSR should become mandatory. This would be accompanied by supporting activities, e.g. by publishing examples of good quality CSRs in various real-life situations. ECHA will continue working closely with industry and other interested parties to identify further measures that could effectively support the production of good quality CSRs and exposure scenarios.

The fourth area relates to supporting industry in fulfilling their obligations under the CLP Regulation. The rules of the CLP Regulation for classification and labelling will become mandatory for mixtures only from 1 June 2015, and since many companies (in particular SMEs) might not be aware of this, a targeted awareness raising campaign will be conducted. ECHA will continue to support industry to make every effort to come to an agreed classification and labelling of their substances and to update the results of their discussion in the Classification and Labelling Inventory

As a specific topic, the Agency will embark on developing more refined guidance on the registration of substances in nano-form to provide further detailed advice reflecting the state-of-the-art in regulatory science in this respect and the anticipated adaptation of information requirements for nanomaterials in the REACH Annexes.

Finally, ECHA will also assess how best to help registrants of substances in small quantities (from 1 to 10 tonnes) to identify whether their substances meet any of the criteria laid down for higher data requirements or whether they could instead benefit from reduced ones. In this context, ECHA intends to investigate how the QSAR Toolbox, which aims to predict properties and fill data gaps, could be of help.

In parallel, ECHA is preparing the guidance documents, submission IT tools and manuals for the submission of biocidal dossiers and will benefit from the experience gained under REACH to set up the best possible systems and support structures for the many SMEs that operate in this sector.

### **3.1.2 Submission of dossiers**

The second stage where the quality of dossiers is tackled is at the point of submission of dossiers. In its preparations to the 2018 registration deadline, ECHA will make the IT portals through which registration processes are initiated (e.g. REACH-IT) more user-friendly, allowing a more flexible interface and communication channel with registrants. Specific consideration will also be given to enhancing the level of multilingualism of the submission tools.

The completeness check ECHA performs is an important step in enforcing conformity of the registrations. The formats, tools and processes within ECHA that check the completeness of dossier information and verify its relevance will be reviewed based on the experience of the first two registration deadlines.

To help registrants, ECHA will upgrade the IUCLID plug-in tools and guidance for registrants so that they can check their own dossiers for completeness and verify them before submission. There will also be a new tool that, prior to submission, enables companies to verify that frequently occurring shortcomings have been addressed ("Dossier Quality Assistant").

ECHA also intends to identify the dossiers that warrant follow-up action outside the dossier evaluation phase. For example, substances registered for intermediate use only will continue to be screened systematically to check whether the uses are in line with the definition of intermediate or that strictly controlled conditions are being applied.

### **3.1.3 Evaluation of dossiers**

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

ECHA will continue to examine the compliance of entire dossiers - based either on a random selection or using concern-based criteria. In addition to that, ECHA will continue to target selected elements in the dossiers that are particularly important for the safe use of a substance. The majority

(up to 70%) of the compliance checks will be targeted to either specific areas of concern or broader areas such as human health or environment information. The targeted compliance check does not only concern the information requirements per hazard endpoint, but also the substance identity, exposure and use information and the exposure scenarios for the supported uses. Such a concern-driven, targeted approach will be based on a systematic scanning of compliance of all dossiers with regard to the concern in question. It will also increase the proportion of examinations far above the regulatory minimum of five percent.

ECHA's aim is to address registration dossiers that give cause for concern from both the 2010 and 2013 deadlines, either by an ECHA decision or by other communication with the registrant. The Agency will be using increasingly sophisticated scientific IT tools to systematically screen all higher tier endpoints in the registration dossiers in order to achieve this aim. Any relevant incompliance will be addressed in a compliance check draft decision. ECHA will continue to inform and engage both the Member State competent authorities and the Member State Committee on a regular basis so that the machinery of evaluation decision making will work in the best possible way. Dossier evaluation will also specifically address scientifically challenging issues, such as dossiers on substances in nano-forms.

In addition to issuing formal and legally binding decisions, ECHA wants companies to update and improve their dossier quality voluntarily. To this end ECHA will i.e. communicate actively dossier evaluation findings.

ECHA will follow-up on registrants' updates after an ECHA decision in order to keep the momentum up and proceed to a conclusion on each dossier as quickly as possible after the deadline set in the ECHA decision. ECHA will pay special attention to the need for timely and efficient communication with the national authorities in order to ensure maximum efficiency in enforcing decisions. Ultimately, ECHA will consider declaring a registration invalid if REACH cannot otherwise be implemented. Furthermore, ECHA will consider publishing the names of companies where non-compliances persist after the expiry of the deadline given in the final decision.

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

## **3.2 Maximising the impact of the communication of risk management advice in the supply chain**

The communication of information through the supply chain has to be compliant with the legal requirements and fit for purpose. In addition to checking the legal compliance of CSRs and their exposure scenarios, the focus of ECHA's action will be on measures to help registrants and downstream users to improve the communication of risk management advice throughout the supply chain – right the way up to the articles produced for workers and consumers.

### **3.2.1 Exposure scenarios and safety data sheets**

Vital to the successful implementation of the safe use concept under REACH is that the exposure scenarios included in the CSR are transferred into good quality exposure scenarios for communication in safety data sheets (SDSs). ECHA will increase its support to registrants and downstream users as they develop the necessary methods, tools and standardised formats to develop good quality exposure scenarios for communication as part of the SDS. Given the important role of mixtures in the supply chain, special attention will be paid to the development of a scientifically sound methodology for exposure scenario development that can be easily understood. The potential risks of substances in consumer articles during their life span as well as when they become waste will be specifically addressed. Further efforts will also be made to expand and simplify the ECHA tools that downstream users use to comply with their reporting obligations.

ECHA will also work to increase the capability of registrants and downstream users on exposure scenario related issues, and to promote the communication and sharing of information between industry and authorities on the effective implementation of scenarios as a novel communication vehicle (e.g. via the ENES<sup>7</sup> platform). Based on the information received via the downstream user reports, discussions with the enforcement authorities may be needed to address specific sectors where problems with the implementation of the exposure scenario concepts have been identified.

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<sup>7</sup> Exchange Network on Exposure Scenarios.

### **3.2.2 Substances in articles**

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

## **3.3 Improving the dissemination of information**

### **3.3.1 Dissemination of substance information**

Transparency provides an important incentive for companies to provide reliable, scientifically sound and understandable data that will uphold their reputation of being compliant with the EU chemicals safety regime. Industry and civil society themselves can scrutinise the information and draw attention to any incoherence or inadequacies. ECHA is committed to making the best use of the unique data generated by companies in response to the EU chemicals legislation.

ECHA has published information on almost all of the registered substances and nearly all notified substances to the classification and labelling inventory on its website. These public databases are updated quarterly. The information is complemented by other types of data resulting from ECHA's regulatory activities, such as the list of pre-registered substances, the Candidate List of substances of very high concern, the list of authorisations and restrictions, etc. This goes a long way to fulfilling one objective of REACH, namely granting EU citizens "free and easy access to basic data on chemicals" in order to "allow them to make informed decisions about their uses of chemicals". This information is, and always must be, scientific and technical in nature. However, ECHA is keen to do what it can to make it more easily accessible for wider audiences. The intention is to better integrate the information on a specific substance arising from different legislation and regulatory processes (e.g. REACH and Biocidal Products) so that the user can, at a glance, get an overview of the available data for that substance. ECHA also plans to enable synchronisation with the users' own websites so that they may be alerted to new information published. The Agency will investigate the possibility of presenting the information in a way which is more useful for the public at large.

### **3.3.2 Publication of decisions**

ECHA intends to be ever more open and transparent on the Agency's activities by informing on the outcome of a regulatory process or reasoning for an opinion or decision. ECHA is committed to transparency and the openness of information and decision making. ECHA has started publishing dossier evaluation decisions and will also consider publishing other relevant decisions.

## 4 USING INFORMATION INTELLIGENTLY TO IDENTIFY AND ADDRESS CHEMICALS OF CONCERN

Under REACH and CLP, it is the individual Member States and the Commission who have the right to initiate regulatory risk management<sup>8</sup>. Progress in developing the necessary documentation to start risk management action as well as, in some cases, inexperience has been limited in some Member States due to policy choices and/or resource availability. Resources will always be a limiting factor but experience is being gained as the Agency and its Committees work through the REACH and CLP processes.

Thanks to REACH and CLP, the biggest database on the impact of chemicals in the world now exists in ECHA. It is therefore crucial, particularly in these early stages, to use the information intelligently and to first seek out the substances which appear to be most harmful and whose risks, as yet, may not be well managed. It is of course important that the risks of well known, hazardous substances are adequately assessed and managed, but REACH provides a unique opportunity to focus on substances which are not on the risk management radar screen and therefore may not be adequately regulated.

Together, the authorities need to use the REACH and CLP information to target regulatory action as early as possible on priority substances and uses that cause the highest potential risks. Those concerns need to be addressed by well-informed decisions on regulatory measures which are proportionate and effective in reducing the risk. Achieving a common view amongst authorities on how to select the best regulatory instrument and to use this in an effective manner will be a prerequisite to make this objective a success.

By focusing on identifying new substances for risk management and including such substances on the Candidate and Authorisation lists, ECHA will be contributing significantly to the promotion of the substitution of the most dangerous substances in the EU. In particular, by focusing the authorisation discussions on the analysis of alternatives the process will not only increase the level of protection of human health and the environment but will also contribute to enhancing innovation and the competitiveness of European industry.

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

The overall implementation approach is divided into three action areas:

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

### 4.1 Mobilising authorities and aligning views

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

ECHA will continue to work together with the Member States and the Commission to develop a common framework for regulatory risk management which would enable choices on the best regulatory instruments to be taken quickly and more efficiently. This should allow key questions such as: is further information needed and how can information gaps be best filled to clarify the initial concern, when and when not to initiate the authorisation requirement for substances fulfilling

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<sup>8</sup> Member States or companies can initiate the development of proposals for a harmonised classification and labelling and Member States and the Commission for identifying substances of very high concern and restrictions.

SVHC criteria, would a restriction under REACH be more appropriate, is there a need to consider initiating actions under other Union legislation, is there a need to enhance compliance by enforcement to be answered.

All of ECHA's REACH Committees (MSC, RAC, SEAC) are also involved in the risk management processes and framework according to their respective competences. Therefore, the ECHA Secretariat will continue to inform the Committees and engage them in the development of such a framework. In addition, Member States will need to provide scientific and technical support to the members of the Committees.

The intelligent use of information also comes into play with enforcement. ECHA will intensify its support to the national enforcement authorities, including developing a common understanding on enforcement needs and priorities, and developing tools and approaches for enforcement. Special attention will be given to the authorisation process as the important aims of this new process can only be achieved if the authorisation application requirements and any conditions of granted authorisations are complied with.

## **4.2 Identification of candidate substances for regulatory risk management**

The Agency's initial experience strengthened the view that the focus should be on newly identified substances that may give cause for concern and for which there are no (or limited) risk management measures in place. Therefore, the screening of substances based on the information provided in REACH dossiers and CLP notifications is key. The current database of substances is already the largest in the world but, over time, it is becoming much more useful as a tool to screen for risks as it is updated to include newer data. Firstly, the work carried out to improve the quality of information will result in updates of the hazard and risk profiles of already registered substances – including the most common and the most hazardous. Secondly, given that the 2013 deadline will provide information on substances, many of which have not previously been addressed from a risk management point of view, it is reasonable to assume that there will be substances that require further examination. Thirdly, the classification and labelling inventory is a source of additional information which can help to identify the need for industry to substitute harmful chemicals as well as for further regulatory actions. Finally, there are other industry dossiers, in particular downstream user reports and substances in articles notifications, which can be added into the mix.

ECHA will also explore how information generated under other Union legislation and complementary information sources (e.g. results from enforcement activities) can be used to broaden the knowledge base. By cross checking and taking an overview of the information available, it should improve decision making about the need for targeted information gathering as well as risk management measures. Much of the screening will be automated and ECHA will intensify the development of a solid and integrated IT database and flexible IT screening tools to ensure that the MSCAs and ECHA can fully benefit from the information provided.

ECHA will continue to develop approaches to identify substances of an equivalent level of concern to CMRs and PBT/vPvBs<sup>9</sup>. Furthermore, ECHA will consider establishing discussion platforms on the scientific and regulatory aspects of using criteria for identifying new groups of substances such as endocrine disruptors and sensitisers.

Filling information gaps and improving the quality of information in dossiers is essential for effective risk management decisions and that process, based on the REACH compliance check, is ongoing. These decisions may result in additional operating conditions or risk management measures at company level, or in decisions to substitute with alternatives. In addition, substance evaluation allows Member States to prepare draft decisions requesting information which goes beyond the standard information requirements, to clarify a potential concern for human health or the environment. Substance evaluation will include evaluation of substances in nano-form and thereby contribute to advancing the information and understanding of hazards and risks posed by nanomaterials. The aim for the coming five years is to fully develop the functional interlinks between substance evaluation and other REACH processes as well as with the CLP and Biocidal Products Regulations. The information collected and received should lead to the identification of candidates for regulatory risk management.

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<sup>9</sup> Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative.

With regard to hazardous substances entering the European market in already produced articles, ECHA will look to cooperate with authorities and industry in third countries to better communicate the REACH requirements on EU importers and explain to industry outside the EU how they can best ensure compliance with REACH .

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

### **4.3 Addressing identified concerns through REACH, CLP and other legislation**

Based on the results of the screening and subsequent activities, the authorities should be able to conclude on the best risk management option to address the identified concerns. In the context of the 2020 Roadmap<sup>10</sup> developed by the Commission together with ECHA and the Member States, the RMO analysis framework will be further developed, streamlined and regularly reviewed allowing authorities to efficiently make informed choices. In addition to continuing with its own efforts in developing RMO analyses as well as SVHC and restrictions dossiers, ECHA plans to play an active role in coordinating the actions foreseen under this roadmap to ensure that all relevant substances of concern covered by this roadmap are identified and addressed via the most appropriate risk management route. The actual number of SVHCs or restriction dossiers that ultimately will need to be managed depends on the conclusions of the more than 400 RMO analyses that are foreseen to be carried out until 2020.

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

ECHA will make the process for submitting applications for authorisations and developing the RAC and SEAC opinions as transparent and efficient as possible whilst ensuring the generation of high quality information to enable the potential applicants to analyse the alternatives to the substances of very high concern and thus make an informed decision on whether to substitute or to apply for an authorisation. With good quality information ECHA's scientific committees can then adopt their opinions efficiently.

ECHA will actively use its website during the public consultation on the substance and its alternatives to ensure that the authorisation would only be granted when there are no suitable alternatives. Where feasible, active participation of those companies producing the alternatives will be encouraged. ECHA will further increase its efforts to build confidence with all parties involved and to provide practical information to potential applicants, in particular downstream users, so that they can prepare their applications in a fit-for-purpose and cost-effective manner, whilst respecting their responsibility for the quality of their applications. ECHA also intends to improve the instructions to third parties to ensure that further information on alternatives is effectively fed into the opinion-making process.

Successful implementation of the 2020 Roadmap will most likely lead to an increase in the number of restrictions. This will also oblige Member States to become more efficient and develop more targeted approaches. ECHA expects that in this period the first proposals will be developed to restrict the use of substances in imported articles after the sunset date for the authorisation process has passed.

When considering regulatory action it may be the case that REACH is not the most effective solution to address concerns about the impact of a substance through a specific use. In those cases, ECHA will liaise with the Commission and other relevant authorities about the need to use legislative or other regulatory action. In the same way, it is possible to use REACH to manage environmental or health concerns identified during the implementation of other EU legislation. This could lead to

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<sup>10</sup> Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020

requests for information on registered substances or even requests for ECHA to prepare Annex XV restrictions or SVHC dossiers, or to suggest that MSCAs take action in the context of REACH (e.g. for substance evaluation or classification).

ECHA will work together with the Commission to increase the understanding of how REACH could support other EU legislative processes and contribute to developing effective communication between the relevant parties. More generally, ECHA will explore ways of enhancing the coherent implementation of the different pieces of Union legislation related to chemicals.

## 5 ADDRESSING SCIENTIFIC CHALLENGES BY SERVING AS A HUB FOR BUILDING THE SCIENTIFIC AND REGULATORY CAPACITY OF MEMBER STATES, EUROPEAN INSTITUTIONS AND OTHER ACTORS

ECHA is a regulatory organisation with a mission in a scientific and technical context. Scientific knowledge related to chemicals management is progressing on all fronts. Significant and rapid development is being made, especially in (eco)toxicology, with an emphasis on better understanding the biological mechanisms leading to an adverse effect, rather than just observing the effect. Systems biology, bioinformatics, increased understanding of modes of action and adverse outcome pathways will also affect the way chemicals are tested, or how their properties can be predicted, thus enabling reduction in traditional animal testing. Other examples of scientific developments include effects on endocrine systems of humans and wildlife, hazards and risks posed by nanomaterials, and combination effects of chemicals. In addition to understanding the effects of chemicals better, methodological advancements are taking place in the areas of exposure assessment. Even beyond natural sciences, there are challenges and developments relevant for ECHA also in the areas of socio-economic assessment, and especially on how to evaluate the benefits of proposed risk reduction measures.

The above areas are seen as main priorities for ECHA where the Agency needs to be fully aware of these developments when making judgments about the scientific adequacy of information provided by companies, when issuing regulatory opinions and decisions, or when providing guidance about how to fulfil the requirements of the legislation. Therefore, ECHA has to further develop its scientific and regulatory capacity and expertise, in partnership and dialogue with the science community, and encompass scientific developments and emerging regulatory needs.

An essential element in ECHA's regulatory science capacity is the expertise and knowledge of its staff, and their professionalism and commitment. ECHA also needs to take into account the scientific capacity of its own Committees, of Member State authorities, other agencies, international partners and relevant actors.

Another aspect of ECHA's scientific capacity is as an active participant in the science community of professionals and academics.

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

The overall implementation approach is divided into three action areas:

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

### 5.1 Expertise and capacity building

ECHA needs a knowledge management framework to identify the needs for further capacity-building and support their implementation as an integral part of the overall strategic and day-to-day management. While many elements to support this are already in place, a more systematic approach needs to be developed. This framework will ensure that ECHA can be proactive in adapting its scientific and regulatory capacity through training and development to meet the new competence challenges it will be facing. Due to the dynamic nature of the progress in science and in the regulatory field a regularly reviewed competence mapping will provide a basis for the framework.



The starting point will be carrying out a benchmark study of knowledge management concepts and practices in relevant institutions. Benchmarking can be made against other EU agencies (e.g. EFSA and EMA) but may also include ECHA's international partners and relevant national institutes. This will set the basis for building a competence map to identify current strengths and needs for development in the medium term.

The next step is to ensure that the identified development needs are given correct priority; the priority setting will reflect both the current operational needs and foreseen medium and longer term challenges. In this way, the regulatory relevance of the capacity building activities will be taken into account in a formal and clear way, in focused development of in-house expertise in areas of special relevance to ECHA's work and where there are gaps and areas of scientific developments.

Continuous professional development of skills of staff is important. This encompasses both training and development for junior staff and developing and keeping up to date in the field for all staff. Examples of how to do this, in addition to on-the-job learning, are active participation on scientific and professional meetings and workshops, co-authoring scientific papers, lectures by invited experts and professional accreditation schemes.

The results of the mapping and capacity building will be linked directly to ECHA's regulatory activities (e.g. the update of work plans for nanomaterials or test methods, development of approaches for addressing endocrine disruptors, or guidance development in relevant areas). Both the mapping and the implementation plan for capacity building will be revised on a regular basis.

ECHA plans to start developing this framework firstly for internal use, but will also extend it to cover its Scientific Committees. This is a necessity as a major part of ECHA's scientific output is coming via Committee opinions and agreements, and also as the Committee members hold an invaluable amount of scientific knowledge and expertise that is already building part of the shared knowledge asset supporting ECHA. After these first steps, ECHA will also assess the feasibility of extending the approach to also cover ECHA's key partners to enable efficient coordination and optimal use of resources of all relevant actors.

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

## **5.2 Serving as a hub for excellence in regulatory science**

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

At the same time, the concept of the hub does not mean or require ECHA to be the top expert in all areas. It is rather providing a platform and a network of expertise where the experts from ECHA together with those i.e. from Member States, the Commission, other Agencies, international organisations and academia can come together to address relevant topics. The other important aspect of the hub is that it is not intended to focus on academic research topics, but instead it will be strongly need oriented and serving the regulatory decision-making and scientific opinion-forming of ECHA. ECHA already has useful elements and structures in place that are based on the hub concept. Examples include the PBT expert group and nanomaterials expert group. In addition, many adhoc workshops are taken place annually with a strong focus on science in regulatory decision-making, such as substance identity and the application of new test methods or alternative approaches to testing. To create synergies, ECHA is also inviting Member State authorities to training sessions primarily designed for ECHA's internal staff. Similarly, ECHA is contributing to, and benefiting from activities hosted by other actors; examples include Commission work on endocrine disruptors and combination effects, and OECD work on adverse outcome pathways.

In addition, this approach means strengthening and developing activities already in place under the agreements or memoranda of understanding with other relevant EU and international partners. In particular, ECHA will invest in further developing the partnership and cooperation with the

Commission's JRC, to maximise the synergies of combining R&D and regulatory activities in the areas of alternative test methods, computational toxicology and other non-testing approaches, integrated testing strategies, as well as nanomaterials.

To facilitate a closer dialogue between academia and regulatory science, ECHA foresees organising topical scientific workshops, e.g. with a view to assess the regulatory impact of the latest scientific developments on a specific area and how they could be transferred to methodologies applied and guidance and tools developed by ECHA. The workshops will have a strong regulatory perspective and relatively high visibility. ECHA plans to also engage Member States, the Commission, and other relevant actors as co-organisers of or contributors to these workshops in the spirit of the hub concept. ECHA will also participate and contribute to equivalent initiatives from other relevant actors.

Topics in regulatory science of high priority, also in the future, include endocrine disruptors, nanomaterials, combination effects, read-across/grouping of substances, integrated testing strategies, non-standard methods for information for the 2018 registrations and dealing with uncertainty in predicted properties for risk assessment and classification.

With regard to nanomaterials, ECHA aims to ensure that the regulatory requirements of REACH, CLP, and BPR can be fully implemented to address the hazards and risks of substances in nano-form. ECHA will further extend its internal capacities in the area of the characterisation, hazard and safety assessment and risk management of nanomaterials; the Agency will also enable Member States' experts to participate in capacity building and will share experience with stakeholders. ECHA will participate in relevant scientific and regulatory activities at the EU and OECD level with the aim of developing appropriate guidance for industry, as well as being able to evaluate registration dossiers that contain information on the hazards, risks and risk management of nanomaterials, effectively.

The expected benefits of this activity include:

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

### 5.3 ECHA's Regulatory Science Strategy

The scientific credibility of ECHA requires the active involvement of its staff in the new developments in regulatory science, particularly in the areas of hazard and risk assessment and risk management. ECHA will therefore review the various elements already in place concerning its scientific activities and interface and cooperation with scientific organisations and projects. This means building a more coherent strategy that will have the four strategic objectives as its starting points, and can set overall goals for ECHA's scientific activities.

The strategy will allow for clear and consistent prioritisation of contributing to research activities. On regular basis, ECHA is requested to be a partner or a reference in research projects, for example under the Framework Programme projects. As ECHA cannot use its resources to actually carry out research, the participation is normally foreseen in the form of membership in steering boards, and contributing to project plans and research programmes to ensure regulatory relevance of these activities. In addition, publication and dissemination of scientific assessments arising from ECHA regulatory work will be considered. Furthermore in developing the strategy, ECHA can set general principles and priorities for allowing research projects to benefit from ECHA's databases and information assets.

As described in the previous section, ECHA aims to strengthen its strategic cooperation with the Commission's JRC with a view of creating a mutually beneficial regulatory science partnership. This will be elaborated in the science strategy. This strategy should also have an effect on the MoU's with other EU agencies and other partners mentioned above so synergies can be identified. As part of this activity the current ECHA graduate scheme to promote career development of young regulatory scientists will be further developed.

The expected benefits of this activity include:

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

## **6. EMBRACING CURRENT AND NEW LEGISLATIVE TASKS EFFICIENTLY AND EFFECTIVELY, WHILE ADAPTING TO UPCOMING RESOURCE CONSTRAINTS**

As mentioned earlier in the chapter on ECHA's drivers, the Agency is facing a challenging time. This is caused by the combination of expected resource constraints in the EU's next multi-annual financial framework 2014–2020; the continuously high volume of regulatory tasks under REACH and CLP; the work on future strategic objectives as outlined here; and the assignment of new regulatory tasks to ECHA such as biocides and PIC.

Without achieving higher efficiency and maximising the synergies between the Agency's tasks, ECHA will not be able to achieve the ambitions set out in this five-year plan. At the same time, higher levels of efficiency must not mean lower levels of effectiveness. The continuous improvement of its more mature operations should aim at both higher efficiency and increased effectiveness.

Whereas initially the focus of the work on biocides and PIC has been on setting up new processes and structures to cope with the new tasks and rapidly increasing workload, the real challenge is to demonstrate that by handing over these tasks to ECHA, an overall efficiency gain has indeed been achieved, as foreseen by the EU regulator.

In terms of organisation, ECHA's approach to absorbing the new legislative demands has been based on two principles. Firstly, it has integrated new processes which have significant commonalities with the existing REACH and CLP ones in the same organisational units already performing them. Good examples of this have included the dossier submission function, IT development, HelpDesk, guidance production, communications, human resources and so on. Secondly, the new and unique elements of the legislation are the responsibility of a specific biocides function. The appropriateness of ECHA's organisation will be reviewed, if needed.

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

1. Maximising the effectiveness and efficiency of existing and new work processes;
2. Delivering integrated and re-usable IT systems and services; and
3. HR policies and initiatives for maximising the potential of staff members and coping with decreasing staff levels.

### **6.1 Maximising the effectiveness and efficiency of existing and new work processes**

All four pieces of legislation (REACH, CLP, Biocides and PIC) have many similarities. These commonalities suggest that many of the processes and tools established for REACH and CLP should be able to be used in a similar fashion for Biocides and PIC. In this way, time, money and effort will be saved as well as there being a net gain in terms of the possibility to link the information on chemicals together so that it is more helpful and user friendly for the public. However, it is also true to say that, when looked at in detail, the processes required for the differing legislation are not identical and so there still remains work to re-engineer them so that they are fit for purpose for all four laws. In the area of biocides a topic of specific importance for ECHA is to take over the review programme of active biocidal substances from the European Commission. ECHA has the ambition to increase the efficiency and to speed up the output of that programme, in cooperation with the Member States. This is crucial both from the point of view of achieving the desired impact of the BPR, and also has a direct impact on future fee income for ECHA arising from subsequent product authorisation.

Starting in 2014, after the second REACH registration deadline, the efficiency and effectiveness of the REACH and CLP work processes will be reviewed. These reviews will be done both from an internal and external – i.e. customers' point of view – and specific attention will be given to the needs of SMEs. Based on that review, the need for refinement or re-engineering will be planned. The aim will be to make any necessary changes well before the run up to the 2018 REACH deadline.

ECHA will also review the overall effectiveness and efficiency of the work processes that involve the other European regulatory actors: the European Commission and the Member State competent authorities. Lessons could well be learnt after the first two deadlines and initial enforcement

experiences. ECHA's scientific committees are expected to make efficiency gains and thus be able to cope with the increasing workload.

During the programme period, the objective will also be the integration of any new processes into existing ones to the greatest extent possible, thus limiting the development of new work to the minimum, as was done for Biocides.

## **6.2 Delivering integrated and re-usable IT systems and services**

IT has a fundamental role to play in maximising efficiency where processes can be automated and datamining can be developed to support the Agency's scientific and regulatory work. All four pieces of legislation are very heavily dependent on the use of automated IT systems – to manage the large scale submission processes on paper would require thousands of members of staff. The challenge in 2012 and 2013 was to make use of the tools and know how already developed for REACH and CLP and to use them to improve and integrate the tools necessary for the new legislation. From 2014 to 2018, the new components and services developed for Biocides and PIC will be integrated into ECHA's existing systems with a view to harmonising and consolidating shared solutions to facilitate efficiency in the business processes and in the future maintenance work.

ECHA is committed to making the best use of its IT know-how, components and services to deliver integrated IT support to the new legislative tasks and avoiding a proliferation of new systems and technologies. A key part of that is building on what works and designing out the most time consuming and error-prone manual tasks. ECHA will implement these IT systems in a modular architecture to ensure that the common components are reusable. In this respect, the data and systems integration programme which began in 2011 will deliver a data integration platform and an interactive portal in the first part of the period.

Particular attention will be devoted to the devolved processes where ECHA and the MSCAs both play roles and need to share the same IT tools to avoid the inefficiency and risks of moving data from one system to another in a manual or poorly automated fashion.

Also during the period 2014-2018, ECHA will plan the improvement of the IT systems for dissemination. Through REACH, CLP, Biocides and PIC, the volume of data on chemicals in Europe will be massive – presenting a valuable source for stakeholders worldwide. Starting in 2012 with a study on stakeholders' requirements, ECHA plans to increase the automation of data processing, improve the integration of the data sources, enhance the usability and searchability and prepare for the integration of ECHA data sources with those available from other actors including regulatory bodies, academia, consumer groups and industry. In this way, maximum use will be made of the data generated in the EU.

On an internal level, IT developments during the period will further automate and streamline some elements of the management processes, planning and reporting.

Of course the increased reliance on IT requires an assurance that it is resilient enough to withstand major incidents or disruptions. Therefore, ECHA will continue its investment in making its ICT infrastructure more resilient, easy to operate and flexible; easy to expand and more redundant to withstanding incidents.

Finally, given the fast-paced evolution of technology and the natural life-cycle of IT systems, there will be one major technological and architectural revision of the broad landscape of IT solutions and services within the period.

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

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

The Agencies' human resources policies and practices must therefore cater for the current demands (through the short-term cycle of objective setting, performance appraisal, training, etc), but must also be flexible enough to deliver on new areas of work and in situations of decreasing staff levels

(through the long-term cycle of organisation development and flexibility, priority setting, culture and leadership).

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

## **7 RESOURCE OUTLOOK**

**[To be completed once MFF has progressed]**

## **ANNEXES**



## Annex 1 : Milestones

<b>1 High quality information for safe manufacture and use</b>							
<b>Strategic action area 1.1 Improving quality of information in dossier</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>1,5,6,10</b>	<b>1.1.1 Preparation of dossiers</b>	Industry making best use of ECHA's advice, training and tools provided to registrants and downstream users	<p>Proposal for a structured data format for the CSR</p> <p>Screening of the C&amp;L notification database in order to identify substances that need further investigation</p>	<p>Criteria established for substance sameness</p> <p>Strategy, methods and tools (e.g. linked to the QSAR Toolbox) for supporting 2018 registrants in relation to REACH Annex III</p> <p>Chesar upgraded for CSA of complex substances</p>	<p>Review of the Guidance on Substance Identification and Naming</p> <p>New and revised dossier preparation tools and manuals</p>	<p>Simplified Guidance helping SMEs</p> <p>Webinars and workshops for 2018</p> <p>Training (update) of national helpdesk correspondents on dossier preparation</p>	<p>Training (update) of national helpdesk correspondents on dossier submission</p>

				(e.g. UVCBs)			
<b>2,6,10</b>	<b>1.1.2 Submission of dossiers</b>	Industry is making use of the IT tools to achieve successful registration and enable authorities to use the information.	New version of IUCLID specified for improving the data structure  IT-based screening of all 2013 intermediate dossiers completed	Upgrade of Completeness check tool, in particular for checking safety information or biocidal information  Inconsistencies on intermediate dossiers addressed		REACH-IT ready for the 2018 registration deadline  Multilingual support in place  Outreach campaign in preparation of the 2018 deadline	Successful management of the 2018 registration deadline
<b>2,6,10</b>	<b>1.1.3 Evaluation of dossiers</b>	IT-tools for screening and processing of compliance checks available and at an advanced level.  Support from MSCAs to the	Framework of screening/prioritisation tools for compliance checks on IUCLID data in place  Plan for systematic	All 2010 dossiers screened and majority of the significantly non-compliant dossiers have been addressed under CCH	5% of 2013 dossiers checked for compliance	Relevant findings on registration dossier quality reported in Article 117(3) report	All 2013 dossiers screened and majority of the significantly non-compliant dossiers have been addressed under CCH

		approach chosen.	approach for compliance check on CSRs  Relevant findings on registration dossier quality reported in Article 117(3) report				
<b>Strategic action area 1.2 - Maximising the impact of communication of risk management advice in the supply chain</b>							
<b>WP Activity</b>	<b>Priority</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>1,3,5,10</b>	<b>1.2.1 Exposure scenarios and safety data sheets</b>	Sufficient industry coordination and development of industry tools.	Updated downstream user guidance available in EU languages  New examples of good exposure scenarios  Long term plan	Updated SDS guidance available in EU languages  Review of the CSA Roadmap	Review of downstream user support tools	Review of the progress achieved under CSA Roadmap (Cross-Stakeholder Roadmap to ensure accuracy and clarity in CSAs)	

			for awareness raising campaigns for registrants and downstream users				
<b>3,10</b>	<b>1.2.2 Substances in articles</b>	Clarity of the interpretation of the 0.1% criterion.	Communication campaign(s) towards importers of articles	Setup of targeted regulatory cooperation with non-EU countries to increase understanding on the REACH requirements			
<b>Strategic action area 1.3 – Improving the dissemination information</b>							
<b>WP Activity</b>	<b>Priority</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>1</b>	<b>1.3.1 Dissemination of substance information</b>	IT systems for REACH, C&L, Biocides and PIC Regulations integrated to streamline processes and	Information from 2013 registration deadline and from existing Biocides dossiers published	Launch of the new fully fledged REACH and C&L dissemination web pages based on the			Dossiers from 2018 registration deadline published

		reduce time to publication.  Stakeholders' engagement.	GHS information available on eChemPortal	2012-2013 stakeholders' study  Assessment of the confidentiality requests on 2013 registration dossiers completed			
<b>1,2,3,4</b>	<b>1.3.2 Publication of decisions</b>		Policy on access to data and publication of REACH and CLP decisions put in place	All decisions on 2010 dossiers published			All decisions on 2013 dossiers published

## 2 Using information intelligently to identify and address chemicals of concern

<b>Strategic action area 2.1 – Mobilising authorities and aligning their views</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>2, 3, 4, 8</b>	<b>2.1.1 Mobilising authorities and aligning views</b>	Policy support; Availability of resources in Member States.	Progress review workshop  Agreed decision logic for identifying needs for and addressing concerns through RRM  Common understanding on priorities for enforcement on RRM  Further Forum interlinks workshops	Joint enforcement project on authorisation initiated	Progress review workshop  Review of the approaches for recommendation for Annex XIV  Further Forum interlinks workshops	Conclusion of the joint enforcement project	Progress review workshop  Further Forum interlinks workshops

<b>Strategic action area 2.2 – Identification of candidate substances for regulatory risk management</b>
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<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>1, 3, 4</b>	<b>2.2.1 Screening</b>	Constantly improving quality of registration and notification data.	Preliminary analysis of 2013 registration data for potential regulatory risk management  Database on regulatory status of CMRs available	System developed to define and initiate regulatory actions on Annex XIV after the sunset date  System in place to monitor harmonisation of self-classifications			
<b>3,7</b>	<b>2.2.2 Criteria, approaches and tools</b>	Criteria on endocrine disruptors decided by the Commission.	Set up of expert group relevant to RM, e.g. on endocrine disruptors  2020 Roadmap Implementation Platform		Review report on 2020 roadmap implementation		Review report on 2020 roadmap implementation

			operational				
<b>2, 3</b>	<b>2.2.3 Filling information gaps</b>	Resources available in MSCAs and ECHA.	Results of screening of 2013 registration for candidates for substance evaluation	Evaluation of the implementation and relevance of the outcome of the substance evaluation process in the first three years (2012 – 2014) for RRM.	Reporting on the findings of the evaluation and recommendations [in Article 117(2) report.]	Implementation of the recommendations	Second evaluation of the substance evaluation process (2015-2017)
<b>3, 4</b>		Effective screening and agreement on priorities for CLH.  Potential applicants, including downstream users are well	Further awareness campaign to enforce harmonisation of self-classifications  Willingness to pay reference values on first set of health	Reduction of the average processing time of C&L proposal by 20%  Report identifying priority areas for industry efforts to	Database of Commission decisions on authorisations operational  First proposals developed on Annex XIV substances in		



		informed about the requirements for application for authorisation.	endpoints  First substance specific workshop for RAC and SEAC on applications for authorisation	harmonise self-classification  Adaptation of submission tools and guidelines for SMEs and downstream users  Willingness to pay reference values on 2 <sup>nd</sup> set of health endpoints	articles  Workshop on how to prepare restrictions dossiers		
<b>3</b>	<b>2.3.4 Addressing identified concerns through REACH, CLP and other legislations</b>		1-2 workshops on interface between other legislations	Update Guidance when overlaps with other EU legislation  Improved coordination mechanism in place for implementation of legislations related to chemicals	1-2 workshops on interlinks between other legislations	Update Guidance accordingly	1-2 workshops on interlinks between other legislations

<b>3 Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors</b>							
<b>Strategic action area 3.1 – Expertise and capacity building</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>7</b>	<b>3.1.1 Expertise and capacity building</b>	ECHA's scientific and regulatory capacity is adequate and continuously developed to response to the needs.	The concept of knowledge management framework (KMF) is developed and regular competence mapping is started  ECHA workplan on nanomaterials updated	Extend KMF to ECHA Committees  Analyse and conclude on feasibility to extend the KMF to external partners  ECHA workplan on Test Methods updated	External review of ECHA scientific capacity	Actions resulting from the 2016 REACH review	
<b>Strategic action area 3.2 – A hub for excellence in regulatory science</b>							
<b>WP</b>	<b>Priority area</b>	<b>Critical</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>

Activity		success factors					
	<p><b>3.2.1 Hub for excellence in regulatory science</b></p>	<p>A network approach is used to optimise the effectiveness and efficiency of scientific and regulatory capacity building.</p>	<p>A regulatory science workshop; management of uncertainty in predicting chemical properties</p> <p>Creation of network of MS and stakeholders on SEA in Restrictions and Applications for Authorisation</p> <p>ECHA's second report on the use of alternatives to testing on chemicals under REACH. Follow-up actions agreed to advise the 2018 registrants</p> <p>Review of bilateral cooperation agreements with ECHA's international partners to better</p>	<p>1-2 regulatory science workshops (possible topic: how to improve assessment of health impacts to advise regulatory risk management)</p> <p>ECHA Committee members and MSCA's are integrated into the capacity building planning.</p> <p>Improved read-across and grouping using new-</p>	<p>1-2 regulatory science workshops</p> <p>Improved assessment of skin sensitisation using an ITS approach from JRC/ OECD AOP approach</p>	<p>1-2 regulatory science workshops</p> <p>Other relevant actors (e.g. other Agencies) are integrated into the capacity building planning</p>	<p>1-2 regulatory science workshops</p>

			reflect scientific developments  Read-across assessment framework (RAAF) established	approach data from SEURAT-1			
<b>Strategic action area 3.3 – ECHA’s regulatory science strategy</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	
	<b>3.3.1 ECHA’s Regulatory Science Strategy</b>	ECHA is able to both influence and benefit from the relevant scientific agenda.	ECHA Science Strategy is established  ECHA priorities for the next Framework Programme for research established and communicated	ECHA’s cooperation with JRC reviewed and strengthened	External review of ECHA scientific capacity	Update to the Science Strategy resulting from the 2016 REACH review	

<b>4 Embracing current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints</b>							
<b>Strategic action area 4.1 – Maximising the effectiveness and efficiency of existing and new work processes</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>All</b>	<b>4.1.1 Quality system</b>	Management and staff have an understanding of what IQMS serves.  All relevant elements of the system are in place.		ISO 9001 certification			
<b>1-6, 8</b>	<b>4.1.2 Process re-engineering</b>		Review of the REACH and CLP processes			Re-engineering of REACH and CLP processes completed	
<b>16</b>	<b>4.1.3 Biocides</b>	Biocides IT systems are in place.  Member states and applicants are using	All biocides processes operational including those related to the Review Programme			First extension of the scope of Union Authorisation	

		consistently the IT systems.					
<b>17</b>	<b>4.1.4 PIC</b>		PIC process operational				
<b>Strategic action area 4.2 – Delivering integrated and re-usable IT systems and services</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Act 6,15</b>	<b>4.2.1 Deliver IT support for regulatory processes</b>	<p>The change management for external actors is effective.</p> <p>Industry takes up and adopts the non-mandatory IT tools and formats delivered by ECHA.</p> <p>The IT strategy foundations (implemented in 2011-2013)</p>	Deliver IT support for distributed processes in Biocides, PIC, REACH	Complete the data and system integration programme (data integration hub, portal dashboard)	Complete refactoring of the IT systems for dissemination processes	<p>Complete refactoring of industry facing systems to consolidate IT tools for incoming and communication processes and to enhance usability (SMEs)</p> <p>Readiness for last REACH deadline</p>	

		prove to be a good platform for sustaining IT growth in an efficient manner.					
	<b>4.2.2 Deliver IT support for administrative processes</b>	Change management for internal actors is effective.	Deliver IT support for HR management	Deliver IT support for integrated planning and reporting			
	<b>4.2.3 Ensure adequacy of ICT infrastructure</b>	The IT strategy foundations (implemented in 2011-2013) prove to be a good platform for sustaining IT growth in an efficient manner.	Enhance IT for Business Continuity (focus back-up environments) and efficient operability	Deliver enhanced IT for communication and collaboration (Local Area Network, voice, mobile, email, etc.)	Possible refactoring	Readiness for last REACH deadline	
<b>Strategic action area 4.3 – HR policies and initiatives</b>							
<b>WP Activity</b>	<b>Priority area</b>	<b>Critical success factors</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>14</b>	<b>4.3.1</b>		Implementation of	Implementation	Development	Development	Enhance

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	<b>HR Policies and Initiatives</b>		knowledge management framework	of HRMS	of long-term vision for HR requirements	of five year HR Strategy	
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**Annex 2 : Multi-annual staffing plan**

	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>REACH and CLP</b>					
TAs	446	442	438	434	434
CAs	96	97	98	99	100
<b>Total</b>	<b>542</b>	<b>539</b>	<b>536</b>	<b>533</b>	<b>534</b>
<b>Biocides</b>					
TAs	48	49	50	60	63
CAs	11	11	11	9	12
<b>Total</b>	<b>59</b>	<b>60</b>	<b>61</b>	<b>69</b>	<b>75</b>
<b>PIC</b>					
TAs	6	6	6	6	6
CAs	1	1	1	1	1
<b>Total</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>7</b>

**Annex 3: Baseline figures for 2014-2018<sup>11</sup>**

<b>ECHA's main activity drivers</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Dossiers arriving REACH and CLP</b>					
Registration dossiers (including updates)	5800	5700	5000	6700	69000
Testing proposals	70	70	70	70	70
Confidentiality requests	250	240	320	390	3460
Access to data older than 12 years	270	290	320	350	390
PPORD notifications (incl. requests for prolongation)	400	400	420	420	420
Inquiries (initial)	1300	1400	1600	1700	1900
Data sharing disputes	7	7	8	10	50
Number of notifications under REACH Art. 7(2)	70	70	70	70	70
Number of reports/notifications under Article 38	4400	270	120	220	310
Restriction proposals (REACH Annex XV)	8	9	10	11	12
Including Restriction proposals developed by ECHA	3	3	4	5	6
Proposals for harmonised classification and labelling (CLP Annex VI)	70	70	70	70	70
Proposals for identification as SVHC (REACH Annex XV) <sup>12</sup>	50	50	50	50	50
Including SVHC dossiers developed by ECHA	5	5	5	5	5
Authorisation applications	20	40	100	100	100
Alternative name requests	150	200	250	250	250
Substances on the CoRAP to be evaluated by MSs	50	50	50	50	50
<b>ECHA decisions REACH and CLP</b>					
Evaluation					
- No. of decisions on TP	180	180	180	70	70
- No. CCH concluded	290	290	290	290	570
- Out of which CCH decisions	180	180	180	180	350
- No of substance evaluation decisions	45	45	45	45	45
Decisions on data sharing	2	0	0	0	4
Decisions on completeness	190	180	164	213	2084

<sup>11</sup> The baseline numbers are assumptions made at the time of preparing the MAWP to indicate the future workload. These numbers are based on the original Commission estimates updated with any new information ECHA has gained.

<sup>12</sup> The actual number of SVHC dossiers arriving will depend on the outcome of the RMO analyses.

<b>ECHA's main activity drivers</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
check (negative)					
Decisions on confidentiality requests (negative)	50	30	39	49	350
Decisions on access to documents requests	500	600	700	800	900
<b>Appeals</b>					
<b>Appeals</b>	20	20	20	20	50
<b>Others</b>					
Updates of the CoRAP for substances subject to substance evaluation	1	1	1	1	1
Recommendations to the European Commission for the Authorisation List	1	1	1	1	1
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	6 000	6 000	6000	6000	6000
General enquiries by phone or email	600	600	600	600	600
Press enquiries	2000	1500	1500	2000	2500
Press releases and news alerts					
SME checks	350	400	400	400	400
Management Board meetings	4	4	4	4	4
MSC meetings	6	6	6	6	6
RAC meetings	6	6	6	6	6
SEAC meetings	5	6	6	6	6
Forum meetings	3	3	3	3	3
Recruitment due to turnover	25	25	25	25	25
<b>Biocides</b>					
Applications for new active substance approval	5	5	5	5	5
Applications for renewal or review of active substances	3	3	0	2	4
Opinions on active substances in the Review Programme	40	50	50	50	50
Applications for Union authorisation	20	60	60	90	100
Assessment of technical equivalence	50	50	20	20	20
BPC meetings	4	6	7	7	7
New TA/CA posts to be filled for Biocides	2	0	0	10	3
<b>PIC</b>					
Notifications	4000	4400	4900	5400	5900

<b>ECHA's main activity drivers</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
New TA posts to be filled for PIC	1	0	0	0	0