ECHA
EUROPEAN CHEMICALS AGENCY

Multi-Annual Work Programme 2014-2018

Annexes - Review 2015

Multi-Annual Work Programme 2014-2018:

Annexes Review 2015

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Annex 1 : Milestones 2016 - 2018 Review 2015

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1 High Quality information for safe manufacture and use							
Strategic action area 1.1 Improving quality of information in dossier							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
1,5,6,10	1.1.1 Preparation of dossiers	Industry making best use of ECHA's advice, training and tools provided to registrants and downstream users.	Proposal for a structured data format for the CSR. Screening of the C&L notification database in order to identify substances that need further investigation.	Methodology established for substance sameness. Potential Review of the Guidance on Substance Identification and Naming or other types of material for addressing substance sameness Strategy, for supporting 2018 registrants in relation to REACH Annex III Chesar upgraded (e.g. for complex substances and alignment with IUCLID 6)	Simplified access to guidance helping SMEs Launch of Phases 3 and 4 of the REACH 2018 Roadmap New and revised dossier preparation tools (IUCLID 6, Validation Assistant (including Completeness check) and Chesar 3) and manuals	Launch of Phases 5 and 6 of the REACH 2018 RoadmapTraining (update) of national helpdesk correspondents on dossier preparation	Training (update) of national helpdesk correspondents on dossier submission

1 High Quality information for safe manufacture and use							
Strategic action area 1.1 Improving quality of information in dossier							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
1, 2, 6, 10	1.1.2 Submission of dossiers	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 Review of the compliance check process and a plan for an upgrade, if necessary	Implementation of the plan regarding the Completeness check tool and process, as appropriate, in particular for checking safety information Plan for use of measures complementary to CCH developed Inconsistencies on intermediate dossiers or other types of dossiers (depending on the revised strategy in 2014) addressed	REACH-IT ready for the industry for the 2018 registration deadline (including preparation for multilingual support, as appropriate) Launch of the revised completeness check process including a manual verification of certain data requirements (e.g. substance identity)	Outreach campaign in preparation of the 2018 deadline REACH-IT: Further simplified online functions for submitting dossiers (DCM) Measures complementary to CCH reviewed and refined	Successful management of the 2018 registration deadline

1 High Quality information for safe manufacture and use							
Strategic action area 1.1 Improving quality of information in dossier							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
2,6,10	1.1.3 Evaluation of dossiers	IT-tools for screening and processing of compliance checks available and at an advanced level Support from MSCAs to the approach chosen	Framework of screening/ prioritisation tools for compliance checks on IUCLID data in place Plan for systematic approach for compliance check on CSRs Relevant findings on registration dossier quality reported in Article 117(3) report	› 1000 tpa and 100 – 1000 tpa dossiers screened with available IT-tools and priorities for CCH (and complementary measures) till end of 2018 set	100% of the TPs from 2013 registration concluded (DDs issued) In line with the CCH Strategy, at least 100 priority substances of concern arising from the common screening approach are addressed under complementary measures or CCH, in accordance with the priorities set in 2015	At least 100 priority substances of concern are addressed under complementary measures or CCH, in accordance with the set priorities Testing proposals re-submitted in 2016 on reproduction toxicity concluded (DDs issued) Review of the CCH strategy and priorities	At least 100 priority substances of concern are addressed under complementary measures or CCH, in accordance with the refined priorities set in 2017 Plan for compliance checks 2019-2020 established

Strategic action area 1.2 - Maximising the impact of communication of risk management advice in the supply chain							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
1,3,5,10	1.2.1 Exposure scenarios and safety data sheets	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 for awareness raising campaigns for registrants and downstream users	Review of progress made on the CSR/ ES Roadmap and revision of the document if needed	Review of downstream user support tools	Review of the progress achieved under CSR/ES Roadmap and analysis of further needs to ensure effective supply chain communication	
3,10	1.2.2 Substances in articles	Sufficient level of priority put by MSCAs (and NEAs) on the implementation of the SiA activities Clarity of the interpretation of the 0.1% criterion	Communication campaign(s) towards importers of articles	Awareness raising and support activities towards importers of articlesSetup of targeted regulatory cooperation with non-EU countries to increase understanding on the REACH requirements	Awareness raising and support activities towards importers of articles	Review of the SiA notification support tools, including information on SVHCs in materials	

Strategic action area 1.3 – Improving the dissemination information							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
1	1.3.1 Dissemination of substance information	IT systems for REACH, C&L, Biocides and PIC Regulations integrated to streamline processes and reduce time to publication Stakeholders' engagement	Information from 2013 registration deadline and from existing Biocides dossiers published GHS information available on eChemPortal	Launch of the new REACH and C&L dissemination web pages based on the 2012-2013 stakeholders' study Assessment of the confidentiality requests on 2013 registration dossiers completed	Adaptation of the Dissemination web pages following the changes introduced by IUCLID 6 Disseminated substance information extended and linked to on-going cases under dossier evaluation or Regulatory lists (CoRAP, Candidate List, Annex XIV, etc.)		Dossiers from 2018 registration deadline published and linked to eChemportal for maximising public availability of information on chemicals
1,2,3,4	1.3.2 Publication of decisions		Policy on access to data and publication of REACH and CLP decisions put in place	Decisions on dossiers published in accordance with the policy			

2 Using information intelligently to identify and address chemicals of concern							
Strategic action area 2.1 Mobilising authorities and aligning their views							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
2, 3, 4, 8	2.1.1 Mobilising authorities and aligning views	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	Workshop to promote coherent and effective implementation of REACH and CLP processes Pilot enforcement project on authorisation initiated to gain first experience and build processes for controlling authorisation-related obligations	Workshop on REACHing the WSSD 2020 goals Results of the first enforcement pilot project on authorisation Review the implementation of the authorisation process	Results of the second enforcement pilot project on authorisation Further Forum interlinks workshops	Progress review workshop(s) on the SVHC roadmap and reaching the WSSD 2020 goals

Strategic action area 2.2 Identification of candidate substances for regulatory risk management							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
1, 3, 4	2.2.1 Screening	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 (e.g restrictions under article 69(2) on Annex XIV after the sunset date The identification of substances/-dossiers for REACH/ CLP processes is based on the integrated screening approach Development of targeted actions to stimulate convergence of self classifications		Revision of the screening scenarios to identify substances that matter most to take into account the changed IUCLID 6 and 2018 registrations	
3,7	2.2.2 Criteria, approaches and tools		Set up of expert group relevant to RM, e.g. on endocrine disruptors 2020 Roadmap Implementation Platform operational		Annual report on 2020 SVHC roadmap implementation An approach to address petroleum and coal stream substances under the SVHC Roadmap agreed and implementation started	Annual report on 2020 SVHC roadmap implementation Review of the co-operation supporting the SVHC roadmap implementation	Annual report on 2020 SVHC roadmap implementation

Strategic action area 2.2 Identification of candidate substances for regulatory risk management							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
2, 3	2.2.3 Filling information gaps	Resources available in MSCAs and ECHA	Results of screening of 2013 registration for candidates for substance evaluation	Evaluation of the imple-mentation and relevance of the outcome of the substance evaluation process in the first three years (2012 – 2014) for RRM		Implementation of the recommendations	Second evaluation of the substance evaluation process (2015-2017)

Strategic action area 2.3 Addressing identified concerns through REACH, CLP and other legislation							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
3, 4	2.3.1	Increased awareness of CLH as effective RRMM Potential applicants, including downstream users are well informed about the requirements for application for authorisation	Further awareness campaign to promote harmonisation of self-classifications Willingness to pay reference values on first set of health endpoints First substance specific workshop for RAC and SEAC on applications for authorisation	Reduction of the average processing time of C&L proposal by 20% Report identifying priority areas for industry efforts to harmonise self-classification Adaptation of authorisation submission tools and guidelines for SMEs and downstream users Monetary reference values on 2PndP set of health endpoints	Register of the notifications of downstream users of authorised uses of substances of very high concern Report identifying priority areas for industry efforts to harmonise self-classification First proposals developed on Annex XIV substances in articles Workshop on how to prepare restrictions dossiers based on recommendations from the Restrictions Efficiency Task Force	Analysis of the possibilities to improve the C&L inventory Review of the priority setting approach used for the Annex XIV recommendation Conference on lessons learned of the applications for authorisation	

Strategic action area 2.3 Addressing identified concerns through REACH, CLP and other legislation							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
3	2.3.2 Other legislation		1-2 workshops on interface between other legislations	Update Guidance when overlaps with other EU legislation Scoping study on how to promote the flow and use of information between REACH and CLP and other legislations related to chemicals at company and at authority levels	1-2 workshops on the practical use of REACH/CLP information to support compliance with other legal obligations at company level		1-2 workshops on the practical use of REACH/CLP information to support compliance with other legal obligations at company level

3 Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors							
Strategic action area 3.1 Expertise and capacity building							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
7	3.1.1 Expertise and capacity building	ECHA's scientific and regulatory capacity is adequate and continuously developed to respond to the needs	The concept of knowledge management framework (KMF) is developed and regular competence mapping is started ECHA workplan on nanomaterials updated	Examine the feasibility of extending ECHA's competency management process to ECHA's Committees Analyse and conclude on feasibility to extend the KMF to external partners ECHA workplan on Test Methods, including alternative test methods updated	ECHA scientific staff capacity to assess applicability of alternative methods and approaches reviewed and necessary improvement actions agreed	Review of the competences management framework	

Strategic action area 3.2 A hub for excellence in regulatory science							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
5, 7	3.2.1 Hub for excellence in regulatory science	A network approach is used to optimise the effectiveness and efficiency of scientific and regulatory capacity building	A regulatory science workshop; Creation of network of MS and stakeholders on SEA in Restrictions and Applications for Authorisation ECHA's second report on the use of alternatives to testing on chemicals under REACH. Follow-up actions agreed to advise the 2018 registrants Review of bilateral cooperation agreements with ECHA's international partners to better reflect scientific developments Read-across assessment framework (RAAF) established	1 regulatory science workshop Improved methodology for read-across and grouping Guidance for nanomaterials updated following the scientific and regulatory developments. Updated guidance on reproductive toxicity	1 regulatory science workshop Use of alternatives to animal testing promoted by: i) Guidance for assessment of skin sensitisation using an alternative approach based on OECD AOP concept ii) Guidance for a weight of evidence to predict acute oral toxicity making use of information from repeated dose toxicity studies iii) Improved methodology for read-across and grouping including approaches for nanomaterials ECHA work plan on nanomaterials updated	1 regulatory science workshop Actions resulting from the 2016 ECHA report under Art 117.2 of REACH 3rd Report on use of alternatives under Art 117.3 published	1 regulatory science workshop

Strategic action area 3.3 Expertise and capacity building							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
	3.3.1 ECHA's Regulatory Science Strategy	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		Review of the Science Strategy taking into account the 2016 ECHA report under Art 117.2 of REACH and the 2020 "REACH" goals	
All	4.1.1 Quality system	Management and staff have an understan-ding of what IQMS serves. All relevant elements of the system are in place		ISO 9001 certification		Renewal of certification and possible extension of its scope to biocides and PIC processes	
1-6, 8	4.1.2 Process re-engine-ering	Achieve higher levels of efficiency in a context of increasing resource constraints	Review of the REACH and CLP processes		Efficiency improvements through re-engineering of REACH and CLP processes	Efficiency improvements through re-engineering of REACH and CLP processes	Efficiency improvements through re-engineering of REACH and CLP processes completed
16	4.1.3 Biocides	Biocides IT systems are in place.Member states and applicants are using consistently the IT systems and the guidance of ECHA	All biocides processes operational including those related to the Review Programme		IT support for case management extended to the Biocides processes	Preparedness for the first extension of the scope of Union Authorisation	Review the Union Authorisation process on the basis of experience gained with first years of implementation
17	4.1.4 PIC		PIC process operational				

Strategic action area 4.3 HR policies and initiatives							
WP Activity	Priority area	Critical success factors	2014	2015	2016	2017	2018
14	4.3.1 HR Policies and Initiatives	The HR policies and initiatives are aligned with, and enable ECHA's achievement of its objectives	Implementation of knowledge management framework	Implementation of HRMS	Implementation of a general competency exercise for non-scientific staff	Decision on ECHA's future physical workplace	Review of competency mapping framework

Annex 2 : Multi-annual staffing plan Review 2015

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	2014	2015	2016	2017	2018
REACH and CLP					
TAs	441	437	420	410	404
CAs	98	98	100	106	106
Total	539	535	520	516	510
Biocides					
TAs	48	48	42	42	48
CAs	14	14	10	11	12
Total	62	62	52	53	60
PIC					
TAs	6	6	6	6	7
CAs	1	1	1	1	1
Total	7	7	7	7	8

Annex 3: Baseline figures for 2014-2018[1] Review 2015

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ECHA's main activity drivers	2014	2015	2016	2017	2018
Dossiers arriving REACH and CLP					
Registration dossiers (including updates)	5800	5700	10000	13000	69000
Testing proposals	20	60	70	150	70
Confidentiality requests	250	240	390	540	3290
Access to data older than 12 years	270	350	320	350	390
PPORD notifications (incl. requests for prolongation)	300	400	300	300	300
Inquiries concluded	1300	1400	1600	1700[2]	1900
Data sharing disputes	3	7	10	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	60	70	70	70

1 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.

2 After May 2017 it is no longer possible to submit late pre-registrations. If the current trend observed in the number of late pre-registrations received (12.000 late pre-registrations/year) continues, the number of inquiries is likely to increase dramatically.

ECHA's main activity drivers	2014	2015	2016	2017	2018
Proposals for identification as SVHC (REACH Annex XV)[3]	30	50	50	50	50
Authorisation applications	20	100	30	30	0
Alternative name requests	100	150	100	150	150
Substances on the CoRAP to be evaluated by MSs	50	50	50	50	50
ECHA decisions REACH and CLP					
Evaluation decisions					
Testing proposal	200	220	250	70	70
Compliance Check	150	155	180	180	350
Substance evaluation	35	45	45	45	45
Decisions on data sharing	3	7	10	15	50
Decisions on completeness check (negative)	190	60	100	130	690
Decisions on confidentiality requests (negative)	50	30	50	65	340
Decisions on access to documents requests	100	120	140	160	200
Appeals					
Appeals	20	20	25	25	45
Others					
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

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

ECHA's main activity drivers	2014	2015	2016	2017	2018
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	6 000	6 000	7950	11000	15000
General enquiries by phone or email	600	600	600	600	600
Press enquiries	600	500	500	550	600
Press releases and news alerts	75	60	60	60	60
SME checks	600	400	250	250	400
Management Board meetings	4	4	4	4	4
MSC meetings	6	6	6	6	6
RAC meetings	4	6	8	6	6
SEAC meetings	4	5	6	6	6
Forum meetings	3	3	3	3	3
Recruitment due to turnover	25	20	25	25	25
Biocides					
Applications for new active substance approval	5	2	2	5	5
Applications for renewal or review of active substances	3	3	0	2	4
Opinions on active substances in the Review Programme	50	50	50	50	50
Applications for Union authorisation	20	12	10	10	20
Assessment of technical equivalence	50	50	20	20	20
BPC meetings	5	6	5	6	6
New TA/CA posts to be filled for Biocides	2	0	0	6	7
Biocide appeals	3	3	1	1	1

ECHA's main activity drivers	2014	2015	2016	2017	2018
PIC					
Notifications	4000	4000	6000	6800	7700
New TA posts to be filled for PIC	1	0	0	0	1

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