ECHA
EUROPEAN CHEMICALS AGENCY

Consolidated Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2017

LIST OF ACRONYMS

BPR	Biocidal Products Regulation
CA	Contract Agent
CAAR	Consolidated Annual Activity Report
CLP	Classification, Labelling and Packaging
CSA	Chemical Safety Assessment
DCM	Directors' Coordination Meeting
DNA	Designated National Authority
DPO	Data Protection Officer
ECA	European Court of Auditors
ECHA	European Chemicals Agency
ED	Executive Director
EFTA	European Free Trade Association
ENES	Exchange Network of Exposure Scenarios
EUCLEF	EU Chemical Legislation finder
EUON	EU Observatory for Nanomaterials
Forum	Forum for Exchange of Information on Enforcement
FR	ECHA Financial Regulation
FTE	full-time equivalent
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Union
IMS	ECHA Integrated Management Standards
ISO	International Organization for Standardization
IQMS	Integrated Quality Management System
KPI	Key Performance Indicator
MB	Management Board
MBWG	Management Board Working Group
MSCA	Member State Competent Authority
PIC	Prior Informed Consent
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	central IT system providing support for REACH
SEV	substance evaluation
SO4	Strategic objective 4
SME	small and medium-sized enterprise
TA	Temporary Agent

MANAGEMENT BOARD'S ANALYSIS AND ASSESSMENT

The Management Board provides its assessment of the Consolidated Annual Activity Report and instructs the Executive Director to send the Assessment of the Consolidated Annual Activity Report as adopted not later than 1 July 2018 to the Court of Auditors, the European Parliament, the Commission and the Council.

The European Chemicals Agency (ECHA) was created in 2007 to manage and steer the implementation of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. As initially foreseen, REACH was implemented in 2009 together with the Classification, Labelling and Packaging (CLP) regulation. Later, the Commission decided to transfer the work on more activities and regulations to ECHA. Those new tasks started with the entry into force of the Biocidal Products Regulation (BPR) in 2013 and the Prior Informed Consent (PIC) regulation in 2014. ECHA was asked to manage the latter regulations separately from REACH/CLP and make sure that fee revenues from REACH/CLP and BPR would not be mixed.

INTRODUCTION

The Consolidated Annual Activity Report of the Authorising Officer responds to the requirements as laid down in the Financial Regulation of ECHA and reports on the performance of the duties of the Executive Director as the Authorising Officer and Appointing Authority of the Agency.

The report is drawn up by the Executive Director under his own responsibility and submitted to the Management Board for information.

In line with the Financial Regulation, the Management Board is expected to make an assessment of the Consolidated Annual Activity Report (CAAR) which has to be submitted, together with the CAAR, to the Court of Auditors, the European Parliament, the Commission and the Council no later than 1 July 2018.

The Consolidated Annual Activity Report covers Parts II, III and IV and the pertaining annexes.

The Achievements of the year (Part I) are covered by the General Report.

EXECUTIVE SUMMARY

A summary on key achievements of the year are covered by the General Report (Part I) which together with its pertinent Key Performance Indicators (KPIs) are an integral part of the Authorising Officer's report. Despite the risks and constraints in some areas, ECHA has reached most of its KPI targets of 2017 (70 out of 79 targets were met).

In 2017, the Agency has been able to adapt to changes in the external environment having impact on its activities and resources and has taken further steps in designing its next strategic plan for the years 2019-2023. Major preparations and scenarios planning were conducted in view of preparing for the 2018 registration deadline.

The fees and charges collected covered 38% of the Agency's expenditure. Managing the annual budget was challenging similarly to previous years, as the magnitude of the fee-based financing was difficult to foresee. As a result, a considerable amount of the initially-foreseen EU subsidy financing was not necessary due to more favourable fee income receipts, although the expenditure was revised upwards slightly to finance further development of critical Biocides Scientific IT tools.

Actions resulting from audit recommendations, as well as risks identified have been managed as high priority, thus resulting in effective risk management and continuous improvement of ECHA's management system. Following the establishment of the ex-ante and ex-post evaluations framework and approach, one ex-ante and one ex-post evaluations were conducted and recommendations treated as high priority by Management. In addition, the Commission mandated Deloitte to perform the review of all ECHA's activities, which gives input into the second review of the REACH Regulation.

The assessment of the effectiveness of the internal control systems indicates that the Agency is fully or mostly compliant with the Integrated Management Standards (Annex III).

PART I ACHIEVEMENTS OF THE YEAR *(SEE GENERAL REPORT)*

PART II GOVERNANCE AND MANAGEMENT

2.1 Management Board

In 2017 the Management Board held four plenary sessions, one hosted by the Belgian Federal Public Service (FPS) Health, Food Chain Safety and Environment in Brussels. A total of 15 working group meetings were organised, mostly linked to the plenary meetings or as virtual meetings. These meetings prepared decisions, in particularly in the area of planning and reporting, or facilitated the Board's oversight function in specific areas, including the performance evaluations of the Executive Director and the members of the Board of Appeal.

For the appointment of a new Executive Director, the Management Board established a temporary preparatory group which met four times.

Apart from adopting all statutory documents as foreseen in the applicable rules and regulations, the Management Board:

- Appointed a new Executive Director
- Elected a Deputy Chairman
- Approved ECHA's future building project and notified it to the EU budgetary authority which decided to not object the project
- Adopted, after having obtained a favourable opinion from the Commission, a revised decision on the transfer of fees to Member States
- Adopted implementing rules to the Staff Regulations, to align the internal rules with the revised EU Staff Regulation
- Adopted an update of the ECHA Transparency Approach
- Reviewed its Decision on the remuneration of experts and co-opted members
- Approved a limited technical cooperation with Switzerland in the area of the REACH Regulation and the participation of Swiss authorities in the CLP work of the HelpNet
- Adopted revised Audit Charters of the Internal Audit Service and the Internal Audit Capability

In its meetings, the Board received regular reports from the Executive Director on ECHA's activities. Also the specialised Working Groups of the Management Board gave regular reports in the area of audit, planning and reporting, transfer of fees and the Board of Appeal.

In terms of risks discussed with the Management Board, there have been updates provided to the working group on audit twice per year. In the discussions at Management Board level the risks resulting from the allocation of new tasks to the Agency without the provision of adequate resources were an important reoccurring topic.

In June 2017 the Management Board organised a 3rd workshop on the development of the future strategy of ECHA.

For the December Management Board meeting in Brussels ECHA invited institutional partners from the Commission, Parliament, Member States as well as Stakeholder Organisations to participate in an open session where key strategic topics for the future of EU chemicals legislation implementation were discussed. This session was also web-streamed.

2.2 Major developments

The year 2017 was crucial for the last registration deadline of phase-in substances in 2018 and ECHA undertook numerous initiatives to encourage and enable companies to register their dossiers. ECHA furthermore continued the work on implementing the improvement actions in the application for authorisation (AfA) process and presented a final report to the Management Board in December 2017.

ECHA continued to stimulate the adequate use of the scientific methods to justifiably replace the standard information requirements and in particular by drawing registrants' attention to the Read-Across Assessment Framework (RAAF). ECHA also published a report on the regulatory applicability of alternative methods and approaches to promote an up to date assessment on the opportunities and limitations of alternatives to animal testing. Furthermore, the Agency continued its activities to improve the quality of registration data for nanomaterials and concluded the work on a substitution strategy. On the basis of the criteria for identifying endocrine disrupters adopted by the Commission, ECHA also developed guidance in cooperation with EFSA, the European Food Safety Authority.

In 2017, ECHA published its first report on the operation of the PIC regulation covering the period 2014-2016 and integrated the commitments made in the second report on the operations of REACH and CLP regulations into its programming documents.

ECHA continued in 2017 with the implementation of its Integrated Regulatory Strategy which brings together all regulatory processes under the REACH and CLP Regulations to achieve the aims of these Regulations, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development (WSSD). Addressing substances in groups, rather than one-by-one, was the main theme for evaluation in 2017, thereby aiming to increase the efficiency of the evaluation process.

ECHA marked its 10 anniversary in 2017 with a series of dedicated events. This included a high level conference with institutional partners, Member States and stakeholders on 7 June 2017 in Helsinki. ECHA also organised an exhibition on the benefits of 10 years chemicals regulation implementation in the European Parliament and Commission buildings. Other events included a litigation conference and internal events with staff to take stock of the achievements since 2007 and the challenges ahead.

During 2017 the Executive Director maintained an open dialogue with the EU institutions, in particular the European Parliament. An exchange of views with the ENVI Committee of the Parliament was organised in July 2017 and regular meetings and interactions took place between the Executive Director and the appointed liaison person of the Parliament. New or revised memoranda of understanding were signed with the European Food Safety Authority and the European Aviation Safety Authority.

A challenge for the Agency in 2017 was the transition to a new Executive Director, after the first 10 years of operation. The Agency approached the appointment process and the handover from the incumbent to the new Executive Director with the outmost diligence in order to avoid any potential operational or reputational repercussions. The same applied for the procedure related to the approval of the plans for the future building to which ECHA will relocate in 2019.

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

2.3 Budgetary and financial management

As stated in Article 92 of the Financial Regulation applicable to the budget of ECHA, the annual accounts of the Agency are accompanied by a report on budgetary and financial management for the year. This report is drawn up, by the Accounting Officer, under the responsibility of the Executive Director and the relevant part will be part of his Consolidated Annual Activity Report.

In accordance with the REACH Regulation (No 1907/2006), ECHA is financed through fees paid by industry and by an EU balancing subsidy, as referred to in Article 208 of the general Financial Regulation. In 2017, ECHA collected fee income totalling EUR 33 960 276 (EUR 33 377 004 in 2016), while the EU subsidy amounted to EUR 64 289 500 (58 919 188 in 2016). Additionally, the received European Free Trade Association (EFTA) contribution totalled EUR 1 587 950 in the year.

In accordance with the Regulation on Biocidal Products (BPR, No 528/2012), ECHA is financed through fees paid by industry and a balancing EU subsidy, as referred to in Article 208 of the general Financial Regulation. In 2017, ECHA collected fee income totalling EUR 8 127 680 (EUR 7 612 146 in 2016), while the EU subsidy amounted to EUR 3 867 798 (EUR 850 000 in 2016). Additionally, the received EFTA contributions, including the one from Switzerland, totalled EUR 183 156 in the year.

In accordance with the Prior Informed Consent (PIC) Regulation (No 649/2012), ECHA is fully financed by an EU subsidy, as referred to in Article 208 of the general Financial Regulation. In 2017, this subsidy amounted to EUR 1 185 770 (EUR 1 151 000 in 2016).

The initial total budgetary payment appropriations for the expenditure of 2017, as concluded by the Management Board in December 2016, amounted to EUR 109 223 390.

In addition, the Agency has signed a Delegation agreement with the Commission on the European Union Observatory for Nanomaterials and for the set-up of the European Union Chemical Legislation Finder. The final 2017 budget included an amount of EUR 900 000 for these tasks.

During the year 2017, the Management Board adopted one amending budget in September. The amending budget adapted the Agency's revenue estimates to the observed trend in the area of REACH/CLP Regulations by increasing the fee income budget estimate with an amount of EUR 5.2 million. At the same time, the REACH expenditure was reduced by EUR 0.1 million and consequently the need for balancing EU subsidy (including the EFTA contribution) was reduced by an amount of EUR 5.3 million.

The amending budget aligned also the Agency's revenue estimate to the real income situation in the area of Biocidal Products Regulation. The budget estimate for Biocides fee income was increased by EUR 1.7 million, due to a higher than expected numbers of applications for Union authorisation. At the same time, the expenditure budget was increased by an amount of EUR 1.0 million, which was added to IT expenditure in Title 4 to allow, primarily, for the further development of critical Biocides Scientific IT tools. Consequently, the need for balancing EU subsidy (including the EFTA contribution) was reduced by an amount of EUR 0.7 million.

Budget overview (in EUR '000)

Revenue	Initial voted budget	Amending budgets	Final voted budged
Total revenue	109 223 390	910 347	110 133 737
Expenditure	**Initial voted budget**	**Amending budgets**	**Final voted budged**
Commitment appropriations	109 275 607	654 947	109 930 554
Payment appropriations	109 223 390	910 347	110 133 737

2.3.1 Revenue

The budget funding of ECHA in 2017 consisted of the following:

Description	Initial Budget 2017 €	Amending Budget No 1 2017 €	Final Budget 2017 €	Entitlements established €	Revenue received €
Fees and charges from Registrations	24 795 753	4 757 247	29 553 000	31 583 306	31 583 306
Fees and charges from Authorisations	523 418	191 243	714 661	759 094	759 094
Fees SME Administration	1 008 716	224 984	1 233 700	1 397 342	1 397 342
Fees and charges from CLP	148 613	0	148 613	184 800	184 800
Fees and charges from Appeals	0	14 315	14 315	35 734	35 734
Total REACH Fee & Charges Income (incl. Appeals)	**26 476 500**	**5 187 789**	**31 664 289**	**33 960 276**	**33 960 276**
Fees relating to Biocidal Active Substances	1 170 000	(332 200)	837 800	1 026 700	1 026 700
Fees for Union Authorisation of Biocidal products	2 881 300	2 449 700	5 331 000	5 628 980	5 628 980
Miscellaneous fees	1 720 000	(400 800)	1 319 200	1 469 500	1 469 500
Fees and charges from appeals	0	0	0	2 500	2 500
Total BPR Fee & Charges Income (incl. Appeals)	**5 771 300**	**1 716 700**	**7 488 000**	**8 127 680**	**8 127 680**
REACH subsidy	69 489 500	(5 200 000)	64 289 500	64 289 500	64 289 500
BPR subsidy	4 500 000	(632 202)	3 867 798	3 867 798	3 867 798
PIC subsidy	1 183 000	0	1 183 000	1 185 770	1 185 770
EFTA Contribution - REACH	1 716 390	(128 440)	1 587 950	1 587 950	1 587 950
EFTA Contribution - BPR	55 393	(33 500)	21 893	35 815	35 815
Conferderation of Switzerland Contribution - BPR	31 307	0	31 307	147 341	147 341
Total EU Contributions	**76 975 590**	**(5 994 142)**	**70 981 448**	**71 114 174**	**71 114 174**
IPA Programme	0	0	0	180 000	180 000
Delegation Agreements (EUON, EUCLEF)	600 000	0	600 000	900 000	900 000
Total Contributions under specific agreements	**600 000**	**0**	**600 000**	**1 080 000**	**1 080 000**
Total Other income - miscellaneous	**0**	**0**	**0**	**210 883**	**210 883**
Total	**109 823 390**	**910 347**	**110 733 737**	**114 493 013**	**114 493 013**

REACH/CLP Revenue

A) REACH/CLP Fees and Charges

The fees and charges collected by ECHA are determined by the REACH Fee Regulation and by the decisions of the Management Board. Due to the once-off nature of the REACH fees and their dependence on strategic decisions of the chemical industry players, there is high uncertainty as to their amount and timing. The budgetary revenue from REACH fees/charges in 2017 in terms of the cash received amounted to EUR 33 924 542 (EUR 33 310 921 in 2016). In addition, income of EUR 35 734 (EUR 66 083 in 2016) was recorded in relation to REACH appeal fees giving a total of fees and charges of EUR 33 960 276 (EUR 33 377 004 in 2016). Income from appeal fees is recognised by ECHA only when a case has been decided and the Board of Appeal rules that the fee should not be refunded to the applicant.

Approximately 41% of the REACH/CLP fees and charges income generated in 2017 relates to a relatively small quantity of registration dossiers, with a high monetary value, for registration of substances above 1 000 tonnes and in the range 100 to 1 000 tonnes. Registration of substances in the range 10 to 100 tonnes represent a share of 18% and the lowest tonnes range 1 to 10 tonnes of 8%.

Approximately 15 900 registration dossiers were received in 2017 (including updates). This is an increase of almost 50% compared to the 2016 level. Out of all the registration dossiers received, about 8 500 generated a fee. The increased registration activity is a direct consequence of the approaching registration deadline on 1 June 2018.

In 2017, the Agency received payment for 12 applications (77 in 2016) for REACH Authorisation. In addition, 5 applicants self-declared their company size as larger for previously paid applications generating additional income of EUR 98 533. The total REACH authorisation income collected in 2017 amounts to EUR 759 094 (EUR 6 074 483 in 2016). For 10 out of the 12 applications received, work will still be performed in 2018.

The Agency received payments for 48 applications under the CLP regulation (46 applications under Article 24 and 2 applications under CLH). The total receipts for 2017 amounts to EUR 184 800 (EUR 188 600 in 2016).

The additional registration fee income generated via the SME size verification process (included in the REACH Registration income) in 2017 amounted to EUR 1 499 985 (EUR 1 611 101 in 2016). A total of 332 enterprises (570 in 2016) were verified for their company size during the year. In addition to the additional registration fees, the Agency generated EUR 1 397 333 in administrative charges (EUR 1 723 927 in 2016) levied on companies who were not eligible for the already received rebates. The income resulting from the SME verification work was higher than initially estimated due to the higher number of wrong size declarations detected.

B) REACH/CLP Contributions:

During 2017, the Agency received a REACH/CLP subsidy of EUR 64 289 500 (EUR 58 919 188 in 2016) and an EFTA contribution of EUR 1 587 950 (EUR 1 626 575 in 2016).

C) Delegation agreements

The Agency had signed a delegation agreement with the Commission in December 2016 to build an EU-wide Observatory for Nanomaterials (EUON) and to develop an EU Chemical Legislation finder (EUCLEF). In 2017, the Agency signed two transfer of funds agreements and received an amount of EUR 600 000 for EUON and EUR 300 000 for EUCLEF.

BPR Revenue

A) BPR Fees and Charges

The biocide fees and charges collected by ECHA are determined by the Biocidal Product Regulation, the Fees and charges Regulation and by the decisions of the Management Board. The budgetary revenue from Biocidal product fees/charges, for 2017, in terms of the cash received amounted to EUR 8 125 180 (EUR 7 609 646 in 2016). In addition, income of EUR 2 500 (EUR 2 500 in 2016) was recorded in relation to BPR appeal fees giving a total of fees and charges of EUR 8 127 680 (EUR 7 612 146 in 2016).

Despite the fact that the majority of the resources and work required to process these applications will be utilised in 2018 and onwards, ECHA is required to fund this work from future income.

In addition, ECHA completed 28 ex-ante SME verifications (25 in 2016) under the Biocidal Product Regulation. These verifications do not entail levying administrative charges.

B) BPR Contributions

During 2017, the Agency received a subsidy of EUR 3 867 798 (EUR 850 000 in 2016) and an EFTA contribution of EUR 35 815 (EUR 14 342 in 2016). In addition, the Agency received a contribution from the Federation of Switzerland of EUR 147 341 (EUR 128 037 in 2016).

PIC Revenue

ECHA received an EU contribution for the PIC Regulation totalling EUR 1 185 770 in 2017 (EUR 1 151 000 in 2016).

Other miscellaneous income

The table below shows the other miscellaneous income received by the Agency in 2017.

Description	Entitlement established 2016 €	Entitlement established 2017 €	Revenue received €
Legal recoveries	0	81 762	81 762
Carparking recovery	0	76 500	76 500
Interest generated	0	0	0
Other miscellaneous	15 165	34 733	49 898
Miscellaneous Income	**15 165**	**192 996**	**208 161**

Fee Invoicing 2017 (other information in accordance with Article 67 of FR)

In accordance with Article 67 of the Agency's Financial Regulation, the number of debit notes issued and their global amount shall be provided in the Agency's report on budgetary and financial management. In addition, where fees and charges are entirely determined by legislation or decisions of the Management Board, the Authorising Officer may abstain from issuing recovery orders and directly draw up debit notes after having established the amount receivable. Where the Agency uses a separate invoicing system, the Accounting Officer shall regularly, and at least on a monthly basis, enter the accumulated sum of fees and charges received into the accounts.

The Agency uses a separate invoicing and debtors system for daily transactions related to fee income namely, the REACH IT (REACH/CLP Fees and charges) and REACH-NG (Biocidal Product Fees and charges) invoicing modules. The invoices raised and the payments received are recorded in the central accounting system on a monthly basis.

A) REACH Fees and Charges

The total net invoiced by the Agency in 2017 amounted to EUR 34 108 821 (EUR 35 123 877 in 2016). The table below depicts the breakdown of the net invoiced REACH fees during the year.

REACH Description	2017 No of Transactions	€	2016 No of Transactions	€
Invoices issued	9 535	41 355 205	5 984	41 517 533
Credit Notes	693	(6 291 392)	679	(4 980 078)
Unpaid	138	(954 452)	167	(1 413 309)
Considered paid	25	(540)	15	(269)
Waived	0	0	0	0
Net Invoiced		**34 108 821**		**35 123 877**

In accordance with Article 65 of the Agency's Financial Regulation, the Accounting Officer shall keep a list of the amounts due to be recovered. At the 31 December 2017, the amount to be recovered for REACH/CLP fees and charges stood at EUR 4 696 826. Included in this amount is EUR 3 187 938 relating to overdue administrative charges arising from the SME verification work.

The above mentioned list shall also indicate decisions by the Authorising Officer to waive or partially waive recovery of established amounts. During 2017, bank charges were deducted by the senders' banks for 25 invoices (15 invoices in 2016) relating to REACH fee income. For management efficiency reasons, these invoices have been "considered paid" and therefore a total amount of EUR 540 (EUR 269 in 2016) has been waived.

B) Biocidal Products Fees and Charges

The total net invoiced by the Agency in 2017 amounted to EUR 8 203 380 (EUR 8 016 095 in 2016). The table below depicts the breakdown of the net invoiced BPR fees during the year.

BPR Description	2017 No of Transactions	€	2016 No of Transactions	€
Invoices issued	1 828	8 888 100	1 701	9 296 200
Credit Notes	89	(274 580)	65	(1 008 500)
Unpaid	73	(410 200)	132	(271 400)
Considered paid	2	(40)	10	(205)
Net Invoiced		**8 203 280**		**8 016 095**

In accordance with Article 65 of the Agency's Financial Regulation, the Accounting Officer shall keep a list of the amounts due to be recovered. At the 31 December 2017, the amount to be recovered for Biocidal product fees and charges stood at EUR 584 800. This list shall also indicate decisions by the Authorising Officer to waive or partially waive recovery of established amounts. In 2017, bank charges were deducted by the sender's banks for 2 payments (10 cases in 2016) relating to BPR fee income. For management efficiency reasons, these invoices have been "considered paid" and, therefore, a total amount of EUR 40 (EUR 205 in 2016) has been waived.

2.3.2 Expenditure

Budget expenditure includes payments made during the year and the carry-over of budgetary appropriations. The following paragraphs and table summarises the execution of appropriations per Title and a more detailed breakdown is provided in the Annex II.

Budget 2017: Breakdown & changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Title*

(€'000)

Title	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	69 105 290	183 175	69 288 465	68 446 720	98.8%	69 288 465	67 930 696	98.0%	511 571	0.8%	846 198
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	15 085 831	-88 716	14 997 115	14 616 353	97.4%	14 997 115	12 693 356	84.6%	1 922 997	13.2%	380 763
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	22 780 002	-626 823	22 153 179	21 397 254	96.5%	22 356 362	13 898 595	62.2%	7 649 547	40.4%	755 925
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 967 208	1 118 394	3 085 602	2 952 739	95.5%	3 085 602	1 004 874	32.6%	1 947 865	66.0%	132 863
B0-5	OPERATIONAL EXPENDITURE - PIC	337 276	68 917	406 193	406 143	100.0%	406 193	233 437	57.5%	172 705	42.5%	50
		109 275 607	**654 947**	**109 930 554**	**107 819 209**	**98.1%**	**110 133 737**	**95 760 959**	**86.9%**	**12 204 684**	**12.3%**	**2 115 799**

**Note: As ECHA operates with both differentiated (multiannual) and non-differentiated (annual) budget lines, the funds reserved for commitments (commitment appropriations) do not equal the funds reserved for payments (payment appropriations).The results for the administrative titles 1 and 2 are combined for all three Regulations.*

Budget 2016: Implementation of differentiated appropriations (€'000)

Budget line		Available commitment appropriations	Commitments made	%	Available payment appropriations	Payments made	%
B3-111	Committees and Forum (Multiannual)	317	261	82%	14	13	93%
B3-801	Cooperation with internat organisat for IT program	2 048	2 047	100%	645	645	100%
Total		**2 365**	**2 308**	**98%**	**659**	**658**	**100%**

Title 1: staff expenditure

The initially adopted budget for Title 1 in 2017 was EUR 69.1 million and the overall increase during the year, including transfers and amending budgets, was EUR 0.8 million to arrive at EUR 69.3 million. The final executed amount totalled EUR 68.5 million corresponding to an execution rate of 98% for the payment appropriations. The carry-over appropriations, totalling EUR 0.5 million for Title 1, mainly relate to the commitments for trainings and interim services.

An amount of EUR 21 000 carried over from the previous year (C8) was not used in payments and was cancelled (overall implementation per Title presented in Annex II).

Title 2: infrastructure expenditure

The initial Title 2 appropriations totalled to EUR 15.1 million and during the year the amount was reduced by EUR 0.1 million to arrive at EUR 15.0 million. For the year, EUR 14.6 million were committed which corresponds to an execution rate of 97%.

The largest expenditure areas, apart from the rent of the building, were the IT outsourced services, the costs of security, cleaning and electricity of the building, purchases of IT hardware, software and their maintenance. The carry-over appropriations, totalling EUR 1.9 million for Title 2, is mainly stemming from outsourced IT services and building related commitments including rental of furniture.

An amount of EUR 35 000 carried over from the previous year (C8) was not used in payments and was cancelled (overall implementation per Title presented in Annex II).

Title 3: operational expenditure REACH and CLP

Title 3 contains exclusively the operational expenditure needed to implement the REACH and CLP regulations. The initial budgeted payment appropriations amounted to EUR 22.8 million and were subsequently reduced during the year by EUR 0.6 million to arrive at EUR 22.2 million. The executed commitment appropriations for 2017 were EUR 21.4 million corresponding to an execution rate of 97% and the appropriations carried over amounted to EUR 7.7 million representing 36% of the committed amount.

The expenditure related to IT projects and services for ECHA's operations, totalling to c. EUR 12.1 million, represents c. 55% of the total expenditure in Title 3 and the related carry-over accounts for c. 70% of the overall amounts carried over in Title 3 totalling EUR 7.7 million. The significant carry-over of appropriations is due to the multi-annual nature of ECHA's IT projects and is partly stemming from the fact that the financing for certain IT initiatives, mainly the development of a Poison Centre Portal, was secured only late during the year and thus the related funds were carried over in full.

Other significant expenditure items in REACH/CLP operational expenditure are the Registration related expenditure totalling EUR 1.2 million and Communication and Translation costs totalling EUR 3.2 million.

An amount of EUR 289 000 carried over from the previous year (C8) was not used in payments and was cancelled. The amount is largely stemming from contracts with the Member States for substance evaluation as per MB decision 45/2014[1], where the amounts invoiced based on actual hours worked were below the maximum hours covered by the contract. As this type of cancellation in beyond ECHA's control, these contracts have, since 2017, been budgeted under the differentiated budget line to mitigate the risk of cancelled appropriations. Some cancelled C8 amounts stem also from certain IT projects and infrastructure (overall implementation per Title presented in Annex II).

Title 4: operational expenditure Biocides

The Biocides related operational expenditure in the initial budget totalled to EUR 2.0 million and, during the year, was increased to EUR 1.1 million. The total committed amount was EUR 3.3 million corresponding to 96% commitment rate and the carried over amount was EUR 1.9 million, representing 66% of the committed amount. The carry-over appropriations mainly stem from the large scale IT projects to further develop the R4BP3 and Biocides Dissemination, totalling c. EUR 1.4 million. The financing for the projects was only secured during the second half of the year when sufficient fee income had been received, which has resulted in a significant carry-over of the project funds.

An amount of EUR 15 000 carried over from the previous year (C8) was not used in payments and was cancelled (overall implementation per Title presented in Annex II).

Title 5: operational expenditure PIC

The adopted budget for Title 5 was EUR 0.34 million and, during the year, was increased to EUR 0.41 million. The executed commitment appropriations amounted EUR 0.41 million corresponding to a 100% execution rate, whereas the carried over amount was EUR 0.17 million (43%).

[1] https://echa.europa.eu/documents/10162/17208/decision_ms_fee_transfers_en.pdf/0104391f-6ae0-4b6e-b096-f73bebe60fa5

As with REACH, the expenditure related to IT services is the biggest expenditure item representing c. 88% of the total expenditure in Title 5. The carry-over of appropriations relates mainly to expenditure for support, maintenance and application management of Epic system.

The amount of EUR 4 000 carried over from the previous year (C8) was not used in payments and was cancelled (overall implementation per Title presented in Annex II).

Late interest payments

During the year 2017, ECHA paid EUR 89.73 as a late interest for three invoices.

In addition, ECHA received a debit note from the Commission regarding a late payment of the 2016 outturn for REACH/CLP. ECHA contested the late interest claim, due to administrative delay incurred at the Commission side, but agreed to settle the amount of € 1 855.41 in January 2017 due to the relative low value and the costs associated to the administrative proceedings required to pursue the rectification further.

Transfers

During 2017, 23 transfers totalling EUR 684 000 were carried out.

Procurement procedures

In 2017, in implementation of its budget, ECHA signed 687 contracts and purchase orders. Moreover, ECHA issued 372 catering orders and 696 travel orders through the electronic ordering tools of the relevant framework contracts. Out of the 687 signed contracts, 547 were specific contracts and orders under framework contracts, 134 were contracts resulting from tendering procedures, four were renewals and one was a modification of a contract. A total of 45 contracts were signed following exceptional negotiated procedures based on the relevant rules of the Financial Regulation, 14 of which refer to legal services, two to the increase of ceiling of IT framework contracts, as foreseen in the original procurement procedure, and the remaining ones mainly refer to subscriptions, participation to events, direct purchase of services for technical reasons and maintenance of technical installations. Furthermore, in 2017, ECHA signed a contract for the lease of its future premises as of January 2020, following a Negotiated Procedure for buildings contracts (based on Article 134(1)(g) RAP).

The annual list of contractors is published by ECHA by 30 June of each year for the previous year to ECHA website[1]. The detailed procurement implementation for the year 2017 is available under Annex II Statistics on financial management and procurement.

2.4 Human resources management

In 2017, ECHA maintained a sharp focus on its human resources management practices and, in particular, on the attraction, retention and development of staff. The recruitment target of the Agency was achieved with 98% of posts filled at the end of the year for REACH/CLP, PIC and Biocides. It should be noted that this percentage cannot exceed 98% as ECHA is required to be aligned with the 2018 establishment plan as of 01 January 2018 (that is, a reduction of 6 posts (-1.5%) for REACH/CLP). Overall, ECHA's staff planning exercise is increasingly demanding due to

[1] https://echa.europa.eu/view-article/-/journal_content/title/annual-list-of-awarded-contracts

the need to take account of the imposed post cuts and the continued uncertainty in the biocides area.

A staff engagement survey was conducted, attaining a very high response rate of 86%. The response rate is stable compared to the previous survey conducted in 2015. In accordance with international benchmarking data provided by the service provider (Kantar), the current overall staff engagement score categorises ECHA as an organisation of "strength" in this important area. Feeding from the analysis of the results of the survey, each Unit and each Directorate have formulated specific action plans to best answer their needs. In parallel, the Corporate-level action plan focuses on developing 3 priority areas: organisation efficiency, working culture and motivation.

In 2017, the HR IT tool was further developed in order to achieve its aim to integrate the different HR procedures in one tool while improving the efficiency of the underlying processes. For instance, the implementation of the electronic payslip contributed to ECHA's internal efficiency and commitment to become a more environmentally friendly workplace.

The screening/benchmarking exercise was conducted at the end of 2017 (see Annex I). In comparison with the 2015 and 2016 benchmarking exercise at the Agency, there was an increased percentage of operational staff (that was higher than the percentage indicated in the benchmarking results of the EU Commission). The percentage of administrative support staff is continuing to follow a descending trend, in line with the EU Commission benchmarking results.

ECHA continued also to follow-up its commitment for improving the staff wellbeing. Two major actions were taken in this area. Firstly, the teleworking possibilities were increased significantly for staff as a further step in defining the Agency's new ways of working. Colleagues can avail of more days of occasional teleworking and even enter into regular teleworking agreements with their managers. A first review of the new teleworking policy showed a high level of acceptance and delivered positive feedback from both staff members and managers, whom appreciate the empowerment to plan their working days independently. Secondly, ECHA introduced an early support policy that follows the practice under Finnish occupational health care. In practice, ECHA managers are required to address any signs of physical or psychological distress among their staff as early as possible in order to avoid longer periods of sick leave.

Finally, HR participated in the Agency's preparatory group for the 2018 registration deadline and designed a staffing plan for the temporary additional workforce requirements for 2017 and 2018. This has been ensured by recruiting additional short-term Contract Agents, interim staff and trainees, as well as redeploying a number of internal staff for these activities.

2.5 Assessment by management

As required by ECHA Financial Regulation, the Authorising Officer performed an assessment of the effectiveness and efficiency of the internal control system, based on the ECHA Integrated Management Standards (Annex III).

In addition, and in order to fulfil the requirements of the Quality management standard ISO 9001: 2015, a management review meeting involving all Directors took place on 9 February 2018. A number of surveys, reports, audit results, non-conformities[2], complaints, risks, opportunities, ex-post evaluations and other sources of information were analysed in order to draw conclusions. The assessment of the internal controls acknowledged their effectiveness and yet reinforced the commitment of the Agency to pursuing further improvements under some of the standards (see Annex III for more details).

[2] As per the internal and external audits conducted in 2017, there have been no major non-conformities found. The minor non-conformities raised and the observations are being addressed accordingly.

The forward looking elements of the Management system review were aligned to the new strategic priorities of ECHA for the years 2019-2023.

The first building block of ECHA Integrated Management Standards, "Governance", was considered well-functioning with positive findings from audits performed in 2017 and good survey results. Staff and stakeholders satisfaction were once again selected as two of the Agency's quality objectives.

In 2018, there may be an opportunity to review the mission and vision, as well as to identify the behavioural changes needed to support the implementation of the new strategy.

It was concluded that stakeholder management is working well overall. More consideration should be given on how to approach key stakeholders, i.e. in the Commission and Member States. The focus in 2018 will be on the critical aspects in the cooperation with stakeholders and partners

Though a lot has been done in the area of further delegating decision-making where the risks have been considered low, further challenging of the controls and steps is needed in order to build an optimal risk-based system.

Work-life balance has improved in 2017 mainly due to the teleworking opportunities, widely appreciated by staff. Developing both the HR strategy and reviewing ECHA's competence management process to create more agility in the organisation to be able to respond to changes was a priority set for next year.

With regard to the second building block covering strategy, planning and risk management, the Management noted the well-functioning risk management process. The fourth strategic objective was again proposed as a quality objective for 2017. The environmental objectives selected in 2017 (electricity, paper and colour printing consumption to decrease by 10% from the level of 2015 and 2016 respectively) were reconfirmed for 2018 as well.

Following ECHA's new strategy, Directors confirmed the need to reflect on the relevant impact measurements to be established.

The third building block "Operations and operational structure" was reviewed with the conclusion that the framework established is overall effective and fit-for-purpose.

Still, further progress needs to been made in the area of decision making in view of gaining process efficiencies. Measures, such as providing top-down support in advance to focus the discussion, as well as reflecting on the relevance of the topics submitted to the decision-making bodies were discussed.

Further increasing the alignment between planning and budgeting in IT development considering business needs was pointed out as an area to focus on in 2018.

The opportunity for improving the process structure was discussed, in relation to ECHA's new strategic priorities and the value stream mapping exercise, with a focus on solving the main practical operational problems as identified.

Management noted also the progress in the fourth building block "Evaluation and improvement". In the area of analysis and evaluation, shifting the focus from numerical data to analysis of trends, has resulted in better management reviews. Performing audits and evaluations has been beneficial for improving decision-making. On the other hand, the process for managing non-conformities is apt for further improvement.

2.6 Budget implementation tasks entrusted to other services and entities

Not applicable

2.7 Assessment of audit results during the reporting year

All "very important" audit recommendations were followed up as high priority by the Management. The important and other recommendations are equally followed up, monitored and reported for the periodical and the management reviews.

2.7.1 Internal Audit Service (IAS)

According to ECHA's Financial Regulation, the Internal Auditor for ECHA is the Internal Auditor of the European Commission (IAS). IAS carried out in 2017 a Risk Assessment and prepared the IAS Strategic Audit Plan 2018-2020 with prospective audit topics. IAS conducted preliminary interviews for an audit on Conflicts of interest and ethics in October 2017. This audit will be completed in 2018.

2.7.2 Internal Audit Capability (IAC)

In line with the ECHA Financial Regulation (FR) art. 84 and the relevant Integrated Management Standards of the Agency, the local "Internal Audit Capability" (IAC), as a permanent resource, adds value by providing the Executive Director with additional assurance and consulting activities. In 2017, the IAC carried out assurance audits on Substance evaluation –process and Capacity building of ECHA's scientific and regulatory staff. IAC also conducted in co-operation with the Information Security Manager an audit on ECHA Cloud Services for SMEs.

<u>Substance evaluation process</u>

- Scope: The main objective of this audit was to assess and provide reasonable assurance on the regularity and the quality of internal control systems applied as well as efficiency and effectiveness of the Substance evaluation -process
- Two very important recommendations were put forward:

    1. Prepare an overview and reinforce the monitoring of the status of the CORAP substances in particular to ensure that the evaluating MSCA has examined the new information within 12 months of all the requested information being submitted.

    Provide additional support to eMSCA where feasible in case of issues delaying the progress and consider eventual incentives to eMSCAs to speed-up progress on the subsequent steps.

    2. Develop further the status monitoring of those substances where the substance evaluation (SEV) conclusion document indicates a need for follow-up regulatory action at EU level.

    Analyse the need to align MSC's and RAC's views to ensure that tests required in SEV decisions are sufficient for RAC to conclude on the classification in a subsequent CLH dossier.

ECHA management developed an action plan to respond to the recommendations of the IAC. IAC believes that the action plan is adequate.

<u>Capacity building of ECHA's scientific and regulatory staff</u>

- Scope: The main objective of this audit was to assess and provide reasonable assurance on the regularity and the quality of internal control systems applied as well as efficiency and effectiveness of the Substance evaluation –process
- One very important recommendation was put forward: To enhance continued active use of the competence management, collect lessons learnt from competence mapping exercise to review the competence mapping framework and the methodology where needed.

ECHA management developed an action plan to respond to the recommendations of the IAC. IAC believes that the action plan is adequate.

ECHA Cloud Services for SMEs

- Scope: The main objective of this audit is to assess whether the resilience, data integrity and security of the ECHA Cloud Services (ECS) are in conformity with applicable rules and regulations and its efficiency and effectiveness.
- No critical or very important recommendations were put forward.

2.7.3 European Court of Auditors (ECA)

In the Court's preliminary observations as of 25 April 2017, the accounts of the Agency for the year ended 31 December 2016 present fairly, in all material respects, the financial position of the Agency at 31 December 2016, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission's accounting officer.

2.8 Follow up of recommendations and action plans for audits

European Court of Auditors (ECA)

There were no actions to be implemented from previous years.

Internal Audit Service (IAS)

No very important issues are pending from earlier IAS audits.

Internal Audit Capability (IAC)

IAC conducted two follow-up audits to verify the implementation of the action plans.

The following partially implemented "very important" recommendations are reclassified to "important" level:

Contract management and payments:

- Establish a consistent filing plan for contract management and ensure appropriate storage of all documents, including deliverables

Follow-up to dossier evaluation process:

- Ensure better integration of Follow up to dossier evaluation with other REACH processes by e.g. continuing the efforts to reinforce the Directorate E's co-operation with

Directorate D Risk management and the newly established ACROSS screening Team and optimising communication and appropriate follow up actions through existing tools and collaboration instruments

2.9 Follow up of observations from the Discharge authority

ECHA reported on the follow-up of the observations made by the discharge authority for 2015 in its annual report under Article 110 of the Financial Regulation. This report was also submitted to the Management Board for information and is publicly available at: https://echa.europa.eu/documents/10162/23601668/report_2015_discharge_recommendations_mb48_en.pdf/a242c0b2-ea9d-68ea-29f7-be2e8e8b9313

ECHA accepted all observations and keeps working to improve the impact measurements in the multi-annual section of its Single Programming Document (SPD 2019-2021), as well as to improve its financial management in order to limit carry-overs of committed appropriations to the following financial year, in line with the budgetary principle of annuality.

2.10 Ex-ante and ex-post evaluations

The legal basis of the ex-ante and ex-post evaluations is stipulated in ECHA Financial Regulation (MB/WP/03/2014) and Implementing rules (MB/55/2014, Chapter 7, Art.29). ECHA's evaluation framework and approach, established in 2015 and presented to the 40th Management Board on 16-17 December 2015, is based on the Better Regulation guidelines of the Commission as well as on the benchmarking performed with other agencies.

2.10.1. Evaluations performed in 2017

In 2017 the Agency performed one ex-ante and one ex-post evaluation, and further integrated the ex-ante criteria in its project governance structure. Both evaluations were presented to the Management Boards in June and December respectively.

The ex-ante evaluation covers a cost-risk-benefit analysis of two different options for continuity and strategic transformation of IT infrastructure services. The first option is "continuity of services first", "renovation of infrastructure later". The second option is "renovation of infrastructure first". The second option was preferred, as it stands out for levelling the playing field for the tenderers and, even though it is more demanding in the preparation phase, its cost is lower compared to the first option. The second option also allows better alignment with the parallel Building 2020 project and ensures a continuation of the service delivery as well.

The ex-post evaluation covers the compliance of the Corporate Efficiency Programme and two of its closed projects with seven evaluation criteria (effectiveness, efficiency, incl. economy, coherence, relevance, added value, sustainability and proportionality).

The main conclusions of the evaluation of the Corporate Efficiency Programme are as follows:

Overall, the Efficiency Programme has achieved most of its objectives, has been beneficial to ECHA with a number of process improvements, has increased the creativity and has resulted in a general mind-set change, though there is still work to be done to implement the mind-set change on an Agency-wide basis. The mind-set change is the most important prerequisite for self-sustainability, thus it could be concluded that even if the Corporate Programme stops existing in its current form, processes (and in particular processes that have already been part of the Programme) may find the way to self-regulate and keep improving. Certainly, the above is only valid if the focus of the

Agency in the future remains mostly on process improvements. However, in case a higher efficiency impact is sought such as addressing tools, systems, behaviours, interactions and practices as a whole, there needs to be top-down support and a formalised way of running the relevant corporate initiatives. At general Programme level, the results of Strategic Objective 4 (SO4) measurement demonstrate that more work has been done with the same or less resources since 2011 until 2017, which is a strong evidence of using the efficiency savings to cope with increased workload.

One of the identified weaknesses of the Programme is the insufficient coherence across the Programme, as well as the incoherence with documents and records management, planning and reporting cycle overall and development of specific IT tools. All in all, the "process per process" approach under the Programme and the strong focus on process (re)-engineering (instead of focusing on tools, systems and interactions as a whole) may have hampered the realisation of maximum efficiency benefits. It has to be noted though, that the Agency was not mature enough for big changes when this Programme was undertaken. At the current stage, the learnings of the Programme may allow for bigger changes, provided that there is adequate top-down support and guidance. Another weakness of the Programme is the inconsistent planning at project level, e.g. baselines, targets and measurements are not sufficiently quantitative in nature, thus making it difficult to judge on the progress of the projects. Full-time equivalents (FTEs) savings, where calculated, were based on a conversion of the throughput time into FTEs, which includes the waiting (idle) time. It has to be noted though that due to the sensitivity of the topic on FTEs savings, the Programme was never promoted as an instrument to reduce FTEs, but rather as a tool to optimise the processes performance. In that context, the measurement of the throughput time is a good (neutral) metric to serve that purpose.

At project level, both the financial workflows and dossier evaluation projects have achieved most of their objectives and added value with the process improvements implemented. More importantly, the two projects have proved to be self-sustainable, with some of the improvements happening after the projects entered into production mode. For both projects (as well as for the rest of the efficiency projects), there is no measurement on where exactly the time freed from the efficiency initiatives has been allocated at process level, thus making it difficult to judge quantitatively on whether the achieved efficiency savings have been used in the same or in a different process, and to what extent their use has helped in handling a higher volume or higher complexity of operational or strategic work. It has to be noted that that this measurement was not included in the scope of the Programme.

A number of recommendations were formulated and accepted as a priority by the Senior Management. The most important ones referring to the Programme governance are listed as follows:

There is a need to ensure that the efficiency projects initiated cover the whole process including interactions with input and output processes, relevant tools and systems. Along with that, behavioural changes and providing top-down support are recommended to ensure that changes are not limited to processes.

When new efficiency projects are started, it is also important to ensure that the plans include a clear indication on the baselines, targets and measurements foreseen and to document measurements consistently in line with the specified frequency. When measuring the efficiency savings, it is recommended to indicate both the savings and how they are used to tackle more complex/higher workload.

In view of improving the coherence with the IT tools development, it is recommended to perform thorough process analysis to identify exact business needs before starting development of any IT tools and ensure that the proposed process changes can be accommodated in the foreseen IT tools. To improve the coherence with the planning and reporting cycle, it is important to consider the

added value of both the efficiency (change) objectives and process indicators and if those are adding value, to consistently include and align them to the planning and reporting cycle of ECHA.

When addressing cross-cutting process changes, it is important to involve cross-functional actors both in the project team and the steering committee in order to optimise the resources use, avoid duplication of work and change resistance.

Following the new strategic priorities of ECHA (2019-2023), where the focus is on substances of concern and impactful work aiming to improve human health and environment, the Senior Management needs to consider if the existing format of the Efficiency Programme is suitable and whether to place the future focus on process re-design or on processes, tools, systems, interactions and behaviours as a whole.

A number of recommendations were formulated for the dossier evaluation and financial workflows projects. In the dossier evaluation project, those refer to searching for alternative ways to tackle high peaks in the workload, unifying stakeholders' comments gathering and optimising decision making. In the financial workflows project, the recommendations refer to the clarification of roles and responsibilities within the three financial and procurement support centres, regularly sharing good practices, improving interaction between customers and support centre actors during the whole procurement, ensuring better visibility of processes, files circulation and steps and limiting the process changes (e.g. after the "to-be" process state is implemented), in order to allow for building routine and running standardized processes.

2.10.2. Follow up on evaluations performed in previous years

In 2016 ECHA performed one ex-post evaluation of ECHA's Chemical Safety Assessment (CSA) programme / Exchange Network of Exposure Scenarios (ENES) and one ex-ante evaluation of the future options of ECHA building strategy and project.

The ex-ante evaluation of the building project covered the options available (lease or buy) including the risks, the results and impacts including economic, social and environmental, the most appropriate method of implementation, the internal coherence, the volume of the appropriations and lessons learned from similar experiences. The project team concluded on the most favourable approach in September 2017 (lease) and at that stage the ex-ante evaluation was completed.

The interim ex-post evaluation of the CSA programme /ENES, performed by internal and external evaluators was an evidence based-judgement of the extent to which the programme has been effective, efficient (incl. economical), relevant, coherent and achieved EU added-value. Main findings, recommendations and follow-up are listed below:

The main recommendations of the internal evaluators refer to reshaping the scope and focus of the CSA programme and ENES, implementation of existing tools, ensuring a clear strategy and effective/efficient governance and implementation, better communication of objectives to staff, further support of the improvement of Safety Data Sheets (SDSs) and stakeholders support in benefiting from Programme's tools and products. The external evaluators recommended that implementation and consolidation work should be carried out to maximise the take-up and use of ENES products, for which ENES needs to produce a communication plan to promote the ENES/CSR roadmap. Based on the outcome of the evaluation of the CSA Programme ECHA's new strategy for the 2017-2020 programme for improving the information on uses and risk management advice generated and communicated under REACH has been generated.

The scope of CSA programme/CSR-ES roadmap and ENES were re-shaped with a new focus on the implementation of existing tools and promotion of the most relevant and useful tools. Since the evaluation, sector use maps (a key tool) have been developed and published in ECHA's Use Maps

Library; more are still under development. The strategy and governance of the Programme have improved internally and the focus has been on transparent management of resources, roles and responsibilities and adequate communication of priorities. The new governance has taken into account elements such as cross-directorate cooperation, clear accountabilities, including roles and responsibilities of its members, strategy implementation and monitoring derived by senior management, corrective actions on results obtained and effective (cross-directorate) communication. Nevertheless, more efforts are needed in terms of implementation of the new strategy and expanding it to external parties.

The communication of objectives to staff has been done as part of job objectives setting. The further support of improvement of Safety Data Sheets, the work on articles and circular economy and stakeholders support in benefiting from the Programme's tools and products, taking into account the relevant REACH related legislation (work safety and environmental legislation for instance) is a focus area in the new strategy. A communication plan to promote the ENES/CSR roadmap has been included in ENES Work Programme to 2020 in view of maximising the take-up and use of ENES products. In respect of downstream end users, a number of projects have been initiated to find out more on their real information needs for managing chemical risks, and these findings will determine how existing ENES tools need to adapt, or where new tools may need to be developed. In addition, work to restructure ECHA's current web page on communication in the supply chain has been undertaken to link ENES tools to the different actors.

The skill set of ENES remains broad attracting registrants, distributors, downstream users, Member State authorities, contractors and IT companies that provide software solutions for the supply chain.

PART III ASSESSMENT OF THE EFFECTIVENESS OF THE INTERNAL CONTROL SYSTEMS

3.1 Risk Management

ECHA conducts an annual risk assessment exercise to identify, assess and manage the potential events that could put the achievement of the objectives defined in the annual work programme at risk.

An annual risk management exercise was conducted in 2016 in order to identify, assess and manage the potential events that could put at risk the achievement of the objectives defined in the annual Work Programme 2017. The exercise is an integral part of the Work Programme preparation. The Senior Management followed up the implementation and reviewed the effectiveness of the risk mitigation measures on a quarterly basis during 2017.

Based on this assessment, ECHA's management identified eight main risks which were included in the corporate Risk Register. The Senior Management also agreed that four of these risks should be reduced through specific actions that were described in the action plan relating to the Risk Register and four should be accepted provided that they are due to external factors to which ECHA has no or limited influence. The risks for which a response "accept" was chosen were strictly monitored throughout the year to determine whether the triggers of their likelihood and impact have increased or decreased.

The Senior Management followed up the implementation and reviewed the effectiveness of the risk mitigation measures two times per year (T1, January to April and T2, May to August). The final review of the Risk Register is performed after the year-end (T3 follow-up) and the analysis of the risks and mitigation measures taken is included in the Agency's CAAR for that year.

In the last follow-up done in the beginning of 2018, the Management concluded that the actions taken to mitigate the risks have been implemented according to the plan, have proved to be effective and have not lead to major secondary risks.

One of the risks with highest impact in 2017 which materialised as of 31/12/2017 was related to the achievement of the Biocides Review Programme target set at 50 opinions per year. Even though ECHA was undertaking mitigating actions in both 2016 and 2017, such as creating guiding templates, supporting the quality of the assessment reports and using scenario planning to be able to respond to different market situations, the target of the Review Programme was not met in 2 consecutive years (31 out of the foreseen 50 opinions were adopted in 2017 and 41 in 2016). This was mainly due to the postponement of a number of deliverables by Member State Competent Authorities (MSCAs).

All the other risks did not impact the execution of Work Programme 2017. Some of them continue to be relevant in the future.

The risk ranked highest by Directors at the time of initial risk assessment refers to the smooth processing of registration dossiers for the 2018 deadlines and in particular to the smooth functioning and capacity-development in the One Substance One Registration (OSOR) and enhanced technical completeness check (TCC) projects at a time of insufficient resources. The risk has been properly managed throughout the years through proper recruitment plan and good cross-unit cooperation. The stable submission rate has also been a beneficial factor decreasing the likelihood of the risk in 2017. However, the risk remains high in 2018, due to the uncertainty with regard to the submission rate in 2018 and its potential mismatch with the foreseen recruitment.

Another risk related to the 2018 registration deadline is the potential delay in implementing new functionalities and efficiencies in the REACH-IT software. This risk has been managed through holistic planning, proper scope management and extensive training of staff. The risk is relevant and

needs to be properly managed in 2018 as well, through early (re-)deployment of resources, training and good cooperation with the contractor.

The risk with regard to the insufficient resources of ECHA to provide the new and complex technical solution of the Cloud service, thus causing delays in the planned timetable, did not materialise as of 31 December 2017. The Cloud service was released according to the plan by the end of July 2017. A secondary risk with regard to the actual use of the tool by the SMEs appeared during the year, thus rendering the promotion of the tool a key for its success. The target number of SMEs registering was around 40% or 2000 subscriptions while the actual number was considerably lower.

The risk with regard to the lack of a financial balancing mechanism, present in previous years as well, did not materialise in 2017. Due to the higher income received than foreseen for 2017, ECHA was able to cover its expenditure, thus the financial risk did not materialise in 2017. The risk however remains high for the coming years.

The risk related to the Integrated Regulatory Strategy and in particular the risk of not making sufficient progress in the characterisation of substances and regulatory actions around substances that matter was mitigated mainly through a clear annual and multi-annual plan for triggering action by industry, tracking and tracing of outcomes, informal interaction with certain priority category cases and close monitoring and communication to MSCAs of SVHC roadmap activities. The risk is relevant for 2018 as well and the work on the above aspects will continue.

The risks related to the malfunctioning of the current building of ECHA and in particular to the air quality issues have been mitigated through specific short-term measures such as testing, measuring and improving the air quality, as well as through long-term measures, such as selecting a new building for the future ECHA premises as of January 2020.

The market risk for the authorisation applications related to a potential peak of applications was successfully mitigated. Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) opinions are being processed with the expected level of quality and meeting deadlines despite a peak in the number of authorisation applications received.

Risk management at process level was further strengthened during 2017 through the implementation of the "Methodology for risk assessment and cost-benefit analysis at process level" in the scope of the Efficiency Programme. In 2017, there have been a number of projects under which the cost-risk-benefit methodology was applied resulting in elimination of multiple controls. Examples of those are available under Section 3.3. Specific efforts to improve the economy and efficiency of financial and non-financial activities. The concept of cost-risk-benefit assessment was also systematically implemented in the "vision document" for projects above EUR 1 000 000 and thus subject to ex-ante analysis.

3.1.1 Transparency, accountability and integrity

Throughout 2017, the Agency lived up to its values of transparency and independence. These values were demonstrated during ECHA's contribution to the controversial public debate about glyphosate. During this debate, the Agency brought in its scientific expertise and explained its well-established practices to the public with an open and proactive approach.

As a result, ECHA's process for providing scientific opinions through the Committee for Risk Assessment stood up to the intense scrutiny from stakeholders and public. In a dedicated hearing at the European Parliament, the Agency assured MEPs that transparency and independence are indispensable pillars of its work on chemicals – even though there may be different points of view on how to interpret scientific information. The experience provided further confidence of ECHA's procedures for ensuring transparency and how it deals with perceived conflicts of interest. Both

elements are key to public and stakeholder trust in ECHA's impartial and objective work.

Transparency improvements

ECHA maintains one of the world's largest regulatory databases on chemicals. Its dissemination portal provides information on the 120 000 chemicals used in Europe today in three layers of complexity: the simple infocard for consumers, the more detailed brief profile for professionals and the full source data. In 2017 the portal was adapted to the latest IUCLID format, prepared for processing the 2018 deadline dossiers and performance and stability improvements were made. ECHA also started a project to further develop Biocides data dissemination, which will be finalised by the end of 2018.

A feasibility study on the proposed EU Chemicals Legislation Finder has been concluded in 2017 identifying 55 EU legislations in the desired scope of the tool as first priority. Based on the identification of ECHA as the most suitable body, it has been decided to proceed with the task in the form of a delegation agreement between the Commission and ECHA, which was signed on 8 December 2017. This will make it possible for ECHA to start to develop the appropriate conceptual and architectural models for the portal.

On 8 October 2017 the new improved layout for the ECHA website was launched, including content optimisation and new functionalities. Further transparency on ECHA's interaction with stakeholder organisations was provided by extending the public agenda of the Executive Director to all senior managers.

Prevention of Conflicts of Interest

Policy implementation

On the basis of its Procedure for Prevention and Management of potential Conflicts of Interest, ECHA has implemented an approach which involves a systematic check for potential conflicts before assigning tasks to ***staff members***. Based on a thorough risk assessment of its activities, the Agency has identified the processes and sub-process that require (conflict of) interest management. For more than 30 processes, sub-processes or process steps conflict of interest checks are performed, including the main operational processes of the Agency. In all of these processes a review of the annual declaration of interest is performed by the process owner each time a task is assigned to a staff member, while in some sensitive processes this is complemented with a case-specific no-interest declaration by the staff member. In case of a potential conflict, the case is assigned to a different staff member. The approach is documented in detailed work instructions and guidance is available to the interest managers to deal with individual cases. As a result, no actual case of a conflict of interest has been identified in 2017.

At the time of their appointment all ***members of the ECHA bodies*** are assessed against the eligibility criteria agreed upon by the Management Board. Once they take up their function their annual declaration of interest is reviewed by the respective chair and published on the ECHA website. Before each meeting specific declarations with regard to the items on the agenda are collected and documented in the (publicly available) minutes together with the mitigating measures imposed. As the large majority of the members of the ECHA bodies are Member State public officials, most conflicts of interest declared by the members concerned involvement in the preparation of a dossier submitted by their Member State Competent Authority. In all such cases, the members concerned were considered not to be in a position to participate in the voting on such dossiers.

Post-employment

When leaving the service of the Agency, members of staff have a duty to request authorisation for new occupational activities for the first two years. ECHA can forbid the new activity or impose conditions. There were 28 staff members who left ECHA in 2017: 16 of them went to work for another EU institution, body or agency and one for a national public authority. Four staff members left to the private sector or started self-employment and in one of these cases, the Agency saw it necessary to impose specific conditions before authorising the new employment. In the remaining seven cases, the departure was due to the end of contract, unemployment after resignation, retirement or permanent invalidity. One of these cases concerned the retirement of the previous Executive Director of the Agency and as he intends to continue to remain active, the Commission as his appointing authority decided to impose conditions at the proposal of ECHA's Management Board. In this context it was also decided to publish on the ECHA website an overview of the post-employment decisions on all former senior managers, including their names, date of departure, positions, their foreseen new occupational activities, and the outcomes of ECHA's assessments. No breach of trust or disciplinary procedure was initiated in the area of conflict of interest management.

Fraud prevention

The Agency's internal control systems are designed with fraud prevention embedded, with emphasis on risky areas such as financial transactions, procurement and selections.

ECHA's Code of Good Administrative Behaviour is well communicated to all staff members. Management Board decision 30/2009 of 23 April 2009 stipulates the terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests. Guidelines for whistle-blowers were also adopted in June 2015.

The ECHA Anti-Fraud Strategy, last revised by the ECHA Management Board in December 2016, includes a focus on maintaining and further developing the anti-fraud culture in the Agency and regularly reviewing key policies and procedures. Some important actions implemented during 2017 include a mandatory online training on prevention of conflicts of interest for all staff and a continued focus on awareness on important topics such as ethics, procurement and contract management and information security for newcomers and established staff.

3.1.2 Data protection

In 2017 the Data Protection Officer (DPO) focused his efforts on the advisory role and supported management and staff in their tasks. Specific attention was given to the following projects:

- The refinement of contractual clauses for outsourcing to cloud service providers;
- The implementation of Data Protection by design in the new Events Logistics Management tool set up as ECHA's regular event and meeting management tool;
- The handover of the medical files to the new service provider.

Several awareness actions were organised and training of staff also got the necessary attention, with a special focus on newcomers.

In view of the upcoming reform of the legal framework regarding personal data protection, the DPO performed a gap analysis of the old and new standards and drafted an action plan to implement the necessary changes by the entry into force on 25 May 2018.

3.1.3. Security and business continuity

Currently there are three areas of security at ECHA following the structure adopted in 2015: IT security management, physical security and business continuity.

ECHA did not suffer from any major IT security incident, i.e. confidential business information was not stolen or leaked as a result of any cyber-attack. The cyber risks were mitigated and a high level of IT security was maintained by delivering the following IT security services:

- Proactive vulnerability management services: IT security continuously monitored new vulnerabilities and threats, coordinated related mitigation actions (e.g. patching or other preventive actions). Vulnerability scans were regularly performed to ECHA IT infrastructure and the bespoken applications releases were security tested before moved to the production.
- Detective security monitoring and reactive incident response services: Security of ECHA IT infrastructure was actively monitored, suspected incidents and unusual events were carefully investigated, and malware infections and intrusion attempts responded to professionally and timely before impact was escalated.
- Consultative advisory service: among other things, IT security supported IT projects and services to design new, secure solutions, implement security measures and continuously maintain and improve the security of IT processes.

IT security initiated and coordinated several improvement actions. Several significant risks and vulnerabilities were mitigated in 2017, by installing a new highly secure printing solution, revising the Standard Security Requirements for MSCAs and enabling better remote services for IT contractors.

The annual Crisis Exercise was carried out in November 2017, and some improvement actions from it will be implemented to improve the readiness to react of the ECHA's Crisis Management Group. The rescue plan was updated in October 2017 and a fire inspection by Helsinki City Rescue Department was performed in part of the building in December 2017. The disaster recovery exercise which was agreed at the last Management review was prepared in 2017 and launched in 2018.

The external audit on the Cloud Services for SMEs performed in 2017 did not raise any risks or significant issues.

3.2 Compliance with and effectiveness of the implementation of ECHA Integrated Management Standards

The Management Board adopted the ECHA Integrated Management Standards, replacing the ECHA Quality and Internal Control Standards on 17 December 2013. A first assessment of ECHA's Management system against the requirements of the standards took place and was reflected in the Annual Activity Report of the Authorising Officer for 2013. In March 2014, a new ECHA Financial Regulation entered into force bringing a number of new provisions focusing on elimination of multiple controls and improving the cost-benefit ratios of controls. Following those provisions, the Authorising Officer focused both on effectiveness and efficiency in assessing the functioning of the control systems against the requirements of the ECHA Integrated Management Standards for 2014, which practice has continued in the following years as well.

In 2017, a thorough assessment of ECHA's compliance with the Integrated Management Standards was performed, following the approach as described below:

A preliminary assessment was performed by the Directors and the Internal Control Officer based on staff and stakeholders surveys, audit results (including IAC and IAS audits, internal quality audits, ISO 9001:2015 and ISO 14001:2015 recertification audits in 2017), ex-ante and ex-post evaluations, non-conformities, complaints, risks, opportunities, performance measurements and other reports. Those sources analysed fed the assessment of the Integrated Management Standards, discussed by the Directors and concluded at the Management review (see point 2.5).

The Authorising Officer performed his final assessment of the Agency's system compliance with ECHA Integrated Management Standards taking into account the Directors' and the Internal Control Officer's preliminary assessment. Overall, ECHA is either fully or mostly compliant with all requirements to the Integrated Management Standards. In 2017, the Agency has undertaken several internal and external assessments of its Management system and some of them have indicated minor gaps in the implementation of some of the standards. This has been the reason for downgrading the compliance with three requirements of the standards. The assessment of the year 2017 is presented together with the assessment of years 2016 and 2015 in detail in Annex III.

3.3 Specific efforts to improve the economy and efficiency of financial and non-financial activities

The work on setting the foundations for an effective and efficient Management system started in 2008 with the commitment of the Management Board to implement a system compliant with ISO 9001:2008 Quality Management Standard. In 2014, ECHA Management system was audited by Lloyd's Register Quality Assurance and the Agency was certified against the ISO 9001:2008 Standard. The surveillance audit performed in November 2015 confirmed that ECHA complies with the requirements of the new ISO 9001:2015 as well. The second surveillance audit performed in November 2016, whose scope included all Agency's activities (under the REACH, Biocides and PIC Regulations) concluded that ECHA is compliant to both ISO 9001:2015 and the Environmental Management Standard ISO 14001:2015. The re-certification audit in 2017 confirmed once again the compliance of the Agency with the requirements of both of the standards (ISO 9001:2015 and ISO 14001:2015).

In 2017, ECHA continued implementing projects under the Efficiency Development Programme with a strong focus on process improvements.

The cross-functional improvement projects from previous years, implemented in the processes of Dossier Evaluation, Substance Evaluation, Processing of External Requests, Applications for Authorisation, and procurement and financial workflows have transitioned to continuous

improvement mode as they have met most of their improvement goals. Two of those projects (dossier evaluation and procurement and financial workflows) were evaluated in the ex-post evaluation of the Efficiency Programme (more details on the results of the evaluation are available in Section 2.10. Ex-ante and ex-post evaluations). The project on optimising the Planning Monitoring and Reporting processes will continue in 2018 as well. Two new topics (Committees & Meetings and Biocides) have been added to the portfolio in 2017. The results of the Committees & Meetings project measured in 2017 indicate that the declaration handling steps in the Committees Efficiency project were reduced by 50% (from 14-16 steps down to 6-8 steps) mainly due to the removal of the physical signature and centralising their administration. The rationalised filing plan in the Biocides processes, improving the search functions, together with creating a clearer handbook improving the quality and consistency internally, as well as interacting with MSCAs earlier for better quality and consistency of inputs have led to savings of approximately 300 person-hours.

The cost-risk-benefit methodology was also applied when deciding on the steps to remain in the newly introduced documents workflow of the IMS (Integrated Management System) tool. Besides introducing an electronic process to replace the paper-based documents approval workflow, the approval steps were decreased more than 50% (previously 6 steps, reduced to 2-3 steps).

The overall efficiency of the Efficiency Programme is measured via the score indicating the progress towards achievement of Strategic objective 4 (SO4) "To enhance the Agency's ability to provide services and deliver planned output while efficiently using resources". The SO4 score in 2017 registered an increase of 8.1% compared to the previous year. More information about the logic of the model and the trend in previous years is available in the General Report (Annex I).

PART IV MANAGEMENT ASSURANCE

4.1. Review of the elements supporting assurance

No significant weaknesses that may have a potential impact on the declaration of assurance of the Authorising Officer were identified and reported in any of the building blocks (Part I, II and III of this report).

4.2 Reservations (where applicable)

Not applicable

4.3 Overall conclusion on assurance (where applicable)

Not applicable

4.4 Declaration of assurance

The declaration of assurance is available in Annex IV.

Annexes[3]

Annex I	**Human resources statistics**
Annex II	**Statistics on financial management**
Annex III	**Assessment of ECHA Integrated Management Standards**
Annex IV	**Declaration of assurance**

[3] Other annexes such as Achievements of Work programme 2017, Workload drivers and performance indicators representing the core business statistics of the Agency, Resources per activity, ECHA organisation chart, as well as the MB assessment of the Consolidated Annual Activity Report for 2017 are included in the General Report 2017. The final annual accounts for 2017 will be submitted together with the Consolidated Annual Activity Report for 2017 before 1 July 2018.

ANNEX I. HUMAN RESOURCES STATISTICS

1. Last establishment plan adopted

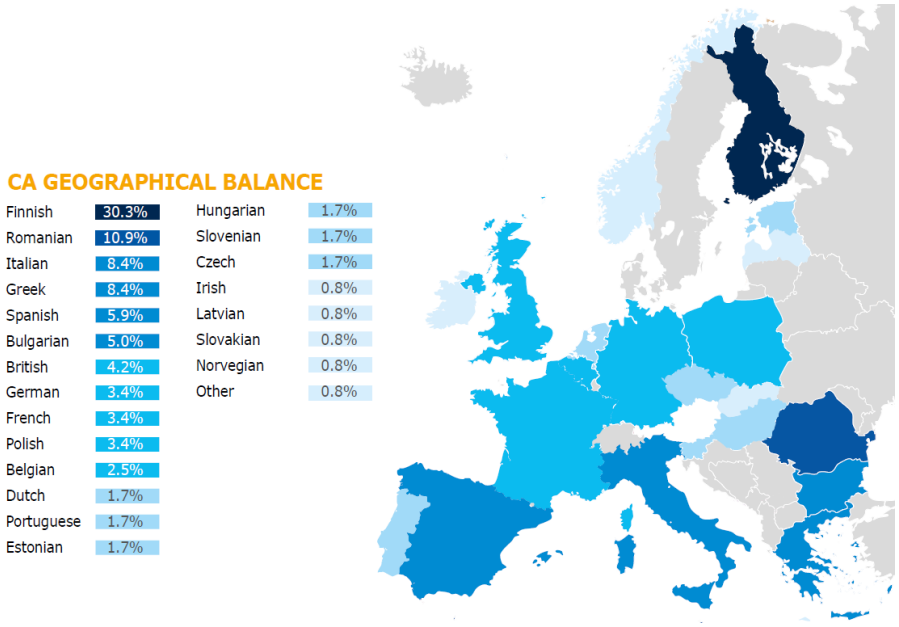
Category and grade	Establishment plan in voted EU Budget 2017				Posts filled 31 December 2017*			
	TA				TA			
	REACH/ CLP	Biocides	PIC	**TOTAL**	REACH/ CLP	Biocides	PIC	**TOTAL**
AD 15	1		0	**1**	1	0	0	**1**
AD 14	5		0	**5**	4	0	0	**4**
AD 13	15		0	**15**	10	0	0	**10**
AD 12	18	2	0	**20**	11	1	0	**12**
AD 11	31	3	0	**34**	20	1	0	**21**
AD 10	36	3	0	**39**	21	1	0	**22**
AD 9	48	6	0	**54**	49	2	0	**51**
AD 8	49	12	1	**62**	47	5	0	**52**
AD 7	59	5	0	**64**	71	9	0	**80**
AD 6	31	4	0	**35**	53	13	0	**66**
AD 5	8		0	**8**	15	3	1	**19**
Total AD	**301**	**35**	**1**	**337**	**302**	**35**	**1**	**338**
AST 11	0		0	**0**	0	0	0	**0**
AST 10	0		0	**0**	0	0	0	**0**
AST 9	5		0	**5**	2	0	0	**2**
AST 8	7		0	**7**	3	0	0	**3**
AST 7	11	1	2	**14**	5	0	0	**5**
AST 6	15		0	**15**	10	0	1	**11**
AST 5	31	3	0	**34**	21	1	1	**23**
AST 4	19	2	1	**22**	26	5	1	**32**
AST 3	13	3	2	**18**	23	2	2	**27**
AST 2	5		0	**5**	10	1	0	**11**
AST 1	3		0	**3**	0	0	0	**0**
Total AST	**109**	**9**	**5**	**123**	**100**	**9**	**5**	**114**
AST/SC 6				**0**				**0**
AST/SC 5				**0**				**0**
AST/SC 4				**0**				**0**
AST/SC 3				**0**				**0**
AST/SC 2				**0**				**0**
AST/SC 1				**0**				**0**
TOTAL AD+AST	**410**	**44**	**6**	**460**	**402**	**44**	**6**	**452**

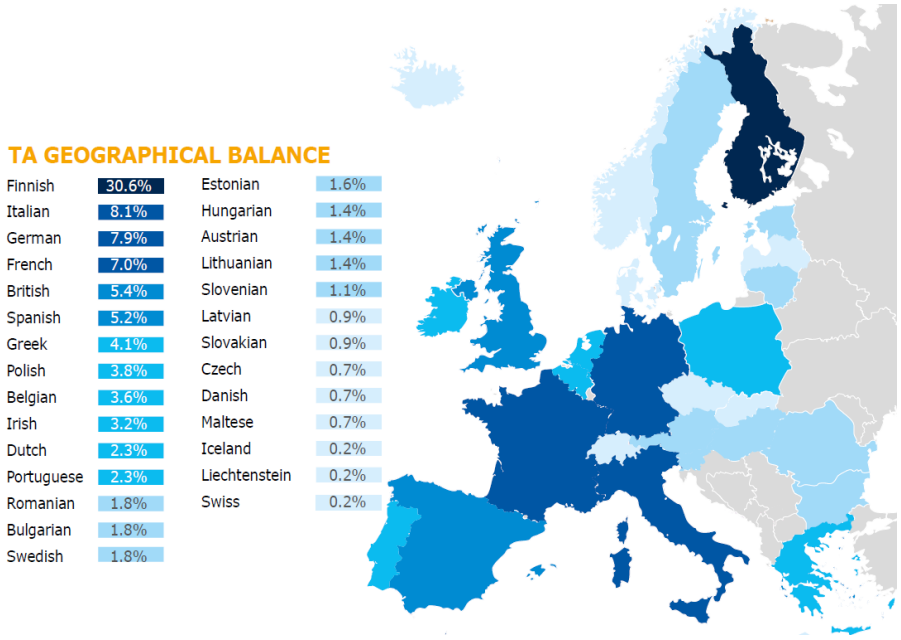
	CA					CA posts filled 31 December 2017*				
	REACH/ CLP	Biocides	PIC	Delega-ted tasks	**TOTAL**	REACH/ CLP	Biocides	PIC	Delega-ted tasks	**TOTAL**
CA FG IV	19	6	1	2	28	16	7		1	24
CA FG III	65	7		1	73	56	5		1	61
CA FG II	18	2			20	31	3	1		35
CA FG I					0					0
TOTAL CAs in place						**103**	**15**	**1**	**2**	**121**
Total CA (FTE)	**102**	**15**	**1**	**3**	**121**	**96.96**	**13.33**	**0.84**	**1.8**	**113**

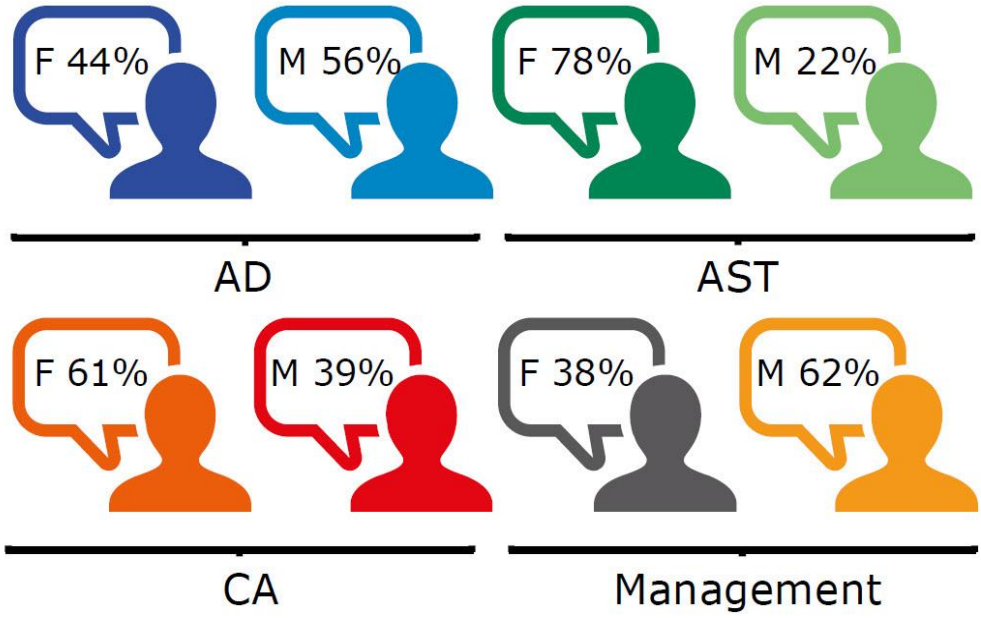
* 8 REACH TAs, 1 REACH CA, 1 Biocides CA under recruitment

Percentage of posts filled on 31 December 2017		
	REACH/CLP/PIC	Biocides
TA posts	98%	100%
CA posts	100%	100%

2. Geographical and gender balance (as per 31 December 2017)







Note: The gender balance for Management includes grades in the range of AD 9-AD 14

3. Results of the screening / benchmarking exercise

Key functions	***Type of contract (official, TA or CA)***	***Function group, grade of recruitment (or bottom of the brackets if published in brackets)***	***Indication whether the function is dedicated to administrative support or operations*** *[subject to definitions used in screening methodology]*
CORE FUNCTIONS			
Executive Director	TA - 5 + 5 years	AD 14	Management
Deputy Executive Director	TA - 5 + 5 years + indefinite	AD 14	Management
Director (Head of Directorate) (Level 2)	TA - 5 + 5 years + indefinite	AD 13	Policy (operational)/ Administration
Head of Unit (Level 3)	TA - 5 + 5 years + indefinite	AD 9 – AD 12	Operations/ Administration
Administrator	TA - 5 + 5 years + indefinite	AD 5 – AD 9	Operations/Administration
SUPPORT FUNCTIONS			
Head of Administration (Head of Directorate) (Level 2)	TA 5 + 5 years + indefinite	AD 13	Administration
Head of Human Resources (Level 3)	TA - 5 + 5 years + indefinite	AD 9 – AD 11	Administration
Head of Finance (Level 3)	TA - 5 + 5 years + indefinite	AD 12	Administration
Head of Communication (Level 3)	TA - 5 + 5 years + indefinite	AD 10	Administration
Head of IT Unit	TA - 5 + 5 years + indefinite	AD 10	Administration
Senior Assistant	TA - 5 + 5 years + indefinite	AST 10 – AST 11	Operations/Administration
Assistant	TA - 5 + 5 years + indefinite	AST 1 – AST 5	Operations/Administration
SPECIAL FUNCTIONS			
Data Protection Officer	TA - 5 + 5 years + indefinite	AD 6	Administration
Accounting Officer	TA - 5 + 5 years + indefinite	AD 9	Administration
Internal Auditor	TA - 5 + 5 years + indefinite	AD 10	Administration

4. Benchmarking against previous year results

ECHA has undertaken the benchmarking exercise in 2017, in accordance with the Commission requirements. Overall, the percentage of the administrative support and coordination staff decreased from 2016 by 3%, while the percentage of operational staff increased, following the same trend. This exceptional 3% increase in the operational staff is directly linked to the additional staff required for the operations relates to the REACH Registration Deadline 2018 and no additional support staff recruited for managing the temporary peak in the workload. In light of this, to date it is expected that the benchmarking exercise in 2018 will highlight a decrease in comparison with the 2017 exercise, as the additional staff required for the Registration Deadline will be most probably not be required by the end of 2018.

Job Type (sub) category	**2016 (%)**	**2017 (%)**
Administrative support and Coordination	**20**	**17**
Administrative Support	16.4	14
Coordination	3.5	3
Operational	**74.6**	**77.7**
General operational	22.7	22.7
Programme management	44	48.2
Top level Operational Coord	3.3	3.5
Evaluation & Impact assessment	4.6	3.3
Neutral	**5.4**	**5.3**
Finance	5.1	5.0
Control	0.3	0.3

ANNEX II. STATISTICS ON FINANCIAL MANAGEMENT

Budget 2017: Breakdown & changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Regulation and Title

REACH/CLP

Title	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	61 505 966	364 257	61 870 223	61 208 225	98.9%	61 870 223	60 787 613	98.3%	416 200	0.7%	666 410
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	13 448 639	-133 485	13 315 154	12 976 045	97.4%	13 315 154	11 262 885	84.6%	1 713 160	13.2%	339 109
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	22 780 002	-626 823	22 153 179	21 397 254	96.5%	22 356 362	13 898 595	62.2%	7 649 547	40.4%	755 925
		97 734 607	**-396 051**	**97 338 556**	**95 581 524**	**98.2%**	**97 541 739**	**85 949 093**	**88.1%**	**9 778 907**	**11.3%**	**1 761 444**

Biocide

Title	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	6 931 428	-116 508	6 814 920	6 641 274	97.5%	6 814 920	6 556 226	96.2%	85 006	1.3%	173 688
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 459 364	49 112	1 508 476	1 467 673	97.3%	1 508 476	1 279 359	84.8%	188 314	12.8%	40 803
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 967 208	1 118 394	3 085 602	2 952 739	95.5%	3 085 602	1 004 874	32.6%	1 947 865	66.0%	132 863
		10 358 000	**1 050 998**	**11 408 998**	**11 061 686**	**96.9%**	**11 408 998**	**8 840 459**	**77.5%**	**2 221 185**	**20.1%**	**347 354**

PIC

Title	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	667 896	-64 574	603 322	597 222	99.0%	603 322	586 857	97.3%	10 365	1.7%	6 100
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	177 828	-4 343	173 485	172 634	99.5%	173 485	151 112	87.1%	21 522	12.5%	851
B0-5	OPERATIONAL EXPENDITURE - PIC	337 276	68 917	406 193	406 143	100.0%	406 193	233 437	57.5%	172 705	42.5%	50
		1 183 000	**0**	**1 183 000**	**1 175 999**	**99.4%**	**1 183 000**	**971 406**	**82.1%**	**204 593**	**17.4%**	**7 001**

Budget 2017: Breakdown & changes in commitment appropriations and implementation of the appropriations for the year (C1) per Chapter

Chapter	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-11	STAFF IN ACTIVE EMPLOYMENT	63 249 757	403 039	63 652 796	63 243 188	99%	63 652 796	63 238 734	99%	0	0%	414 062
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	688 801	-148 716	540 085	472 767	88%	540 085	453 612	84%	19 156	4%	67 317
A-13	MISSIONS AND DUTY TRAVEL	60 000	0	60 000	47 881	80%	60 000	46 468	77%	1 413	3%	12 119
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	1 920 667	-138 197	1 782 470	1 743 647	98%	1 782 470	1 650 768	93%	92 879	5%	38 823
A-15	TRAINING	1 150 332	-78 877	1 071 455	889 890	83%	1 071 455	789 115	74%	100 775	11%	181 565
A-16	EXTERNAL SERVICES	2 015 733	148 915	2 164 648	2 034 392	94%	2 164 648	1 745 060	81%	289 332	14%	130 256
A-17	ENTERTAINMENT AND REPRESENTATION EXPENSES	20 000	-2 989	17 011	14 956	88%	17 011	6 940	41%	8 016	54%	2 055
	Total	**69 105 290**	**183 175**	**69 288 465**	**68 446 720**	**99%**	**69 288 465**	**67 930 696**	**98%**	**511 571**	**1%**	**846 198**

Chapter	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	7 459 243	256 816	7 716 059	7 704 610	100%	7 716 059	7 419 260	96%	285 351	4%	11 449
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	6 969 820	-308 187	6 661 633	6 333 526	95%	6 661 633	4 955 536	74%	1 377 990	22%	328 107
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	371 073	-30 205	340 868	321 860	94%	340 868	96 752	28%	225 108	70%	19 008
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	279 695	-5 640	274 055	253 672	93%	274 055	219 323	80%	34 349	14%	20 384
A-25	MEETINGS EXPENDITURE	6 000	-1 500	4 500	2 685	60%	4 500	2 486	55%	199	7%	1 815
	Total	**15 085 831**	**-88 716**	**14 997 115**	**14 616 353**	**97%**	**14 997 115**	**12 693 356**	**85%**	**1 922 997**	**13%**	**380 763**

Chapter	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
B3-0	REACH	21 291 402	-270 668	21 020 734	20 290 605	96%	21 020 734	12 641 058	60%	7 649 547	38%	730 129
B3-1	Multiannual activities	1 188 600	-356 155	832 445	811 869	97%	250 816	182 739	73%		97%	20 576
B3-8	INTERNATIONAL ACTIVITIES	300 000	0	300 000	294 780	98%	1 084 812	1 074 798	99%		73%	5 220
	Total	**22 780 002**	**-626 823**	**22 153 179**	**21 397 254**	**97%**	**22 356 362**	**13 898 595**	**62%**	**7 649 547**	**40%**	**755 925**

Chapter	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
B4-0	BIOCIDES	1 967 208	1 118 394	3 085 602	2 952 739	95%	3 085 602	1 004 874	33%	1 947 865	66%	132 863
	Total	**1 967 208**	**1 118 394**	**3 085 602**	**2 952 739**	**95%**	**3 085 602**	**1 004 874**	**33%**	**1 947 865**	**66%**	**132 863**

Chapter	Description	Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
B5-0	PIC	337 276	68 917	406 193	406 143	100%	406 193	233 437	57%	172 705	43%	50
	Total	**337 276**	**68 917**	**406 193**	**406 143**	**100%**	**406 193**	**233 437**	**57%**	**172 705**	**43%**	**50**

Total ECHA		Budget 2017 (1)	Transfers (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (4)/(3)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
		109 275 607	**654 947**	**109 930 554**	**107 819 209**	**98%**	**110 133 737**	**95 760 959**	**87%**	**12 204 684**	**11%**	**2 115 799**

Budget 2017: Implementation of assigned revenue (C4, C5, R0)

Title	Desciption	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A-1	STAFF	CND	C4	36 144	28 320	737%	36 144	28 320	88%	7 824	7 824
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C4	77 064	505	737%	77 064	0	88%	76 560	77 064
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C4	83 846	1 345	737%	83 846	1 345	88%	82 501	82 501
			C4	**197 055**	**30 170**	**15%**	**197 055**	**29 666**	**15%**	**166 885**	**167 389**

Title	Desciption	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A-1	STAFF	CND	C5	11 287	11 287	737%	11 287	11 287	88%	0	0
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C5	97 328	97 328	737%	97 328	76 958	88%	0	20 370
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C5	5 080	5 080	737%	5 080	5 080	88%	0	0
			C5	**113 696**	**113 696**	**100%**	**113 696**	**93 325**	**82%**	**0**	**20 370**

BL	Desciption	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
B03902	IPA programme agr. 2012/291-934	CND	R0	180 000	0	737%	180 000	0	88%	180 000	180 000
B03903	IPA programme agr. 2015/361-049	CND	R0	175 941	167 189	737%	175 941	148 070	88%	8 752	27 870
B03911	Delegated tasks	CND	R0	1 800 000	683 957	737%	1 800 000	410 808	88%	1 116 043	1 389 192
			R0	**2 155 941**	**851 146**	**39%**	**2 155 941**	**558 878**	**26%**	**1 304 795**	**1 597 062**

Budget 2017: Implementation of the appropriations carried forward from previous year (C8) Per Title

Title	Description	Carried Forward from 2016	Paid	Cancelled	% cancelled
A-1	STAFF	439 024	417 542	21 482	5%
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 811 788	1 776 780	35 008	2%
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	10 093 668	9 804 892	288 776	3%
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 310 235	1 295 012	15 223	1%
B0-5	OPERATIONAL EXPENDITURE - PIC	130 458	126 916	3 542	3%
		13 785 173	**13 421 142**	**364 031**	**3%**

ANNEX III. ASSESSMENT OF ECHA INTEGRATED MANAGEMENT STANDARDS

1. GOVERNANCE

1.1 Mission

The Agency's fundamental mission is clearly defined in an up-to-date and concise mission statement developed from the perspective of its stakeholders.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
Senior Management shall define the Agency's Mission from the perspective of the Agency's Stakeholders.	**Yes** --- *Main references:* *ECHA Integrated Management System Manual (MAN-0001)* *ECHA's Quality Policy (POL-0001)* *Annual and multiannual working programmes*	**Yes** --- *Main references:* *ECHA Integrated Management System Manual (MAN-0001)* *ECHA's Quality Policy (POL-0001)* *Annual and multiannual working programmes*	**Yes** --- *Main references:* *ECHA Integrated Management System Manual (MAN-0001)* *ECHA's Quality and Environmental Policy (POL-0001)* *Single Programming Document (annual and multiannual working programmes)*
The Mission shall be communicated and explained to the entire organisation and to its Stakeholders.	**Yes** In accordance with the Staff survey conducted in 2015, staff commitment to ECHA's mission has increased from 73% in 2013 to 77% in 2015 on the average. The mission is clearly defined and communicated across the Agency (on ECHA internal and external website, noticeboards etc.) and staff is aware of it. There has been a positive trend on how the staff see their own work contributing to	**Yes** According to the Directors' self-assessment of the IMS as of December 2016, ECHA's mission statement is clear, strong and easily understood and communicated to both staff and stakeholders.	**Yes** According to the Directors' self-assessment of the IMS as of December 2017, ECHA's mission statement is clear, strong and easily understood and communicated to both staff and stakeholders, as far as it refers to the current tasks undertaken by ECHA. Still, most of them consider that ECHA's mission, together with the vision and values, would need to be reviewed in 2018 in line with the new strategy and priorities for the years 2019-2023.

	ECHA's mission (increased from 74% in 2013 to 77%).		Staff survey 2017 indicates an increase in the staff commitment to ECHA's mission. Compared to 2015 when 85% of the staff have stated that they believe and support ECHA's mission, in 2017, this percentage has increased to 92%.

1.2 Ethical and organisational values

The Agency's Management and staff members are aware of and share appropriate ethical and organisational values and uphold these through their own behaviour and decision-making.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
Senior Management shall define the ethical and organisational values it stands by, through an open process of consultation and agreement, involving management, staff and stakeholders.	**Yes** The Agency has defined corporate values and they have been communicated largely, discussed in Unit meetings, published on the information screens. The internal Fraud Risk Assessment exercise that preceded the adoption of the Strategy revealed however that the risk profile of the Agency is rather low and therefore the main aim of the Strategy is to develop a widespread anti-fraud culture in ECHA, with a focus on awareness raising. The corporate and fraud risk assessment exercises were combined	**Yes** ECHA attaches great importance to its core value of independence and has since many years implemented strict controls via its policy on Prevention and Management of Conflicts of Interest. The external stakeholders of the Agency, including also its institutional stakeholders, demand a continued strong focus on this topic to guarantee regulatory output free from bias. ECHA also further fostered the anti-fraud culture in the Agency via the implementation of its anti-fraud action plan 2015-2016, including in 2016 e.g. an all-staff presentation by OLAF on	**Yes** In 2017, feedback from stakeholders collected through surveys and events has been positive on the areas of trustworthiness, transparency, independence and openness to dialogue. ECHA also further fostered the anti-fraud culture in the Agency via the ECHA Anti-Fraud Strategy, last revised by the ECHA Management Board in December 2016. It includes a focus on awareness and regularly reviewing key policies and procedures. Some important actions implemented during 2017 include a mandatory online training on prevention of conflicts of interest for all staff and a continued focus on awareness on

	in one in 2015 with a result of no specific fraud risks identified. In 2015, there has been almost 50% decrease compared to 2013 in the interventions dealt by the confidential counsellors, which is a good indication of the effectiveness of their work and the internal policy on harassment. --- *Main references:* *ECHA's Anti-fraud strategy [MB/60/2014]* *ECHA's Code of Good Administrative Behaviour [MB/11/2008]* *Management Board policy for managing conflicts of interest [MB/45/2011]* *WIN-0105 Prevention of Conflicts of Interest* *MB/42/2012/D final Prevention of psychological and sexual harassment in the European Chemicals Agency* *Staff survey 2015*	fraud prevention. The Anti-Fraud Strategy was also consolidated by the Management Board in December 2016. The draft discharge report for 2015 points out that ECHA has implemented a robust conflict of interest policy and detailed anti-fraud strategy in order to contribute to a culture of high ethical behaviour among the staff and experts working for the Agency, but not has set up specific rules on obligations after leaving the service for its experts and staff. --- *Main references:* *ECHA's Anti-fraud strategy [MB/60/2014]* *ECHA's Code of Good Administrative Behaviour [MB/11/2008]* *Management Board policy for managing conflicts of interest [MB/45/2011]* *WIN-0105 Prevention of Conflicts of Interest* *MB/42/2012/D final Prevention of psychological and sexual harassment in the European Chemicals Agency* *Draft discharge report for 2015*	important topics such as ethics, procurement and contract management and information security for newcomers and established staff. The review of all ECHA's activities undertaken by Deloitte in 2017 has concluded that ECHA has a fit for purpose transparency policy in place and the transparency of the Agency on its internal functioning is also appreciated by stakeholders, as it is the transparency of the regulatory processes of the Agency. --- *Main references:* *ECHA's Anti-fraud strategy [MB/60/2014]* *ECHA's Code of Good Administrative Behaviour [MB/11/2008]* *Management Board policy for managing conflicts of interest [MB/45/2011]* *WIN-0105 Prevention of Conflicts of Interest* *MB/42/2012/D final Prevention of psychological and sexual harassment in the European Chemicals Agency* *Staff Survey 2017* *Review of all ECHA's activities undertaken by Deloitte in 2017*
The Agency's management and staff members' behaviour, as well as the procedures and working methods	**Mostly** According to the Staff survey 2015, 78% of ECHA's staff (vs 72% in	**Yes** During 2016, actions such as a temporary rotation of Directors during 3 months and intensification of	**Yes** According to the Directors' self-assessment of the IMS as of December 2017, values are clearly communicated

shall be in line with its ethical and organisational values.	2013) believe and support ECHA's corporate values. Since 2013 many actions have been taken in promoting an atmosphere of openness and trust, among which dedicating a management seminar to that topic in September 2015. Further actions will be followed in 2016.	management seminars were taken in order to give opportunities for improvement in the area of trust in Management.	both internally and externally. In line with the new strategy, a review of the values, involving staff should be undertaken in 2018, together with the review of ECHA's mission and vision. During 2017, actions to intensify the Management seminars and to open the agenda to proposals from HoUs were taken in order to give opportunities for improvement in the area of trust in Management.

1.3 Management responsibility

The Agency's management is committed to setting up and implementing a comprehensive management system and standards. Delegation of powers is appropriate to the importance and number of decisions to be taken and the risks involved.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall have an Integrated Management System combining quality and internal control requirements and ensuring the efficiency and effectiveness of the controls imposed.	**Yes** In 2014, ECHA received ISO 9001:2008 certification. In 2015, ECHA underwent the ISO 9001:2015 surveillance audit which assessed Management commitment to be at a good level; roles, responsibilities and authorities well defined in the organisation; and the Management system based on a logical concept and clear structure complying with the ISO 9001:2015 requirements.	**Yes** In 2016, ECHA underwent a surveillance audit to assess the continuous compliance of ECHA management system to the requirements of ISO 9001:2015 and to extend the scope of the certification to cover the Biocides Regulation, thus covering all ECHA activities. In addition, the auditors performed a certification assessment against the requirements of the	**Yes** The review of all ECHA's activities undertaken by Deloitte in 2017 has concluded that ECHA's organisational structure, which is function-based, is fit for purpose for ECHA's current tasks and has so far allowed ECHA to work in an efficient way. The re-certification audit of ISO 9001:2015 and ISO 14001:2015 conducted in 2017 concluded for a third consecutive year, that

	The quality policy was assessed by the ISO 9001:2015 surveillance audit and was considered well communicated to ECHA staff and available on ECHA web site. ISO 9001:2015 certification is planned to be extended to include the Biocides activities in 2016. Further efforts were made towards ensuring efficiency of the controls imposed (see point 2.2.Risk Management). --- *Main reference:* *Integrated Management Standards [MB 36/2013]* *ECHA Integrated Management System Manual (MAN-0001)* *ECHA Financial Regulation MB/WP/03/2014* *ISO 9001:2008 certificate* *ISO 9001:2015 surveillance audit*	environmental management system standard ISO 14001:2015. The conclusions of the audit were mostly positive, confirming the assessment of 2015, with no major non-conformity found, and ECHA was considered compliant to both standards. The IAS audit on the BPR operations performed in 2016 concluded that the design and the practical implementation of the internal control system in ECHA in relation to the processes/activities under the BPR is effective and efficient. --- *Main reference:* *Integrated Management Standards [MB 36/2013]* *ECHA Integrated Management System Manual (MAN-0001)* *ECHA Financial Regulation MB/WP/03/2014* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment* *IAS audit on the BPR operations*	Management commitment continues being at high level and roles, responsibilities and authorities are well defined in the organisation. In addition, the auditors found that the Management Review was held in a structured way. In 2017, ECHA implemented all recommendations of the IAS audit on the BPR operations from 2016. According to the Directors' self-assessment of the IMS as of December 2017, the integrated management system is comprehensive, with well integrated quality and internal control elements, which is best evidenced by the ISO 9001:2015 certification. --- *Main reference:* *Integrated Management Standards [MB 36/2013]* *ECHA Integrated Management System Manual (MAN-0001)* *ECHA Financial Regulation MB/WP/03/2014* *ISO 9001:2015 and ISO 14001:2015 re-certification audits in 2017* *Review of all ECHA's activities undertaken by Deloitte in 2017* *IAS audit on the BPR operations*
The Agency shall have a system of delegation of powers appropriate to	**Mostly** In 2015, implementation of sub-delegations and new workflows	**Yes** In 2016, further efforts were made towards using delegation of powers	**Mostly** In 2017, further efforts were made towards using delegation of powers as a means for

the importance, number and risks of the decisions to be taken.	where the risk was assessed to be low and the effectiveness of controls preserved continued both under the Efficiency programme and as a separate initiative. E.g. in the dossier evaluation activities in 2013 many sub-delegations were made to Head of Unit level, in 2014 sub-delegations to Team Leader level were added, while in 2015 the focus was more on implementing and monitoring the new workflows. Still, more actions are foreseen in 2016 in order to ensure an optimal system of delegation of powers.	as a means for gaining efficiency where the risk was assessed to be low and the effectiveness of controls preserved. Implementation of sub-delegations continued in the evaluation activity: further sub-delegations to Team Leader level were added. Other activities, such as Human Resource management also took new initiatives to use sub-delegations as a tool to gain efficiency in 2016. For example, in the area of entitlements of statutory staff, the decision-making was lowered down 3 steps, with a result to make the process flow efficiently when taken over this task from PMO. Further efforts towards ensuring efficiency of the controls imposed are presented under standard 2.2. Risk Management.	gaining efficiency where the risk was assessed to be low and the effectiveness of controls preserved. Slight improvements from the previous year's situation are to be noted in the increase of the authority score of Staff Survey 2017 (73% in 2017 vs 70% in 2015 of staff have replied that they can make their own decisions in their work, and 78% in 2017 vs 74% in 2015 have the freedom to act without asking for permission of their manager). Nevertheless, staff and middle management still consider that there is more to be done in that area. At the Management seminar hold early in 2018, HoUs have expressed their opinion that there is further need for delegation and staff empowerment. An analysis of the open replies in the Staff survey 2017 also points to the need for further empowerment and less fear of mistakes. According to the Directors' self-assessment of the IMS as of December 2017, delegation of powers is in place to ensure efficiency and business continuity of operations, though more could be done in that area, i.e. to find the right balance between risk and cost and to render the management system as lean as possible, as well as to increase staff motivation and initiatives.

	---------- *Main references:* *Efficiency programme* *Delegation and sub-delegation register* *PRO-0059 Internal decision-making and delegation of power*	---------- *Main references:* *Efficiency programme* *Delegation and sub-delegation register* *PRO-0059 Internal decision-making and delegation of power*	---------- *Main references:* *Efficiency programme* *Delegation and sub-delegation register* *PRO-0059 Internal decision-making and delegation of power* *Staff survey 2017*

1.4 Human Resources Policy

The Agency has competent and efficient staff, provides conditions for staff development and work-life balance and an adequate working environment. The Agency's management has mechanisms to monitor and assess the performance of staff in an equal and transparent manner.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall have rigorous selection procedures ensuring recruitment of competent staff and provisions ensuring staff development	**Yes** In line with the results of ISO 9001:2008/2015 audit where the auditors pointed out that ECHA's staff competence is at excellent level, the Staff survey 2015 shows increase in competence from 79% in 2013 to 81% in 2015 and in the ability to cooperate (from 54% in 2013 to 60% in 2015 respectively). In 2015, ECHA-level prioritised group learning and development needs were collected from the Directors, presented to the DCM and published on ECHAnet. Those constitute the	**Yes** According to the ISO 9001:2015 and ISO 14001:2015 audits in 2016, ECHA has excellent competence in both planning and implementation, which was also the conclusion of the ISO 9001:2008/2015 audits in 2014 and 2015. The learning and development framework (established in 2014 and implemented in 2015) was used in 2016 to improve organisational performance through dedicated	**Yes** According to the ISO 9001:2015 and ISO 14001:2015 audits conducted both in 2016 and 2017, ECHA has very skilled personnel, structured way of working and excellent competence in both planning and implementation (which was also the conclusion of the ISO 9001:2008/2015 audits in 2014 and 2015). Staff survey 2017 shows that 81% of staff also perceive their competence as high. The review of all ECHA's activities undertaken by Deloitte in 2017 pointed out that the Agency was able to attract the right talent and is perceived as an attractive

	ECHA-level Learning and Development Plan. The monitoring of the plan is done quarterly in terms of whether the training has taken place and whether the staff member considers it useful. In 2014, ECHA implemented the Commission's system for reclassification of Contract Agents (CAs) which allowed CAs promotion for the second time in 2015 and which is expected to help reducing the CAs turnover. --- *Main references:* *ED/99/2014 Learning and Development Framework* *Commission Decision C(2013) 2529 of 03.05.2013* *Management Board decision MB/24/2014* *POL-0020 Staff retention policy* *PRO-0035 Selection and recruitment of statutory staff (management posts)* *PRO-0036 Selection and recruitment of statutory staff (non-management posts* *PRO-0038 Organisation and management of ECHA staff training* *WIN -0158 Publication of Vacancy Notices and the nomination of Selection Committees* *WIN- 0157 Coordination of selection procedures for statutory staff (non-management)* *ISO 9001:2008 & ISO 9001:2015 surveillance audit* *Staff Survey 2015*	competence development efforts at personal, Unit, and corporate level. A promotion system for Contract Agents, applied for the first time in 2014, repeated in 2015 and 2016, is expected to help further reducing the CAs turnover. Compared to 2013 when the CA turnover was 12.5%, in 2015 it dropped to 7.6% and in 2016 to 7%, which indicates that measures taken have so far been effective. --- *Main references:* *ED/99/2014 Learning and Development Framework* *Management Board decision MB/24/2014* *POL-0020 Staff retention policy* *PRO-0036 Selection and recruitment of statutory staff* *PRO-0038 Organisation and management of ECHA staff training* *WIN -0158 Publication of Vacancy Notices and the nomination of Selection Committees* *WIN- 0157 Coordination of selection procedures for statutory staff (non-management)* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment*	workplace, with a relatively high staff commitment, although it remains difficult to attract highly specialised profiles given the competition with the private sector on the job market. Internal mobility has been considered to be only used in a limited way in ECHA, thus missing on the opportunity to recruit staff in a very cost-efficient way. To capture staff perceptions on the quality and added value of trainings provided, the Agency has adopted a qualitative performance indicator. ISO 9001:2015 and ISO 14001:2015 auditors also concluded in 2017 that HR and training processes are well working at ECHA. --- *Main references:* *ED/99/2014 Learning and Development Framework* *Management Board decision MB/24/2014* *POL-0020 Staff retention policy* *PRO-0036 Selection and recruitment of statutory staff* *PRO-0038 Organisation and management of ECHA staff training* *WIN -0158 Publication of Vacancy Notices and the nomination of Selection Committees* *WIN- 0157 Coordination of selection procedures for statutory staff (non-management)* *ISO 9001:2015 and ISO 14001:2015 re-certification audits in 2017* *Review of all ECHA's activities undertaken by Deloitte in 2017*

Senior Management shall ensure that the staff performance is monitored and assessed in an objective, equal and transparent way.	**Yes** Staff survey 2015 has indicated improvement in staff motivation and job satisfaction – 56% in 2015 from 52% in 2013. The recognition of personal contribution has also increased from 69% in 2013 to 74% in 2015. In 2015, there were no legal appeals related to the performance appraisal last year and only 1 request for review was made to the Joint committee for appraisal and reclassification resulting from the staff appraisal exercise. A new system of appraisal, which is much more consistent with the Commission's system was adopted by the MB of ECHA in June 2015 and will be implemented in ECHA as of 2016. --- *Main references:* *ECHA's Regulatory Science Strategy* *PRO-0037 Organisation of performance appraisal exercise* *Staff survey 2015*	**Yes** Following the Commission's system for reclassification, a new reclassification process for temporary and contract agents was designed and carried out in 2016. The staff opinion on the new system for reclassification will be gathered in the next Staff Survey planned for 2017. So far, the results from the previous Staff Survey show satisfaction with the recognition of personal contribution, which has increased from 69% in 2013 to 74% in 2015. In 2016, there were no legal appeals related to the performance appraisal for the reference period 2015. --- *Main references:* *ECHA's Regulatory Science Strategy* *PRO-0037 Organisation of performance appraisal exercise* *Staff survey 2015*	**Yes** The working culture index in ECHA Staff Survey 2017 has remained at the same level as the one in 2015 (59% overall), with almost the same level of satisfaction with the recognition of the personal contribution (72% in 2017 and 74% in 2015) and an increase in the perception that overall ECHA is a good place to work (74% of staff in 2017 vs 71% in 2015). In 2017, there was 1 legal appeal related to the performance appraisal for the reference period 2016. --- *Main references:* *ECHA's Regulatory Science Strategy* *PRO-0037 Organisation of performance appraisal exercise* *Staff survey 2017*

The Agency shall have provisions to ensure a good work-life balance and an adequate working environment for its staff members	**Mostly** In 2015, teleworking was also made more widely available to staff by setting proper security arrangements and integrating the teleworking request as an electronic form in the new Human Resources Management System (HRMS). Based on the agreed refurbishment plan with the landlord, major projects have been completed in 2015 without major disruption of ECHA's normal work process or worsening of the air quality. Thus, the corporate risk as identified in 2015 has been under control throughout the year. Still, a number of building related issues remain for the coming years and those will be addressed as part of the Building 2020 project.	**Yes** Some of the measures to ensure a better work-life balance adopted by the Management refer to new teleworking rules, effective as of February 2017. The new rules follow relevant information security arrangements set already in 2015 and allow for 50% of structural teleworking and 5 days of occasional teleworking with possibilities for remote participation in meetings via Skype for Business or teleconferences. In order to address health issues, in particular with regard to the air quality, in 2014 ECHA reached an agreement with the landlord on implementation of urgent renovations in the coming years, some of which were completed in both 2015 and 2016. ECHA also decided to launch a survey on the air quality whose results will be available in 2017. In 2016 ECHA launched a call for tender for the selection of a service provider for the construction or the lease of a new building in the area of Helsinki. The procurement as well as all other building related matters are	**Yes** Some of the measures to ensure a better work-life balance adopted by the Management refer to new teleworking rules, effective as of February 2017. A survey conducted at the end of 2017 shows a high staff satisfaction with the teleworking opportunities, due to increase in drafting productivity and a better work-life balance. In 2017, ECHA conducted a survey on the air quality, whose results show normal values for most of the areas studied in the building. For the areas where different results were obtained (still within the norms), air purifiers will be provided and special monitoring will follow. In 2016 ECHA launched a call for tender for the selection of a service provider for the construction or the lease of a new building in the area of Helsinki. The ex-ante evaluation of the options (buy or lease), as well as the procurement procedure were completed in 2017 and the future building of ECHA was selected. The building location, premises organisation and other relevant arrangements have provoked a lot of interest from ECHA staff who have been involved to certain extent in some options analysis. Further involvement of staff in the

	---------- *Main references:* *Rules of procedure of the Staff Committee* *Teleworking rules* *ED/74/2012 as of 26/04/2012 Terms of Reference of the Joint Committee on Health and Wellbeing* *PRO-0044 Maintenance of premises and equipment*	addressed as part of the Building 2020 project. ---------- *Main references:* *Rules of procedure of the Staff Committee* *Revised teleworking rules* *ED/74/2012 as of 26/04/2012 Terms of Reference of the Joint Committee on Health and Wellbeing* *PRO-0044 Maintenance of premises and equipment*	future choices to make is foreseen in the years to come. ---------- *Main references:* *Rules of procedure of the Staff Committee* *Revised teleworking rules* *ED/74/2012 as of 26/04/2012 Terms of Reference of the Joint Committee on Health and Wellbeing* *PRO-0044 Maintenance of premises and equipment*

1.5 Stakeholders' management

The Agency's engagement of its stakeholders is based on the Agency's corporate identity and values and their involvement in the Agency's operations, enhanced through effective and targeted communication.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
ECHA's engagement with its stakeholders shall be based on the Agency's corporate values enhanced through effective communication strategy targeted to the different stakeholders' categories	**Yes** ISO 9001:2015 surveillance audit concluded that the Agency is collecting and using the stakeholders feedback in a good way, which confirms their initial finding during the certification audit in 2014 that ECHA is committed to its stakeholders, to building good	**Yes** The ISO 9001:2015 surveillance audit concluded that the Agency is collecting and using the stakeholders feedback in a good way, which confirms their initial finding during the certification audit in 2014 that ECHA is committed to its stakeholders, to building good	**Yes** Overall, the results of the Stakeholder Survey 2017 reflect a positive view of the Agency's activities, with most performance indicators indicating a high satisfaction level, and thus meeting the target level of quality objective N° 2 "Stakeholders satisfaction" – "High".

	relations with them and gathering their feedback, and that stakeholders are defined widely and maintained at good level. The stakeholders survey of 2015 shows improvement in the stakeholders satisfaction in most of the areas, with the highest improvement in the level of satisfaction of MSCA with ECHA's support for substance evaluation (followed by the stakeholders' satisfaction with the information received by ECHA and ECHA's commitment to stakeholders). Though Biocides is a comparatively new process where some working practices are still being modified, stakeholders seem satisfied with the level of scientific, technical and administrative support, provided to the members of the BPC, CG, and to the Commission, MSCAs and industry. --- *Main references:* *MB/61/2014 ECHA's approach to Transparency*	relations with them and gathering their feedback, and that stakeholders are defined widely and maintained at good level. In 2016 ECHA upgraded its website to reach out to smaller companies and expanded the use of social media and drew additional audiences' attention to the ECHA website. Overall, the results of the Stakeholder Survey 2016 consisting of both an external and internal survey reflect a positive view of the Agency's activities, with most performance indicators indicating a high satisfaction level, and thus meeting the target level of quality objective N° 2 "Stakeholders satisfaction" – "High". --- *Main references:* *WIN-0145 Stakeholder Survey Coordination and Management*	The stakeholders survey of 2017 shows improvement in the stakeholders satisfaction in most of the areas. The ISO 9001:2015 re-certification audit in 2017 concluded that the Agency is collecting and using the stakeholders feedback in a good way, which confirms their initial finding during previous years that ECHA is committed to its stakeholders, to building good relations with them and gathering their feedback, and that stakeholders are defined widely and maintained at good level. In their visit in 2017, auditors noted the high stakeholder satisfaction and the good follow up of actions. The review of all ECHA's activities undertaken by Deloitte in 2017 concluded that overall ECHA and its Committees have established a strong and trustful relationship with its stakeholders. The evaluation also pointed out that ECHA offers additional ways of involving stakeholders, thus increasing the quality and acceptability of its activities compared to the pre-REACH process. --- *Main references:* *WIN-0145 Stakeholder Survey Coordination and Management*

	WIN-0145 Stakeholder Survey coordination and Management *LIS -0014 Task list for the management of the Stakeholders' Day event* *ISO 9001:2008 audit* *ISO 9001:2015 surveillance audit* *IAC audits* *External communication strategy of ECHA – MB/66/2011 from 15/12/2011* *PRO-0047 Management of the relations with ECHA Stakeholders* *WIN-0074 Accredited Stakeholder Application Management* *Stakeholders survey 2015*	*LIS -0014 Task list for the management of the Stakeholders' Day event* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment* *External communication strategy of ECHA – MB/66/2011 from 15/12/2011* *PRO-0047 Management of the relations with ECHA Stakeholders* *WIN-0074 Accredited Stakeholder Application Management* *Stakeholders surveys 2015 and 2016*	*PRO-0047 Management of the relations with ECHA Stakeholders* *WIN-0074 Accredited Stakeholder Application Management* *Stakeholders surveys 2017 and 2016* *ISO 9001:2015 and ISO 14001:2015 re-certification audits in 2017* *Review of all ECHA's activities undertaken by Deloitte in 2017*

2.1. Objectives planning and resources allocation

The Agency's Management defines the strategy and the annual and multiannual objectives, prioritises tasks and allocates resources accordingly.

Requirement	**Is the requirement fulfilled - Assessment 2015**	**Is the requirement fulfilled - Assessment 2016**	**Is the requirement fulfilled - Assessment 2017**
The Agency shall have a corporate vision and strategy expressed in multiannual work programmes and translated to annual work programmes	**Yes** --- *Main references:* *Annual and multiannual work programmes*	**Yes** --- *Main references:* *Annual and multiannual work programmes*	**Yes** --- *Main references:* *Single Programming Document (annual and multiannual work programmes)*

The Senior Management shall define the strategic and annual objectives clearly in a way that makes it possible to measure their performance, identify the risks related to them and cascade them to lower levels.	**Mostly** In view of further optimising the Agency's planning and reporting, the structure of the Annual Work Programme (AWP) 2016 structure was changed to more logically group and present ECHA's activities to the general public. Other measures, such as reviewing the number of baseline figures and performance indicators and creating a database with all metrics of the Agency were undertaken in 2015 following the recommendations of the audit on key performance indicators (KPI) and the feasibility study on planning and reporting, both conducted in 2014. The purpose of those measures was to clean duplicate metrics and to remove/replace metrics with little added value compared to the cost of their production. In addition, a new Unit Level Template (ULP) was created, with a result to better cascade the Work programme objectives to Unit level, create automation between different Excel databases, minimize the manual and remove the duplicate input. Still, there is more progress to be done in 2016, as ISO 9001:2015	**Yes** For the 2016 Work Programme, ECHA has adopted a new activity structure for its corporate plans and reports, with the aim to better link objectives, actions, and relevant human and financial resources, around action areas which produce impact. In parallel, significant effort has been put into streamlining the planning and reporting content and working practices at ECHA. During 2016, ECHA has also drafted the 2017 plan, executing the transition from Annual Work Programme to Single Programming document (which includes a multi-year forecasting dimension). This has determined an increase in planning content, due to the additional multi-annual forecasting dimension added to the annual planning cycle. However, the transition has been managed without significant increase in resources by streamlining the procedures, concentrating the planning in specific periods of the year, and more tightly linking objectives, budget and human resources planning.	**Mostly** In 2017, the Agency emphasised further to streamline the interplay between management and operational service in how activities are planned, to what extent they are monitored and by which means and how they are reported. As the 2017 Work Programme introduced performance indicators per each of the activities, those had to be added to a monitoring system. The monitoring in 2017 allowed to visualise for the management of the Agency how processes are performing against the initially planned figures. For that purpose monthly dashboards of some selected activities in form of charts were maintained as way to communicate the monitoring data. The review of all ECHA's activities undertaken by Deloitte in 2017 concluded that the link between strategic and operational objectives and performance indicators is not fully established. The same report also indicated that although the Agency has defined strategic objectives and is taking action in a multi-annual and strategic perspective, the Agency does not yet monitor achievements of all its strategic objectives to the fullest extent and places the focus more on quantitative

	surveillance audit found that the relationship between objectives and indicators is not always clear or logical. Some of the recommendations under the IAC KPI audit will be addressed in 2016 as well. --- *Main references:* *Models and measurement of the 4 strategic objectives* *Annual and multiannual work programmes* *PRO-0080 IQMS planning* *Multi-annual staff policy plans* *Unit level plans* *ECHA Financial regulation* *PRO-0013 Planning and reporting*	--- *Main references:* *Models and measurement of the 4 strategic objectives* *Annual and multiannual work programmes* *PRO-0080 IQMS planning* *Multi-annual staff policy plans* *Unit level plans* *ECHA Financial regulation* *PRO-0013 Integrated Planning, Monitoring and Reporting*	indicators, rather than on quality performance indicators. --- *Main references:* *Models and measurement of the 4 strategic objectives* *Annual and multiannual work programmes* *PRO-0080 IQMS planning* *Multi-annual staff policy plans* *Unit level plans* *ECHA Financial regulation* *PRO-0013 Integrated Planning, Monitoring and Reporting* *Review of all ECHA's activities undertaken by Deloitte in 2017*
The Agency shall ensure that human and financial resources are allocated based on the Agency's objectives and workload and aligned with the organisational structure and the principles of efficiency, effectiveness and economy.	**Yes** In 2015, the Agency has made progress in cascading the Work Programme objectives to the Unit objectives and in aligning top down and bottom up resource allocations. Between the future goals of the planning and reporting project for the coming years is the testing of an IT tool, which could be potentially used for activity planning and resource	**Yes** The reporting and resourcing practices have been streamlined in 2016. The workload drivers and indicators have been simplified and consolidated, with focus on prioritised KPIs that best support decision making. The reporting cadence and content has also been better aligned with the decision making moments	**Yes** In a further step to automate the input from various sources and align resources to objectives and workload, a tailor-made software – the PMR tool – has been developed and tested. Though parts of the PMR tool are already operational, there are still a number of issues which prevent implementing the tool in the real environment.

	allocation and replace the current Excel systems in house. --- *Main references:* *PRO-0013 Planning and reporting*	and the needs of internal and external stakeholders. An ICT analysis has also been conducted in 2016, resulting in the decision to implement a database for ECHA's corporate objectives and indicators, which will be developed in 2017. The development will follow a focused approach, concentrating the investment in the most added-value parts of the data model, those where integrity and linking of data is most important. --- *Main references:* *PRO-0013 Integrated Planning, Monitoring and Reporting*	According to the Directors' self-assessment of the IMS as of December 2017, ECHA invests considerable efforts in planning. The main weakness is the integration of new initiatives for which resources are often limited. So far, the Agency has managed to absorb the staff cuts in a way which does not reduce business outputs, thus proving it is a lean organisation. --- *Main references:* *PRO-0013 Planning and reporting*

2.2. Risk management

Risk management is integrated into the annual planning and reporting cycle and embedded in the decision–making process at all levels.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall conduct a corporate risk management exercise at least once per year as part of the Work programme preparation, and at Unit level whenever the Senior Management considers it necessary.	**Yes** As per ISO 9001:2015 surveillance audit, risks and opportunities are well managed, in parallel to the work programme and changes are implemented in a well-controlled manner. --- *Main references:* *ED decision on Risk Management in ECHA ED/65/2015* *Risk Management in the Commission – Implementation guide*	**Yes** According to the ISO 14001:2015 certification audit in 2016, both risks and opportunities associated with environmental threats and positive environmental impacts are evaluated. The positive environmental impacts /objectives are handled and monitored through quality objectives and targets. Similarly, according to the ISO 9001:2015 surveillance audit, auditors confirmed that risks and opportunities are well managed, in parallel to the work programme and changes are implemented in a well-controlled manner. --- *Main references:* *ED decision on Risk Management in ECHA ED/65/2015* *Risk Management in the Commission – Implementation guide* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment*	**Yes** According to the ISO 9001:2015 and ISO 14001:2015 re-certification audit in 2017, ECHA follows a systematic way to evaluate risks, confirming the findings from the previous year's surveillance audit that risks and opportunities (including risks and opportunities associated with environmental threats and positive environmental impacts) are well managed, in parallel to the work programme and changes are implemented in a well-controlled manner. --- *Main references:* *ED decision on Risk Management in ECHA ED/65/2015* *Risk Management in the Commission – Implementation guide* *ISO 9001:2015 and ISO 14001:2015 re-certification audit in 2017*

The Agency shall use risk management at process level, whenever the Senior Management deems it necessary, in order to gain efficiency and ensure effectiveness of the internal controls (to be) imposed.	**Mostly** In 2015, there have been a number of projects under which the cost-risk-benefit methodology was applied resulting in elimination of multiple controls. Examples with their relevant measurements of time savings are available under Section 3.1. Risk Management of the CAAR. --- *Main references:* *Methodology for risk assessment and cost-benefit analysis at process level* *Efficiency development programme*	**Yes** As a result of risk assessment and cost-benefit analysis and following the ED decision on risk management ECHA ED/65/2015, the number of steps and controls decreased in a number of workflows in 2016, some examples are listed in Section 3.3. Specific efforts to improve the economy and efficiency of financial and non-financial activities. --- *Main references:* *Methodology for risk assessment and cost-benefit analysis at process level* *Efficiency development programme* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment*	**Yes** Risk management at process level was further strengthened during 2017. There have been a number of projects under which the cost-risk-benefit methodology was applied resulting in elimination of multiple controls, some examples are listed in Section 3.3. The concept of cost-risk-benefit assessment was also implemented in the "vision document" for projects above EUR 1 000 000 and thus subject to ex-ante analysis. --- *Main references:* *Methodology for risk assessment and cost-benefit analysis at process level* *Efficiency development programme* *ISO 9001:2015 and ISO 14001:2015 re-certification audit*

3. OPERATIONS AND OPERATIONAL STRUCTURE

3.1. Decision making

The Agency's operational structure supports effective decision-making by a clear definition of responsibilities and authority.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall have an effective decision-making framework, where roles and responsibilities are defined and reflected in relevant documentation, accessible by all staff members	**Yes** The surveillance audit of ISO 9001:2015 concluded that roles, responsibilities and authorities are well defined in the organisation. In 2015, improvement was made on how Directors Coordination Meetings decisions are proposed, recorded and communicated.	**Yes** The surveillance audit of ISO 9001:2015 performed in 2015 concluded that roles, responsibilities and authorities are well defined in the organisation. In 2016, ECHA launched a revision of decision-making practices in the area of IT projects and services, with the idea of grouping of projects and services with similar objectives, to allow for economies of scale and efficiency in coordination and decision-making. The cooperative approach to decision making and mutual understanding was further enhanced through a rotation programme for Directors, who swapped in pairs for periods of three months. The programme received a positive feedback by both Directors and staff.	**Yes** The review of all ECHA's activities undertaken by Deloitte in 2017 concluded that ECHA is operating within the boundaries of the rules and regulations applying for a Regulatory Agency, it has an established organisational structure and the necessary administrative procedures in place. The decision-making framework was overall considered effective by the evaluators, while more could be done in the area of efficiency via delegations and further controls removal (see Standard 1.3. Management responsibility).

	---------- *Main references:* *ED decisions for delegations of financial, scientific and administrative powers* *Delegation and sub-delegation register* *PRO-0059 Internal decision-making and delegation of power* *ISO 9001:2008 audit* *ISO 9001:2015 surveillance audit*	---------- *Main references:* *ED decisions for delegations of financial, scientific and administrative powers* *Delegation and sub-delegation register* *PRO-0059 Internal decision-making and delegation of power* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment*	---------- *Main references:* *ED decisions for delegations of financial, scientific and administrative powers* *Delegation and sub-delegation register* *PRO-0059 Internal decision-making and delegation of power* *Review of all ECHA's activities undertaken by Deloitte in 2017* *ISO 9001:2015 and ISO 14001:2015 re-certification audit*

3.2. Process design and deployment

The Agency is managed through a process structure. The Agency has a coherent and effective framework integrating all processes and process controls used for the implementation and control of its activities in line with the provisions of its Regulations.

Requirement	**Is the requirement fulfilled - Assessment 2015**	**Is the requirement fulfilled - Assessment 2016**	**Is the requirement fulfilled - Assessment 2017**
The Agency shall ensure that its processes are designed in line with its strategies and objectives, reflect process interactions, allow process measurement and are documented in a user friendly manner,	**Mostly** The surveillance audit of ISO 9001:2015 found that the description of interaction of processes in the high level process map of ECHA Integrated Management Standards (IMS Manual at ECHA is not clear. Also, the relationship between process and regulation was assessed not to give a clear picture of what the main process is. A recommendation to clarify the	**Mostly** The ISO 9001:2015 and ISO 14001:2015 audits in 2016 found that the process structure, as well as the description of the process interactions, has improved compared to the previous year when the same auditors made the remark that the description of interaction of processes in the high level process map of ECHA IMS	**Mostly** The ISO 9001:2015 and ISO 14001:2015 audits in 2017 concluded that the main process structure as well as the description of the interaction of processes is well described. This confirms their finding from 2016 that the process structure, as well as the description of the process interactions, has improved compared to 2015, when the same auditors made the remark that the

readily accessible and useful for the staff.	main process structure to make it less complicated was made and will be followed in the course of 2016. --- *Main references:*	Manual at ECHA was not clear. The updated manual shows the interaction between the data management processes and the operational processes that produce regulatory outputs and other outputs requested by stakeholders. Still, in 2016, this continues being the area with the highest number of non-conformities. The IAS audit on the BPR operations performed in 2016 found that ECHA has established processes and procedures, as well as tools that enable it to carry out the many tasks entrusted to it through this Regulation. Still, some gaps in the BPR process documentation (e.g. in guidance) entail the risk of potentially ineffective implementation of the Regulation. --- *Main references:*	description of process interactions in the high level process map of ECHA IMS Manual at ECHA was not clear. The updated manual shows the interaction between ECHA data management processes and the operational processes that produce regulatory outputs and other outputs requested by stakeholders. Still, despite the fact that there is a good process description available and processes may work well on their own, there is more work to be done in terms of establishing common process objectives and process interactions. The trend from the previous year to have most of the NCs in operations (service provision and control) continues in 2017 as well. According to the Directors' self-assessment of the IMS as of December 2017, the process approach is well established, with a framework and a good structure in place. Even though there is an effective system of processes and sub-processes in place, the structure is not flexible to be adapted to new priorities or to fully integrate processes. --- *Main references:* *LIS-0009 ECHA Activity and Process Structure*

	LIS-0009 ECHA Activity and Process Structure *Efficiency programme* *ISO 9001:2008 audit* *ISO 9001:2015 surveillance audit*	*LIS-0009 ECHA Activity and Process Structure* *Efficiency programme* *IAS audit* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment*	*Efficiency programme* *IAS audit* *ISO 9001:2015 and ISO 14001:2015 re-certification audits* *Staff survey 2017*

3.3. Security and Business continuity

Adequate and preventive measures are in place to ensure protection and security of the Agency's information and continuity of service in case of major disruptions that might threaten the Agency's operations.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall have a Security and Business continuity policy and plans that are regularly tested to ensure uninterrupted operations, continuity and everyday protection of the Agency's staff and information with respect to different scenarios of major disruptions	**Mostly** A new ECHA security framework was adopted in 2015, changing a number of structures and tasks. Currently there are 3 areas of security: • Information security • ICT security managing the outsourced data centre. Many improvement actions have been implemented in 2015 following the audit on "Data centre assessment" • Physical security which is consolidated with the facility services	**Mostly** In 2016, ECHA implemented a new security policy on IT Contractors' remote access, updated the Standard Security Requirements (SSR) for Access to ECHA's Information Systems by MSCA/MNI/DNA/ European Commission, improved IT security monitoring solution to detect intrusions to ECHA information systems in their early stage and made several improvements to preventive security measures (e.g. on ECHA website). The major improvement program, following the audit on "Data centre	**Mostly** The annual analysis in the area of IT security performed by Directorate I indicates that besides the fact that some cyber threats were detected in 2017, ECHA managed to respond to the attacks early enough to prevent undesirable consequences such as leakage of confidential information. Several risks and vulnerabilities were mitigated in 2017, by installing a new highly secure printing solution, revising the Standard Security Requirements for MSCAs and enabling better remote services for IT contractors. The review of all ECHA's activities undertaken by Deloitte in 2017 has noted that outsourcing IT activities has been

	In 2015, the decentralised organisation has brought responsibility closer to the operations; However, the competence of responsible persons and the detailed processes would need to be further developed. The level of security compliance with ECHA standards in some MSCAs remains an area for further improvement which will be addressed in 2016.	assessment, with a major IT outsourcing contractor was completed. In 2016, ECHA did not suffer from any major IT security incident, i.e. confidential business information was not stolen or leaked as result of any cyberattack. During year 2016 all business continuity plans were reviewed except the plan which covers recovery planning for the ICT systems. Two separate crisis management exercises were organized - one for the strategic and operational crisis management teams and one for the communication unit. There have been a number of audit findings in the area of emergency preparedness both in the ISO 9001:2015 surveillance audit and ISO 14001:2015 certification audit and the internal quality audit on the EMS, pointing out that the list of fire wardens is not kept up to date, emergency signs are only in Finnish or not visible and the rescue plan has obsolete information and no authority for approval defined.	used to a very high extent at ECHA, and while it can ensure business continuity, it can also bring business continuity risks given the reliance on external service providers. On the other hand, the external audit of the Cloud Services for SMEs performed in 2017 did not raise any risks or significant issues. The internal IQMS audit of the IT BCP Advisory Service raised an observation with regard to the lack of a documented analysis on indicators and incidents that are related to the ICT tools/services availability and resilience, and relevant for business continuity management. The auditors also found that there is a lack of clear criteria defined in which cases the IT-BCP Advisory Service should be called upon and when.

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	Main references: *POL-0004 Business Continuity Management Policy* *PLA-0001 ECHA Crisis Management Plan (tested annually in Crisis Exercises)* *POL-0002 Security Policy Statement* *ED/97/2010 Security Organisation* *ED/29/2008 Security Rules and related procedures* *ED/125/2012 Rules for access to the ECHA premises* *PRO-0033 Video-surveillance at the ECHA premises* *POL-0006 Information Security Policy* *POL-0005 Classification and Handling of ECHA Information Policy* *POL-0011 Use of ICT Facilities Policy* *PRO-0065 ECHA ICT Security Management System* *HAN-0011 Handbook on Practical instructions for handling of ECHA equipment (lost items) and access to ECHA premises* *ED/24/2009 Instructions for the use of ECHA Conference Centre*	*Main references:* *POL-0004 Business Continuity Management Policy* *PLA-0001 ECHA Crisis Management Plan (tested annually in Crisis Exercises)* *POL-0002 ECHA Security Policy* *ED/97/2010 Security Organisation* *ED/29/2008 Security Rules and related procedures* *ED/125/2012 Rules for access to the ECHA premises* *PRO-0033 Video-surveillance at the ECHA premises* *POL-0007 Information Management and Security Policy* *PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to be added: ECHA Retention Schedule)* *PRO-0085 Access to ECHA Information* *POL-0011 Use of ICT Facilities Policy* *PRO-0065 ECHA ICT Security Management System* *HAN-0011 Handbook on Practical instructions for handling of ECHA equipment (lost items) and access to ECHA premises* *ED/24/2009 Instructions for the use of ECHA Conference Centre* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment*	*Main references:* *POL-0004 Business Continuity Management Policy* *PLA-0001 ECHA Crisis Management Plan (tested annually in Crisis Exercises)* *POL-0002 ECHA Security Policy* *ED/97/2010 Security Organisation* *ED/29/2008 Security Rules and related procedures* *ED/125/2012 Rules for access to the ECHA premises* *PRO-0033 Video-surveillance at the ECHA premises* *POL-0007 Information Management and Security Policy* *PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to be added: ECHA Retention Schedule)* *PRO-0085 Access to ECHA Information* *POL-0011 Use of ICT Facilities Policy* *PRO-0065 ECHA ICT Security Management System* *HAN-0011 Handbook on Practical instructions for handling of ECHA equipment (lost items) and access to ECHA premises* *ED/24/2009 Instructions for the use of ECHA Conference Centre* *ISO 9001:2015 and ISO 14001:2015 re-certification audits*

3.4. Information management

The management and staff obtain sufficient and timely information needed for the performance of their responsibilities and for effective decision-making.

The Agency has an adequate information management system.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall conduct regular assessments that the information available in the Agency's Management system is fit for purpose.	**Yes** Following the recommendations of the ISO 9001:2008 audit in 2014, simplification and integration of relevant information management documentation, took place in 2015. On ECHAnet, the control on the content and documents was significantly improved.	**Yes** In 2016 The ISO 9001:2015 surveillance audit and ISO 14001:2015 certification audit in 2016 assessed ECHA management system and did not find any weaknesses in the information and document management system of ECHA.	**Yes** The ISO 9001:2015 and ISO 14001:2015 audits in 2016 and 2017 assessed ECHA management system and did not find any weaknesses in the information and document management system of ECHA.
The Agency shall have an Information management system, complying with applicable legislation and providing adequate audit trails, where the principles of organisation, control, retention, archive and communication with regards to documents and records are defined.	**Mostly** As of 31/12/2015, the procedure for control of documents and records was implemented: retention periods were defined for most of the records, filing plans were developed and implemented, and records migrated to DMS (the Shared Drives were closed), thus responding to the ISO 9001:2008 audit recommendations and closing this recurrent issue in IAC audits as well. NC-CAPA report as of 2015 also	**Yes** The recommendations of the ISO 9001:2008 audit in 2014 with regard to the procedure for control of documents and records were implemented in both 2015 and 2016, by defining retention periods for most records, developing and implementing filing plans and migrating records to DMS. To tackle the cumbersome mail registration process, in 2016 ECHA made some significant changes in Dynamic Case so as to re-enforce its use as	**Mostly** Though a lot of efforts have been put into documents and records management in 2017, there are some recurrent issues in IAC audits which remain still open. Among them, functional mailboxes are still used as storage location for documents and records and mail registration is considered cumbersome and time-consuming and therefore not systematically implemented. To tackle the mail registration weakness, ECHA introduced an automatic ingestion of emails from Outlook into Dynamic case in 2016. The technical solution was

	shows improvement in the area of documents and records. A number of IT projects are on-going in order to improve the operational process management and facilitate the implementation of the information management policies. The records management tool is now fully integrated with Dynamic Case to manage the permanent records of the Agency and a more secure external collaboration platform (S-CIRCA BC) was taken into use. --- *Main references:* *ISO 9001:2008 audit* *ISO 9001:2015 surveillance audit* *ED 86/2014 Electronic storage of documents in ECHA* *POL- 0007 Information Management Policy* *PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to be added: ECHA Retention Schedule)* *LIS-0009 Activity and Process Structure with Common Nomenclature and Ownerships* *LIS – 0012 ECHA Default Metadata*	a registration tool avoiding duplication with SharePoint Mail Registry. In 2016, work to further optimise data management in the Agency included a pilot project for mapping the "chemical universe" which has delivered its first results and the single point of entry improvement project that has been concluded. The latter project aimed at better channelling all the incoming requests to the right services in an efficient manner. --- *Main references:* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment* *ED 86/2014 Electronic storage of documents in ECHA* *POL- 0007 Information Management Policy* *PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to be added: ECHA Retention Schedule)* *LIS-0009 Activity and Process Structure with Common Nomenclature and Ownerships* *LIS – 0012 ECHA Default Metadata*	implemented and awareness raised in 2017. Nevertheless, one audit indicates weaknesses in the search function for documents. Documents and records management weaknesses were also identified in the ex-post evaluation of the Efficiency programme performed in 2017. Those refer to difficulties to trace the relevant documentation and to compare plans with implementation, due to multiple storage places and inconsistent approach to documents preparation. --- *Main references:* *ISO 9001:2015 and ISO 14001:2015 re-certification audits* *Ex-post evaluation of the Efficiency programme* *ED 86/2014 Electronic storage of documents in ECHA* *POL- 0007 Information Management Policy* *PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to be added: ECHA Retention Schedule)* *LIS-0009 Activity and Process Structure with Common Nomenclature and Ownerships* *LIS – 0012 ECHA Default Metadata*

4. EVALUATION AND IMPROVEMENT

4.1. Monitoring and measurement

Accurate, timely, complete and relevant data are available to ensure effective and efficient monitoring of the use of the Agency's resources, activities, processes and products.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Agency shall have adequate monitoring and measurement structures to ensure the accuracy, completeness and timeliness of data and related information used for producing its reports.	**Mostly** The surveillance audit of ISO 9001:2015 found that although the monitoring, measurement and analysis of the Management system is well structured, and results are collected and reported to the management, corrective actions and improvements are not consistently documented. In addition, the audit found that the relationship between unit objectives and indicators is not always clear or logical. In order to address those, in 2015 ECHA reviewed the Work programme indicators and baseline figures from a cost-benefit perspective, created a database of all metrics in house, aligned the timing of a number of	**Yes** In 2016 after having changed the WP structure and after having performed a thorough review of the performance indicators and baseline figures in order to remove duplicates and focus on value-add, ECHA managed to establish more informative and visual reporting focused on crucial operations, work in process and tracking of milestones. Also the link between each activity objective and performance indicators was further strengthened through a thorough revision of existing indicators and introduction of new ones, measuring the effort and average time needed per one output. This	**Yes** In 2017 after having performed a review of the metrics, ECHA managed to establish more informative and visual reporting, dashboards and more efficiency indicators focused on crucial operations, work in process and tracking of milestones. This new more analytical reporting allowed Management to take faster decisions and focus on corrective actions. The review of all ECHA's activities undertaken by Deloitte in 2017 concluded that overall the Agency has set up a fit-for-purpose system of monitoring its performance and reporting on the implementation of its Annual and Multi-Annual Work Programmes. The evaluators also identified areas for improvement, among them, better monitoring the

	reporting obligations and automated the Unit level reporting template which will be in use for the year 2016. In addition, testing of the proof of concept of an IT tool to further streamline and automate the existing monitoring and measurement structures is foreseen for 2016. Those actions followed also the recommendations of the KPI audit and the feasibility study, both conducted in 2014 (for more details, see 2.1. Objectives planning and resource allocation). --- *Main references:* *ISO 9001:2008 audit* *ISO 9001:2015 surveillance audit* *Annual and multiannual work programmes* *ECHA Financial Regulation* *General financial regulation and implementing rules* *Annual budget* *European Union accounting rules* *REACH regulation (including implementing Fee regulations)* *PRO-0013 Planning and reporting*	new more analytical reporting allowed Management to take faster decisions and focus on corrective actions. In that way, the observation from ISO 9001:2015 audit that corrective plans need to be more consistently implemented and the recommendations of the KPI audit on defining specifications of all metrics in house and integrating the metrics and reporting (both audits from 2015) have been closed. --- *Main references:* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment* *Annual and multiannual work programmes* *ECHA Financial Regulation* *General financial regulation and implementing rules* *Annual budget* *European Union accounting rules* *REACH regulation (including implementing Fee regulations)* *PRO-0013 Planning and reporting*	achievements of ECHA's strategic objectives, and improvement of the communication on the monitoring and reporting of efficiency gains of individual projects. There was a similar conclusion with regard to the better efficiency measurements at project level in the ex-post evaluation of the Efficiency programme conducted in 2017. After evaluating the proof of concept of an integrated IT solution for monitoring and measurement in 2016, ECHA started the implementation of a new tailored-made tool in 2017 (more details are available in 2.1.). --- *Main references:* *ISO 9001:2015 and ISO 14001:2015 re-certification audits* *Ex-post evaluation of the Efficiency Programme* *Review of all ECHA's activities undertaken by Deloitte in 2017* *Annual and multiannual work programmes* *ECHA Financial Regulation* *General financial regulation and implementing rules* *Annual budget* *European Union accounting rules* *REACH regulation (including implementing Fee regulations)* *PRO-0013 Planning and reporting*

The Agency shall have adequate controls to capture, manage and report on non-conformities and suggestions for improvements, including handling of corrective actions.	**Mostly** In 2015, the NC–CAPA tool was improved by adding information about root-cause analysis and categorisation of NCs, which helps with drawing more structured conclusions on the areas to which the NCs refer. Still, the process has some drawbacks mainly with regard to the user-friendliness of the tool used. A feasibility study on the existing strengths and weaknesses of the action management processes at ECHA (incl. audits, NCs, risks, DCM actions) was performed in 2015. Among the recommendations of the study which refer to aligning and streamlining all action management processes at ECHA, a number of potential IT solutions are proposed which may potentially replace the existing NC-CAPA (Remedy) tool.	**Mostly** According to the ISO 9001:2015 surveillance audit and ISO 14001:2015 certification audit in 2016, the nonconformity process in Remedy is not working well enough and needs further efforts. Use of Remedy was assessed very complicated and difficult to use. Even though efforts were made to more consistently categorise NCs and perform root cause analysis in 2016 compared to previous years, the overall activity of NCs management seems to be slowing down (in particular the action management and the follow up of actions). This was also a shortcoming found in the ISO 9001:2015 and ISO 9001:2008 audits from previous years referring to inconsistent implementation of corrective plans and actions.	**Mostly** In 2017, the ISO 9001:2015 and 14001:2015 auditors brought again the nonconformity process as an area for senior management attention. The internal IQMS audit performed in 2017 concerning the NC-CAPA handling and the follow up of internal audit findings has raised two observations that point to the following areas for attention and risks: no alignment of the concepts in handling NCs and exceptions and no overall analysis related to the exception notes is available. 1 minor NC was raised in the same audit with regard to NCs, complaints and exceptions handling. The finding refers to the lack of relevant information and the missing clear distinction between the correction/remedial action and the measures taken to act on the root cause and prevent recurrence (corrective action) or occurrence (preventive action). All the above issues are to be addressed in the new NC-CAPA tool and workflow rolled out in the first half of 2018. The monitoring of exceptions in 2017 (all with exception notes) identified 19 exceptions, with the most common reasons related to the article 70 of the Financial regulation (11 cases), i.e. cases

	---------- *Main references:* *PRO-0079 Preventive and risk-based approach to management* *PRO-0015 Nonconformities, Corrective and Preventive Action*	---------- *Main references:* *ISO 9001:2015 surveillance audits in 2015 and 2016* *ISO 14001:2015 assessment* *PRO-0079 Preventive and risk-based approach to management* *PRO-0015 Nonconformities, Corrective and Preventive Action*	not having correct budgetary and/or legal commitment in place and to situations, where the Agency accepted late payments or extended payment deadlines for companies (5 cases). There is a similar situation in 2016, when there were 21 exception, with 18 of which referring to the article 70. ---------- *Main references:* *ISO 9001:2015 and ISO 14001:2015 re-certification audits* *PRO-0079 Preventive and risk-based approach to management* *PRO-0015 Nonconformities, Corrective and Preventive Action*

4.2. Analysis and evaluation

Evaluations of strategies, activities and projects are performed to assess the benefits, results, impacts and needs that these activities aim to achieve and satisfy. The effectiveness, adequacy and suitability of the management system are reviewed.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
Senior Management shall review periodically and carry out an annual management review	**Mostly** In 2015, the focus shifted from providing purely numerical data to analyses and trends identification, as	**Yes** In 2016, following the focus on analysis, rather than purely numerical data, ECHA revised its	**Yes** In 2017 ECHA continued focusing on analysis, rather than on purely numerical data, in support of a more effective and

on the effectiveness, adequacy and suitability of the Agency's Integrated management system.	well as to exceptional and risk-based reporting. Those analyses aim at facilitating the decision-making of the Management in particular at the time of the quarterly and management reviews. --- *Main references:* *PRO-0016 Management review* *ECHA Integrated Management System manual (MAN-0001)* *Quarterly reviews at DCM* *Management review*	way to perform quarterly reviews and adopted the so-called T1/T2 reviews, where focus on objectives at risk and visual data presentation allowed for faster decision-making. Positive observations both with regard to the structure and compliance of the management review with all applicable legislation and the T1/T2 reviews were made in the ISO 9001:2015 and ISO 14001:2015 audits in 2016. The action lists from both reviews and their implementation were also listed as positive observations. The project management processes and in particular the project closure were considered to work well including a number of success criteria "in use, not in use, meets objectives, in schedule". --- *Main references:* *ISO 9001:2015 surveillance audit in 2016* *ISO 14001:2015 assessment* *PRO-0016 Management review* *ECHA Integrated Management System manual (MAN-0001)* *T1/T2 reviews* *Management review*	efficient decision making, and following the good practice established in 2016 when the Agency revised its way to perform quarterly reviews and adopted the so-called T1/T2 reviews with focus on objectives at risk and visual data presentation. Positive observations both with regard to the structure and compliance of the management review with all applicable legislation and the T1/T2 reviews were made in the ISO 9001:2015 and ISO 14001:2015 audits, both in 2016 and 2017. The auditors also noted that the management review is well prepared and analysed beforehand and there are good templates and clear structure of how to analyse actions. --- *Main references:* *ISO 9001:2015 and ISO 14001:2015 re-certification audits* *PRO-0016 Management review* *ECHA Integrated Management System manual (MAN-0001)* *T1/T2 reviews* *Management review*

Agency projects shall be carried out according to defined project management procedures. Upon closure of each project, an assessment of its benefits, results and impacts shall be performed.	**Mostly** Following the Commission's guidelines and the FR requirements setting the evaluation limits, ECHA's framework and approach to evaluations was presented to the MBWG on audit on 15 December 2015 and reported to the 40th MB on 16-17 December 2015. The approach is described in detail in Section 2.10 Ex-ante and ex-post evaluations of the CAAR. --- *Main references:* *ECHA FR and Implementing rules* *PRO-0018 Project Management* *PRO-0026 IT Governance bodies, roles and functions* *PRO- 0027 IT Governance and Process Description* *Better Regulation Guidelines of the Commission*	**Mostly** Following the establishment of the evaluation framework and the pilot in 2015, the first ex-ante and ex-post evaluations were performed and the results presented to the Management Board. Results are available in Section 2.10. Ex-ante and ex-post evaluations of the CAAR. --- *Main references:* *ECHA evaluation framework and roadmap* *ECHA FR and Implementing rules* *PRO-0026 IT Governance bodies, roles and functions* *PRO- 0027 IT Governance and Process Description* *Better Regulation Guidelines of the Commission*	**Mostly** Following the establishment of the evaluation framework, one ex-ante and one ex-post evaluations were performed in 2017 and the results presented to the Management Board. Also, the Commission mandated Deloitte to perform the 5-year review of all working programme activities of the Agency. Further efforts were made in 2017 to integrate the ex-ante approach in the Agency's project governance structure. Results are available in Section 2.10. Ex-ante and ex-post evaluations of the CAAR. --- *Main references:* *ECHA evaluation framework and roadmap* *ECHA FR and Implementing rules* *PRO-0026 IT Governance bodies, roles and functions* *PRO- 0027 IT Governance and Process Description* *Better Regulation Guidelines of the Commission*

4.3. Internal Audit

The Agency has an Internal Audit Capability (IAC), the role of which is to provide independent, objective assurance and consulting services designed to add value and improve the operations of the Agency. The Agency has other qualified staff members who support audits performed in the area of data protection, security, quality and other specialised areas.

Requirement	Is the requirement fulfilled - Assessment 2015	Is the requirement fulfilled - Assessment 2016	Is the requirement fulfilled - Assessment 2017
The Internal Audit Capability and the other qualified staff members supporting audits shall provide independent and objective assurance and consulting services based on risk assessment, designed to add value and improve the operations of the Agency.	**Yes** The Independent External Validation of IAC conducted in 2015 concluded that the IAC of ECHA's structure, policies and procedures, as well as the processes with which these are applied, conform with both attribute and performance standards and the objectives with which they have been formulated. The highest level of assessment "generally conformant" was granted to IAC. --- *Main references:* *Independent External Validation audit of IAC* *Audit Work Programme* *IAC Annual Work Plan* *Audit follow-up table* *PRO-0020 Internal audit of the Internal audit capability (IAC)* *PRO-0014 Internal IQMS audit*	**Yes** Positive observations with regard to the internal (IQMS) audit planning and execution were made in the ISO 9001:2015 and ISO 14001:2015 audits in 2016. Similarly, the Independent External Validation of IAC, conducted in 2015, found that ECHA's internal audit structure, policies and procedures, as well as the processes with which these are applied, conform to both attribute and performance standards and the objectives with which they have been formulated. --- *Main references:* *Independent External Validation audit of IAC* *Audit Work Programme* *IAC Annual Work Plan* *Audit follow-up table* *PRO-0020 Internal audit of the Internal audit capability (IAC)* *PRO-0014 Internal IQMS audit*	**Yes** The review of all ECHA's activities undertaken by Deloitte in 2017 has concluded that there is an effective system and dedicated functions to follow-up the recommendations of internal and external audits. They however noted that ECHA is only reporting on 'very important' recommendations. Positive observations were made in ISO 9001:2015 and ISO 14001:2015 re-certification audits in 2017 with regard to the combination of internal quality audits with IAC assurance audits. Auditors also noted the importance of keeping internal auditors competence up to date and improving their auditing to optimize the use of internal audits (provided the small amount of internal audits per year). --- *Main references:* *Audit Work Programme, IAC Annual Work Plan* *Audit follow-up table* *PRO-0020 Internal audit of the Internal audit capability (IAC)* *PRO-0014 Internal IQMS audit* *Review of all ECHA's activities undertaken by Deloitte in 2017* *ISO 9001:2015 and ISO 14001:2015 re-certification audits*

Legend:

Yes – refers to an assessment of the Management system, where the requirements to the standards are considered fulfilled.

No – refers to an assessment of the Management system, where the requirements to the standards are considered not yet fulfilled.

Partially - refers to an assessment of the Management system, where the requirements to the standards are considered fulfilled with some major gaps.

Mostly - refers to an assessment of the Management system, where the requirements to the standards are considered fulfilled with some minor gaps.

ANNEX IV. DECLARATION OF ASSURANCE OF THE EXECUTIVE DIRECTOR

I, the undersigned,

Bjorn HANSEN

Executive Director of the European Chemicals Agency

In my capacity as Authorising Officer,

Declare that the information contained in this report gives a true and fair view.

State that I have reasonable assurance that the resources assigned to the Activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex post controls, evaluations, the work of the internal audit capability, the recommendations of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors[4] for years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the Agency.

Done at Helsinki, on 07 March 2018

signed

Bjorn HANSEN

Executive Director

[4] *As regards the implementation of the European Union legislation and the fee regulations under the Agency's remit, this assurance has to be limited to the field of competences of the Agency. Since the mandate of the European Chemicals Agency does not include controls or inspections at national level, it cannot be confirmed that only registered or authorised substances and products, for which a fee has been paid to the Agency, are circulating on the European Union market.*