

Consolidated Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2018

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LIST OF ACRONYMS

BPR	Biocidal Products Regulation
CA	Contract Agent
CAAR	Consolidated Annual Activity Report
CCH	Compliance check
CLP	Classification, Labelling and Packaging
COSO	Committee of Sponsoring Organisations of the Treadway Commission
DCM	Directors' Coordination Meeting
DNA	Designated National Authority
DoI	Declaration of interest
DPO	Data Protection Officer
ECA	European Court of Auditors
ECHA	European Chemicals Agency
ED	Executive Director
EFTA	European Free Trade Association
EUON	EU-wide observatory for Nano-materials
Forum	Forum for Exchange of Information on Enforcement
HoU	Head of Unit
FR	ECHA Financial Regulation
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Union
ICF	Internal Control Framework
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
NC-CAPA	Nonconformity – Corrective and Preventive Action
NEA	National Enforcement Authority
OEL	Occupational Exposure Limit
PIC	Prior Informed Consent
POP	Persistent Organic Pollutant
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	Central IT system providing support for REACH
SO4	Strategic objective 4
SP	Strategic priority
SPD	Single Programming Document
SME	small and medium-sized enterprise
TA	Temporary Agent
WFD	Waste Framework Directive

MANAGEMENT BOARD'S ANALYSIS AND ASSESSMENT

The Consolidated Annual Activity Report (CAAR) 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 Executive Director under his own responsibility and submitted to the Management Board for information.

In line with the Financial Regulation, the Management Board provides its assessment of the Consolidated Annual Activity Report, which has to be submitted, together with the Consolidated Annual Activity Report, to the Court of Auditors, the European Parliament, the Commission and the Council no later than 1 July 2019.

INTRODUCTION

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.

In 2018, ECHA prepared for future challenges in carrying out the tasks under new areas of work such as Poison Centres, Occupational Exposure Limits, the Waste Framework Directive, the EU Chemicals Legislation Finder and Persistent Organic Pollutants.

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 of the key achievements of 2018 is covered by the General Report (Part I), which together with its pertinent Key Performance Indicators (KPIs) is 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 2018 (58 out of 69 targets were met).

In 2018, the Agency underwent a reorganisation, driven by stakeholders' needs and expectations, aiming to create a new organisational structure, which supports synergies in the Agency's activities and processes, staff development, efficient and flexible ways of working, while allowing the smooth on-boarding of new tasks. The re-organisation was well aligned with ECHA's new 5-year strategy, which established new strategic priorities that link closely to the UN Sustainable Development Goals and the recommendations of the second REACH Review¹.

With the successful management of the third REACH registration deadline in 2018, ECHA can – together with the EU Member States – now use the unique source of information it holds on all chemicals on the EU market to determine which substances can be considered safe and which require further regulatory action.

Under the mixed financing regime, ECHA financed its expenditure through a combination of EU subsidy and fee income. In 2018, accurately anticipating fee revenue from the REACH registration deadline and from incoming biocides applications was particularly challenging. With regard to the REACH registration deadline, the associated fee income was exceptionally high. This allowed ECHA to reduce its EU subsidy request for the REACH/CLP budget by 20 % (EUR 6 million). However, under the BPR, lower than expected fee income forced the Agency to cut expenditure throughout the year and to request an extra EU contribution of EUR 2.65 million to cover the shortfall.

Actions resulting from audits and ex-post evaluations 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. In line with the evaluations roadmap, two ex-post evaluations were conducted and recommendations treated as high priority by the Agency's Management.

ECHA also ensured that relevant actions are taken to respond to the recommendations from 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).

¹ <https://echa.europa.eu/-/echa-welcomes-the-reach-review-outcome>

PART I ACHIEVEMENTS OF THE YEAR (SEE GENERAL REPORT)

PART II GOVERNANCE AND MANAGEMENT

2.1 Management Board

In 2018, the Management Board (MB) held four plenary sessions. A total of seven working group meetings were organised, mostly linked to the plenary meetings or as virtual meetings. For the first time, there were joint working group meetings on audit and planning & reporting. These meetings prepared decisions in the areas of planning, reporting, budget, audits, ex-post evaluations, or facilitated the Board's oversight function in specific areas as stipulated below.

Apart from adopting all statutory documents as foreseen in the applicable rules and regulations, in 2018 the Management Board also dealt with the following matters:

- Adopted ECHA's new multi-annual strategy and strategic priorities, ensuring that all REACH Review-related recommendations are taken into account in the Programming Document(s) of ECHA for the years 2019-2022.
- Confirmed the mandate of its Chair for a 2nd mandate of two years, until September 2020.
- Monitored the actions taken in response to the Commission's second REACH Review, including the second evaluation of ECHA.
- Performed, under the leadership of the Chair and in line with good practice, a self-evaluation. This covered approximately 36 interviews with members and a "Board only" discussion of the findings. The recommendations from the self-evaluation are focused in the areas of reviewing the rules of procedures to ensure they are "fit for purpose", reviewing the number and format of working groups to align them better with the MB's needs, and implementing an induction/training programme for MB members to ensure that adequate capacity is available in all areas relevant for the Management Board's operation. This review addressed also the recommendations from the Commission's REACH Review.
- Prepared the adoption of a revised policy on Conflict of Interest, following the recommendations of the audit performed by IAS.
- Performed the appraisal of the Executive Director at the end of his probationary period and confirmed his functions. In the performance appraisal, the MB considered, among other achievements, the impact of ECHA's reorganisation undertaken in 2018 on the Agency's activities, processes, staff development, and also on meeting external stakeholders' needs. The Board also performed the annual appraisal exercise of all full-time members of the Board of Appeal.

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 to the Board in the areas of audit, ex-post evaluations, planning and reporting. Special attention was paid in 2018 to address all recommendations of an audit report from the Commission's Internal Audit Service on Conflicts of Interest and Ethics.

In terms of risks discussed with the Management Board, the risks resulting from the allocation of new tasks, such as Poison Centres and the Waste Framework Directive to the Agency without the provision of adequate resources were an important reoccurring topic.

2.2 Major developments

Following the recommendations of the second REACH Review, in 2018 ECHA underwent a reorganisation, driven by stakeholders' needs and expectations, aiming to create a new organisational structure, which supports synergies in the Agency's activities and processes, staff development, efficient and flexible ways of working, while allowing the smooth on-boarding of new tasks. Focus areas and priorities for the years to come changed towards more impact-oriented ones.

ECHA adopted its next 5-year strategy establishing new strategic priorities that link closely to the United Nations sustainable development goals. The input from the REACH Review helped to focus ECHA's priorities on where they matter most for protecting human health and the environment. By developing its new strategy, the Agency prepared for future challenges in efficiently and effectively carrying out tasks under REACH, CLP, BPR and PIC together with new areas of work such as for Poison Centres, Occupational Exposure Limits (OEL), the Waste Framework Directive, the EU Chemicals Legislation Finder, Persistent Organic Pollutants (POPs) and the European Union Observatory for Nanomaterials (EUON).

The performance management model of the Agency was revised in line with ECHA's new strategic priorities, with the purpose to define more outcome and impact-oriented indicators to allow for the measurement of the intermediate and long-term impact of the Agency's actions in protecting the human health and environment.

In line with its new strategy, ECHA developed an approach to map the chemical space of REACH registered substances to support achieving the aim of the integrated regulatory strategy and increasing transparency on how authorities address all substances on the EU market in a proportionate manner.

The last REACH registration deadline on 31 May 2018 was successfully managed with extensive amounts of information on chemicals on the European market now publicly available.

In 2018, ECHA analysed and mapped the requirements of the new Internal Control Framework against ECHA's Integrated Management Standards with the conclusion that all elements of the Framework are covered in the annual internal control assessments of the Agency. Also, the Agency started the process towards developing a new internal control strategy focused on risk-based decision making.

The withdrawal of the United Kingdom from the European Union demanded actions from the Management in cooperation with the Commission in order to address issues affecting a wide scope of ECHA's activities and interest groups. To help industry, ECHA created a dedicated section on its website² providing relevant assistance and advice for various scenarios that companies may face. As an employer of British citizens, the statutory situation of the UK staff members also needed to be clarified.

The new Executive Director continued the process for establishing solid relations with the Member States, the Commission institutions and external stakeholders, resulting in acknowledgement of ECHA's competences and appreciation for the work, the synergies and the improved consistency created.

² <https://echa.europa.eu/uk-withdrawal-from-the-eu>

2.3 Budgetary and financial management

The present section of the Consolidated Annual Activity Report will also be included in the annual accounts of the Agency, as stated in Article 92 of the Financial Regulation applicable to the budget of ECHA.

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 2018, ECHA collected fee income totalling EUR 81.61 million (EUR 33.96 million in 2017), while the EU subsidy amounted to EUR 24.37 million (64.29 million in 2017). Additionally, the received European Free Trade Association (EFTA) contribution totalled EUR 0.61 million 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 2018, ECHA collected fee income totalling EUR 6.37 million (EUR 8.13 million in 2017), while the EU subsidy amounted to EUR 4.88 million (EUR 3.87 million in 2017). Additionally, the received EFTA contributions, including one from Switzerland, totalled EUR 0.22 million 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 2018, this subsidy amounted to EUR 1.10 million (EUR 1.19 million in 2017).

The initial total budgetary payment appropriations for the expenditure of 2018, as concluded by the Management Board in December 2017, amounted to EUR 115.68 million. In addition, the Agency has signed a Delegation agreement with the Commission on the European Union Observatory for Nanomaterials and for the implementation of the European Union Chemical Legislation Finder. In 2018 ECHA received an amount of EUR 1.60 million for these tasks.

During the year 2018, the Management Board adopted two amending budgets. The first amending budget in September 2018 adapted the Agency's revenue estimate to the observed trend in the area of REACH/CLP Regulations. The fee income budget estimate was increased by EUR 8.5 million and at the same time, the REACH expenditure was increased by EUR 2.4 million, i.e. to accommodate the higher than estimated salary costs as well as the further development of the Poison Centre portal. Consequently, the need for a balancing EU subsidy was reduced by an amount of EUR 6.0 million.

For Biocides, the first amending budget aligned the Agency's revenue estimate to the observed trend in the area of Biocidal Products Regulation. The budget estimate for Biocides fee income was decreased by EUR 2.4 million, due to lower than expected number of applications. At the same time, the expenditure was reduced by an amount of EUR 0.4 million and the need for a balancing EU subsidy was increased by an amount of EUR 1.9 million.

In the second amending budget in December 2018, the REACH/CLP income estimates were revised upwards by an amount of EUR 0.9 million and expenditure was increased accordingly to provisionally accommodate the development of a prototype database service under the Waste Framework Directive (WFD) in 2019.

The second amending budget in December 2018 further aligned 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 further reduced by EUR 1.2 million, again due to the lower than expected numbers of active substance applications, for which the legal deadline was 01 January 2019. At the same time, the expenditure was reduced further by an amount of EUR 0.4 million and the need for balancing EU subsidy was increased by an amount of EUR 0.8 million.

Budget overview (amounts in EUR)

Revenue	Initial voted budget	Amending budgets	Final voted budget
Total revenue	116 611 156	2 370 039	118 981 195
Expenditure	Initial voted budget	Amending budgets	Final voted budget
Commitment appropriations	117 281 746	1 478 963	118 760 709
Payment appropriations	116 611 156	2 370 039	118 981 195

2.3.1 Revenue

The budget funding of ECHA in 2018 consisted of the following (amounts in EUR):

Description	Initial Budget 2018	Amending Budgets 2018	Final Budget 2018	Entitlements established 2018	Revenue received 2018
Fees and charges from Registrations	68 198 170	10 009 830	78 208 000	79 116 508	79 116 508
Fees and charges from Authorisations	1 186 000	(615 923)	570 077	610 652	610 652
Fees SME Administration	1 357 000	0	1 357 000	1 725 546	1 725 546
Fees and charges from CLP	148 000	0	148 000	136 500	136 500
Fees and charges from Appeals	0	20 329	20 329	20 329	20 329
Total REACH Fee & Charges Income (incl. Appeals)	70 889 170	9 414 236	80 303 406	81 609 535	81 609 535
Fees relating to Biocidal Active Substances	4 288 333	(2 268 333)	2 020 000	2 045 200	2 045 200
Fees for Union Authorisation of Biocidal products	3 256 555	(1 111 555)	2 145 000	2 312 400	2 312 400
Miscellaneous fees	2 006 070	(246 070)	1 760 000	2 008 121	2 008 121
Total BPR Fee & Charges Income (incl. Appeals)	9 550 958	(3 625 958)	5 925 000	6 365 721	6 365 721
REACH subsidy	30 517 000	(6 000 000)	24 517 000	24 374 800	24 374 800
BPR subsidy	2 226 000	2 650 000	4 876 000	4 876 000	4 876 000
PIC subsidy	1 096 320	0	1 096 320	1 096 320	1 096 320
EFTA Contribution - REACH	609 611	(142 199)	467 412	609 612	609 612
EFTA Contribution - BPR	40 068	3 945	44 013	44 013	44 013
Confederation of Switzerland Contribution - BPR	82 029	70 015	152 044	179 682	179 682
TOTAL EU Contributions	34 571 028	(3 418 239)	31 152 789	31 180 427	31 180 427
Delegation Agreements (EUON, EUCLEF)	1 600 000	0	1 600 000	1 600 000	1 600 000
Delegation Agreements (EUON, EUCLEF)	1 600 000	0	1 600 000	1 600 000	1 600 000
Total Other income - miscellaneous	0	0	0	227 325	211 625
Total	116 611 156	2 370 039	118 981 195	120 983 008	120 967 308

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 one-off nature of 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 2018 in terms of the cash received amounted to EUR 81.59 million (EUR 33.92 million in 2017). In addition, income of EUR 0.02 million (EUR 0.04 million in 2017) was recorded in relation to REACH appeal fees giving a total of fees and charges of EUR 81.61 million (EUR 33.96 million in 2017). 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.

During 2018, which was the year of the final REACH registration deadline, ECHA received 37 400 dossiers, compared to 15 900 dossiers during 2017, representing an increase of almost 135%. Approximately 35% of the REACH/CLP fees and charges income generated in 2018 (41% for 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 30% (18% for 2017) and the lowest tonnes range 1 to 10 tonnes a share of 14% (8% for 2017). ECHA continued to observe a constant number of high tonnage registrations within 2018, which have a significant impact on the overall income.

In 2018, the Agency received payment for six applications (12 in 2017) for REACH Authorisation. In addition, ECHA collected EUR 0.16 million as a result of invoices issued for top-up fees issued to four authorisation applicants subsequent to the SME verification process (during 2017, four applicants self-declared their company size as larger for previously paid applications generating additional income of EUR 0.01 million). The total REACH authorisation income collected in 2018 amounts to EUR 0.61 million (EUR 0.76 million in 2017). For three out of the six applications, work will still be performed in 2019. The Agency received payments for 36 applications under the CLP regulation (35 applications under Article 24 and one application under CLH). The total receipts for 2018 amount to EUR 0.14 million (EUR 0.18 million in 2017).

The additional registration fee income generated via the SME size verification process (included in the REACH Registration income) in 2018 amounted to EUR 1.13 million (EUR 1.50 million in 2017). A total of 414 enterprises (332 in 2017) were verified for their company size during the year. On top of the additional registration fees, the Agency generated EUR 1.73 million in administrative charges (EUR 1.40 million in 2017) levied on companies who were not eligible for the already received rebates. A declining trend of wrong-size cases was observed 2018 verifications. The percentage of wrong size cases identified during 2018 was 32% while the error rate in the 2011-2017 period was 55%. On the other hand, income collected from administrative charges increased during 2018 mainly due to the initiative for collection of the unpaid debts via law firms, which resulted in collection of EUR 0.87 million of overdue administrative charge invoices (please see also section "Fee Invoicing 2018" below).

B) REACH/CLP Contributions:

During 2018, the Agency received an EU subsidy for REACH/CLP of EUR 24.37 million (EUR 64.29 million in 2017) and an EFTA contribution of EUR 0.61 million (EUR 1.59 million in 2017).

The Agency had signed a delegation agreement with the Commission to build an EU-wide observatory for Nano-materials (EUON) and to develop an EU Chemical Legislation finder (EUCLEF). In 2018, the Agency signed two transfer of funds agreements for the above and received an amount of EUR 0.60 million for EUON and EUR 1.00 million 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 2018, in terms of the cash received amounted to EUR 6.37 million (EUR 8.13 million in 2017). Despite the fact that the majority of the resources and work required to process these applications will be utilised in 2019 and onwards, ECHA is required to fund this work from future income. In addition, ECHA completed 20 ex-ante SME verifications in 2018 (28 in 2017) under the Biocidal Product Regulation, representing all incoming

cases for which the verification deadline fell within the year. This verification process is a non-fee generating activity.

B) BPR Contributions

During 2018, the Agency received an EU subsidy of EUR 4.88 million (EUR 3.87 million in 2017) and an EFTA contribution of EUR 0.044 million (EUR 0.036 million in 2017). In addition, the Agency received a contribution from the Federation of Switzerland of EUR 0.18 million (EUR 0.15 in 2017).

PIC Revenue

ECHA received an EU contribution for the PIC Regulation totalling EUR 1.10 million in 2018 (EUR 1.19 million in 2017).

Other miscellaneous income

The table below shows the other miscellaneous income received by the Agency in 2018 (amounts in EUR).

Description	Entitlements established 2018	Revenue received 2018
Legal recoveries	76 868	61 168
Carparking recovery	78 660	78 660
Sale of Goods	39 010	39 010
Other cost recoveries	32 787	32 787
Miscellaneous Income	227 325	211 625

Fee Invoicing 2018 (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 2018 amounted to EUR 80.29 million (EUR 34.11 million in 2017). The table below depicts the breakdown of the net invoiced REACH fees during the year.

REACH	2018		2017	
	Description	No of Transactions	EUR	No of Transactions
Invoices issued	28 473	86 297 847	9 535	41 355 205
Credit Notes	607	(4 420 295)	693	(6 291 392)
Unpaid	198	(840 926)	138	(954 452)
Considered paid	71	(1 131)	25	(540)
Write offs	43	(749 145)	0	0
Net Invoiced		80 286 350		34 108 821

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. On the 31 December 2018, the invoiced amount to be recovered for REACH/CLP fees and charges stood at EUR 3.45 million (EUR 4.70 million as at 31 December 2017). Included in this amount is EUR 1.45 million (EUR 3.18 million as of 31 December 2017) relating to invoiced overdue administrative charges arising from the SME verification work. This decrease in the outstanding amount mainly relates to the efforts made by ECHA during 2018 on the collection of the overdue administrative charges. In particular, 24 new contracts for pre-litigation actions with three law firms were signed, covering ECHA claims in 24 Member States. Based on a detailed case by case analysis, as had been recommended by the Commission in 2017, a total amount of EUR 0.75 million relating to 43 invoices of overdue outstanding administrative charges have been written off. Furthermore, as a result of the efforts, a total amount of EUR 0.87 million of overdue administrative charge invoices has been collected.

Finally, during 2018, bank charges were deducted by the senders' banks for 71 invoices (25 invoices in 2017) relating to REACH fee income. For management efficiency reasons, these invoices have been "considered paid" and therefore a total amount of EUR 1 131 (EUR 540 in 2017) has been waived.

B) Biocidal Products Fees and Charges

The total net invoiced by the Agency in 2018 amounted to EUR 6.33 million (EUR 8.20 million in 2017). The table below depicts the breakdown of the net invoiced BPR fees during the year.

BPR	2018		2017	
	Description	No of Transactions	EUR	No of Transactions
Invoices issued	1 830	8 671 400	1 828	8 888 100
Credit Notes	97	(2 244 500)	89	(274 580)
Unpaid	97	(93 600)	73	(410 200)
Considered paid	0	0	2	(40)
Net Invoiced		6 333 300		8 203 280

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. On the 31 December 2018, the amount to be recovered for Biocidal product fees and charges stood at EUR 0.55 million (EUR 0.58 million as of 31 December 2017). This list shall also indicate decisions by the Authorising Officer to waive or partially waive recovery of established amounts. In 2018, there were no cases where bank charges were deducted by the senders' banks (two cases in 2017).

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 Annex II.

Budget 2018: Breakdown & changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Title* (EUR)

Title	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	74 397 206	431 896	74 829 102	73 946 905	98.8%	74 829 102	73 690 517	98.5%	256 388	0.3%	882 197
A-2	BUILDING, EQUIPMENT AND MISCELL. OPER EXPEND	17 021 310	-247 359	16 773 951	16 596 556	98.9%	16 773 951	12 700 154	75.7%	3 896 402	23.5%	177 395
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	21 704 060	1 800 602	23 504 662	23 065 058	98.1%	23 725 148	12 877 586	54.3%	10 361 391	44.9%	439 604
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 331 786	-529 572	1 802 214	1 735 591	96.3%	1 802 214	1 309 340	72.7%	426 251	24.6%	66 623
B0-5	OPERATIONAL EXPENDITURE - PIC	227 384	23 396	250 780	241 560	96.3%	250 780	110 278	44.0%	131 282	54.3%	9 220
		115 681 746	1 478 963	117 160 709	115 585 671	98.7%	117 381 195	100 687 876	85.8%	15 071 714	13.0%	1 575 038

*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 2018: Implementation of differentiated appropriations (EUR)

Budget line	Available commitment appropriations	Commitments made	%	Available payment appropriations	Payments made	%	
B3-111	Substance evaluation and Rapporteurs (Multiannual)	1 413 123	1 387 071	98%	794 018	751 756	95%
B3-801	Cooperation with international organisations for IT programs	1 272 671	1 262 226	99%	612 380	607 438	99%
Total		2 685 794	2 649 296	99%	1 406 398	1 359 194	97%

Out of the total available commitment appropriations, EUR 1 499 882 are stemming from commitments made in earlier financial years. The available commitment appropriations for 2018 totalled EUR 1 185 912 out of which EUR 1 185 274 (99%) were committed. The amount of commitments carried forward to 2019 totals EUR 1 290 103.

Title 1: staff expenditure

The initially adopted budget for Title 1 in 2018 was EUR 74.4 million and the overall increase during the year, including transfers and amending budgets, was EUR 0.4 million to arrive at EUR 74.8 million. The final executed amount totalled EUR 73.9 million corresponding to an execution rate of 99% for the payment appropriations. The carry-over appropriations, totalling EUR 0.3 million for Title 1, mainly relate to the commitments for trainings and interim services. An amount of EUR 16 858 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 17.0 million and during the year the amount was reduced by EUR 0.2 million to arrive at EUR 16.8 million. For the year, EUR 16.6 million were committed which corresponds to an execution rate of 99%.

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 3.9 million for Title 2, is mainly stemming from outsourced IT services and costs related to the new ECHA building project. An amount of EUR 39 103 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 the operational expenditure needed to implement the REACH and CLP regulations. The initial budgeted payment appropriations amounted to EUR 21.7 million and were subsequently increased during the year by EUR 1.8 million to arrive at EUR 23.5 million. The executed commitment appropriations for 2018 were EUR 23.1 million corresponding to an execution rate of 98% and the appropriations carried over amounted to EUR 10.4 million representing 45% of the committed amount.

The expenditure related to IT projects and services for ECHA's operations, totalling to c. EUR 14.3 million, represents c. 65% of the total expenditure in Title 3 and the related carry-over accounts for c. 60% of the overall amounts carried over in Title 3 totalling EUR 8.3 million. The significant carry-over of appropriations is largely due to the fact that IT projects cannot be exactly aligned with the annuality, as the durations can be more than 12 months and not all projects can be started at the beginning of the year. Furthermore, due to the uncertainty related to the fee income, ECHA had to wait that sufficient income was received, before proceeding with certain projects. Consequently, some of the large-scale projects started only towards the end of the year resulting in a full carry-over. In 2018, the further development of a Poison Centre Portal and start of WFD database development are some of the examples. Furthermore, due to the budgetary constraints in 2019, it was decided to use some of the 2018 budget available to frontload certain IT projects from 2019, again resulting in a full carry-over as the projects will only be finalised in the course of the following year. In addition, the carry-over of appropriations is resulting from retention of payments, from payments to be done for accepted work and ongoing work that is to be finalised in 2019.

Other significant expenditure items in REACH/CLP operational expenditure are the Registration related expenditure totalling EUR 1.7 million and Communication and Translation costs totalling EUR 1.5 million.

An amount of EUR 206 979 carried over from the previous year (C8) was not used in payments and was cancelled (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 2.3 million. Due to the shortfall in income, the expenditure was reduced during the year by EUR 0.5 million to EUR 1.8 million. The total committed amount was EUR 1.7 million corresponding to 96% commitment rate and the carried over amount was EUR 0.4 million, representing 25% of the committed amount. The carry-over appropriations mainly stem from the area of IT. An amount of EUR 16 278 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 0.23 million and, during the year, was increased to EUR 0.25 million. The executed commitment appropriations amounted EUR 0.24 million corresponding to a 96% execution rate, whereas the carried over amount was EUR 0.13 million (54%). As with REACH, the expenditure related to IT services is the biggest expenditure item representing c. 90% of the total expenditure in Title 5. The carry-over of appropriations relates mainly to expenditure for IT investment in the area of ePIC further development and enhancements. Furthermore, the carry-over also stems from support, maintenance and application management of ePic system, where the carry-over of appropriations is resulting from retention of payments, from payments to be done for accepted work and ongoing work that is to be finalised in 2019, as IT services cannot be exactly aligned with the annuality in all cases due to necessity to secure uninterrupted continuity of delivery of the business applications.

The amount of EUR 47 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 2018, ECHA did not pay late interest for commercial invoices.

Transfers

During 2018, 17 internal budget transfers totalling EUR 1 854 678 were carried out.

Procurement procedures

In 2018, in implementation of its budget, ECHA signed 595 contracts and purchase orders. Moreover, ECHA issued 284 catering orders and 668 travel orders through the electronic ordering tools of the relevant framework contracts. Out of the 595 signed contracts, 475 were specific contracts and orders under framework contracts, 76 were contracts resulting from tendering procedures, three were renewals. A total of 41 contracts were signed following exceptional negotiated procedures based on the relevant rules of the Financial Regulation, 30 of which refer to legal services and the remaining ones mainly refer to subscriptions, participation to events and direct purchase of services for technical reasons.

In 2018, the performance of the suppliers of the Agency was overall satisfactory and in accordance with the terms of the contracts, with no relevant exceptions. Green procurement continued being a priority for ECHA as an integral part of the Agency's management system. In this regard the Agency purchased a 'Renewable Energy Certificate for 2019' and fully outsourced the data centres and moved into the Cloud.

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 2018 is available under Annex II Statistics on financial management and procurement.

2.4 Human resources management

The recruitment target for 2018 was achieved with 97 % of posts filled at the end of the year for REACH/CLP, PIC and the BPR – although the cumulative rate was 99 % throughout the year. The higher vacancy rate towards the end of 2018 was due to the Agency's ongoing reorganisation that entered into force on 1 January 2019, facilitating increased flexibility for human resource allocation. This result is in line with the 2018 establishment plan – that is, 6 fewer posts to comply with overall staff reductions of 2 % - as communicated by the Commission in its 2013 communication on programming of human and financial resources for decentralised agencies for 2014-2020. At the end of 2018, ECHA's turnover rate was 3.3 % for contract agents and 1.3 % for temporary agents. For the 2018 registration deadline, HR played a key role in managing the resource needs for staffing the Agency, with posts being filled by short-term contract agents, trainees and interims to ensure that appropriate staff were in place to handle the deadline successfully.

During the second half of 2018, major input was placed into planning, and preparing, for the Agency's reorganisation. A significant amount of work was carried out in staff allocation – by reallocating tasks, posts and staff - in accordance with the new organisational design. This design aims to be the most optimal structure for the Agency, facilitating the achievement of ECHA's strategic objectives.

On staff well-being, ECHA organised a workshop for practising collaborative discussions to support managers and team leaders maintain a culture of early support. In 2018, ECHA launched a specific website on resilience and stress management to prepare staff before the peak workload of the 2018 registration deadline. In addition, negotiations for a memorandum with Helsinki-Uusimaa

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

Hospital District (HUS) were finalised in December 2018 to ensure equal treatment for ECHA staff in terms of entrance to, and pricing of, public healthcare.

In 2018, ECHA increased teleworking possibilities for staff as a further step in developing the Agency's agenda on modern ways of working. This enables staff to plan their working days more independently and facilitates management based on deliverables, rather than physical presence in the building. The first review of the new teleworking policy indicated a high level of acceptance and delivered positive feedback from both staff members and managers. Additionally, the efficiency of the HR portal was further developed to integrate additional HR procedures into a single IT tool in a user-friendly way.

The proposed exit of the UK from the European Union will also affect the Agency's human resources insofar as British staff members would no longer be eligible to work for ECHA. To prepare the Agency for the challenges related to Brexit, the HR unit designed a process to assess and, ultimately, decide on applications for an exceptional continuation of employment of British staff members when the UK has left the EU.

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). A number of surveys, reports, audit results, non-conformities, 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).

In order to fulfil the requirements of the Quality management standard ISO 9001:2015, a Management review meeting involving all Directors will be held at the Directors' meeting on 12 March 2019. The internal controls assessment of the Authorising Officer will be used in order to reflect on the strengths, weaknesses, risks and opportunities of the Management system. On the basis of this retrospective assessment, Directors will collectively decide on the priorities and actions to take in 2019 in line with the Agency's new strategy.

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 conducted an audit on conflicts of interest and ethics in 2018. The objective of the audit was to assess the adequacy of the design and the effectiveness of the internal processes set up to uphold the ethical values of the organisation and compliance with the policy, rules and guidelines on ethics and fraud prevention and on conflicts of interest by staff and by external stakeholders participating in the work of the Agency.

The audit resulted in:

- One critical recommendation: Review and revise the procedures for selection and appointment of the chair, members and alternates of ECHA's Board of Appeal.
- One very important recommendation: Enhance the management of the annual and specific declarations of interests (DoI) by e.g. establishing a standard way of documenting the assessment and review of DoIs as well as by clarifying the requirements concerning the content of the DoI with all process owners and actors and adjusting the templates and guidance if necessary.

ECHA management developed an action plan to respond to the recommendations of the IAS. IAS confirmed that the action plan is adequate. In a follow-up to the audit and key learnings from past years, the policy for prevention of conflicts of interest underwent a thorough review, adding further controls, to continue to ensure impartial, science-based opinions and decisions.

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 2018, the IAC carried out assurance audits on restriction activities; external communication and media management; and on reporting and monitoring of the budget execution.

• Restrictions

- 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 restrictions process
- No critical or very important recommendations were put forward. The important recommendations concerned e.g. increasing number of REACH Art. 69.2 assessments to contribute to successful implementation of ECHA's regulatory strategy with regards to restrictions; ensuring documentation of verification of conflicts of interest and raising awareness of the Member State Competent Authorities (MSCAs) to ensure verification of the conflicts of interest for their teams (including potential outside contractors); developing further co-operation with the Forum to increase quality of the REACH Art 77.4 advice on the enforceability of the restriction proposals.

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

• External communication and media management

- 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 external communication and media management.
- One very important recommendation was put forward: Align the communication strategy with ECHA's corporate strategy. Set clear objectives to the communication strategy and cascade them into an annual implementation plan with milestones, monitor and, when possible measure achievement of them regularly and take corrective actions, when needed.

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

• Reporting and monitoring of the budget execution

- 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 Reporting and monitoring of the budget execution.
- No critical or very important recommendations were put forward. The important recommendations concerned e.g. explaining the impact of budget and procurement plan amendments in the Programming Document, including strategic objectives; continuing the work, as foreseen, to improve fee income forecasting as well as the discussion with the Commission to find the most sustainable way to ensure stability for ECHA's financing.

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

2.7.3 European Court of Auditors (ECA)

As per the Court's "Statement of Assurance provided to the European Parliament and the Council" published within ECA's "Annual Report on EU Agencies for the financial year 2017"³ as of 9 October 2018, ECA audited:

a) the accounts of the Agency which comprise the financial statements and the reports on the implementation of the budget for the financial year ended 31 December 2017, and

(b) the legality and regularity of the transactions underlying those accounts,

as required by Article 287 of the Treaty on the Functioning of the European Union.

According to this Statement of Assurance the accounts of the Agency for the year ended 31 December 2017 present fairly, in all material respects, the financial position of the Agency at 31 December 2017, 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.

Without calling into question the opinion as described above, the Court emphasised that "the Agency is partly self-financed and receives a fee from every company applying for the registration of chemicals as required under the REACH Regulation. The Agency calculates and invoices the fees on the basis of information provided by the companies on application. Ex-post verifications by the Agency identified the need for considerable fee corrections, with the total amount of corrections being unknown at the end of 2017". According to the Court, this observation demonstrates the limitations of a system that relies excessively on self-declarations made by applicants.

Finally, according to the Court's opinion, revenue and payments underlying the accounts for the year ended 31 December 2017 are legal in all material aspects.

2.8 Follow up of recommendations and action plans for audits

European Court of Auditors (ECA)

One of the actions following ECA's audits from previous years (2014-2016) with regard to improving the carry-over rates is ongoing due to its long-term nature. One action with regard to ECHA's founding regulation, not explicitly requiring periodic external evaluation of its activities, is considered outstanding (not under Agency's control).

³ The full report, including the follow up on the actions from previous years is available on ECA's website <https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=47110>

Internal Audit Service (IAS)

No very important issues are pending from earlier IAS audits (actions closed for the Biocides audit).

Internal Audit Capability (IAC)

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

The following partially implemented “very important” recommendation is 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

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 2016 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 ECHA’s website under the following link:

https://echa.europa.eu/documents/10162/3430273/report_2016_discharge_MB51_en.pdf/00c8a275-9c12-9813-f1c0-33a2d30e03d1

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 2018

In 2018 the Agency performed two ex-post evaluations, as described below. Both evaluations were presented to the Management Boards in June and December respectively.

The objective of the ex-post evaluation of the **Portal Dashboard for Member States Competent Authorities (PD-MSCA) and National Enforcement Authorities (PD-NEA)** has been to evaluate the value added brought by the tool, potential shortfalls to be addressed as well as success factors based on selected evaluation criteria (effectiveness, efficiency, economy, proportionality, relevance, coherence, utility and added value). The ex-post evaluation results were also to be used in any future decisions, for example whether the Portal Dashboard should be extended to support Biocides National Enforcement Authorities. Based on the analysis of surveys, interviews and documentation, all evaluation criteria were met to high or some extent.

The key recommendations for PD-MSCA made by the evaluators are focused on:

- Consolidating databases to increase the data available in PD

- Addressing technical and access issues with regard to login process, password management or missing links, improving the search functionality
- Further fostering visibility on substance specific activities in MSCAs in order to avoid duplication of work and improving the PD features to ensure better presentation of the content
- Including additional content (more processes) into the PD

The key recommendations for PD-NEA made by the evaluators are focused on:

- Improving the search functionality of the PD by making it more “Google+-like”
- Ensuring regular update of data, by implementing an automated update of data on regular basis
- Increasing the data and information available through the PD, by further consolidating databases to increase the data available in PD and create a one-stop-shop for all data needs or by offering an umbrella solution with a single login process to access various tools
- Providing capacity building activities to NEAs in the form of trainings, e-learnings) to ensure appropriate use of all features of the tool.
- Strengthening the utility of the tool by offering it in more EU languages, considering the additional cost versus benefits

The objective of the ex-post evaluation of **ECHA Cloud Services** has been to evaluate the extent to which objectives have been met and benefits achieved against selected evaluation criteria (knowledge, use, effectiveness, efficiency, economy, proportionality, relevance, coherence and added value). The ex-post evaluation results are to be used in any future decisions with regard to ECHA’s strategy on the Cloud Services. Based on the analysis of surveys, interviews and documentation, all evaluation criteria were met to high or some extent.

A comparison with the downloadable IUCLID version has been made in order to review the similarities and differences with the Cloud Services, with the conclusion that even if they have some unique and complementary features, there is room for further improvement in the coherence and complementarity of both of them, in particular in the user interface.

The reasons for the lower uptake of the Cloud Services have been investigated in depth, with the conclusion that it can be mainly attributed to the fact that many companies had already installed IUCLID and Cloud Services were introduced very close to the registration deadline. In a big number of cases, the reasons for the lower uptake included also companies’ security policies, prohibiting the transfer.

In the cost-benefit assessment, besides the investment cost analysis, potential synergies and economies of scale have been explored as well. For example, by re-using the ECHA Cloud Services architecture for the Poison Centres, ECHA increased the added value for the EU by reducing the development cost of another IT system built for a new regulation. This will also allow additional savings on the industry side by providing the benefits of the ECHA Cloud Services to the Poison Centres Notifiers community.

The key recommendations made by the evaluators are focused on:

- Improving the user experience for first time users, by consolidating the information in the Cloud Services, providing direct support, simplifying the language and providing more examples.
- Extending the functionalities and addressing technical issues, by integrating more IUCLID features into the Cloud Services, including an opt-out mechanism, improving navigation

and table of content, providing an option to manage multiple legal entities and additional storage for large companies.

- Implementing service extensions considering their added value versus additional costs, such as data exchange mechanism between companies, support to the update process, joint dissemination platform and others.
- If keeping both ECHA Cloud Services and downloadable IUCLID, increase the update of the Cloud Services and streamline the two to avoid overlaps and increase complementarity (i.e. by aligning the user interface, including more services, simplifying the guidance, generating greater stakeholders' buy-in and targeting large companies).
- Investigate how to tackle the data security limitations of companies.

2.10.2. Follow up on evaluations performed in previous years

The last follow up on the evaluations performed has been provided to the Management Board on 13th December 2018. A summary of the follow-up status is presented below per evaluation.

• PD-MSCA and PD-NEA (evaluation finalised in June 2018)

The further improvements of both PD-MSCA and PD-NEA are included in a broader umbrella initiative called Interact, aiming at providing MSCA and NEA one-stop shop for data and a single secure stakeholders gateway. Databases are being further consolidated and the data increased in the PD, with the result to already include certain non-public documents. Some process specific list views have already been provided to MSCA. Work on adding additional processes for both PD-MSCA and PD-NEA (i.e. Biocides processes) is ongoing. In the context of the broader initiative, training and capacity building for both MSCA and NEA have been planned. Translating the tool in more EU languages will not be implemented due to several technical and cost limitations.

• Efficiency development programme governance; Dossier evaluation and financial workflows projects (evaluation performed in 2017)

ECHA's re-organisation undertaken in 2018 is tackling most of the recommendations made from the ex-post evaluation of the Efficiency programme. The organisational review of ECHA allows for scoping of broader end-to-end processes, so that inefficiencies in current processes become more visible. The Programming document(s) 2019-2022 contain an updated performance management model with more outcome oriented metrics. Resource prioritisation exercise is ongoing to identify savings. Review of the role of IT/business interfaces to improve integration of business services with their IT component is ongoing. New cross-functional initiatives, such as organisation support and integrated regulatory strategy groups have been set up to enhance cross-functional cooperation.

With regard to the recommendations for the two projects, there have been further actions taken to clarify roles and responsibilities in the three financial centres and share good practices. As a result of the reorganisation, two of the financial support centres will merge, thus eliminating overlaps and further enhancing cooperation. In addition, process visibility and interaction with customers of the financial support centres are being further improved through the existing IT tools and knowledge sharing. ECHA's reorganisation, bringing processes together, is expected to bring MSC secretariat and dossier evaluation processes closer together, thus further improving the coordination and avoiding high peaks of workload, ultimately aiming at steadier workload distribution. Unifying documents and tools in particular to gather stakeholders' comments are tackled in the ongoing integrated development of key IT tools aiming at reducing the manual work.

- **Chemical Safety Assessment (CSA) programme/ Exchange Network of Exposure Scenarios (ENES) (evaluation performed in 2016)**

Due to the long-term nature of the recommendations, some of them are still ongoing. There is currently work ongoing to increase the number of sector use maps ongoing. The new strategic priorities of the Agency for the years 2019-2023, and in particular SP2 focus on the exposure assessment and the communication in the supply chain, thus the CSA programme governance needed to be accordingly aligned. Studies to identify downstream users' needs in respect of the safe use of information communicated down the supply chain are still ongoing. ECHA's stakeholder Coordination group expanded to include five sector organisations (downstream users). Programme contribution to Forum initiatives was enhanced to improve safety data sheets quality. With regard to the implementation and consolidation work to maximize the take up and use of ENES products, ENES Work plan 2019 includes all communication elements in progress. In 2018, multiple media channels have been used to communicate news on ENES tools and continue their promotion.

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 2017 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 2018. The exercise is an integral part of the Work Programme preparation. The senior management team followed up the implementation and reviewed the effectiveness of the risk mitigation measures regularly during 2018.

Based on this assessment, ECHA's management identified eight main risks which were included in the corporate Risk Register. The senior management team also agreed that three of these risks should be reduced through specific actions that were described in the action plan relating to the Risk Register, two should be accepted provided that they are due to external factors to which ECHA has no or limited influence, one risk should be avoided by changing the objectives of the Work Programme and one (carried over from previous years) should be shared with third parties. All risks were strictly monitored throughout the year to determine whether the triggers of their likelihood and impact have increased or decreased.

The risk that the Directors ranked the highest at the time of the initial risk assessment referred to the risk of insufficient fee income due to lower-than-foreseen BPR applications for active substances and Union authorisation. The risk materialised and the shortfall of BPR fee income continued throughout 2018, resulting in a request to the Commission to provide an additional EU balancing subsidy of EUR 2.65 million in total, through the amending budgets of September and December 2018.

Another risk with high impact, which also materialised as of 31/12/2018, 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 the last three years, 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 three consecutive years (24 out of the foreseen 50 opinions were adopted in 2018, 31 in 2017 and 41 in 2016). In previous years this was mainly due to the postponement of a number of deliverables by Member State Competent Authorities (MSCAs). In 2018, a new requirement to include endocrine disruptors' properties in the BPC opinions, according to the new endocrine disruptors criteria has been introduced, thus further delaying the approval process.

The risk related to absorbing new tasks was tackled through changing the Work Programme objectives and using scenario planning with different resource simulations in order to avoid a negative impact on the achievement of the objectives. Internal re-allocation of resources has assisted in absorbing some tasks under the Poison Centres and the Waste Framework Directive. To be able to fully on-board those tasks, and also the tasks under Occupational Exposure Limits and Persistent Organic Pollutants, further resources will be needed in the future years and, in this respect, negotiations with the Commission are ongoing.

All the other risks did not impact the execution of Work Programme 2018, however some of these will continue to be relevant in the future. The risk with regard to the lack of a financial balancing mechanism, present in previous years as well, did not materialise in 2018. Due to the higher REACH-related income received than foreseen for 2018 (that is, a surplus of EUR 1.3 million), ECHA was able to cover its expenditure. The risk, however, remains high for the coming years. To mitigate this risk, ECHA has engaged external expert support to advise on improve its fee-related planning for the future years.

The risks related to the smooth processing of registration dossiers for the 2018 deadline have been properly managed throughout the year through scenario planning and relevant adjustment of interim human resources to the incoming number of dossiers. The scenario with an overall lower number of registrations, and a higher income level was confirmed, with the levels of interim support reduced accordingly.

The risk with regard to the lower uptake and thus the return on the investment of the Cloud services during the preparations for 2018 deadline and beyond has been investigated in-depth. An ex-post evaluation of the Cloud services and their added value, including also a detailed comparison with the downloadable IUCLID version has been performed in 2018 and the results submitted to the MB in December 2018. More details on the evaluation are available in Section 2.10. "Ex-ante and ex-post evaluations".

The risk related to a lower than planned number of Compliance Check and Testing Proposals draft decisions under REACH, due the increased complexity and time required to address groups and categories did not materialise in 2018, mostly due to the preventive measures taken to improve the process efficiency and the resource re-allocation.

The implementation of the cost-risk-benefit concept in order to review controls and ensure they are proportionate to the level of the risks, is covered under Section 3.3. "Specific efforts to improve the economy and efficiency of financial and non-financial activities".

3.1.1 Transparency, accountability and integrity

Throughout 2018, the Agency lived up to its values of transparency and independence. 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 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 2018 the portal saw major enhancements, especially in the area of biocides: more information on biocidal active substances and products were made available, including any final Summary of Product Characteristics (SPCs), non-confidential assessment reports and decision documents. The information pages will also give the public access to data from current and previous lifecycles of active substance approvals and product authorisations, from the initial application to any subsequent amendments and renewals.

Furthermore, the scope of the Public Activities Coordination Tool (PACT) has been extended to also cover substances under dossier and substance evaluation, as well as substances in the registry of intentions for harmonised classification and labelling, substance of very high concern identification or restriction. The PACT offers companies an overview of information on substances that are on an authority's radar for potential regulatory risk management. Users can find a summary of each activity per substance, and be directed to process-specific lists, which give an information on all the substances subject to a particular process. The advance notice enables companies to consider their business strategy and gives all stakeholders more time to prepare their contributions to the public consultations that are ran during the formal risk management processes.

To specifically address consumers with information on chemicals, ECHA has launched the Chemicals in our life website. The website, available in 23 EU languages, provides useful information on the benefits and risks of using chemicals and explains how the EU legislation on chemicals protects us.

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 cases of actual conflicts of interest affecting the output of the Agency have been identified in 2018.

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 42 staff members who left ECHA in 2018: 9 of them went to work for another EU institution, body or agency. Nine staff members left to the private sector or started self-employment and in 3 of these cases, the Agency saw it necessary to impose specific conditions before authorising the new employment.

In the remaining 27 cases, ECHA has not (yet) been informed about a new occupational activity, as the departure was due to the end of contract, unemployment after resignation, retirement or permanent invalidity. One of these cases concerned the retirement of a senior management staff member. An overview of the post-employment decisions on all former senior managers is published on the ECHA website, 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 first adopted in 2015 and updated in September 2018.

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 2018 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 view of the 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 11 December 2018. The focus was on the following actions:

- Awareness activities towards the staff of the Agency;
- The setup of an effective procedure for personal data breach notifications;
- Adapting contractual clauses with service providers of the Agency;
- Adapting the privacy policies and terms and conditions of ECHA's IT systems;
- Adaptations to ECHA's Event's Logistics Management tool;
- Adaptations to the privacy statements regarding ECHA's processing operations and the build-up of a public register of records as required.

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.

During year 2018, all business continuity plans were reviewed. Crisis scenario was tested in January as a preparation for the registration deadline in May 2018. The registration deadline went on smoothly and without interruptions to the normal functioning of the IT systems of the Agency. A physical security online course was launched in 2018 to remind ECHA's staff about the physical security rules. Fire safety training for ECHA was also organised.

In 2018, 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 bespoke 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

One of the main achievements in 2018 is the new inclusive approach to secure access to information in one stop-shop for data, thus providing a single secure stakeholders gateway, instead of dedicating systems per user group. Those initiatives are being organised and performed

under the umbrella of ECHA Interact project, which is expected to enhance collaboration with stakeholders, unify commenting practices, and further mitigate security risks.

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

The Management Board adopted the ECHA Integrated Management Standards (IMS), replacing the ECHA Quality and Internal Control Standards on 17 December 2013. The Integrated Management Standards of ECHA are based on the COSO Framework, but also incorporate all relevant quality elements to ensure compliance with the requirements of the quality standard ISO 9001:2015. They also follow the provisions of the Framework Financial Regulation and in particular Article 30, focusing on the elimination of multiple controls and improving the cost-benefit ratios of controls.

Following those provisions, since 2014 onwards, the Authorising Officer has focused both on effectiveness and efficiency when assessing the functioning of the internal control systems against the requirements of the ECHA IMS.

In 2018, ECHA performed an in-depth analysis of the requirements of the revised Internal control Framework (ICF) of the Commission in order to determine whether those are covered in ECHA Integrated Management Standards. ECHA's IMS are a combination of internal control and quality elements, merged to avoid overlaps and ensure assessments which comply with both the quality and internal control standards. The in-depth analysis of the characteristics of the new ICF and cross-referencing their principles with the requirements of ECHA's Integrated Management Standards has led to the conclusion that all elements of the new ICF are covered in the annual assessments of ECHA, even if the structure followed is different.

In 2018, a thorough assessment of ECHA's compliance with the Integrated Management Standards was performed, following the approach as described below:

A preliminary comparative analysis was performed by the Internal Control Officer based on audit results (including IAC, IAS and ECA audits, internal quality audits, ISO 9001:2015 and ISO 14001:2015 recertification audits), ex-ante and ex-post evaluations, non-conformities, complaints, risks, opportunities, performance measurements, staff, stakeholders and internal surveys, as well as other internal documentation. The purpose of this analysis was to triangulate the evidence from different sources, compare with the previous years' assessments and identify trends and areas for improvement. The analysis of the above sources fed the assessment of the Integrated Management Standards, performed by the Authorising Officer. This assessment, together with the rest of the information from the Consolidated Annual Activity Report will be discussed by the Directors and concluded at the Management review (see Section 2.5).

Overall, ECHA is either fully or mostly compliant with all requirements of the Integrated Management Standards. In 2018, the Agency undertook a reorganisation resulting from the change of the Agency's strategy, but also following the recommendations of the second REACH Review. In addition, ECHA started addressing also the minor gaps identified in internal and external assessments of its Management system during the years 2017 and 2018. As a result of the annual internal controls' assessment, the compliance with the requirements of the Integrated Management Standards has been downgraded in two and upgraded in other two of the standards. The internal controls' assessment of the year 2018 is presented together with the assessment of years 2017 and 2016 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 re-certification 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 audits in 2017 and 2018 confirmed once again the compliance of the Agency with the requirements of both of the standards (ISO 9001:2015 and ISO 14001:2015).

In 2018, following the REACH review and the adoption of ECHA's new strategy for the period 2019-2022, ECHA shifted its improvement focus from optimising individual processes to reviewing its overall operational model and organisational structure. Thus, the Efficiency development programme, which was executed as part of ECHA's Multi-annual work programme 2014-2018, was discontinued during 2018. The ex-post evaluation of the programme, as well as the feedback from participants, highlighted that the drive and capability for process improvements and efficiency are more embedded in the mentality of ECHA's staff and Management.

ECHA's new organisational structure is expected to bring processes closer together, enabling further efficiencies through better linking and coordination across tasks. In order to facilitate the transition, in 2018 ECHA initiated a review of its delegations and process documentation, to ensure that decisions are taken and tasks are documented at the appropriate level corresponding to the level of inherent process risk (cost-risk-benefit analysis). This work will further continue in 2019, in alignment with ECHA's internal control strategy.

In 2018, ECHA identified focus areas for further improving its organisational efficiency, also thanks to the results of the Staff survey 2017 and the Senior Management reflection at the Management Review. This resulted in the drafting of a new Human resource strategy, aligned to ECHA's new strategy, focusing on competence development and improved way of working. Increased attention was paid to efficiencies to be achieved by improving existing IT tools. IT staff members and users of IT tools jointly identified areas to address, such as internal communication, service support and functioning of some IT tools. User feedback in the internal services survey 2017 gathered on ICT services and IT tools was thoroughly addressed. As a result, certain IT services for staff have been restructured and simplified to be more user focused. A framework was established to assess the levels of satisfaction and to ensure continual improvement. Four main objectives were pursued: ensure continuity of the service, make it easier for users to gain knowledge on a service, improve user experience and manage customers/users expectations. By improving the functioning of its IT tools, ECHA was aiming both to increase the process efficiency, while improving the internal customers' satisfaction. A preliminary analysis of the internal services survey conducted in 2018 indicates improvement in the satisfaction compared to the previous year and may be an indication that the measures taken so far have been effective.

ECHA's overall efficiency improvement was, for the last years, measured via the score indicating the progress towards achievement of Strategic objective 4 (SO4) of the Multiannual work programme 2014-2018 "To enhance the Agency's ability to provide services and deliver planned output while efficiently using resources". During the five years of implementing SO4, a continuous positive trend in the ratio between ECHA's weighted outputs and the resources employed, demonstrates that the measures and efforts towards a higher level of efficiency brought the desired results. However, in 2018 the limitations of the measurement method became apparent in the context of a high peaks of workload. The score for 2018 was highly influenced by the registration deadline outputs and by the corresponding workload peak, handled with short-term interim staff resources for irregular intervals. The increase in efficiency score for 2018 compared to 2017 is exceptionally high, which renders the quantitative comparison of the 2018 score with

the score from previous years unreliable. More details on the measurement of all strategic objectives of ECHA for the year 2018 are available in the General Report.

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.

Annexes⁴

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

⁴ Other annexes such as Achievements of Work programme 2018, 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 2018 are included in the General Report 2018. The final annual accounts for 2018 will be submitted together with the Consolidated Annual Activity Report for 2018 before 1 July 2019.

ANNEX I. HUMAN RESOURCES STATISTICS

1. Last establishment plan adopted

Category and grade	Establishment plan in voted EU Budget 2018				Posts filled 31 December 2018*			
	TA				TA			
	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL
AD 15	0	0	0	0				0
AD 14	8	0	0	8	4			4
AD 13	16	0	0	16	10			10
AD 12	19	2	0	21	8	2		10
AD 11	31	3	0	34	19			19
AD 10	39	4	0	43	30	2		32
AD 9	52	6	0	58	45	2		47
AD 8	52	12	1	65	47	4		51
AD 7	60	5	0	65	76	12		88
AD 6	21	6	0	27	45	13		58
AD 5	5	0	0	5	13	2	1	16
Total AD	303	38	1	342	297	37	1	335
AST 11	0	0	0	0				0
AST 10	0	0	0	0				0
AST 9	3	0	0	3	2			2
AST 8	7	0	0	7	3			3
AST 7	11	1	2	14	5			5
AST 6	18	0	0	18	12		1	13
AST 5	31	3	0	34	21	1		22
AST 4	17	3	2	22	24	4	1	29
AST 3	13	2	2	17	17	2	2	21
AST 2	1	0	0	1	11	1	2	14
AST 1	0	0	0	0				0
Total AST	101	9	6	116	95	8	6	109
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	404	47	7	458	392	45	7	444

	CA					CA posts filled 31 December 2018*				
	REACH/CLP	Biocides	PIC	Delegated tasks	TOTAL	REACH/CLP	Biocides	PIC	Delegated tasks	TOTAL
CA FG IV	20	7	1	2	30	19	6		2	27
CA FG III	66	6		1	73	55	4		1	59
CA FG II	24	2			26	32	5	1		38
CA FG I					0					0
TOTAL CAs in place						106	15	1	3	125
Total CA (FTE)	110	15	1	3	129	108.31	13.82	1	2.13	125.26

* 3 REACH TAs under recruitment

Percentage of posts filled on 31 December 2018		
	REACH/CLP/PIC	Biocides
TA posts	97%	96%
CA posts	97%	100%

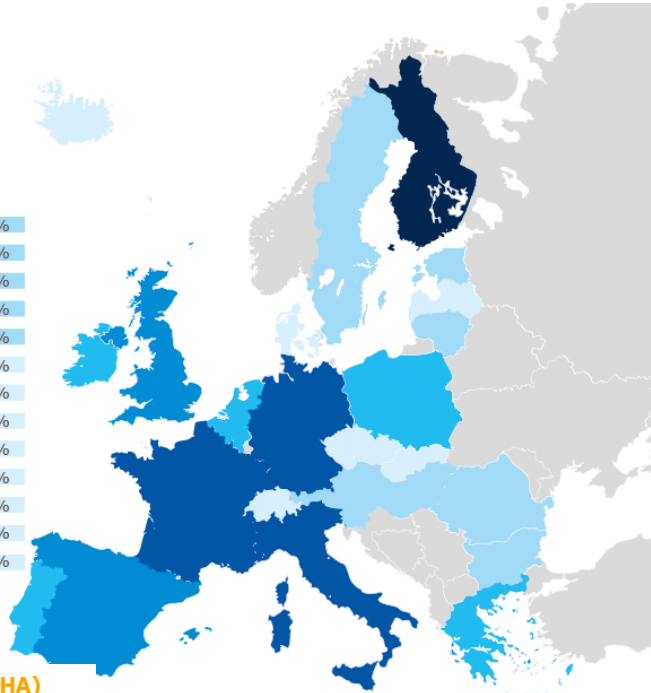
2. Geographical and gender balance (as per 31.12.2018)

TA GENDER BALANCE (ECHA)



TA GEOGRAPHICAL BALANCE

Finnish	32.7%	Swedish	1.6%
Italian	8.6%	Romanian	1.4%
German	7.3%	Lithuanian	1.4%
French	6.8%	Austrian	1.4%
Spanish	5.2%	Slovenian	1.1%
Greek	4.3%	Latvian	0.9%
British	3.6%	Slovakian	0.9%
Polish	3.6%	Czech	0.7%
Belgian	3.2%	Danish	0.7%
Irish	3.2%	Maltese	0.7%
Dutch	2.7%	Swiss	0.2%
Portuguese	2.3%	Icelandic	0.2%
Bulgarian	1.8%	Liechtenstein	0.2%
Hungarian	1.6%		
Estonian	1.6%		

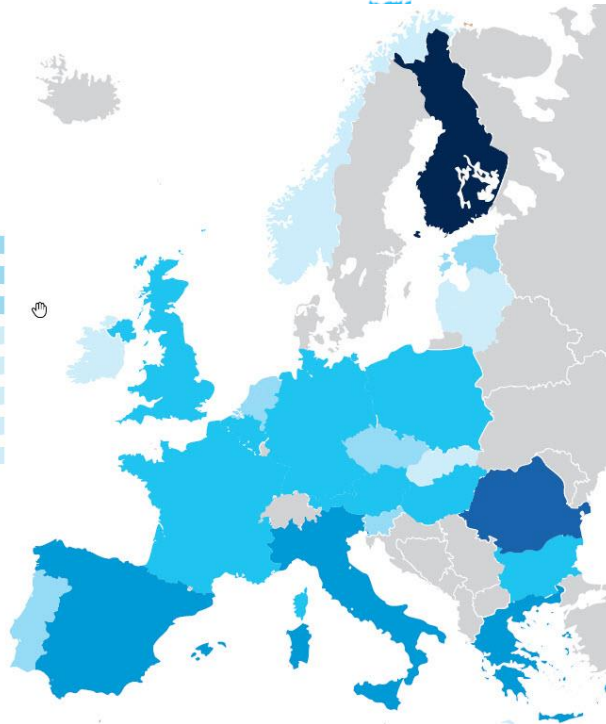


CA GENDER BALANCE (ECHA)

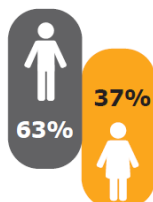


CA GEOGRAPHICAL BALANCE

Finnish	27.2%	Estonian	1.6%
Romanian	12.0%	Slovenian	1.6%
Greek	9.6%	Czech	1.6%
Italian	8.0%	Irish	0.8%
Spanish	6.4%	Lithuanian	0.8%
British	4.8%	Latvian	0.8%
Bulgarian	4.8%	Slovakian	0.8%
French	4.0%	Norwegian	0.8%
German	3.2%		
Polish	3.2%		
Belgian	2.4%		
Hungarian	2.4%		
Dutch	1.6%		
Portuguese	1.6%		



GENDER BALANCE (MANAGEMENT)



3. Results of the screening / benchmarking exercise

ECHA undertook the annual benchmarking exercise in 2018, in accordance with the Commission requirements, with required information on key functions indicated below.

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 8	Administration
Internal Auditor	TA - 5 + 5 years + indefinite	AD 10	Administration

Overall, as illustrated below, the percentage of the administrative support and coordination staff increased from 2017 by 1.4%, while the percentage of operational staff decreased, as anticipated, as that the operational staffing levels related to the 2018 registration deadline (included in 2017 figures) had decreased by end-2018.

Job type (sub) category	2016 (%)	2017 (%)	2018 (%)
Administrative support and coordination	20	17	18.4
Administrative support	16.4	14	15.1
Coordination	3.5	3	3.3
Operational	74.6	77.7	75.9
General operational	22.7	22.7	25.2
Programme management	44	48.2	44.3
Top level operational coordination	3.3	3.5	3.1
Evaluation & impact assessment	4.6	3.3	3.3
Neutral	5.4	5.3	5.7
Finance	5.1	5.0	5.4
Control	0.3	0.3	0.2

ANNEX II. STATISTICS ON FINANCIAL MANAGEMENT

Budget 2018: Breakdown & changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Regulation and Title

REACH/CLP

Title	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	66 014 722	786 785	66 801 507	65 953 886	98.7%	66 801 507	65 726 477	98.4%	227 410	0.3%	847 621
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	14 967 589	-206 426	14 761 163	14 601 047	98.9%	14 761 163	11 166 210	75.6%	3 434 837	23.5%	160 116
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	21 704 060	1 800 602	23 504 662	23 065 058	98.1%	23 725 148	12 877 586	54.3%	10 361 391	44.9%	439 604
		102 686 371	2 380 961	105 067 332	103 619 992	98.6%	105 287 818	89 770 273	85.3%	14 023 639	13.5%	1 447 340

Biocide

Title	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	7 751 434	-335 850	7 415 584	7 391 244	99.7%	7 415 584	7 364 504	99.3%	26 740	0.4%	24 340
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 815 835	-36 576	1 779 259	1 764 491	99.2%	1 779 259	1 356 373	76.2%	408 117	23.1%	14 768
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 331 786	-529 572	1 802 214	1 735 591	96.3%	1 802 214	1 309 340	72.7%	426 251	24.6%	66 623
		11 899 055	-901 998	10 997 057	10 891 326	99.0%	10 997 057	10 030 217	91.2%	861 109	7.9%	105 731

PIC

Title	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	631 050	-19 039	612 011	601 775	98.3%	612 011	599 537	98.0%	2 238	0.4%	10 236
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	237 886	-4 357	233 529	231 018	98.9%	233 529	177 571	76.0%	53 447	23.1%	2 511
B0-5	OPERATIONAL EXPENDITURE - PIC	227 384	23 396	250 780	241 560	96.3%	250 780	110 278	44.0%	131 282	54.3%	9 220
		1 096 320	0	1 096 320	1 074 353	98.0%	1 096 320	887 386	80.9%	186 967	17.4%	21 967

Budget 2018: Breakdown & changes in commitment appropriations and implementation of the appropriations for the year (C1) per Chapter

Chapter	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-11	STAFF IN ACTIVE EMPLOYMENT	68 983 900	391 800	69 375 700	68 947 238	99%	69 375 700	68 947 238	99%	0	0%	428 462
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	582 656	72 801	655 457	581 063	89%	655 457	566 005	86%	15 059	3%	74 394
A-13	MISSIONS AND DUTY TRAVEL	65 000	-11 916	53 084	41 602	78%	53 084	39 802	75%	1 800	4%	11 482
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	1 874 255	-24 131	1 850 124	1 748 120	94%	1 850 124	1 669 181	90%	78 939	5%	102 004
A-15	TRAINING	977 270	-42 484	934 786	758 873	81%	934 786	675 184	72%	83 689	11%	175 913
A-16	EXTERNAL SERVICES	1 898 124	57 576	1 955 700	1 866 841	95%	1 955 700	1 790 186	92%	76 656	4%	88 859
A-17	ENTERTAINMENT AND REPRESENTATION EXPENSES	16 001	-11 750	4 251	3 168	75%	4 251	2 922	69%	246	8%	1 083
Total		74 397 206	431 896	74 829 102	73 946 905	99%	74 829 102	73 690 517	98%	256 388	0%	882 197

Chapter	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	7 978 773	-500 745	7 478 028	7 472 823	100%	7 478 028	7 176 283	96%	296 540	4%	5 205
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	7 585 699	-278 557	7 307 142	7 192 828	98%	7 307 142	5 117 711	70%	2 075 118	29%	114 314
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	1 194 905	520 806	1 715 711	1 698 877	99%	1 715 711	294 340	17%	1 404 537	83%	16 834
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	249 802	266 247	266 247	225 691	85%	266 247	105 703	40%	119 988	53%	40 556
A-25	MEETINGS EXPENDITURE	12 131	-5 308	6 823	6 336	93%	6 823	6 117	90%	219	3%	487
Total		17 021 310	-247 359	16 773 951	16 596 556	99%	16 773 951	12 700 154	76%	3 896 402	23%	177 395

Chapter	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
B3-0	REACH	19 547 060	2 771 690	22 318 750	21 879 784	98%	22 318 750	11 518 392	52%	10 361 391	47%	438 966
B3-1	Multiannual activities	1 477 000	-941 088	535 912	535 486	100%	794 018	751 756	95%	0	0%	426
B3-8	INTERNATIONAL ACTIVITIES	680 000	-30 000	650 000	649 788	100%	612 380	607 438	99%	0	0%	212
Total		21 704 060	1 800 602	23 504 662	23 065 058	98%	23 725 148	12 877 586	54%	10 361 391	45%	439 604

Chapter	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
B4-0	BIOCIDES	2 331 786	-529 572	1 802 214	1 735 591	96%	1 802 214	1 309 340	73%	426 251	25%	66 623
Total		2 331 786	-529 572	1 802 214	1 735 591	96%	1 802 214	1 309 340	73%	426 251	25%	66 623

Chapter	Description	Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
B5-0	PIC	227 384	23 396	250 780	241 560	96%	250 780	110 278	44%	131 282	54%	9 220
Total		227 384	23 396	250 780	241 560	96%	250 780	110 278	44%	131 282	54%	9 220

Total ECHA		Budget 2018 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
		115 681 746	1 478 963	117 160 709	115 585 671	99%	117 381 195	100 687 876	86%	15 071 714	13%	1 575 038

Budget 2018: Implementation of assigned revenue (C4, C5, R0)

Title	Description	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	29 506	14 154	48%	29 506	14 154	48%	15 352	15 352
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C4	119 292	1 001	1%	119 292	1 001	1%	118 291	118 291
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C4	62 826	682	1%	62 826	682	1%	62 144	62 144
			C4	211 625	15 838	7%	211 625	15 838	7%	195 787	195 787

Title	Description	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	7 824	7 824	100%	7 824	7 824	100%	0	0
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C5	76 560	76 560	100%	76 560	76 560	100%	0	0
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C5	82 501	82 501	100%	82 501	82 501	100%	0	0
			C5	166 885	166 885	100%	166 885	166 885	100%	0	0

BL	Description	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	111 422	62%	180 000	87 758	49%	68 578	92 242
B03903	IPA programme agr. 2015/361-049	CND	R0	27 870	27 870	100%	27 870	11 722	42%	0	16 148
B03911	Delegated tasks	CND	R0	2 989 192	1 101 588	37%	2 989 192	913 837	31%	1 887 603	2 075 354
			R0	3 197 062	1 240 881	39%	3 197 062	1 013 318	32%	1 956 181	2 183 744

Budget 2018: Implementation of the appropriations carried forward from previous year (C8) Per Title

Title	Description	Carried Forward from 2017	Paid	Cancelled	% cancelled
A-1	STAFF	511 571	494 713	16 858	3%
A-2	BUILDING, EQUIPMENT AND MISCELL. OPER EXPEND	1 943 872	1 904 769	39 103	2%
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	7 649 547	7 442 568	206 979	3%
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 947 865	1 931 587	16 278	1%
B0-5	OPERATIONAL EXPENDITURE - PIC	172 705	172 658	47	0%
		12 225 559	11 946 295	279 265	2%

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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
Senior Management shall define the Agency's Mission from the perspective of the Agency's Stakeholders.	Yes	Yes	Yes Following its new strategy for more impactful work, in 2018 ECHA updated its mission and vision.
The Mission shall be communicated and explained to the entire organisation and to its Stakeholders.	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 2019-2022. 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%.	Yes ECHA's new mission and vision have been published on ECHA's website and communicated internally and externally. The new vision also serves a wider range of EU policies and global initiatives.

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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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.</p>	<p>Yes</p> <p>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.</p> <p>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 fraud prevention. The Anti-Fraud Strategy was also consolidated by the Management Board in December 2016.</p> <p>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.</p>	<p>Yes</p> <p>In 2017, feedback from stakeholders collected through surveys and events has been positive on the areas of trustworthiness, transparency, independence and openness to dialogue.</p> <p>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 important topics such as ethics, procurement and contract management and information security for newcomers and established staff.</p> <p>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.</p>	<p>Yes</p> <p>The outcome of the public consultation conducted in the scope of the second REACH review (finalised in 2018) indicates stakeholders' satisfaction with the transparency of certain REACH processes, with the conclusion that the increased availability of information of substances and the higher transparency enable the users of chemicals to make better choices in the design of products and in their use.</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, the link between values and actual behaviour of staff and Management could be strengthened. Even if the values are reflected in the objectives of the Management, they could be better translated in everyday life and behaviour.</p> <p>At the Management seminar hold on 30 January 2019, ECHA's organisational values were reviewed in-depth, with the conclusion that they are fit for purpose and serve well ECHA's new strategic priorities.</p>

<p>The Agency's management and staff members' behaviour, as well as the procedures and working methods shall be in line with its ethical and organisational values.</p>	<p>Yes</p> <p>During 2016, actions such as a temporary rotation of Directors during 3 months and intensification of management seminars were taken in order to give opportunities for improvement in the area of trust in Management.</p>	<p>Yes</p> <p>According to the Directors' self-assessment of the IMS as of December 2017, values are clearly communicated 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.</p> <p>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.</p>	<p>Mostly</p> <p>In the first half of 2018, IAS conducted an audit on the implementation of ECHA's policy on Prevention and Management of Conflicts of Interest with the conclusion that there is a need to enforce the controls in the implementation phase. One critical and one very important recommendations were issued (see details in Section 2.7. of the CAAR).</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>The Agency shall have an Integrated Management System combining quality and internal control requirements and ensuring the efficiency and effectiveness of the controls imposed.</p>	<p>Yes</p> <p>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 environmental management system standard ISO 14001:2015. The</p>	<p>Yes</p> <p>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.</p> <p>The re-certification audit of ISO 9001:2015 and ISO 14001:2015 conducted in 2017 concluded for a third consecutive year, that Management</p>	<p>Mostly</p> <p>In 2018, ECHA undertook a major re-organisation following both the findings and recommendations of the REACH review, as well as its new strategy paving the way to a new more –impactful oriented way of working. Following the new way of working, ECHA's governance, delegation and process structure will need to be adjusted in order to ensure staff and middle level management is sufficiently empowered, flexible and able to grow</p>

	<p>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.</p> <p>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.</p>	<p>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.</p> <p>In 2017, ECHA implemented all recommendations of the IAS audit on the BPR operations from 2016.</p> <p>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.</p>	<p>their capabilities and take decisions in particular in lower risk areas.</p>
<p>The Agency shall have a system of delegation of powers appropriate to the importance, number and risks of the decisions to be taken.</p>	<p>Yes</p> <p>In 2016, further efforts were made towards using 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.</p>	<p>Mostly</p> <p>In 2017, further efforts were made towards using delegation of powers as a means for 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</p>	<p>Mostly</p> <p>The results from the online dialogue held in summer 2018 with regard to the forthcoming reorganisation show that staff are aiming to get more empowerment, more cross-team collaboration and better understanding of the interdependencies between parts of ECHA.</p> <p>The need for further empowerment has been also identified previously at Management seminars by HoUs, as well as in previous years' staff surveys and the first actions taken already in 2018. First steps were taken already in 2018 by evaluating different options in the implementation of a more streamlined operational delegation process. The preferred option will ensure that duplicate registries of decisions and delegations will be removed.</p>

		<p>open replies in the Staff survey 2017 also points to the need for further empowerment and less fear of mistakes.</p> <p>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.</p>	
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>The Agency shall have rigorous selection procedures ensuring recruitment of competent staff and provisions ensuring staff development</p>	<p>Yes</p> <p>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.</p> <p>The learning and development framework (established in 2014 and implemented in 2015) was used in 2016 to improve organisational performance through dedicated competence development efforts at personal, Unit, and corporate level.</p>	<p>Yes</p> <p>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.</p> <p>The review of all ECHA's activities undertaken by Deloitte in 2017 pointed out that the Agency was able to attract</p>	<p>Yes</p> <p>In 2018, for a third consecutive year, the ISO 9001:2015 and ISO 14001:2015 auditors concluded that ECHA has very skilled personnel and structured way of working. The last staff survey 2017 also shows that 81% of staff also perceive their competence as high. This is supported by ECHA's online dialogue in 2018 preceding the re-organisation, where expertise, knowledge, skills, competence, professionalism and quality were among the main strengths of the Agency.</p>

	<p>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.</p>	<p>the right talent and is perceived as an attractive 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.</p> <p>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.</p>	<p>According to the Directors' self-assessment of the IMS as of December 2018, recruitment procedures work well, more attention could be paid to targeted procedures and different ways of advertising specific and difficult-to attract competences.</p> <p>In 2018, ECHA developed its new Human resource strategy, aligned to ECHA's new strategic priorities and focusing on competence development, building a high performing and flexible work environment, promoting staff engagement by facilitating career development opportunities and enhancing management and leadership capabilities by strengthening the role of managers.</p>
<p>Senior Management shall ensure that the staff performance is monitored and assessed in an objective, equal and transparent way.</p>	<p>Yes</p> <p>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.</p> <p>In 2016, there were no legal appeals related to the performance appraisal for the reference period 2015.</p>	<p>Yes</p> <p>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).</p> <p>In 2017, there was 1 legal appeal related to the performance appraisal for the reference period 2016.</p>	<p>Yes</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, overall there is a well-developed HR and performance management system in place. Both the strengths and weaknesses of the current HR system are captured in the new HR strategy and the actions stemming from it. Focus should be in implementing the reorganisation, setting more ambitious objectives to Senior staff, promoting staff development, flexibility and delegations.</p> <p>In 2018, there were two legal appeals related to the performance appraisal for the reference period 2017 and one for the reference period 2016.</p>
<p>The Agency shall have provisions to ensure a good work-life balance and an adequate</p>	<p>Yes</p> <p>Some of the measures to ensure a better work-life balance adopted by the</p>	<p>Yes</p> <p>Some of the measures to ensure a better work-life balance adopted by the</p>	<p>Yes</p> <p>Following the results from the air quality survey, in 2018 ECHA provided air</p>

<p>working environment for its staff members</p>	<p>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.</p> <p>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.</p> <p>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 addressed as part of the Building 2020 project.</p>	<p>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.</p> <p>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.</p> <p>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 future choices to make is foreseen in the years to come.</p>	<p>purifiers for the areas where different results were obtained (still within the norms). In 2020, ECHA will move to a new building, which respects health and safety at work, thus eliminating air quality issues.</p> <p>ECHA's reorganisation performed in 2018 will also influence the organisation of the workplaces in ECHA's new building which is expected to be finalised as of 01 January 2020. Focus will be on further enhancing the team work. As per the feedback gathered in the online dialogue in August 2018 preceding the reorganisation, bringing some teams closer can bring opportunities to expand competences and increase flexibility of tasks for staff.</p> <p>Satisfaction with the teleworking arrangements remains high.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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</p>	<p>Yes</p> <p>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 relations with them and gathering their feedback, and that stakeholders are defined widely and maintained at good level.</p> <p>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.</p> <p>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".</p>	<p>Yes</p> <p>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".</p> <p>The stakeholders survey of 2017 shows improvement in the stakeholders satisfaction in most of the areas.</p> <p>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.</p> <p>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</p>	<p>Yes</p> <p>The second REACH review used extensively the stakeholders' feedback in evaluating the effectiveness of implementing the REACH regulation. The main conclusions from the public consultation are that REACH Regulation includes a number of mechanisms enabling stakeholders to participate in the decision-making processes, stakeholders have mostly benefited from REACH in increasing their knowledge about chemicals, their participation has been constructive during the preparation of guidance as well as during policy discussions in CARACAL and has improved in the different REACH processes.</p> <p>The registration deadline of 2018 was widely seen as success - ECHA has once again demonstrated its commitment to the stakeholders and their needs.</p> <p>The ISO 9001:2015 surveillance audit in 2018 raised a positive observation on the stakeholders survey action plans and execution, in line with its conclusions from previous years that the Agency is collecting and using the stakeholders feedback in a good way, is committed to its stakeholders, to building good relations with them and gathering their feedback,</p>

		<p>offers additional ways of involving stakeholders, thus increasing the quality and acceptability of its activities compared to the pre-REACH process. Nevertheless, a number of issues that deserve attention by the Management have been reported: politically driven discussions in MSC and SEAC, transparency and visibility of the Forum, limited output from BPC public consultations. The evaluators also pointed out the need for ECHA to consider how to tackle the declining response rates and to refine its methodology of calculation of the satisfaction levels, to capture a more realistic picture and meaningful results.</p>	<p>and that stakeholders are defined widely and maintained at good level.</p> <p>Overall, the results of the Stakeholder Survey 2018 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".</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, ECHA's stakeholders' engagement is extensive and strong and is well perceived by stakeholders. Still, ECHA could further simplify its stakeholders' communication, follow a coherent approach and focus on the most important issues to interact with stakeholders, especially in light of ECHA's new strategy and organisation.</p>
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2. STRATEGY, PLANNING AND RISK MANAGEMENT

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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
The Agency shall have a corporate vision and strategy expressed in multiannual work programmes and translated to annual work programmes	Yes	Yes	Yes In 2018, the Agency adopted its new strategy towards more impactful work to ensure better protection of human health and environment. The development of the new strategy was done in parallel to the revision of the mission and vision of the Agency. The new strategy aims to increase the added value to the European citizens from ECHA's work.
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.	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	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	Yes Taking into account the recommendations from the second REACH Review, in 2018 ECHA defined its new strategic priorities, where the focus is placed on the quality of data, on the adequacy of the measures taken to handle substances of high concern, and subsequently on the measurement of the intermediate and long-term impact of the Agency's actions in protecting the human health and environment. ECHA also performed benchmarking and an in-depth analysis in order to define the models for the measurement of its three

	<p>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.</p>	<p>maintained as way to communicate the monitoring data.</p> <p>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 indicators, rather than on quality performance indicators.</p>	<p>new strategic priorities (SPs), thus following up the actions from the previous Management review, ex-post evaluation of the Efficiency programme and responding to the long-term requests of the MB, Commission and Parliament to define impact indicators. Even if the measurements are not refined yet and further work and testing needs to be performed in 2019, the logic behind the models for the measurement of the three SPs has been established.</p> <p>As a result of the new strategic orientation towards more impactful measures, all metrics in the Programming Document(s) (SPD 2019-2022) were reviewed with the result to remove certain input and output metrics with limited value and to replace them with outcome and intermediate impact metrics. In that way, the Agency addressed the finding from the REACH review ensuring that it has in place a holistic integrated performance management system.</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, the new SPD with the new SPs has been successfully developed and provides a steer for the work in the coming years.</p>
<p>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,</p>	<p>Yes</p> <p>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 and the</p>	<p>Yes</p> <p>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</p>	<p>Yes</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, the overall system is well run and comprehensive, and the SPD provides a steer for the work in the coming years. Still, more work needs to be done in aligning the resource allocation to the new</p>

<p>effectiveness and economy.</p>	<p>needs of internal and external stakeholders.</p> <p>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.</p>	<p>implementing the tool in the real environment.</p> <p>According to the Directors' self-assessment of the IMS as of December 2017, ECHA invest considerable efforts in planning. The main weakness is the integration of new initiatives for which often resources are limited. So far, the Agency has managed to absorb the staff cuts in a way that do not reduce the business outputs, thus proving it is a lean organisation.</p>	<p>strategic priorities (in particular SP2 and SP3).</p> <p>A tailor-made software – the PMR tool – has been implemented in 2018. It combines as different metric sources the time recording for the whole organisation, the planning on unit level in accordance with the objectives and annual actions of the Agency with the collection of corporate metrics. Even if there have been some positive feedback on its implementation mainly with regard to the increased reliability of data, it's difficult to judge on the efficiency gains from its use at this time.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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.</p>	<p>Yes</p> <p>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</p>	<p>Yes</p> <p>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.</p>	<p>Yes</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, the Agency is quite advanced in the area of risk management, the process is well structured and working, in line with relevant standards. Nevertheless, some consider that more efforts are needed to truly embed it into the relevant operations.</p> <p>The ISO 9001:2015 and ISO 14001:2015 surveillance audit noted that corporate risk</p>

<p>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.</p>	<p>changes are implemented in a well-controlled manner.</p> <p>Yes</p> <p>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.</p>	<p>Yes</p> <p>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.</p> <p>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.</p>	<p>management is now integrated in the IMS tool, which is in use.</p> <p>Yes</p> <p>In 2018, following the REACH review and the creation of ECHA's new strategy for the period 2019-2022, ECHA shifted the level of its improvement focus, from optimising individual processes to reviewing its overall operational model and organisational structure. Thus, the Efficiency Development Programme, which was executed as part of ECHA's Multi-annual work programme 2014-2018, was discontinued during 2018. The ex-post evaluation of the programme, as well as the feedback from participants, highlighted that the drive and capability for process improvements and efficiency appeared to be more embedded in the mentality of ECHA's staff and Management. More information on the initiatives undertaken to increase efficiency in 2018 are available in Section 3.3. “Specific efforts to improve the economy and efficiency of financial and non-financial activities” of the CAAR.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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</p>	<p>Yes</p> <p>The surveillance audit of ISO 9001:2015 performed in 2015 concluded that roles, responsibilities and authorities are well defined in the organisation.</p> <p>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.</p> <p>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.</p>	<p>Yes</p> <p>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 3.1.Management responsibility).</p>	<p>Yes</p> <p>According to the ISO 9001:2015 and ISO 14001:2015 surveillance audit in 2018, the documents workflow in the new IMS tool works well and facilitates systematic documenting of documentation approvals. In the previous year, the auditors concluded that roles, responsibilities and authorities are well defined in the organisation.</p> <p>Still, it has to be noted that in 2018, the biggest proportion of the root causes of the NCs (around 30%) refer to roles and responsibilities, followed by written instructions (23%).</p> <p>Some of the conclusions of the REACH Review refer to the decision-making process of ECHA bodies such as MB, RAC, SEAC and MSC. While the evaluators recognised the multiple actions taken to improve the decision-making processes (such as changing the meeting's format, fast-track procedures and streamlining and optimisation of the discussions), they concluded that there is still a need to continue improving the efficiency in the dossier and substance evaluation processes, increase the socio-economic</p>

			<p>expertise of SEAC and improve the efficiency of the Management Board through flexible working methods.</p> <p>In 2018, in line with the reorganisation undertaken, decision –making bodies were merged in order to allow for more coherence and efficiency in decision – making. In addition, measures, such as simpler documentation, drafting and approval of the minutes at the end of the relevant Directors’ meeting were introduced in order to streamline the decision-making process.</p> <p>According to the Directors’ self-assessment of the IMS as of December 2018, the decision making framework is in place, but there is a need to enable further delegations to appropriate levels, set clear policy lines to staff, stick to agreed decisions, as well as simplify documentation in line with the reorganisation undertaken.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
The Agency shall ensure that its processes are designed in line with its strategies and objectives,	<p>Mostly</p> <p>The ISO 9001:2015 and ISO 14001:2015 audits in 2016 found that the process structure, as well as the description of the</p>	<p>Mostly</p> <p>The ISO 9001:2015 and ISO 14001:2015 audits in 2017 concluded that the main process structure as well as the</p>	<p>Mostly</p> <p>The ISO 9001:2015 and ISO 14001:2015 audits in 2018 concluded that processes are working according to ECHA’s</p>

<p>reflect process interactions, allow process measurement and are documented in a user friendly manner, readily accessible and useful for the staff.</p>	<p>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 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.</p> <p>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.</p>	<p>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 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.</p> <p>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 common process objectives and process interactions according to an analysis of the open replies in Staff survey 2017.</p> <p>The trend from the previous year to have most of the NCs in operations (service provision and control) continues in 2017 as well.</p> <p>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.</p>	<p>management system. This confirms their positive observations in the last two years, that main process structure as well as the process interactions are well described. The online dialogue preceding the re-organisation conducted in 2018, shows that staff perceive the processes as well working and mostly efficient.</p> <p>The review of ECHA's high level activities, linked as a value stream mapping exercise in 2018 resulted in the confirmation of the importance of screening and prioritisation as key phases in ECHA's regulatory work and contributed to the scoping of ECHA's new organisational setup.</p> <p>ECHA's process structure was updated in 2018 to include the emerging new activities and tasks, and also the existing processes and process ownerships, as impacted by the reorganisation.</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, the process structure is well established and robust, and the strength is clear processes and clear responsibilities. One weakness is that there are too many details and strict roles in the process framework that may impede delegation of tasks to lower levels and may prompt to silo thinking. The reorganisation should be taken as an opportunity to review the process structure and pursue process simplifications.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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</p>	<p>Mostly</p> <p>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 assessment, with a major IT outsourcing contractor was completed.</p> <p>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.</p> <p>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.</p> <p>There have been a number of audit findings in the area of emergency</p>	<p>Mostly</p> <p>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 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.</p> <p>The review of all ECHA’s activities undertaken by Deloitte in 2017 has noted that outsourcing IT activities has been 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 didn’t raise any risks or significant issues.</p> <p>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</p>	<p>Mostly</p> <p>During year 2018, all business continuity plans were reviewed and other relevant actions were taken, following the risk assessment of IAS performed in 2017. Crisis scenario was tested in January as a preparation for the registration deadline in May 2018. The registration deadline went on smoothly and without interruptions to the normal functioning of the IT systems of the Agency. A physical security online course was launched in 2018 to remind ECHA’s staff about the physical security rules.</p> <p>The annual analysis in the area of IT security performed by Directorate I indicates that besides the fact that cyber threats have evolved rapidly and become more sophisticated in 2018 compared to 2017, ECHA managed to respond to the attacks early enough to prevent undesirable consequences such as leakage of confidential information.</p> <p>According to the Directors’ self-assessment of the IMS as of December 2018, system is well functioning with updated security and business continuity policy and plans, which need to be expanded to cover new tasks.</p>

	<p>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.</p>	<p>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.</p>	
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>The Agency shall conduct regular assessments that the information available in the Agency's Management system is fit for purpose.</p>	<p>Yes</p> <p>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.</p>	<p>Yes</p> <p>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.</p>	<p>Yes</p> <p>The ISO 9001:2015 and ISO 14001:2015 audits in 2018 assessed ECHA management system and did not find any weaknesses in the information and document management system of ECHA.</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, there is a well-functioning information management system in place, though the reorganisation and the new tasks are certainly going to impact its functioning.</p>
<p>The Agency shall have an Information management system, complying with applicable legislation and providing adequate audit trails, where the</p>	<p>Yes</p> <p>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</p>	<p>Mostly</p> <p>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</p>	<p>Mostly</p> <p>In 2018 ECHA developed its data strategy aiming at identifying how best to employ and further develop its data management capabilities according to a comprehensive</p>

<p>principles of organisation, control, retention, archive and communication with regards to documents and records are defined.</p>	<p>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 a registration tool avoiding duplication with SharePoint Mail Registry.</p> <p>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.</p>	<p>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 implemented and awareness raised in 2017. Nevertheless, the audit on Restrictions performed in 2017 indicated that the metadata (such as recipient’s name) is not systematically filled-in in Dynamic case, which prevents efficient 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.</p>	<p>strategy, in order to enable ECHA to achieve its vision, to strengthen the role of ECHA as hub of chemical safety data, while responding to the needs of other pieces of legislation and policy areas related to sustainable use of chemicals.</p> <p>As an improvement example, in 2018 ECHA continued implementing the automatic ingestion of formal email messages into its digital case management tool Dynamic case, thus avoiding duplicate registration of mails. As of 31.12.2018, there is an open IAC audit recommendation (partially implemented) on ensuring appropriate storage of documents, in particular contract deliverables.</p> <p>In 2018, IT staff members and users of IT tools jointly identified areas to address, such as internal communication, service support and functioning of some IT tools. More information is available in Section 3.3. “Specific efforts to improve the economy and efficiency of financial and non-financial activities” of CAAR.</p> <p>The results from the online dialogue conducted in 2018 prior to the reorganisation (similarly to the results of the ex-post evaluation of the Efficiency programme in 2017) show that staff considers that there is a need for further involvement of the operational actors in the IT product management, prioritisation and budget in order to optimise the alignment of the tools with the relevant needs.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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.</p>	<p>Yes</p> <p>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 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</p>	<p>Yes</p> <p>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.</p> <p>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, not monitoring the achievements of ECHA's strategic objectives to the fullest extent and only measuring quantitative and no quality performance indicators. In addition, the evaluators pointed out that the Agency could improve its communication on the</p>	<p>Yes</p> <p>In 2018, after performing a benchmarking with other Agencies, ECHA reviewed its Work programme indicators in line with its new strategy and established new outcome and impact-oriented indicators, thus replacing some of the current input and output activity indicators. Along with this initiative, there has been more informative and visual reporting, dashboards and more efficiency indicators focused on crucial operations, work in progress and tracking of milestones, allowing for faster Management decisions and focus on corrective actions. In that way, ECHA is handling the observations from the REACH Review with regard to need to review its indicators in order to allow for monitoring the achievements of ECHA's strategic objectives to the fullest extent.</p> <p>In addition, the Agency further refined the models and initiated measurements of the effort-per- output indicators of its Work programme, thus addressing the observation on the need to improve the monitoring and reporting of efficiency</p>

	<p>reporting (both audits from 2015) have been closed.</p>	<p>monitoring and reporting of efficiency gains of individual projects. There was a similar conclusion from the ex-post evaluation of the Efficiency programme conducted in 2017 referring to inconsistent measurements at individual projects level, let alone the overall Programme.</p> <p>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.).</p>	<p>gains made in the same review, but also in the internal ex-post evaluation of the Efficiency programme.</p> <p>In 2018, ECHA implemented its integrated IT solution for unit-level planning, monitoring and measurement (PMR tool), which received some positive feedback with regard to the improvement of the reliability and traceability of the data. There are no indications yet that the efficiency of the process has improved as a result of the PMR tool.</p> <p>According to the Directors' self-assessment of the IMS as of December 2018, though the monitoring and measurement system has improved throughout the years, there are still a number of issues that need to be handled. Further rationalisation of the system could be pursued in order to ensure that similar information is not collected more than once for multiple purposes.</p>
<p>The Agency shall have adequate controls to capture, manage and report on non-conformities and suggestions for improvements, including handling of corrective actions.</p>	<p>Mostly</p> <p>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</p>	<p>Mostly</p> <p>In 2017, the ISO 9001:2015 and 14001:2015 auditors brought again the nonconformity process as an area for senior management attention.</p> <p>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,</p>	<p>Yes</p> <p>The new workflow for handling non-conformities was rolled out in the first half of 2018 as part of the IMS tool, thus replacing the Remedy tool used in previous years. The previous tool has been pointed out in two ISO 9001:2015 and ISO 14001:2015 audits from 2016 and 2017 as inappropriate for NCs handling, and as a main cause for inconsistent implementation of corrective actions and plans. The new IMS tool aims at providing transparency and clarity for the responsible actors, facilitating the handling of the NCs with built-in workflows. External complaints and</p>

	<p>and ISO 9001:2008 audits from previous years referring to inconsistent implementation of corrective plans and actions.</p>	<p>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).</p> <p>All the above issues are to be addressed in the new NC-CAPA tool and workflow rolled out in the first half of 2018.</p> <p>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 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 of the Financial regulation.</p>	<p>improvement proposals - including recommendations from the litigation process - were integrated into the Tool as well.</p> <p>In 2018, a total of 89 new (validated) nonconformities were recorded. The number of NCs was higher than in 2017 (64), however the proportion of the open cases at the year-end is lower in 2018 (36% vs 51% in 2017), which may be due to the implementation of the new, simplified, user-friendly tool. The most common root causes for the NCs in 2018 can be attributed to the category of roles and responsibilities (7), written instructions (6), communication / access to relevant information (5) and human element / distraction / ethics (5).</p> <p>In 2018, the Agency received and followed up on 18 external complaints, with a reply to the complainants, the majority of which referring to the registration processes.</p> <p>With regard to the monitoring of exceptions, in 2018 there has been a decrease in the number to 14 exceptions (from 19 in 2017 and 21 in 2016). The most common reason for the exceptions (similarly to 2017) was related to the article 70 of the Financial regulation.</p>
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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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>Senior Management shall review periodically and carry out an annual management review on the effectiveness, adequacy and suitability of the Agency's Integrated management system.</p>	<p>Yes</p> <p>In 2016, following the focus on analysis, rather than purely numerical data, ECHA revised its 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.</p> <p>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".</p>	<p>Yes</p> <p>In 2017 ECHA continued focusing on analysis, rather than on purely numerical data, in support of a more effective and 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.</p> <p>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.</p>	<p>Yes</p> <p>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 the last three years. The auditors had also noted in previous years that the Management review is well prepared and analysed beforehand and there are good templates and clear structure of how to analyse actions.</p> <p>A minor nonconformity with regard to the environmental management review process was issued in 2018. The auditors considered that it would be good to make an effort to define ECHA's most significant positive environmental aspects even if they are part of the normal operations.</p> <p>In 2018, the Management Board performed a self-evaluation in order to review the MB's current working arrangements and to reflect on the Commission's REACH Review concerning it. The recommendations from the self-evaluation are focused in the areas of reviewing MB rules of procedures to ensure they are "fit for purpose", reviewing the number and format of all working groups to align them better with MB and ECHA's needs, determining criteria for MB membership and implementing an induction/training programme for MB members.</p>

			<p>According to the Directors' self-assessment of the IMS as of December 2018, even if there is a robust system in place, there may be a need to review the timing, content and frequency of the measurements foreseen, in order to allow Management to take corrective actions on time.</p>
<p>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.</p>	<p>Mostly</p> <p>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.</p> <p>Results are available in Section 2.10. Ex-ante and ex-post evaluations of the CAAR</p>	<p>Mostly</p> <p>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.</p> <p>Results are available in Section 2.10. Ex-ante and ex-post evaluations of the CAAR.</p>	<p>Mostly</p> <p>According to the Directors' self-assessment of the IMS as of December 2018 and as per the feedback received by some MB members, the ex-post evaluations performed are of good quality. There may be a need to develop a light review mechanism for some activities. Introducing time limit boundaries for projects could be also considered.</p> <p>With regard to the ex-ante analysis, even if it is formally included in ECHA's project governance, there is a need to further re-inforce its implementation.</p> <p>Details on the evaluations performed and the recommendations stemming from them are available in Section 2.10. of the CAAR.</p>

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 2016	Is the requirement fulfilled - Assessment 2017	Is the requirement fulfilled - Assessment 2018
<p>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.</p>	<p>Yes</p> <p>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.</p>	<p>Yes</p> <p>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.</p> <p>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).</p>	<p>Yes</p> <p>In 2018, IAC followed its improvement plan for the year, whose actions were formulated as a result of surveys performed to gather the opinion of both Directors and MBWG members on audit. As a result of those, in 2018 IAC included in its audits an element of assessment of ECHA’s impact (in particular in the External communication and media management audit). IAC continued to look for simplification potential in the processes audited from the perspective whether all produced information is needed for opinion- and decision-making. In the recommendations (in particular in the External communication and media management audit), examples of how to implement the recommendations in practice were provided as well.</p>

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, 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 Auditors⁵ 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 5 March 2019

signed

Bjorn HANSEN

Executive Director

⁵ 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.