

Consolidated Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2015

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LIST OF ACRONYMS

AWP	Annual Work Programme
BPR	Biocidal Products Regulation
CA	Contract Agent
CAAR	Consolidated Annual Activity Report
CLP	Classification, Labelling and Packaging
DG	Directorate General
DPO	Data Protection Officer
ECA	European Court of Auditors
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
ED	Executive Director
EDPS	European Data Protection Supervisor
EFTA	European Free Trade Association
EMS	Environmental Management System
Forum	Forum for Exchange of Information on Enforcement
FR	ECHA Financial Regulation
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Union
ISO	International Organization for Standardization
IQMS	Integrated Quality Management System
IMS	ECHA Integrated Management Standards
KPI	Key Performance Indicator
MAWP	Multi-Annual Work Programme
MB	Management Board
MSCA	Member State Competent Authority
PIC	Prior Informed Consent
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	central IT system providing support for REACH
SME	small and medium-sized enterprise
TA	Temporary Agent

MANAGEMENT BOARD'S ANALYSIS AND ASSESSMENT

The Management Board provides its assessment of the Consolidated Annual Activity Report and instructs the Executive Director to send the Assessment of the Consolidated Annual Activity Report as adopted not later than 01 July 2016 to the Court of Auditors, the European Parliament, the Commission and the Council.

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

INTRODUCTION

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

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

In line with the Financial Regulation, the Management Board is expected to make an assessment of the Consolidated Annual Activity Report (CAAR) which has to be submitted, together with the CAAR, to the Court of Auditors, the European Parliament, the Commission and the Council no later than 1 July 2016.

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

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

EXECUTIVE SUMMARY

A summary on key achievements of the year are covered by the General Report (Part I) which together with its pertinent Key Performance Indicators (KPIs) are an integral part of the Authorising Officer's report. Despite the risks and constraints in some areas, ECHA has reached almost all of its KPI targets of 2015. In 2015 ECHA developed an integrated regulatory strategy utilising all capabilities, regulatory processes and tools it has at its disposal, thus significantly further advancing in the integration of REACH and CLP processes.

The opening reserve and the revenues in 2015 were higher than expected. This, together with the reductions on the expenditure side, resulted in the Agency not eventually needing a balancing EU subsidy for its REACH/CLP operations. With regard to the BPR, ECHA received higher than the expected income, but given the fact that the Agency was unable to fill in the open posts, and that it took a considerable time to agree on the new IT programme, a large proportion of the Biocides subsidy will have to be returned to the Commission in 2016.

In 2015, the Agency has been able to adapt to changes in the external environment having impact on its activities and resources, and has started implementing its strategic approach for the coming years towards becoming a leaner and more impactful regulatory agency. Actions resulting from audit recommendations, as well as risks identified have been managed as high priority, thus resulting in effective risk management and continuous improvement of ECHA's Management system. Ex-ante and ex-post evaluations framework and approach have been agreed and established in 2015. The assessment of the effectiveness of the internal control systems indicates progress towards compliance with the Integrated Management Standards compared to the previous years.

PART I ACHIEVEMENTS OF THE YEAR (SEE GENERAL REPORT)

PART II GOVERNANCE AND MANAGEMENT

2.1 Management Board

In 2015 the Management Board held four plenary meetings, one hosted by the Luxembourgish EU Presidency. In addition, twelve working group meetings were organised for preparing Management Board Decisions or supporting the Board's oversight function in specific areas, including the performance evaluations of the Executive Director and the members of the Board of Appeal. Two Decisions were agreed by written process.

Apart from adopting all statutory documents, including the new Draft Programming Document, as foreseen in the applicable rules and regulations, the Board for example:

- Considered the consequences of a EU General Court judgment related to the application of its Decision on administrative charges in the context of small and medium-sized enterprise (SME) verification¹
- Took a number of decisions related to the appointment of members of the Board of Appeal and concerning the appeal body's structure
- Put arrangements in place to allow the reinforcement of the scientific Committees under the REACH Regulation through the co-option of members
- Agreed to the participation of Switzerland in ECHA's work under the BPR Regulation
- Endorsed an approach for revising the implementation of the completeness check process under the REACH Regulation
- Received reports on the implementation of ECHA's ICT Security Approach and of the new compliance check strategy, ECHA's work plan for nanomaterials and the approach for avoiding unnecessary testing on vertebrate animals.

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

In June 2015 the Management Board organised a first workshop on the development of the future strategy of ECHA.

2.2 Major developments

The strategic approach of ECHA, fully focussed on delivering operational and impactful regulatory work in line with its founding legislations was first shaped in 2014. In 2015, it further refined, by involving Heads of Units and Directors in determining the impact of their operations and by defining change objectives in the Unit level plans, which will allow ECHA to pursue more efficiency in its operations, while still keeping the process effectiveness and delivering impactful regulatory work. As a result of determining the process impact, a number of processes subject to re-design were selected and included under the Efficiency programme which started in 2014 and staff reductions decided in proportion to the impactful regulatory work. All these efforts aim at demonstrating ECHA's added value to the European citizens and increasing its chances of acquiring new regulatory activities in the coming years.

While the activity level for REACH/CLP and PIC during the year was rather intense as predicted, the volume of fee-based activity under the BPR was for the first time much higher than predicted and demonstrated that industry wished to make use of the EU authorisation route for biocidal products. However, the early communication of the Commission that the unfilled posts at the start of the year would be eliminated in the 2016 budget forced the Agency not to fill any of the posts and only to seek agreement on the development of the IT tools after agreeing with the Commission and Management Board in September 2015.

2.3 Budgetary and financial management

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

In accordance with the REACH Regulation (No 1907/2006), ECHA is financed through fees paid by industry and by an EU balancing subsidy as referred to in Article 208 of the general Financial Regulation. In 2015 and contrary to the original assumption, ECHA was fully financed through higher than expected fee income and the reserve from the income of previous years for its REACH/CLP operations.

In accordance with the Regulation on Biocidal Products (BPR, No 528/2012), ECHA is financed partially through fees paid by industry and a balancing EU subsidy as referred to in Article 208 of the general Financial Regulation. In 2015, ECHA collected fee income totalling € 5,423,667 (€ 1,265,774 in 2014), while the EU subsidy amounted to € 5,789,000 (€ 5,064,194 in 2014). Additionally, the received EFTA contributions, including Switzerland, totalled € 307,791 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 2015, this subsidy amounted to € 1,222,001 (€ 1,297,244 in 2014).

The initial budgetary payment appropriations for the expenditure of 2015, as concluded by the Management Board in December 2014, amounted to € 115,168,730.

During the year 2015, the Management Board adopted three amending budgets. The first amending budget in June 2015 increased the REACH reserve with the surplus resulting from the positive outturn of 2014 and, at the same time, the REACH expenditure was reduced. Finally, a new entry for the new IPA programme was included for an amount of € 0.3 million.

The second amending budget in September 2015 adapted the Agency's revenue to the real income situation in the area of Biocidal Products Regulation. The Biocides fee income was increased by € 2.8 million, thus reducing the actual 2015 balancing subsidy need. As the full 2015 EU contribution was already received by ECHA, the Commission advised to proceed with the normal outturn procedure, which is to recover the full outturn in the subsequent year N+1 and to reuse it as assigned revenue in year N+2. Furthermore, the Translation Centre for the Bodies of the European Union (CdT) returned a surplus reserve to their clients and ECHA received a total amount of € 354,000 that was budgeted as income proportionally for all the regulations. At the same time, an amount of € 1 million was added to IT expenditure in Title 4 to allow, primarily, for the further development of critical Biocides Scientific IT tools, and a further amount of € 750,000 was budgeted for the renewal of ICT equipment.

The third amending budget in December 2015 adapted the revenues from fees and charges for REACH/CLP to reflect the actual income situation, resulting in an increase of c. € 1.8 million, and bringing the total budget for fees and charges to € 22 million. At the same time, an amount of c. € 7 million was budgeted to cater for the requirement to pay the employer's part

of the pension contribution to the Paymaster's Office of the Commission, as no balancing EU subsidy would be needed for 2015.

Budget overview (in EUR '000)

Revenue	Initial voted budget	Amending budgets	Final voted budget
Fees and subsidies	32 299	1 109	33 408
Reserve consumption	82 870	-1 509	81 361
Total revenue	115 169	-400	114 768
Expenditure			
Commitment appropriations	115 141	-728	114 413
Payment appropriations	115 169	-400	114 768

2.3.1 Revenue

The budget funding of ECHA in 2015 consisted of the following:

Description	Initial Budget 2015 €	Amending Budgets No 1, No 2 & No 3 2015 €	Final Budget €	Entitlements Established €	Revenue received €
Fees and charges from registrations	8 665 001	11 376 760	20 041 761	21 720 585	21 720 585
Fees and charges from authorisations	3 417 060	(2 688 821)	728 239	728 239	728 239
Fees SME Administration	1 500 000	(400 000)	1 100 000	1 174 227	1 174 227
Fees and charges from CLP	835 000	(705 000)	130 000	134 147	134 147
Fees and charges from Appeals	0	28 276	28 276	28 276	28 276
Total REACH Fee & Charges Income (incl Appeals)	14 417 061	7 611 215	22 028 276	23 785 474	23 785 474
Fees relating to Biocidal active substances	481 000	392 000	873 000	1 003 000	1 003 000
Fees for Union authorisation of Biocidal products	378 000	1 276 000	1 654 000	1 654 000	1 654 000
Miscellaneous fees Biocides	1 384 574	1 101 426	2 486 000	2 761 667	2 761 667
Fees and charges from appeals	0	0	0	5 000	5 000
Total BPR Fee & Charges Income (incl Appeals)	2 243 574	2 769 426	5 013 000	5 423 667	5 423 667
REACH subsidy	7 800 000	(7 800 000)	0	0	0
Biocide Subsidy	5 789 000	(1 977 000)	3 812 000	5 789 000	5 789 000
PIC Subsidy	1 222 000	0	1 222 000	1 222 000	1 222 000
EFTA Contribution - REACH	236 340	(236 340)	0	0	0
EFTA Contribution - BPR	165 866	141 925	307 791	307 791	307 791
Other contributions - IPA	0	300 000	300 000	300 000	300 000
Total EU contributions	15 213 206	(9 571 415)	5 641 791	7 618 791	7 618 791
Revenue from Bank Interest on Fee income	375 000	(55 000)	320 000	317 787	317 787
Other - miscellaneous	50 000	354 627	404 627	832 735	439 864
Total Other income	425 000	299 627	724 627	1 150 521	757 651
Reserve	82 869 889	4 319 804	87 189 693	87 189 693	87 189 693
Total	115 168 730	5 428 657	120 597 387	125 168 146	124 775 276

Collected fees and charges in 2015

A) REACH/CLP

The fees and charges collected by ECHA are determined by the REACH Fee Regulation and by the decisions of the Management Board. Due to the once-off nature of the REACH fees, there is high uncertainty as to their amount and timing. The budgetary revenue from REACH fees/charges in 2015 in terms of the cash received amounted to € 23,757,198 (€ 25,895,180 in 2014). In addition, income of € 28,276 (€ 55,705 in 2014) was recorded in relation to REACH appeal fees giving a total of fees and charges of € 23,785,474.

Approximately 60% of the budgetary income generated in 2015 relates to a small quantity, with a high monetary value, of registration dossiers for registration of substances above 1,000 tonnes and registrations for substances in the range of 100 to 1,000 tonnes.

Approximately 8,200 registration dossiers (mainly updates) and 250 product and process orientated research and development (PPORD) notifications were received in 2015. The total number of submissions decreased by 10% compared to the 2014 level. There were 20% more initial dossiers, and 35% less updates, received in 2015 than in 2014.

In 2015, the Agency received 7 applications for REACH Authorisation which was much less than initially planned as companies preferred only to apply closer to respective deadlines². The total REACH authorisation income received in 2015 amounts to € 728,239 (reflecting an average fee of EUR 104,000 per application).

The Agency received payments for 45 applications under the CLP regulation, which was much lower than planned but was in line with the final budget of 2015. The total receipts to the end of Q4/2015 amounts to € 134,147 (reflecting an average fee of € 2,978).

The additional fee income generated via the SME verification process (included in the REACH Registration income) in 2015 amounted to € 1,074,426 (€ 1,136,338 in 2014). A total of 423 enterprises were verified during the year. In addition to the additional registration fees, the Agency generated € 1,174,227 in administrative charges as a result of the verification work.

B) Biocides

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 2015, in terms of the cash received amounted to € 5,418,267 (€ 1,265,774 in 2014). The income received was in excess of the initial budget/estimates for 2015 by approximately €3.2 million. Despite the fact that many of the applications (particularly Union authorisations) received in 2015 require a significant amount of work to be performed in 2016 and onwards, ECHA is required to return the excess to the Commission as part of the 2015 budget outturn exercise. The Agency also received € 5,000 as a result of a Board of Appeal decision.

In addition, ECHA completed 17 ex-ante SME verifications under the Biocidal Product Regulation, which is a non-fee generating activity.

C) PIC

ECHA received an EU contribution for the PIC Regulation totalling € 1,222,000 in 2015 (€ 1,297,224 in 2014).

² Additional 27 applications for authorisation were submitted in November 2015. Those were processed up to the fee payment in early 2016 (the invoices were issued in January 2016 and the fees were received by mid-February 2016).

D) Other miscellaneous income

During the year, the Agency recorded gross interest income of € 317,787 (€ 1,820,488 in 2014). Practically all of this income relates to interest received on deposit account investments (€ 317,517). As the REACH reserve will be exhausted in 2016 and interest rates remain very low, the return achievable will continue to fall.

In addition, the Management Board of the Translation Centre for the Bodies of the European Union (CdT) decided that part of the reserve accumulated should be returned to the Agencies as their clients. ECHA received € 354,627 in two instalments of € 180,673 and € 173,954, respectively.

The balance of the miscellaneous income, totalling € 85,237, mainly relates to the recovery of the carpark costs from staff and other miscellaneous administrative income.

Fee Invoicing 2015 (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 which is implemented in 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 were recorded in the central accounting system on a monthly basis during 2015.

A) REACH Fees and Charges

The total net invoiced by the Agency in 2015 amounted to € 24,860,388 (€ 24,885,688 in 2014). The table below depicts the breakdown of the net invoiced REACH fees during the year.

REACH Description	2015		2014	
	No of Transactions	€	No of Transactions	€
Invoices issued	4554	28 194 149	3 847	28 301 758
Credit Notes	387	(3 072 408)	315	(2 962 849)
Unpaid	50	(240 522)	80	(453 095)
Considered paid	10	(131)	10	(154)
Waived	1	(20 700)	0	0
Net Invoiced		24 860 388		24 885 660

It is noted that out of the credit notes mentioned above, 262 (219 in 2014) were issued to cancel the original invoices following the verification of the SME status of enterprises claiming to be entitled to fee reductions. From these credit notes an additional net amount of € 1,360,048 (€ 1,034,326 in 2014) was invoiced.

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. The list is added to the Agency's report on budgetary and financial management. This list shall also indicate decisions by the Authorising Officer to waive or partially waive recovery of established amounts. During 2015, bank charges were deducted by the senders' banks for 10 invoices (10 invoices in 2014) relating to REACH fee income. For management efficiency reasons these invoices were considered paid and therefore a total amount of € 131 (€ 154 in 2014) was waived. In addition to this the Authorising Officer waived one SME Administrative charge invoice totalling € 20,700. (The enterprise had not paid the additional registration fee invoices and, therefore, had its registrations revoked. The work performed by the Dutch bailiff and ECHA's own investigations confirmed that this enterprise had discontinued operations in March 2015.)

B) Biocidal Products Fees and Charges

The total net invoiced by the Agency in 2015 amounted to € 5,453,467 (€ 1,233,674 in 2014). The table below depicts the breakdown of the net invoiced fees under the Biocidal Products Regulation during the year.

BPR Description	2015		2014	
	No of Transactions	€	No of Transactions	€
Invoices issued	1845	5 809 600	585	1 386 100
Credit Notes	45	(167 200)	38	(106 500)
Unpaid	118	(188 900)	60	(45 900)
Considered paid	2	(33)	2	(26)
Net Invoiced		5 453 467		1 233 674

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. The list is added to the Agency's report on budgetary and financial management. This list shall also indicate decisions by the Authorising Officer to waive or partially waive recovery of established amounts. In 2015, bank charges were deducted by the sender's banks for two payments (two in 2014) relating to BPR fee income. For management efficiency reasons, these invoices were considered paid and, therefore, a total amount of € 33 (€ 26 in 2014) was waived.

2.3.2 Expenditure

Budget overview per Title

Title	Budget line description	Voted Budget commitment appropriations	Amending budget commitment appropriations	Transfers	Final budget commitment appropriations
Title 1	STAFF	68 025 780	3 769 000	0	71 794 780
Title 2	BUILDING, EQUIPMENT AND MISCELL.OPER. EXPENDITURE	17 097 050	-463 576	0	16 633 474
Title 3	OPERATIONAL EXPENDITURE – REACH	28 450 000	-5 171 700	0	23 278 300
Title 4	OPERATIONAL EXPENDITURE – BIOCIDES	1 119 070	1 138 087	0	2 257 157
Title 5	OPERATIONAL EXPENDITURE – PIC	449 130	0	0	449 130
TOTAL		115 141 030	-728 189	0	114 412 841

Title	Budget line description	Voted Budget payment appropriations	Amending budget payment appropriations	Transfers	Final budget payment appropriations
Title 1	STAFF	68 025 780	3 769 000	0	71 794 780
Title 2	BUILDING, EQUIPMENT AND MISCELL.OPER. EXPENDITURE	17 097 050	-463 576	0	16 633 474
Title 3	OPERATIONAL EXPENDITURE – REACH	28 477 700	-4 844 000	0	23 633 700
Title 4	OPERATIONAL EXPENDITURE – BIOCIDES	1 119 070	1 138 087	0	2 257 157
Title 5	OPERATIONAL EXPENDITURE – PIC	449 130	0	0	449 130
TOTAL		115 168 730	-400 489	0	114 768 241

Budget Execution per Title / Fund source C1 - Current year appropriations – 2015*

Title	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)	Cancelled %
Title 1	71 794 780	71 185 445	99.15%	71 794 780	70 343 772	97.98%	841 482	609 335	0.85%
Title 2	16 633 474	16 082 969	96.69%	16 633 474	13 631 486	81.95%	2 451 483	550 505	3.31%
Title 3	23 278 300	22 844 674	98.14%	23 633 700	15 933 378	67.42%	7 263 007	433 626	1.86%
Title 4	2 257 157	2 113 977	93.66%	2 257 157	564 038	24.99%	1 549 940	143 180	6.34%
Title 5	449 130	447 397	99.61%	449 130	336 451	74.91%	110 946	1 733	0.39%
	114 412 841	112 674 462	98.48%	114 768 241	100 809 124	87.84%	12 216 857	1 738 379	1.52%

***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 expenditure includes payments made during the year and the carry-over of budgetary appropriations. The following paragraphs and table summarises the execution of appropriations for the current year (C1 credits) per Title and a more detailed breakdown is provided in the Annex II.

Title 1: staff expenditure

The initially adopted budget for Title 1 in 2015 was € 68.0 million and the overall increase during the year including transfers and amending budgets was € 3.8 million to € 71.8 million. The final executed amount totalled to € 70.3 million corresponding to an execution rate of 98% for the payment appropriations. The carry over appropriations, totalling € 0.9 million for Title 1, mainly relate to the commitments for trainings and interim services.

An amount of € 91,704 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 € 17.1 million and during the year the amount was reduced by € 0.5 million to € 16.6 million. During the year, € 16.1 million were committed which corresponds to execution rate of 97%.

The largest expenditure areas, apart from the rent of the building, were the IT outsourced hosting services, the costs of security, cleaning and electricity of the building, purchases of IT hardware, software and their maintenance. The carry over appropriations, totalling € 2.5 million for Title 2, mainly relate to the commitments for External ICT services and for Audio Visual equipment and consumables.

An amount of € 93,911 carried over from the previous year (C8) was not used in payments and was cancelled (overall implementation per Title presented in Annex II).

Title 3: operational expenditure REACH and CLP

Title 3 contains exclusively the operational expenditure needed to implement the REACH and CLP regulations. The initial budgeted payment appropriations amounted to € 28.5 million and were subsequently decreased during the year by € 4.8 million to € 23.3 million. The executed commitment appropriations for 2015 were € 22.8 million corresponding to 98% and the appropriations carried over amounted to € 7.3 million representing 32% of the committed amount.

The expenditure related to Scientific IT tools, totalling to c. € 13.7 million, represents c.50% of the total expenditure in Title 3. This IT expenditure and the expenditure related to Evaluation (€ 2.1 million) account for c. 75% of the amounts carried over totalling € 7.3 million for Title 3. The carry over appropriations mainly relate to the commitments for the substance evaluation process which entails 12 months period starting from adoption of the Community rolling action plan in March and operational IT projects.

An amount of € 380,010 carried over from the previous year (C8) was not used in payments and was cancelled, largely due to challenges in the implementation of IT projects (overall implementation per Title presented in Annex II). This amount will become part of the opening fee income reserve thus reducing the 2016 REACH/CLP subsidy need.

Title 4: operational expenditure Biocides

The Biocides related operational expenditure in the initial budget totalled to € 1.1 million and, during the year, was increased to € 2.3 million. The total committed amount was € 2.1 million corresponding to 94% commitment rate and the carried over amount was € 1.5 million, representing 74% of the committed amount. The carry over appropriations mainly stems from the large scale IT project to further develop the R4BP3 system, totalling about € 1.4 million. The financing for the project was only secured during the second half of the year when sufficient fee income had been received, which has resulted in a full carry-over of the project funds.

An amount of € 8,728 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 € 0.45 million and the executed commitment appropriations amounted € 0.45 million corresponding to 99.6%, whereas the carried over amount was € 0.1 million (25%).

As with REACH, the expenditure related to Scientific IT tools is the biggest expenditure item representing c. 50% of the total expenditure in Title 5. The carry-over of appropriations relates to expenditure for support, maintenance and application management of Epic.

The amount of € 1,192 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 2015, ECHA paid € 85.68 in late interest for a total of 3 invoices.

Transfers

In total there were 44 transfers carried out totalling € 1.395 million.

Procurement procedures

In 2015, in implementation of its budget, ECHA has signed 739 contracts, out of which 540 contracts were under framework contracts and 199 contracts as a result of new tendering procedures. 25 contracts included in the latter category were signed as a result of exceptional negotiated procedures based on the relevant rules of the Financial Regulation: 10 of those refer to legal services while the other mainly refer to subscriptions, participation to events and maintenance of technical installations.

2.4 Human resources management

In 2015, the recruitment target of the Agency was achieved with 98% of posts filled at the end of the year for REACH/CLP and PIC. It should be noted that this percentage cannot exceed 98% as ECHA is required to be aligned with the 2016 establishment plan as of 01 January 2016 (that is, a reduction of 10 posts (-2%) for REACH/CLP). The percentage of posts filled for biocides was 83% due to uncertainty with respect to fee income levels and ECHA's authorised staff allocation for 2016. Overall, ECHA's staff planning exercise is increasingly demanding due to the need to take account of the imposed post cuts and the continued uncertainty in the biocides area. Turnover of temporary agents remained relatively low at 4.5%.

ECHA has fully implemented the imposed COM reductions for REACH/CLP in authorised staff numbers. As the Agency's workload has not decreased during 2015, ECHA achieved the agreed reductions through a sharper focus on workload prioritisation (and related staff allocation), efficiency gains and the implementation of robust performance management and contract renewal processes.

In the learning and development area, a new learning and development framework was implemented in 2015. In the career development area, a streamlined, project-based internal mobility process was developed and the competency mapping process continued through the development of a managerial competency framework.

In 2015 a staff engagement survey was conducted, attaining a response rate of 87% and indicating a 9% overall increase in ECHA's staff survey index since the previous survey (and representing an overall 29% increase since the initial survey in 2011). In accordance with international benchmarking data provided by the service provider (TNS Gallup), the current overall staff engagement score categorises ECHA as an organisation of 'strength' in this important area.

In 2015, the first two modules of a new IT tool, the HR Portal, were rolled out to staff in the areas of benefits and personal information and time and leave management. The aim of the tool is to empower staff to better manage and review its own data while, at the same time, improve the efficiency of the underlying processes. The HR services can now also retrieve the necessary data for well-informed decision-making more easily and comprehensively.

Finally, preparations were made to take over from the European Commission the decision-making related to entitlements of staff upon recruitment and during their service at the Agency.

The screening/benchmarking exercise was conducted at the end of 2015 (see Annex I). In comparison with the 2014 benchmarking exercise at the Agency, there was an increase percentage of operational staff (that was higher than the percentage indicated in the benchmarking results disseminated by the EU Commission). The percentage of administrative support staff is continuing to follow the same trend as the EU Commission benchmarking results.

2.5 Assessment by management

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

In addition, and in order to fulfil the requirements of the Quality management standard ISO 9001:2008/2015, a Management Review meeting took place on 5 February 2016. A number of surveys, reports, audit results, non-conformities, complaints, risks, opportunities, pilot evaluations and other sources of information were analysed in order to draw conclusions.

The Management Review focused on a number of important topics for the coming year:

- Improve the link between the retrospective assessment of the Integrated Management Standards of the Agency and the strategic planning
- Integrate the Environmental Management System (EMS) into the ISO 9001:2008/2015 certified Quality Management System of ECHA
- Continue the good work done in 2015 towards compliance with the requirements of the Integrated Management Standards of the Agency and ISO 9001:2008/2015 Standard

The assessment of 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).

The first building block of ECHA Integrated Management Standards, "Governance", was considered well-functioning. The mission may need to be updated as part of the ECHA strategy for the years 2019-2023.

No new actions are needed in addition to the ones in progress stemming from the Staff and Stakeholders survey both conducted in 2015. Efforts will be both focused on new actions, but also on assessing the effectiveness of the measures already taken in both areas. Work-life balance for staff and more contacts with stakeholders, such as downstream users and industry associations are some of the priority actions. Stakeholders' satisfaction was proposed as a quality objective for 2016.

The management system adaptability to external factors was also assessed, with a conclusion that there is a need for more internal flexibility in terms of rules and procedures, and towards building an optimal risk-based delegations system.

With regard to the second building block covering strategy, planning and risk management, the Management acknowledged the good progress since 2014 in terms of simplification and alignment of planning structures, and in further promoting risk management at process level. The fourth strategic objective was proposed as a quality objective for 2016. Despite the fact that the building block is effectively functioning and good progress was made in 2015, Management concluded that further progress is needed to improve the efficiency of the internal controls in more areas based on risk-cost-benefit analysis and critical evaluation of the control levels. In the area of planning, the priorities for 2016 will be to continue with the initiatives under the "Planning and reporting" project (which focuses on simplifications and process optimisations) and define new performance indicators to measure the performance of the core areas of the Agency.

The third building block "Operations and operational structure" was reviewed with the conclusion that good progress has been made since 2014 in the area of decision making and

information management with better defining roles and responsibilities, communicating decisions, finalising and harmonising filing plans and integrating records management within new IT systems.

More progress is still feasible and actions for 2016 are foreseen in the area of process design and deployment, to ensure a clearer description of process interactions. In the area of security and business continuity, the efforts in 2016 will be focused on ensuring compliance of Member State Competent Authorities (MSCAs) with ECHA standards and further development of the business continuity processes under the new security structure adopted in 2015.

Management noted also the good progress in the fourth building block "Evaluation and improvement", which was considered a priority for 2015. The area of monitoring and measurement has improved mainly as a result of the initiatives undertaken under the "Planning and reporting" project. In the area of analysis and evaluation, shifting the focus from the numerical data to analysis of trends, has resulted in better quarterly reviews and a well-structured and focused Management review.

In 2015, ECHA set its evaluation framework and approach and a number of actions were agreed, however their implementation is mainly foreseen for 2016. Management confirmed their commitment to ensure that evaluations are well integrated in ECHA's management system and taken into account in the Management decision making.

In 2015, the Internal Audit Capability (IAC) was subject to an external validation with the highest level of assessment granted "generally conformant". In its review of the audit process, the Management concluded that the business benefits of the audits could be further improved in 2016.

2.6 Budget implementation tasks entrusted to other services and entities

Not applicable

2.7 Assessment of audit results during the reporting year³

All "very important" audit recommendations were followed up as high priority by the Management.

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). The IAS performed an audit on "Forecasting, Calculation and Collection of Fee Income and Charges under REACH, CLP and BPR" in 2015 to assess the design and the effective and efficient implementation of the management and the internal control systems for the process of forecasting, calculation and collection of fee income and charges under the REACH, CLP and BPR regulations. Based on the results of the audit, IAS raised two "very important" and one "important" recommendation. No "critical" recommendations were issued.

The two very important recommendations were following:

³ The results of ISO 9001:2008/2015 certification audit have been taken into account in the assessment of the Agency's compliance with the Integrated Management Standards (Annex III).

- o Enhance the process of fees and charges income forecasting and revenue budgeting by formalising it and further refining its accuracy and reliability
- o Enhance the effectiveness of the SME verification process

An action plan has been developed in response to the IAS recommendations.

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 2015, the IAC carried out assurance audits on Performance Indicators in the General report, ECHA Helpdesk as well as Contract management and payments.

Performance Indicators in the General report

- 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 Performance Indicators –process.
- Two very important recommendations were put forward:
 - o Utilise the available IT tools to automatically calculate the performance indicators
 - o Ensure exact specification of the calculations and storage of the source data for the performance indicators

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

ECHA Helpdesk

- 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 ECHA Helpdesk –process
- Three "very important" recommendations were put forward:
 - o Ensure timely replies to all helpdesk questions
 - o Increase efficiency of the Helpdesk process where feasible
 - o Ensure appropriate helpdesk activity for BPR questions

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

Contract management and payments

- 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 Contract management –process
- Two "very important" recommendations were put forward:
 - o Improve reporting and monitoring process for contract management
 - o Establish a consistent filing plan for contract management and ensure appropriate storage of all documents, including deliverables

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)

The European Court of Auditors, as the Agency's external auditor, performed an audit in October 2015. According to the EU Financial Regulation's Article 208 (4) an independent external audit firm shall verify the annual accounts of the Agency. ECHA launched a call for tender for the external audit services within the DG BUDG framework contract in August 2015 and the contract was signed in November 2015 with Ernst & Young. The external audit will be carried out in March 2016 by Ernst & Young who will report to the European Court of Auditors by 31 March 2016. In accordance with the Article 99 (1) of the Agency's Financial Regulation, the European Court of Auditors shall make its observations on the provisional accounts by 1 June 2016 and shall be attached to the final accounts to be established by 1 July 2016.

2.8 Follow up of recommendations and action plans for audits

European Court of Auditors (ECA)

All observations from ECA's audit on the annual accounts of ECHA for year 2014 are closed. The observation from the autumn 2013 audit mission: "The Agency should take account of the General Court's decision on administrative charges and assess whether this has also consequences for the other administrative charges collected." was addressed and concluded by the Management Board during 2015 (Management Board Decision Nos 14/2015 (MB/43/2014) and 33/2015 (MB/32/2015).

Internal Audit Service (IAS)

The IAS closed all the outstanding actions from the 2014 Applications for Authorisation audit.

Internal Audit Capability (IAC)

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

The following remaining "very important" recommendation is pending from audit on "Integrated Quality Management System (IQMS) Process documentation":

- Ensuring effective control measures over rights of access in order to prevent any access, any elimination, any alteration, and unauthorised moving of documents, files, metadata and stages of the procedure in DEP tool.

The following remaining "very important" recommendation is pending from audit on "Confidentiality claim verification":

- Develop further the dissemination website and pipeline, to allow retrieval of information on the outcome of the confidentiality claim assessment, so that rejected claims and accepted public names can be disseminated and their dissemination can be tracked.

The IAC annual audit plan 2014 included a third party assessment of security and business continuity controls implemented by the Contractor in the outsourced data centre operations of ECHA. A follow-up conducted in 2015 to the "Data centre assessment" resulted in a few remaining open issues which are currently being addressed by the service provider.

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 2014 in its annual report under Article 110 of the Financial Regulation.

The report is publicly available at:

https://polcms.secure.europarl.europa.eu/cmsdata/upload/e33185d6-3779-42e3-8548-c5cbc1a544d7/ECHA_2013Discharge_report_follow-up.pdf and has been submitted to the Management Board in December 2015.

The report explains that most of the recommendations have been addressed. Actions are, in particular, still ongoing in the areas of continued attention to the level of carry-overs in operational titles and the integration of an environmental management system (EMS) into its quality management system.

2.10 Ex-ante and ex-post evaluations

The new Financial Regulation further emphasised the importance of ex-ante and ex-post evaluations as a tool to improve decision-making. Following the Commission's Better regulation guidelines and the Financial Regulation requirements setting the evaluation limits, in 2015 ECHA started reflecting on different approaches and performing benchmarking with 4 other Agencies in view of setting its own evaluation framework and approach. ECHA's framework and approach to evaluations was presented to the MBWG on audit on 15 December 2015 and reported to the 40th Management Board on 16-17 December 2015. The approach covers the following elements:

1. Set up the evaluation framework and governance.
2. Establish an Evaluation Coordination Function to ensure the methodological consistency, meeting the evaluation standards, coordinate the performance of the evaluations and collect feedback on how evaluations results are taken into account.
3. Strengthen the existing project/programme governance framework for ex-post and ex-ante evaluations: a) Analyse the current coverage of evaluation criteria in the project/programme governance; b) Modify the existing project templates to cover the evaluation criteria.
4. Draft the first multi-annual rolling evaluation plan to improve decision-making and enhance organisational learning.
5. Create evaluation checklists, including criteria and methodology.
6. Perform the ex-ante and ex-post evaluations as specified in the rolling plan.

The work on some of the elements above started in 2015, with a pilot evaluation of the Enterprise content management (ECM) programme based on the outcome of the Benefits realisation management exercise (outsourced evaluation covering the ECM programme retrospectively and the future ECM strategy). The gap analysis performed by ECHA helped to assess the coverage of the evaluation criteria as stipulated in the Commissions' Better regulation guidelines and to collect lessons learnt for the purposes of future evaluations. In addition, the contract management audit performed in 2015 covered some sampling of the existing project documents (vision and project closure documents in particular) in order to identify the gaps compared to the evaluation criteria as per the Financial Regulation and Commission's guidelines, in view of strengthening the existing project and programme governance framework. Its recommendations have been taken into account in the development of the evaluation approach as stipulated above.

PART III ASSESSMENT OF THE EFFECTIVENESS OF THE INTERNAL CONTROL SYSTEMS

3.1 Risk Management

In 2015, a new ED decision on Risk Management in ECHA ED/65/2015 was signed thus revoking the old one ED/29/2010. The main changes introduced with the new ED decision refer to covering Unit and process level risk management and introducing the concept of cost-risk-benefit analysis at process level in particular when imposing or removing controls.

An annual risk management exercise was conducted in 2014 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 2015. The exercise is an integral part of the Work Programme preparation. The Senior Management followed up the implementation and reviewed the effectiveness of the risk mitigation measures on a quarterly basis during 2015.

Based on this assessment, ECHA's management identified seven main risks which were included in the corporate Risk Register. The Senior Management also agreed that all these risks should be reduced through specific actions that were described in the action plan relating to the Risk Register.

Regular follow-up of the actions was undertaken during the year. In the last follow-up done in the beginning of 2016, the Management concluded that the actions taken to mitigate the risks have been implemented according to the plan, have proved to be effective and have not lead to major secondary risks.

A number of risks that were identified for the year 2015 did not impact the Work programme 2015 execution due to change in the external factors rendering the risk likelihood lower. However they continue to be relevant for Work programme 2016:

-Due to the higher income received than foreseen for 2015, ECHA was able to fully cover its expenditure and prepared to return part of the collected EU subsidy, thus the financial risk did not materialize in 2015.

-Due to delay on behalf of the Commission in processing the testing proposal draft decisions on reproductive toxicity, expected to create an unmanageable workload for ECHA, no resubmitted testing proposals were received by ECHA in 2015. The risk is taken into account in the workload planning of Work programme 2016.

-The market risk for the authorisation applications related to a potential peak of applications didn't impact the output targets for 2015. Nevertheless, actions and fall-back plans such as building a contingency and increasing the process efficiency, have been taken to prevent the occurrence or mitigate the impact as the peak will now happen in 2016. These measures will continue to be further implemented in 2016.

-A number of Biocides -related risks were identified for Work programme 2015 that could have negatively impacted the Review programme targets and the ability of ECHA to process applications within legal deadlines. Among the most important actions completed in order to mitigate those risks are the exchange with MSCA on their resources needs, creating guiding templates, supporting the quality of the assessment reports and using scenario planning to be able to respond to different market situations. As a result of those, no legal deadlines were missed and the target of the Review programme was almost met (46 out of the foreseen 50 opinions were adopted in 2015).

-The risks with regard to balancing the uncertain Biocides income with the resources needs have been tackled through scenario planning and fall-back plans, however those still remain high for the coming years.

-Clear scope and contract management has been effective in view of handling the risk related to ECHA's commitment to launch the new dissemination portal in 2015 and has helped to avoid

causing delays in implementation. Some secondary risks related to the change of the contractor at a time when a new release is foreseen have emerged and will be handled in 2016.

-The risk with regard to the general maintenance problems further worsening the air quality of the building have been handled through careful implementation of the agreed refurbishment plan with the landlord, with a result that major projects have been completed in 2015 without any serious disruption of ECHA's normal work process or worsening of the air quality. The options with regard to the future of the building are being analysed as part of the Building 2020 project.

-On the other hand, the change in the Compliance Check strategy, which was not identified as a risk in the Corporate risk register, but only during the year 2015 (when it was followed at the quarterly reviews), impacted the constant delivery of compliance check outputs on substances of potential concern. Nevertheless, ECHA adapted to the situation and took relevant risk-mitigation measures, so that the newly set target of 100 concluded compliance checks for such substances was achieved by the end of the year.

-Risk management at process level was further strengthened during 2015 through the implementation of the "Methodology for risk assessment and cost-benefit analysis at process level" in the scope of the Efficiency programme. In 2015, there have been a number of projects under which the cost-risk-benefit methodology was applied resulting in elimination of multiple controls:

-The number of controls in some financial low –risk workflows was decreased from 7 to 4, by removing duplicate checks, paper workflows, merging steps to be performed by the same actor and allocating responsibilities based on key competences, thus resulting in a decreased throughput time from 18.8 to 10.6 days (44% time savings) as per the measurement of Q4/2015.

-The dossier evaluation process was simplified by removing multiple checks and reviews where the risk was considered low. Risk was determined to be low in standard cases having already a precedent. A database to check for precedents was built and the decision-making was lowered for standard cases. As a result, the time to issue a draft decision (throughput time) decreased by 10.5% to 296 days in 2015 compared to 331 days in 2014. The case backlog decreased by 19.1% to 317 days in 2015 from 388 days in 2014. In the review of draft decisions, 2 verification steps were cut and the sign-off channel was widened thus resulting in decrease of the total signataire circulation time from 72 to 44 days on the average (42% reduction).

3.1.1 Prevention of Conflicts of Interest

Policy implementation

On the basis of its Procedure for Prevention and Management of potential Conflicts of Interest, ECHA has implemented an approach which involves a systematic check for potential conflicts before assigning tasks to **staff members**. Based on a thorough risk assessment of its activities, the Agency has identified the processes and sub-process that require (conflict of) interest management. For more than 30 processes, sub-processes or process steps conflict of interest checks are performed, including the main operational processes of the Agency. In all of these processes a review of the annual declaration of interest is performed by the process owner each time a task is assigned to a staff member, while in some sensitive processes this is complemented with a case-specific no-interest declaration by the staff member. In case of a potential conflict the case is assigned to a different staff member. The approach is documented in detailed work instructions and guidance is available to the interest managers to deal with individual cases. As a result, no actual case of a conflict of interest has been identified in 2015.

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 to the voting on such dossiers.

Post-employment

When leaving the service of the Agency members of staff have to sign a declaration related to post-employment duties. There were 44 staff members who left ECHA in 2015: 21 of them went to work for another EU institution, body or agency, two for a national public authority and one for an inter-governmental organisation. Five staff members left to the private sector or started self-employment and in one of these cases, the Agency saw it necessary to impose specific conditions before authorising the new employment (it did not concern a Senior Management post). In the remaining cases (15), the departure was due to the end of contract, unemployment after resignation or retirement. No breach of trust or disciplinary procedure was initiated in the area of conflict of interest management.

ECA follow-up audit

Between June and November 2015 the European Court of Auditors (ECA) carried out a follow-up review of their Special Report on the “Management of conflict of interest in selected EU Agencies (SR 15/2012)”. The conclusion of the ECA was that ECHA has implemented all of their eleven recommendations to the full extent, with the exception of some additional training to be provided to the Management Board members (to which ECHA committed) and the need for additional post-employment measures for the Management Board and Committee members. However, the latter recommendation can only be implemented by the legislator, as ECHA is not the employer and in most cases not even the appointing authority of these external members and has therefore no legal power to impose a mandatory and legally enforceable cooling-off period.

3.1.2 Data protection

In 2015 the Data Protection Officer (DPO) focused his efforts on his main advisory role and replied to 136 individual requests for advice. Several awareness actions were organised and training of staff also got the necessary attention.

Two new notifications were added to the Data Protection register and a review exercise of notifications older than two years continued in order to ensure up-to-date information. One consultation (web proxy) and two prior checking notifications (whistleblowing and the 360 degree programme for managers) were sent to the European Data Protection Supervisor (EDPS) for review.

In the 2015 general monitoring exercise of the EDPS, ECHA received praise for good implementation of the Data Protection requirements with 100% of processes in the register of processing operations and 100% of the required prior checks undertaken.

3.1.3 Security and business continuity

A new ECHA security framework was adopted in 2015, changing a number of structures and tasks. Currently there are 3 areas of security:

- Information security
- ICT security managing the outsourced data centre. In 2015, the action plan of the audit on the outsourced data centre operations of ECHA was followed with a result to further improve the security and business continuity, as confirmed by

- the IAC follow –up audit in 2015 (only two remaining open issues).
- Physical security whose function is consolidated with the facility services

3.1.4 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 whistleblowers were also adopted in December 2015.

In line with the Common Approach for decentralised agencies which requires all agencies to put in place an Anti-Fraud Strategy, ECHA's Management Board adopted an Anti-Fraud Strategy for the Agency in December 2014. The Strategy covers the years 2015-2016 and contains an action plan with specific actions, many of which have already been implemented in 2015. The internal Fraud Risk Assessment exercise that preceded the adoption of the Strategy revealed however that the risk profile of the Agency is rather low and therefore the main aim of the Strategy is to develop a widespread anti-fraud culture in ECHA, with a focus on awareness raising.

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

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

In 2015, a thorough assessment of ECHA's compliance with the Integrated Management Standards was performed, following the approach as described below:

A preliminary assessment was performed by the Directors based on staff and stakeholders surveys, audit results (including IAC audits, internal quality audits, ISO 9001:2008 certification and ISO 9001:2015 surveillance audits), gap analyses, pilot evaluations, non-conformities, complaints, risks, opportunities, performance measurement and other reports. Those sources analysed fed the assessment of the Integrated Management standards which were first discussed by the Directors and concluded at the Management review (see point 2.5).

The Authorising Officer performed his final assessment of the Agency's system compliance with ECHA Integrated Management Standards taking into account the Directors' preliminary assessment. The assessment of year 2015 is presented together with the assessment and the compliance trend since 2013 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.

In 2015, ECHA continued building the foundations for its 4th Strategic objective⁴ by implementing the projects under the Efficiency Development Programme by driving the direct implementation of small improvements that have been identified already, but mainly by analysing the performance and issues in the assigned process area, looking for root causes, designing a future state and implementing actions to achieve it.

The first two projects whose implementation started in 2014 were "Procurement, contract management and financial workflows" and "Evaluation". In 2015, a number of new projects were added to the Efficiency programme, among which "Speaking requests", "Applications for authorisation" and "Planning and reporting".

An analysis of the as-is situation was performed for the projects above, and different alternatives considered for the to-be state on the basis of risk assessment and cost-benefit analysis. The re-design principles in all projects aim at process simplification, e.g. cutting out low-risk steps, merging steps, limiting actors, limiting escalation of decisions thus accelerating the process, while keeping the controls effectiveness.

In 2015, the redesign of the first two projects was implemented and measurement of the achieved efficiency savings was performed (see Section 3.1. for more details on the measurement).

Together with the projects initiatives, there has been also progress made in the area of competence development, where a number of training sessions on lean management, quality management and cost-risk-benefit analysis were delivered. Good communication during the year has helped in spreading lessons learnt from the projects and promoting exchange of good practices between the project teams.

The models for the measurement of ECHA's strategic objectives were further refined in 2015. The model measuring the achievement of the 4th Strategic objectives is based on historical measurement of the final output of the Agency in correlation to the trend of the Agency's resources covering the years 2011-2015. The trend indicates that the Agency's output is increasing faster than its personnel (results are available in the General Report).

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

PART IV MANAGEMENT ASSURANCE

4.1. Review of the elements supporting assurance

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

4.2 Reservations (where applicable)

Not applicable

4.3 Overall conclusion on assurance (where applicable)

Not applicable

4.4 Declaration of assurance

The declaration of assurance is available in Annex IV.

ANNEXES

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

Annex I. Human Resources statistics

1. Last establishment plan adopted

Category and grade	Establishment plan in voted EU Budget 2015				Posts filled 31 December 2015*				Posts returned to the Budgetary Authority
	TA				TA				TA
	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP
AD 16	0	0	0	0	0	0	0	0	
AD 15	1	0	0	1	1	0	0	1	
AD 14	4	0	0	4	3	0	0	3	
AD 13	14	1	0	15	8	0	0	8	
AD 12	23	2	0	25	11	1	0	12	
AD 11	29	3	0	32	15	2	0	17	
AD 10	31	4	0	35	27	1	0	28	
AD 9	48	7	0	55	40	1	0	41	
AD 8	48	12	1	61	52	5	0	57	
AD 7	48	6	0	54	55	3	0	58	
AD 6	53	4	0	57	64	11	0	75	5
AD 5	9	0	0	9	28	7	1	36	
Total AD	308	39	1	348	304	31	1	336	5
AST 11	0	0	0	0	0	0	0	0	
AST 10	1	0	0	1	0	0	0	0	
AST 9	7	0	0	7	3	0	0	3	
AST 8	8	0	0	8	1	0	0	1	
AST 7	12	1	2	15	6	0	0	6	1
AST 6	16	0	0	16	8	0	1	9	
AST 5	29	3	0	32	24	2	1	27	
AST 4	16	2	0	18	20	2	0	22	3
AST 3	18	3	3	24	38	4	3	45	
AST 2	10	0	0	10	14	1	0	15	2
AST 1	5	0	0	5	3	0	0	3	
Total AST	122	9	5	136	117	9	5	131	6
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	430	48	6	484	421	40	6	467	11

	CA				CA			
	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL
CA FG IV	18	3	1	22	14	4		18
CA FG III	62	5		67	53	6		59
CA FG II	15	2		17	23	0	1	24
CA FG I	3	0		3	2			2
TOTAL CAs in place					92	10	1	103
Total CA (FTE)	98	10	1	109	84.98	9.08	1	95.06

* 2 REACH TAs, 2 REACH CAs, 1 Biocides TA and 1 Biocides CA under recruitment

Percentage of posts filled on 31 December 2015		
	REACH/CLP/PIC	Biocides
TA posts	98%	83%
CA posts	94%	100%

2. Results of the screening / benchmarking exercise

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment (or bottom of the brackets if published in brackets)	Indication whether the function is dedicated to administrative support or operations [subject to definitions used in screening methodology]
CORE FUNCTIONS			
Executive Director	TA - 5 + 5 years	AD 15	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)/ Management
Head of Unit (Level 3)	TA - 5 + 5 years + indefinite	AD 9 – AD 12	Operations/ Management
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 11	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 10	Administration
Internal Auditor	TA - 5 + 5 years + indefinite	AD 10	Administration
Scientific Advisor	TA - 5 + 5 years + indefinite	AD 12	Operations/
Administrative Assistant – Short term	TA - 1 + 1 year	AST 1 & AST 3	Operations/Administration

3. Benchmarking against previous year results

ECHA has undertaken the benchmarking exercise in 2015 (for the second time), in accordance with the Commission requirements. Overall, the percentage of the administrative support and coordination staff decreased from 2014 by 1% (which represents approximately 7 staff members), while the percentage of operational staff increased, following the same trend.

Job Type (sub) category	2014 (%)	2015(%)
Administrative support and Coordination	22	21
<i>Administrative Support</i>	17.2	16.4
<i>Coordination</i>	4.7	4.6
Operational	72.2	73.4
<i>General operational</i>	21.5	21.7
<i>Programme management</i>	42.6	43.5
<i>Top level Operational Coord</i>	3.7	3.6
<i>Evaluation & Impact assessment</i>	4.4	4.6
Neutral	5.8	5.6
<i>Finance</i>	5.5	5.3
<i>Control</i>	0.3	0.3

Annex II. Statistics on financial management

Budget Execution per Chapter / Fund source C1 - Current year appropriations – 2015

Chapter	Description	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)
A-11	STAFF IN ACTIVE EMPLOYMENT	65 443 913.22	65 061 591.36	99.42%	65 443 913.22	65 061 399.47	99.42%	0	382 321.86
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	703 137.94	644 689.43	91.69%	703 137.94	636 866.15	90.57%	7823.28	58 448.51
A-13	MISSIONS AND DUTY TRAVEL	52 020.00	39 576.99	76.08%	52 020.00	39 576.99	76.08%	0	12 443.01
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	1 969 000.00	1 915 541.63	97.28%	1 969 000.00	1 774 805.27	90.14%	140736.36	53 458.37
A-15	TRAINING	1 487 119.74	1 463 789.86	98.43%	1 487 119.74	1 120 194.20	75.33%	343595.66	23 329.88
A-16	EXTERNAL SERVICES	2 129 499.90	2 055 567.57	96.53%	2 129 499.90	1 706 656.27	80.14%	348911.3	73 932.33
A-17	ENTERTAINMENT AND REPRESENTATION EXPENSES	10 089.20	4 688.54	46.47%	10 089.20	4 273.60	42.36%	414.94	5 400.66
	Total	71 794 780.00	71 185 445.38	99.15%	71 794 780.00	70 343 771.95	97.98%	841481.54	609 334.62
A-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	7 922 624.04	7 895 237.32	99.65%	7 922 624.04	7 602 031.23	95.95%	293206.09	27 386.72
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	7 479 071.34	7 045 685.54	94.21%	7 479 071.34	5 645 640.91	75.49%	1400044.63	433 385.80
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	919 465.62	884 297.90	96.18%	919 465.62	179 406.91	19.51%	704890.99	35 167.72
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	303 503.00	248 966.84	82.03%	303 503.00	196 135.41	64.62%	52831.43	54 536.16
A-25	MEETINGS EXPENDITURE	8 810.00	8 780.98	99.67%	8 810.00	8 271.05	93.88%	509.93	29.02
	Total	16 633 474.00	16 082 968.58	96.69%	16 633 474.00	13 631 485.51	81.95%	2451483.07	550 505.42
B3-0	REACH	23 085 700.00	22 652 383.72	98.12%	23 085 700.00	15 389 376.24	66.66%	7263007.48	433 316.28
B3-1	Multiannual activities	37 700.00	37 390.07	99.18%	207 000.00	206 294.45	99.66%	0	309.93
B3-8	INTERNATIONAL ACTIVITIES	154 900.00	154 900.00	100.00%	341 000.00	337 706.81	99.03%	0	0.00
	Total	23 278 300.00	22 844 673.79	98.14%	23 633 700.00	15 933 377.50	67.42%	7263007.48	433 626.21
B4-0	BIOCIDES	2 257 157.34	2 113 977.16	93.66%	2 257 157.34	564 037.66	24.99%	1549939.5	143 180.18
	Total	2 257 157.34	2 113 977.16	93.66%	2 257 157.34	564 037.66	24.99%	1549939.5	143 180.18
B5-0	PIC	449 130.00	447 397.10	99.61%	449 130.00	336 451.34	74.91%	110945.76	1 732.90
	Total	449 130.00	447 397.10	99.61%	449 130.00	336 451.34	74.91%	110945.76	1 732.90
Total C1		114 412 841.34	112 674 462.01	98.48%	114 768 241.34	100 809 123.96	87.84%	12 216 857.35	1 738 379.33

Budget Execution per Regulation and Chapter / Fund source C1 - Current year appropriations – 2015

REACH

Chapter	Description	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)
A-11	STAFF IN ACTIVE EMPLOYMENT	60 032 896.34	59 942 126.37	99.85%	60 032 896.34	59 941 934.48	99.85%	0.00	90 769.97
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	577 300.00	545 186.70	94.44%	577 300.00	539 433.62	93.44%	5 753.08	32 113.30
A-13	MISSIONS AND DUTY TRAVEL	45 300.00	35 417.96	78.19%	45 300.00	35 417.96	78.19%	0.00	9 862.04
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	1 761 440.00	1 743 439.56	98.98%	1 761 440.00	1 618 333.95	91.88%	125 105.6	18 000.44
A-15	TRAINING	1 338 580.00	1 328 577.09	99.25%	1 338 580.00	1 020 834.31	76.26%	307 742.78	10 002.91
A-16	EXTERNAL SERVICES	1 634 034.46	1 589 748.49	97.29%	1 634 034.46	1 377 089.02	84.28%	212 659.47	44 285.97
A-17	ENTERTAINMENT AND REPRESENTATION EXPENSES	8 089.20	4 215.75	52.12%	8 089.20	3 844.46	47.53%	371.29	3 873.45
A-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	7 426 030.38	7 420 586.35	99.93%	7 426 030.38	7 144 958.45	96.22%	275 627.90	5 444.03
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	6 856 795.27	6 512 770.63	94.98%	6 856 795.27	5 239 543.91	76.41%	1 273 226.72	344 024.64
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	805 264.35	785 304.60	97.52%	805 264.35	159 331.81	19.79%	625 972.79	19 959.75
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	271 560.00	224 969.40	82.84%	271 560.00	177 684.81	65.43%	47 284.59	46 590.60
A-25	MEETINGS EXPENDITURE	7 800.00	7 797.51	99.97%	7 800.00	7 344.69	94.16%	452.82	2.49
B3-0	REACH	23 085 700.00	22 852 383.72	98.12%	23 085 700.00	15 389 376.24	66.66%	7 263 007.48	433 316.28
B3-1	Multianual activities	37 700.00	37 390.07	99.18%	207 000.00	206 294.45	99.66%	0.00	309.93
B3-8	INTERNATIONAL ACTIVITIES	154 900.00	154 900.00	100.00%	341 000.00	337 706.81	99.03%	0.00	0.00
	Total	104 043 390.00	102 984 814.20	98.98%	104 398 790.00	93 199 128.97	89.27%	10 137 204.53	1 058 575.80

BIOCIDE

Chapter	Description	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)
A-11	STAFF IN ACTIVE EMPLOYMENT	4 936 106.48	4 662 382.85	94.45%	4 936 106.48	4 662 382.85	94.45%	0.00	273 723.63
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	113 300.00	87 999.87	77.67%	113 300.00	85 940.23	75.85%	2 059.64	25 300.13
A-13	MISSIONS AND DUTY TRAVEL	6 000.00	3 713.40	61.89%	6 000.00	3 713.40	61.89%	0.00	2 286.60
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	194 870.00	163 426.41	83.86%	194 870.00	149 470.39	76.70%	13 956.02	31 443.59
A-15	TRAINING	126 739.05	120 676.20	95.22%	126 739.05	88 664.52	69.96%	32 011.68	6 062.85
A-16	EXTERNAL SERVICES	416 314.47	387 381.88	93.05%	416 314.47	273 047.98	65.59%	114 333.90	28 932.59
A-17	ENTERTAINMENT AND REPRESENTATION EXPENSES	2 000.00	472.79	23.64%	2 000.00	429.14	21.46%	43.65	1 527.21
A-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	415 594.90	395 102.36	95.07%	415 594.90	380 468.83	91.55%	14 633.53	20 492.54
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	547 079.03	464 238.32	84.86%	547 079.03	351 474.20	64.25%	112 764.12	82 840.71
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	101 933.07	88 406.55	86.73%	101 933.07	17 917.44	17.58%	70 489.11	13 526.52
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	28 533.00	21 530.56	75.46%	28 533.00	16 469.46	57.72%	5 061.10	7 002.44
A-25	MEETINGS EXPENDITURE	900.00	878.09	97.57%	900.00	827.10	91.90%	50.99	21.91
B4-0	BIOCIDES	2 257 157.34	2 113 977.16	93.66%	2 257 157.34	564 037.66	24.99%	1 549 939.50	143 180.18
	Total	9 146 527.34	8 510 186.44	93.04%	9 146 527.34	6 594 843.20	72.10%	1 915 343.24	636 340.90

PIC

Chapter	Description	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)
A-11	STAFF IN ACTIVE EMPLOYMENT	474 910.40	457 082.14	96.25%	474 910.40	457 082.14	96.25%	0.00	17 828.26
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	12 537.94	11 502.86	91.74%	12 537.94	11 492.30	91.66%	10.56	1 035.08
A-13	MISSIONS AND DUTY TRAVEL	720.00	445.63	61.89%	720.00	445.63	61.89%	0.00	274.37
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	12 690.00	8 675.66	68.37%	12 690.00	7 000.93	55.17%	1 674.73	4 014.34
A-15	TRAINING	21 800.69	14 536.57	66.68%	21 800.69	10 695.37	49.06%	3 841.20	7 264.12
A-16	EXTERNAL SERVICES	79 150.97	78 437.20	99.10%	79 150.97	56 519.27	71.41%	21 917.93	713.77
A-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	80 998.76	79 548.61	98.21%	80 998.76	76 603.95	94.57%	2 944.66	1 450.15
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	75 197.04	68 676.59	91.33%	75 197.04	54 622.80	72.64%	14 053.79	6 520.45
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	12 268.20	10 586.75	86.29%	12 268.20	2 157.66	17.59%	8 429.09	1 681.45
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	3 410.00	2 466.88	72.34%	3 410.00	1 981.14	58.10%	485.74	943.12
A-25	MEETINGS EXPENDITURE	110.00	105.38	95.80%	110.00	99.26	90.24%	6.12	4.62
B5-0	PIC	449 130.00	447 397.10	99.61%	449 130.00	336 451.34	74.91%	110 945.76	1 732.90
	Total	1 222 924.00	1 179 461.37	96.45%	1 222 924.00	1 015 151.79	83.01%	164 309.58	43 462.63

Budget Execution of Operational Titles per Budget line / Fund source C1 - Current year appropriations – 2015

REACH

Budget line	Description		Voted Budget Payment Appropriations	Amending Budget Payment Appropriations	Transfers	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)	Cancelled %
B3-003	Registration datasharing and dissemination	B3-003	660 000.00	-150 000.00	54 147.12	564 147.12	562 987.62	99.79%	564 147.12	196 122.38	34.76%	366 865.24	1 159.50	0.21%
B3-004	Evaluation	B3-004	2 230 000.00	-570 000.00	0.00	1 660 000.00	1 654 668.57	99.68%	1 660 000.00	218 613.72	13.17%	1 436 054.85	5 331.43	0.32%
B3-005	Authorisations and restrictions	B3-005	758 500.00	-220 000.00	0.00	538 500.00	536 197.86	99.57%	538 500.00	272 285.46	50.56%	263 912.40	2 302.14	0.43%
B3-006	Classification and labelling	B3-006	45 000.00	-45 000.00	0.00	0.00	0.00	0.00%	0.00	0.00	0.00%	0.00	0.00	-
B3-007	Advice assistance through guidance and helpdesk	B3-007	227 000.00	-45 000.00	-20 700.00	161 300.00	154 965.23	96.07%	161 300.00	146 092.23	90.57%	8 873.00	6 334.77	3.93%
B3-008	Scientific IT tools	B3-008	13 729 500.00	0.00	78 500.00	13 808 000.00	13 704 527.94	99.25%	13 808 000.00	9 858 508.67	71.40%	3 846 019.27	103 472.06	0.75%
B3-009	Scientific technic advice to EU institut and bodies	B3-009	361 000.00	-169 000.00	0.00	192 000.00	188 688.74	98.28%	192 000.00	100 469.28	52.33%	88 219.46	3 311.26	1.72%
B3-011	Committees and Forum	B3-011	2 656 500.00	-1 015 000.00	-258 163.81	1 383 336.19	1 371 658.54	99.16%	1 383 336.19	1 062 472.00	76.81%	309 186.54	11 677.65	0.84%
B3-012	Board of appeal	B3-012	115 500.00	-17 000.00	0.00	98 500.00	58 793.30	59.69%	98 500.00	24 486.96	24.86%	34 306.34	39 706.70	40.31%
B3-013	Communications including translations	B3-013	3 330 000.00	-611 000.00	146 216.69	2 865 216.69	2 852 904.73	99.57%	2 865 216.69	2 179 961.82	76.08%	672 942.91	12 311.96	0.43%
B3-022	Management Board and management of the Agency	B3-022	1 288 000.00	-130 500.00	0.00	1 157 500.00	1 032 474.07	89.20%	1 157 500.00	817 989.96	70.67%	214 484.11	125 025.93	10.80%
B3-030	Missions	B3-030	612 200.00	45 000.00	0.00	657 200.00	534 517.12	81.33%	657 200.00	512 373.76	77.96%	22 143.36	122 682.88	18.67%
B3-090	Refunds REACH/CLP	B3-090	2 000 000.00	-2 000 000.00	0.00	0.00	0.00	0.00%	0.00	0.00	0.00%	0.00	0.00	-
B3-111	Committees and Forum (Multiannual)	B3-111	1 022 500.00	104 500.00	0.00	37 700.00	37 390.07	99.18%	207 000.00	206 294.45	99.66%	0.00	309.93	0.82%
B3-801	Cooperation with internat organisat for IT program	B3-801	362 000.00	-21 000.00	0.00	154 900.00	154 900.00	100.00%	341 000.00	337 706.81	99.03%	0.00	0.00	0.00%
	Total		28 477 700.00	-4 844 000.00	0.00	23 278 300.00	22 844 673.79	98.14%	23 633 700.00	15 933 377.50	67.42%	7 263 007.48	433 626.21	1.86%

BIOCIDE

Budget line	Description		Voted Budget Payment Appropriations	Amending Budget Payment Appropriations	Transfers	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)	Cancelled %
B4-007	Advice assistance through guidance and helpdesk	B4-007	72 400.00	-29 900.00	0.00	42 500.00	27 057.34	63.66%	42 500.00	27 057.34	63.66%	0.00	15 442.66	36.34%
B4-008	Scientific IT tools	B4-008	339 550.00	1 165 387.34	-33 750.00	1 471 187.34	1 470 732.81	99.97%	1 471 187.34	123 951.67	8.43%	1 346 781.14	454.53	0.03%
B4-011	Biocidal products Committee and Rapporteurs	B4-011	271 720.00	48 000.00	0.00	319 720.00	293 161.74	91.69%	319 720.00	146 548.95	45.84%	146 612.79	26 558.26	8.31%
B4-012	Board of Appeal	B4-012	20 000.00	0.00	0.00	20 000.00	3 658.26	18.29%	20 000.00	3 658.26	18.29%	0.00	16 341.74	81.71%
B4-013	Communications including Translations	B4-013	193 000.00	-28 000.00	0.00	165 000.00	162 591.38	98.54%	165 000.00	126 028.40	76.38%	36 562.98	2 408.62	1.46%
B4-022	Management Board and management of the Agency	B4-022	155 000.00	2 600.00	33 750.00	191 350.00	126 482.53	66.10%	191 350.00	107 999.94	56.44%	18 482.59	64 867.47	33.90%
B4-030	Missions	B4-030	67 400.00	-20 000.00	0.00	47 400.00	30 293.10	63.91%	47 400.00	28 793.10	60.74%	1 500.00	17 106.90	36.09%
	Total		1 119 070.00	1 138 087.34	0.00	2 257 157.34	2 113 977.16	93.66%	2 257 157.34	564 037.66	24.99%	1 549 939.50	143 180.18	6.34%

PIC

Budget line	Description		Voted Budget Payment Appropriations	Amending Budget Payment Appropriations	Transfers	Final Available Commitment Appropriations (1)	Executed Commitment Amount (2)	% Committed (2)/(1)	Final Available Payment Appropriations (3)	Executed Payment Amount (4)	% Paid (4)/(3)	Carried over RAL (C8) (2)-(4)	Cancelled (1)-(2)	Cancelled %
B5-000	Studies and consultants	B5-000	35 000.00	0.00	-35 000.00	0.00	0.00	0.00%	0.00	0.00	0.00%	0.00	0.00	-
B5-008	Scientific IT tools	B5-008	223 230.00	3 000.00	0.00	226 230.00	225 853.15	99.83%	226 230.00	138 610.75	61.27%	87 242.40	376.85	0.17%
B5-013	Communications including Translations	B5-013	177 500.00	-3 000.00	35 000.00	209 500.00	208 688.94	99.61%	209 500.00	184 985.58	88.30%	23 703.36	811.06	0.39%
B5-030	Missions	B5-030	13 400.00	0.00	0.00	13 400.00	12 855.01	95.93%	13 400.00	12 855.01	95.93%	0.00	544.99	4.07%
	Total		449 130.00	0.00	0.00	449 130.00	447 397.10	99.61%	449 130.00	336 451.34	74.91%	110 945.76	1 732.90	0.39%

Budget Execution per Title / Fund source C8 - Appropriations carried over - 2015

Title	Description	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Cancelled
A-1	STAFF	571 637.64	571 637.64	100.00%	571 637.64	479 933.84	83.96%	91 703.80
A-2	BUILDING EQUIPMENT AND MISCELL. OPER EXPEND	1 778 625.15	1 778 625.15	100.00%	1 778 625.15	1 684 714.25	94.72%	93 910.90
B0-3	OPERATING EXPENDITURE	8 184 483.11	8 184 483.11	100.00%	8 184 483.11	7 804 473.26	95.36%	380 009.85
B0-4	OPERATING EXPENDITURE - BIOCIDES	142 823.13	142 823.13	100.00%	142 823.13	134 095.06	93.89%	8 728.07
B0-5	OPERATING EXPENDITURE - PIC	168 531.81	168 531.81	100.00%	168 531.81	167 339.73	99.29%	1 192.08
	Total C8	10 846 100.84	10 846 100.84	100.00%	10 846 100.84	10 270 556.14	94.69%	575 544.70

Budget Execution / Fund source C4, C5 and R0 - Assigned revenue – 2015

BL	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A01100	Basic salaries	CND	C4	12 555.45	423.45	3.37%	12 555.45	423.45	3.37%	12 132.00	12 132.00
A02000	Rental costs	CND	C4	68 370.00	62 400.00	91.27%	68 370.00	62 400.00	91.27%	5 970.00	5 970.00
A02020	Water gas electricity heating	CND	C4	0.00	0.00	0.00%	0.00	0.00	0.00%	0.00	0.00
B03022	Management Board and management of the Agency	CND	C4	4 279.90	279.90	6.54%	4 279.90	279.90	6.54%	4 000.00	4 000.00
B04022	Management Board and management of the Agency	CND	C4	31.52	31.52	100.00%	31.52	31.52	100.00%	0.00	0.00
	Total			85 236.87	63 134.87	74.07%	85 236.87	63 134.87	74.07%	22 102.00	22 102.00

BL	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A02000	Rental costs	CND	C5	13 800.00	13 800.00	100.00%	13 800.00	13 800.00	100.00%	0.00	0.00
A02250	Documentation and library expenditure	CND	C5	375.49	375.49	100.00%	375.49	375.49	100.00%	0.00	0.00
A02350	Miscellaneous insurance	CND	C5	45.36	45.36	100.00%	45.36	14.85	32.74%	0.00	30.51
B03022	Management Board and management of the Agency	CND	C5	1 038.56	1 038.56	100.00%	1 038.56	1 038.56	100.00%	0.00	0.00
B03030	Missions	CND	C5	1 366.69	1 366.69	100.00%	1 366.69	1 366.69	100.00%	0.00	0.00
B04030	Missions	CND	C5	321.97	321.97	100.00%	321.97	321.97	100.00%	0.00	0.00
	Total			16 948.07	16 948.07	100.00%	16 948.07	16 917.56	99.82%	0.00	30.51

BL	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A01113	Seconded national experts	CND	R0	0.01	0.00	0.00%	0.01	0.00	0.00%	0.01	0.01
B03902	IPA programme agr. 2012/291-934	CND	R0	27 908.70	0.00	0.00%	27 908.70	0.00	0.00%	27 908.70	27 908.70
B03903	IPA programme according to agreement 2015/361-049	CND	R0	300 000.00	27 242.77	9.08%	300 000.00	26 572.65	8.86%	272 757.23	273 427.35
B04901	Preparatory work BPR 13/3938 Norwegian	CND	R0	177 057.00	177 057.00	100.00%	177 057.00	55 075.52	31.11%	0.00	121 981.48
B09000	Provision for Future expenditure - REACH	CND	R0	5 529 145.47	0.00	0.00%	5 529 145.47	0.00	0.00%	5 529 145.47	5 529 145.47
	Total			6 034 111.18	204 299.77	3.39%	6 034 111.18	81 648.17	1.35%	5 829 811.41	5 952 463.01

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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
Senior Management shall define the Agency's Mission from the perspective of the Agency's Stakeholders.	Yes ----- <i>Main references:</i> PRO-0042 Organization and approach to management POL-00011 Quality Policy Statement Annual and multiannual working programmes Quality manual (under preparation)	Yes ----- <i>Main references:</i> ECHA Integrated Management System Manual (MAN-0001) ECHA's Quality Policy (POL-0001) Annual and multiannual working programmes	Yes ----- <i>Main references:</i> ECHA Integrated Management System Manual (MAN-0001) ECHA's Quality Policy (POL-0001) Annual and multiannual working programmes
The Mission shall be communicated and explained to the entire organisation and to its	Yes The Mission has been actively shared with and communicated to staff and stakeholders and is available to the general public. According to the Staff survey 2013, 81%	Yes The Mission has been actively shared with and communicated to staff and stakeholders and is available to the general public.	Yes In accordance with the Staff survey conducted in 2015, staff commitment to ECHA's mission has increased from 73% in 2013 to 77% in 2015 on the average. The mission is clearly defined and communicated across the Agency (on

Stakeholders.	of the staff believe in ECHA's mission and 74% can see how their work contributes to the corporate Mission.	Staff is committed to ECHA's mission.	ECHA internal and external website, noticeboards etc.) and staff is aware of it. There has been a positive trend on how the staff see their own work contributing to ECHA's mission (increased from 74% in 2013 to 77%).
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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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
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>Yes</p> <p>The Agency has defined corporate values and they have been communicated largely, discussed in Unit meetings, published on the information screens.</p> <p>In 2013 specific efforts were made in the field of strengthening the management of Conflicts of Interest and in the area of prevention of harassment. The policy on Conflict of Interest was adopted by the Management Board and demonstrated a good level of implementation.</p> <p>Confidential counsellors were nominated by Senior Management and are available for staff.</p>	<p>Yes</p> <p>The Agency has defined corporate values and they have been communicated largely, discussed in Unit meetings, published on the information screens.</p> <p>In 2014, ECHA's Management Board adopted an anti-fraud strategy and an action plan to it, whose implementation is foreseen in 2015-2016.</p> <p>4 new confidential counsellors were trained and nominated, bringing the total number of confidential counsellors to 6 in 2014.</p>	<p>Yes</p> <p>The Agency has defined corporate values and they have been communicated largely, discussed in Unit meetings, published on the information screens.</p> <p>The internal Fraud Risk Assessment exercise that preceded the adoption of the Strategy revealed however that the risk profile of the Agency is rather low and therefore the main aim of the Strategy is to develop a widespread anti-fraud culture in ECHA, with a focus on awareness raising. The corporate and fraud risk assessment exercises were combined in one in 2015 with a result of no specific fraud risks identified.</p> <p>In 2015, there has been almost 50% decrease compared to 2013 in the</p>

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<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>Mostly</p> <p>According to the Staff survey 2013, 72% of the staff support ECHA's corporate values and 78% feel committed to ECHA.</p> <p>Some progress has to be made towards strengthening an atmosphere of openness and trust.</p>	<p>Mostly</p> <p>In 2014, a Senior and Middle Management Development programme was carried out responding in part to the results from Staff survey 2013.</p>	<p>Mostly</p> <p>According to the Staff survey 2015, 78% of ECHA's staff (vs 72% in 2013) believe and support ECHA's corporate values.</p> <p>Since 2013 many actions have been taken in promoting an atmosphere of openness and trust, among which dedicating a management seminar to that topic in September 2015. Further actions will be followed in 2016.</p>

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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<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>Mostly</p> <p>ECHA Integrated Management Standards combining quality and internal control elements were adopted by the MB on 17/12/2013.</p> <p>Preparations for ISO 9001: 2008 certification are on-going.</p> <p>The internal controls imposed are effective, however not always efficient (see point 2.2.Risk Management).</p> <p>-----</p> <p><i>Main reference:</i></p> <p><i>Integrated Management Standards [MB]</i></p>	<p>Yes</p> <p>In 2014, ECHA received ISO 9001:2008 certification which assesses Management commitment to be at a good level and the Management system to have a very logical concept and clear structure.</p> <p>IAS audit of AARs 2013 of all agencies places ECHA's Management system and standards among the good Agencies' practices.</p> <p>Further efforts were made towards ensuring efficiency of the controls imposed (see point 2.2.Risk Management).</p> <p>-----</p> <p><i>Main reference:</i></p> <p><i>Integrated Management Standards [MB]</i></p>	<p>Yes</p> <p>In 2014, ECHA received ISO 9001:2008 certification. In 2015, ECHA underwent the ISO 9001:2015 surveillance audit which assessed Management commitment to be at a good level; roles, responsibilities and authorities well defined in the organisation; and the Management system based on a logical concept and clear structure complying to the ISO 9001:2015 requirements. The quality policy was assessed by the ISO 9001:2015 surveillance audit and was considered well communicated to ECHA staff and available on ECHA web site. ISO 9001:2015 certification is planned to be extended to include the Biocides activities in 2016.</p> <p>Further efforts were made towards ensuring efficiency of the controls imposed (see point 2.2.Risk Management).</p> <p>-----</p> <p><i>Main reference:</i></p> <p><i>Integrated Management Standards [MB]</i></p>

	<p>36/2013]</p> <p><i>Quality manual (under preparation)</i></p> <p><i>Framework Financial Regulation</i></p> <p><i>Annual Activity Report</i></p>	<p>36/2013]</p> <p><i>ECHA Integrated Management System Manual (MAN-0001)</i></p> <p><i>ECHA Financial Regulation MB/WP/03/2014</i></p> <p><i>Annual Activity Report 2013</i></p> <p><i>ISO 9001:2008 certificate</i></p>	<p>36/2013]</p> <p><i>ECHA Integrated Management System Manual (MAN-0001)</i></p> <p><i>ECHA Financial Regulation MB/WP/03/2014</i></p> <p><i>Annual Activity Report 2013</i></p> <p><i>ISO 9001:2008 certificate</i></p> <p><i>ISO 9001:2015 surveillance audit</i></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>Mostly</p> <p>There is a framework for delegation of powers and specific delegation decisions have been adopted for all Directors in the Agency. Many of them have also further sub-delegated these powers. There is still room for streamlining controls in the delegation system.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Delegation and sub-delegation register</i></p> <p><i>PRO-0059 Internal decision-making and</i></p>	<p>Mostly</p> <p>In 2014, further efforts were made towards using sub-delegation as a means for gaining efficiency where the risk was assessed to be low and the effectiveness of controls preserved. More actions are foreseen in 2015.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Delegation and sub-delegation register</i></p> <p><i>PRO-0059 Internal decision-making and</i></p>	<p>Mostly</p> <p>In 2015, implementation of sub-delegations and new workflows where the risk was assessed to be low and the effectiveness of controls preserved continued both under the Efficiency programme and as a separate initiative. E.g. in the dossier evaluation activities in 2013 many sub-delegations were made to Head of Unit level, in 2014 sub-delegations to Team Leader level were added, while in 2015 the focus was more on implementing and monitoring the new workflows. Still, more actions are foreseen in 2016 in order to ensure an optimal system of delegation of powers.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Efficiency programme</i></p>

	<i>delegation of power</i>	<i>delegation of power</i>	<i>Delegation and sub-delegation register</i> <i>PRO-0059 Internal decision-making and delegation of power</i>
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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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
The Agency shall have rigorous selection procedures ensuring recruitment of competent staff and provisions ensuring staff development	<p>Yes</p> <p>Actions have been taken in 2013 to improve the selection procedures and to retain competent staff. The turnover rate for 2013 is 3.7%.</p> <p>A mechanism for internal mobility of staff has been functioning since 2011. Initiatives to further promote internal mobility, such as expression of interest by staff members have been undertaken.</p> <p>According to the Staff Survey 2013, 51% of the staff believe that there are opportunities for professional development, 59% of the staff feel that they develop in their jobs and 70% consider their work interesting.</p>	<p>Yes</p> <p>ECHA's Learning and Development Framework was established in 2014 with the aim of providing a basis to strategically align learning and development needs with the business requirements of ECHA and to design, deliver and evaluate appropriate learning and development interventions to improve organisation performance and staff contribution.</p> <p>ISO 9001:2008 auditors pointed out that ECHA's staff competence is at excellent level.</p> <p>In 2014, ECHA implemented the Commission's system for reclassification of Contract Agents (CAs) which allowed CAs promotion for the first time and which is expected to help reducing the CAs</p>	<p>Yes</p> <p>In line with the results of ISO 9001:2008/2015 audit where the auditors pointed out that ECHA's staff competence is at excellent level, the Staff survey 2015 shows increase in competence from 79% in 2013 to 81% in 2015 and in the ability to cooperate (from 54% in 2013 to 60% in 2015 respectively).</p> <p>In 2015, ECHA-level prioritised group learning and development needs were collected from the Directors, presented to the DCM and published on ECHA.net. Those constitute the ECHA-level Learning and Development Plan. The monitoring of the plan is done quarterly in terms of whether the training has taken place and whether the staff member considers it useful.</p> <p>In 2014, ECHA implemented the</p>

	<p>-----</p> <p><i>Main references:</i></p> <p><i>POL-0020 Staff retention policy</i></p> <p><i>PRO-0035 Selection and recruitment of statutory staff (management posts)</i></p> <p><i>PRO-0036 Selection and recruitment of statutory staff (non-management posts)</i></p> <p><i>PRO-0038 Organisation and management of ECHA staff training</i></p> <p><i>WIN -0158 Publication of Vacancy Notices and the nomination of Selection Committees</i></p> <p><i>WIN- 0157 Coordination of selection procedures for statutory staff (non-management)</i></p>	<p>turnover.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED/99/2014 Learning and Development Framework</i></p> <p><i>Commission Decision C(2013) 2529 of 03.05.2013</i></p> <p><i>Management Board decision MB/24/2014</i></p> <p><i>POL-0020 Staff retention policy</i></p> <p><i>PRO-0035 Selection and recruitment of statutory staff (management posts)</i></p> <p><i>PRO-0036 Selection and recruitment of statutory staff (non-management posts)</i></p> <p><i>PRO-0038 Organisation and management of ECHA staff training</i></p> <p><i>WIN -0158 Publication of Vacancy Notices and the nomination of Selection Committees</i></p> <p><i>WIN- 0157 Coordination of selection procedures for statutory staff (non-management)</i></p>	<p>Commission's system for reclassification of Contract Agents (CAs) which allowed CAs promotion for the second time in 2015 and which is expected to help reducing the CAs turnover.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED/99/2014 Learning and Development Framework</i></p> <p><i>Commission Decision C(2013) 2529 of 03.05.2013</i></p> <p><i>Management Board decision MB/24/2014</i></p> <p><i>POL-0020 Staff retention policy</i></p> <p><i>PRO-0035 Selection and recruitment of statutory staff (management posts)</i></p> <p><i>PRO-0036 Selection and recruitment of statutory staff (non-management posts)</i></p> <p><i>PRO-0038 Organisation and management of ECHA staff training</i></p> <p><i>WIN -0158 Publication of Vacancy Notices and the nomination of Selection Committees</i></p> <p><i>WIN- 0157 Coordination of selection procedures for statutory staff (non-management)</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>ISO 9001:2015 surveillance audit</i></p> <p><i>Staff Survey 2015</i></p>
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<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>In the context of the performance appraisal system, focus has been given to individual development plans. The system for performance appraisal has been reorganized to ensure a better link between individual and corporate objectives.</p> <p>Guidelines on performance assessment of staff are provided to all Managers.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0037 Organisation of performance appraisal exercise</i></p>	<p>Yes</p> <p>In 2014, efforts were made towards mapping Agency's available and needed competences and skills. ECHA's Regulatory Science Strategy was established to define which areas are of importance in regulatory science, how to identify ECHA-level desired and actual competence needs in these areas of importance and how to further develop the ECHA-level capacity where needed.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ECHA's Regulatory Science Strategy</i></p> <p><i>PRO-0037 Organisation of performance appraisal exercise</i></p>	<p>Yes</p> <p>Staff survey 2015 has indicated improvement in staff motivation and job satisfaction – 56% in 2015 from 52% in 2013. The recognition of personal contribution has also increased from 69% in 2013 to 74% in 2015.</p> <p>In 2015, there were no legal appeals related to the performance appraisal last year and only 1 request for review was made to the Joint committee for appraisal and reclassification resulting from the staff appraisal exercise.</p> <p>A new system of appraisal, which is much more consistent with the Commission's system was adopted by the MB of ECHA in June 2015 and will be implemented in ECHA as of 2016.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ECHA's Regulatory Science Strategy</i></p> <p><i>PRO-0037 Organisation of performance appraisal exercise</i></p> <p><i>Staff survey 2015</i></p>
<p>The Agency shall have provisions to ensure a good work-life balance and an adequate working</p>	<p>Mostly</p> <p>There are a number of provisions facilitating work-life balance, such as parental leaves, flexitime arrangements,</p>	<p>Mostly</p> <p>In 2014, priority has been given to follow up the results of Staff survey 2013, thus enhance the work-life balance and ensure</p>	<p>Mostly</p> <p>In 2015, teleworking was also made more widely available to staff by setting proper security arrangements and integrating the teleworking request as an electronic form</p>

<p>environment for its staff members</p>	<p>paid leave to take care of a sick child.</p> <p>A Health and Wellbeing Committee has been set up in 2012 to monitor and advise on health and wellbeing issues at ECHA.</p> <p>A staff survey is conducted every year since 2011 to measure the staff satisfaction and to detect potential problems.</p> <p>According to the Staff survey 2013, 44% of the staff believe that ECHA provides a safe and healthy environment for staff.</p> <p>Management addresses concerns raised by staff with regard to the air quality at ECHA premises.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED/74/2012 as of 26/04/2012 Terms of Reference of the Joint Committee on Health and Wellbeing</i></p> <p><i>PRO-0044 Maintenance of premises and equipment</i></p>	<p>a healthy environment for staff.</p> <p>The Management and Staff committee are analysing and discussing with respective Heads of Units the working overtime per Unit for 2014. Potential actions are expected to follow in 2015.</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.</p> <p>Teleworking was also made more widely available to staff by setting proper security arrangements and providing relevant security training.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Rules of procedure of the Staff Committee</i></p> <p><i>Teleworking rules</i></p> <p><i>ED/74/2012 as of 26/04/2012 Terms of Reference of the Joint Committee on Health and Wellbeing</i></p> <p><i>PRO-0044 Maintenance of premises and equipment</i></p>	<p>in the new Human Resources Management System (HRMS).</p> <p>Based on the agreed refurbishment plan with the landlord, major projects have been completed in 2015 without major disruption of ECHA's normal work process or worsening of the air quality. Thus, the corporate risk as identified in 2015 has been under control throughout the year. Still, a number of building related issues remain for the coming years and those will be addressed as part of the Building 2020 project.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Rules of procedure of the Staff Committee</i></p> <p><i>Teleworking rules</i></p> <p><i>ED/74/2012 as of 26/04/2012 Terms of Reference of the Joint Committee on Health and Wellbeing</i></p> <p><i>PRO-0044 Maintenance of premises and equipment</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<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>Mostly</p> <p>A stakeholder survey is conducted every year to assess the Agency's cooperation with its stakeholders and to detect potential problems.</p> <p>A Stakeholders' Day event is organized annually to exchange views and ideas on how to improve cooperation.</p> <p>The communication strategy has to be further aligned to the different stakeholders' categories.</p> <p>Audits have indicated a need to improve the coordination of stakeholder activities.</p>	<p>Yes</p> <p>According to ISO 9001:2008 certification audit, ECHA's stakeholders are defined widely, maintained at good level, ECHA is committed to its stakeholders, to building good relations with them and to gathering their feedback.</p> <p>Stakeholders were consulted with regard to ECHA's transparency approach which was endorsed by the Management Board on 17/12/2014.</p> <p>According to the stakeholder survey conducted every year, stakeholders are generally satisfied with ECHA's services.</p>	<p>Yes</p> <p>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>The stakeholders survey of 2015 shows improvement in the stakeholders satisfaction in most of the areas, with the highest improvement in the level of satisfaction of MSCA with ECHA's support for substance evaluation (followed by the stakeholders' satisfaction with the information received by ECHA and ECHA's commitment to stakeholders). Though Biocides is a comparatively new process where some working practices are still being modified, stakeholders seem satisfied with the level of scientific, technical and administrative support, provided to the members of the BPC, CG, and to the Commission, MSCAs and</p>

	<p>-----</p> <p><i>Main references:</i></p> <p><i>External communication strategy of ECHA – MB/66/2011 from 15/12/2011</i></p> <p><i>PRO-0047 Management of the relations with ECHA Stakeholders</i></p> <p><i>WIN-0074 Accredited Stakeholder Application Management</i></p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>MB/61/2014 ECHA's approach to Transparency</i></p> <p><i>WIN-0145 Stakeholder Survey coordination and Management</i></p> <p><i>LIS -0014 Task list for the management of the Stakeholders' Day event</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>External communication strategy of ECHA – MB/66/2011 from 15/12/2011</i></p> <p><i>PRO-0047 Management of the relations with ECHA Stakeholders</i></p> <p><i>WIN-0074 Accredited Stakeholder Application Management</i></p>	<p>industry.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>MB/61/2014 ECHA's approach to Transparency</i></p> <p><i>WIN-0145 Stakeholder Survey coordination and Management</i></p> <p><i>LIS -0014 Task list for the management of the Stakeholders' Day event</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>ISO 9001:2015 surveillance audit</i></p> <p><i>IAC audits</i></p> <p><i>External communication strategy of ECHA – MB/66/2011 from 15/12/2011</i></p> <p><i>PRO-0047 Management of the relations with ECHA Stakeholders</i></p> <p><i>WIN-0074 Accredited Stakeholder Application Management</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
The Agency shall have a corporate vision and strategy expressed in multiannual work programmes and translated to annual work programmes	Yes ----- <i>Main references:</i> <i>Annual and multiannual work programmes</i>	Yes ----- <i>Main references:</i> <i>Annual and multiannual work programmes</i>	Yes ----- <i>Main references:</i> <i>Annual and multiannual work programmes</i>
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	Mostly Roadmaps of on-going multiannual activities and indicators have been established in 2013. Methodologies for monitoring the 4 strategic objectives are under development. The annual Work Programme includes the planning of both human and financial resources. To break down the objectives to more detailed level, Unit Level Plans are prepared and monitored on a regular basis. Individual staff objectives are	Mostly Methodologies for monitoring the 4 strategic objectives have been finalised and a first measurement of the strategic objectives took place (results available in the General report). In alignment with Agency's quality policy and strategic approach, 3 organisational quality objectives were established in 2014. The Agency is planning to cascade quality objectives to process level in 2015. In view of further optimising the Agency's	Mostly In view of further optimising the Agency's planning and reporting, the structure of the Annual Work Programme (AWP) 2016 structure was changed to more logically group and present ECHA's activities to the general public. Other measures, such as reviewing the number of baseline figures and performance indicators and creating a database with all metrics of the Agency were undertaken in 2015 following the recommendations of the audit on key performance indicators (KPI) and the feasibility study on planning and reporting,

<p>to lower levels.</p>	<p>linked to the Unit objectives.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Annual and multiannual work programmes</i></p> <p><i>Multi-annual staff policy plans</i></p> <p><i>Unit level plans</i></p> <p><i>ECHA Financial regulation</i></p> <p><i>PRO-0013 Planning and reporting</i></p>	<p>planning and reporting, a review of the Annual Work Programme (AWP) 2016 structure was undertaken. In addition, a feasibility study on planning and reporting was launched, whose results are expected in 2015.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Models and measurement of the 4 strategic objectives</i></p> <p><i>Annual and multiannual work programmes</i></p> <p><i>PRO-0080 IQMS planning</i></p> <p><i>Multi-annual staff policy plans</i></p> <p><i>Unit level plans</i></p> <p><i>ECHA Financial regulation</i></p> <p><i>PRO-0013 Planning and reporting</i></p>	<p>both conducted in 2014. The purpose of those measures was to clean duplicate metrics and to remove/replace metrics with little added value compared to the cost of their production. In addition, a new Unit Level Template (ULP) was created, with a result to better cascade the Work programme objectives to Unit level, create automation between different Excel databases, minimize the manual and remove the duplicate input.</p> <p>Still, there is more progress to be done in 2016, as ISO 9001:2015 surveillance audit found that the relationship between objectives and indicators is not always clear or logical. Some of the recommendations under the IAC KPI audit will be addressed in 2016 as well.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Models and measurement of the 4 strategic objectives</i></p> <p><i>Annual and multiannual work programmes</i></p> <p><i>PRO-0080 IQMS planning</i></p> <p><i>Multi-annual staff policy plans</i></p> <p><i>Unit level plans</i></p> <p><i>ECHA Financial regulation</i></p> <p><i>PRO-0013 Planning and reporting</i></p>
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<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, effectiveness and economy.</p>	<p>Mostly</p> <p>There is a procedure for producing AWP and Multi-Annual Work Programme (MAWP). The procedure needs to be revised to specify how to better align the resources.</p> <p>The allocation of human and financial resources takes into account procurement plans, baseline figures and IT strategies.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0013 Planning and reporting</i></p>	<p>Mostly</p> <p>The Agency is exploring potential IT tools for alignment of resources to objectives and workload to replace the current non-automated systems. Further analysis is needed to ensure that they are fit for purpose and cost-effective before potentially implementing them.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0013 Planning and reporting</i></p>	<p>Yes</p> <p>In 2015, the Agency has made progress in cascading the Work Programme objectives to the Unit objectives and in aligning top down and bottom up resource allocations. Between the future goals of the planning and reporting project for the coming years is the testing of an IT tool, which could be potentially used for activity planning and resource allocation and replace the current Excel systems in house.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0013 Planning and reporting</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<p>The Agency shall conduct a corporate risk management exercise at least once per year as</p>	<p>Yes</p> <p>A general risk management framework is applied at corporate level and is part of the Work programme preparation.</p>	<p>Yes</p> <p>Corporate risk exercise ensures effective management of Agency's risks and is followed up on a quarterly basis by the Senior Management.</p>	<p>Yes</p> <p>As per ISO 9001:2015 surveillance audit, risks and opportunities are well managed, in parallel to the work programme and changes are implemented in a well-</p>

<p>part of the Work programme preparation, and at Unit level whenever the Senior Management considers it necessary.</p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>ED decision on Risk Management in ECHA ED/29/2010</i></p> <p><i>Risk Management in the Commission – Implementation guide</i></p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>ED decision on Risk Management in ECHA ED/29/2010</i></p> <p><i>Risk Management in the Commission – Implementation guide</i></p>	<p>controlled manner.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED decision on Risk Management in ECHA ED/65/2015</i></p> <p><i>Risk Management in the Commission – Implementation guide</i></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>Partially</p> <p>In many cases, risks are minimized at all costs, without considering the cost-benefit ratios of controls.</p> <p>Guidelines for Heads of Units and process owners to perform both Unit level- and process risk assessment have been elaborated and some training has been delivered in 2013.</p> <p>An Efficiency Development programme, focusing on process streamlining, is under development.</p>	<p>Partially</p> <p>In order to address the provisions of Art.30 of ECHA FR, a Methodology for risk assessment and cost-benefit analysis at process level was elaborated and implemented under the projects of the Efficiency programme. Targeted group training was also delivered.</p> <p>Processes where excessive level of controls will be eliminated have been identified under the Efficiency programme. E.g. the number of controls for reimbursement and payment workflows as well as for catering orders was proposed to be reduced by more than 50% by merging a number of steps and responsibilities.</p> <p>Still, more efforts are needed and planned for 2015 to further popularise the concept of cost-risk-benefit analysis at process level.</p>	<p>Mostly</p> <p>In 2015, there have been a number of projects under which the cost-risk-benefit methodology was applied resulting in elimination of multiple controls. Examples with their relevant measurements of time savings are available under Section 3.1. Risk Management of the CAAR.</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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<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>Mostly</p> <p>Roles and responsibilities are defined in the relevant documentation of the Integrated Management System of ECHA. Documentation is not yet available for all processes.</p> <p>There is a delegation and sub-delegation register accessible by all staff.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED decisions for delegations of financial, scientific and administrative powers</i></p> <p><i>Delegation and sub-delegation register</i></p> <p><i>PRO-0059 Internal decision-making and delegation of power</i></p>	<p>Mostly</p> <p>ISO 9001:2008 certification audit has found that the Agency's has well described procedures and working instructions for REACH and CLP processes in its Integrated Management System. The auditors also considered that better definition and communication of roles and responsibilities is needed in some areas. This observation will be addressed in 2015.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED decisions for delegations of financial, scientific and administrative powers</i></p> <p><i>Delegation and sub-delegation register</i></p> <p><i>PRO-0059 Internal decision-making and delegation of power</i></p> <p><i>ISO 9001:2008 audit</i></p>	<p>Yes</p> <p>The surveillance audit of ISO 9001:2015 concluded that roles, responsibilities and authorities are well defined in the organisation.</p> <p>In 2015, improvement was made on how Directors Coordination Meetings decisions are proposed, recorded and communicated</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED decisions for delegations of financial, scientific and administrative powers</i></p> <p><i>Delegation and sub-delegation register</i></p> <p><i>PRO-0059 Internal decision-making and delegation of power</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>ISO 9001:2015 surveillance audit</i></p>

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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<p>The Agency shall ensure that its processes are designed in line with its strategies and objectives, reflect process interactions, allow process measurement and are documented in a user friendly manner, readily accessible and useful for the staff.</p>	<p>Mostly</p> <p>There is an Activity and Process Structure with defined ownerships.</p> <p>Reports and audits are indicating that processes are not always purposefully described and/or mapped.</p> <p>Process measurements need to be developed.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>LIS-0009 ECHA Activity and Process Structure</i></p>	<p>Mostly</p> <p>Progress has been made in the area of process definition and mapping. The Activity and Process Structure of ECHA was reviewed in 2014 in order to re-define some processes and their ownerships, and to integrate the criticality levels of the processes. A process dependency matrix was elaborated to illustrate the interactions between processes. Some process designs have been reviewed under the Efficiency programme.</p> <p>Audits and analyses have indicated some short-comings in the process implementation, which implies review of design, interfaces, controls and follow-up indicators. Actions are planned to address those in 2015.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>LIS-0009 ECHA Activity and Process Structure</i></p>	<p>Mostly</p> <p>The surveillance audit of ISO 9001:2015 found that the description of interaction of processes in the high level process map of ECHA IMS Manual at ECHA is not clear. Also, the relationship between process and regulation was assessed not to give a clear picture of what the main process is. A recommendation to clarify the main process structure to make it less complicated was made and will be followed in the course of 2016.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>LIS-0009 ECHA Activity and Process Structure</i></p>

		<p><i>Efficiency programme</i></p> <p><i>ISO 9001:2008 audit</i></p>	<p><i>Efficiency programme</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>ISO 9001:2015 surveillance audit</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<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</p>	<p>Yes</p> <p>Security and Business Continuity Policies exist.</p> <p>Risks and crisis scenarios are covered in the Business continuity management policy; the level of criticality at process level has been established. Actions are further specified in the business continuity plans.</p> <p>In 2013, a crisis test covering a number of scenarios was conducted at Management level. Interactive on-line security training has been undertaken by staff.</p> <p>An ECHA back-up procedure is available to staff through the Intranet, and has been</p>	<p>Yes</p> <p>For the ensuring business continuity, all business continuity plans for critical processes were updated and capability to handle crisis situations was tested by crisis exercise in December 2014.</p>	<p>Mostly</p> <p>A new ECHA security framework was adopted in 2015, changing a number of structures and tasks. Currently there are 3 areas of security:</p> <ul style="list-style-type: none"> • Information security • ICT security managing the outsourced data centre. Many improvement actions have been implemented in 2015 following the audit on "Data centre assessment" • Physical security which is consolidated with the facility services <p>In 2015, the decentralised organisation</p>

<p>disruptions</p>	<p>implemented. Handover files have been fostered in case of mobility or leaving of service.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>POL-0004 Business Continuity Management Policy</i></p> <p><i>PLA-0001 ECHA Crisis Management Plan (tested annually in Crisis Exercises)</i></p> <p><i>POL-0002 Security Policy Statement</i></p> <p><i>ED/97/2010 Security Organisation</i></p> <p><i>ED/29/2008 Security Rules and related procedures</i></p> <p><i>ED/125/2012 Rules for access to the ECHA premises</i></p> <p><i>PRO-0033 Video-surveillance at the ECHA premises</i></p> <p><i>POL-0006 Information Security Policy</i></p> <p><i>POL-0005 Classification and Handling of ECHA Information Policy</i></p> <p><i>POL-0011 Use of ICT Facilities Policy</i></p> <p><i>PRO-0065 ECHA ICT Security Management</i></p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>POL-0004 Business Continuity Management Policy</i></p> <p><i>PLA-0001 ECHA Crisis Management Plan (tested annually in Crisis Exercises)</i></p> <p><i>POL-0002 Security Policy Statement</i></p> <p><i>ED/97/2010 Security Organisation</i></p> <p><i>ED/29/2008 Security Rules and related procedures</i></p> <p><i>ED/125/2012 Rules for access to the ECHA premises</i></p> <p><i>PRO-0033 Video-surveillance at the ECHA premises</i></p> <p><i>POL-0006 Information Security Policy</i></p> <p><i>POL-0005 Classification and Handling of ECHA Information Policy</i></p> <p><i>POL-0011 Use of ICT Facilities Policy</i></p>	<p>has brought responsibility closer to the operations; However, the competence of responsible persons and the detailed processes would need to be further developed. The level of security compliance with ECHA standards in some MSCAs remains an area for further improvement which will be addressed in 2016.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>POL-0004 Business Continuity Management Policy</i></p> <p><i>PLA-0001 ECHA Crisis Management Plan (tested annually in Crisis Exercises)</i></p> <p><i>POL-0002 Security Policy Statement</i></p> <p><i>ED/97/2010 Security Organisation</i></p> <p><i>ED/29/2008 Security Rules and related procedures</i></p> <p><i>ED/125/2012 Rules for access to the ECHA premises</i></p> <p><i>PRO-0033 Video-surveillance at the ECHA premises</i></p> <p><i>POL-0006 Information Security Policy</i></p> <p><i>POL-0005 Classification and Handling of ECHA Information Policy</i></p> <p><i>POL-0011 Use of ICT Facilities Policy</i></p>
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	<p><i>System</i></p> <p><i>HAN-0011 Handbook on Practical instructions for handling of ECHA equipment (lost items) and access to ECHA premises</i></p> <p><i>ED/24/2009 Instructions for the use of ECHA Conference Centre</i></p>	<p><i>PRO-0065 ECHA ICT Security Management System</i></p> <p><i>HAN-0011 Handbook on Practical instructions for handling of ECHA equipment (lost items) and access to ECHA premises</i></p> <p><i>ED/24/2009 Instructions for the use of ECHA Conference Centre</i></p>	<p><i>PRO-0065 ECHA ICT Security Management System</i></p> <p><i>HAN-0011 Handbook on Practical instructions for handling of ECHA equipment (lost items) and access to ECHA premises</i></p> <p><i>ED/24/2009 Instructions for the use of ECHA Conference Centre</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
The Agency shall conduct regular assessments that the information available in the Agency's Management system is fit for purpose.	<p>Yes</p> <p>It is a common audit objective to assess the reliability of the operational information. A specific audit has been conducted in 2013 and an audit plan adopted.</p>	<p>Yes</p> <p>In 2014, ISO 9001:2008 assessed ECHA information management system. Recommendations for improvement are being followed up.</p>	<p>Yes</p> <p>Following the recommendations of the ISO 9001:2008 audit in 2014, simplification and integration of relevant information management documentation, took place in 2015. On ECHANet, the control on the content and documents was significantly improved.</p>

<p>The Agency shall have an Information management system, complying with applicable legislation and providing adequate audit trails, where the principles of organisation, control, retention, archive and communication with regards to documents and records are defined.</p>	<p>Partially</p> <p>There is a policy defining how information is handled, controlled, communicated and implemented by all staff</p> <p>The procedure for control of Documents and Records has not yet been fully implemented</p> <p>There are retention periods defined for some records, in line with the existing regulations</p> <p>There are IT projects which will facilitate the implementation of the information management policies. A project on archives is on-going.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>POL- 0005 Classification and Handling of ECHA Information</i></p> <p><i>POL- 0007 Information Management Policy</i></p> <p><i>PRO-0010 Control of Documents and Records,</i></p> <p><i>LIS-0009 Activity and Process Structure with Common Nomenclature and</i></p>	<p>Mostly</p> <p>Considerable progress was made in that area in 2014. The procedure for control of Documents and Records is under implementation: retention periods were defined for most of the records; filing plans were already developed and will be implemented in Q2/2015.</p> <p>Simplification of relevant information management documentation, including integration of existing documents took place in 2014.</p> <p>A number of IT projects are on-going in order to improve the operational process management and facilitate the implementation of the information management policies.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ED 86/2014 Electronic storage of documents in ECHA</i></p> <p><i>POL- 0007 Information Management Policy</i></p> <p><i>PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to</i></p>	<p>Mostly</p> <p>As of 31/12/2015, the procedure for control of documents and records was implemented: retention periods were defined for most of the records, filing plans were developed and implemented, and records migrated to DMS (the Shared Drives were closed), thus responding to the ISO 9001:2008 audit recommendations and closing this recurrent issue in IAC audits as well. NC-CAPA report as of 2015 also shows improvement in the area of documents and records.</p> <p>A number of IT projects are on-going in order to improve the operational process management and facilitate the implementation of the information management policies. The records management tool is now fully integrated with Dynamic Case to manage the permanent records of the Agency and a more secure external collaboration platform (S-CIRCA BC) was taken into use.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>ISO 9001:2015 surveillance audit</i></p> <p><i>ED 86/2014 Electronic storage of documents in ECHA</i></p>
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	<p><i>Ownerships</i></p> <p><i>LIS-0011 ECHA Retention Schedule</i></p> <p><i>LIS – 0012 ECHA Default Metadata</i></p>	<p><i>be added: ECHA Retention Schedule)</i></p> <p><i>LIS-0009 Activity and Process Structure with Common Nomenclature and Ownerships</i></p> <p><i>LIS – 0012 ECHA Default Metadata</i></p>	<p><i>POL- 0007 Information Management Policy</i></p> <p><i>PRO-0010 Control of Documents and Records including Classification and Handling of ECHA Information (Annex to be added: ECHA Retention Schedule)</i></p> <p><i>LIS-0009 Activity and Process Structure with Common Nomenclature and Ownerships</i></p> <p><i>LIS – 0012 ECHA Default Metadata</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
<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>Mostly</p> <p>Monitoring structures exist to follow the financial, HR and accounting results, the KPIs and baseline figures per Activity, as well as the audit findings. The structures however are not fully automated, neither fully aligned to prevent duplication and manual work.</p>	<p>Partially</p> <p>ISO 9001:2008 auditors have made an observation that plans need to be more consistently implemented. Management analyses have identified a number of short-comings, mainly related to the efficiency of the monitoring and measurement structures. In order to address those and to provide a structure for a number of improvements in the area of monitoring and measurement identified as a result of audits and analyses, ECHA started a feasibility study whose results are expected to streamline and automate the existing monitoring and measurement structures.</p> <p>Improved measurement structures will facilitate ECHA to respond to the new provisions under the ECHA FR with regard to the effectiveness and efficiency of internal controls.</p>	<p>Mostly</p> <p>The surveillance audit of ISO 9001:2015 found that although the monitoring, measurement and analysis of the Management system is well structured, and results are collected and reported to the management, corrective actions and improvements are not consistently documented. In addition, the audit found that the relationship between unit objectives and indicators is not always clear or logical.</p> <p>In order to address those, in 2015 ECHA reviewed the Work programme indicators and baseline figures from a cost-benefit perspective, created a database of all metrics in house, aligned the timing of a number of reporting obligations and automated the Unit level reporting template which will be in use for the year 2016. In addition, testing of the proof of concept of an IT tool to further streamline and automate the existing monitoring and measurement structures is foreseen for 2016. Those actions followed also the</p>

	<p>-----</p> <p><i>Main references:</i></p> <p><i>Annual and multiannual work programmes</i></p> <p><i>ECHA Financial Regulation</i></p> <p><i>General financial regulation and implementing rules</i></p> <p><i>Annual budget</i></p> <p><i>European Union accounting rules</i></p> <p><i>REACH regulation (including implementing Fee regulations)</i></p> <p><i>PRO-0013 Planning and reporting</i></p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>Annual and multiannual work programmes</i></p> <p><i>ECHA Financial Regulation</i></p> <p><i>General financial regulation and implementing rules</i></p> <p><i>Annual budget</i></p> <p><i>European Union accounting rules</i></p> <p><i>REACH regulation (including implementing Fee regulations)</i></p> <p><i>PRO-0013 Planning and reporting</i></p>	<p>recommendations of the KPI audit and the feasibility study, both conducted in 2014 (for more details, see 2.1. Objectives planning and resource allocation).</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ISO 9001:2008 audit</i></p> <p><i>ISO 9001:2015 surveillance audit</i></p> <p><i>Annual and multiannual work programmes</i></p> <p><i>ECHA Financial Regulation</i></p> <p><i>General financial regulation and implementing rules</i></p> <p><i>Annual budget</i></p> <p><i>European Union accounting rules</i></p> <p><i>REACH regulation (including implementing Fee regulations)</i></p> <p><i>PRO-0013 Planning and reporting</i></p>
<p>The Agency shall have adequate controls to capture, manage and report on non-conformities and suggestions for improvements, including handling of corrective</p>	<p>Partially</p> <p>There is a procedure for the handling of non-conformities and complaints and the management of corrective and preventive actions. The Agency-wide implementation has to be furthered. Not all deviations, non-conformities and complaints are recorded. IT assisted workflows and systems for a centralised deviation and</p>	<p>Mostly</p> <p>In 2014, efforts have been put towards formalising and implementing the procedures for handling of non-conformities and complaints and management of corrective and preventive actions, with a result of establishing a centralised system for handling those. A procedure on preventive and risk – based</p>	<p>Mostly</p> <p>In 2015, the NC–CAPA tool was improved by adding information about root-cause analysis and categorisation of NCs, which helps with drawing more structured conclusions on the areas to which the NCs refer. Still, the process has some drawbacks mainly with regard to the user-friendliness of the tool used. A feasibility</p>

actions.	action management are in development.	<p>approach was issued as well.</p> <p>More efforts are needed in order to ensure that corrective actions and improvements are taken and followed up by all Units in the Agency.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0079 Preventive and risk-based approach to management</i></p> <p><i>PRO-0015 Nonconformities, Corrective and Preventive Action</i></p>	<p>study on the existing strengths and weaknesses of the action management processes at ECHA (incl. audits, NCs, risks, DCM actions) was performed in 2015. Among the recommendations of the study which refer to aligning and streamlining all action management processes at ECHA, a number of potential IT solutions are proposed which may potentially replace the existing NC-CAPA (Remedy) tool.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0079 Preventive and risk-based approach to management</i></p> <p><i>PRO-0015 Nonconformities, Corrective and Preventive Action</i></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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
Senior Management shall review periodically and carry out an annual management	<p>Mostly</p> <p>The effectiveness, adequacy and suitability of the management system is evaluated by the Senior Management on annual basis during the Management review and</p>	<p>Mostly</p> <p>In 2014, efforts have been made towards providing analysis of data to the Management, in order to facilitate their quarterly and Management reviews.</p>	<p>Yes</p> <p>In 2015, the focus shifted from providing purely numerical data to analyses and trends identification, as well as to exceptional and risk-based reporting. Those analyses aim at facilitating the</p>

<p>review on the effectiveness, adequacy and suitability of the Agency's Integrated management system.</p>	<p>followed up on a quarterly basis.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0016 Management review</i></p> <p><i>PRO-0042 Organization and approach to management</i></p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0016 Management review</i></p> <p><i>ECHA Integrated Management System manual (MAN-0001)</i></p> <p><i>Quarterly reviews at DCM and Management review minutes</i></p>	<p>decision-making of the Management in particular at the time of the quarterly and Management reviews.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0016 Management review</i></p> <p><i>ECHA Integrated Management System manual (MAN-0001)</i></p> <p><i>Quarterly reviews at DCM</i></p> <p><i>Management review</i></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>Assessments should be implemented more systematically for all projects.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>PRO-0018 Project Management</i></p> <p><i>PRO-0026 IT Governance bodies, roles and functions</i></p> <p><i>PRO- 0027 IT Governance and Process</i></p>	<p>Partially</p> <p>The new FR of ECHA and in particular, its implementing rules adopted in December 2014 brought new provisions with regard to the ex-ante and ex-post evaluation of programmes, projects or activities (applicable for amounts EUR 1 million for ex-ante and EUR 2 million for ex-post evaluation). Implementation is foreseen to start in 2015.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ECHA FR and Implementing rules</i></p> <p><i>PRO-0018 Project Management</i></p> <p><i>PRO-0026 IT Governance bodies, roles and functions</i></p>	<p>Mostly</p> <p>Following the Commission's guidelines and the FR requirements setting the evaluation limits, ECHA's framework and approach to evaluations was presented to the MBWG on audit on 15 December 2015 and reported to the 40th MB on 16-17 December 2015. The approach is described in detail in Section 2.10 Ex-ante and ex-post evaluations of the CAAR.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>ECHA FR and Implementing rules</i></p> <p><i>PRO-0018 Project Management</i></p> <p><i>PRO-0026 IT Governance bodies, roles and functions</i></p>

	<i>Description</i>	<i>PRO- 0027 IT Governance and Process Description</i>	<i>PRO- 0027 IT Governance and Process Description</i> <i>Better Regulation Guidelines of the Commission</i>
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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 2013	Is the requirement fulfilled – Assessment 2014	Is the requirement fulfilled – Assessment 2015
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>Yes</p> <p>The annual audit plan is risk-based and is part of a multi-annual strategic plan coordinated with the IAS and is approved by the Executive Director.</p> <p>IAC and the other personnel carrying out audits preserve independence in relation to the activities subject to review.</p> <p>Management engages in audits by supporting the audit teams, preparing action plans, implementing the actions and by following up on them in order to correct weaknesses identified.</p> <p>The mechanism for management of action</p>	<p>Yes</p> <p>The annual audit plan is risk-based and is part of a multi-annual strategic plan coordinated with the IAS and is approved by the Executive Director.</p> <p>IAC and the other personnel carrying out audits preserve independence in relation to the activities subject to review.</p> <p>Management follows up the audits on a quarterly basis.</p> <p>To avoid duplication of efforts, IAC and internal quality audits complement each other and are planned in joint internal</p>	<p>Yes</p> <p>The Independent External Validation of IAC conducted in 2015 concluded that the IAC of ECHA's structure, policies and procedures, as well as the processes with which these are applied, conform with both attribute and performance standards and the objectives with which they have been formulated. The highest level of assessment "generally conformant" was granted to IAC.</p>

	<p>plans needs to be simplified.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Audit Work programme</i></p> <p><i>IAC Annual Work plan</i></p> <p><i>Audit follow up table</i></p> <p><i>PRO-0020 Internal audit of the Internal audit capability (IAC)</i></p> <p><i>PRO-0014 Internal IQMS audit</i></p>	<p>audit programme.</p> <p>-----</p> <p><i>Main references:</i></p> <p><i>Audit Work programme</i></p> <p><i>IAC Annual Work plan</i></p> <p><i>Audit follow up table</i></p> <p><i>PRO-0020 Internal audit of the Internal audit capability (IAC)</i></p> <p><i>PRO-0014 Internal IQMS audit</i></p>	<p>-----</p> <p><i>Main references:</i></p> <p><i>Independent External Validation audit of IAC</i></p> <p><i>Audit Work programme</i></p> <p><i>IAC Annual Work plan</i></p> <p><i>Audit follow up table</i></p> <p><i>PRO-0020 Internal audit of the Internal audit capability (IAC)</i></p> <p><i>PRO-0014 Internal IQMS audit</i></p>
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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,

Geert DANCET

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 7 March 2016

signed

Geert DANCET

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.