EUROPEAN
COURT
OF AUDITORS

Report on the annual accounts of the European Chemicals Agency for the financial year 2014 together with the Agency's reply

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INTRODUCTION

1. The European Chemicals Agency (hereinafter "the Agency", aka "ECHA"), which is located in Helsinki, was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[1]. Its main tasks are to ensure a high level of protection of human health and the environment as well as the free movement of substances on the internal market while enhancing competitiveness and innovation. The Agency also promotes the development of alternative methods for the assessment of hazards relating to substances[2].

INFORMATION IN SUPPORT OF THE STATEMENT OF ASSURANCE

2. The audit approach taken by the Court comprises analytical audit procedures, direct testing of transactions and an assessment of key controls of the Agency's supervisory and control systems. This is supplemented by evidence provided by the work of other auditors and an analysis of management representations.

STATEMENT OF ASSURANCE

3. Pursuant to the provisions of Article 287 of the Treaty on the Functioning of the European Union (TFEU), the Court has audited:

(a) the annual accounts of the Agency, which comprise the financial statements[3] and the reports on the implementation of the budget[4] for the financial year ended 31 December 2014, and

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

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[1] OJ L 396, 30.12.2006, p. 1.

[2] ***Annex II*** summarises the Agency's competences and activities. It is presented for information purposes.

[3] These include the balance sheet and the statement of financial performance, the cash flow table, the statement of changes in net assets and a summary of the significant accounting policies and other explanatory notes.

[4] These comprise the budgetary outturn account and the annex to the budgetary outturn account.

The management's responsibility

4. The management is responsible for the preparation and fair presentation of the annual accounts of the Agency and the legality and regularity of the underlying transactions[5]:

(a) The management's responsibilities in respect of the Agency's annual accounts include designing, implementing and maintaining an internal control system relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies on the basis of the accounting rules adopted by the Commission's accounting officer[6]; making accounting estimates that are reasonable in the circumstances. The Director approves the annual accounts of the Agency after its accounting officer has prepared them on the basis of all available information and established a note to accompany the accounts in which he declares, inter alia, that he has reasonable assurance that they present a true and fair view of the financial position of the Agency in all material respects.

(b) The management's responsibilities in respect of the legality and regularity of the underlying transactions and compliance with the principle of sound financial management consist of designing, implementing and maintaining an effective and efficient internal control system comprising adequate supervision and appropriate measures to prevent irregularities and fraud and, if necessary, legal proceedings to recover funds wrongly paid or used.

The auditor's responsibility

5. The Court's responsibility is, on the basis of its audit, to provide the European Parliament and the Council[7] with a statement of assurance as to the reliability of the annual accounts and the legality and regularity of the underlying transactions. The Court conducts its audit in accordance with the IFAC International Standards on Auditing and Codes of Ethics and the INTOSAI International Standards of Supreme Audit Institutions. These standards require the Court to plan and perform the

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[5] Articles 39 and 50 of Commission Delegated Regulation (EU) No 1271/2013 (OJ L 328, 7.12.2013, p. 42).

[6] The accounting rules adopted by the Commission's accounting officer are derived from the International Public Sector Accounting Standards (IPSAS) issued by the International Federation of Accountants or, where relevant, the International Accounting Standards (IAS)/International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board.

[7] Article 107 of Regulation (EU) No 1271/2013.

audit to obtain reasonable assurance as to whether the annual accounts of the Agency are free from material misstatement and the transactions underlying them are legal and regular.

6. The audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and regularity of the underlying transactions. The procedures selected depend on the auditor's judgement, which is based on an assessment of the risks of material misstatement of the accounts and material non-compliance by the underlying transactions with the requirements in the legal framework of the European Union, whether due to fraud or error. In assessing these risks, the auditor considers any internal controls relevant to the preparation and fair presentation of the accounts, as well as the supervisory and control systems that are implemented to ensure the legality and regularity of underlying transactions, and designs audit procedures that are appropriate in the circumstances. The audit also entails evaluating the appropriateness of accounting policies, the reasonableness of accounting estimates and the overall presentation of the accounts. In preparing this report and Statement of Assurance, the Court considered the audit work of the independent external auditor performed on the Agency's accounts as stipulated in Article 208(4) of the EU Financial Regulation[8].

7. The Court considers that the audit evidence obtained is sufficient and appropriate to provide a basis for its statement of assurance.

Opinion on the reliability of the accounts

8. In the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2014 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts

9. In the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2014 are legal and regular in all material respects.

10. The comments which follow do not call the Court's opinions into question.

[8] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 298, 26.10.2012, p. 1).

COMMENTS ON BUDGETARY MANAGEMENT

11. Budget implementation rates for the year 2014 improved in comparison with the previous year. The level of committed appropriations carried over to 2014 for titles III, IV, and V (operational expenses) was 8,5 million euro, i.e. 35 % (2013: 10,6 million euro, i.e. 46 %). These carry-overs mainly resulted from the multiannual nature of planned IT development projects (4,5 million euro), costs for translations ordered in 2014 but not received and paid by the end of the year (0,5 million euro) and substance evaluations with a regulatory deadline in 2015 (1,9 million euro). The expenditure for procedures associated with one new specific activity of the Agency, the implementation of the Regulation concerning biocidal products[9], was to be, in principle, covered by application fees for the registration of these products[10]. However, fees collected in 2014 covered only 17 % of this expenditure and the remaining part was in fact financed by contributions to the Agency's budget from the Union (6,3 million euro) and EFTA countries (0,2 million euro).

FOLLOW-UP OF PREVIOUS YEAR'S COMMENTS

12. An overview of the corrective actions taken in response to the Court's comments from the previous year is provided in ***Annex I***.

This Report was adopted by Chamber IV, headed by Mr Milan Martin CVIKL, Member of the Court of Auditors, in Luxembourg at its meeting of 8 September 2015.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA

President

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[9] Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 167, 27.6.2012, p. 1).

[10] Article 80 (3) (a) of Regulation (EU) No 528/2012.

Annex I

Follow-up of previous year's comments

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2013	As in the previous year, budget implementation rates for the year 2013 were satisfactory for titles I and II. Although the level of committed appropriations carried over to 2014 remained high for titles III, IV and V (operational expenses) at 10,6 million euro (46 %), this mainly resulted from the multiannual nature of planned IT development projects (6,3 million euro), cost for translations ordered in 2013 but not received by the year end (1,3 million euro) and substance evaluations for which the regulatory deadline was February 2014 (1,7 million euro).	**N/A**
2013	In his Declaration of assurance for the year 2013 ECHA's Executive Director confirmed reasonable assurance that resources have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures in place give the necessary guarantees concerning the legality and regularity of the underlying transactions. However, a reservation to this assurance was made since the mandate of the Agency does not include controls or inspections at national level and therefore no confirmation could be given that only registered or authorised substances and products, for which a fee has been paid to the Agency, were circulating on the European Union market.	**N/A**

Annex II

European Chemicals Agency

(Helsinki)

Competences and activities

Areas of Union competence deriving from the Treaty	**Collection of information** – The legal base of ECHA's founding regulation – the REACH Regulation (EC) No 1907/2006 – is Article 114 of the Treaty on the Functioning of the EU.
Competences of the Agency *(as defined in Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH Regulation), Regulation (EC) No 1272/2008 of the European Parliament and of the Council (Classification, labelling and packaging of substances and mixtures - CLP Regulation), Regulation (EU) No 528/2012 of the European Parliament and of the Council (Biocidal Products Regulation) and Regulation (EU) No 649/2012 of the European Parliament and of the Council (Prior informed consent)*	**Objectives** – The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for the assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation (Article 1(1) of the REACH Regulation, Article 1 of CLP Regulation). – ECHA is established for the purposes of managing and, in some cases, carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency at Union level in relation to these aspects (Article 75 of the REACH Regulation) and to manage tasks related to the classification and labelling of chemical substances deriving from the CLP Regulation. **Tasks** – To receive registrations and other dossiers of chemical substances and undertake a completeness check thereof (Title II of the REACH Regulation). – To process inquiries regarding the registrations and take decisions on data sharing disputes (Title III of the REACH Regulation). – To examine registration dossiers for compliance with the REACH Regulation and the testing proposals therein, and coordinate the substance evaluation process (Title VI of the REACH Regulation). – To process proposals of substances of very high concern for the Candidate List and make recommendations for some of these substances to be included in the Authorisation List and handle authorisation applications (Title VII of the REACH Regulation). – To process restriction dossiers (Title VIII of the REACH Regulation). – To establish and maintain public database(s) with information on all registered substances and make certain information publicly available over the Internet (Article 77, 119 of the REACH Regulation). – To provide technical and scientific guidance and tools where appropriate (Article 77 of the REACH Regulation, Article 50(2) of CLP Regulation) and under the Biocidal Product Regulation (EU) No 528/2012. – To provide the Member States and the EU institutions with the best possible scientific and technical advice on questions relating to chemicals

	which fall within its remit and which are referred to it in accordance with the provisions of the REACH and CLP Regulations (Article 77(1) of the REACH Regulation, Article 50(1) of CLP Regulation). – To receive C&L notifications, maintain a public C&L inventory, handle requests for alternative names and process proposals for the harmonised classification and labelling of substances (CLP). – To implement technical and scientific tasks in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013. – To implement tasks under the PIC ('Prior Informed Consent') Regulation (EU) No 649/2012, which came into force on 1 March 2014.
Governance	**Management Board** One representative of each Member State appointed by the Council and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights and, in addition, two independent persons appointed by the European Parliament. (Article 79 of the REACH Regulation). *Tasks* Article 78 of the REACH Regulation and framework financial regulation for agencies, mainly adopting annual and multi-annual work programmes, the final budget, a general report, internal rules of procedures and the appointment of and disciplinary authority over the Executive Director. In addition, the appointment of the Board of Appeal and Committee members. **Executive Director** *Tasks* Article 83 of the REACH Regulation **REACH Committees** The Agency comprises three Scientific Committees (Risk Assessment, Member States and Socio-Economic Analysis) *Tasks* Article 77(3)(a-c) of the REACH Regulation **BPR Committee** The Agency has a Biocidal Products Committee *Tasks* Article 75(1) of the Biocidal Products Regulation **Forum for Exchange of Information on Enforcement** *Tasks* Article 77(4)(a-h) of the REACH Regulation **Secretariat** *Tasks* Article 77(2)(a-o) of the REACH Regulation **Board of Appeal** *Tasks* Article 76(1)(h) of the REACH Regulation

	External audit European Court of Auditors **Internal audit** European Commission's Internal Audit Service (IAS) **Discharge authority** European Parliament on a recommendation from the Council (Article 97(10) of REACH Regulation
Resources made available to the Agency in 2014 *(2013)*	**Budget (including amending budgets)** – 113,2 *(107,7)* million euro, including: – Revenue from fees: 27,2 *(86,1)* million euro; 25,9 *(85,8)* million euro in respect of fees and charges under the REACH Regulation (EC) No 1907/2006 and 1,3 *(0,3)* million euro in respect of fees and charges collected under the Biocidal Products Regulation (EU) No 528/2012. – Union contribution: 7,8 *(8,6)* million euro, including support for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (5,1 million euro), the balancing contribution (1,2 million euro), an EFTA contribution (0,2 million euro) and a contribution under Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (1,3 million euro). **Staff at 31 December 2014** – Number of posts in the establishment plan: 495 *(503)* – Number of posts occupied: 479, *of which 9 under recruitment (468)* – Other staff: 118 *(95)* (106 contract staff, of which 1 under recruitment and 12 seconded national experts) – Total staff: 587 *(563)* assigned to the following*: – Operational tasks: 78 % / 458 *(386)*; – Administrative and support tasks: 22 % / 129 *(177)* **based on the benchmarking exercise*
Activities and services provided in 2014 *(2013)*	ECHA's Work Program was divided into the following 17 Activities: **Registration, Pre-registration and Data-sharing** – Number of registration dossiers processed: 9 001 *(14 839)* – Number of confidentiality requests assessments completed: 636 *(860)* assessments (initial and final) of which 67 (*198*) negative decisions – Number of new inquiries received: 1 000 *(1 903)* – Number of decisions issued on data sharing disputes: 5 *(11)* – Number of substances on which info made public (excluding confidential info): 12 888 *(10 561)* **Evaluation** – Number of compliance checks completed: 283 *(637)* – Number of final decisions on testing proposals: 204 *(111)* **Risk Management**

	– Number of substances identified for inclusion in the Candidate List: 10 *(13)* – Number of recommendations of substances for inclusion in Authorisation List: 1 *(1)* – Number of restriction dossiers submitted for Commission decision: 4 *(2)* – Number of authorisation applications received: 19 *(8)* – Number of notifications of Candidate List substances in articles: 14 *(93)* **Classification and Labelling (C&L)** – Number of C&L notifications received: 6,4 million for over 133 000 substances (of which over 118 000 are included in the publicly disseminated notifications) – Number of proposals for harmonised classification and labelling received: 44 *(29)* – Number of requests for alternative names for substances in mixtures received: 28 *(28)* **Advice and assistance** – Number of questions answered by ECHA Helpdesk: 7 628 *(5 975)* – Number of new guidance documents issued: 10 *(1)* – Number of guidance updates and corrigendas issued: 9 *(3)* updates and 8 *(4)* corrigenda **Scientific IT Tools** – 2 new versions of R4BP were released in 2014 – An SPC editor developed and released to support the authoring of structured SPC for Biocides – A new system supporting PIC Regulation, ePIC, released in time to manage notifications arriving for 2015 – The current dissemination system enhanced to cover Biocides and PIC data and to achieve operational efficiencies – An update to the Chesar 2 product (version 2.3) released – The case management platform Dynamic Case was launched and already supporting 17 REACH&CLP processes by year-end – Two new versions of Odyssey were released – Two maintenance versions of ECM-DEP released **Scientific and Technical Advice to EU institutions and bodies** – A successful Topical Scientific Workshop on Regulatory Challenges in Risk Assessment of Nanomaterials was organised in October 2014 – ECHA 2nd report under Article 117(3) of REACH on use of alternatives to animal testing was published – ECHA's 2-year work plan on nanomaterials was updated – Two meetings of the nanomaterials working group were held – Contributions to the Commission's work for the revision of REACH annexes regarding specific requirements for nanomaterials – ECHA and JRC published a report on "Awareness of non-animal methods for the assessment of chemicals – View to promote non-animal testing and alternative methods" – Contribution to the development of OECD test guidelines and testing

strategies (IATAs) especially in the areas of skin and eye irritation/corrosion, skin sensitisation, genotoxicity, endocrine disrupters, reproductive toxicity and aquatic and terrestrial ecotoxicity.

Committees and Forum

- Number of unanimous MSC agreements: 149 *(155)*
- Number of RAC opinions: 88 *(41)*
- Number of SEAC opinions: 34 *(3)*

Board of Appeal

- Number of appeals lodged: 18 *(22)*
- Number of decisions on appeals: 16 *(8)*

Communication

- 3 Stakeholder events organized:
  - 2 Stakeholders' Days
  - Accredited Stakeholder Workshop
- 8 webinars organized with 2 060 participants
- 264 *(250)* translations.
- 1 481 986 website visitors for a total of 4 430 136 visits.
- 61 *(53)* publications.
- 21 press releases produced , 49 interviews with media organized
- 57 news alerts, e-News bulletins, newsletters
- 1 136 tweets, 51 Facebook posts and 38 LinkedIn posts published

Cooperation

- Scientific and technical co-operation with the OECD (e.g. IUCLID) and peer agencies (Australia, Canada, Japan and USA) and technical support to the Commission's international work (e.g. UN GHS)

Management

- Continued development and improvement of administrative and management systems
- ISO 9001 certification achieved

Finance, Procurement and Accounting

- Rigorous budget and cash reserve management
- In 2014 ECHA procured scientific, IT, communication and administrative services under its existing Framework Contracts (548 specific contract/orders) and through procurement procedures (188 contracts). In particular, the Agency successfully concluded open calls for tenders to establish new Framework Contracts for language training, for the certification of the ECHA IQMS against ISO 9001:2008 Standard, for current account banking services and launched a project to increase efficiency in its procurement and contract management and related financial processes.
- Total number of companies verified regarding SME status: 271 *(516)*

Human resources and corporate services

- 22 *(27)* selection procedures finalized; 62 (*87)* staff members recruited (TA and CA)

Information and Communication Technology

	– The first modules of the HRMS were launched – A totally restructured document management system is in use **Biocides** – 2 094 biocides applications (applications for new active substances, renewals or review, Union authorisations of products) were processed and transmitted to Member States – 4 data sharing disputes solved – Assessment of suppliers' applications of active substances and maintenance of the list of approved suppliers: 1 decision – Assessment of technical equivalence applications: 7 decisions – Assessment of chemical similarity of active substances: 1 case **PIC** – 5 289 notifications were processed

Source: Annex supplied by the Agency.

THE AGENCY'S REPLY

11. ECHA appreciates the conclusion of the European Court of Auditors and will continue to be attentive to avoid any non-justified carry-over operations.

It is true that the fees triggered by the 2014 applications under the Biocidal Products Regulation (BPR) covered the Agency's related cost only for a small part. The original Commission assumption, that the Agency would be largely self-financing, has proven to be incorrect, as the national and EU fees have a bias in favour of national applications and mutual recognitions rather than Union authorisations for Biocidal products.

The Commission has, meanwhile, adapted its fee estimates downwards several times and now recognises the need for a continuing annual EU subsidy sufficient to cover most of ECHA's non-fee related tasks. The Commission has also launched an independent study that should provide the necessary input to review the Fee Regulation, as foreseen by the BPR in 2015.