ЕВРОПЕЙСКА СМЕТНА ПАЛАТА
TRIBUNAL DE CUENTAS EUROPEO
EVROPSKÝ ÚČETNÍ DVŮR
DEN EUROPÆISKE REVISIONSRET
EUROPÄISCHER RECHNUNGSHOF
EUROOPA KONTROLLIKODA
ΕΥΡΩΠΑΪΚΟ ΕΛΕΓΚΤΙΚΟ ΣΥΝΕΔΡΙΟ
EUROPEAN COURT OF AUDITORS
COUR DES COMPTES EUROPÉENNE
CÚIRT INIÚCHÓIRÍ NA HEORPA

EUROPSKI REVIZORSKI SUD
CORTE DEI CONTI EUROPEA
EIROPAS REVĪZIJAS PALĀTA
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Report on the annual accounts of the European Chemicals Agency for the financial year 2013

together with the Agency's replies

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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 (where relevant) 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 2013, and

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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 economic outturn account, the cash flow table, the statement of changes in net assets and a summary of the significant accounting policies and other explanatory notes.

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

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

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

[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.

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 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

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

reasonableness of accounting estimates and the overall presentation of the accounts.

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 2013 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 2013 are legal and regular in all material respects.

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

COMMENTS ON BUDGETARY MANAGEMENT

11. 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).

OTHER COMMENTS

12. 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.

FOLLOW-UP OF PREVIOUS YEARS' COMMENTS

13. An overview of the corrective actions taken in response to the Court's comments from previous years 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 1 July 2014.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

ANNEX I

Follow-up of previous years' comments

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2011	The Agency's 2011 budget amounted to 93,2 million euro, of which 14,9 million euro (16 %) were carried over to 2012. Carry-overs related to title III (operational expenditure) amounted to 11,5 million euro (55 %). The level of carry-overs is excessive and at odds with the budgetary principle of annuality.	**N/A**
2011	The results of the latest physical inventory carried out in 2011 show several shortcomings, notably as regards the low proportion of ICT assets checked in terms of value. No formal policy on the inventory of fixed assets is in place.	**Completed**
2012	Physical inventory results show serious weaknesses in the safeguarding and tracking of fixed assets. There is no tracking procedure for software and internal components (2 370 items out of the 5 878 ICT fixed assets recorded). In addition, 306 items could not be found, of which 93 laptops and 29 computers.	**Completed**

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2012	Budget implementation rates for the year 2012 were satisfactory for titles I and II. While the rate of committed appropriations carried over was high for title III at 50 % (11,3 million euro), this primarily relates to the multiannual nature of significant IT development projects (3,7 million euro), substance evaluations with an annual regulatory deadline set at February N+1 (1,8 million euro), translations not yet delivered by year-end (1,3 million euro) and the start of two new activities Biocides (1,2 million euro) and PIC (1,3 million euro) in the second half of the year.	**N/A**

ANNEX II

European Chemicals Agency (Helsinki)

Competencies 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 the 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 the 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 the 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 when it enters into operation in 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. **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. **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, upon a recommendation from the Council (Article 97(10) of the REACH Regulation).

Resources made available to the Agency in 2013 *(2012)*	**Budget (including amending budgets)**
	
	− 107,7 *(98,9)* million euro, including:
	  − Revenue from fees: 86,1 *(26,6)* million euro;
	  − Union contribution: 8,6 *(4,9)* million euro to support the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (6,1 million euro) and the balancing contribution (0,9 million euro), Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (1,5 million euro) and the instrument for pre-accession – IPA (0,1 million euro).
	
	Staff at 31 December 2013
	
	− Number of posts in the establishment plan: 503 *(470)*
	− Number of posts occupied: 468 *(447)*
	− Other staff: 95 *(90)* (contract staff and seconded national experts)
	− Total staff: 563 *(506)*, assigned to the following:
	  − Operational tasks: 386 *(352)*;
	  − Administrative and support tasks: 177 *(185)*

Activities and services provided in 2013 *(2012)*	ECHA's Work Program was divided into the following 17 Activities: **Registration, Pre-registration and Data-sharing** − Number of registration dossiers processed: 14 839 *(9 773)* − Number of confidentiality requests assessments completed: 662 *(630)* decisions (positive or negative) out of 860 assessments (initial and final) − Number of inquiries received: 1 903 *(1 632)* − Number of decisions issued on data sharing disputes: 11 *(1)* − Number of substances on which info made public (excluding confidential info): 10 561 *(7 884)* **Evaluation** − Number of compliance checks completed: 637 *(198)* − Number of final decisions on testing proposals: 111 *(171)* **Risk Management** − Number of substances identified for inclusion in the Candidate List: 13 *(67)* − Number of recommendations of substances for inclusion in Authorisation List: 1 *(0)* − Number of restriction dossiers submitted for Commission decision: 2 *(1)* − Number of authorization applications received: 8 *(0)* − Number of notifications of Candidate List substances in articles: 93 *(31)* **Classification and Labelling (C&L)** − Number of C&L notifications received: 6,1 million for over 125 000 substances (out of which almost 116 000 are included in the publicly disseminated notifications) − Number of proposals for harmonised classification and labelling received: 29 *(27)* − Number of requests for alternative names for substances in mixtures received: 28 *(13)* **Advice and assistance** − Number of questions answered by ECHA Helpdesk: 5 975 (includes questions received via the contact forms, during webinars and one-to-one sessions). The ECHA Helpdesk also processed 755 requests-for-action for other units in ECHA which were received from companies via the contact forms. − Number of new guidance documents issued: 1 *(0)* and number of guidance updates issued: 7 *(30)* including 4 *(17)* corrigenda. **Scientific IT Tools** − Completion of REACH-IT preparations for the 2013 deadline. − Development and release of R4BP3 application and Biocides section in Dissemination website for Biocidal Products Regulation. − Further enhancement and releases of IT Tools: IUCLID, CHESAR, Odyssey, RIPE, C&L Inventory. − Release of an IT solution for Member States for single point of access to dossiers and substance data. − Further enlargement of the scope of the disseminated information on substances. − Development of a new application for processing notifications and consents under Prior Informed Consent Regulation. − Further enhancement and releases of the Dossier Evaluation Process and Odyssey, in order to support the achievement of the check objectives for 2013. − Development of a new application designed to support all REACH and CLP internal processes with an integrated case management system supporting the preparation of decisions and records. **Scientific and Technical Advice to EU institutions and bodies** − Contributions provided for the development of new test methods, mainly via the OECD Test Guidelines Programme. − Software on non-test methods procured and made accessible, taking into account scientific developments, expert knowledge build up by training, practical experience and active

exchange with experts outside ECHA. Training events organised in the field of alternatives to testing for in-house and external experts.

- Webinar on "How to ensure the safe use of NM under REACH – Part II: Current best practices for human health and environmental hazard assessment for NM".
- "Assessing human health and environmental hazards of nanomaterials – Best practice for REACH Registrants" report published.
- ECHA input into the establishment of a baseline for the purpose of an impact assessment of possible modifications of REACH Annexes for nanomaterials.
- Draft summary of the main outcomes of the discussions of the Topical Scientific Workshop on Risk Assessment for the Sediment Compartment.
- Co-operation with the IHCP/JRC.

Committees and Forum

- Number of unanimous MSC agreements: 155 *(179)*
- Number of RAC opinions: 41 *(34)*
- Number of SEAC opinions: 3 *(1)*
- Number of advices on restrictions: 6 *(4)*

Board of Appeal

- Number of appeals lodged: 22 *(8)*
- Number of decisions on appeals: 8 *(1)* and Number of procedural decisions:16 *(6)*

Communication

- 4 Stakeholder events organised:
  - 8th REACH&CLP Stakeholders' Day in March (280 on-site + 1 700 online participants),
  - 1st Biocides Stakeholders' Day in June (270 on-site + 1 200 online participants),
  - Accredited Stakeholder Workshop in November (35 participants),
  - Briefing event for new accredited stakeholders (11 participants).
- 15 webinars organised with 2 060 participants.
- Approx. 250 products (online and offline content) published in 23 EU languages.
- Approx. 1 800 updates performed on the website.
- Approx. 1 300 000 website visitors for a total of approx. 3 600 000 visits.
- 53 publications.
- 45 press releases produced, 2 e-press briefings and 71 interviews with media organised.
- 50 news alerts, 51 e-News bulletins, 6 newsletters, 503 Tweets.
- 6 bi-monthly e-bulletins published for accredited stakeholders.
- 449 internal news items, 50 internal news summaries.
- 4 quarterly Staff Assemblies organised, 3 ED Breakfast meetings with ECHA staff and the Executive Director.

International 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, including IQMS.

Finance, Procurement and Accounting

- Rigorous budget and cash reserve management.
- ECHA procured scientific, IT and administrative services under its existing Framework Contracts; successfully concluded open calls for tenders for the establishment of new Framework Contracts for a human resources (HR) integrated management system, for phase 3 of the QSAR toolbox and for travel and medical services; carried out an audit to increase efficiency in its procurement and contract management processes that resulted in

	planned actions to be implemented in 2014. − Total number of companies verified regarding SME status: 516. **Human resources and corporate services** − 27 *(23)* selection procedures finalised; 87 *(65)* staff members recruited (TA and CA). **Information and Communication Technology** − 67 services defined and maintained to provide the ICT infrastructure and keep ICT resources operational and at the appropriate level of performance. − Continued identification and establishment of HA solutions in compliance with BCP requirements. − Successful outsourcing of management and hosting of several IT Systems. − Migration of 700 workstations to provide a more mobile, secure and feature-rich solution. − Implementation of a Record Management System based on the records relating to the Secretariat of the Management Board, the planning, monitoring and review process and the Director's coordination meetings. − Framework contract concluded for a Human Resources Management System based on a hosted software package; implementation begun. − Identity Management System implemented providing increased user-management efficiency among systems with automated provisioning and de-provisioning of users **Biocides** − Analysis, design and implementation of the Register for Biocidal Products (R4BP): 1 release on 1.9.2013. − First key guidance documents finalised and published in 2013: *Guidance for Human Health Risk Assessment, Guidance on data sharing, Guidance on applications for technical equivalence, Guidance on information requirements and Guidance on active substance suppliers.* − 1 preliminary work plan for the Biocidal Products Committee. − Member States appointed Members for the Coordination Group. **PIC** − Preparatory activities.

Source: Annex supplied by the Agency.

THE AGENCY'S REPLY

Para 11:

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

Para 12:

In response to the European Court of Auditors' observation made during the autumn 2013 mission, the Executive Director of the European Chemicals Agency included the following text in his Declaration of Assurance for 2013:

"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."