COUNCIL OF THE EUROPEAN UNION

Brussels, 26 November 2013 (OR. en)

16500/13

FIN 798

COVER NOTE

From:	Mr Vítor CALDEIRA, President of the European Court of Auditors
date of receipt:	22 October 2013
To:	Mr Linas LINKEVICIUS, President of the Council of the European Union
Subject:	Report on the annual accounts of the European Chemicals Agency for the financial year 2012 together with the Agency's replies

Delegations will find attached the European Court of Auditors' report on the annual accounts of the European Chemicals Agency for the financial year 2012.

This report is accompanied by the Agency's replies and will shortly be published in the *Official Journal of the European Union*.

Encl.: Report on the annual accounts of the European Chemicals Agency for the financial year 2012 together with the Agency's replies.[1]

[1] In English only. The other languages of this report are available on the European Court of Auditors' website: http://eca.europa.eu/.

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
EUROPOS AUDITO RŪMAI

EURÓPAI SZÁMVEVŐSZÉK
IL-QORTI EWROPEA TAL-AWDITURI
EUROPESE REKENKAMER
EUROPEJSKI TRYBUNAŁ OBRACHUNKOWY
TRIBUNAL DE CONTAS EUROPEU
CURTEA DE CONTURI EUROPEANĂ
EURÓPSKY DVOR AUDÍTOROV
EVROPSKO RAČUNSKO SODIŠČE
EUROOPAN TILINTARKASTUSTUOMIOISTUIN
EUROPEISKA REVISIONSRÄTTEN

Report on the annual accounts of the European Chemicals Agency for the financial year 2012

together with the Agency's replies

12, RUE ALCIDE DE GASPERI
L - 1615 LUXEMBOURG
TELEPHONE (+352) 43 98 – 1
TELEFAX (+352) 43 93 42
E-MAIL: eca-info@eca.europa.eu
INTERNET: http://eca.europa.eu

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 2012, and

---

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. In accordance with Articles 33 and 43 of Commission Regulation (EC, Euratom) No 2343/2002[5], 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:

(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.

---

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

[5] OJ L 357, 31.12.2002, p. 72.

[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.

(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 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

[7] Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002 (OJ L 248, 16.9.2002, p. 1).

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.

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 2012 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 2012 are legal and regular in all material respects.

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

COMMENTS ON INTERNAL CONTROLS

11. 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.

COMMENTS ON BUDGETARY MANAGEMENT

12. 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.

FOLLOW-UP OF PREVIOUS YEAR'S COMMENTS

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

This Report was adopted by Chamber IV, headed by Dr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 9 July 2013.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

ANNEX I

Follow-up of previous year's 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.	**Ongoing**
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.	**Ongoing**
2011	The Agency records costs related to ICT projects that are already in use as expenditure instead of recognising them as fixed assets.	**Completed**
2011	The Court identified shortcomings in the recruitment procedures. There is no evidence that thresholds for passing the various stages of the procedures or questions for interviews or written tests were set before the examination of applications. Declarations of interests were inadequate to detect and prevent conflict of interests of members of the selection board. In one case the selection procedure was irregular since the agent was recruited for a post different from the one published.	**Completed**

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), 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). – 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 when it enters into operation. – To implement tasks under the PIC ('Prior Informed Consent') Regulation when it enters into operation.
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 76(1)(c-e) of the REACH Regulation. **Forum for Exchange of Information on Enforcement** *Tasks* Article 76(1)(f) of the REACH Regulation. **Secretariat** *Tasks* Article 76(1)(g) 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 recommendation from the Council (Article 97(10) of REACH Regulation.

Resources made available to the Agency in 2012 *(2011)*	**Budget (including amending budgets)**
	
	− 98,9 *(93,2)* million euro, including:
	
	  − Revenue from fees: 26,6 *(33,5)* million euro;
	
	  − Union contribution: 4,9 *(0,0)* million euro to support the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (3,2 million euro), 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 (1,5 million euro) and the instrument for pre-accession – IPA (0,2 million euro).
	
	Staff at 31 December 2012
	
	− Number of posts in the establishment plan: 470 *(456)*
	
	− Number of posts occupied: 447 *(441)*
	
	− Other staff: 65 *(90)* (contract staff and seconded national experts)
	
	− Total staff: 506 *(537),* assigned to the following:
	
	  − Operational tasks: 352 *(333)*;
	
	  − Administrative and support tasks: 185 *(173)*

Activities and	ECHA's Work Program was divided into the following 16 Activities:

services provided 2012 *(2011)*	**Registration, Pre-registration and Data-sharing** – Number of registration dossiers processed: 9 773 *(6 100)* – Number of confidentiality requests assessments completed: 871 *(630)* [note: 639 *(229)* confidentiality requests in accordance with Article 119(2)] – Number of inquiries received: 1 632 *(1 970)* – Number of decisions issued on data sharing disputes: 1 *(3)* – Number of substances on which info made public (excluding confidential info): 7 884 *(4 100)* **Evaluation** – Number of compliance checks completed: 198 *(146)* – Number of final decisions on testing proposals: 171 *(22)* **Risk Management** – Number of substances identified for inclusion in the Candidate List: 67 *(28)* – Number of recommendations of substances for inclusion in Authorization List: 0 *(1)* – Number of restriction dossiers submitted for Commission decision: 1 *(4)* – Number of authorization applications received: 0 *(0)* – Number of notifications of Candidate List substances in articles: 31 *(203)* **Classification and Labelling (C&L)** – Number of C&L notifications received: 5,7 million for over 120 000 substances – Number of proposals for harmonized classification and labeling received: 27 *(56)* – Number of requests for alternative names for substances in mixtures: 13 *(0)* **Advice and assistance** – Number of questions answered by helpdesk: 5 684 – Number of new guidance documents issued: 0 *(3)* and no. of guidance updates issued: 30 including 17 corrigenda *(14)* **Scientific IT Tools** – REACH-IT modifications for the 2013 deadline. – Further enhancement and release of IT Tools: IUCLID, CHESAR, Odyssey. – IT solutions for Member States to access dossier and substance data. – Further enlargement of the scope of the disseminated information on substances. – Release and maintenance of the C&L Inventory. – Development of a C&L platform for collaboration. – Release of IT workflow support for the evaluation processes. **Scientific and Technical Advice to EU institutions and bodies** – Contract signed to support further development of risk assessment methodologies for 'complex' substances. – Computational methods are routinely applied in support of the different processes. – First GAARN (Group Assessing Already Registered Nanomaterials) meeting organized. – Publication of "Best Practices on physicochemical and substance identity information for nanomaterials" and other guidance documents updated. – OECD expert meeting hosted where testing strategy for skin irritants was drafted. – Contributions provided to the development of core genotoxicity test methods provided for in REACH ITS (Integrated Test Strategy) and to the work of PARERE (Preliminary Analysis of

Regulatory Relevance).

Committees and Forum

- Number of unanimous MSC agreements: 179 *(2)*
- Number of RAC opinions: 34 *(36)*
- Number of SEAC opinions: 1 *(0)*

Board of Appeal

- Number of appeals lodged: 8 *(6)*
- Number of decisions on appeals:1 *(6)* and Number of procedural decisions: 6 *(10)*

Communication

- 4 Stakeholder events organized:
  - 1st Lead Registrant Workshop in February (74 + 175 via web-stream),
  - 2nd Lead Registrant Workshop in October (76 + 200 via web-stream),
  - 7th Stakeholders' Day in May (287 external participants + 353 via web-stream),
  - Accredited Stakeholder Workshop in November (21 participants).
- 16 webinars organized with 2 999 participants.
- 276 documents translated.
- 92 publications.
- 39 press releases, 62 news alerts, 6 newsletters.
- 3 million website visitors.

International Cooperation

- Scientific and technical cooperation with OECD (e.g. ChemPortal; QSAR Toolbox).

Management

- Continued development and improvement of administrative and management systems, including IQMS.

Finance, Procurement and Accounting

- Rigorous budget and cash reserve management.
- High number of procurement actions undertaken, e.g. to establish a new generation of framework contracts for IT services and framework contracts in the areas of scientific services, communication and administrative services.
- Total number of companies verified regarding SME status: 315.

Human resources and corporate services

- 23 *(24)* selection procedures finalized; 65 (*93*) staff members recruited (TA and CA).

Information and Communication Technology

- Provision of services to keep the ICT infrastructure and ICT resources operational and at the appropriate level of performance.
- Establishment of a Business Continuity solution for mission-critical IT systems leveraging on the outsourced hosting services.
- Deployment of a time recording system.
- Migration of all the workstations software to update versions.

Biocides

- Analysis, design and implementation of the Register for Biocidal Products (R4BP).
- First draft key guidance documents developed.
- Preliminary work plan for the Biocidal Products Committee.

	– Member States have been invited to appoint Members, provide the Chair and Secretariat for the new Committee and undertake preparations for the Coordination Group. **PIC** – Preparatory activities.

Source: Information supplied by the Agency.