



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 4 December 2012**

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**COVER NOTE**

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from: Mr Vítor CALDEIRA, President of the Court of Auditors  
date of receipt: 31 October 2012  
to: Mrs Erato KOZAKOU-MARCOULLIS, President of the Council of the  
European Union

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Subject: Report on the annual accounts of the European Chemicals Agency for the  
financial year 2011 together with the Agency's replies

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Madam,

I enclose in all the official languages of the European Union a copy of the Court of Auditors' report on the annual accounts of the European Chemicals Agency for the financial year 2011.

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

(Complimentary close).

(s.) Vítor CALDEIRA

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Encl.: Report on the annual accounts of the European Chemicals Agency for the financial year 2011 together with the Agency's replies.

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



CORTE DEI CONTI EUROPEA  
EIROPAS REVĪZIJAS PALĀTA  
EUROPOS AUDITO RŪMAI

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EUROPEISKA REVISIONSRÄTTEN

Report on the annual accounts  
of the European Chemicals Agency  
for the financial year 2011

together with the Agency's replies

## **INTRODUCTION**

1. The European Chemicals Agency (hereinafter "the Agency" or "ECHA"), which is located in Helsinki, was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>1</sup>. 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 their own, in preparations and in articles, while enhancing competitiveness and innovation. The Agency also promotes the development of alternative methods for the assessment of hazards relating to substances<sup>2</sup>.

## **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, the Court has audited the annual accounts<sup>3</sup> of the Agency, which comprise the "financial statements"<sup>4</sup> and the "reports on the

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> The ***Annex*** summarises the Agency's competences and activities. It is presented for information purposes.

<sup>3</sup> These accounts are accompanied by a report on the budgetary and financial management during the year which gives further information on budget implementation and management.

<sup>4</sup> The financial statements 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.

implementation of the budget”<sup>5</sup> for the financial year ended 31 December 2011, and the legality and regularity of the transactions underlying those accounts.

#### The Management’s responsibility

4. As authorising officer, the Director implements the revenue and expenditure of the budget in accordance with the financial rules of the Agency, under his own responsibility and within the limits of the authorised appropriations<sup>6</sup>. The Director is responsible for putting in place<sup>7</sup> the organisational structure and the internal management and control systems and procedures relevant for drawing up final accounts<sup>8</sup> that are free from material misstatement, whether due to fraud or error, and for ensuring that the transactions underlying those accounts are legal and regular.

#### The Auditor’s responsibility

5. The Court’s responsibility is to provide, on the basis of its audit, the European Parliament and the Council<sup>9</sup> with a statement of assurance as to the reliability of the annual accounts of the Agency and the legality and regularity of the transactions underlying them.

6. The Court conducted its audit in accordance with the IFAC International Standards on Auditing and Codes of Ethics and the INTOSAI International

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<sup>5</sup> The budget implementation reports comprise the budget outturn account and its annex.

<sup>6</sup> Article 33 of Commission Regulation (EC, Euratom) No 2343/2002 (OJ L 357, 31.12.2002, p. 72).

<sup>7</sup> Article 38 of Regulation (EC, Euratom) No 2343/2002.

<sup>8</sup> The rules concerning the presentation of the accounts and accounting by the Agencies are laid down in Chapters 1 and 2 of Title VII of Regulation (EC, Euratom) No 2343/2002 as last amended by Regulation (EC, Euratom) No 652/2008 (OJ L 181, 10.7.2008, p. 23) and are integrated as such in the Financial Regulation of the Agency.

<sup>9</sup> Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002.

Standards of Supreme Audit Institutions. These standards require that the Court plans and performs the audit to obtain reasonable assurance as to whether the annual accounts of the Agency are free of material misstatement and the transactions underlying them are legal and regular.

7. An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and regularity of the transactions underlying them. The procedures are selected based on the auditor's judgment, including an assessment of the risks of material misstatement of the accounts and of material non-compliance of the underlying transactions with the requirement of the legal framework of the European Union, whether due to fraud or error. In assessing those risks, the auditor considers internal controls relevant to the preparation and fair presentation of the accounts and supervisory and control systems implemented to ensure the legality and regularity of underlying transactions, in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the accounts.

8. The Court considers that the audit evidence obtained is sufficient and appropriate to provide a basis for the opinions set out below.

#### ***Opinion on the reliability of the accounts***

9. In the Court's opinion, the Agency's Annual Accounts<sup>10</sup> present fairly, in all material respects, its financial position as of 31 December 2011 and the results of its operations and its cash flows for the year then ended, in accordance with

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<sup>10</sup> The Final Annual Accounts were drawn up on 19 June 2012 and received by the Court on 28 June 2012. The Final Annual Accounts, consolidated with those of the Commission, are published in the Official Journal of the European Union by 15 November of the following year. These can be found on the following website <http://eca.europa.eu> or <http://echa.europa.eu>.

the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer<sup>11</sup>.

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

10. In the Court's opinion, the transactions underlying the annual accounts of the Agency for the financial year ended 31 December 2011 are legal and regular in all material respects.

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

**COMMENTS ON BUDGETARY AND FINANCIAL MANAGEMENT**

12. The Agency's 2011 budget amounted to 93,2 million euro, of which 14,9 million euro (16 %) were carried over to 2012. Carryovers related to Title III (operational expenditure) amounted to 11,5 million euro (55 %). The level of carryovers is excessive and at odds with the budgetary principle of annuality.

**COMMENTS ON KEY CONTROLS OF THE AGENCY'S SUPERVISORY AND CONTROL SYSTEMS**

13. 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.

14. The Agency records costs related to ICT projects that are already in use as expenditure instead of recognising them as fixed assets.

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<sup>11</sup> The accounting rules adopted by the Commission's accounting officer are derived from International Public Sector Accounting Standards (IPSAS) issued by the International Federation of Accountants or, in their absence, International Accounting Standards (IAS)/International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board.

**OTHER COMMENTS**

15. 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.

16. The Court carried out an audit aimed at evaluating the policies and procedures for the management of conflict of interest situations for four European Agencies, including ECHA. The results of the audit are presented in a separate document (Special Report 15/2012).

This Report was adopted by Chamber IV, headed by Dr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 5 September 2012.

*For the Court of Auditors*

Vítor Manuel da SILVA CALDEIRA  
*President*

**European Chemicals Agency (Helsinki)****Competencies and activities**

<b>Areas of Union competence deriving from the Treaty</b>	<b>Collection of information</b> <ul style="list-style-type: none"> <li>- 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.</li> </ul>
<b>Competences of the Agency</b>  <i>(as defined in Regulation (EC) No 1907/2006 (REACH Regulation) and Regulation (EC) No 1272/2008 (Classification, labelling and packaging of substances and mixtures))</i>	<b>Objectives</b> <ul style="list-style-type: none"> <li>- 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).</li> <li>- 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 (Art 75 of the REACH Regulation) and to manage tasks related to the classification and labelling of chemical substances deriving from the CLP Regulation.</li> </ul> <b>Tasks</b> <ul style="list-style-type: none"> <li>- Receive registrations and other dossiers of chemical substances and undertake a completeness check thereof (Title II of the REACH Regulation).</li> <li>- Process inquiries regarding the registrations and take decisions on data sharing disputes (Title III of the REACH Regulation).</li> <li>- 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).</li> <li>- Process proposals of substances of very high concern for the Candidate List and make recommendations for some of these substances to be included on the Authorisation List and handle authorisation applications (Title VII of the REACH Regulation).</li> <li>- Process restriction dossiers (Title VIII of the REACH Regulation).</li> <li>- Establish and maintain public database(s) with information on all registered substances and make certain information publicly available over the Internet (Art 77, 119 of the REACH Regulation).</li> <li>- Provide technical and scientific guidance and tools where appropriate (Art 77 of the REACH Regulation, Article 50(2) of CLP Regulation).</li> <li>- 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).</li> <li>- Receive C&amp;L notifications, maintain a public C&amp;L inventory, handle requests for alternative names and process proposals for the harmonised classification and labelling of substances (CLP).</li> </ul>
<b>Governance</b>	<b>Management Board</b> 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. (Art 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 of the Executive Director. In addition, the appointment of the Board of Appeal and Committee members.  <b>Executive Director</b> Tasks: Art 83 of the REACH Regulation.  <b>Committees</b> ECHA comprises three Scientific Committees (Risk Assessment, Member States and Socio-Economic Analysis) Tasks: Article 76(1) (c-e) of the REACH Regulation.  <b>Forum for Exchange of Information on Enforcement</b> Tasks: Article 76(1) (f) of the REACH Regulation.  <b>Secretariat</b> Tasks: Article 76(1) (g) of the REACH Regulation.  <b>Board of Appeal</b> Tasks: Article 76(1) (h) of the REACH Regulation.  <b>External audit</b> Court of Auditors.  <b>Internal Audit</b> Internal Audit Service of the Commission (IAS).  <b>Discharge authority</b> European Parliament upon recommendation from the Council (Art. 97(10) of REACH Regulation.

<b>Resources made available to the Agency in 2011 (2010)</b>	<p><b>Budget (including amending budgets)</b></p> <ul style="list-style-type: none"> <li>- 93,2 (75,5) million euro, including: <ul style="list-style-type: none"> <li>- Revenue from fees: 33,5 (35,0) million euro</li> <li>- Union contribution: 0,0 (36,0) million euro</li> </ul> </li> </ul> <p><b>Staff at 31 December 2011</b></p> <ul style="list-style-type: none"> <li>- No. of posts in the establishment plan: 456 (426)</li> <li>- No. of posts occupied: 441 (382)</li> <li>- Other staff: 101 (90) (Contract agents and seconded national experts)</li> <li>- Total staff number: 542 (472) assigned to the following: <ul style="list-style-type: none"> <li>- Operational tasks: 443 (341);</li> <li>- Administrative and support tasks: 99 (131)</li> </ul> </li> </ul>
<b>Activities and services provided 2011 (2010)<sup>1</sup></b>	<p>ECHA's Work Programme was divided into the following 15 Activities:</p> <p><b>Registration, Pre-registration and Data-sharing</b></p> <ul style="list-style-type: none"> <li>- No of registration dossiers (exc. PPORDs) processed, inc. 2010 carry over : 6 100 (24 000)</li> <li>- No of confidentiality requests assessments completed: 630</li> <li>- No of inquiries received: 1970 (1 600)</li> <li>- No of decisions issued on data sharing disputes: 3 (6)</li> <li>- No of substances on which info made public (exc. confidential info): 4100 (400) 24000 dossiers</li> </ul> <p><b>Evaluation</b></p> <ul style="list-style-type: none"> <li>- No of compliance checks completed: 146 (70)</li> <li>- No of final decisions on testing proposals: 22 (4)</li> </ul> <p><b>Authorisation and restrictions</b></p> <ul style="list-style-type: none"> <li>- No of substances identified for inclusion in the Candidate List: 28 (16)</li> <li>- No of recommendations of substances for inclusion in Authorisation List: 1 (1)</li> <li>- No of restriction dossiers submitted for Commission decision: 4 (0)</li> <li>- No of authorisation applications received: 0 (0)</li> <li>- No of notifications of Candidate List substances in articles: 203 (0)</li> </ul> <p><b>Classification and Labelling (C&amp;L)</b></p> <ul style="list-style-type: none"> <li>- No of C&amp;L notifications received: 3,4 million for over 110 000 substances</li> <li>- No of proposals for harmonised classification and labeling received: 56 (81)</li> <li>- No of requests for alternative names for substances in mixtures: 0 (0)</li> </ul> <p><b>Advice and assistance</b></p> <ul style="list-style-type: none"> <li>- No of questions answered by helpdesk: 5 400 (10 000)</li> <li>- No of new guidance documents issued: 3 (2) and no. of guidance updates issued: 14 (12)</li> </ul> <p><b>IT Support to operations</b></p> <ul style="list-style-type: none"> <li>- Further development of REACH-IT and other scientific IT systems</li> </ul> <p><b>Scientific and Practical Advice for the further development of legislation</b></p> <ul style="list-style-type: none"> <li>- At the request of the European Commission, contributions on nanomaterials and to OECD program on test guidelines and to the proposal on Biocides Regulation</li> <li>- Delivery of first reports under REACH Arts. 117(2) and (3)</li> </ul> <p><b>Committees and Forum</b></p> <ul style="list-style-type: none"> <li>- No of unanimous MSC agreements: 70 (26)</li> <li>- No of RAC opinions: 36 (16)</li> <li>- No of SEAC opinions: 4 (0)</li> </ul> <p><b>Board of Appeal</b></p> <ul style="list-style-type: none"> <li>- No of appeals lodged: 6 (1)</li> <li>- No of decisions on appeals: 2 (0) and No of procedural decisions: 10 (1)</li> </ul> <p><b>Communication</b></p> <ul style="list-style-type: none"> <li>- 1 (2) Stakeholder Day with 430 (700) participants</li> <li>- 135 (3000) participants in lead registrant webinars</li> <li>- 70 (60) publications; 1 500 (2 300) pages translated into EU 21 languages</li> <li>- 2,9 million (2,5 million) website visits from 200 (200) countries</li> </ul> <p><b>Relations with EU Institutions and International Cooperation</b></p> <ul style="list-style-type: none"> <li>- Scientific and technical cooperation with OECD e.g. eChemPortal; QSAR Toolbox)</li> </ul> <p><b>Management</b></p> <ul style="list-style-type: none"> <li>- Continued development and improvement of administrative and management systems, inc. IQMS</li> </ul> <p><b>Finance, Procurement and Accounting</b></p> <ul style="list-style-type: none"> <li>- Rigorous budget and cash reserve management including repayment of EU subsidy received in 2010</li> <li>- Total number of companies verified regarding SME status: 245</li> </ul> <p><b>Human resources and infrastructure</b></p> <ul style="list-style-type: none"> <li>- 24 (35) selection procedures finalized; 93 (121) staff members recruited (TA and CA)</li> </ul> <p><b>Informatics and Communication Technology</b></p> <ul style="list-style-type: none"> <li>- Maintenance of ICT; provision of new workspaces to new staff</li> </ul>

Source: Information supplied by the Agency.

<sup>1</sup>

Where appropriate, figures have been rounded up/down to the nearest 10, 100, or 1000.

## **THE AGENCY'S REPLY**

12 ECHA achieved its work programme objective on carryover in 2011. The Agency will re-assess its carryover policy in 2012 and establish a more rigorous motivation and limitation on possible carryovers to the financial year 2013.

13. ECHA fully acknowledges the importance of the accuracy of the physical inventory. The Agency will formalise its fixed asset management policy in 2012, while due attention will be given to the physical check at year end.

14. ECHA will further develop the method to capitalise the costs for internally developed software, and capitalise them at the level of the different software versions. The approach will be closely linked and integrated with the ongoing cost accounting project.

15. ECHA is fully committed to the principles of transparency and equal opportunity in its recruitment and selection procedures. ECHA has conducted a review of its recruitment procedure, including the declarations of interests, with the aim to further improve them and to ensure adherence to best practice. The resulting update of the procedures took into account the points raised by the Court of Auditors. In the meantime, the referred agent has been moved to a post equivalent to one published.

16. The Agency's replies will be published together with the Court's Special Report (15/2012).