

Helsinki, 25 March 2011

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**ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT  
OF THE AUTHORISING OFFICER FOR THE YEAR 2010**

THE MANAGEMENT BOARD,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006,

Having regard to the Financial Regulation of the European Chemicals Agency (MB/53/2008) and in particular Article 40 thereof,

Having regard to the Work Programme of the European Chemicals Agency for the year 2010 adopted by the Management Board at its meeting of 29 September 2009 and updated on 17 December 2009,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2010 as submitted to the Board on 14 March and subject to the signing of the declaration of assurance,

1. Welcomes the results presented in the Annual Activity Report of the Authorising Officer as well as the performance level achieved with regard to discharging the tasks under the REACH Regulation (EC) 1907/2006 and the CLP Regulation (EC) No 1272/2008.
2. Congratulates the ECHA Secretariat for the operational work performed in 2010 and, in particular, for the achievements in:
  - (a) Rising to the challenge of processing almost 25 000 registrations covering some 4 300 distinct substances by the first registration deadline, despite the uncertainties that prevailed on the number of registration dossiers expected; planning and preparing well for this major milestone in the implementation of the REACH Regulation and having its staff, procedures, IT tools and support to registrants in place to allow smooth registration with very few rejections and consequently almost no appeals launched.
  - (b) Processing over 3.1 million CLP notifications covering over 107,000 different substances by the 3 January 2011 deadline, which exceeded expectations by 50%.
  - (c) Re-engineering REACH-IT and IUCLID5 to obtain efficiency gains for the registrants and the Agency, including improved functionalities; developing IUCLID

plug-in tools to allow companies to check completeness of dossiers before submission, the information which will be disseminated on the ECHA website and to verify their invoice before submitting the dossier; publishing CHESAR, the ECHA tool for chemical safety assessment and reporting ahead of the registration deadline.

(d) Supporting industry in building up capacity to submit complete registration and notification dossiers via various communication tools in the form of webinars and targeted materials in 22 EU languages.

(e) Investing substantial work and resources in providing direct support to registrants via the helpdesk and in producing updated and new guidance documents for industry and making a substantial number of these available in 22 EU languages well ahead of the registration deadline.

(f) Publishing detailed instructions for data sharing and setting up procedures for settling data sharing disputes as data sharing in SIEFs posed a major challenge to industry, contributing to a low number of notified disputes; also, putting potential and previous registrants of the same substance in contact, as the number of inquiries peaked ahead of the registration deadline.

(g) Defining the strategy for dissemination, publishing information on 383 substances on the dissemination portal and starting the assessment of confidentiality claims.

(h) Rapidly building up capacities in relation to the evaluation tasks with a focus on setting up small multidisciplinary teams to ensure efficient dossier evaluation of a high number of registrations coming from the first registration deadline.

(i) Completing two updates of the Candidate List of Substances of Very High Concern, adding 16 substances to the Candidate List, bringing thereby the total number of substances on the List to 46; submitting to the Commission its second recommendation for inclusion of a further 8 priority substances in the Authorisation List and submitting 4 restriction dossiers to RAC and SEAC for opinion, of which one proposal was developed by ECHA on request of the Commission.

(j) Concluding the first cooperation agreements with third countries (Canada and the US) and assisting the Commission effectively in international chemicals work undertaken by OECD and the UN.

3. Notes the high quality of the scientific advice provided by the Agency on request by the Commission, in particular in relation to the first reading of a legislative proposal for a regulation on biocidal products, the technical work on developing a regulatory framework for chemical substances on nano-scale and on alternative testing methods that may reduce the use of test animals.

4. Welcomes that the scientific Committees work transparently and involve observers from stakeholder organisations and that these observers and case owners will now have the opportunity to attend the Member State Committee discussions on draft decisions on dossier evaluation; also, commends the Committees in finding in all instances unanimous agreements and RAC in arriving at 15 opinions on harmonised classification and labelling proposals; encourages RAC to further ensure the participation of observers from any sector affected by a particular C&L proposal for harmonisation.

5. Notes the progress in revising the stakeholder policy, which is sent to the Commission for agreement.
6. Supports the management in its commitment taken during the adoption process of the 2011 Work Programme to conduct a feasibility and needs assessment with regard to enhancing SME accessibility to communication with the Agency, including via REACH-IT, in different languages.
7. Acknowledges the work of the Board of Appeal and its Registry to establish an effective and efficient appeals procedure through the adoption of the necessary implementing rules, the creation of helpful guidance in 22 languages and the development of internal quality tools.
8. Appreciates the Agency's substantial recruitment efforts, managing a notable increase of staff compared to the year before by recruiting more than 120 staff members.
9. Acknowledges the Agency's efforts to put the necessary procedures and staff in place to be able to cash fee incomes of € 349.7 million, but also appreciates the Commission's temporary 2010 subsidy, which was not fully used but helped to bridge the many months when fee revenue was below payments.
10. Notes that 2010 was an unusual budgetary year for the Agency due to the uncertainties attached to the size and timing of fee income and therefore understands the need for prudent budgeting and the timely planning of two budget reductions.
11. Highly welcomes the Agency's choice to accept or organise three important audits on registration-related topics and its responsiveness to the results of these audits, and acknowledges the further development of an Integrated Quality Management System, while stressing the need for balancing between the flexibility of procedures and the need for proper documenting of the processes.
12. Welcomes the efforts undertaken towards addressing business continuity issues, especially with a view to ensuring the success of the first registration deadline by developing and putting into place a back-up system for REACH-IT.
13. Appreciates the Agency's endeavour to successfully resolve the difficulties related to the access of Member State authorities to the REACH-IT system; also appreciates the implementation of a strong protection of physical and information security, and encourages the Agency to further improve the user-friendliness of the access to dossier information.
14. Notes the Agency's efforts in providing more detailed multi-annual planning of its activities and its commitment to revise the Commission's staff and finance model of the Agency.

15. Strongly appreciates the efforts of management and the entire staff in achieving the ambitious goals set by the regulations; also takes note of the high levels of stress measured due to the heavy workload and therefore encourages the Agency in identifying and resolving the main factors behind this problem, as it is key to maintaining high staff morale and retaining the highly qualified staff.

Helsinki, 25 March 2011

*signed*  
For the Management Board  
Thomas JAKL