

## ASSESSMENT OF THE CONSOLIDATED ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2014

## THE MANAGEMENT BOARD,

- Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),
- Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP),
- Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR),
- Having regard to Regulation (EU) 649/2012 of the European Parliament and of the Council of 04 July 2012 concerning the Prior Information Consent on the export and import of hazardous chemicals (PIC),
- Having regard to the Financial Regulation of the European Chemicals Agency (MB/WP/03/2014), and in particular Article 47 thereof (ECHA FR),
- Having regard to the Work Programme of the European Chemicals Agency for the year 2014 adopted by the Management Board at its meeting of September 2013,

Having regard to the Consolidated Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2014 as submitted to the Board on 19 March 2015.

## WHEREAS,

The authorising officer shall report to the Management Board on the performance of his duties in the form of a consolidated annual activity report, containing information on the implementation of the Agency's annual work programme in line with the Multi-Annual Work Programme, budget and staff resources, management and internal control systems, audits and the actions taken on those, budgetary and financial management, confirming that the information contained in the report presents a true and fair view except as otherwise specified in any reservations related to defined area of revenue and expenditure,

By no later than 1 July each year, the Management Board shall send to the Commission, Parliament, Council and the Court of Auditors an assessment of the consolidated annual activity report on the previous financial year. This assessment shall be included in the annual report of the Agency, in accordance with the provisions of REACH.

## HAS ADOPTED THE FOLLOWING ASSESSMENT:

1. Welcomes the results presented in the Consolidated Annual Activity Report of the Authorising Officer as well as the high performance level achieved with regard to discharging the tasks under REACH and CLP. This is reflected in the fact that 45 out of the 50 performance targets set in the Work Programme 2014 were met. Satisfaction was medium in two of the 18 areas measured. Legal deadlines were missed in a handful of cases. More decisions than planned on reprotoxicity were sent for decision to the Commission due to a lack of unanimous agreements in the Member States Committee.



- 2. Appreciates ECHA's strategic and operational work performed in 2014 and, in particular, the achievements in:
  - a. Developing the strategic vision of ECHA 2020 as a lean public organisation fully focused on delivering operational and effective regulatory work in line with its founding legislations, and demonstrating its added value to the European citizens,
  - b. Starting the implementation of the first two projects under the Efficiency programme to be able to cope with staff reductions as required from all EU agencies while facing increased workload.
  - c. Developing the models and implementing the first measurements of the ECHA's four strategic objectives indicating progress towards their achievement.
  - d. Getting certified against ISO 9001:2008 Quality Management Standard.
  - e. The smooth entry into operation of PIC in March 2014 and the successful hand over of PIC operations from the Joint Research Centre.
  - f. Establishing the 2018 registration deadline roadmap based on an extensive stakeholder consultation and launching the new REACH 2018 webpages designed from a small and medium sized enterprise (SME) point of view.
  - g. Continuing to make the information on the chemicals registered or notified publicly available, in particular from all dossiers registered by the 2013 deadline.
  - h. Instigating the improvement of substance identification in dossiers via a letter campaign, resulting in a large number of updates, and including the substance identification checks in the Validation Assistant tool.
  - i. Promoting the development of best practice on exposure scenarios and aimed at making safety data sheets clearer and understandable by downstream users.
  - j. Meeting the annual targets for dossier evaluations, including the conclusion of 224 testing proposals, 283 compliance checks and 282 follow-up evaluations.
  - k. Updating the Community rolling action plan for substance evaluation, including 68 new substances for 2014-2016, and preparing the draft of the next Community Rolling Action Plan update with up to 75 newly selected substances for 2015-2016.
  - I. Supporting Member States in the evaluations of substances and leading to 24 decisions that received agreement in the Member States Committee and 9 conclusion documents.
  - m. Adding 10 Substances of Very High Concern (SVHCs) to the Candidate List bringing the total number of substances on the Candidate List to 161 by the end of the year.
  - n. Finalising the fifth recommendation for inclusion of a further five priority substances in the authorisation list and preparing the sixth recommendation.
  - o. Continuing the implementation of the SVHC 2020 Roadmap Implementation Plan.
  - p. Getting the authorisation process to a cruising speed and successfully processing the applications received, including pre-submission support and improved format of public consultations.



- q. Providing support to industry and Member State Competent Authorities on the biocides processes, including further development of dedicated IT tools.
- r. Increasing significantly the number of opinions adopted by ECHA Committees: 5 Committee for Risk Assessment (RAC) and 4 Committee for Socio-Economic Analysis (SEAC) opinions on restriction proposals, 51 RAC opinions of on Harmonised Classification and Labelling proposals and 30 SEAC and RAC opinions on the authorisation applications. Adopting 34 Biocidal Products Committee opinions on applications for approval of active substances under the Review Programme.
- s. Maintaining up-to-date the Classification & Labelling inventory with information on 116 000 substances.
- t. Supporting industry, in particular SMEs, via targeted communication tools in the form of webinars, targeted materials as well as sector-specific support for example for the essential oil and dye industries, where many SMEs are affected by the upcoming registration deadline.
- u. Providing direct support to registrants via the ECHA Helpdesk and in producing updated and new guidance documents for industry and engaging national helpdesks via the HelpNet in this effort.
- v. Achieving a high rate of budget execution of commitment appropriations and in filling the establishment plan posts for temporary agents, both reaching 97% on average for all Regulations.
- 3. Notes the continued high quality of the scientific advice provided by the Agency, in particular in relation to the development of test methods, including alternatives of animal testing, chemical safety assessment, nanomaterials, Persistent, Bioaccumulative and Toxic substances, endocrine disruptors and Commission studies on REACH data requirements.
- 4. Welcomes the Agency's strengthened and continued efforts to improve dossier quality, including the new integrated compliance check strategy, and encouraging registrants to proactively update their dossiers.
- 5. Welcomes the transparency approach adopted by the Management Board (MB/61/2014), hereby also responding to the European Ombudsman's request.
- 6. Welcomes the work of the Secretariat in ensuring and improving the functioning of ECHA Committees, and especially in achieving an increased awareness of resource implications of the Committee membership, and concluding on the improvement actions for the restriction process from the specific task force.
- 7. Welcomes the work of the Forum in harmonising the approach to enforcement, which provides an improved basis for the enforcement of the provisions of REACH, CLP and PIC Regulations, including ECHA's regulatory decisions.
- 8. Notes the continuing efforts in verifying the SME status of registrants and the Agency's response to the Court of Justice case in this regard.
- 9. Notes that the appeal system, with 16 closed cases in 2014, provides effective and efficient legal redress to companies. Notes further the importance to integrate the consequences thereof in ECHA's operational activities and being transparent on that.
- 10. Notes that the Biocides fees were much lower than estimated, thus appreciates the efforts of the Agency to balance the lower income with its expenditure.



- 11. Notes with concern the difficulties of the Agency, in the absence of a financial reserve, to obtain additional subsidy in those years where the financial revenue will be lower than estimated.
- 12. Notes that the revenue from fees and charges under REACH and CLP activities in 2014 amounted to 26 million euro thus exceeding the forecasts.
- 13. Congratulates the Agency on reducing its carry-over rate to below 10% on the average for all Regulations and encourages the Agency to continue its efforts to reduce the carry over where possible.
- 14. Notes the Agency's continuing work to support the access of Member State authorities to ECHA's systems, as well as the secure use of the information in these systems.
- 15. Notes the further progress made in implementing risk management at process level in view of eliminating multiple controls and ensuring both effectiveness and efficiency of the internal control systems in line with Article 30 of ECHA FR.
- 16. Notes the further progress made in the area of fraud prevention by developing the Agency's strategy and action plan as well as in refining its practices on avoiding conflicts of interest.
- 17. Welcomes that ECHA has taken action on the recommendations of the MB in last year's assessment of the annual report:
  - a. New structure for the annual Work Programme 2016 was introduced with a closer link to the Multi-Annual Work Programme.
  - b. RAC and SEAC agreed on a streamlined working procedure for developing and agreeing authorisation opinions.
  - c. REACH and CLP processes have now been documented and audited. The initiation of the Efficiency programme permitted to identify efficiency and synergy gains.
  - d. A simplified guidance in a nutshell document on Scientific Research and Development and Product and Process Orientated Research and Development to support innovation was published.
  - e. User-friendliness of dissemination website was improved.
  - f. Multi-language approach towards SMEs was initiated.
  - g. A proposal made to the Management Board on how to improve substance identity assessment in the completeness check.
  - h. Variety of online material relating to the CLP deadline and 2018 registration section was published, benefitting in particular the SMEs.
  - i. Using the experience gained in data sharing ECHA reinforced advice to companies in particular SMEs, and released guiding documents on cost sharing and Substance Information Exchange Forum management, and supported the Commission in preparing an implementing act on data sharing under REACH and practical guides on data sharing for Biocides.
  - j. Active contribution to the work of the Task Force on simplified approach for special cases by developing simplified formats for the Chemical Safety Report, Analysis of Alternatives and Socio-Economic Analysis thus making the submission of authorisation applications less expensive and lighter for the industry.



- 18. Recommends that ECHA, while facing resource constraints, in 2015:
  - a. Continues active follow up of the implementation of the audit recommendations.
  - b. Further promotes the use of multilingual communication in its communication with companies in particular SMEs.
  - c. Continues identifying synergies within its activities to support companies to promote competitiveness and innovation, within the Agency's remit.
  - d. Continues to support industry to meet their obligations so that substances are safely handled, in particular along the supply chain.
  - e. Continues and strengthens its own work to ensure high dossier quality in a cost efficient and effective manner.
  - f. Reflects, which further actions would be necessary to contribute to achieving the "REACH 2020 goals".
  - g. Supports Member States and encourages them to take up their roles under the legislations and provide adequate resources and expertise.
  - h. Continues implementation of the efficiency programme.

For the Management Board

The Chair

signed Nina CROMNIER