

DECISION OF THE MANAGEMENT BOARD ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2013

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,

Having regard to Regulation (EU) 649/2012 of the European Parliament and of the Council of 04 July 2012 concerning the export and import of hazardous chemicals,

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 2013 adopted by the Management Board at its meeting of 28 September 2012,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2013 as submitted to the Board on 07 March 2014.

WHEREAS,

The authorising officer shall report to the Management Board on the performance of his duties in the form of an annual activity report, together with financial and management information 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 15 June each year, the Management Board shall send the budgetary authority and the Court of Auditors an analysis and an assessment of the authorising officer's annual report on the previous financial year. This analysis and assessment shall be included in the annual report of the Agency, in accordance with the provisions of the Regulation (EC) No 1907/2006.

HAS ADOPTED THE FOLLOWING ANALYSIS AND ASSESSMENT,

- Welcomes the results presented in the Annual Activity Report of the Authorising Officer as well as the high performance level achieved with regard to discharging the tasks under the REACH Regulation (EC) 1907/2006 and the CLP Regulation (EC) No 1272/2008. This is reflected in the fact that 53 out of the 56 performance targets set in the Work Programme 2013 were met.
- 2. CONGRATULATES ECHA for the operational work performed in 2013 and, in particular, for the achievements in:



- a) The successful management of the 2013 REACH registration deadline, the smooth entry into operation of the Biocidal Products Regulation in September 2013 and the preparatory work for the entry into operation of the PIC Regulation in March 2014.
- b) Continuing to make the information on the chemicals registered or notified publicly available, in particular from all dossiers registered by the 2013 deadline. By the end of the year, information from about 40,000 registration dossiers covering more than 10,000 substances was freely available on the ECHA website.
- c) Concluding 928 compliance checks performed on dossiers registered during the first registration deadline of 2010, thereby exceeding the 5% target, adopted in 2013 as a self-commitment.
- d) Updating the Community rolling action plan for substance evaluation, including 36 substances for 2012-2014, supporting Member States in the evaluations of 55 substances and leading to the first decisions that received agreement in the Member States Committee.
- e) Adding 13 Substances of Very High Concern (SVHCs) to the Candidate List bringing the total number of substances on the Candidate List to 151 by the end of the year.
- f) Finalising the fourth recommendation for inclusion of priority substances in the authorisation list and preparing the fifth recommendation.
- g) Providing support to applicants for authorisation by organising 9 pre-submission sessions for companies applying for authorisation and successful handling of the first applications submitted.
- h) Finalising the SVHC 2020 Roadmap Implementation Plan and further developing screening tools to support the Risk Management Option Analysis Approach.
- i) Facilitating the sharing of information between Member States to enhance coordination and cooperation in risk management.
- j) Adopting 2 RAC and 2 SEAC opinions on restriction proposals and adopting 34 opinions of RAC on CLH proposals and 1 SEAC and RAC opinion each on the first authorisation application.
- k) Helping to considerably increase the output of the three committees (RAC, SEAC and MSC), while maintaining quality and respecting the legal deadlines. Establishing and making operational the new Biocidal Products Committee and the Coordination Group.
- Maintaining up-to-date the C&L inventory with a total number of processed notifications since 2010 of 6.1 million, covering 125,000 distinct substances, and having publicly disseminated C&L information for 116,000 substances.
- Supporting industry in building up capacity, particularly for registration and authorisation, via various communication tools in the form of webinars and targeted materials in 23 EU languages.
- n) Taking an important step in designating an "SMEs' Ambassador" to take due account of SMEs efforts and challenges to comply with additional administrative and financial burdens and to provide SMEs with tailored additional support and guidance.
- Providing direct support to registrants via the ECHA Helpdesk and in producing updated and new guidance documents for industry and making a substantial number of these available in 23 EU languages well ahead of the registration deadline; engaging national helpdesks via the Helpnet in this effort.
- p) Putting in place the necessary tools and procedures by 1 September to allow companies to submit their applications under the new Biocidal Products Regulation; providing industry with the necessary guidance and manuals to start implementing



their obligations under that Regulation, and extending both the ECHA Helpdesk and the Helpnet to provide advice also for biocides.

- q) Designing the Efficiency Development programme 2014-2016 to be able to cope with staff reductions as required from all EU agencies while facing growing dossier numbers.
- r) Achieving a high rate of budget execution of commitment appropriations over 98% for all Regulations.
- s) Achieving the recruitment target for all legislations and developing a Staff Retention Policy and an outplacement service.
- 3. Notes the 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, PBT substances and endocrine disruptors.
- 4. Welcomes, that the Agency continues to work transparently, that the committees involve stakeholders and case owners as appropriate and that a workshop with those organisations was held in Brussels to facilitate their input in ECHA's work programmes.
- 5. Welcomes that the Agency took an important step towards an improved dissemination website in response to a stakeholders' survey.
- 6. Welcomes the Agency's strengthened and continued efforts to improve dossier quality, including with regard to intermediates, through the revision of the completness and compliance check strategy and encouraging registrants to proactively update their dossiers.
- 7. Notes that the MSC continued to be unable to reach unanimous agreement on any of the proposals for testing reproductive toxicity and that over 82 dossiers have been referred to the EU Commission last year.
- 8. Welcomes the annual meeting with Directors of MSCAs, as of 20 November 2013, which considerably helps to deliver effective planning.
- 9. Welcomes the work of the Forum in harmonising the approach to enforcement and in particular in concluding the Interlinks project, which provides a basis for the enforcement of regulatory decisions.
- 10. Notes with concern that the final report on the second coordinated enforcement project of the Forum highlighted significant deficiencies with regard to Safety Data Sheets.
- 11. Appreciates the delivery of the first appeal decisions on dossier evaluation of the Board of Appeal.
- 12. Looks forward to being informed of further progress towards ISO 9001:2008 certification, as well as towards meeting the requirements of the Framework Financial Regulation on efficiency and effectiveness of the internal control systems, and in particular the adoption of the Integrated Management Standards and the continuing analysis and management of risks.
- 13. Notes the success of the Agency and its continuing efforts in verifying the SME status of registrants.
- 14. Notes that the revenue from fees and charges under REACH and CLP activities in 2013 amounted to 85.8 million euro thus exceeding the forecasts, and from the Biocidal



Products Regulation activities to 313,000 euro.

- 15. 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.
- 16. Congratulates the Agency on reducing its carry-over rate of REACH and CLP funds to 10.4% and encourages the Agency to continue its efforts to reduce the carry over as far as possible.
- 17. Notes that the carry-over rates on Biocides and PIC funds were lower than the previous year, and encourages the Agency to further reduce it.
- 18. Notes the Agency's continuing work to support the access of Member State authorities to the R4BP, REACH-IT and IUCLID IT systems, as well as the secure use of the information in these systems.
- 19. Notes that in 2013 ECHA upgraded its ICT infrastructure and set up outsourced services for the management of REACH- IT to ensure 24/7 monitoring and support in line with its IT Business Continuity Plan for the IT systems necessary to support the 2013 REACH registration deadline.
- 20. Notes the further progress made in the area of conflicts of interest in developing and implementing the Agency's procedures to address the recommendations of the Court of Auditors.
- 21. Recommends that ECHA:
 - a) Better aligns its planning and reporting processes, by pursuing further improvement of the links between the Multiannual and Annual Work Programmes and the preparation of the budget and informing the Management Board respectively.
 - b) Continues improving the efficiency of its bodies, such as streamlining of RAC and SEAC opinion development processes.
 - c) Continues finding synergies between the different activities and revises procedures in order to better manage the resource constraints of the coming years.
 - d) Reinforces competitiveness and innovation by further articulating where its activities support and reflect such aspects in its work.
 - e) Continues making efforts to improve the user-friendliness of its dissemination website.
 - f) Uses multilingual communication in its contacts with companies, in particular SMEs.
 - g) Continues efforts to streamline substance identity information requirements.
 - h) Reinforces support to SMEs in view of the next deadlines of 2015 (CLP mixture classification) and 2018 (REACH registration of lower volumes).
 - i) Continues using the experience gained in data-sharing to provide targeted advice to companies, in particular SMEs.
 - j) Builds on experience from authorisation applications to enable industry to put together their dossiers in the most effective and efficient manner.

signed For the Management Board Nina Cromnier