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2nd Commission General Report on the operation of REACH / Evaluation of ECHA (REACH review)

49th Meeting of the Management Board 22-23 March 2018

Key messages

The Commission published on 5 March 2018 the 2nd General Report on the operation of REACH (Reach review). This report contains also the outcome of the 2nd evaluation of ECHA as central agency implementing REACH.

The Commission's report is addressed to the European Parliament and the Council, according to the legal requirements of the Regulation. Its findings and the actions proposed will also be discussed in CARACAL.

The specific follow-up to the evaluation of ECHA is a task of the Management Board. In line with the provisions of the Common Approach on EU agencies the Secretariat plans to develop a Roadmap for implementation of the recommendations resulting from the ECHA review. A first discussion with the Management Board is planned in June 2018.

Background

The Commission's 2nd General Report on REACH is an evaluation carried out as part of the programme for Regulatory Fitness and Performance (REFIT) in accordance with the Commission's Better Regulation guidelines[2]. It is accompanied by a staff working document providing the detailed analysis and presenting evidence to substantiate its conclusions. The report also includes three reviews: one on possible registration of polymers and two on minimum information requirements for low tonnage substances (1-10 tonnes/year). Furthermore, the report contains the outcome of the 2nd evaluation of ECHA[1].

As regards the 2nd evaluation of ECHA, the Joint Statement and Common Approach on decentralised agencies, agreed between the Commission, Parliament and Council in 2012, contains the following procedural provision in[2]:

"*Evaluation of the agencies*

1. *Each agency's founding act should provide for a periodic overall evaluation, to be commissioned by the Commission. The first evaluation should take place five years after the agency has started its operational phase. Subsequent evaluations should be conducted every five years and on the occasion of every second evaluation the sunset/review clause should be applied. Evaluations should be conducted in a manner that provides solid grounds for a decision to continue or discontinue the agency's mandate. The feasibility of a common template for agencies' evaluation should be explored.*
2. *[…]*
3. *Agencies should prepare a roadmap with a follow-up action plan regarding the conclusions of retrospective evaluations, and report on progress bi-annually to the Commission. Follow-up to evaluations should be a task of the Management Board, and of the Executive Board if there is one. […]"*

[1] The report has been presented in June 2017 to the Management Board – see MB/30/2017
[2] http://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

Furthermore, the Common Approach provides that: "Multi-annual work programmes should include the actions necessary to respond to the outcome of overall evaluations"

Rationale

The Commission notes that the REACH Regulation functions well, delivers results and addresses citizens' concerns about chemical safety. However, further improvements are needed to make the legislation more efficient – especially for the evaluation, restriction and authorisation processes. The report sets out actions for ECHA, the Member States, Commission and industry.

In line with the above, the Management Board is invited to take note of the 2nd Commission General Report on the operation of REACH. The Secretariat will closely coordinate the follow-up with the Commission services and keep the Management Board and stakeholders informed.

Generally, the Secretariat welcomes the findings in the Commission report, in relation to ECHA but also more broadly regarding the operation of the REACH Regulation and looks forward to strengthening ECHA's future role in chemicals management. The Secretariat will consider the actions proposed by the Commission, in particular action 15(2) in relation to ECHA staff reallocation and efficiency gains.

The Management Board has a dedicated role in the follow-up of the evaluation of ECHA as EU agency. To this end, ECHA will prepare a roadmap with a follow-up action plan regarding the conclusions of the report, and report on the progress bi-annually to the Commission. Contributions from the Management Board will be sought in June, either in the Management Board meeting or at a dedicated workshop.

It should be noted that some recommendations of the ECHA evaluation concern the Management Board's operation and can be taken into account in the context of a planned self-evaluation of the Management Board in 2018. This concerns in particular the creation of a two-level governance structure with a Management Board in charge of providing strategic direction, assisted by one enlarged working group.

Attachments:

- Annex 1: Commission General report 2018 on the operation of REACH *(open this* link)
- Annex 2: Key recommendation from the REACH review addressed to ECHA

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Annex 2: Key recommendation from the REACH review addressed to ECHA

I.	**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions - Brussels, 5.3.2018 COM(2018) 116 final**

KEY ACTIONS ADDRESSED TO ECHA

Action 1: E*ncourage updating of registration dossiers*
The Commission in collaboration with ECHA, Member States and industry will identify why registrants are not updating their dossiers and make proposals for improvements by first quarter 2019, as appropriate.

Action 2: *Improve evaluation procedures*
ECHA is requested to significantly increase the efficiency of the evaluation procedures by 2019 by:
(1) identifying the main reasons for non-compliance of registration dossier and developing remedies;
(2) where appropriate, applying the various evaluation procedures in parallel;
(3) systematically implementing a grouping approach 25, where this is possible;
(4) improving work-sharing across evaluation activities with Member States; and
(5) improving decision-making procedures.

Action 3: *Improving the workability and quality of extended Safety Data Sheets*
(1) The Commission encourages more industry sectors to develop and use harmonised formats26 and IT tools that would provide more user-targeted information and simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution.
(2) The Commission will consider including minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets and request ECHA to develop a methodology for Safety Data Sheets of mixtures.

Action 5: *Promote substitution of SVHCs*
The Commission, ECHA and Member States will step up support activities to facilitate substitution of SVHCs. Such activities may include the promotion of capacity building and collaborative networks and promoting R&D investment (EU, Member States resources) in sustainable chemicals and technology innovations.

Action 7: *Early socio-economic information for possible regulatory measures*
ECHA in co-operation with the Commission and Member States will consider options to further develop and use available socio-economic information for consideration at the RMOA stage.

Action 8: *Improve Restriction Procedure*
(1) ECHA is requested to clarify the information needed from the public consultations, including the minimum information to be submitted by industry when requesting derogations (time-limited or not) from restrictions.
(2) ECHA is requested to identify relevant cases for restriction as part of its regular screening activities, considering also substances for which only national legislation exists.
(3) The Commission will continue its efforts to identify suitable cases for restricting CMR substances in consumer articles through a simplified procedure, according to Article 68(2).

Action 9: *Further enhance Member State involvement in the restriction procedure*
The Commission and ECHA will work with Member States to further simplify the requirements for submitting a restriction dossier and to increase Member State capacities to develop dossiers for new restrictions and provide constructive solutions such as encouraging joint dossiers prepared by several Member States and/or in cooperation with ECHA.

Action 10: *Frame the application of the precautionary principle31*
ECHA's Risk Assessment Committee and Socio-Economic Assessment Committee should ensure that their opinions indicate when scientific data do not permit a complete evaluation of risk. This should include what information is needed to address the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction to enable the Commission to consider if action is warranted on the basis of the precautionary principle, underpinned in the legal text of REACH.

Action 11: *Interplay between authorisation and restriction*
(1) ECHA is requested to consider systematically the preparation of a restriction dossier before the sunset date of each substance that is subject to authorisation and present in articles in accordance with Article 69(2).
(2) The Commission, ECHA and Member States will assess the interplay between restriction and authorisation to achieve a comparable risk reduction more efficiently through risk management and substitution.

Action 13: *Enhance enforcement*
(2) ECHA's Forum and Member States are requested to establish comparable parameters on enforcement. On the basis of those parameters, Member States should report annually to ECHA for the purpose of monitoring enforcement activities by Member States.

Action 14: *Support compliance by SMEs*
ECHA and Member States are requested to step up efforts to develop, with input from voluntary actions by industry organisations, tailored guidance and support instruments focused on the needs of SMEs. Such instruments may include collection of best practice, generation of sector specific solutions and publication of documents in national languages.

Action 15: *Fees and the future of ECHA*
(1) Bearing in mind that budgetary constraints will remain also in the post 2020 Multiannual Financial Framework, the Commission will explore ways of guaranteeing ECHA mission and independence and to assess all possible options for financing in a context of projected reduced fee income, including by containing expenditure.
(2) ECHA is invited by 2019 to:
i) reallocate staff to other areas of work following the completion of the registration process for phase-in substances to enhance the scientific and technical expertise related to the safety of chemicals as well as the evolving methodologies for their assessment;
ii) continue to identify efficiency gains and propose targets.
(3) Given the constraints identified above, the Commission will carefully assess whether to assign further tasks to ECHA and the associated resources.

II. COMMISSION STAFF WORKING DOCUMENT Accompanying the Commission General Report on the operation of REACH and review of certain elements Annex 6 {COM(2018) 116 final}

5 Conclusions and recommendations

Overall, ECHA has been effective in executing the tasks allocated to it by the REACH Regulation according the annual work plans adopted by the management board in all its work areas. ECHA has however not delivered the outputs expected in 2006. Efficiency has improved over time both within ECHA and in how ECHA works with member States and other stakeholders. There is still though room for improvement to increase efficiency by reducing costs and speeding up processes. Pursuing these efforts is key against the backdrop of resource constraints of the Multiannual Financial Framework for the years 2014-202048.

Key findings include:

- The processes could be improved for deriving dose curve response for non-threshold substances, and for preparing scientific guidance when needed to implement restriction proposal (case of Nickel, PAH, Lead). Also, there is scope for improving the guidance documents and IT tools.
- The effectiveness of the reinforced completeness check for registration still needs to be demonstrated and not all recommendations from the 2013 REACH Review relevant to this have been fully implemented.
- Forecasts for revenues from fees and charges, and the process for verification of the SME status of registrants can be further upgraded, as well as for execution of the budget. Therefore, the Agency should budget more carefully and realistically in the future. Whilst ECHA has recently implemented an Activity Based Budgeting/Activity Based Management system, the Agency needs to further improve integrated budget planning, linking the workforce planning to the overall budget planning, and to put in place a clear audit trail between changes in the workforce planning and the overall budget planning of the Agency. This would be instrumental in keeping track of the ring-fencing principle of revenues related to the various Regulations entrusted to the Agency.
- ECHA has improved efficiency in line with the recommendations in the 2013 REACH review. However, there is still room for improvement in particular for dossier and substance evaluation where the output is not proportionate to the resources invested, and also for restrictions and authorisation and for expenditure on IT Tools. Internal collaboration and re-allocation of resources to respond to peaks in workload in the different areas of activity can be reinforced.
- The efficiency of the Management Board could be improved through flexible working methods and through the creation of a two-level governance structure in line with the EU's Common Approach for Agencies as is the case in many EU decentralised agencies.
- Pursuing these efforts is key against the backdrop of resources constraints of the Multiannual Financial Framework for the years 2014-2020.
- The creation of a two-level governance structure with a Management Board in charge of providing strategic direction, assisted by one enlarged working group was considered an alternative model by some members of the Management Board and European Commission staff and could be also conducive to more effectiveness and efficiency. The enlarged working group will group members of the Management board with experience in budgetary, financial, audit and human resources matters.
- On the Committees and its members, the Commission considers that for SEAC there is a need to ensure that members have sufficient socio-economic expertise, ideally socio-economic expertise applied to chemicals and to human health and the environment, in order to properly fulfil their duties according to Article 76 (1) (d) of REACH. The two ECHA Committees, RAC and SEAC may face increased workloads in the future due to the number of application for authorisations received; therefore the members should really commit to dedicate 50% of their time to this work.

- ECHA should set up training sessions targeted to members dedicated to specific SEAC-related knowledge and processes.

3.4 The Management Board

ECHA activities are overseen at strategic level by the Management Board, while the day-to-day management falls under the responsibility of the Executive Director. The respective roles and areas of responsibilities are defined in the REACH Regulation.

Article 79 (1) of REACH prescribes the composition of the Management Board.[…]

With regards to the profile of the Management Board members appointed by the national competent authorities, a number of interviewees in the framework of the ECHA evaluation study, including members of the Management Board themselves, pointed to the lack of expertise in financial and legal matters among members of the Management Board. The majority of members of the Management Board are not "managers", rather experts with a scientific profile. This is explained by the fact that national competent authorities, which are in the majority of cases ministries in charge of Health or Environment, send their experts with relevant scientific expertise. Consequently, discussions at the Management Board can sometimes deviate from the consideration of strategic planning, financial and legal matters, and instead focus on scientific and operational aspects. Different priorities on national policy agendas might also come into play. A number of interviewees considered that the efficiency and effectiveness of the Management Board could be optimised by giving more importance to the managerial qualifications of potential candidates for membership.

Members of the Management Board hold generally positive views on the internal organisation, rules of procedures and working practices of the Board have been generally positive, although a number of improvements were suggested:

- The efficiency and effectiveness of the Management Board could be optimised by giving more importance to the managerial qualifications of potential candidates. Member States should appoint members of the boards in light of their knowledge of the agency's core business and taking into account relevant managerial, administrative and budgetary skills and limit their turnover;
- The establishment of an executive board or a similar structure in line with the Common Approach on EU decentralised agencies, reducing the overall number of Management Board sub-groups and using more written procedures could increase the efficiencies of the Management Board;
- Discussions in the Management Board could be more focused on the management issues of the agency and less on scientific aspects.

The Management Board's decision-making procedure, i.e. two-thirds majority, has not hampered efficiency. The "proxy" system allowing individual members to be replaced in discussions if they are unable to attend a meeting is perceived positively.

The number of meetings of the Management Board (i.e. four two-day meetings per year) is considered to be adequate. The frequency and number of meetings is in line with those of similar EU Agencies, e.g. the European Medicines Agency (EMA) and the European Food Safety Agency (EFSA). However, to increase efficiency, ECHA could resort to written procedures for the adoption of decision not requiring discussion in the Management Board and reduce the length of the meetings from two to one day.

The Management Board has set up a number of specialised Working Groups to plan and organise its work more efficiently, and to focus the quarterly meetings of the Management Board on strategic discussions and the adoption of decisions prepared in the Working Groups. Working Groups have been established on different topics, either related to tasks of the Board or to thematic issues such as 'Planning and Reporting', 'Audit', etc. The small size of the MB Working

Groups, composed of 4 to 9 members, facilitates discussions in preparation for the plenary meetings of the Board. However, whilst this system was chosen at the start-up and consolidation phase of ECHA's operations, the Commission services are of the view that ECHA should investigate the possibility of merging and reducing the numbers of working groups will enhance the efficiency of the Management Board.

Some interviewees in the ECHA evaluation study considered that the size and composition of the Management Board is not optimal to ensure efficient and effective ways of working and suggested to review its set-up. For example, a number of interviewees suggested either the reduction of the number of members or the creation of a two-level governance structure with a Management Board, in charge of providing strategic direction, assisted by a more professional, small-sized Executive Board, responsible for the monitoring of ECHA's activities and the supervision of administrative and budgetary matters. This latter structure could potentially replace (in part) and/or simplify the system of Working Groups. In fact, this would align the ECHA with the recommendations of the EU's Common Approach for a two-level structure[3].

[3] Quote: "in order to streamline the decision making process in the agency and contribute to enhancing efficiency and effectiveness, a two-level governance structure should be introduced, when this promises more efficiency: in addition to the Management Board, giving general orientations for the agency's activities, a small-sized Executive Board, with the presence of a Commission representative, should operate and be more closely involved in the monitoring of the agency's activities, with a view to reinforcing supervision of administrative and budgetary management, in particular on audit matters."