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Commission REACH Review - Preliminary analysis of implications to ECHA

Introduction

The European Commission has recently published its first general report on the operation of the REACH Regulation, together with a review of certain elements of the Regulation (COM(2013)49 final of 5.2.2013).

ECHA has done a preliminary analysis of the recommendations in the report as far as these are addressed to the Agency. This analysis was considered by the ECHA Mangement Board in March 2013.

The Commission's review report will in the coming month be discussed with stakeholders, Member States and institutional partners, and the Agency will take the outcome of these discussions into account for refining its analysis. ECHA's next multi-annual work programme (MAWP 2014-18) will be adopted by the Management Board in September 2013 and reflect the activities resulting from the REACH review, taking into account the existing resource constraints. The Agency's annual work programmes will describe the more detailed implementation. Hence, the implementation of the relevant Commission recommendations will be integrated into the overall planning process of ECHA, where the final outcome depends on agreed priorities and resources available.

Summary

Overall, ECHA welcomes the Comission's report and notes that its conclusions are very much in line with the Agency's four strategic objectives and the findings of ECHA's first five-year report on REACH operation. Most of the recommendations are already covered by ECHA's planning, and the draft MAWP 2014-2018 which will be submitted for public consultation in June/July will reflect this. However, some of the recommendations are closely interlinked with the overall priority setting of ECHA activities and with the resource constraints ECHA will be facing in the coming years. For certain recommendations ECHA believes it may be appropriate that another body takes the lead on those. The forthcoming additional review steps (substance identity and nano implementing regulations, 1-10 tonnes/a information requirements, eventual polymers registration obligation) that the Commission will undertake in the coming 12 months are of essential importance to ECHA's future work and strategic planning.

Preliminary analysis

In the following the most important, from ECHA perspective, recommendations are summarised and assessed, following the main sections of the Commission report.

Protection of human health and the environment

ECHA fully supports the views of the Commission regarding the need for industry to improve the quality of the registration dossiers, and ECHA will continue to increase its efforts

towards improved compliance of the dossiers. These aspects are fully covered by the first strategic aim of ECHA, and addressed especially in the draft MAWP 2014-2018 and in the new compliance check strategy. Hence, these activities are already on ECHA's radar but as ECHA will have achieved the 5% compliance check target on the high volume dossiers in 2013 it can only reach a significantly higher percentage if it is able to maintain its expert staff level working on evaluation and related IT tools. The related Commission recommendations under the section '**Animal testing'**, coincide with ECHA's strategic planning as it will be working on how to enhance the use of alternatives to testing, including the quality of justifications for waiving testing.

Similarly the recommendation of the Commission for ECHA and industry to address problems related to compilation, communication, and use of extended safety data sheets is covered by ECHA's existing activities and planning, in particular as part of work with the ENES network[1] and activities foreseen under the Chemical Safety Assessment Programme which also is covered by the MAWP.

Regarding substance identification (SID) and substance sameness, ECHA wants to re-emphasise the importance of this area. It was specifically addressed in ECHA's 1st report on the operation of REACH[2] ith a recommendation for the Commission to issue implementing legislation for clarifying the concept of substance sameness. Further evidence of the nature and extent of the problem is already available in the annual evaluation reports[3] which also demonstrate that substance identification (SID) problems in the registrations dossiers are complicating the evaluation work especially of ECHA but also of Member States (MS).

ECHA welcomes the Commission commitment to "increase its efforts to identify the relevant SVHC's[4], building on the Risk Management Option framework". This work is covered by the SVHC roadmap for 2020 which is under development and for which the Secretariat has already communicated its full support and willingness to provide a coordinating role for the practical implementation. ECHA wants to emphasise that it is prepared to take a reasonable share of the burden to ensure that all relevant substances of concern are identified and addressed via the most appropriate risk management route but assumes that also the MS's will express a clear commitment to take their share. It should not be assumed that ECHA will have the resources to compensate with additional efforts should other parties fail to deliver. Also these aspects are covered by ECHA's strategic multi-annual planning.

Internal market and competitiveness

In this section of the Communication the Commission is addressing i.a. concerns about the financial impact of REACH to companies (and in particular SME's), and suggests ECHA to provide more specific guidance on transparency, non-discrimination, and fair cost-sharing, and more "user-focused guidance" on the operation of SIEF's. ECHA notes that its guidance regarding data and cost sharing was updated in April 2012. ECHA is reflecting on ways to improve better overall access and usefulness of its guidance see also section on SMEs but considers it challenging to provide more specific guidance in this area. Further discussion will be needed on this and alternative means should be considered, such as implementing regulations by the Commission or a role for industry associations that have the specific knowledge and experience in this area., Regarding the encouragement of the Commission for ECHA and MSs to "strengthen efforts in relation to prepare industry for the crucial milestones" of 2013 and 2018 ECHA is currently intensively working on the 2013 deadline, and has already started preliminary planning for the third registration deadline in 2018. For the latter ECHA is already outlining many support activities in the draft MAWP 2014-2018.

[1] Exchange Network on Exposure Scenarios
[2] Report under Article 117.2 of the REACH Regulation of July 2011
[3] Annual reports in accordance with Article 54 of the REACH Regulation
[4] Substances of Very High Concern

Not only for 2013 but also for the 2018 deadline the useful concept of Directors Contact Group should continue given a more prominent role to representatives of SMEs. In addition, ECHA is looking for ways to have the substances to be registered and the Lead Registrants for the 2018 deadline identified earlier than for the two previous deadlines considering also that the risk for unplanned withdrawal of critical substances from the market is bigger than before.

Enforcement of REACH and CLP (under section MS's reports on operation of REACH)

ECHA welcomes the appreciation that the REACH Review expresses for the work of the Forum and of the Forum Secretariat. The Agency regards this as an encouragement to continue and intensify the Forum's work on harmonising the approach of Member States to the enforcement of REACH as well as to implement ECHA's regulatory decisions through enforcement action, where necessary. The completion of the Interlinks Project and nomination of Focal Points in Member States and at ECHA has been a key milestone in providing the requisite avenues for the latter. With regard to the intention of the Commission to develop enforcement indicators 'in liaison with the Forum', ECHA suggests that a Working Group of the Forum would be the more appropriate instrument for that purpose. Such indicators should be established as the outcome of a truly collaborative effort. This would give due regard to the sovereignty of Member States in their responsibility for enforcing REACH and benefit the exercise by providing a tangible element of 'ownership'.

Review of ECHA

The recommendations of the Commission under this section concern efficiency and economy, stakeholder engagement, and sharing of information and data with the Commission and MS authorities.

The Agency agrees in principle with the recommendations and has taken a number of actions already in 2011 and 2012 which address these recommendations. It is useful to note that the elements mentioned are also to a large extent covered by the fourth strategic aim, and consequently by the update of MAWP for 2014-2018.

Review of the scope of REACH

Although not listed as one of the action points or recommendations this section contains the following suggestion for ECHA: "Taking into account the existence of various EU legislations containing substance restrictions, the Commission considers useful to invite ECHA to develop an inventory of all existing restrictions in EU legislation on an individual substance basis". ECHA does not consider this task possible or appropriate for ECHA to undertake as the scope and the related workload are extensive. The recommendation is not only about restrictions under REACH (which can be accessed via the ECHA website already, and for which ECHA is planning improvements) but also about restrictions under other EU legislation. This goes beyond ECHA's remit and expertise, and would also involve a considerable workload and potentially also financial resources (database development), which are not in ECHA's planning for future years. Hence, it would be more to the Commission to develop such an inventory.

Review of the requirements for registration on 1 to 10 tonnes substances and on the need to register certain types of the polymers

ECHA wishes to be closely associated to this work as it is likely to have resource and revenue implications. For both areas, low tonnage substances and polymers, ECHA has relevant expertise from the various points of view, i.a. scientific knowledge about hazards

and risks, possibilities for use of alternative methods and approaches for the generation of hazard data, and assessment of options for technical implementation, including IT tools. It should also be considered that new chemicals of nano or other form are mostly introduced at low tonnage in the markets.

Nanomaterials

ECHA welcomes the overall conclusion from the Second Regulatory Review on Nanomaterials (NM), including the ongoing Commission work related to potential amendment of REACH annexes to ensure further clarity on how NMs are addressed in registration dossiers. ECHA considers an Implementing Act by the Commission useful and necessary to eliminate any remaining uncertainty as to how NMs are covered by the registration provisions. This was also highlighted in ECHA's report on the operation of REACH in June 2011. ECHA however notes that this is an area where ECHA would need to increase its resources, both to provide more advice and support to industry but also, and in particular, to address the obvious non-compliances in registration dossiers covering NM's. As virtually all - and not just 5% - dossiers containing nanoforms of substances would merit either a dossier or substance evaluation, ECHA is interested to discuss various options to address the resource issue, including also potentially via a specific fee or charge mechanism.

SMEs (Annex)

An Annex to the Communication lists eight specific recommendations to reduce the administrative burden of REACH on SMEs while maintaining their ability to fulfil all REACH obligations. These are supporting the general statements in earlier sections regarding the challenges the SMEs are facing, and in particular under the section "Internal market and competitiveness". ECHA is supportive of the general aim of facilitating REACH implementation by SMEs and will take action where ECHA clearly has a role to play, but strongly advocates doing this in partnership with many other actors (COM, MSs, industry associations, other stakeholders).

ECHA considers it very useful to note that among SMEs a fairly clear distinction can be made between the roles and related challenges for SMEs as registrants vs SMEs as downstream users. The first group seems to be easier to reach and to support, whereas the latter comprises a much more diverse group of companies, often difficult to reach. It is also difficult to establish a dialogue clarifying what the actual obligations and impacts of REACH are, and consequently to identify what is the best way to provide support for them.Hence, ECHA is already addressing the challenges of SMEs from many different angles and will continue to do so in particular in relation to the 2018 registration deadline. The Commission's recommendations will require more detailed discussion and it will have to be established if the Agency is indeed always the best actor for implementing the proposed measures. It appears that in some areas the actions could be better carried out by the Commission or industry. National Helpdesks can indeed play a role in the activities.