Safer chemicals - focusing on what matters most

A new strategy for compliance check to improve the quality of information provided by companies

1 Introduction

ECHA has a range of tools to improve the quality of data in REACH dossiers and coordinate the development of regulatory measures to manage the risks posed by chemicals. These are highlighted in the Multi-annual Work Programme (MAWP) 2014-2018. The compliance check which ECHA performs on REACH registration dossiers is a central pillar in the implementation of the strategic objectives of improving quality and ensuring safe use of chemicals.

From 2009 to 2013, ECHA established its compliance check process and gained a great deal of experience. The current compliance check strategy was developed with a view to maximising the early impact – in terms of industry and ECHA's learning about the process and the best practice. That approach has been successful in this start-up phase, with compliance checks concluded (targeted or overall) on more than 5% of the 2010 registration dossiers and attention on compliance raised among a large number of registrants. At the same time, ECHA developed IT-tools which can screen all dossiers and support the scientific and administrative processing of dossier evaluation cases, and gained important learning on the value of targeted campaigns to improve dossier quality in general.

Now, after the first five years, is the time to have a different focus for compliance checks. In line with the MAWP strategic objectives, ECHA wants to ensure that the compliance check has an even bigger impact on the safe use of chemicals and reducing the risks to human health and the environment. Furthermore, with additional information becoming available, the approach should also enhance innovation and competitiveness as well as ensure a level playing field for the European industry. This emerging strategy also enables the identification of substances of concern. It then requires ECHA to coordinate better the use of the different REACH and CLP instruments (including compliance check) to address these concerns in an efficient and effective manner.

The proposed strategy has been based on an internal review of results and lessons learnt on compliance check and other actions and on the feedback from ECHA partners and stakeholders (i.a. through the compliance check strategy workshop and consultation of CARACAL). The consultations have shown that there is broad agreement on the strategic direction and priorities and on that basis, the new strategy will be presented at the September Management Board meeting, in the context of the approval of the Work Programme 2015.

2 Main objectives of the revised strategy

The main objectives for the revised compliance check strategy are:

– Providing confidence amongst stakeholders and the public that registrants meet the REACH information requirements, follow this up by improved communication on safe use in the supply chain, and REACH is thereby making a difference;
– Efficiently selecting substances that raise potential concern, generating the standard information for assessing safety through compliance check or other means so that any remaining concerns can subsequently, where necessary, be addressed through the most suitable regulatory instrument;
– Improving the transparency of relevant outcomes of the different steps of the compliance check process, for the benefit of Member States, stakeholders and individual registrants.

The most important change is to first focus on checking the quality of information of those substances which are expected to have the biggest impact on the improved protection of people and the environment. In practical terms, the method for selecting substances for compliance check will be fully aligned with the common screening approach that is used for the selection of substances for substance evaluation and regulatory risk management measures. Furthermore, the outcome of compliance check will be better integrated with the other REACH and CLP processes and compliance check and other regulatory measures to improve data quality will be better coordinated with complementary non-regulatory measures.

3 How we will implement the strategy

3.1 Integrated selection and priority setting

An integrated selection and priority setting mechanism (so called **common screening**) was already developed for substance evaluation and regulatory risk management measures and will now also be used for compliance check. This will lead to improved coordination and a more coherent set of priorities for these processes.

In selecting dossiers for compliance check and other measures, priority is given to substances which have:

– one or more suspected data gaps in the higher tier human health or environment endpoints (see below); and
– high potential for exposure of humans or environment and hence relevance for safe use.

The detailed selection criteria for the common screening will be further refined together with the Member States. Working together on these criteria will help to ensure that, at national and EU level, we are working towards the same goal. The common screening will start by first applying screening and estimation techniques (e.g. QSARs, read-across) but as well external data sources to identify the substances that are most likely to be of highest concern due to their proven or predicted hazard properties and that have possible data gaps especially in the endpoints listed below. The developed Areas of Concern (AoC) IT algorithms will be used to identify potential data gaps. It is assumed that this pool of potential substances of concern will be too large to handle and that additional criteria are needed to pick out those substances which due to their high potential for exposure. In practice, this means the exposure of workers in their professional use of substances or mixtures under poorly controlled conditions; exposure of the general public to substances on their own or used in mixtures and through substances incorporated in articles; and environmental exposure to substances from manufacturing, formulation and use processes, in particular where such uses are high volume and widespread.

Based on the common screening, the chemical will be channeled to the most appropriate process – whether that be compliance check or some other measure.

3.2 Effective use of Compliance check

The strategy aims to improved compliance of those 100-1000 tn and > 1000 tn registration dossiers where there are concerns on safe use. ECHA is fully committed to the quantitative target of 5% (proportion of dossiers selected for compliance check per tonnage band) set in the legal text and works towards reaching this target for the 100-1000 tn tonnage bands at the latest by 2018.

In selecting dossiers for compliance check priority is given to standard (i.e. not intermediate), lead and individual dossiers of chemicals produced in volumes over 100 tonnes per year (i.e. the two highest tonnage bands) and applying the priorities explained above.

This prioritising will exclude some substances, for example, substances already evaluated under former existing substances regulation or under substance evaluation, or those already subject to extensive risk management measures (i.a. substances with harmonised CMR1 classification).

In addition to this more focussed approach, a small portion of compliance checks will continue to be based on a random selection – thereby ensuring that no registrant can be certain that their dossier will not be examined.

The **scope** of compliance check will be matched with potential concerns identified ("fit for purpose" instead of "one size fits all"). The IT screening results, manual screening and expert judgement all play a role in defining the scope.

The main focus will be on the higher tier (Annex IX and X) human health and environment endpoints. These are:
– genotoxicity
– repeated-dose toxicity
– pre-natal developmental toxicity
– reproduction toxicity
– carcinogenicity
– long-term aquatic toxicity
– biodegradation and
– bioaccumulation.

Besides this the substance identity, to the extent relevant, is always assessed once a dossier is opened for a compliance check.

To ensure meeting the objectives of the strategy, ECHA is committed to continue improving both the effectiveness and the efficiency of the dossier evaluation process, thereby increasing the potential output. This is done by i.a. reviewing and revising the process and the tools used, streamlining the content and focus of the decisions, seeking feedback from stakeholders how to improve the process and by improving collaboration with Member States and the Member State Committee.

3.3 Use of soft measures to support compliance check and improve overall dossier quality

Non-regulatory or "soft" measures play an important role in the strategy to improve overall dossier quality. However, they are in addition to the compliance check and not an alternative to it. The priorities explained above will also apply for using the non-regulatory measures.

Apart from the continuing general advice and communication to registrants, ECHA will continue to use targeted campaigns to registrants with potential deficiencies in their dossiers. Examples of issues that, based on experience so far, can be usefully addressed in such campaigns are deficiencies in substance identity or physico-chemical endpoints and erroneous or missing classification and labelling. Where needs be, dossiers which are not improved as a result of such campaigns will be followed up in compliance check or through other regulatory measures.
Where feasible and appropriate, ECHA may provide advance warning to registrants, before launching compliance check on specific types of issues. An example of such campaign is use of read-across in adaptation of information requirements: Once ECHA has consolidated its read-across assessment framework and published more guidance, it plans to alert those registrants relying on such adaptations and invite them to improve their justifications before regulatory action is initiated on their dossiers.

One important element in soft measures is utilising the multiplier effect. This is already done in two ways: first, by informing members of SIEF on certain compliance check (draft) decisions and inviting the members to update also their dossiers if appropriate (e.g. substance identification and eventually the chemical safety report) and second, by initiating discussions at industry sector level to tackle systematic shortcomings in their methodologies affecting many dossiers. Furthermore, ECHA is informing registrants on major deficiencies in the annual evaluation report and disseminating the compliance check decisions. This should provide important learnings to other registrants. Such communication can be further improved i.a. by providing search functions or guided access to compliance check decisions with specific types of non-compliance.

ECHA will also continue collaboration with industry organisations to seek ways to promote and reward well performing companies with the aim of creating incentives for good performance.

3.4 Improved transparency of dossier evaluation and improved collaboration with Member States

ECHA intends to pmprove the transparency and usability of the registration and other information disseminated on its website. This is an important measure to improve the dossier quality and will enable interested parties to follow which parts of the dossiers have been updated as a result of compliance check.. On this ECHA has already a plan available.

To respond to the feedback from Member States and other stakeholders, ECHA intends to improve the statistical reporting of compliance check outcomes. There is a call for providing more end-point specific reporting and to include also information on the final outcome after the follow-up evaluation has been performed. The annual evaluation report will be the main vehicle for such reporting.

For improved collaboration with Member States and more integrated implementation of compliance check and other REACH and CLP processes, also substance/dossier level information is needed. ECHA is looking into the best ways in providing such information to Member State authorities.

National enforcement authorities have a crucial role in ensuring compliance with the data requirements. Hence they play an important role in the implementation of the strategy. Through the Forum, ECHA enhances the collaboration with enforcement authorities and supports alignment of priorities among national enforcement actions.

4 How will we measure the success of the new strategy?

No single measure can guauge the impact of the revised strategy. However, it is expected that a number of combined measures will give a strong indication of success:

- The measurements for the MAWP strategic objectives 1 and 2 address the impact of ECHA's actions; The compliance check work is a fundamental contributor to that;
- Proportion of registered substances of over 100 tn which are not retained by the automated screening;
- The number of lead/individual dossiers in compliance with the key REACH requirements (after compliance check conclusion or follow-up);
- The proportion of dossiers checked for compliance for the two highest tonnage bands;
- The number of substances for regulatory risk management measures which were identified through common screening and compliance check;
- Satisfaction of Member States on their collaboration with ECHA and feedback from ECHA stakeholders.