

## **ECHA's Integrated Regulatory Strategy**

44<sup>th</sup> meeting of the Management Board 13-14 December 2016

### **Key messages**

The Management Board is invited to take note of an update on the implementation of ECHA's Integrated Regulatory Strategy. This strategy is built on the compliance check strategy endorsed by the Board in September 2014 and ECHA's strategic objectives No 1 (*maximise the availability of high quality information to enable the safe manufacture and use of chemicals*) and 2 (*mobilise authorities to use information intelligently to identify and address chemicals of concern*). It has been further developed with the aim to meet, by 2020, the chemicals management goals set by the World Summit on Sustainable Development (WSSD).

The note provides an update to the note shared with the Board at its 40<sup>th</sup> meeting in December 2015 and details on how this strategy is currently being implemented, what measures have been taken or are still planned, and what challenges ECHA observes during further implementation.

### **Background**

The ECHA Management Board endorsed in September 2014 a new compliance check strategy. The attached note was presented on 23 November 2016 to the Management Board Working Group on Planning and Reporting. The Group welcomed the paper and suggested to share it for information with the full Management Board.

### **Attachment:**

- Update on the implementation of ECHA's Integrated Regulatory Strategy

## **ECHA's INTEGRATED REGULATORY STRATEGY – UPDATE ON THE IMPLEMENTATION**

### **1. Background - Regulatory strategy in a nutshell**

The ECHA Management Board endorsed in September 2014 the revised compliance check strategy which has since then been further developed to a comprehensive regulatory strategy integrating all REACH and CLP processes and supported by a suite of other measures. This note provides more details on the progress in implementing the strategy, what other measures have been taken or are still planned and what challenges we observe during further implementation.

The regulatory strategy brings all REACH and CLP processes coherently together to achieve the aims of these Regulations, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development (WSSD). ECHA is currently consulting its partners on the success factors in achieving these 2020 goals and in identifying the measures that still need to be taken to reach them.

The basis for all activities is the REACH registrations. Several activities address the quality of dossiers already before a submission, at the completeness check phase and after a submission is approved. Together with the Member States, ECHA has developed a common screening process which identifies from the registration data base substances that have the greatest potential for negative impact on human health and the environment. The common screening supports reaching a conclusion on which substances need further compliance check and/or substance evaluation and which substances can be directly earmarked for EU risk management measures. Within this work there's an increased focus on identifying and treating larger categories or groups of substances rather than handle substances on an individual basis.

Dossier evaluation is in the core of the strategy. Under the compliance check process, priority is given to full registrations of chemicals produced in volumes over 100 tonnes per year, and with potential concern that may require substance evaluation or regulatory risk management measures. The main focus is on the higher tier (Annex IX and X) human health and environment endpoints which are relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic) and PBT/vPvB (very) persistent, bioaccumulative and toxic) substances. In addition to the formal evaluation processes, a number of other measures support the compliance check and improve the overall dossier quality.

If the concern is confirmed in the screening or evaluation, a risk management option analysis (RMOA) process will usually follow, firstly to confirm if risk management processes need to be initiated, and secondly, to check which process is the most suitable. Where necessary, a Member State (or ECHA) will prepare a proposal for SVHC identification, restriction or harmonised classification and labelling.

Apart from the substances that require further work by authorities, also substances that are concluded to be of no, or low concern are also tracked. ECHA's ambition is that by the end of 2020 the 'universe of registered substances' above 100 tonnes has been gradually mapped through the actions described above. These actions are intended to reduce the pool of substances of potential concern and conclude for as many substances as possible the need for specific action or that they are currently of low priority for further work.

The work is being carried out in collaboration with Member States and increasingly also with industry sectors. Registrants are invited to proactively contribute by updating their

dossiers when informed of the results of the common screening and by providing better use and exposure information.

Integrating REACH and CLP processes and supporting the regulatory measures by other actions is critical to ensure adequate progress in meeting the WSSD 2020 goal: It may take a number of years to receive adequate data, identify a substance of concern and then apply a risk management process to it. This intrinsic time lag can be minimised by ensuring optimal interaction between the various processes (e.g. by running some of them in parallel, reducing the gaps between running each process, or by moving directly to a policy action when justified) and follow-up actions which may be needed by all actors.

In brief, the regulatory strategy ultimately aims to achieve the following impact:

- Providing confidence amongst stakeholders and the public that registrants meet REACH and CLP information requirements, this is followed up by improved communication on safe use in the supply chain;
- Efficiently selecting substances that raise potential concern, generating standard or equivalent information for assessing their safety through a compliance check or other means so that any remaining concerns can subsequently be addressed through the most suitable risk management regulatory instrument;
- Improving the transparency of relevant outcomes of the different steps of the evaluation and risk management processes, for the benefit of Member States, stakeholders and registrants; and
- Ensuring appropriate and timely intervention from all actors (ECHA, Member States, industry and the European Commission) within the different REACH and CLP processes so that chemicals of concern are addressed as soon as possible.

A more detailed description of ECHA's ambition for the integrated regulatory approach was given in the document MB/59/2015 and is hence not repeated here.

## **2. Status of implementation**

### **2.1 Registration related measures**

- Update the reporting format (IUCLID 6) to help registrants clarify i.a. the scope of the substance registered jointly, the relationship between the test substance and the different registered compositions, the justifications for waiving from standard data requirements, the tonnages per uses, etc.
  - Successfully launched in (June) 2016
- Introduce in the completeness check process a manual check to assess whether the information submitted is meaningful, in particular for deviations from standard data requirements.
  - Successfully launched with REACH-IT 3 roll.-out in June 2016
- Introduce retroactive completeness check
  - First pilot initiated in June 2016 with a deadline to complete the dossiers by 28 November 2016; this may lead to a revocation if meaningful information is not provided. Second batch ongoing with a deadline in January 2017
  - Based on the learnings of the pilot, a strategy is being devised to retroactively check the dossiers above 100 tonnes with a target date of

2020

- Support to specific sectors
  - Essential Oils sector: Advice provided on substance identification, PBT assessment and C&L. Guidance written by industry and publicised on ECHA website
  - Inorganic pigments and dyes: Advice provided on substance identification and scope of the registration

## 2.2 Evaluation

- Compliance check: Of the 107 CCHs on substances that matter conducted in 2015 those 81 that led to a draft decisions have been processed in decision making resulting so far into 43 final decisions.
- In 2016 ca. 150 CCHs on substances that matter planned, so far 97 priority CCHs concluded.
- To address abundant and poorly documented application of read-across and grouping, further advice has been developed (environment part of RAAF, practical guide on alternatives to animal testing). In addition, piloting of an integrated and more efficient approach to category/read-across dossiers started in 2016
- Improved integration of dossier evaluation follow-up, screening and risk management identification: cross-Directorate group established in 2016 and information systems are being developed to allow more efficient interfaces.
- Substance evaluations continue addressing substances of potential concern: so far 220 substances evaluated or under evaluation; so far leading to 78 final decisions and 45 conclusion documents published.

## 2.3 Supporting measures

- Carry out specific targeted campaigns (a.o. for short-listed substances) to registrants with potential deficiencies in their dossiers.
  - Effective since 2012, continues in 2016
- Use the multiplier effect (e.g. target all registrants of the same substance).
  - Effective since 2012, continues in 2016
- Publication of a pre-alert list of substances that ECHA plans to address under CCH and thereby encourage timely dossier updates
  - Effective since Q1/2015, continues in 2016, two annual updates
- Use of article 36 decisions i.a. for clarifying the intermediate status for priority substances or bring other relevant data that are in the possession of registrants (e.g. on nanoforms or strictly controlled conditions)
  - Effective since 2013, continues in 2016
  - Analysis of the further use of Art 36 decisions instead or in addition to CCH or SEV, in particular to request information on uses and exposure carried out and discussed with MS experts in the recent REEG meeting in Utrecht
- Publication of substances that are scrutinised by authorities with the concern being investigated with the aim to increase predictability for registrants and

stimulate dossier updates

- Effective since end 2014, further developments on PACT (dissemination via website) and ACT (making info accessible to authorities via the Portal Dashboard) ongoing and foreseen to deliver in 2017.
- Activities under the CSA programme (use descriptors, use maps etc.) in particular to improve the information on uses and volumes
  - ECHA, Cefic and DUCC recently signed a joint statement where they indicated to continue working together to improve the communication along the supply chain for the use of chemical products in Europe.
- Sectoral approach: Concerted measures by industry associations / sectors to ensure that the information in particular on volumes and uses is updated with highest priority. In co-operation with industry sectors identify applications and materials resulting in high exposure and substances used in these applications and materials; Bring in further information from other sources, including those from other regulatory bodies, to enhance the knowledge on the potential uses that may lead to substantial exposure of humans or the environment.
  - Development of the best practice methodology and improved coordination of ongoing activities within ECHA
  - PETCO: in line with the SVHC roadmap an approach on how to identify and assess petroleum and coal stream substances has been developed in close cooperation with industry and interested Member States. Uses have been clarified and a selected group of substances has been prioritised for further scrutiny. For two substances RMOAs are being developed. The overall approach will be discussed in the next RiME and CARACAL meetings.
  - Metals: ECHA has started further interaction with Eurometaux in summer 2016 with the aim to set up a collaborative approach to clarify the (groups of) substances covered by the sector, the quality of the dossiers submitted to far, the quality of the supply chain coordination and information, with the ultimate aim to clarify to which extent sufficient information is available to prioritise or de-prioritise their substances. More detailed scoping of the approach is currently ongoing.
  - Together with CEFIC, ECHA has approached Cefic sector groups representing the plastic additives manufacturing industry, PlasticsEurope representing polymer producers and EuPC representing plastic converters for further discussion to set up a similar type of sector approach which in this case is more specifically based on the function of the substances that are used in plastic. Again, more detailed scoping of the activity is foreseen to take place towards the end of 2016.
  - In addition to these approaches with specific sectors ECHA has recently proposed to industry and the Member States Competent Authorities to start a Pilot Programme for a Cooperative Sectoral Approach with regard to dossier quality with the aim to get volunteering sectors to commit to improve their registration dossiers during the pilot phase and agree on a further timeframe as part of a binding update plan by which evaluation decisions could potentially be avoided. This proposal will be discussed in the meeting with the MSCA Directors on the 17<sup>th</sup> of November. Based on expression of interests obtained, a joint framework will be developed and discussed in a kick-off workshop between ECHA, the volunteering Member States and the volunteering sector associations to be organised in Q1 2017.

- In addition to these initiatives in the context of RiME, a number of specific groups of substances (organotins, PFASs, UV-filters, flame retardants) are being looked at in a collaborative manner by different groups of Member States and ECHA, and here as well collaboration with the relevant industry sectors is being investigated.

#### Incentivising good quality dossiers

- Explore possible incentives together with industry stakeholders – ongoing and launch a specific study on best practices in dossier updating.

## 2.4 Data management

- ECHA has started the development of the method for the “mapping the chemical universe” and further development of the common screening. Essentially the objective of this exercise is to use available information at our disposal from various REACH and CLP processes as well as from external sources to put substances into boxes with the ultimate aim to be able to decide if further regulatory action is needed or not, or whether further information needs to be generated first.
- A first pilot exercise has been carried out over summer and is currently being further discussed and validated, in particular with respect to the criteria that have been used to assess the likelihood of the exposure and hazard potential which are the key input parameters for deciding on concern/low concern.
- Tracking and tracing of deficiencies, concerns and assessment conclusions
  - Further development of ECHA’s IT tools to efficiently record, trace, track and handle data in registration dossiers and in other data sources, and share the information with Member States - Preparation of an IT project vision document ongoing

## 2.5 Dissemination

- Improve the dissemination of information of the registration and other information disseminated on ECHA website (infocards/brief profiles/status of the dossier evaluation process) which will increase the transparency and allows more extensive scrutiny by third parties and make the status of ongoing evaluations more evident
  - Effective Q1, 2016
- Improve the statistical reporting of compliance check outcomes.
  - Effective from 2016 onwards, further improvements planned
- Disseminate “evaluation life-cycle” and outcome
  - Under development – planned go-live postponed till later in 2017
- Make visible when the dossier was last updated (substantial updates)
  - Effective since January 2016
- Make visible whether confidentiality was claimed or is under review

- Effective since January 2016 for indication that data was claimed confidential. Effective December 2016, data for which a confidential assessment was negative will be published.
- Foreseen development will indicate whether a claim is under review

Finally, it is noted that coordinated actions by national enforcement authorities are essential in order to achieve the ambitious goals. Therefore, the Forum has also been updated on the regulatory strategy and on the role that enforcement plays in it.

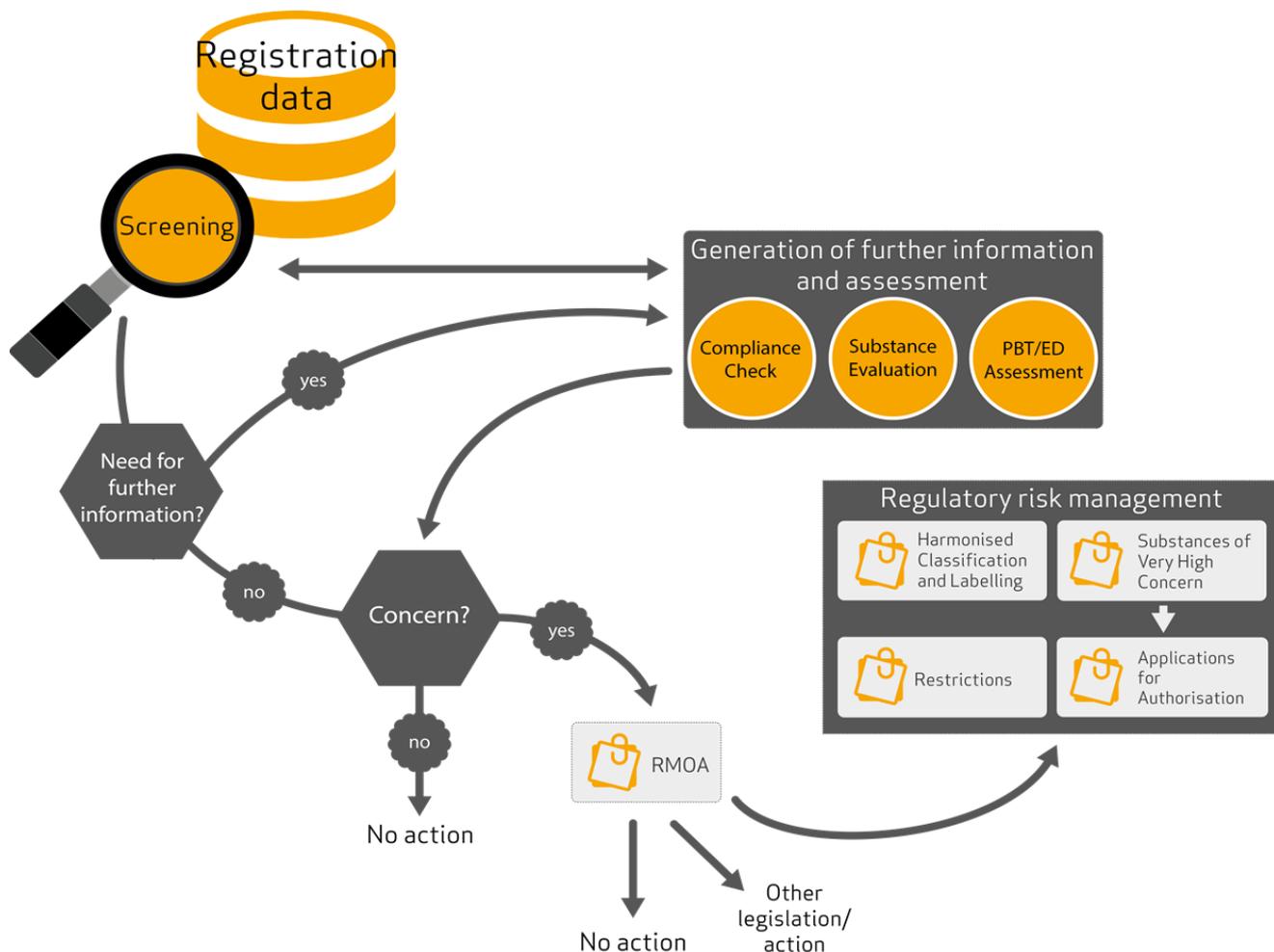
### **3. Key challenges in implementation of the strategy over 2017-2019**

The main challenges identified in 2015 for the implementation of the strategy are currently already been addressed under the actions explained above.

Making sufficient progress towards better compliance and quality of registration dossiers remains one of the main bottlenecks for a successful outcome of the strategy towards 2020. Resources in ECHA are limited but also the resources available for the REACH and CLP implementation in the Member States are scarce and in some cases even reducing. Active input from industry is also expected i.a. in the different sector approaches that are being set up which will require substantial effort and resources.

In order to meet the WSSD 2020 goal, major acceleration work of is necessary. Integration of the processes and systems and efficient, coordinated collaboration of all actors are essential to speed up the delivery of the results.

**Annex 1. Overview on how the common screening work interlinks with evaluation and risk management processes.**



See also our web site which provides an interactive version of this flow chart at:

<http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern>