MB/59/2015
Helsinki, 17.12.2015

Update on the Implementation of the Compliance Check Strategy

40th Meeting of the Management Board 16-17 December 2015

Item	16.4
Action	For information
Status	Final - Public

Key messages

The Management Board is invited to take note of an update on the implementation of ECHA's Strategy to increase registrant's compliance in the light of the multi-annual strategic objectives and the 2020 goals defined at the World Sustainable Development Summit in 2002.

The note provides details on how this strategy is currently being implemented, what complementary measures have been taken or are still planned, what challenges ECHA observes during further implementation and where we believe we will be by the end of 2018.

Background

The ECHA Management Board endorsed in September 2014 a new compliance check strategy.

The attached note[1] was presented on 25 November 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 Strategy to increase registrant's compliance in the light of the multi-annual strategic objectives and the 2020 goals defined at the World Sustainable Development Summit in 2002.

For questions: mb-secretariat@echa.europa.eu

[1] Please note: The document has been slightly updated after the Working Group meeting of 25 November 2015.

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ANNEX

IMPLEMENTATION OF THE STRATEGY TO INCREASE REGISTRANT'S COMPLIANCE IN THE LIGHT OF THE MULTI-ANNUAL STRATEGIC OBJECTIVES AND WSSD 2020 GOALS

1. Background

The ECHA Management Board endorsed in September 2014 a new compliance check strategy. This note provides more details on how this strategy is currently being implemented, what complementary measures have been taken or are still planned, what challenges we observe during further implementation and where we believe we will be by the end of 2018.

The adopted CCH strategy[2] included the following objectives:

- 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.

One of the key elements of the strategy is to prioritise the **"substances that matter"** in the selection of dossiers to undergo a compliance check. Other elements are:

- **Integrated selection and priority setting** (so called common screening) which enables to identify substances that raise potential concern as well as the most suitable route to address the concern, either compliance check, substance evaluation or regulatory risk management (see also Annex 1).

- **Effective use of Compliance check:**

  i. Priority to full registrations from lead and individual dossiers of chemicals produced in volumes over 100 tpa – focusing on substances with potential concern that may require substance evaluation or risk management measures.

  ii. Main focus on the higher tier (Annex IX and X) human health and environment endpoints (so-called super endpoints).

  iii. Assessment of the substance identity, to the extent relevant. [NB: To avoid delays in the process, a targeted substance identity compliance check is only carried out where the scope of the registration dossier is not clear enough]

  iv. If the concern is confirmed based on the data submitted in line with the decision, conclude as part of the RMOA process if and which risk management processes need to be initiated.

  The above approach was further elaborated in the May 2015 CCH Workshop and has thereafter been applied by ECHA. More than 50% of the CCHs concluded in 2015

[2] Published at: http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

follow this approach and the plan is to increase this percentage further in the coming years.

- **Use of complementary measures:** In addition to the formal evaluation processes a number of other measures can support the compliance check and improve the overall dossier quality. The scope of these measures as well as their potential impact and/or achievements have been further analysed in Annex 2 below. In summary the following measures have been taken or are currently being implemented or prepared:

    - Update the reporting format (IUCLID 6) to help registrants clarify e.g. 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.
        - Effective with the launch of IUCLID 6 end of Q1/2016
    - 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.
        - Effective with the launch of REACH-IT 3, end of Q2/2016
    - Carry out targeted campaigns to registrants with potential deficiencies in their dossiers.
        - Effective since 2012
    - Use the multiplier effect (e.g. target all registrants of the same substance).
        - Effective since 2012
    - 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
    - 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
    - Use of article 36 letters for instance 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
    - 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
    - Improve the statistical reporting of compliance check outcomes.
        - Effective from 2016 onwards

2. What has been accomplished so far (end of 2015)

Firstly, to define the pool of substances addressed by the CCH strategy, by the end of 2018, the substances registered under REACH in the range 100-1000 tn are estimated around 7500 with the following breakdown:

55% as full registrations, i.e. ca. 4200 substances

45% as substances registered as intermediates

Therefore the number of substances to be potentially addressed by the compliance check strategy is up to 4200.

- **Substances addressed under screening**: All substances contained in the database are screened, i.e. substances registered in full, substances registered as intermediates and NONS substances, especially those for which the dossier has been updated under REACH. Screening algorithms are applied (400 scenarios developed), as well as estimation techniques (e.g. QSARs, read-across) and cross-checks with external data sources to identify the substances that are most likely to be of highest concern.

  The "profile" of the substance screened is recorded, e.g. "potential ED according current criteria". This creates a pool of substances for subsequent manual verification at a later stage.

- **Substances addressed under evaluation**
  - **Compliance check:**
    - By the end of 2013 ECHA had concluded compliance checks on ca. 1000 substances with registrations in the tonnage band >1000 tn; However, in the early years, criteria for selection for CCH has varied and hence not all of those CCHs would be in line with the currently applied criteria for addressing "substances that matter". Furthermore, many of the CCHs were targeted to SID or one or more hazard endpoints, including many on phys-chem properties [440 AoC].
    - In 2014 ECHA continued CCHs and addressed 516 substances: 144 under overall CCH, 372 targeted CCH.
    - In 2015, ECHA aims to conclude ca. 200 CCH, including at least 100 on substances with concern and focusing on the key higher tier endpoints.
    - More comprehensive (and comparable) statistics on the number of substances and the key endpoints addressed in CCH in 2009 – 2015 are being prepared for the Evaluation Report to be published in February 2016.
  - Substance evaluation has been or is currently addressing 181 substances.

  Taking into account overlaps between dossier and substance evaluation and the number of targeted compliance checks on SID: ca. 800-1000 substances have been checked to a reasonable extent.

  These figures do not include concluded testing proposals. So far, ECHA has concluded up to a final decision over 600 testing proposal examinations (on roughly as many substances), covering one or more Annex IX-X tests. Furthermore, an important number (ca. 180) of draft decisions on testing proposals on the two-generation reproduction toxicity endpoint are pending in COM.

- **Substances addressed under risk management processes**: It is also important to note that the properties and effects of the substances over 100 tonnes are also checked under other processes (in particular identification of SVHCs, and harmonised classification) as well as other expert groups (in particular PBT and EDs expert groups). Ca. 460 substances have been addressed under various RRMM processes.

Overall and considering the potential overlap across processes, it is estimated that, by the end of 2015, at least 1400 substances over 100 tonnes have been checked to a certain extent. Furthermore, all 4200 have been screened with IT-algorithms. A substantial part of them was subject to an expert screening that was sufficient to de-prioritise further evaluation.

3. Implementation of the strategy over 2016-2018

Key challenges:

- Low quality / resolution of **use and exposure information** in the registration dossiers is hampering effective and timely identification and priority setting of substances that matter and increases the risk of addressing 'false positives'. Likewise this hampers de-prioritisation.
  - Ways to overcome:
    - Activities under the CSA programme (use descriptors, use maps etc).
    - Concerted measures by industry associations / sectors (e.g. ref. CONCAWE approach) to ensure that the information 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.
- Abundant and poorly documented application of **read-across and grouping**, complicating CCH (dossier-specific process) and making it scientifically challenging. This includes classes of difficult substances like petroleum derivatives, metals and other complex UVCBs.
  - Ways to overcome:
    - RAAF and advice and guidance on read-across and grouping to registrants
    - Targeted campaigns inviting improved justifications and documentation
- Lack of advanced tracing and tracking system of substance/dossier specific checks, screening and their outcomes
  - Ways to overcome:
    - 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.

Note: CCH or SEv cannot be used to generate further information on substances in imported in articles, (i.e., substances which are not registered and are in the EU market only due to imported articles). These substances are an important source of potential risk and their identification and prioritisation for further work require a dedicated approach.

Our ambition by the end of 2018:

- Using the existing annual capacity efficiently for performing CCHs, ECHA estimates to conclude in the years 2016-2018 **at least further 400 compliance checks on the priority endpoints of the priority substances in the 100-1000 and >1000 tn tonnage bands**. The remaining CCH capacity (up to 200) is used for specific or more targeted CCHs (e.g. SID when required for TPE or SEV, cases related to follow-up of earlier cases).
- As a result of this and the checks performed in the earlier years, by the end of 2018, at least [30%] of the substances registered over 100 tonnes in full (i.e. [1400] substances) will have been checked for compliance to a relevant extent and data have been submitted or are in the process of being submitted. As a result, for these substances we can claim that sufficient clarity on the identification of the substance and sufficient hazard data has been made available (or is in the process of becoming available) so that conclusions can be draw on the concern identified.
- Cases where a concern is confirmed (with or without CCH) and regulatory risk management measures seem to be warranted, ECHA has communicated the conclusions to MSCAs and the Commission in an effective manner (mainly through the SVHC roadmap coordination activities and RiME), leading to an increasing number of proposals for CLH, SVHC and restrictions.
- In parallel, by the end of 2018, when required in addition or alternative to a compliance check, over 300 priority substances have been evaluated by MSCAs under substance evaluation and necessary data has been requested.
- Testing proposals have been examined for over 1000 substances.
- For the remaining substances with full registrations, we have a strategy in place that enables us:
    - To conclude that these substances are currently of no or lower priority for further action because:
        - Information on their volumes, uses and/or exposure indicates no or no significant exposure)
        - Information included in the registration dossiers topped up with information from prediction techniques and other potential sources indicates that they are not likely to possess important hazard properties
        - They are already subject to stringent risk management measures (e.g. substances with CMR classification and included in candidate list)
        - They are already identified as RRM/RMOA candidates based on strong evidence from risk assessments, prioritisation schemes from other regulatory bodies, grouping or structural alerts.
    - Or to tackle them in batches (e.g. through sector-specific targeted activities, substances grouped by structural similarities or specific functionalities (e.g. plasticisers, flame retardants) to ensure priority substances can be identified.

In essence, the Agency will try in the coming years to gradually map the 'universe of registered substances' above 100 tonnes through a number of actions, where relevant in collaboration with industry sectors, with the intention to be reduce the pool of substances of potential concern and be able to conclude for as many substances as possible the need for specific action or that they are currently of low priority for further work (see Annex 3).

- Furthermore:
    - Targeted campaigns and other complementary measures have helped to increase the overall quality of all registration dossiers with a measurable impact (ref. SO1 measurements).
    - All substances registered as intermediate only which are listed in the candidate list have been addressed to clarify their intermediate use.
    - The potential to use article 36 of REACH more extensively to request from industry (exposure) information that should be readily available will be further explored.
    - Important cases of "abuse" (distortion of market) have been handled by other methods than CCH (e.g. through informal letters and revocation of registration decisions). CCH will be used as last resort.
    - Transparency of CCH outcomes is increased by completing the tasks under dissemination (i.e. life-cycle of decision making is online, and we have an efficient traceability system in place to be able to report detailed statistics).
    - The substances with registrations only in 1-10 tn and 10-100 tn tonnage bands have been preliminarily screened with IT-tools to allow planning of CCH for years 2019-2025 and support the decision whether priority should continue to be assigned to >100 tn dossiers.

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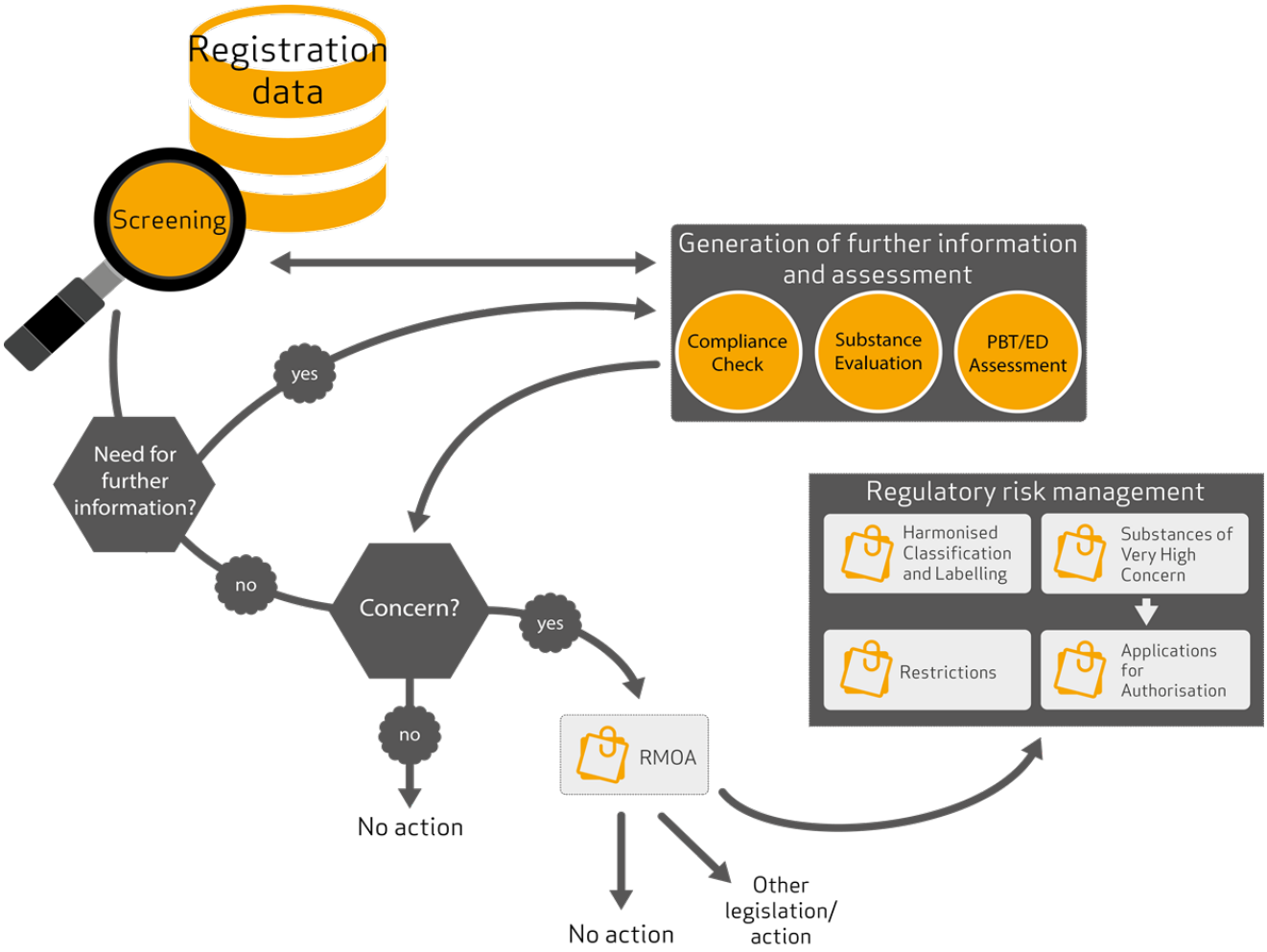
Annex 1. Overview on how the common screening work interlinks with evaluation and risk management processes.



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

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Annex 2. Overview of complementary measures and their impact/achievements

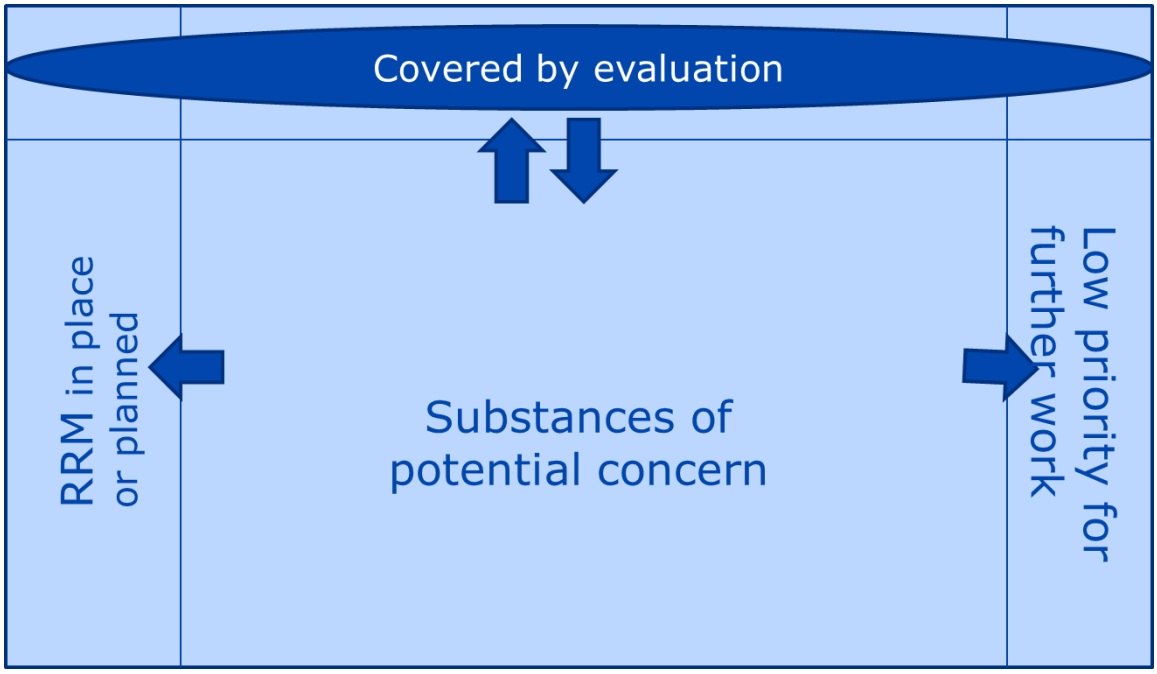
Measure	Scope	Impact/Achievements
Targeted Letter campaigns	- One topic addressed - Issues that can be communicated in short letters - Timeline needed for correcting the dossier is short - ECHA can easily verify the update and take additional action (CCH) if needed - Quality improvement is measurable	- Good response rate: can exceed 80% - Efficient for clarification - Domino effect: registrants in general correct other dossiers than those targeted in the campaign - Validation assistant updated to address quality deficiencies before submission - Valuable input for improving the reporting format in IUCLID
	- 2012: Intermediate uses - Aim: Clarify the intermediate status and strictly controlled conditions - All 2010 intermediate dossiers screened (5500) - 2400 letters for 760 substances	- 90% dossiers updated - 100 updated to full registration - Follow-up: Art. 36 letters sent to selected non respondents - Significant improvement of the use information in 2013 dossiers
	- 2014: substance identification - Aim: Address obvious SID deficiencies - 40,000 dossiers screened - 1350 letters for 300 substances	- >80% dossiers updated - Domino effect: >1000 dossiers updated in top of target dossiers - In 50% dossiers: no remaining issue identified - CCH for some cases
	- 2014: Full registrations with intermediate use - Aim: Support prioritisation for inclusion in A14 and clarify the intermediate use - 280 letters for 25 substances on the candidate list	- 50% dossiers updated - 25% of the cases: no intermediate use anymore - Better basis for A14 recommendations
	- 2015: Substances short-listed for authorities' scrutiny - Aim: Invite registrants to update their dossiers before CCH starts and increase transparency - 1340 letters for 178 substances	- 104 dossiers updated after 4 months (Lead dossiers) - i.e. information received for 33% of the substances - Update plans received - Registrants are aware that these substances are under authorities scrutiny (increased predictability and transparency) - Lessons learnt for preparing the 2016 campaign

Measure	Scope	Impact / Achievements
Art. 36 letters	- Small scale - Bring data that should be in registrant's possession, e.g. nanoforms or justifications for strictly controlled conditions	- Stronger regulatory stick - Follow-up possible by NEAs
	- Continuous action on intermediates - Aim: clarify the intermediate status for priority substances (candidate list, under RMOA, substances which might be used as substitutes for CL/AXIV substances) - > 200 letters	- Information received - Some cases handled by NEA - Quality improved since process started - Input for developing the practical guide on intermediates and updating reporting format in IUCLID 6 - Early action on potential unwished substitutes
Sector specific approach	- Problem common to all registrants of a sector - Potentially complex matters - Too many dossiers to address companies one by one	- Efficiency - Can be used prior to submission so that dossiers are not picked by CCH
	- Petroleum substances: PetCo approach in 2014-2015 - Aim: Identification of petroleum/coal substances under SVHC roadmap - > 4000 dossiers for 200 substances	- Information on use and tonnage per use received - Pool of 65 substances of interest with priority for further work - Approach valid also for coal/hydrocarbon solvents, etc.
	- Essential oils in 2015-2016 - Aim: Support the sector for identifying their substances and preparing the environmental assessment and reviewing the classification - 20 000 substance pre-registered, and probably 2000 registrations expected	- Complex issues clarified before registration - Guidelines published on SID in 2015 - Guidelines to be published on Ecotox in 2016
	- Inorganic pigments in 2015-2016 - Aim: Clarify the substance identification of very complex substances	- SID complex issues clarified before registration - Guidelines to be published in 2016
IUCLID 6 format	- Start in 2016 - Upgrade of the IUCLID format - Aim: Clarify the reporting format so that it is easier to report SID, study results and justify waivers	- Increased clarity with an impact on quality - Dossier updates can benefit from the improved format - Authorities understand better the information provided, hereby increasing the efficiency of the process

Measure	Scope	Impact / Achievements
Completeness check	- Start in 2016 - Process upgraded through reviewing the rules based on the updated IUCLID format and introduce a manual check	- Expected impact: - Increase meaningfulness of information - Avoid free riders - Avoid that obvious issues are addressed at compliance check to increase CCH throughput
Invalidation of registration dossiers	- Pilot in 2016 - Aim: Legacy dossiers that should have been picked by the revised completeness check	- Ensure meaningful information in 2010 and 2013 dossiers
Dissemination	- New Dissemination platform in 2016 - Aim: make the information easily understandable and accessible to increase transparency and scrutiny by 3rd parties - Aim: make evident the status of ongoing evaluations and whether information has been updated further to CCH	- Much easier for 3rd parties to spot inconsistencies especially in uses and C&L - Reputation impact: Registrants will spontaneously update their dossiers to address errors or lack of information - 3rd parties will be able to verify how information is updated further to an evaluation decision
PACT	- Publication of substances scrutinised by authorities with the concern being investigated	- Increased predictability for registrants and stimulate dossier updates
Alerts on public consultations	- Alerts when PCs for CLH, SVHC identification AXIV recommendation, AfA and restriction start - Aim: Registrant and C&L notifiers are informed of the PC and of the ongoing regulatory process	- Increased predictability for registrants and stimulate dossier updates

Annex 3: Visualisation of ECHA's intentions to 'map the registration universe'

Situation now:



Situation mid-term: