Workshop on the implementation of ECHA's integrated regulatory strategy Proceedings

28 February – 1 March 2017

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Summary

The workshop on the implementation of the integrated regulatory strategy, organised by ECHA on 28 February – 1 March 2017, reviewed the state of play of the regulatory strategy and other actions that can be done to efficiently implement this strategy.

Discussions at the workshop were strongly focused on mapping the chemical universe and grouping substances as new approaches to enhance the implementation of the strategy. Several issues related to the quality and compliance of information on the registered substances were also addressed.

Representatives from the Member States and EEA countries, the European Commission, Member State Committee accredited stakeholder observers and the ECHA Secretariat participated in the workshop.

It was stressed that REACH and CLP are the key instruments in reaching the goal agreed in the 2002 Johannesburg World Summit on Sustainable Development (WSSD): "*By 2020…chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment*".

The regulatory strategy gives a clear focus on where to spend authorities' resources to obtain the maximum impact. However, there is still a need to enhance the interplay of the regulatory processes and data compliance, and quality of registration dossiers is a major issue.

With regard to registration dossier compliance and quality, it was concluded that sufficient data for long-term endpoints is missing for many substances and justifications for adaptations are often not adequate. Furthermore, both hazard and use/exposure information are often not good or sufficient enough to allow appropriate (de)prioritisation.

The workshop concluded that grouping in addressing substances for further action was, in principle, supported. The grouping approach has many benefits, including that it can save resources, improve consistency and focuses on risk management measures. However, quite a number of process practicalities were identified as well.

There was agreement that the outcome of the screening and assessment work should be adequately recorded and transparently communicated. This is essential for answering the WSSD 2020 challenge. Whereas identifying and addressing priority substances for regulatory action is and remains the highest priority, conclusions that substances are of low(er) priority for further regulatory action are important as well and should be recorded. Nevertheless, communication on conclusions on whether substances have priority or not for further regulatory action need to be very clear and explicit to avoid misunderstanding and 'misuse'.

The workshop agenda is included in Annex I. Explanations of abbreviations used in this report can be found in Chapter 5.

1. Aim of the workshop

ECHA organised a workshop on the implementation of the integrated regulatory strategy from 28 February to 1 March 2017. The objectives of the workshop were:

- to review the current state of play of the regulatory strategy and other actions undertaken to implement ECHA's integrated regulatory strategy;
- to explore new, collaborative measures to enhance the implementation of the strategy;

- to strengthen the role of Member States in implementing the strategy to increase the impact of the strategy;
- to further improve coordination of actions by different parties; and
- to gather ideas about how to best monitor and measure progress in meeting the objectives of the strategy.

The workshop was organised in five plenary sessions. The presentations were followed by prepared commentaries and the topics were then discussed in detail at the end of each session.

2. Participants

The workshop had 30 participants from 18 Member States and Norway, four participants from the Commission services, two observers from Serbia as well as representatives from seven stakeholder organisations covering industry, animal welfare and environmental NGOs.

3. Topics discussed at the workshop

3.1 State of play of implementing ECHA's integrated regulatory strategy

Jack de Bruijn of ECHA gave an update on the implementation of the Agency's integrated regulatory strategy, showing the key factors and highlights of the work done under the REACH and CLP processes.

The key challenge behind the pursuit of better integration is the 2020 goal agreed in the 2002 Johannesburg World Summit on Sustainable Development (WSSD): "*By 2020…chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment.*"

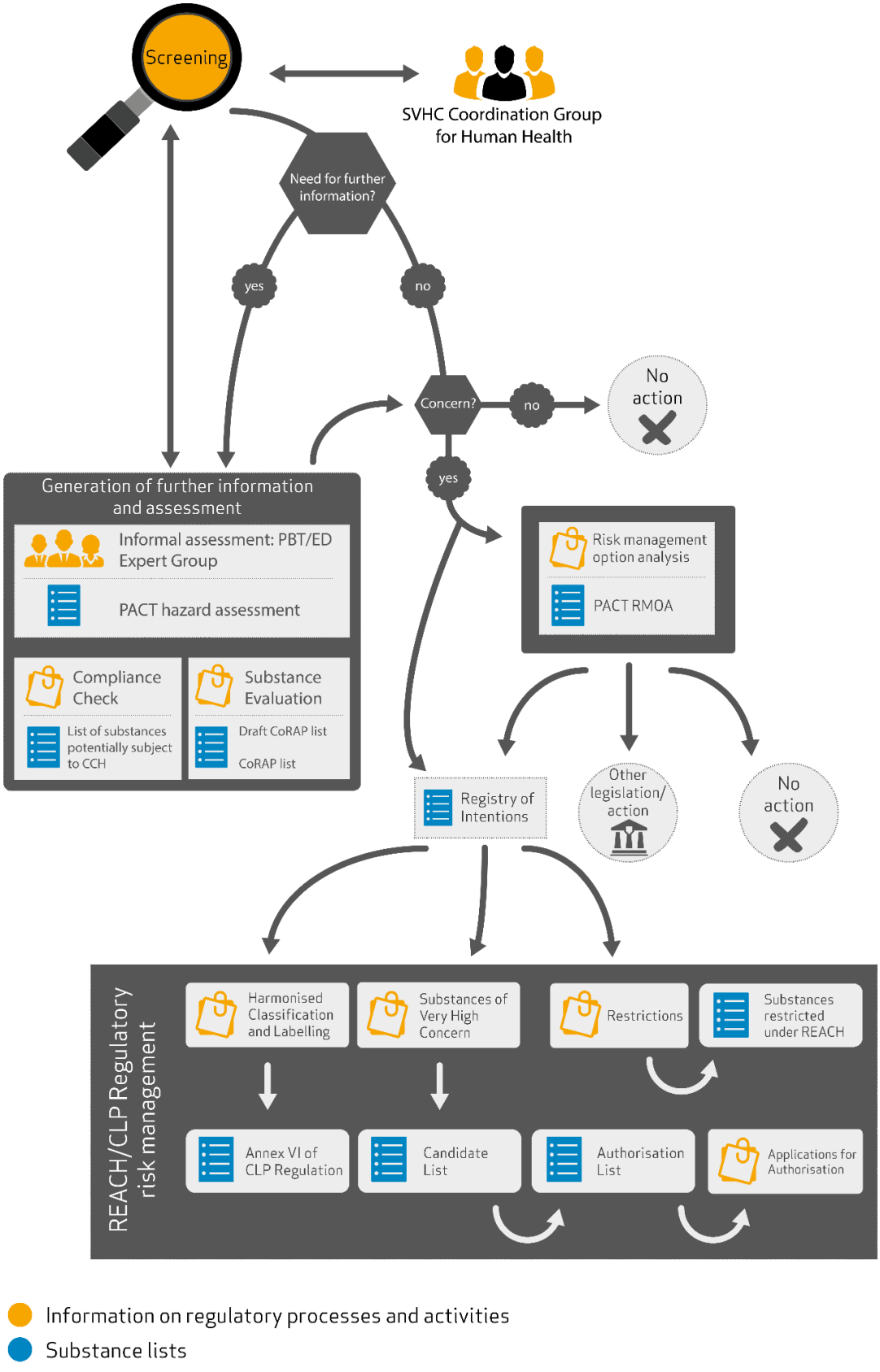
REACH and CLP are the key EU instruments that help achieving this goal, especially to ensure that robust data is available on all chemicals in Europe and that effective regulatory risk management of the most dangerous chemicals takes place. Figure 1 shows how the processes work towards this. Hence, efficiency and effectiveness of REACH and CLP play a key role in achieving this WSSD 2020 goal.

ECHA recently revised the registration-related tools and enhanced the related approaches as part of the 2018 registration roadmap. These are now improving the quality of current and future dossiers. The revisions include the enhanced completeness check, which was launched in June 2016 and foresees a manual verification where completeness cannot be verified automatically.

In parallel, retrospective completeness checks started to bring existing registrations to the level of the enhanced completeness implementation. IUCLID 6 was also released with enhanced support for data input, in particular for reporting information in a more structured and transparent way.

ECHA and Member States have implemented the common screening, which is a showcase for the full integration of the REACH and CLP processes. Common screening aims to identify and prioritise those substances where regulatory action can best support substitution and increase the protection of human health and the environment, ensuring an optimal use of authorities' resources.

Figure 1: How substances of concern are identified and managed under the REACH and CLP processes.



Information on regulatory processes and activities

Substance lists

Its main benefits include considering the need for regulatory risk management (RRM) early on and keeping it in mind consistently during the further actions taken. Another benefit is that all REACH/CLP data are used effectively and complemented with external data sources.

The regulatory strategy has also been fully implemented in evaluation: the focus of compliance checks has shifted towards substances that matter and substance evaluation is being better addressed to substances of potential concern and where further, also non-standard data may be needed to clarify the concerns.

Recent highlights of dossier and substance evaluation are available in the 2016 Evaluation Report[1]. Furthermore, the PBT Expert Group has supported evaluation by providing informal scientific advice for substances with potential PBT/vPvB concerns and the Endocrine Disruptor Expert Group has provided informal scientific advice on questions related to the identification of the endocrine disruptive properties of chemicals.

Risk management option analysis (RMOA) aims to support decision-making by authorities on the need for RRM and on the best regulatory instrument to be used to address the concern. It allows other authorities to have an early input (information, concerns, views) and hence speeds up the formal opinion forming and decision making. RMOA is currently a well-established and flexible voluntary tool, which has improved the transparency and predictability of authorities' work. Although it takes time, the questions discussed in the RMOA phase are relevant and they would be raised anyway later in the process. Addressing them early in the process is more efficient.

Together with the Member State competent authorities (MSCAs), ECHA has also implemented other measures supporting regulatory actions. Regular letter campaigns and pre-warnings for substances shortlisted for further work have been organised. The pre-warning has been effective with 40 % of substances having updated dossiers within four months. Further developments on PACT (dissemination through ECHA's website) and ACT (information to authorities through the Portal Dashboard) are ongoing and foreseen for 2017.

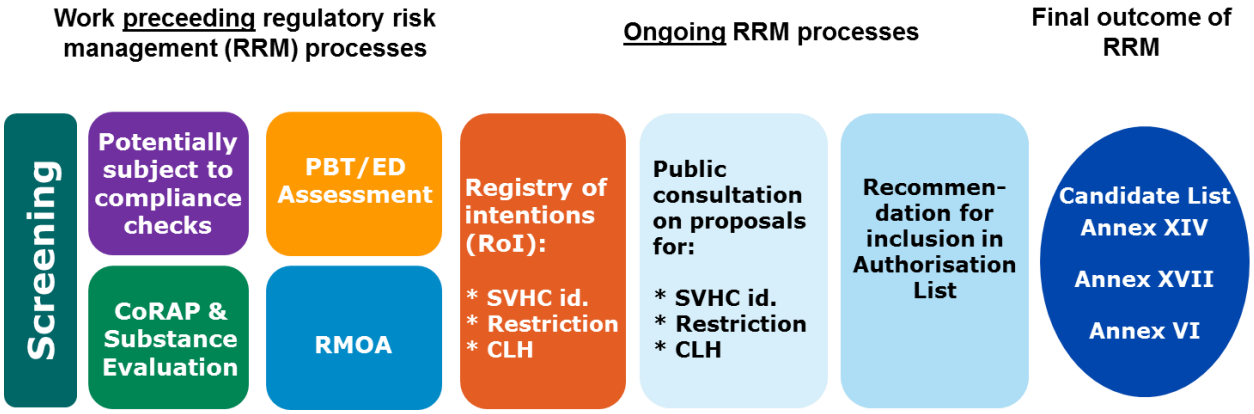
In addition, complementary activities are ongoing to address substances within certain sectors. These include petroleum and coal substances (PETCO), metals and metal compounds, plastic additives as well as certain specific groups of substances (organotins, PFASs, UV-filters, flame retardants).

Information disseminated on ECHA's website has been substantially improved (infocards/brief profiles) since early 2016. This is an important measure to increase transparency, implementing one of the regulatory strategy's aims. The statistical reporting of compliance check (CCH) outcomes has also been improved and the dissemination of the "evaluation life-cycle", showing in which phase of the process the dossier evaluation case is, is planned for 2017-2018. Dates for (substantial) dossier updates are now visible on ECHA's website. In addition, ECHA publishes a lot from the REACH and CLP processes. Figure 2 shows what is publicly available from these processes (on top of background information).

The integrated regulatory strategy integrates all of the REACH and CLP processes, ECHA teams and expert groups, in cooperation with MSCAs. It gives a clear focus on where to spend the resources and time for the maximum impact. A lot has been achieved, the machinery is largely in place. However, there are still many challenges ahead and overall resources are scarce.

[1] Available at: https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports?panel=evaluation-reports#evaluation-reports

Figure 2: Information publicly available from REACH and CLP processes.



The remaining challenges for industry are to:

- improve the quality and compliance of registrations;
- prioritise work in line with the priorities of authorities; and
- address the long-term effects and use/exposure information adequately.

The remaining challenges for authorities are to:

- stay focused on the effectiveness of the actions, with increased protection, support to substitution and the need for RRM in mind;
- increase the throughput keeping the WSSD 2020 goals in mind; and
- address the scientific and practical questions when assessing groups.

3.2 Mapping the universe of substances for further action

3.2.1 Registration dossier compliance and quality

Katrin Maul and Angelika Oertel of the Federal Institute for Risk Assessment (BfR), Germany, presented the German project results of a formal and refined check on the availability of human health and environmental data in REACH registrations.

The project has three phases:

- Project I (March 2014 - March 2015):
    - Screening of 1 814 dossiers ≥ 1 000 tpa (submitted – including potential updates – to ECHA until March 2014).
    - Assessment of the availability of the standard information requirements according to REACH using a systematic screening approach with decision trees.

- Project II (April 2015 - July 2016):
    - Verifying substance sameness within SIEFs and within individual registrations.
    - Check the formal conformity of data waiving and adaptation with the respective requirements of REACH.
- Project III (August 2016 - January 2017):
    - In-depth analysis of endpoints without conclusion after project I and II (for selected endpoints).

The German project results so far for the human health data are that there is high proportion of "non-compliant" endpoints. The main concerned endpoints are developmental and reproductive toxicity.

The project has recommended adaptations of the regulatory guidance and registration tools including the REACH annexes, the guidance documents on information requirements and chemical safety assessment (CSA), and IUCLID .

The overall conclusions from the project so far are that there are significant data gaps and inappropriate waiving/adaptations identified in 1 000 tpa registrations: 12-59 % of the examined endpoints were "non-compliant". Thus, a need to improve registrations and further actions were identified. A follow-up project on >100 tpa registrations with adapted and refined evaluations is starting soon.

Mike Rasenberg of ECHA presented an overview of the status and consequences of REACH registration data quality with the following observations. Many dossiers and substances are often non-compliant for higher tier human health and environmental endpoints although there is a potential relevant use/exposure. This poses challenges to the safe use of chemicals.

The question was raised whether it could be linked to the lack of liability in relation to missing higher tier endpoints. In other words, does it pay off for companies to wait for revising use/exposure information until authorities possibly identify the substance for further scrutiny and action?

It seems that compliance check, dissemination and enforcement as concepts do not alone create the required pressure. Therefore, a relatively large group of chemicals is still in the "grey zone" due to a lack of sufficient (reliable) information, especially use information, preventing authorities from deciding whether a substance should be (de-)prioritised. Generating the necessary hazard information is time and resource consuming and hence identifying substances that matter is challenging and can take several years. Even with the use of other sources of information (hazard and use), an effective prioritisation is difficult.

Erwin Annys of the chemicals industry (Cefic) confirmed that they are committed to making REACH work and to work together with authorities to clarify the necessary information requirements if there are problems in certain dossiers. They also believe that a joint activity can be a win-win for all, including a better understanding of authorities' priorities for industry so that it can focus more on those substances and issues.

3.2.2 Mapping the chemical universe: method and preliminary results

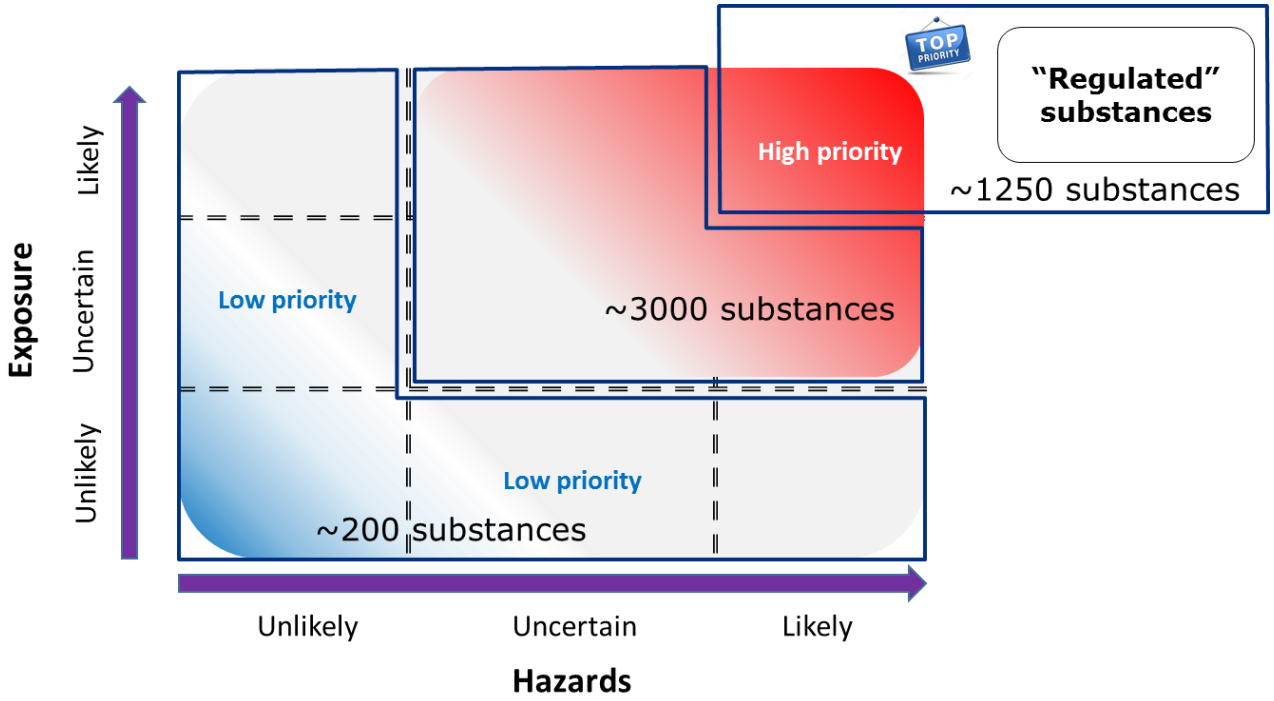
Panagiotis Karamertzanis of ECHA presented the work done to develop the 'chemical universe mapping'. Its purpose is to assign a substance in the right location in the universe based on its hazardous properties and exposure as shown in Figure 3.

Authorities are expected to address the uncertainties on higher volume substances by 2020 by

identifying relevant candidates for RRM or consider the substances to currently have a low priority for regulatory action. Both outcomes push the substances to the extremities of this ECHA chemical universe map. It is also possible that before a decision is taken, further information needs to be generated. While information is generated the substance remains in the central part of the chemical universe. Substances that have been assessed and have an outcome of "no action" are placed in the {hazard=unlikely, exposure=unlikely} region. High priority substances and their subgroup "regulated substances" are addressed in Chapter 3.2.3.

The chemical universe map gives an estimation of regulatory coverage and the state of play of the REACH and CLP implementation. Therefore, it is a kind of time-stamped regulatory footprint. The chemical universe map is not an indication of a single process but an amalgamation of all known information for substances. Figure 3 shows the preliminary results of the first mapping exercise for substances registered above 100 tonnes under REACH.

Figure 3: Preliminary results of the first mapping exercise for substances registered above 100 tonnes under REACH.



It should be noted that the chemical universe map is a simplified representation of the regulatory status of substances. Chemical universe mapping is not meant to be a reporting tool. It is proposed to be used as a long-term work planning instrument.

3.2.3 High and low priority substances

The above explained mapping of the chemical universe contains the following three spheres:

1. High priority for further work by authorities Substances with identified concern and regulatory work has already been initiated or further work can be initiated based on currently available data
2. Substances of unknown priority Substances for which there is at present uncertainty regarding the hazardous properties and/or the potential exposure; risk cannot be excluded although it cannot be established based on currently available data.
3. Low priority for further work by authorities Substances for which available data suggest that no further regulatory action is needed at present

The current high priority pool of the chemical universe map includes two types of substances, which are fundamentally different:

1 A. Substances which are already subject to sufficient RRM, i.e. no further RRM is required based on the current information.

1 B. Substances on which regulatory work is planned or ongoing (evaluation or RRM).

Jack de Bruijn of ECHA indicated that the low(er) priority substances are substances which do not currently merit further regulatory attention. Allocating resources to these substances is not likely to lead to significant improvement in safe use.

There are two different main reasons for allocating low(er) priority to a substance:

(1) there is sufficient information that the substance has no long-term hazard effects; and

(2) based on current uses, exposure is unlikely and the substance is not a potential substitute to substances of high priority.

Of course, both of these arguments can be valid at the same time as well. Currently, low(er) priority for further regulatory work is not always communicated to the public, but this should be considered. "No action" conclusions from RMOAs are, for instance, published but they are not easy to find and follow.

Where an authority has stopped working on a substance, it has in essence decided that it is of low(er) priority for further regulatory action. Making these decisions more publicly available would help to transparently identify substances of low concern and could support industry in finding safer alternatives.

3.2.4 Substances with unknown priority

Hannu Braunschweiler of ECHA indicated that the chemicals universe mapping done by ECHA has identified overall about 3 000 substances with unknown priority registered above 100 tonnes.

About 1 350 of them are being partially or fully addressed (e.g. on-going testing following a CCH or SEV decision or on-going testing following a TPE or targeted CCH decision).

About 650 of these 3 000 are covered by comprehensive and concern-driven evaluation (CCH and SEV). So all these are "evaluation work in progress" substances. Hence, about 1 650 substances (>100 tonnes) in the "middle" zone are not yet subject to any regulatory action and their priority is uncertain.

The main part of these 1 650 substances are with uncertain hazard and likely exposure and a minor part with uncertain hazard and exposure. This "middle" zone also contains many categories and broad "clouds" of read-across inter-linkages.

The key issue for substances in this "middle" zone is to either to prioritise or de-prioritise them with a view to achieving the 2020 goals. Therefore, there is a need to continue addressing substances and endpoints that matter the most and to have a programme of concerted actions that makes effective use of different evaluation processes as well as complementary measures such as the sector approach, early interaction with registrants for categories/groups under CCH, retroactive TCC and screening campaigns.

ECHA sees substance grouping as both a must and an opportunity and is therefore launching collaborative approach pilot projects to explore how to address 'groups of related substances' in collaboration with Member States and concerned registrants or industry groups.

Louise Conway of Irish Health and Safety Authority shared their CA experience from identifying substances for further regulatory action. She indicated that up to now there has been general reluctance to tackle groups of substances but the current view is that grouping can result in efficiencies in terms of regulatory outcomes and workload. She also questioned if CCH is always best instrument to deal with dossier quality as it can result in significant delay in initiating regulatory action.

Vito Buonsante of ClientEarth gave environmental NGOs' perspective on how to best address substances with unknown priority, with views of ClientEarth, ChemSec and EEB. He highlighted that the main goal of REACH is to protect health and environment, so the time lag between identifying a concern and managing its risks must be minimised. He proposed i.a. enhanced use of external knowledge and further development of grouping of substances as solutions to speed up the work.

3.3 Role of grouping in addressing substances for further action

The grouping approach used under the regulatory strategy should not be confused with the grouping and read-across approach as described in Annex XI, 1.5.

The scope of the grouping approach under the regulatory strategy is to cluster potentially related registered and even non-registered substances (e.g. by means of structural similarity, read-across made by the registrants) to enhance consistency and efficiency in all processes and to support sustainable substitution.

Chrystélè Tissier of ECHA reminded that grouping of substances is not a new concept. Substances have been grouped together and addressed under different regulatory processes based on e.g. structural similarity or the same use profile. Examples of grouping approaches are available from:

- REACH/CLP risk management processes: from harmonised classification and labelling (the perfluorinated carboxylic acids class such as PFOA, APFO, PFNA, PFDA), SVHC identification (chromium compounds, cadmium compounds, PFASs), Annex XIV inclusion to restriction (lead and its compounds, phthalates).

- REACH processes to generate further information: substance evaluation (small groups of similar substances, e.g. xylenes) and compliance check (limited experience so far (e.g. optical brighteners), few pilots planned for 2017) and testing proposal examination (large categories such as hydrocarbons, crude oils, resins/rosins, silanes).

- Steps supporting the REACH/CLP processes: screening and RMOA (isocyanates, phosphor-based chlorinated flame retardants (TCEP, TCPP, TDCP) in articles used by children).

Grouping has been used under RRM because it makes sense to address similar substances at the same time from a safe use point of view. Usually a larger pool of (eco)toxicologically relevant data can be considered (e.g. classification) which can increase the consistency of the assessment.

Grouping has also been used because of potential interchangeability of very similar substances (with similar hazard properties) in (some of) their uses. Grouping allows those substances where there is enough data and confidence that the SVHC criteria are fulfilled to be processed first before processing others using, for instance, read-across considerations.

Grouping has also been used to support functioning of the authorisation process to avoid substituting Annex XIV substances with substances that have similar properties and to enable applications for groups of similar substances. Grouping also allows more substances to be addressed with fewer resources.

Grouping has been used under compliance check (CCH) and substance evaluation (SEv) to:

- ensure a consistent approach when having substances with testing proposals or under CCH belonging to a same group of substances or same category allowing, in some cases, only one representative member to be selected for testing;

- enhance consistency and efficiency of SEv while ensuring transparency towards registrants of similar substances; and

- avoid unnecessary (animal) testing.

Grouping under both RMOA and screening gives a chance for cooperation among MSCAs before entering one of the REACH/CLP processes. It also ensures that the group can be looked at in a holistic way before taking regulatory action. Under RMOA, it ensures transparency towards stakeholders that the work is done on a group and not only on a single substance in isolation.

The overall benefits of looking at groups of substances are:

- Enhanced coherence of authorities' work through all steps from screening through further information generation (CCH, SEv, other means including direct contacts with industry) to RRM (harmonised classification and labelling, SVHC identification and authorisation, restriction, but possibly also actions under other legislation);

- Optimised use of available resources by avoiding overlaps/gaps of activities while providing transparency towards industry;

- Supporting industry and other actors to avoid regrettable substitution; and

- Clearly linked to SVHC Roadmap supplementary activities focusing on potential substitutes for substances already identified for regulatory actions.

Giovanni Bernasconi of ECHA indicated that the challenges for the grouping approach include:

- Resources and time needed for developing a 'grouping' strategy together with MSCAs and registrants;
- Interaction with different registrants/consortia;
- Legal considerations (data and cost sharing between substances); and
- Timelines when addressing multiple substances.

In view of these, ECHA has started to develop a more integrated approach on grouping.

Björn Hansen of European Commission, DG Environment, pointed out that there are no legal limitations in REACH or CLP for using substance grouping or proceeding in parallel with different regulatory processes (e.g. SEv and CCH or TPE). He also indicated that the baseline what needs to be considered when applying grouping is to compare what work (including number of vertebrate tests) needs to be done if the group members are addressed one by one versus addressing them as a group.

Hugo Waeterschoot of Eurometaux highlighted that for inorganic substances, hazard properties of their soluble salts, exposure conditions (to the environment) and (to some extent) exposure levels at the workplace, and uses and conditions of use are usually known. However, a grouping strategy is needed for handling unknowns such as assessing the relevance of the read across for the "less soluble forms" or for assessing the contribution to the "overall exposure".

Also, grouping substances based on their diffuse sources can help define their potential priority sources, appropriate substance or grouping/categories for further exposure assessment/risk characterisation refinement or for risk management. Another good example is that RMMs are often technology driven, so if we define all substances used for the same service/use we may define "a group" for RMM.

3.4 How to assign priority to substances with unknown priority

Claudio Carlon of ECHA highlighted that from the beginning when addressing any substance, the potential need for further regulatory action should be the main driver. Priority assignment can be done throughout all the steps of all the regulatory strategy processes: manual screening, pre-check, evaluation, RMOA. Therefore, there are different "low priority" baskets, reasons and meaning for low priority, depending on the process step. However, low priority assignment is not forever, but should be reviewed with time. Also, high priority is not forever, because action (e.g. data generated following evaluation, changes in uses and exposure) can lead to low priority.

Low priority assigned to a substance or group of substances should be explicit and duly recorded, regardless of which authority or process step it is resulting from.

"Explicit" does not necessarily mean public: the external communication is another aspect. As for the latter, it is noted that the substances considered to be high priority and therefore addressed by regulatory processes, are published. Claudio Carlon indicated that ECHA and the MSCAs should also consider communicating the substances regarded of low priority for regulatory work. Such communication would enhance transparency and act as an incentive for industry to improve the quality of dossiers. To make it public can also be useful to gather new relevant information for a revision of such de-prioritisation.

In any case, the low priority assignment should not be intended as "green listing" or claiming substances as safe, but meaning "low priority for further regulatory action". Furthermore, it can even be a preliminary assignment based on a screening assessment, and open to a further level of scrutiny.

Claudio Carlon presented examples of conclusions for no action regularly taken along the regulatory strategy pipeline (manual screening, pre-check, compliance check, substance evaluation, RMOA) where in practice the substance is considered as low priority for further work. In these cases, ECHA and the MSCAs should clearly conclude and record the low priority in view of what it means for a refinement of the chemical universe mapping and future considerations of the substance.

As an example, under CCH a substance is regarded as a low priority for further action if it shows compliance with eight super-endpoints, and there are no relevant concerns requiring consideration of RRM. In some cases, addressing a formal non-compliance in an ECHA decision can also be concluded as a low priority if the substance is very likely to be non-hazardous for the relevant endpoint or exposure is negligible or the requested information could, in any case, not bring any improved risk management (e.g. the substance is already severely classified).

Such an approach is instrumental if we wish to effectively address substances and concerns that matter the most for RRM. Consequently, "low priority for further action" does not necessarily mean that the dossier is formally compliant.

Assignment of high/low priority labels along the regulatory strategy pipeline is an essential part of the work towards the 2020 goals. The main driver is to move faster and more efficiently to cases that may require RRM. RRM thinking should start from the very beginning and follow through the processes.

Overall, it was felt that low priority label is often more like a side product when pursuing the identification of high priority substances, so they could also be called "not high priority substances". It was noted that REACH Annex IV is introducing a concept of listing low risk substances, which could eventually be updated.

4. Conclusions of the workshop and next steps

4.1 Conclusions

Based on the discussions in the workshop sessions, the following conclusions were made.

State of play

REACH and CLP are the key instruments to reach the WSSD 2020 goal. The integrated regulatory strategy gives a clear focus on where to spend authorities' resources to obtain the maximum impact. However, there is still a need to enhance the interplay of the regulatory processes. Furthermore, data compliance and quality remains a major issue.

When reviewing the state of play of the implementation of ECHA's integrated regulatory strategy it was noted that the enhanced completeness check is delivering an important contribution to the implementation of the strategy. Furthermore, the common screening is an excellent example of the fully integrated approach.

Information disseminated on ECHA's website and in ECHA's regular reports has been substantially improved to increase transparency, implementing one of the aims of the regulatory strategy.

Compliance check has shifted its focus to substances and endpoints that matter whereas substance identity issues are now mostly solved through informal interaction with registrants. Many decisions on long-term endpoints for substances that matter have been adopted and the generation of information is ongoing. In addition, supporting measures such as letter campaigns also seem to support the regulatory processes well. Now, more work is needed to address categories and groups of substances.

Furthermore, RMOA is a well established, flexible and transparent tool. Although it takes time, it is still better to raise the questions in RMOA for discussion early in the process. Further policy discussion is needed in CARACAL and/or RIME on how to increase/improve the output.

Dossier compliance and quality

With regard to registration dossier compliance and quality, it was concluded that sufficient data for long-term endpoints is missing for many substances and justifications for adaptation are often not adequate. Furthermore, both hazard and use/exposure information are often not good or sufficient enough to allow appropriate (de)prioritisation. Prioritisation is important also for industry as they cannot address all substances at the same time, either, especially when at the same time preparing for the 2018 registration deadline.

Mapping the universe of substances, low and high priority substances

The methodology for mapping the universe to support the efficient implementation of the strategy needs to be transparent but there is no need to strive for perfection.

The explicit assignment and recording of high and low priority substances is very important. Communication and transparency are very important as well. Proportionality is needed in what needs to be achieved for high priority substances; for already regulated or soon to be regulated substances, there is no need to address "every last kilogram" but rather focus on 'new' substances of concern.

An enhanced way forward with risk management could be to assume, in the absence of solid data, worst-case exposure situations (presence of risk vs. absence of risk) and try out with specific cases to see whether RAC and SEAC can accept such an approach.

It is important to be transparent about why substances are identified as being low priority for further regulatory action. The question was raised if it is necessary to manually confirm all low priority substances or if we can rely on IT screening flags for low exposure.

An informal collaboration with registrants can be useful to better address groups of substances. Authorities need to be clear and transparent what is the role of the informal interactions or projects versus the official evaluation processes in addressing substances with unknown priority.

The role of informal interactions is to clarify the scope and prioritise the substances in the group for risk management measures (RMMs). Evaluation is used especially for generating hazard data for prioritised substances considered to be representative for the substance group.

So, informal interactions will not replace CCH or SEv when more hazard data is needed. However, such informal interactions should substantially speed up and focus the subsequent evaluation processes. Additional approaches are also needed as CCH is not effective in delivering exposure information.

Public interest NGOs could also contribute to the unofficial approaches such as sector and collaborative approaches. In any case, CCH (besides TCC) needs to also keep its function to control the level playing field for registrants.

Grouping approach

The grouping approach in addressing substances for further action was in principle supported. There are no legal limitations in REACH for using substance grouping or proceeding in parallel with different regulatory processes (e.g. SEv and CCH or TPE). The grouping approach has many benefits, including that it can save resources, improves consistency and focuses on RMMs. Grouping of substances is also important to avoid unwanted substitution. However, quite a number of process practicalities need improvement for dealing with groups. So, there is a need to collect lessons learned from the experience gained so far with groups. Overall, the group approaches need a plan and strategy to be concern driven, be clear on what is the foreseen RMM outcome.

Having at least some group members listed in CoRAP would give the MSCAs resources. Such a strategy for grouping should be based on similar concerns and a group of substances can then be built around that, based on structural similarity or uses/exposure. First, one would need to define the scope of the group and on which members to focus. The default assumption is that the test results would be applied to the related (sub)group of substances. Some group members may be deprioritised due to low exposure but may be addressed later.

The grouping approach may need more cooperation between different actors and needs to be adapted group-by-group. So, it is not to be seen as a "straight jacket".

However, there are challenges that need to be addressed for the grouping approach. A grouping approach is an iterative activity in the function of concerns, and it is to be further refined or re-scoped based on information generated. The scope of work and questions to be solved are wider compared to addressing single substances.

The roles and responsibilities in defining or agreeing on a category (industry vs ECHA/MSCA/MSC) needs to be discussed further. It was noted that different or non-standard requirement data (e.g. toxicokinetics) may be necessary to support read-across or categories.

The process practicalities in applying the grouping approach need further elaboration including:

- Cooperation between MSs, and between MSs and ECHA;
- How to deal with willing versus non-willing companies;
- Explore how to address a group of substances in one evaluation decision; and
- Cost sharing.

Assigning priority to substances with unknown priority

There was agreement on the principle that the outcome of the screening and assessment work done should be adequately recorded and transparently communicated. This is essential for answering the WSSD 2020 challenge. Identifying priority substances for regulatory action is and remains the highest priority.

Assigning 'low priority for regulatory action' conclusion is not a goal as such, but an important 'side-product'. It is important to note that the objective to have an answer for all high volume substances should be reached very soon, by 2020.

Nevertheless, conclusions on whether substances have priority or not for further regulatory action need to be very clear and explicit, as well as on what is meant with low priority given that it can result from various levels of scrutiny of the substance (i.a. manual screening, CCH, SEV, RMOA).

Furthermore, care needs to be taken about how to communicate 'low priority for regulatory action' conclusion to avoid misunderstanding and 'misuse'. A low priority for regulatory action is not to be mixed with "green listing". Priority is always relative, time-bound and can or should be revisited. A 'no action' outcome from manual screening can neither be seen as authorities taking responsibility on the safety of that substance.

4.2 Next steps after the workshop

ECHA reported on the workshop conclusions in the 23rd meeting of competent authorities for REACH and CLP (CARACAL), 22-23 March 2017, and in the 53rd meeting of the Member State Committee, 26 April 2017.

ECHA will elaborate further on the following key open issues after the workshop:

- Addressing groups of substances by MSCAs and ECHA effectively and efficiently throughout the regulatory processes; ensuring that the approaches, tools and working methods and practices are up to the challenge;
- Enhancing information exchange and collaboration between authorities; ensuring appropriate recording and reporting;
- Communication to the registrants and wider audience of conclusions on substances and groups of substances at different process levels, including when the (group of) substances is regarded as having low priority for further regulatory action; preventing misunderstanding and misuse of such conclusions;
- Further use of the enhanced completeness check and retroactive completeness check for strengthening the implementation of the regulatory strategy;
- Understanding and finding incentives for companies to take a proactive role in providing adequate data and updating the dossiers.

5. List of abbreviations

ACROSS	A common road to substance screening
CA	Competent authority
CARACAL	(Meeting of) competent authorities for REACH and CLP
CCH	Compliance check
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging Regulation
CoRAP	Community rolling action plan
CSR	Chemical safety report
DD	Draft decision
ECHA	European Chemicals Agency
ECHA-S	Secretariat of the European Chemicals Agency
ED	Endocrine disrupter
EEB	European Environment Bureau
EOGRTS	Extended one-generation reproduction toxicity study
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
PACT	Public activities coordination tool
PfA	Proposal for amendment
PBT	Persistent, bioaccumulative, toxic
RMM	Risk management measure
RMO	Risk management option
RMOA	Risk management option analysis
SEv	Substance evaluation
SID	Substance identification
SVHC	Substance of very high concern
TPE	Testing proposal examination
WSSD	(2002 Johannesburg) World Summit on Sustainable Development

Appendix 1. Agenda

Workshop on the implementation of ECHA's integrated regulatory strategy

28 February – 1 March 2017

ECHA Guido Sacconi conference room

Annankatu 18, Helsinki, Finland

Tuesday 28 February 2017		
08.30	Registration	
09.00	Welcome and background and objectives of the workshop	Leena YLÄ-MONONEN ECHA
09:15 - 09:45	**Session 1** **Introduction and setting the scene**	Chair: Leena YLÄ-MONONEN ECHA
09:15	1. State of play of the actions undertaken to implement ECHA's integrated regulatory strategy	Jack DE BRUIJN ECHA
09:30	Discussion	
09:45 - 14:15	**Session 2** **Mapping the universe of substances for further action**	Chair: Christel MUSSET ECHA
09:45	2. a) Availability of human health data in REACH registrations – German project results	Katrin MAUL Federal Institute for Risk Assessment, Germany
10:00	2. b) Availability of environmental data in REACH registrations – German project results	Angelika OERTEL Federal Institute for Risk Assessment, Germany
10:15	2. c) Data quality – status and what are the consequences	Mike RASENBERG ECHA
10:25	2. d) Mapping the universe of substances for further action - industry perspective	Erwin ANNYS, Cefic
10:35	Discussion	
10:50 - 11:10	Coffee break	

11:10	2. e) Mapping the chemical universe: method and preliminary results	Panagiotis KARAMERTZANIS ECHA
11:25	2. f) High and low priority substances	Jack DE BRUIJN, ECHA
11:35	Discussion	
12:00 - 13:00	Lunch break	
13:00	2. g) How to best address substances with unknown priority?	Hannu BRAUNSCHWEILER, ECHA
13:20	2. h) Identifying substances for further regulatory action – IE CA experience	Louise CONWAY, Health and Safety Authority, Ireland
13:30	2. i) How to best address substances with unknown priority - NGO perspective	Vito BUONSANTE, Clientearth, Jerker LIGTHART, ChemSec and Dirk BUNKE, EEB
13:40	Discussion	
14:15 - 17:00	**Session 3 Role of grouping in addressing substances for further action**	Chair: Jack DE BRUIJN ECHA
14:15	3. a) Grouping of substances from a regulatory perspective	Chrystele TISSIER ECHA
14:30 – 15:00	Coffee break	
15:00	3. b) Grouping approach by ECHA/authorities in the regulatory strategy	Giovanni BERNASCONI ECHA
15:15	3. c) Commentary on the use of substance grouping under REACH and CLP	Björn HANSEN DG ENV
15:25	3. d) Industry perspective on the use of substance grouping in addressing substances with unknown priority	Hugo WAETERSCHOOT Eurometaux
15:35	Discussion	
17:00	End of Day 1	

Wednesday 1 March 2017		
09:00	Information session: technical completeness check as an element of the regulatory strategy	Mercedes VIÑAS, ECHA
09:15 - 10:15	**Session 4 How to assign priority to substances with unknown priority?**	Chair: Watze DE WOLF ECHA
09:15	4. How to assign priority to substances with unknown priority?	Claudio CARLON, ECHA
09:35	Discussion	
10:15 - 10:45	Coffee break	
10:45 – 12:00	**Session 5 Conclusions – enhancing the implementation of the strategy**	Chair: Björn HANSEN DG ENV
10:45	5. a) Reflections on the implementation of ECHA's integrated regulatory strategy	Leena YLÄ-MONONEN ECHA
11:00	Discussion	
11:30	5. b) Conclusions of the workshop and next steps	Jack DE BRUIJN ECHA
12:00	End of the workshop	
12:00 – 13:00	Lunch	

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