

Interim Evaluation of the CSA programme, roadmap and Exchange Network on Exposure Scenarios (ENES)

External Evaluation Report

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Executive Summary

In 2013, the European Chemicals Agency (ECHA) and industry set up a formal programme to support Chemical Safety Assessment (CSA) and Exposure Scenarios (ESs) carried out under the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (1907/2006). The overall purpose of the Chemical Safety Report (CSR)/ES Roadmap is to facilitate the provision of good quality information on the use of chemicals (e.g. use description, conditions of use) in the REACH CSR and the extended Safety Data Sheet (ext-SDS). In 2016 ECHA decided to undertake an interim evaluation of the CSR Roadmap/Exchange Network on Exposure Scenarios (ENES) after 2 years of operation. There are two parallel but interconnected workstreams; the internal aspects of ECHA's organisation and the external use of its resources and their impact. The main objective is to assess the extent to which the programme has met its objectives. It will allow ECHA, and all stakeholders, to appreciate what has been achieved so far and what any next steps might be.

To support the external evaluation, ECHA appointed two external independent evaluators; Christine Northage and Chris Money; who, together, have extensive practical knowledge of the needs of regulators or industry in connection with the CSR/ES Roadmap and ENES. This report only relates to the external evaluation.

A web-based questionnaire was devised by ECHA, with input from the external evaluators. The survey was conducted in mid-May/early June 2016. Responses were collated by ECHA and then shared with the external evaluators. Following a blind assessment of the questionnaire responses the external evaluators chose 20 industry and 9 Member State (MS) respondents for follow-up telephone interviews. Additional questions were developed by the external evaluators to further explore and amplify questionnaire responses.

Eighteen industry telephone interviews took place, with one additional written response. Of the 15 questionnaire responses from 10 different MSs, nine individuals (from 7 different MSs) were selected for follow-up interviews. Seven telephone interviews took place. ECHA also contacted 6 non-responder MSs again by email, who were asked if they were willing to be interviewed, despite not filling in the questionnaire. No responses were received.

Key Learning Points (Industry)

The overwhelming majority consider that the CSR Roadmap/ENES is relevant to their organisation and that the current suite of tools are sufficient to meet the demands for effective CSA/ES development and communication, both now and in the future. Industry values ENES as a forum for discussing problems concerning the workability of the CSR/ES processes with stakeholders with the aim of developing practical solutions to these problems. Industry views the Roadmap products as being critical in ensuring that the ESs are relevant and consistent, although many SME (small and medium sized enterprise) downstream user (DU) groups consider that further simplification of the communicated ES and ext-SDS information would also be beneficial. There is a frustration that the ENES tools are not being consistently adopted, worked and/or maintained by different industry sectors/companies/consortia. There is a lack of knowledge of what's happening at ENES outside of those companies/sectors that operate at the European level. Most DU users consider that the translation of Roadmap products into other EU languages will enhance implementation.

Industry is divided in its support for expanding the Roadmap to embrace SDS topics. Such an extension is supported more by larger organisations, based on their desire for automated approaches to the communication of SDS information. Smaller companies (SMEs) are more focused on ES relevance, understandability and harmonisation (across suppliers). The relationship between REACH ESs and the

position they occupy in EU safety, health and environmental legislation continues to remain unclear for most of industry and this is reported to be compounded by differences in MS enforcement approaches.

Key Learning Points (MSs)

All MS respondents (15, from 10 different MSs) to the questionnaire thought that the CSR Roadmap/ENES was relevant to their organisation. However, only 46% thought it was relevant outside of REACH and 27% Didn't Know. 80% of respondents supported expanding the Roadmap to cover SDS topics.

However, some MSs see ENES mainly as a forum for industry, including DUs, to discuss problems with the workability of the CSR and ES processes with ECHA and identify and develop solutions to these problems. There is a lack of knowledge of what's happening now at ENES, except for the relatively few who attend the meetings and there is limited sharing of knowledge gained between different functions in individual MSCAs, and so people find it difficult to keep up to date. Where resources are scarce, the CSR Roadmap and ENES are not prioritised by MSs. There is limited knowledge and understanding of what tools are available, how they work and how they can be used to aid the work of MSs. Different functions within the MSCAs have different needs from, and uses of, the tools. In order to encourage their use within authorities, MSs would like to see independent evaluation/review of the tools produced to give greater confidence in the outputs of the tools.

Recommendations

Implementation and consolidation - work should be carried out to maximise the take up and use of ENES products. Attention should be directed to those sectors not engaged in ENES or which are slow adopters of the tools. The technical language often used in products should be simplified and key documents and products translated into EU languages beyond English. Testing and potential further development of methods/tools (for mixtures) should be undertaken to ensure that the ES information arriving at end-users is in a form that is helpful to them.

There needs to be a programme of evaluation and review of the tools and their outputs, both in terms of the technical content and in their capacity to meet the needs of the users, in order to promote confidence and encourage wider use. ENES should produce a matrix showing how/when the different products can be used by all concerned with REACH processes. Suitable case studies and other training materials should be developed to illustrate how the most appropriate Roadmap products can be identified, applied and their added value.

Communication - ENES to produce and deliver a Communication Plan to actively promote the work of ENES/CSR Roadmap to MSs and Industry, particularly those currently not involved. This plan to include national (and sector) initiatives as well as working in partnership with groups already active in the field, e.g. Forum, RIME, CARACAL, Helpnet, SLIC.

Targeted marketing – there is a need for the currently available products and the added value they bring to be marketed to relevant people. The information should be targeted at the level of the different actors and the different activities these are expected to perform in REACH.

Expanded skills - the skill set of ENES, consistent with the requirements of targeted marketing, needs to be enhanced. Should the scope extend to SDSs, it should also include hazard assessment and Classification and Labelling.

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Introduction

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006 placed the responsibility for the safe use of chemicals on industry and introduced a new framework in Europe for the assessment of chemical substances and their uses. The information from this assessment is summarised in the REACH Chemical Safety Report (CSR). A key component of the CSR is the Exposure Scenario (ES), in which manufacturers and/or importers set out the conditions for the safe use of their substance.

In 2013, the European Chemicals Agency (ECHA) and industry set up a formal programme to support Chemical Safety Assessment (CSA) and ESs. This programme is documented in the “CSR/ES roadmap - A cross-stakeholder plan of actions to 2018”. The overall purpose of the CSR/ES Roadmap is to facilitate the provision of good quality information on the use of chemicals (e.g. use description, conditions of use) in the REACH CSR and the extended Safety Data Sheet (ext-SDS).

The Roadmap has been in operation for about two and a half years and many of its outputs should be delivered in 2016. In January 2016, ECHA proposed to undertake an interim evaluation of the CSR Roadmap and Exchange Network on Exposure Scenarios (ENES) in 2016. The evaluation involved two parallel but interconnected work streams, one looking at the internal aspects of ECHA’s organisation and resource deployment and the second, to assess the outward (external) use of its resources and their impact.

The main objective of this interim evaluation is to assess the extent to which the programme and roadmap have met their main objectives, what elements have worked well and where, and why, there may have been less progress. It will allow ECHA, industry, Member States (MSs), the European Commission Services as well as other stakeholders to appreciate what has been achieved so far and what any next steps might be. To support the external evaluation, ECHA appointed two external independent evaluators; Christine Northage and Chris Money; who, together, have extensive practical knowledge of the needs of regulators or industry in connection with the CSR/ES Roadmap and ENES.

This report only relates to the external evaluation.

Methodological Approach

ECHA, with input from the external evaluators and CSR/ES Roadmap-ENES Coordination Group, designed a questionnaire to obtain feedback from industry, MSs and the Commission services on the work of the CSR/ES Roadmap and ENES (April/May 2016). ECHA then conducted the web-based survey in mid-May/early June 2016. Responses were collated by ECHA and then shared with the external evaluators. An initial evaluation of the responses by the external evaluators was presented to the CSR/ES Roadmap-ENES Coordination Group in mid-June 2016.

Following a blind assessment of the questionnaire responses by the external evaluators 20 industry and 9 MS respondents were chosen for follow-up telephone interviews. The respondents were chosen on the basis of ‘interesting’ responses and, particularly for MSs, to get as good a cross section as

possible. Additional questions were developed by the external evaluators to further explore and amplify questionnaire responses.

Eighteen industry telephone interviews took place, typically 30 -45 minutes long, with one additional written response. Of the 15 questionnaire responses from 10 different MSs, nine individuals (from 7 different MSs) were selected for follow-up interviews. Seven telephone interviews took place; 1 respondent was on holiday for all of the interview period and no response was received from the other, despite a number of attempts. As a consequence of the relatively low number of MS respondents ECHA contacted 6 non-responder MSs by email. They were asked if they were willing to be interviewed, despite not filling in the questionnaire. Despite being contacted again by the external evaluator no responses were received.

Presentation and Analysis of Information Collected

Presentation and analysis of the Industry information collected

Assessment of CSR Roadmap/ENES Activities

The overwhelming majority (93%) of industry considers the Roadmap to be either relevant or very relevant to their needs. Amongst the comments offered, respondents stated that the Roadmap provides tools that allow for the provision of relevant informative data on the use and risk of substances which is crucial to achieving safe exposures using practical means of control. The emphasis given by the Roadmap to harmonisation was repeatedly supported. So too was the need for consistency among those implementing Roadmap products across supply chains.

Several respondents raised how the Roadmap products need to be developed in order for them to embrace the nature of the formulated products that they routinely handle. The fact that the Roadmap products are rooted in everyday experiences, based on good up- and downstream communications within the supply chains, was noted as being essential for creating common understandings that then form the basis for the creation of realistic ESs.

Specific comments made by industry respondents highlighted the fact that the ENES Roadmap tools provide downstream users (DUs) with more confidence that registrants have properly registered their uses; that the ENES process provides some measure of 'quality assurance' for different industry initiatives and hence build trust and confidence in the DU community; and that the tool development facilitates the ability to deliver more consistent ESs which meet the DU requirement for harmonisation across supply chains. The more effective communication of Roadmap work products, together with developing CSAs for mixtures and the subsequent communication of related ESs appears to be the Roadmap areas where respondents consider more attention is needed by ENES.

Industry is less convinced regarding the relevance of the Roadmap outside REACH. While 41% consider it to be relevant or very relevant, 46% believe it to be only somewhat ir/relevant and 9% of no relevance. The reason for the lack of support appears to be that it is not currently clear how to make occupational health assessment activities and risk assessment procedures to "work together in practice" with REACH CSA.

Respondents emphasised that the REACH ES processes need to align with those operating under workplace occupational health and safety legislation in order that the ES might be more readily understood and accepted. The similarities of the health and safety aspects of REACH to current EU legislation were noted but also the differences in the environmental area were highlighted. The latter may present particular challenges. Apart from the ES itself, respondents highlighted issues relating to the interpretation of DNELs and PNECs when compared to their SHE equivalents. Some respondents questioned whether any individual ES might meaningfully contribute at the workplace level when the nature of SHE controls will be determined by the range of chemicals being handled as well as biological, physical, ergonomic, safety and other risks.

The majority of respondents (61%) consider that a common understanding on the practical use of the information in the chemical safety report (CSR) and in the ES has already been achieved or is immediately achievable as a result of Roadmap activities. The support rises to 72% in terms of the assessment of the ready ability to implement methods and processes for generating the key information inputs for the CSA. The effective implementation of IT tools and standards for generating, processing and exchanging CSR and ES information, however, is considered to be longer term. Industry is more hesitant concerning the ability of most formulators and DUs to be able to understand and process ES information.

Usefulness of CSR roadmap/ENES Products

In terms of the various Roadmap activities, Use Maps are overwhelmingly considered to be useful (over 85% of respondents) both now and in the future. This picture is similar for Sector-specific worker exposure descriptions (SWEDs) and specific environmental release categories (SPERCs), but slightly less so for specific consumer exposure determinants (SCEDs), possibly due to the likelihood that SCEDs will only be relevant for those sectors with strong consumer interests.

Industry is also strongly supportive of those work products designed to improve the manner by which information is communicated in ESs. Over 75% of respondents consider that the ES package (Use Maps, SWEDs, SCEDs, SpERCS, ES template, etc.) is at least useful. The catalogue of standard harmonised phrases is also strongly appreciated. Support for the structured short titles whilst high, is less than for the ES package and catalogue of phrases. The least supported activity is the work undertaken to develop a XML standard/format to communicate ESCom phrase information between company IT systems. Here more than 50% of respondents considered that this aspect currently has limited usefulness although this reduces to 21% when a longer term outlook is applied.

Looking at the findings there appears to be a negative correlation between the perceived complexity of Roadmap products and their usefulness. It may also be a function of the fact that the more complicated products have yet to be used to any great extent by different industry stakeholders and hence the experiences relating to their usefulness are still at an early stage or restricted to first impressions.

Some of the comments offered by respondents included the fact that they needed to better understand some of the more recent tools before they were in a position to either apply them or to

make a valid judgement on their usefulness; that it would be a useful Roadmap activity to translate both the ECom and EuPhrac phrases into community languages rather than this being left to commercial channels (where some translations were reported to vary and be inappropriate); that ENES should improve its portal in order that users can more effectively access those work products which are most likely apply to their particular needs; that more attention needs to be paid to how the risks associated with mixtures should be evaluated and communicated, in particular how SpERCs and SCEDs etc. might be effectively integrated into any CSA process for the mixture; and the challenges arising from 'scaling' this information at the DU level.

Industry's support for tools which have recently been introduced is not as strong as tools which are already available. Therefore it is noticeable that the overall support for the recent developments concerning the International Uniform Chemical Information Database (IUCLID), the Chemical Safety Assessment Reporting tool (Chesar) and mixtures (Lead Component Identification (LCID) methodology and Safe use of Mixtures Information (SUMIs)) received less support than those developments which are directly related to the development of CSAs and the subsequent communication of ESs. One obvious reason why these products are receiving less support is the fact that they are at an early stage in their introduction and implementation, so the wider industry has only had limited opportunities to view their functionalities and merits. The everyday importance of mixtures for REACH and DUs was raised by a number of respondents within the context that more than one approach to the development of ESs for mixtures is likely to be appropriate (such as the mixtures Generic Exposure Scenarios (GESs) developed by the Association Technique de l'Industrie Europeenne des Lubrifiants (ATIEL) and the International Fragrance Association (IFRA)) and hence the workability of SUMIs/LCID may need to be routinely reviewed.

The nature of the supporting comments provided reflected the fact that most respondents appeared to have less experience with these tools. The challenges faced with assessing and communicating the risks of mixtures was highlighted. Some respondents noted that developments affecting IUCLID and Chesar appear to benefit Registrants more than DUs and questioned whether the resource inputs needed were proportional to the benefits accruing. Some respondents also noted that the continued development of new tools and guidance can result in the creation of related issues for Registrants (such as dossier updating) and DUs and that a period of consolidation should ensue before further activities are initiated.

One major factor behind industry supporting any particular ENES work product would appear to be an understanding of the resource demands associated with its implementation and the nature of the subsequent benefits accruing (e.g. the group(s) most likely to benefit from the activity – registrant, supplier, DU, etc.). One theme to emerge from the suggestions relating to improving the uptake of Roadmap products therefore centres on the provision of good guidance and examples. A second theme mentioned is the capability to address industry in other than English, ideally through national initiatives operated at a partnership level.

It should be noted that all 56 industry respondents offered their views on how to enhance the uptake of Roadmap products. Industry therefore is positive regarding the Roadmap products and the need for enhanced adoption by different groups. However, the heterogeneous nature of industry is reflected in the wide range of suggestions for how this might be accomplished. It would therefore appear appropriate for ENES to develop a communication plan which sets out options, timelines,

expectations and responsibilities in order that all industry stakeholders can actively engage in its development and successful delivery.

Industry generally agrees with the statement that if applied enough the CSR Roadmap products will improve the use and exposure information available in the ECHA database. However this agreement is not overwhelming. While over 62% of respondents agree with the statement (14% strongly so), 27% only somewhat agree with it and 9% disagree. Among the comments offered to clarify their ranking, several respondents indicated that they may be inclined to be more strongly supportive if there was wider evidence of the consistent adoption and implementation of Roadmap products. Several comments related to the need to optimise the level of detail to derive fit-for-purpose products which didn't create a burden for those who are expected to use them as, clearly, users are less likely to routinely use products which are perceived as having marginal benefit. The recent changes to IUCLID were specifically mentioned in this respect.

A distinction was made between the usefulness of the data for authorities and end-users of chemical products; it was felt that regulatory agencies benefit more from work products at the current time than end-users. The importance of updated Use Maps for enabling current and accurate information to be available to assist in the process of prioritisation was also commented on. Several respondents felt that the products will benefit authorities but the primary target population should be DUs where, in their view, the utility of the products had still to be proven.

68% of industry either agree or strongly agree that the Roadmap products will result in industry avoiding costs related to the inappropriate communication of information up and down the supply chain. Only 14% either disagree or somewhat disagree with the statement. This response would appear to provide strong evidence that the Roadmap products are meeting a prime industry need.

Respondents emphasised the importance of applying standardised products, supported by procedures relating to their use in order to deliver the harmonisation/consistency both for registrations/CSAs and subsequent ES communications to DUs. Having said this, some respondents believe that these objectives should be capable of being met using simpler approaches, which by implication should also be capable of being readily embraced by a wider stakeholder base. In this context though, the expectations of many smaller DUs do not always equate to the requirements laid down by the Regulation. The product most commonly cited as being useful were Use Maps in that, provided they are properly developed and applied, they avoid the need for needless supply chain communications. It was felt that most of the benefits rest with registrants rather than DUs where the benefits are stated as being less tangible.

Improving the Roadmap's Impact

The Roadmap area where industry appears to be the most equivocal in its support concerns whether or not Roadmap products will increase the availability and usefulness of advice on safe conditions of use in SDS systems; while 55% of respondents either agree or strongly agree with this statement, 11% disagree. The remainder (34%) somewhat agree with the statement. This response appears to be partly due to the fact that many DUs consider that further simplification of ESs is desirable. Industry was also more limited in the range of responses offered in support of this question and the responses were more cautionary in their nature, ranging from highlighting the issues prevalent amongst IT systems suppliers that serve as a constraint in this area; to the suggestion that rather than focusing on the ext-SDS, resources would be better placed improving the local knowledge (at the user level) of

process safety and workplace chemical exposure assessment. It was noted that while the CSR Roadmap products are a prerequisite, their existence alone may not be sufficient to effect the desired improvements i.e. the creation of relevant and understandable ESs often requires experience of product use which exceeds that currently contained in the core Roadmap products.

In terms of support to ENES, 86% of respondents indicated that they had been involved in the work of ENES or of related Roadmap activities. The questions asked did not enable an analysis to be undertaken of which groups were engaged with which activities. However attending ENES meetings was the most common (80%) followed by active involvement in sector activities supporting Roadmap products (57%). For those groups which had not been involved, resource constraints were cited as the principal reason (63%), followed by the lack of perceived value in participation (as opposed to the use of the products). For groups who are participating, the time being invested appears significant; 34% indicated that they spend more than 20 days each year and 82% more than five days.

Presentation and Analysis of Member State Information Collected

Nature of Respondents

Of the 15 responses (10 MSs) to the questionnaire: 6 were from Enforcement Authorities; 6 from Competent Authorities, with varying specialisms; 2 were from bodies that were both Competent and Enforcement Authorities and there was 1 response from an environmental specialist who provided technical support to a CA. For the 7 (5 MSs) follow-up interviews: 4 were from Enforcement Authorities (1 environment specialist, 1 supply side specialist and 2 human health specialists); 1 was an OSH specialist at a CA; 1 was a Policy Advisor at a CA; and 1 was an environmental specialist who provided technical support to a CA.

An important point to note is that the way each MS delivers its responsibilities under REACH is different. There is a wide variation in the number of organisations, often sited in different places, responsible for different functions within individual MSs. The responses given, both to the questionnaire and in interview, usually reflected personal views/specialism or at most the views of the specific organisation the person worked in.

Therefore caution needs to be exercised in how we extrapolate from the limited responses we have. Also, statistical analysis is not really possible both because of the relatively low number of respondents and the variety of expertise/roles. Both questionnaire responses and interview information should be viewed as a snapshot, rather than a scientifically valid sample.

Common Themes

A majority (66%) of respondents attended ENES meetings, with 2 being members of the ENES Co-ordination Group. Few respondents were not already involved in this work. This implies that the people who already know about the CSR Roadmap and the work of ENES took the time to respond to the questionnaire and those that did not perhaps thought they had nothing to contribute. An individual MS may only send one person to any ENES meeting and from the interviews it became apparent that sharing of knowledge gained between different parts of a CA was often limited, dependent on the individual, their interest/expertise and time available. People find it difficult to keep

up to date with what's happening and unless you attend the meeting it can be difficult to find the relevant information or to know what is available.

The two main reasons given for non-involvement in ENES were; "as an authority we see ENES mainly as a forum for industry and ECHA", and lack of resources to participate. It seems reasonable to assume that these 2 reasons are also likely to have influenced whether or not people responded to the questionnaire in the first place, as they may have had little or no knowledge of what was happening. Where resources are scarce the CSR Roadmap/ENES has not been prioritised by MSs.

All respondents thought that the CSR Roadmap was relevant for their organisation, however only 54% thought it relevant in helping to address risk assessment needs outside of REACH, with 27% responding 'Don't Know'. REACH ESs were thought, by some, not to be specific enough for 'real-life' OHS exposure assessment. The tools developed are valid to compare the exposure potential of substances but not detailed enough to assess risks in real workplaces. Having said that it was felt that the development of ESs has given a lot of dynamism to occupational hygiene, as it has initiated discussion about the issues.

Currently only 20% of respondents thought that most DUs understand and can process ES information. 47% believe they will understand within 10 years with 20% considering that understanding was not achievable, particularly in very small companies. There was a widespread belief that for many small companies ESs are difficult to follow and process, especially as most SMEs use mixtures rather than single substances. There is little evidence, as yet, of the use of the tools developed by the CSR Roadmap being used so it's difficult to predict what effect their use will have.

The views on the quality of products were very variable and often dependent on specialism of respondent. In this section 11% of the responses related to specific tools were 'Don't Know'. Overall there was a lack of knowledge/information on how the tools will work, or people had only looked at the tools that related to their specialism. Another concern was how the use of the tools will change the information seen in dossiers.

Regulators need to have confidence in new products otherwise they will default to conservatism. There is sometimes a reluctance on the part of MSs to accept industry generated information and work needs to be done to change this. It was felt by a number of people that in order to gain acceptance by MSs there needs to be an evaluation of the tools and their outputs, both in terms of the technical content and in their capacity to meet the needs of the users. MSs will want to know if tools give realistic outputs; are reasonably representative; what the uncertainties are and where and when to challenge the outputs.

All respondents agreed that if enough companies use the tools developed then use and exposure information available to MSs in the database should improve. This will put authorities in a better position to differentiate between substances that matter most in terms of regulatory priority setting. However, to increase confidence in the results authorities need to have confidence that registrants understand the tools and use them correctly.

Communication

In the interviews there was much discussion on communication. Some interviewees felt at a distance from the process and if they had more time/resource would want to be more involved. Many had heard of the new tools but had not seen them or had experience of their outputs. They felt they were

not seeing updates in a useful form; “just one more email with a link”. It would be helpful to have more proactive communication. There is a lot of information available but there is a need to target the information to make sure people get what they need, rather than everything and then have to work through to find what’s useful for them. It would also be beneficial to have information at different levels for different roles within MSs. The CSR Roadmap is not easy to explain to non-technical colleagues as they don’t understand the technical complexities but they do need to use the information that the new tools provide. Perhaps a different approach is needed for some people – less technical. It would be invaluable if ECHA could summarise and translate the main developments, including an explanation of the context and main issues. It would be advantageous, particularly for Policy colleagues, to explain what the different tools are about, how to use them what the added value of using them is.

It was believed that industry had done a lot of good important work under the aegis of the Roadmap and now might be a good time for MSs to get more involved. MSs often don’t have the right type of expertise to help in the development of the tools but could have a bigger role in spreading the word. There was also interest in the setting up of national activities to raise awareness of the tools available and what they could be used for. Some thought that translating key documents into other EU languages would help to increase understanding of what is needed to fulfil obligations and aid the uptake of the tools, especially in smaller companies.

Future Work Activities

A majority (67%) of respondents wants to maintain the current programme but shift the focus to implementing the products. The views of whether or not to extend the scope of the Roadmap to improve SDSs were more varied. 47% thought it may be useful to do this; 33% thought it important to extend the scope and 20% believed it should not be extended in this direction. Everyone agreed that SDSs are an important way to get risk management measure (RMM) information to DUs but some considered it more important to improve the ES for communication before extending into SDSs. It was also stressed that it is important that there are no contradictions between ESs and SDSs. Good quality SDSs are deemed to be the way forward for SMEs, but they need to be simpler and more product orientated (i.e. covering the formulated product and addressing typical SHE risks that arise from its intended use, including anticipated non-chemical hazards), so that they do not need to look at much else apart from the SDS.

There appears to be a desire to improve the usefulness of the products with respect to enforcement. It can be difficult to use the products as part of any enforcement action as they are not yet mentioned in the guidance or legislation and so the case has to be argued every time. A need for consistency between different legislations was mentioned, particularly with respect to occupational safety and health.

Conclusions

The activities of ENES/CSR Roadmap are generally considered by all stakeholders to have been beneficial and successful. However, this view may not be representative of all groups as only a fraction of those engaged with and affected by ENES/Roadmap responded to the questionnaire and over 90% of the people who responded are already involved with ENES and the Roadmap. The sample size responding to the questionnaire was relatively small, particularly from MSs, and so we should be circumspect about assigning the views expressed to all of the many and various REACH actors. Given the level of response it would seem reasonable to assume that there are many people in the EU who work on REACH who do not know what is currently happening at ENES (or indeed in other areas of REACH). One of the priorities for the future should be to communicate and educate on the latest developments. There is a willingness on the part of stakeholders to support ENES and work to ensure a wider awareness of Roadmap products and their implementation. In this respect, many respondents commented on the value of national and local initiatives e.g. workshops organised by individual MSs and/or industry segments. This form of communication should also be considered within the remit of the Roadmap. Workshops aimed at MSs should also be considered to highlight to them the usefulness of the Roadmap products for their specific REACH processes.

The role played by ECHA in coordinating the ENES activities and driving the Roadmap programme forward is recognised and valued. This is particularly so in the period when the focus of many in industry and MSCAs is on the Registration of substances and their subsequent Evaluation etc. As the Roadmap tools become more accepted and established over the next 2-5 years (most notably in the development of Use Maps and their associated SWEDs, SCEDs and SpERCs, together with related activities in the area of mixtures and harmonisation of ES communication), then the resources devoted to ENES may be expected to decrease, but this will in part be determined by the scope of future Roadmap activities. The benefits brought about from the creation of ENES to share, discuss and work technical solutions are also much valued.

A range of tools have been developed which, together, can serve the need for ensuring CSAs/ESs are relevant and useful. The tools have been developed by industry with the support of ECHA and some MSCAs. Positive impacts arising from the implementation of some Roadmap tools have already been noted by the presence of improved and more consistent ESs in some ext-SDSs. However implementation of the tools is not universal. More action is needed to ensure all sectors of industry apply and maintain the tools adequately.

There is concern amongst some MSs concerning the outputs of the tools. A programme to evaluate and review the tools would promote confidence in the outputs and encourage use in MSCAs. Mechanisms that would serve to encourage and sustain their use e.g. their prominence and preference in Technical Guidance and related DCC and Evaluation activities should also be beneficial, both for industry and for enforcement in MSs.

Many smaller (SME) DUs are reporting that they are not finding the nature of the information contained in the ESs to be helpful. Many are instead seeking simple 'instructions' for what should be done to manage risks, rather than the sort of information currently communicated in ext-SDSs. This

group is particularly interested in the successful trialling and adoption of the Roadmap tools for mixtures (SUMIs and LCID) as they predominantly handle mixtures and report that some suppliers have amplified their problems by attaching the ESs for each component of the mixture to the ext-SDS.

The linkage between REACH ES information and EU SHE regulation remains unclear for industry. This could also be said for MSs as only 54% thought it relevant in helping to address risk assessment needs outside of REACH; with a noteworthy proportion (27%) of MSs responding 'Don't Know'. This lack of clarity shared by both industry and MSs would seem to indicate that further work is needed to determine where the boundaries are in order to resolve any potential confusion. There is also reported to be a lack of consistency in MS enforcement in this area which serves to compound the lack of clarity.

The above points to the need for the next phase of the Roadmap to be less about the development of new tools to support CSAs/ESs and more about their implementation and adoption by various stakeholders. This will demand a change in focus, being oriented towards marketing and communication to those sectors, companies and MSs who have yet to engage. Consequent to this, ENES may need to consider whether its current skills base remains appropriate for such a challenge.

Recommendations

Implementation and consolidation

A strategy should be developed aimed at maximising the take up and use of ENES products. Attention should be directed to those sectors not engaged in ENES or which are slow adopters of the tools.

Work should be carried out to simplify the often, very technical language used in Roadmap products. It would also be very helpful if key documents and products were translated into other EU languages beyond English.

Testing and potential further development of methods/tools (for mixtures) should be undertaken to ensure that the ES information arriving at end-users is in a form that is helpful to them.

There needs to be a programme of evaluation and review of the tools and their outputs, both in terms of the technical content and in their capacity to meet the needs of the users, in order to promote confidence and encourage wider use.

Suitable case studies and other training materials should be developed to illustrate how the Roadmap products can be identified, applied and their added value.

All actors in ENES should contribute to producing a matrix showing how/when the different products can be used by different actors within the REACH processes, both Industry and MSs. This should make it easier for all actors to understand how to use the products and in turn promote wider use.

Communication

All actors in ENES to produce and deliver a Communication Plan to actively promote the work of ENES/CSR Roadmap to MSs and Industry, particularly those currently not involved. Such a plan should look to include national (and sector) initiatives.

Partnership working, with groups already active in this area, e.g. Forum, RIME, CARACAL, Helpnet, SLIC would enhance the effectiveness.

Targeted marketing

To introduce targeted marketing of the currently available products and the added value they bring. The information should be directed at the level the different actors need and for the different activities different actors in REACH have to perform;

Expanded skills

Consider enhancing the skill set of ENES consistent with the requirements of targeted marketing and should the scope extend to SDSs, hazard assessment and Classification and Labelling.

References

Industry CSA Survey Results (2016)

https://echa.europa.eu/documents/10162/2109305/industry_csa_survey_results_en.pdf/5cd3b625-7994-477f-a351-13a3d11ff89e

Member State CSA Survey Results (2016)

https://echa.europa.eu/documents/10162/2109305/member_state_csa_survey_results_en.pdf/79c75d10-8b1e-4b8c-ab32-45a94eb276ca