European Chemicals Agency

Assessment of the current substance evaluation process under REACH

Final Report

Contract ECHA/2015/132 (SR25) under framework contract ECHA/2011/01

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Amec Foster Wheeler Environment & Infrastructure UK Limited in association with BRE and PFA

Report for

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Document revisions

No.	Details	Date
1	First interim report	28/09/2015
2	Second Interim Report	27/10/2015
3	Final report	17/12/2015
4	Revised final report	06/01/2016

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1. Introduction

1.1 Purpose of this report

This report concerns a contract (ECHA/2015/132 (SR25) under framework contract ECHA/2011/01) between the European Chemicals Agency (ECHA) and Amec Foster Wheeler Environment and Infrastructure UK Limited ('Amec Foster Wheeler'), which relates to the "Assessment of the current substance evaluation process under REACH". The work on this contract is being undertaken in association with Building Research Establishment Limited (BRE) and Peter Fisk Associates Limited (PFA).

This is the final report for this study and updates the second interim report dated 27 October 2015.

1.2 Objectives and scope of the study

The overall objective of this service is to undertake an objective assessment of the functioning of the current substance evaluation process, comprising the effectiveness, efficiency, transparency and workability of the process. The work comprises the following main elements:

- Assessment of transparency of substance evaluation, including also the selection of substances for CoRAP (background and outcome documents).
- Survey conducted among Member State Competent Authorities and relevant stakeholders (e.g. Commission, Member State Committee observers, registrants) on workability, efficiency, effectiveness and transparency, and reporting on their views and improvement proposals about SEv and CORAP.
- Preparatory work for a workshop and presentation of the findings and participation in ECHA's workshop on 19-20 November 2015.

The report presents the findings on the above.

1.3 Background

The purpose of this service request is to evaluate and assess the functioning and outcomes of the SEv process during its first three years of application (2012-2014) with particular emphasis on its role in complementing dossier evaluation and supporting regulatory risk management.

SEv in REACH is a key process since it is concerned with the assessment of a substance itself and all its uses in the Union, as opposed to the uses that are presented in a single Registration dossier for a substance. Registration is concerned with the demonstration of safe use of a substance by a legal entity (i.e. the registrant) and by users of the substance placed on the market by that legal entity; this is done in a Registration dossier. However, the dossier does not have to account for any volume or use of the substance that is not placed on the market by that registrant[1].

SEv is the route to be used when there is justified concern that a risk may exist, but the risk is not yet firmly confirmed. SEv allows the possibility to request further information to clarify the concern, and these requests can go beyond these standard REACH information requirements. It enables assessing all uses of a substance by all registrants of that substance and allows an assessment to be made that considers the cumulative exposures, including whether these exposures could lead to a risk that is not otherwise controlled.

Article 44(1) of the REACH Regulation provides the general criteria for substances to be selected for SEv. The triggers for SEv are substances that, due to the combination of their inherent hazards (e.g. suspected

[1] A lead registrant may submit the dossier for a group of member registrants, whose dossiers will contain specific information specific to their company and their substance, for example, information about substance identity, their identified uses and their production volumes etc.

PBTs/vPvBs, endocrine disruptors, CMRs, sensitizers) and use (exposure) patterns (e.g. wide dispersive use, consumer use, aggregated tonnage), are suspected of leading to unacceptable risks to humans or the environment, but there is not sufficient available information to conclude on the risk.

The information obtained through SEv should clarify whether a concern exists and when this is the case it should be considered by both industry and authorities for (regulatory) risk management. In some instances, the conclusion can be that the risks are sufficiently under control with the measures already in place but in others the SEv process can directly lead to the start of the risk management option (appraisal) (RMO(A)) process, either at EU-wide level (restrictions, authorisation, EU-harmonised classification and labelling, occupational exposure limits, measures for the protection of the environment under the Water Framework Directive) or at a national level. It should be however clarified that SEv is not needed for preparing RMOA when all the relevant information is at hand and that Member States could take into account, for instance, all the cumulative exposure without SEv. Moreover, Member States/ECHA may wish to take actions even if there is no demonstrated quantitative risk, if the substance has, for instance, serious/clear SVHC properties.

The evaluation process is significant in REACH since it is the process in which registrants are engaged with MSCAs. Another part of REACH where MSCAs engage directly with industry happens in enforcement, in which the MSCA acts at a national level. However, in SEv an MSCA can be acting on a substance for which legal entities could be in a number of Member States. That way a MSCA reaches beyond the boundaries of its own national jurisdiction and acts at EU level.

Although there are clear rules for the way that MSCAs act and how registrants respond in SEv, it is clear that different MSCAs have their own 'styles'. In addition, there may be specific experts and experience in MSCAs that make a difference to the process. The process of liaison, communication and information gathering by the evaluating MSCA (eMSCA) and the responses from the registrants could be relatively straightforward if a consortium is acting for the substance. However, if that is not the case, the process for the CA could be at best complicated and possibly contradictory (since registrants may not agree on responses and be uncoordinated in responding).

The SEv process has not been running for long (since 2012). However, it has been long enough to reveal that there are notable differences in the way that different MSCAs handle the process and also differences in the way that different registrants (and groups of registrants) act in response to requests for information on their substances. In addition, the process has been perceived by some to be less than transparent from both sides (MSCAs and industry and also for third parties such as NGOs) and more lengthy than it necessarily needs to be.

As outlined in ECHA´s multiannual programme for 2015[2] it is relevant to evaluate whether the SEv process contributes fully to the improvement of dossier quality and efficiently feeds into the regulatory risk management processes. ECHA highlights that this requires the successful implementation of the common screening approach, initiated in 2014[3], to identify substances for both substance evaluation and regulatory risk management processes, as well as effective interaction with dossier evaluation and the close collaboration and involvement of MSCAs, with efficient use of their evaluation capacity.

The findings of this evaluation on the first years of application of the SEv process (2012-2014) will feed into ECHA's report on the status of implementation of REACH due in 2016 in accordance with Art. 117 (2) and will contribute to a broader ongoing review of the process. In this sense, since the adoption of the first CoRAP in February 2012, the SEv process has been subject to reviews and continuous dialogue with relevant stakeholders (e.g. workshop on May 2014[4]) in order to facilitate and improve its implementation. In particular a comprehensive review of REACH undertaken in 2013 by the Commission[5] identified the need to improve certain elements on the basis of lessons learnt with the preparation of the 2012 CoRAP including the substance selection process, the access of IT tools by Member States and the general coordination between ECHA and MSCAs.

[2] https://echa.europa.eu/documents/10162/13608/mb_31_2014_echa_wp_2015_en.pdf
[3] http://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf
[4] https://echa.europa.eu/documents/10162/13628/sev_workshop_2014_en.pdf
[5] http://www.fcio.at/Uploads/30072014094008JBHH1YJHgeneralreportswd_en_133717_DE.pdf

Building on the outcomes of these reviews and the stakeholder dialogue, the current assessment project has been focused on assessing how to improve the effectiveness, efficiency, workability and transparency of the SEv process, in line with the definitions outlined in the service request. These are presented in table below:

Table 1.1 Evaluation criteria

Criteria	Description
Efficiency	Efficiency entails the minimisation of workload (for ECHA, MSCAs and Registrants) against maximisation of increased safety on use of chemicals. Efficiency also entails the use of the SEv process when it is most appropriate action; the main prerogative of SEv is the possibility to request further information to clarify the concern, whereas SEv may be unnecessary when available information is sufficient to conclude on the risk. Therefore, a high rate of evaluations requiring further information is one indicator of an efficient selection of substances for SEv (ECHA is monitoring such indicator). However, this does not mean that evaluations concluded without requests were a failure, as the evaluation process itself can be the way to obtain sufficient information without the need of a formal ECHA decision for a request. Efficiency is also the functional interlink of SEv with other REACH and CLP processes; the use of SEv should be complementary and bring synergies to the use of other evaluation processes (compliance check and testing proposals) and regulatory risk management processes, whereas overlaps and negative interferences should be avoided.
Effectiveness	SEv is effective if it serves the improvement of (regulatory) risk management of substances; it follows that a high rate of conclusions leading to proposals for regulatory risk management is one indicator of an efficient selection of substances for SEv (ECHA is monitoring such indicator). In some cases SEv may lead to the improvement of company level risk management, which can be also regarded as a desirable impact. In relation to this SEv is regarded as an important instrument to achieve ECHA's strategic objective 2: Mobilise authorities to use data intelligently to identify and address chemicals of concern. SEv is effective if it clarifies priority concerns. In relation to this SEv is regarded as an important instrument to achieve ECHA's strategic objective 1: Maximise the availability of high quality and tailor made data to enable reliable assessment for the safe manufacture and use of chemicals. SEv can also be regarded as a way to provide references for registrants on how to assess categories of difficult substances/effects.
Workability	Workability can be related to the administrative burden and complexity of the process and tasks for ECHA, MSCAs and Registrants under SEv.
Transparency	Transparency can be related to i.e. how easy it is for the ECHA stakeholders and interested parties to follow the rationale for selection of substances, understand the process and identify the relevant actors and understand the outcome of the SEv (ECHA decision, conclusion document).

2. Task 1: Assessment of transparency of substance evaluation

2.1 Overview

The objective of Task 1 was to carry out a review of the information available on the ECHA website which relates to the process of substance evaluation. This review was from the point of view of whether the information available makes the process as a whole transparent and understandable. It was also to assess whether the substance evaluation outcome documents provide a clear rationale for the selection of substances, and report clearly the outcomes of the substance evaluation process.

2.2 Methodological approach

The approach taken was to firstly 'map' the relevant pages on the ECHA website using various starting points that could be foreseen to be used in order to locate information on Substance Evaluation. The information and documents available relevant to substance evaluation (including the Commission Rolling Action Plan, CoRAP) on each webpage were noted as were the links to other relevant webpages given on the page. The relevant information and documents available on each webpage were then reviewed.

For ease of reference each webpage has been given a reference number shown in [ ]. Owing to the nature of the website and the different potential routes through the website the reference numbers do not necessarily follow in numerical order.

In order to facilitate visualisation of how the various webpages link together from various potential starting points, a series of 'maps' have been constructed. These are given in Appendix A. In the maps, the reference number is shown for each webpage. The bold arrows show how each of the main webpages links forward to further information. Where a given page links back to other relevant webpages this is shown by inclusion on the map of the relevant reference number(s) for those webpages. This was done in order show the main routes through the webpages more clearly.

As well as the links between the pages, the maps also identify the documents that are available for download from each page. These are shown in red text on the respective maps.

The contents of each webpage and the documents relevant to substance evaluation that are available from each webpage are considered in detail in Appendix A. In all cases the route through the ECHA website is assumed to start with the ECHA homepage. However the order in which the subsequent webpages are encountered depends on the route taken through the site. The review in Appendix A therefore considers each route separately, presenting the webpages in the approximate order that they are encountered, but where a given webpage is encountered on more than one route, a detailed description of the webpage is only given in the first route in which it is encountered.

2.3 Common starting point for the review

The common starting point for anyone looking for information on the ECHA website is the ECHA homepage [1], which can be found at http://echa.europa.eu/web/guest.

The ECHA homepage gives the following points of access for information on substance evaluation:

- Search for Chemicals box [Route A].
- Regulations Tab [Route B].
- Addressing Chemicals of Concern Tab [Route C].
- Information on Chemicals Tab [Route A].

- Support Tab [Route D].

The Search for Chemicals box and the Information on Chemicals Tab essentially provide the same way into the website and so these two routes are considered together. Therefore four main routes of entry into the website have been considered in Appendix A, and maps have been constructed for each of these routes: Route A - search for chemicals/information on chemicals; Route B – Regulations tab; Route C – Addressing chemicals of concern tab; Route D – Support tab.

The route that any one user will take is likely to depend on a combination of a number interrelated factors including:

- Familiarity with the ECHA website (e.g. regular users may have a “preferred” way of finding information).
- Status and experience of the user.
  - Registrant.
  - Downstream User.
  - Regulator.
  - Other Interested Party.
- Familiarity with the Substance Evaluation Process.
  - Looking for general information on the process.
  - Looking for specific information on the process.
  - Looking for specific information on a substance.

However, it is likely that in most situations the differentiator will be between those searching for information on a specific substance and those searching for information on the process.

The page acts as the starting page for users accessing the ECHA website and provides links to the various subpages. On occasions it is possible that information on substance evaluation may appear under the ‘News’ part of the webpage, but at the time of this review, this was not the case.

2.4 Route A - search for chemicals/information on chemicals

There are two possible ways to proceed through this route. The first is to use the ‘Search for Chemicals’ box on the homepage and the second is to use the ‘Information on Chemicals Tab’ available on the homepage. Both starting points lead to essentially the same pathway through the website. The detailed mapping and review of the webpages and documents encountered through this Route is given in Appendix A.

2.5 Route B - regulations tab

The detailed mapping and review of the webpages and documents encountered through this Route is given in Appendix A.

2.6 Route C - addressing chemicals of concern tab

The detailed mapping and review of the webpages and documents encountered through this Route is given in Appendix A.

2.7 Route D – support tab

The detailed mapping and review of the webpages and documents encountered through this Route is given in Appendix A.

2.8 Consideration of the information available on the ECHA website as a whole

Findings and recommendations from the review of the website

In general, the ECHA website contains a wealth of information related to substance evaluation. The information is generally easy to find, although depending on which route is taken through the website, it may involve going through four or five layers of webpages before the relevant information is located. A number of relatively small changes to the website have been suggested in the review in Appendix A that could potentially improve the usability of the website, in terms of finding information relating to substance evaluation, and these are summarised in the Table below.

Table 2.1 Suggested changes to the ECHA website to improve usability

Webpage	Address	Suggested change
[3] – Substance Evaluation – CoRAP	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table	Consider adding brief details of how a substance can get added to the CoRAP
[6] – CoRAP list of substances	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances	Consider editing the last sentence to indicate that the justification documents can be obtained by following the "details" link on the list of "substances" page rather than being attached to the page.
[7] – Community rolling action plan	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan	In the third paragraph consider clarifying that, when a Member State requests further information from the registrant, this will be done via the final decision that will be published on the ECHA website. For example, the third paragraph could potentially be misinterpreted as the Member State informally requesting further information from the registrant during the substance evaluation rather than formally requesting it via the decision as a result of the substance evaluation. Although the paragraphs under the Timeline heading discus the draft and final decision there is no real explanation as to the legal role of the decision. Consider including a short paragraph on what happens after the requested information has been provided by the Registrant. The link to the "Substance Evaluation Factsheet" on this page is misleadingly labelled as "CoRAP Fact Sheet". Although the fact sheet does cover the CoRAP, the same Fact Sheet is referenced as a "Substance Evaluation Fact Sheet" on other webpages.

Webpage	Address	Suggested change
[8] – (Understanding the) Substance Evaluation	http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation	The document on interaction between evaluating Member State and the Registrant under Substance Evaluation provides much useful guidance on the informal interactions between the two parties during the process. Consider better reflecting the recommendations of this guidance on the webpage itself, particularly in relation to how to make initial contact, points of contact etc.
[9] - Q&A on CoRAP and Substance Evaluation	http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/corapandsubstanceevaluation	The answer to the question on interaction between the evaluating Member State and the registrant/stakeholders may potentially be useful to many registrants. Consider including some of this information on the relevant webpages, particularly Substance Evaluation [8]. The answer to the last question on where sources of information on the CoRAP substances can be found currently provides a link to the “registered chemicals” webpage where the information on registered chemicals can be searched (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances). This then allows access to the registration dossiers within the dissemination database. It would be useful to also include a link to the CoRAP table itself [3] (http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table) in the answer to this question, as this provides more information on the substances specific to the CoRAP.
[10] - Community Rolling Action Plan	http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan	It may be useful to include a link to the document outlining the following specific criteria used to establish the CoRAP substances: “Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection Criteria)” - http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf. The draft CoRAP list available on this page has been superseded by the actual CoRAP list for 2015-2017. This is potentially confusing. It may be better to consider putting either a link to the “Annual Draft CoRAP” webpage [11] itself or the actual CoRAP list document for 2015-2017.
[11] (Annual) Draft CoRAP	http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/draft-corap	The link to the legal reference for the REACH Regulation is not active.
[12] - Transitional measures: complementary part to the CoRAP	http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures	The link to the legal reference for the REACH Regulation is not active.

Webpage	Address	Suggested change
[13] – Opinions of the Member State Committee on ECHA's draft CoRAP	http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee/opinions-on-draft-corap	The link to the legal reference for the REACH Regulation is not active. The link to "ECHA's pages on Substance Evaluation" is a duplicate of the link to "About substance evaluation" [8]. Each of the Opinion documents contains a link to the background document: "Selection Criteria to Prioritise Substances for Substance Evaluation" which is reviewed under [7] – Community rolling action plan. However the link given in the document is not working. The correct link should be http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf.
[16] – Evaluation Actors	http://echa.europa.eu/regulations/reach/evaluation/actors	The entry (and the box for related links on the right hand side of the page) for registrants mainly covers the responsibilities of the registrants in registering their substance. It may help clarity if a sentence is added indicating that the registrants may also have a role during substance evaluation (e.g. commenting on draft opinions, and possibly interaction with the evaluating Member State).
[17] – (Evaluation) Steps	http://echa.europa.eu/regulations/reach/evaluation/steps	In order to make the steps clearer and more relevant to substance evaluation consider providing, where necessary, separate sub-headings for dossier evaluation and substance evaluation under each step as appropriate.
[23] Outstanding information requests from existing substances	http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances	The link to the legal reference for the REACH Regulation is not active. The link to the ESIS database should be removed as this database no longer exists (information formerly included is now available through the ECHA website).
[24] – Outstanding information requests for notified substances	http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-notified-substances	The link to the legal reference for the REACH Regulation is not active.
[30] Requests for Further Information	http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information	The information on this webpage is potentially useful for clarifying the process by which requests for further information (decisions) are produced as a result of substance evaluation. This webpage is not easily accessible via Route A, and it might be useful to consider linking this webpage to a relevant part of Route A (for example [8] – (Understanding the) Substance Evaluation).

Webpage	Address	Suggested change
[31] Addressing chemicals of concern	http://echa.europa.eu/addressing-chemicals-of-concern	It is not entirely clear on this webpage which is the best way forwards to find information on substance evaluation. The relevant information can be found by following through the link to "substances of potential concern" and it may be clearer to consider expanding the text here to incorporate a few key words such as "substance evaluation" or "CoRAP" in order to signpost the way forwards a little more clearly. This is already done to some extent in the section on "Registry of Intentions" where certain key words (e.g. "SVHCs", "Restrictions", "CLP", "CLH") are indicated.
[32] Substances of potential concern	http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern	It would be beneficial to provide links here to the relevant pages on the CoRAP and/or Substance Evaluation here (e.g. a link to the webpage (Understanding) Substance Evaluation – CoRAP [8]). This will then provide a way into the webpages outlined in Route A.
[43] Q&As Support	http://echa.europa.eu/support/qas-support/qas	It would be helpful if the relevant questions and answers for substance evaluation also appeared under the evaluation heading/link (or a separate substance evaluation heading) on the webpage. The relevant questions already appear on [9] - Q&A on CoRAP and Substance Evaluation

In terms of clarity, it is useful to distinguish between the information available on the procedural aspects of the CoRAP and Substance Evaluation and that on the information available on specific substances on the CoRAP or subject to Substance Evaluation.

In relation to the procedural aspects, there is a wealth of information, both on the webpages themselves, and in linked documents, on how the CoRAP is developed and how the Substance Evaluation process works. This information ranges from short paragraphs or short documents providing an introduction to the process to more detailed documents outlining the actual process and timelines involved. Therefore users of the website should be able to find information to suit their particular need.

Unlike some of the other processes under REACH, there is currently no overall guidance document on Substance Evaluation. Instead the guidance has been incorporated within the website. A consequence of this is that there is not a single place where most/all of the relevant information can be accessed. Instead, in order to find the relevant information a user may have to access several webpages. These are generally well signposted from the various entry points and so this should not necessarily prevent a user finding the relevant information. However, depending on the users' knowledge of REACH and/or the ECHA website it may not always be intuitively obvious where to start looking for information from the ECHA homepage. For example, the current ECHA homepage has Tabs for regulations, addressing chemicals of concern, information on chemicals and support, as well as a search function for information on chemicals. As a consequence it may not be obvious to users unfamiliar with REACH or the website how to proceed from this page. Given the importance of the CoRAP and Substance Evaluation ECHA could consider adding a dedicated Tab for the CoRAP/Substance Evaluation.

Overall the available webpages and documents provide a relatively clear description of the processes for both the CoRAP and Substance Evaluation in general terms. However when it comes to specific information on specific substances the clarity of the process can be in some, but not all, cases a little less clear. Examples are given below:

- The level of detail in the justification documents for inclusion of a substance on the CoRAP is sometimes low. It is not always clear what information has been considered in the process or where the interpretation of the data may differ from that in the registration dossier. In addition,

although the prioritisation process is described in general terms, it is not always clear how these have been applied to a specific substance.

The clarity of the justification documents could potentially be improved by including some/all of the following information.

- A brief summary of the information that has been considered in relation to the concern suspected, with references if appropriate.
- Whether the information was considered in the registration dossier, and, if so, a brief summary of the conclusion reached by the registrant.
- A brief discussion of the information that led to the substance being prioritised for inclusion on the CoRAP.

It needs to be recognised that, at this stage, the available information may not have undergone a detailed evaluation by the Member State, and so the information in the justification document should necessarily be brief. However inclusion of the above information may help the registrant, or other interested parties, to understand where the concerns of the Member State potentially arise, and how this information has led to the substance being included on the CoRAP.

- Decisions. The draft decision is in some cases the first indication that registrants may get of the likely outcome of the substance evaluation. Although the (draft) decisions are generally reasonably comprehensive and clear on what information is being requested, and the background to the key studies considered, they do not necessarily provide the full evaluation of the data carried out by the evaluating Member State. In addition, by their nature, the content of the (draft) decisions tends to be technical and may not be easily understood by a non-expert in the area.

  In some cases a substance evaluation report is also available to accompany the (draft) decision which provides more background information on the considerations that led to the (draft) decision, and so are useful for the clarity of the (draft) decision.

  The clarity of the Substance Evaluation process, particularly in relation to the availability of the Substance Evaluation Report to the Registrant, was a common theme to most of the Workshops on Substance Evaluation. The proceedings of these workshops are available on the ECHA website (workshops held in Helsinki on 26th-28th May 2014 (ECHS-14-R-19-EN[6]), 23rd-24th May 2013 (ECHA-14-E-08-EN[7]), 4th-5th June 2012 (ECHA-12-R-07-EN[8]) and 23rd-24th May 2011 (ECHA-11-R-008-EN_INT[9]). The outcome of these workshops was that it was agreed that the Substance Evaluation Report will be merged with the conclusion document and a new template produced (the new template was not available on the ECHA website at the time of this review). The evaluating Member State will therefore not necessarily produce, nor ECHA necessarily publish a separate Substance Evaluation Report from now on. However it is still possible for evaluating Member States to generate two separate documents (a Substance Evaluation Report and a conclusion document) if they have already started drafting these under the old templates. These documents (using either the old or new templates) will only be published on the ECHA website once the Substance Evaluation process is complete. Therefore although such reports could potentially add much to the clarity of the (draft) decision, it is unlikely that they will be readily available until the whole process is complete. There are, however, potentially a few areas where the clarity of the (draft) decision could be improved. These could include the following, for example.

  - Inclusion of a list of the studies that have been considered in the Substance Evaluation, not just ones leading to the conclusion[10]. If needed this could be limited to those considered

[6] http://echa.europa.eu/documents/10162/13628/sev_workshop_2014_en.pdf
[7] http://echa.europa.eu/documents/10162/13628/sev_workshop_2013_en.pdf
[8] http://echa.europa.eu/documents/10162/13628/ws_substance_evaluation_201207_proceedings_en.pdf
[9] http://echa.europa.eu/documents/10162/13628/ws_substance_evaluation_may+2011_proceedings_en.pdf
[10] This could also be used as a checklist by the eMS.

beyond those that are in the Registration Dossier. This would then provide the registrant with information on all of the studies that were taken into account in reaching the decision.

- A brief discussion where the interpretation of the study used to justify the (draft) decision is different from the interpretation in the registration dossier(s).

Although the (draft) decisions are often quite technical, and so may not be easily understandable to someone without a technical background, it is important that they precisely outline what information is needed to address the concern and so it is appropriate that they are technical. Therefore summarising the information reviewed and requested in non-technical language may actually lead to a lesser clarity in the (draft) decision rather than improving clarity. Therefore it is considered that the level of technical detail included in the (draft) decision should be appropriate to the nature and complexity of the concern to be addressed.

Consideration of the results of the stakeholder survey

The results of the stakeholder survey are presented in detail in Section 3 of this report. The following paragraphs briefly summarise the main points from the survey relating to transparency.

All of the Member State respondents involved in substance evaluation considered that the common screening approach has improved the transparency of substance selection for the CoRAP. Similarly, all Member State respondents agreed (either wholly or partly) that the information on the ECHA website about the CoRAP and substance selection is sufficient to understand how the process works. It was commented that relevant information on the website could be difficult to find, and that the scope of the evaluation (which dossiers and uses are covered by substance evaluation) could be further clarified on the site.

Registrants involved in substance evaluation also agreed that the information on the CoRAP and substance selection on ECHA's website is sufficient to understand how the process works. There was less agreement on whether the information on the reasons for inclusion of substances on the CoRAP was sufficient, with as many respondents saying "partly" or "no" as saying "yes". Aspects of the draft and final decisions were not always clear to some registrants. Comments on these indicate that these were issues of understanding and of disagreement; the aspects most identified as unclear were the scientific reasoning, and exposure and use-related requests. Interaction with the eMSCA, where this occurred, was helpful in increasing transparency.

Accredited observer stakeholder organisations agreed that the information on the ECHA website about the CoRAP and substance selection is sufficient to understand how the process works. They also agreed that the concerns and reasons for including a substance on the CoRAP were clearly presented in the documentation available. They had a mixed view of the usefulness of the briefing sessions in the Member State Committee. Most responded that the substance evaluation decisions and conclusions published on the ECHA website were understandable and transparent.

Overall conclusions

Based on the review of the information on the ECHA website and the results from the stakeholder survey, it is concluded that the information on the processes related to the CoRAP and Substance Evaluation is in general both comprehensive and clear. A number of recommendations have been made in order to help users of the website in finding the relevant information. The content, when located, is generally appropriate to the different target audiences, with both simple outlines of the process and more detailed procedural information being readily available.

In terms of information on specific substances on the CoRAP or subject to Substance Evaluation, there would appear to be some simple steps that could be taken to improve the clarity of certain key documents. An example relates to the justification documents for inclusion of a substance on the CoRAP and the decisions resulting from the Substance Evaluation, both of which were identified by registrant responders to the survey as areas where they would like more clarity. The documents have to be of a technical nature owing to the complexity of some of the issues they are covering but the clarity could be improved by better indicating the information that has been considered in the process and where the interpretation of data by the Member State differs from that of the registrant. In addition the clarity of the Substance Evaluation process may be improved by making the Substance Evaluation Reports available to registrants but it is understood that this is not currently possible.

3. Task 2: Project survey

3.1 Overview

The overall purpose of this task is to undertake a consultation to gather information and views from MSCAs and other relevant stakeholders across the EU-28 on the effectiveness, efficiency, workability and transparency of the SEv process. The aim is to build a robust evidence base for the evaluation of the SEv and CoRAP processes and the subsequent identification of recommendations for improvement.

3.2 Methodological approach

The consultation was approached through the circulation of a survey which had a mixture of closed and open questions, mainly of a qualitative nature. The full survey can be found within Appendix B of this report, which is provided as a separate document.

The survey was developed in co-operation between the consultants and ECHA to obtain evidence-based information and opinions on the functioning of the substance evaluation process under REACH. The survey was formed of three sections, each addressing one of the following groups of stakeholders:

- Member States Competent Authorities (MSCAs) and members of Member State Committee (MSC) of ECHA.
- A selected number of registrants that have experience with the outcomes of substance evaluation and listing of their substances in the Community rolling action plan (CoRAP).
- Accredited observer stakeholder organisations of the Member State Committee and Commission Services.

Within each section, questions were designed to cover each of the stages of the SEv process plus a final section that covered generic or horizontal question on the process as a whole, taking into consideration the level of involvement and role of each stakeholder type. The table below summarises the different stages considered and their relative importance and level of involvement for the stakeholders identified.

Table 3.1 Steps that form the Substance Evaluation process (SEv) included in the Survey

	MSCAs/MSC	Registrants	STO organisations/ European Commission
Selection of substances to be listed by ECHA in the Community rolling action plan (CoRAP)	✓	✓	✓
Evaluation phase by the evaluating MSCA to decide whether there is a need to request further information from the registrants to clarify the concern (assessment and preparing the draft decision)	✓	✓	✓
Decision making phase (assessment of comments and seeking agreement at Member State Committee (MSC))	✓	✓	✓
Follow up evaluation and drawing conclusions	✓	✓	✓
Interaction between eMSCA and registrants and between registrants	✓	✓	

A large tick identifies stakeholders for which the stage is more relevant and therefore where the survey has placed more emphasis. A smaller tick means that the stakeholder is less involved in that process and therefore the survey only includes a small number of questions.

In developing the survey the project team aimed to strike a balance between multiple-choice and open questions, allowing respondents taking part to express a full opinion.

The survey was made available online via the "survey monkey" software program on 16 July 2015 for a period of seven weeks (which was extended by a few days to allow respondents more time to provide their information). The duration of the survey window was planned in order to ensure that the results of the project would be ready for the next substance evaluation workshop to be held in November 2015. The survey was also advertised by ECHA in their periodic newsletter[11]. The different stakeholders across Europe were contacted by ECHA by e-mail to make them aware that the survey was available for completion.

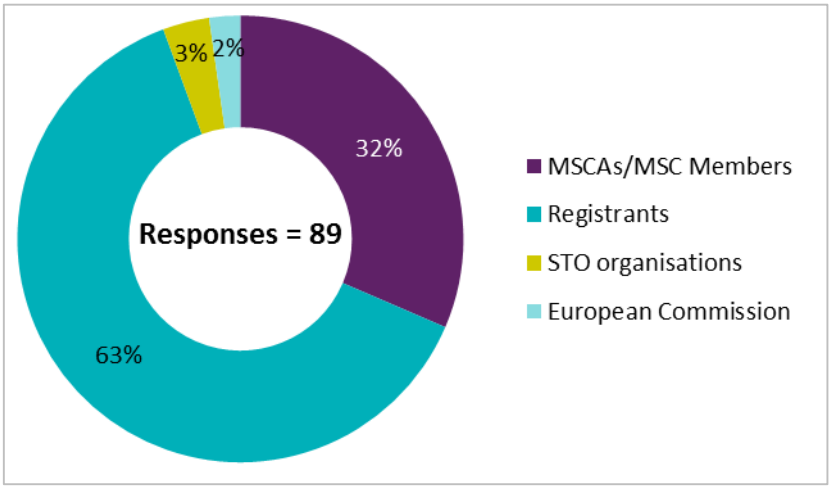
On closure of the survey window the data from the survey were consolidated, with spoiled and duplicate responses removed and the resulting data then used to help identify suggestions for improvement within the SEv process.

3.3 Outcomes of the survey

Overview

In total, 89 responses were received, of which 28 are from MSCAs/MSC members, 56 from registrants, 3 from STO organisations (STOs) and 2 from representatives of the European Commission (DG Environment). More detail on the respondent's profile within each of these categories is provided in Appendix C.

Figure 3.1 Number and type of respondents to the survey



The breakdown of the response rate for each of the different stakeholder groups was as follows:

- Registrants: 11% (56 responses from 512 recipients).
- STO organisations: 16% (3 responses from 19 recipients).
- European Commission: 2 responses were received from 10 recipients, but the response rate is not relevant in this case, because the recipients coordinated the responses. Multiple persons from the Directorates-General Environment and Growth were contacted and coordinated responses from the Commission were received.
- MSCAs/MSC members: in this case it is not relevant to give a response rate based on number of recipients due to the fact that within authorities coordination has been made and generally only one response has been provided per Member State (in some cases integrating the views of the MSC member as well). Here it is more relevant to note that good geographic coverage was

[11] http://echa.europa.eu/view-article/-/journal_content/title/echa-e-news-24-june-2015

attained through the consultation process with responses from either MSCAs or MSC members gathered for almost all of Member States (21 out of 28 or 75%).

Responses to the multiple choice questions have been analysed quantitatively with summaries and examples provided for the open questions. This analysis harvested numerous interesting insights on the SEv process, of which selected examples are reflected in the main body of this report. The complete analysis of responses on a question-by-question basis is presented in Appendix C.

The findings have been structured in sections covering each of the stages of the SEv process as described in Table 3.1, plus an additional section on horizontal issues. A subsequent number of subheadings cover particular topics addressed in each stage and identify which of the evaluation criteria of effectiveness, efficiency, workability and transparency are of most relevance for the given issue.

A) Selection of substances to be listed by ECHA in the Community rolling action plan (CoRAP)

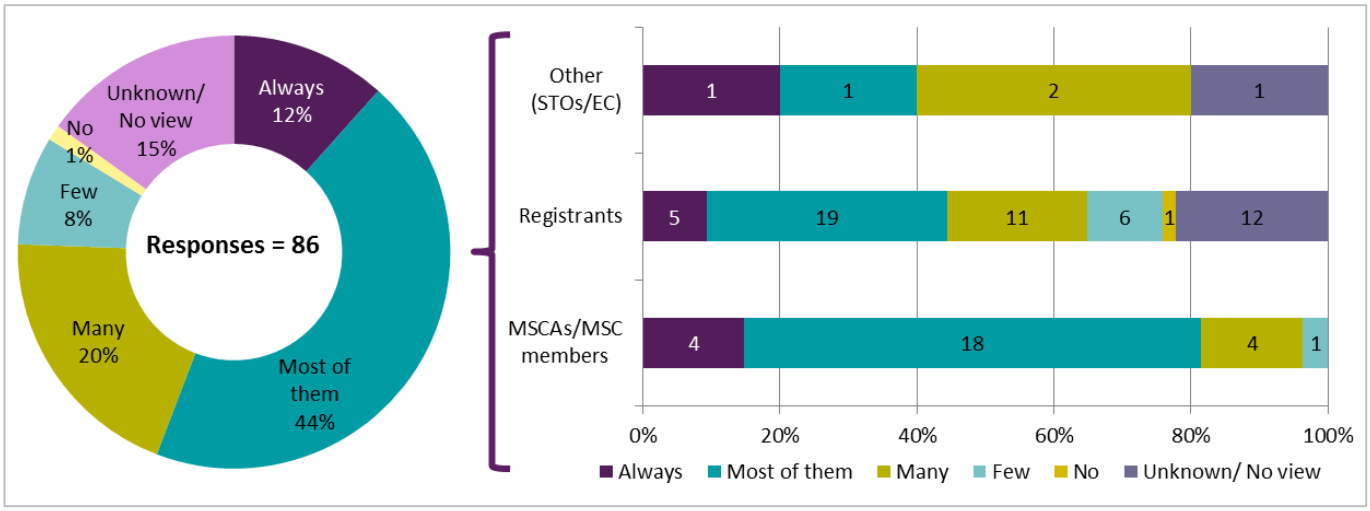
Inclusion of substances in CoRAP (efficiency and workability)

All stakeholder types were asked about their views on whether CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value. The results are summarised in the figure below and show that more than three quarters (76%) of respondents agree that this is the case for many, most, or all of the substances. The analysis of stakeholder types reveals that there is a higher level of agreement among MSCAs and MSC members compared to registrants to this statement. As such, whereas 82% of MSCAs/MSCs consider that for all or most of the substances listed, SEv is needed to clarify the concern with potential regulatory added value, 57% of registrants providing their views agree with this.

Some registrants have expressed concerns with redundancies with parallel processes, such as the dossier evaluation or evaluations of another substance of the same category and for the same concerns, as well as pre-existing regulations and decisions.

In the case of MSCAs/MSC it is noted that a better interplay with the process of compliance checks **(CCH)** could improve the selection of CoRAP substances. As such in some cases a CCH could have been sufficient to clarify the highlighted concerns. Concerns have also been expressed related to the perceived lack of exposure related data used to prioritise some of the substances for SEv.

Figure 3.2 Responses to questions 2.1.1/ 3.2.1/4.1: Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value?



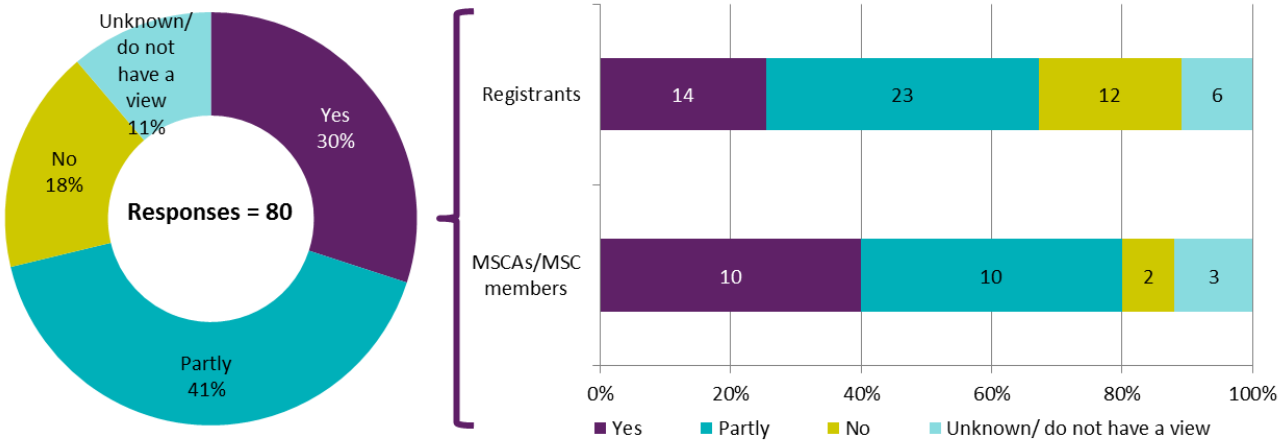
In addition, further insight was requested from MSCAs/MSCs on the **process for identifying and selecting substances of concern** for the update of the CoRAP. Key findings are summarised below:

- A combination of drivers is generally used for the selection of substances across MSCAs. The selection takes places according to the CoRAP criteria for SEv in all Member States responding to the survey (21) and a large number (15) have also indicated that national interests on specific substances can also play a role. Furthermore, the selection as a follow-up to a risk management option analysis is also a relevant driver in some Member States (9).
- Concerning the screening phase, most respondents consider that the common screening approach has enhanced the previous situation, leading to improvements mainly in the selection of substances and the transparency of the process, but also in the linkages with other REACH and CLP processes and to some extent in the collaboration between MSCAs. Notwithstanding with this, a few suggestions to improve the selection and prioritisation of substances are worth highlighting:
  - Consider assessing how many of the substances shortlisted for CoRAP were finally not included in CoRAP (i.e. after manual screening) and the reasons behind this, in order to further refine the shortlisting criteria, as it is noted that a significant number are dropped after manual screening.
  - The screening scenarios for identifying CoRAP candidates are primarily based on information in the registration dossiers, but it would be important to also include information from other sources, particularly to avoid the risk that poor quality dossiers may go undetected. Additional sources can include, monitoring data, workplace inspections, reports from Poison Centres, etc. It is noted that this type of information is normally available to MSCAs and that in order to use it for screening, they should make it available in a structured and searchable way.
  - Further efforts could be applied to improve the tracking and follow-up of substances following screening as they enter other processes, particularly for those selected for CCH.
  - More focus is needed on substances for which dossier evaluation is completed which are flagged by ECHA as potential candidates for SEv in their conclusions.
  - SEv can be used as a targeted instrument to address uses or exposures of potential concern and then find the substances which fit (in textiles, plastic softeners, etc.).
- When MSCAs/MSCs were asked about the evolution of the annual number of substances to be evaluated, 65% out of 26 respondents were in favour of maintaining the current situation of around 50 substances evaluated annually, compared to 23% that recommended a decrease in the annual number and 8% that would support an increase. Overall it appears that the current level has been workable to date but that it should be flexible based on MSCA capacity. In general it is noted that the annual number should depend on the follow-up work from substances evaluated in earlier years 2012-2015 as well as the scale of the evaluations and on the resources ECHA will be able to allocate.

Impact of the listing on the (draft) CoRAP upon improved quality of dossiers (effectiveness)

Both MSCAs/MSCs and registrants were asked on whether the selection of substances for CoRAP has been a driver for the provision of better quality information in a dossier update by the registrants. As illustrated in the figure below, 71% of respondents agree that the listing in CoRAP has improved, at least to some extent, the quality of dossiers, though it is noted that this will vary on a case-by-case basis. Overall, MSCAs/MSCs reflect a more positive view on the impact on dossier quality of CoRAP than registrants.

Figure 3.3 Responses to questions 2.1.5/ 3.2.2: Do you think that inclusion of substances in the (draft) CoRAP has had an impact in the improved quality of dossiers?



As reported by several MSCAs/MSCs, there have been cases where this has occurred before the evaluation phase has started and even at draft CoRAP stage (with reported cases where SEv was no longer necessary after the updated dossier), as well as when the evaluation is ongoing, particularly following first contact and informal questions from the MSCA regarding aspects of their dossier. However, it is noted that it can be challenging to deal with multiple updates during the year especially if these contain significant changes or come late in the process.

Information available about CoRAP and substance selection (Transparency)

All stakeholder types were asked whether the information about CoRAP and substance selection on the website of ECHA and the national authorities is sufficient to understand how the process works.

- Views collected across all stakeholder groups on ECHA´s website are predominantly positive. Excluding those who express no knowledge (6 out of 85), information is sufficient to understand how the process works according to 70% of the respondents and at least partially sufficient according to the rest of the respondents.
- In the case of the national MSCAs' websites, a larger share of respondents stated that the information is considered partly (37%) or not (26%) sufficient to understand how the process works. In addition a high number of registrants noted that they did not know the MSCA's website (21 out of 50). This is mainly explained by the fact that ECHA´s website is used as the main source of information on CoRAP. Therefore national websites only contain a brief description of the process and link to ECHA´s webpage for detailed information.

Additionally, registrants were also asked to provide their views on the information available in ECHA on the reasons for inclusion of a substance in the CoRAP. Out of 55 respondents, 9% consider the information not sufficient, 35% partly sufficient and 44% sufficient. As such some comments state that the information on reasons for inclusion can be unclear or vague and lacks technical detail.

Finally STOs and the Commission indicated their opinion on whether the concern and reason for including a substance in the annual CoRAP update from the documentation that is made available during the forming of opinions at Member State Committee (MSC) or upon publication of the annual CoRAP update is clearly presented. This was considered positively by the respondents (out of 5, for 3 it is sufficient, for 2 is partially sufficient).

B) The evaluation phase of substances by the eMSCAs

Questions in this section were mainly addressed to authorities and aim at understanding, the approach followed, the potential difficulties encountered and their views on the support by ECHA as part of for instance compliance checks and consistency screening.

Compliance checks (CCHs) prior to SEv (efficiency)

Whenever a Compliance Check in preparation for SEv is performed, ECHA informs the relevant MSCAs of any non-compliance on substance identity, human health endpoints and environmental endpoints. The general opinion is that this support provided by ECHA when a Compliance Check is performed is helpful, particularly in terms of form, with 18 out of 20 considering it appropriate. The content of the information provided is also generally regarded as appropriate (15 out of 21 answering "Yes" and none responding negatively). Regarding the timing, the majority of respondents consider that this could be improved (12 consider it "partly appropriate" and 1 "not appropriate"). As such several respondents note that time available for MSCAs to comment is rather brief and that there is a need to improve the communication between ECHA and the eMSCAs in terms of timing expectations and assigned responsibilities. A selection of suggestions in this regard is highlighted:

- It would be helpful if information on the status and timing of the substances under CCH is provided before the referral of the draft decision, so that eMSCAs can plan resources ahead.
- More interaction than just a notification in REACH-IT of the on the possibility to provide comments between MSCA and ECHA might be beneficial, particularly in complex cases where more time might be needed, and also taking into account that some MSCAs do not routinely check REACH-IT for messages.
- A CCH in advance of SEv has many benefits and should always be strived for to improve efficiency. Moreover, it has been also suggested that CCH should be performed before deciding on the inclusion of a substance in CoRAP.

Conducting the evaluation (workability and effectiveness)

MSCAs/MSC have identified a number of difficulties that have been faced with the assessment of substances in general and concerning substance identification (SID), human health and environmental endpoints and exposure. All the difficulties are listed in Appendix C (under the analysis of question 2.2.2) and are of varied nature. However, there are a number of topics that stick out by being addressed by multiple respondents. In particular, most of them identify difficulties with the SID of substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB substances). In such cases, the performance of Compliance Checks by ECHA is considered essential. Also, a few respondents note that it is difficult to phrase a request for information related to exposure. This latter aspect is also highlighted by a representative from the European Commission, which notes that for the exposure part, information needs are harder to define than for hazard ID questions.

In addition, some stakeholders noted that the quality of the registration dossiers is considered not sufficient. For instance it is noted that study summaries aren't robust and/or biased and there is a need to ask for the full study reports to the registrants for reliable assessments. This is linked with the analysis of responses to questions 2.1.5/ 3.2.2 of the survey "*Do you think that inclusion of substances in the (draft) CoRAP has had an impact in the improved quality of dossiers?*" Although most respondents consider that the listing in CoRAP contributes to improving at least to some extent, the quality of dossiers, it is noted that this will vary on a case-by-case basis and often this occurs following first contact and informal questions from the MSCA regarding aspects of their dossier once the SEv has started.

With regards to the process of undertaking the evaluation, most MSCAs (23 out of 35 providing an opinion) use a combination of several information sources in the assessment of substances. Supplementary information is mainly obtained through literature search (e.g. case studies and dossiers from international programmes) and informal contact with industry, and to some extent by requesting it from other authorities or research institutes.

However, it is noted that only seven authorities reported to have contacted another evaluating Member State for a substance that they were not evaluating, but for which they have specific national interests i.e. providing input to the content and scope of the evaluation and expectations for the outcomes. This practice appears to be less common.

Consistency screening of preliminary draft decisions (DDs) performed by ECHA (efficiency)

Overall, all respondents with a view on this topic (23) consider that ECHA´s support during consistency screening has been useful at least to some extent to the improved quality of DDs, with 16 responding that this contributed to a large extent. In particular, it has been useful to receive a legal viewpoint on the requests.

Furthermore, most respondents also consider that the feedback provided was clear to a large extent (13 out of 22 respondents). In this regard it has been commented that the reasoning for some recommendations could be improved, e. g. by referring to other (draft) decisions that address a concern more appropriately or which are otherwise relevant for the case at hand.

C) Decision making phase (assessment of comments and seeking agreement at Member State Committee (MSC))

Under this section a number of questions seek insight into the different stages of the decision making phase, which starts with the notification of any DD issued by the eMSCA to the relevant registrant(s), and which will involve commenting from the registrant(s), consultation of the other MSCAs and ECHA, and possibly the MSC and the Commission.

Submission and processing of comments by registrants on DD (efficiency and workability)

The registrants have the right to comment on the draft decision within 30 calendar days of receipt of the DD plus an additional 7 days according to REACH-IT rules. However, based on the responses to the consultation the given timeline is generally seen as too short. In particular, 60% of respondents that have a view on the matter (36) have experienced difficulties during the preparation of comments on the draft decision, with most of these (77%) specifically stating that the given timeline is too tight. Several reasons for this had been mentioned, the most frequent ones being interference with vacation periods and the difficulty of reaching agreements with other registrants, especially in large consortia. Other stated reasons include the burden of involvement in multiple processes regarding various substances, and the high expenditure of time when the industry needs technical discussions with the MSCA.

Registrants were also asked about the facilitating effect of the information provided by ECHA in the yearly news alert regarding when a draft decision is to be expected. 62% of the respondents providing their view (29) confirmed that the alert facilitates the timely preparation of comments on the draft decision. There was a large number of “unknown” responses to this question (20), with some respondents noting that they had been unaware of the alert.

Once comments from registrants have been received by the respective eMSCAs, ECHA has noticed that in some cases it has taken a long time from the preparation of the draft decision to the referral to the other MSCAs and ECHA to comment i.e. much longer than 12 months. When asked about the potential reasons that could delay this process, MSCAs/MSC indicated that these are mainly related to the late update of dossiers with large volumes of information, coupled with the fact that there is a lack of resources to handle this new information as well as the registrants comments; as noted by 5 stakeholders, this can be too complicated, time consuming or even result in a change of the focus of the evaluation.

In relation to this, 9 registrants stated that for them it was possible to submit a dossier update after the DD, although they were rather sceptical regarding the impact of the update on the content of the draft decision.

Submission and processing of proposals for amendment (PfA) on (amended) DDs (efficiency and workability)

Following the key steps of the process, the following key findings are highlighted:

- **Examination of DDs by MSCAs in order to potentially make a Proposal for amendment**. Out of 24 respondents, more than half (54%) note that the examination of DDs takes place on a case by case basis. Generally MSCAs will tend to focus on similar substances or similar endpoints to their CoRAP substances, for the purpose of harmonisation and learning. Only in 3 Member States was it reported that this is done always on a general basis. On the other side of the spectrum, this is (almost) never done in 5 Member States; mainly due to lack of resources.

- **Potential for making PfAs for a completely new endpoint**. Based on responses provided there is no clear or simple option to address this issue, and a few have expressed that this would need further discussion and flexibility, dependent on each case. Nevertheless, it appears that having a kind of agreement/policy not to widen the scope of the evaluation following a PfA is the preferred option amongst those proposed in the survey, though a few stakeholders have expressed that some legal and practical concerns would need to be considered if this option were chosen. A slightly lower support was given to the other options proposed, which included the possibility to abort the decision making before referral to the MSC and the start of a new round of consultation and keeping the current practise as it is which allows commenting on different endpoints.
- **Answering the PfAs received by the eMSCA:** MSCAs were asked about the difficulties faced during this phase, which appear to be mainly related to the short deadlines involved at this stage and the fact that PfAs can be sometimes be not clear, not properly justified or contradictory, which would take time in the preparation of the "Response to comments" (RCOM). In the latter case it is mentioned that initiating informal contact with the Member State who submitted the PfA was helpful, even though time limitations and the fact that this occurs during the summer period are highlighted as a problem.
- **Amending the DD following the receipt of the PfAs and submitting to the MSC:** Similar to what has been outlined above for answering PfAs, short deadlines are highlighted as a key challenge in this phase. In addition, it is noted that there is lack of suitable instructions/guidance on the level of detail needed in the DD concerning the PfAs.
- **Commenting by registrants on the PfAs from different Member States and ECHA:** Only 33% (4) of the 12 respondents with a view have experienced difficulties with this stage of the process, mainly due to the short timeline available to comment (30 days).
- **Incorporating the registrant's comments on the PfAs in the DD by the eMSCA:** Similarly, short deadlines are highlighted by MSCAs as a key challenge in this phase, particularly where decision in written procedure is envisaged. The challenge is to decide to what extent the comments should be reflected in the DD, especially when these are numerous, contradictory and complex as this can make the DD non-readable. Further guidance on the level of detail needed would be welcomed.

MSC meeting (efficiency and workability)

The survey has collected relevant insights on the following aspects from MSCAs/MSCs:

- **Preparation of the MSC meeting by eMSCAs:**
  - MSCAs were asked about the difficulties faced during this phase, with a variety of aspects being raised by the respondents. One recurring aspect is the time pressure during the meeting, which can be particularly challenging when there are contradictory PfAs or new comments are raised, making it difficult to achieve an agreement. Another challenge appears to be related to many of the experts for the requests discussed not attending the meeting or only some of the discussions (i.e. just stay a few days), thus making it difficult to provide immediate feedback or to reach agreements if discussion extends in time. It is suggested that it could be useful to concentrate the discussion and the agreement on specific cases in a few days in order to ensure the presence of experts.
  - MSCAs have also indicated lessons learnt from this process. One recurring aspect is the importance of having a text prepared beforehand, considering different options for the DD already identified based on the PfAs to allow a more efficient redrafting at the meeting. Informal communications with the MSCAs submitting PfAs before the meeting is also recommended by several respondents.
- **Preparation of MSC meeting by MSC members:**
  - With regards to time spent, assessment of a SEv-DD and the related background documents generally takes on average more than 4 hours as reported by half of the respondents (50%

or 9/18). As noted by one MSCA, this will generally depend on aspects such as the number of substances on the agenda and the related PfAs and the level of involvement of the MSC in any of them. Less time seems to be spent on the assessment of the MSC opinion on the draft CoRAP update, with only 29% stating that more than 4 hours are needed.

- Almost all respondents (18/19 or 95%) confirm that the MSC member is aided by relevant experts with specialist knowledge (i.e. endpoint specific experts, or those previously involved in the DD), which as reported by some MSCAs can be internal or external staff.

- **Newly introduced structure of 10:00 – 17:00 for plenary timings with separate discussion groups:** All of the 21 respondents that provided a view on this question agree that the new structure is a good way for efficiently achieving unanimous agreement on draft decisions.

- **Organisation and role of the MSC meeting:**

  - There is a very positive view among the MSCAs/MSC members regarding the way in which the Chairman chairs the meetings, with 10 out 14 respondents responding that they have no suggestions and most providing a positive view on his job. Suggestions are mainly related to the need to stop some discussions earlier when the same arguments are repeated or are based on hypotheses not backed up by valid reasoning.

  - Some respondents had made a variety of suggestions on how to improve the drafting revisions on DDs at the MSC meeting. These are presented in Appendix C (under analysis to question 2.3.10). Some of these suggest drafting these in a small group of interested parties (not at plenary sessions). It is also suggested that ECHA should before plenum consult with any interested MSC participant who was not able to participate in the corresponding working group meeting because of his attendance in another parallel meeting.

  - Several stakeholders view the guidance and mediation role provided by the MSC secretariat, the chair and the legal team as very helpful in reaching agreements.

STOs and the European Commission were also requested to provide their views on whether the MSC is handling substance evaluation cases efficiently and whether the briefing sessions in the MSC following agreement on SEV cases are giving relevant information in order to help them fulfil their role. The majority of respondents agreed partly to all of the questions, with none fully disagreeing.

Written procedure (efficiency and workability)

All responding MSCAs/MSC members (22) regard the written procedures as valuable. It has been noted that it helps to avoid unnecessary discussion at the MSC meeting and allows focusing the discussion on problematic points.

Some respondents made a variety of propositions for improving the efficiency and/or effectiveness of the use of written procedures. Some suggestions addressed by several respondents include:

- The Chairman's note to written procedure could be further elaborated with even more details to help efficiency.

- It would be useful to have some criteria for the selection of substances for written procedure, which at present appears to be only at the discretion of the eMSCA.

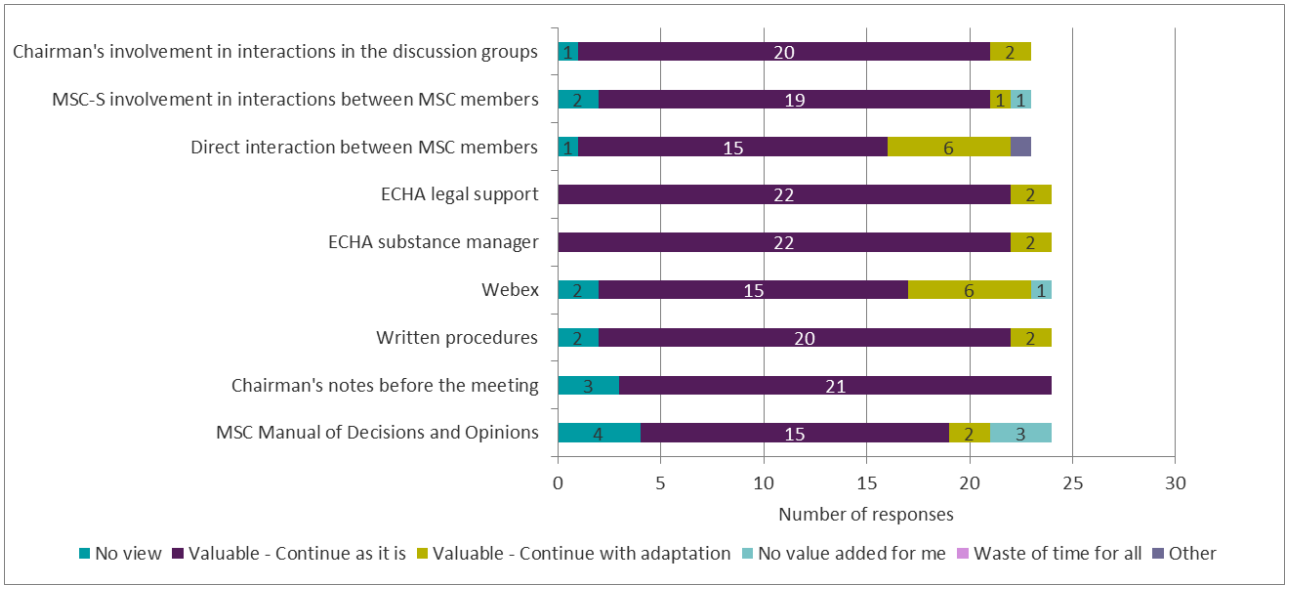
- It would be beneficial to encourage the use of the written procedure as much as possible; however it its use is limited due to the short timelines given to the eMSCA to decide on the use of the procedure and for the drafting of the DD in a detailed and transport way.

In addition, the Member States provided information on the mean periods of time they spend per case in preparation for written procedure voting. The majority of Member States (10 out of 18 responding) reported that this usually takes between 15/30 minutes to up to 4 hours, though this will be highly dependent on the specific case.

Aids in preparation for decision making and forming opinions (efficiency and workability)

As illustrated in figure below, the survey reflects an overall positive view among the MSCAs/MSC members regarding the different aids provided by ECHA for decision making.

Figure 3.4 Responses (number) to question 2.3.7: What is your view on the following aids in preparation for decision making and opinion forming?



In particular, ECHA´s legal support and the role of the substance manager seem to be the most appreciated, with 22 respondents out of 24 indicating that it should continue as it is. Also the Chairman´s notes and its involvement in discussions as well as the written procedures are highly valued. It is of note that none of these have been identified as being a waste of time for everyone. Only a few have noted that certain tools were not relevant for them.

Some respondents have made suggestions to improve some of these aids, which are summarised in Appendix C (under analysis of question 2.3.7). A selection of these is included below:

- For the Webex to be useful, the MSCA submitting the PfAs should always participate in the Webex and this is not always possible. Therefore participation in the Webex of MSCAs should be encouraged by ECHA. In particular it is suggested to set the date/time well in advance (maybe built into the timeline) to help planning and ensure maximum availability of the key parties.
- The MSC manual of decisions could be very valuable but needs updates with entries that have been well discussed (it is noted that it currently contains only one entry relating to substance evaluation). In addition, the ongoing work by the SEv DD working group to establish best practice for SEv DDs is also highlighted as useful for eMSCAs.

Transparency of the decision making process (transparency)

When asked about the potential to improve the transparency of the decision making process, a few MSCAs/MSCs have provided some propositions. These include:

- Limiting closed sessions as much as possible.
- Informing registrants of the start of the consultation on the DD to the MSCA/ECHA, so that they are aware of the start of the 30 day period for the registrants to comment on the PfA beforehand.

In addition, registrants have also suggested that more timely information about imminent steps of the process and more details about the reasons for the decision have to be communicated to the registrants.

Also a more direct contact between authorities and registrants as well as more openness to updated information from the registrants during various stages of the process is sought.

Clarity and impact of DDs and FDs (effectiveness)

The survey indicates an overall positive view among the registrants regarding **the clarity of the decisions** and the reasons behind them. Half of the respondents found the DDs and FDs clear enough, whereas 22% disagreed.

In a follow-up question registrants further specify what issues are perceived as unclear or benefitting from further clarification in the DDs and FDs. Scientific reasoning as well as exposure and use-related requests were rated as most unclear, followed by the requests on the test method to be used. Details on the procedure and on the deadline for submission of data on the other hand are generally perceived as more clear. Regarding length and detail of the decisions, the survey shows a preference for more summarised and shorter decisions (6 respondents), rather than more detailed and longer decisions (2 respondents).

The detailed comments provided by a number of respondents show varying concerns; a full list is included in Appendix C (under the analysis of question 3.3.4). Topics addressed in multiple comments are above all related to testing (particularly in cases of long-term testing plans) as well as a lack of inclusion of registrants in the decision process.

With regards to **the provision of the requested information**, registrants have faced a number of difficulties when providing information in a dossier update in general and concerning substance identification (SID), human health and environmental endpoints and exposure. All the difficulties are listed in Appendix C (under the analysis of question 3.3.5) and are of varied nature. Some topics addressed by several respondents include difficulties with the tests proposed on human health and environmental exposure. Also, information required on exposure needs the cooperation of downstream users who are not addressed by the decision and are thus not obliged to support registrants.

In addition, registrants have been also asked whether, upon receipt of a draft decision or final decision on SEv, they have **taken action other than to comply with the decision**. Based on the responses by 23 registrants, the predominant reactions to draft or final decisions are changes in registered uses and implementation of new risk management methods with nine responses each, whereas the cessation of manufacture is only reported by four. Twelve respondents have also taken other actions, such as: active search for replacements, lodging an appeal (named twice), review and update of exposure scenarios, as well as completing additional studies.

D) Follow up evaluation and taking the conclusions

Conclusion achievement and drafting by the eMSCAs (efficiency and effectiveness)

Although few SEv cases have been concluded following a FD, the survey aimed to gather insight on potential challenges experienced or envisaged by MSCAs/MSCs before concluding on the substance and in drafting the conclusions. As expected, few authorities have provided input on this issue (12), with most noting that they have little or no experience yet on this stage of the process. Six of the respondents that provided further detail identified as a key challenge the fact that information delivered is not what was requested. Comments provided are summarised in Appendix C (under analysis of question 2.4.1).

In addition, a question was formulated to MSCAs/MSC on whether the new format for conclusion documents and reporting on the substance evaluation will improve efficiency. Out of 15 providing their view on the subject, 60% agreed that the new format for conclusion documents and reporting will improve efficiency.

Views and impact of conclusions by registrants (effectiveness)

Finally, registrants were asked for their views on whether the conclusion derived for their substances fairly reflects the information available and helps them in establishing the safe use of the substance. Of the twelve respondents, eight stated that the conclusions on their substances fairly reflected the information available and helped them in establishing the safe use of the substance. Four respondents disagreed. Unfortunately, little further detail had been provided.

E) Interactions between eMSCAs and Registrants and between the registrants themselves

Between eMSCAs and Registrants (efficiency and workability)

The survey has collected relevant insights on the following aspects:

- **The potential existence of problems among MSCAs in identifying the correct contact points for the SEv evaluation within the registrants:** More than half (70% or 14/20) of the respondents have not encountered such problems. One MSCA notes that usually the lead registrant steps up to the task of acting as the contact point during SEV. Further comments supplied by the Member States where problems have been experienced note that these generally occur when the dossier is submitted as a joint submission and registrants are part of a consortium. Also large numbers of registrants requires a lot of manual searching in REACH-IT to obtain contact details.
- **The extent to which informal discussions between the registrants and eMSCAs take place during the different phases of the SEv process and the issues that these covered:** Based on the responses provided by both MSCAs/MSCs and registrants, these discussions appear to have occurred throughout all stages of the process. However, the evaluation appears clearly as the stage with the most respondents experiencing informal discussions with the eMSCAs. Thematically, the answers indicate that the four proposed issues (exposure; substance identity and hazard endpoints; SEv procedure and obligations; and availability of further data) seem quite equally frequent during those informal discussions. Discussions during decision making seem fairly common as well, though in this case discussions mainly covered procedural and obligational aspects.
- **The means of informal interaction used and their frequency:** Based on the responses provided by both MSCAs/MSCs and registrants, email exchange is the most frequently used means of communication between registrants and MSCAs. Face to face meetings, phone calls and teleconferences are in descending order the forms of interaction mentioned the next most by the respondents.
- **The usefulness of informal interaction**: Almost all (19/20 or 95%) of the MSCAs/MSC responding agreed that the interaction with the registrants was helpful and aided the evaluation by providing additional information. The majority of the registrants (20/23 or 86%) also see as useful this interaction regarding obligations and means of addressing the concerns.

Overall the results from the survey have stressed the importance of frequent interaction between the MSCAs and the registrants, though it is noted that this will vary very much depending on the parties involved, with one registrant even noting that with certain Member States no interaction was possible at all. In addition, a few comments or suggestions have been made:

- Interaction should actively be sought by all eMSCAs. Defining a minimum level and a best practice level based on cases of reference has been suggested as a potential improvement.
- To facilitate contact with registrants, it has been suggested that it would be helpful if ECHA could provide a list of the contact points for all registrants from the registration dossiers for each substance. Also it would be helpful if ECHA could send the first correspondence on substance evaluation to all registrants via REACH-IT, based on the development of a template letter which could be amended as necessary by the relevant eMSCA.
- Interaction could be improved by involving the registrants in the meetings of the Member States regarding their respective dossier. This would, according to the respondent, enable registrants to provide the Member State with their interpretation and to discuss scientific issues directly.
- The possibility to comment prior to the CoRAP becoming final was another proposition by a registrant.

Interaction between the registrants themselves

The survey has collected relevant insights on the following aspects from registrants:

- **The potential existence of difficulties in deciding which of the registrants shall perform and submit the requested studies on behalf of the others:** Out of 45 respondents, only 13% reported difficulties in deciding which of the registrants performs and submits the studies. 62% have not encountered such problems and 25% did not have a view. Five of the respondents that provided further detail stated the lead registrant usually took on those tasks or should do so. Nevertheless, some stakeholders have also noted that there are issues regarding cost-sharing and that further instructions/rules on this would be needed.
- **Whether contact with downstream users has taken place when their substance is placed on the CoRAP in order to get more detailed information of uses and exposure:** Out of 44 respondents, 50% had replied yes compared to 32% that had reported not having been in contact with downstream users and 18% which had no view. The further comments supplied by some respondents draw a picture of a complicated and lengthy process, but in most cases a supportive attitude by downstream users.

F) Horizontal and general questions

The survey has also gathered information on the SEv process as a whole, particularly with regards to its overall efficiency and effectiveness. Topics addressed are presented in the following sections:

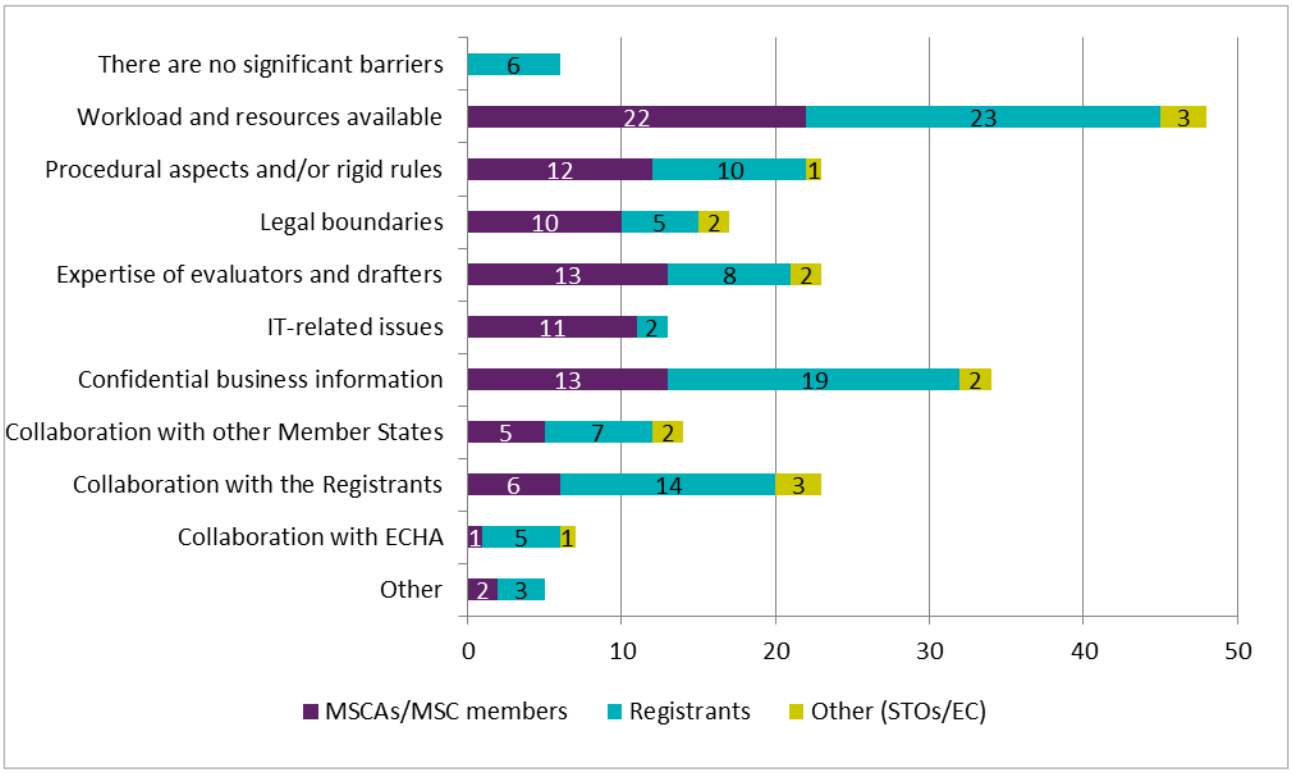
Overall improvement of the SEv process from setting up in 2012 to the present time in 2015

According to the 23 respondents that have provided their views (from MSCAs/MSCs, as well as from STOs and the Commission), the SEv process has clearly improved since 2012. Particularly it was noted among MSCAs that parties involved have a better understanding and are gaining experience in the process, with procedures evolving and improving accordingly. In addition, STOs mentioned the increased transparency as a concrete example of how the process has improved.

Efficiency of the substance evaluation process

All stakeholder types were asked about the barriers hindering the efficiency of the evaluation process. As illustrated in the figure below, workload and resources available is the most recognised barrier. In descending order, confidential business information, the expertise of evaluators and drafters and collaboration with the Registrants appear as the next frequently encountered problems.

Figure 3.5 Responses to questions 2.6.2/3.5.1/4.3.2: Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?



A number of respondents have also specified the issues they encountered:

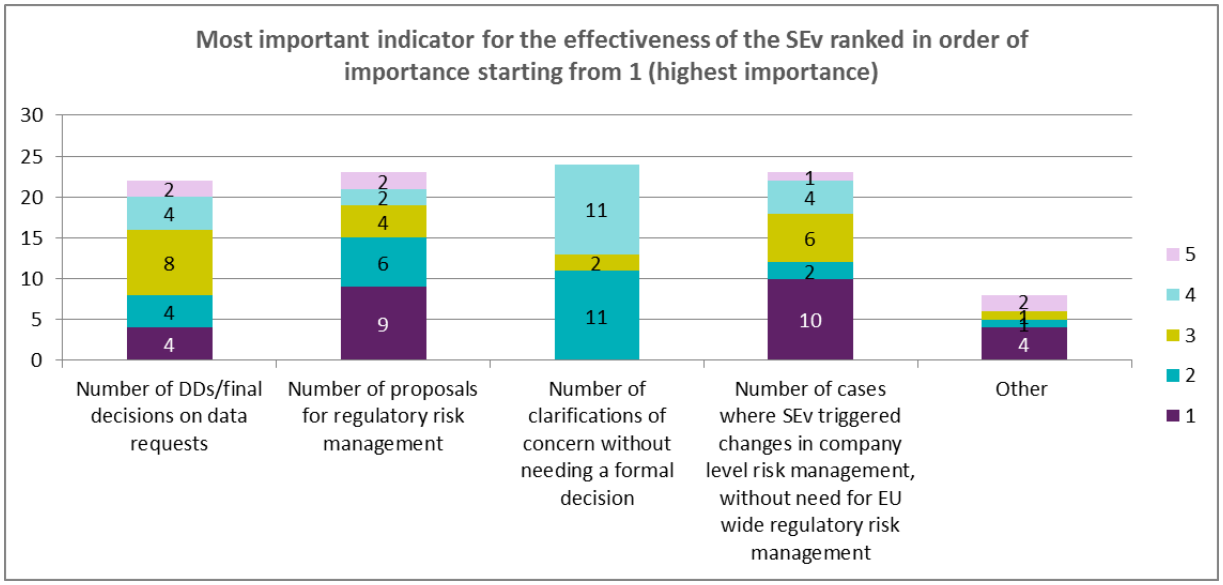
- Among MSCAs/MSCs, main points of concern elaborated in the comments seem to be addressing procedural barriers and/or rigid rules, legal boundaries or the increased workload on the authorities, particularly due to the piling-up of new and old SEv cases (i.e. CoRAP selection combined with the evaluation of new substances plus the follow-up work from previous evaluations).
- Among registrants, the main points of concern seem to be addressing either the flow of information (openness of the authorities to new information, confidentiality, and complicated communication between registrants and with downstream users) or the burden on the business, particularly due to the work load involved.

Effectiveness of the SEv process: Indicators and expectations

Based on the responses from MSCAs/MSCs as well as STOs and the Commission, it is not possible to conclude on which of the indicators proposed by ECHA to measure the effectiveness of the process is the most important. In particular, several respondents have expressed that all these indicators give some measure of the effectiveness of the SEv process as a means to clarify an identified concern (i.e. consideration of all is what determines success) and that care should be taken when ranking them, as this will vary on a case by case basis.

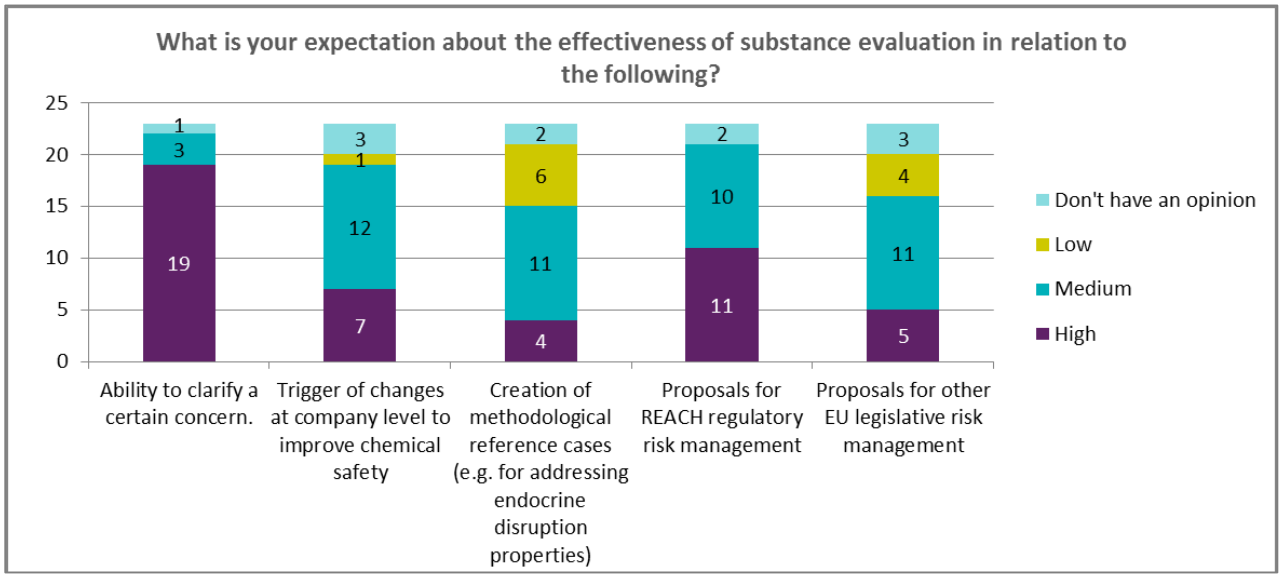
As illustrated in the figure below, the indicators that have been more highly ranked are the number of cases where SEv triggered changes in company level risk management, followed by the number of proposals for regulatory risk management. Interestingly, the number of clarifications of concern without needing a formal decision was ranked as the second most important indicator by most respondents. Less support is given to an indicator based on numbers of DDs or FDs on data requests, with a few stakeholders noting that this indicator should not be taken as the only measure of success.

Figure 3.6 Responses to questions 2.6.3/4.3.3: What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).



23 respondents from MSCAs/MSCs provided their views about their expectations on the effectiveness of the SEv process in relation to a number of outcomes. As illustrated in the figure below, it appears that SEv is expected to be most effective in clarifying a concern (19 respondents or 83%). SEv is also expected to be effective in leading to proposals for REACH regulatory risk management by almost half of respondents (48%).

Figure 3.7 Responses (number) to question 2.6.4: What is your expectation about the effectiveness of substance evaluation in relation to the following outcomes?



Instructions on the different steps of the process

68% of respondents (13/19) consider that instructions on SEv are sufficient for all steps in the process. None identified the instructions as being superfluous or as creating lots of additional (unnecessary) work for one or some steps in the process. Only a few have indicated that these are either not enough for one or some steps (26% or 5/19) or are missing for one or some steps (1/19), though in this latter case no further comments were provided.

Use of national helpdesks by registrants or other stakeholders in order to seek advice on substance evaluation in general or regarding particular substances

Based on the input provided by MSCAs and registrants, questions on SEv or particular substances are received through national helpdesks rather occasionally. These mainly related to the general or procedural aspects of SEv (i.e. CoRAP selection). As such it is noted that questions on SEv are usually received directly by the SEv team responsible at the MSCA.

4. Summary and conclusions

4.1 Transparency assessment (Task 1)

Based on the review of the information on the ECHA website and the results from the stakeholder survey, it is concluded that the information on the processes related to the CoRAP and Substance Evaluation is in general both comprehensive and clear. A number of recommendations have been made in order to help users of the website in finding the relevant information. The content, when located, is generally appropriate to the different target audiences, with both simple outlines of the process and more detailed procedural information being readily available.

In terms of information on specific substances on the CoRAP or subject to Substance Evaluation, there would appear to be some simple steps that could be taken to improve the clarity of certain key documents. An example relates to the justification documents for inclusion of a substance on the CoRAP and the decisions resulting from the Substance Evaluation, both of which were identified by registrant responders to the survey as areas where they would like more clarity. The documents have to be of a technical nature owing to the complexity of some of the issues they are covering but the clarity could be improved by better indicating the information that has been considered in the process and where the interpretation of data by the Member State differs from that of the registrant. In addition the clarity of the Substance Evaluation process may be improved by making the Substance Evaluation Reports available to registrants but it is understood that this is not currently possible.

4.2 Survey on the SEv process (Task 2)

Key findings from the survey are presented in the following sections covering the different phases of the process that have been analysed in section 3. Within each phase, a table identifies the main suggestions for improvement or key discussion points and the influence that each of these has on the effectiveness, efficiency, workability and transparency of the SEv process.

These suggestions, some of which are already being considered by ECHA, will be discussed in the upcoming workshop on SEV.

Selection of substances to be listed by ECHA in the Community rolling action plan (CoRAP)

- Respondents generally think that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value.
- The common screening approach has involved an improvement in the selection compared to the previous situation.
- Listing in CoRAP appears to contribute, at least to some extent, to the improved quality of dossiers, though it is noted that this will vary on a case by case basis.
- Overall it appears that the current number of substances evaluated annually has been workable to date, but in the future this might need to be revised depending on the follow-up work from substances evaluated in earlier years 2012-2015 as well as the scale of the evaluations and on the resources ECHA will be able to allocate.
- Views on the information on ECHA´s website on CoRAP are predominantly positive. For the national websites views are less positive, as these generally contain only a brief description of the process and link to ECHA´s webpage for detailed information.

Table 4.1 Initial suggestions - CoRAP

Suggestions / topics for discussion	Effectiveness	Efficiency	Workability	Transparency
Better interplay with the process of compliance checks (CCH) - Ideally these to be performed prior to all SEv and even before deciding on the inclusion of a substance in CoRAP, as this could be sufficient to clarify concerns (no need for SEv).		✓	✓	
Avoid redundancies with parallel processes when selecting substances (e.g. under review as active substances under the Plant Protection Products Regulation).	✓	✓		
Consider refining the shortlisting criteria under the common screening approach to improve the identification of candidates that make it into the final CoRAP. Include information from other sources in the screening phase (e.g. monitoring data, Poison Centres). These are normally available to MSCAs, who will have to make them available in a structured and searchable way.		✓	✓	
Improve the tracking and follow up of substances following screening as they enter other processes, particularly for those selected for CCH		✓		
Use SEv as a targeted instrument to address uses or exposures of potential concern and then find the substances which fit		✓		
Maintain the current situation of around 50 substances evaluated annually, but taking into consideration MSCA capacity.			✓	
Consider sending a stronger message to the Registrants so that once their substance is included in CoRAP, they use the opportunity to update their dossier, not only with any new information, but also making the current information more detailed.	✓	✓		

A large darker tick identifies criteria for which that suggestion is more relevant. A smaller and lighter tick means that the criteria will also be relevant but to a lesser extent.

Evaluation phase of substances by the eMSCAs

- The support provided by ECHA when a Compliance Check is performed is helpful and should be encouraged more. It is considered mostly appropriate in terms of form and content, but less in terms of timing.
- MSCAs/MSCs have experienced a number of difficulties with the assessment of substances concerning SID, human health and environmental endpoints and exposure.
- A combination of information sources is generally used by eMSCAs in the assessment of substances, though few cases have been reported where an MSCA contacts the eMSCA to provide input.
- Overall, ECHA´s support during consistency screening has been useful and clear, leading to improvements in the quality of DDs, particularly in terms of the legality of the requests.

Table 4.2 Selection of initial suggestions or points for discussion – Evaluation phase

Suggestions/ topics for discussion	Effectiveness	Efficiency	Workability	Transparency
A CCH in advance of SEv should always be strived for to improve efficiency.		✓		
Time available for MSCAs to comment on CCH is rather brief and that there is a need to improve the communication flow		✓	✓	

Suggestions/ topics for discussion	Effectiveness	Efficiency	Workability	Transparency
between ECHA and the eMSCAs in terms of timing expectations and assigned responsibilities				
Address difficulties related to the phrasing of requests for information on exposure.	✓	✓		
Within the consistency screening, potential to further improve the reasoning for some recommendations could be improved, e. g. by referring to other (draft) decisions			✓	✓

A large darker tick identifies criteria for which that suggestion is more relevant. A smaller and lighter tick means that the criteria will also be relevant but to a lesser extent.

Decision making phase

- Tight deadlines have been identified as a common challenge across the different steps of the process by both registrants and MSCAs/MSC members. Interference with holiday periods (e.g. MSC Committee in September after summer) is also a concern for some.
- Examination of DDs by MSCAs in order to potentially make a PfA generally takes place on a case-by-case basis. MSCAs will tend to focus on similar substances or similar endpoints to their CoRAP substances, for the purpose of harmonisation and learning.
- There is no clear or simple option to address the issue of whether MSCAs should be able to make a PfAs for a completely new endpoint. This needs further discussion and flexibility, on a case-by-case basis.
- Lessons learnt from the preparation of MSC meetings include the importance of having a text for the DD prepared beforehand and of having informal communications with the MSCAs submitting PfAs before the meeting.
- There is an overall positive view on the structure, organisation and role of the MSC meetings.
- Written procedures are seen as a valuable tool that should be encouraged as much as possible.
- The survey reflects an overall positive view among the MSCAs/MSC members regarding the different aids provided by ECHA for decision making, particularly with regards to ECHA´s legal support and the role of the substance manager.
- There is potential to increase the transparency of the decision making process by providing the registrants with more timely information about imminent steps of the process and more details about the reasons for the DD/FD.
- Overall, there is a positive view among the registrants regarding the clarity of the decisions and the reasons behind them. However, a number of difficulties have been faced when providing the information requested in a dossier update.
- In addition to complying with the decision, some registrants also report taking other actions, particularly changes in registered uses and implementation of new risk management methods. The lodging of appeals is also named as a reaction to the FD.

Table 4.3 Selection of initial suggestions or points for discussion – Decision making phase

Suggestions/ topics for discussion	Effectiveness	Efficiency	Workability	Transparency
Tight timelines: 30-day commenting period for registrants, time for answering the PfAs and subsequently amending the DD for referral, time pressure during MSC meeting, for written procedures.			✓	
Further discussion on whether MSCAs can make a PfAs for a completely new endpoint	✓	✓		

Suggestions/ topics for discussion	Effectiveness	Efficiency	Workability	Transparency
Potential to develop further instructions/guidance on the level of detail needed in the DD concerning the PfAs and comments.		✓	✓	
During MSC meeting, consider concentrating the discussion and the agreement on specific cases in a few days in order to facilitate the presence of experts.			✓	
Recommendation to do the drafting revisions on DDs during the MSC meeting in small groups of interested parties. If these cannot attend (i.e. due to attendance in parallel sessions) to be consulted before or after the session.			✓	
Consider the definition of criteria for the selection of substances for written procedure, which at present appears to be only at the discretion of the eMSCA.			✓	
ECHA to encourage participation in the Webex and to confirm the date well in advance, to ensure that the MSCA submitting the PfA's participate (otherwise is less useful).		✓	✓	
Potential to update the MSC manual of decisions with more entries related to SEv.			✓	
Limiting closed session's as much as possible and involving registrants more during the decision making process, providing them with timely information on the steps and expectations.				✓

A large darker tick identifies criteria for which that suggestion is more relevant. A smaller and lighter tick means that the criteria will also be relevant but to a lesser extent.

Follow-up phase

- A key challenge identified by MSCAs in this phase is that information delivered is not what was requested, with subsequent delays in the process.
- In general, most MSCAs agreed that the new format for conclusion documents and reporting will improve efficiency.
- In general, most registrants stated that the conclusions on their substances fairly reflected the information available and helped them in establishing the safe use of the substance.

Interactions between eMSCAs and Registrants and between the registrants themselves

- In general, most MSCAs have not encountered problems in identifying the correct contact points for the SEv evaluation within the registrants. However some have faced problems when the dossier is submitted as a joint submission and where registrants are part of a consortium.
- Informal discussions between the registrants and eMSCAs are highly valued and appear to have occurred throughout all stages of the process, but predominantly during the evaluation phase. These are mainly based on email exchange.
- In general, most registrants have not encountered problems in deciding which of the registrants shall perform and submit the requested studies on behalf of the others. The lead registrant usually takes on those tasks or should do so. Nevertheless, it is also noted that there are issues regarding cost-sharing and that further instructions/ clarifications on this would be needed.
- Contacts by registrants with downstream users have taken place in some instances, though this can be a complicated and lengthy process.

Table 4.4 Selection of initial suggestions or points for discussion – Interactions

Suggestions/ topics for discussion	Effectiveness	Efficiency	Workability	Transparency
Encourage all eMSCAs to actively seek interaction. Defining a minimum level and a best practice level based on cases of reference has been suggested as a potential improvement.			✓	
To facilitate contact with registrants, it would be helpful if ECHA could provide a list of the contact points for all registrants from the registration dossiers for each substance. Also it would be helpful if ECHA could send the first correspondence on substance evaluation to all registrants via REACH-IT.			✓	
Interaction could be improved by involving the registrants in the meetings of the Member States regarding their respective dossier.			✓	✓
Further instructions/rules on cost-sharing among registrant could be considered by ECHA.			✓	

A large darker tick identifies criteria for which that suggestion is more relevant. A smaller and lighter tick means that the criteria will also be relevant but to a lesser extent.

Horizontal and general aspects

- The general perception is that the SEv process has clearly improved since 2012.
- A number of barriers hindering the efficiency of the SEv process have been highlighted. Overall, the SEv process can be burdensome on both registrants and authorities and lengthy, due to the arising workload.
- It has not been possible to conclude which of the indicators proposed by ECHA to measure the effectiveness of the process is the most important. All indicators give some measure of the effectiveness of the SEv process and the survey indicates that care should be taken when ranking them, as this will vary on a case-by-case basis.
- SEv is generally expected to be most effective in clarifying a concern, but also in leading to proposals for regulatory risk management.

Table 4.5 Selection of initial suggestions or points for discussion – Horizontal

Suggestions/ topics for discussion	Effectiveness	Efficiency	Workability	Transparency
Further discussion on the definition of indicators to measure effectiveness.	✓			
Review of some instructions seen as not being clear enough on one or more steps			✓	

A large darker tick identifies criteria for which that suggestion is more relevant. A smaller and lighter tick means that the criteria will also be relevant but to a lesser extent.

Appendix A
Review of information on ECHA website

A1 Introduction

A1.1 Purpose of this Appendix

This **Appendix** presents the detailed mapping and review of the information available on the ECHA website. The findings presented in this Appendix have been summarised in the main report (see section 2 on Task 1), and both sections should be considered together.

A1.2 Structure of the Appendix

The objective of Task 1 was to carry out a review of the information available on the ECHA website which relates to the process of substance evaluation. This review was from the point of view of whether the information available makes the process as a whole transparent and understandable. It was also to assess whether the substance evaluation outcome documents provide a clear rationale for the selection of substances, and report clearly the outcomes of the substance evaluation process.

The approach taken was to firstly 'map' the relevant pages on the ECHA website using various starting points that could be foreseen to be used in order to locate information on Substance Evaluation. The information and documents available relevant to substance evaluation (including the Commission Rolling Action Plan, CoRAP) on each webpage were noted as were the links to other relevant webpages given on the page. The relevant information and documents available on each webpage were then reviewed. Section A.2 of this Appendix is structured following four different starting points.

For ease of reference each webpage has been given a reference number shown in [ ]. Owing to the nature of the website and the different potential routes through the website the reference numbers do not necessarily follow in numerical order.

In order to facilitate visualisation of how the various webpages link together from various potential starting points, a series of 'maps' have been constructed. These are embedded in Section A.2.1 of this Appendix. In the maps, the reference number is shown for each webpage. The bold arrows show how each of the main webpages links forward to further information. Where a given page links back to other relevant webpages this is shown by inclusion on the map of the relevant reference number(s) for those webpages. This was done in order show the main routes through the webpages more clearly.

As well as the links between the pages, the maps also identify the documents that are available for download from each page. These are shown in red text on the respective maps.

The following sections consider the contents of each webpage and the documents relevant to substance evaluation that are available from each webpage. In all cases the route through the ECHA website is assumed to start with the ECHA homepage. However the order that the subsequent webpages are encountered depends on the route taken through the site. The review therefore considers each route separately, presenting the webpages in the approximate order that they are encountered, but where a given webpage is encountered on more than one route, a detailed description of the webpage is only given in the first route in which it is encountered. Suggestions for improvement of the clarity of the webpages are given in the Comments section of each review where appropriate.

A1.3 Remarks

The following remarks are made:

- The information included in this report is based solely on the information available on the ECHA website at the time the review was carried out (July-August 2015). The links to the various webpages and documents were correct at the time of the review.
- The review was carried out by people with technical knowledge of the substance evaluation process and that had some familiarity with the ECHA website.

A2 Review of the information on the ECHA website

A2.1 Common starting point for the review

[1] - ECHA homepage

http://echa.europa.eu/web/guest)

Content

The ECHA homepage gives the following points of access for information on substance evaluation:

- Search for Chemicals box [A].
- Regulations Tab [B].
- Addressing Chemicals of Concern Tab [C].
- Information on Chemicals Tab [A]
- Support Tab [D].

The Search for Chemicals box and the Information on Chemicals Tab essentially provide the same way into the website and so these two routes are considered together. Therefore four main routes of entry into the website have been considered here, and maps have been constructed for each of these routes: Route A - search for chemicals/information on chemicals; Route B – Regulations tab; Route C – Addressing chemicals of concern tab; Route D – Support tab. The maps can be found at the end of this Appendix in section A2.7.

The route that any one user will take is likely to depend on a number of factors including:

- Familiarity with the ECHA website.
- Status of the user:
  - Registrant.
  - Downstream User.
  - Regulator.
  - Other Interested Party.
- Familiarity with the Substance Evaluation Process.
  - Looking for general information on the process.
  - Looking for specific information on the process.
  - Looking for specific information on a substance.

Documents

There are no documents specific to substance evaluation that can be downloaded directly from this webpage. On occasions it is possible that information on substance evaluation may appear under the ‘News’ part of the webpage, but at the time of this review, this was not the case.

Comments

None.

A2.3 Route A - search for chemicals/information on chemicals

There are two possible ways to proceed through this route. The first is to use the 'Search for Chemicals' box on the homepage and the second is to use the 'Information on Chemicals Tab' available on the homepage. Both starting points lead to essentially the same pathway through the website.

[2] – Search results

[Note: address is substance-specific]

Content

This page can be accessed by searching for a specific chemical on either the home page or the information on chemicals tab. It provides a link directly to the Community Rolling Action Plan (CoRAP) webpage [3] if this is relevant for the substance. If no link to the CoRAP is given for the substance then it is not possible to proceed any further by this route.

Documents

There are no documents specific to substance evaluation that can be downloaded directly from this webpage.

Comments

None.

[3] – Substance evaluation – CoRAP

http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Content

This can be accessed either from the substance search results (if relevant for that substance, in which case the entry for that substance alone will be displayed) or directly from the information on chemicals tab (in which case entries for all substances on the CoRAP will be displayed).

The webpage presents a short, simple description of the CoRAP list along with a clear table outlining the evaluating Member State, the planned year of evaluation and a short description of the concern (e.g. CMR, PBT, vPvB, exposure/wide dispersive use, high aggregated tonnage etc.) that led to the substance being placed on the list.

Clear links from the page are given to the following webpages. A link is also given from the Table to allow details of any appeals against the decision to be downloaded if relevant.

- Decision/detail [4].
- Notes on substance evaluation table [5].
- Further information on:
  - Understand the Community Rolling Action Plan [7].
  - Community Rolling Action Plan (CoRAP) lists [6].
  - Understand the Substance Evaluation [8].
  - Q&A on CoRAP and Substance Evaluation [9].

Documents

Any appeal documents can be accessed from this page. The appeal documents give details of the appellants, subject matter (and the relevant articles of the REACH Regulation), a summary of the contested decision, the remedy sought by the appellant, the pleas in law and the main arguments. At the time of carrying out this review, there were no documents available on the outcomes of the appeals.

Comments

Although there are links to further information on substance evaluation, the text on this page does not really explain, in brief terms, how a substance can get added to the CoRAP, i.e. on the basis of a suspicion of a concern from a Member State. It rather starts from the fact that a substance is on the CoRAP.

[4] - Decision/detail

The webpage link is substance-specific. An example is Alkanes, C14-17, chloro (MCCP, Medium chained chlorinated paraffins) - http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/substance-rev/3016/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_NAME=Alkanes%2C%20C14-17%2C%20chloro+%28MCCP%2C%20Medium++chained+chlorinated++paraffins%29&_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=287-477-0.

Alternatively the full table can be viewed at http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/.

Content

The page contains an expanded Table of information on the substance on the CoRAP. As well as information on the substance name and identifier numbers, it lists a short summary of the initial grounds for concern, the Member States Contacts' details and the links to download the following documents, where available.

- Justification documents.
- Decision documents.
- Appeal documents.
- Conclusion documents.
- Evaluation documents.

Documents

The webpage provides links to download the following documents, where available: justification documents; decision documents; appeal documents; evaluation documents; and conclusion documents. As many of these documents are important for the dissemination of information from the substance evaluation process, they are considered in more detail in Section 2 of the main report.

For this evaluation, the following subset of reports was randomly selected and briefly reviewed. These cover substances for which the substance evaluation has been concluded, is on-going and has not yet started. The Appeal documents are considered in the review of [3] – Substance Evaluation – CoRAP.

- "Justification for the selection of a candidate CoRAP substance - 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate"[12].

[12] http://echa.europa.eu/documents/10162/aede54b4-5616-4aba-ae78-3c4e8f68b29f

- "Justification for the selection of a candidate CoRAP substance – Xylene"[13].
- "Decision on Substance Evaluation pursuant to Article 46(1) of Regulation (EC) No 1907/2006 - 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate"[14].
- "Decision on Substance Evaluation pursuant to Article 46(1) of Regulation (EC) No 1907/2006 – Alkanes, C_{14-17}, chloro (MCCP, medium-chain chlorinated paraffins)"[15].
- "Substance Evaluation Conclusion Document – Ethylene oxide"[16].
- "Substance Evaluation Conclusion Document – Tributyl phosphate"[17].
- "Substance Evaluation Report – Ethylene oxide"[18].
- "Substance Evaluation Report – Tributyl phosphate"[19].

The Justification Documents give brief background information on/summary of the grounds for concern that led to the substance being included in the CoRAP.

The Decision Documents are the official outcomes of the substance evaluation where it is decided that further information is required in order to clarify the concern with the substance. The documents outline the following.

- Who the decision is addressed to (and which registrants are not covered by the decision) and who carried out the evaluation.
- The procedure used including:
  - The initial grounds for concern/reason the substance was included in the CoRAP.
  - The time-line involved in preparing the draft decision including the date which it was initially submitted to ECHA.
  - The date ECHA sent it to Registrants with a 30 day commenting period.
  - The date comments were received by ECHA from the Registrants.
  - A brief summary of any amendments made as a result of the comments.
  - The date the evaluating Member State notified the Competent Authorities of other Member States and ECHA of the draft decision inviting comments within 30 days.
  - Any proposed amendments as a result of the Member States' comments with the date inviting the Registrant to comment on these proposals within 30 days.
  - The date the draft decision was sent to the Member State Committee.
  - The date agreement was reach by the Member State Committee on the draft decision and the process used to reach agreement.
  - The relevant Article of REACH under which ECHA took the decision.
- Details of the information required to be provided and the date by which it is required to be provided.
- A statement of the reason justifying the information required. This provides a summary of the relevant available data and how this leads to the request for further information.

[13] http://echa.europa.eu/documents/10162/73bc0adb-acca-4c75-9087-f9778ca8f992
[14] http://echa.europa.eu/documents/10162/d1343bad-67b4-47b2-af58-64dc4788d540
[15] http://echa.europa.eu/documents/10162/03800fac-8153-4dfa-a60f-d1217f0419b2
[16] http://echa.europa.eu/documents/10162/520a59a5-6af5-4f98-88e1-3834dc6d2b0e
[17] http://echa.europa.eu/documents/10162/40d949c3-a19b-4d3a-99ed-22b651d9cefa
[18] http://echa.europa.eu/documents/10162/17a5f21e-7055-45ed-aa4c-98317ca43030
[19] http://echa.europa.eu/documents/10162/3f703a8f-bbf9-4b69-8fbb-8eb69ca46467

- Standard paragraphs on the following.
  - Adequate identification of the composition of the tested material.
  - Avoidance of unnecessary testing by data- and cost-sharing.
  - Information on the right to appeal the decision.

The Substance Evaluation Conclusion Documents outline the overall substance evaluation processes, the overall conclusions reached by the evaluating Member State once the substance evaluation is completed and, if relevant, any possible follow-up actions that could potentially result from the substance evaluation

The evaluation documents, where available, provide more detailed information to support the Conclusion Documents, including a summary of the Conclusions and, in some cases, a more detailed discussion of the data evaluated.

Comments

None.

[5] – Notes on substance evaluation

This is a pop-up window that opens on the Decision/detail page [4]. The webpage link is substance-specific. An example is Alkanes, C14-17, chloro (MCCP, Medium chained chlorinated paraffins) - http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/substance-rev/3016/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_NAME=Alkanes%2C%20C14-17%2C%20chloro+%28MCCP%2C%20Medium++chained+chlorinated++paraffins%29&_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=287-477-0

Content

This gives some explanatory notes to the Table of information on the substance on the CoRAP, including the purpose of the justification document and the nature of the suspected concern.

Documents

No further documents other than those identified in the Decision/detail page [4] above.

Comments

None.

[6] – CoRAP list of substances

http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances

Content

This page provides access to the lists of substances included in the CoRAP to be evaluated in the next three years. The list itself is not given on the page, but rather links to the following pages are given.

- Community Rolling Action Plan (CoRAP) List of Substances [3].
- (About) Substance Evaluation [8].
- (About) The Community Rolling Action Plan [10].

Documents

The following documents are available for download from the page.

- CoRAP 2012-2014[20].
- CoRAP 2013-2015[21].
- Additional inclusion to CoRAP list 2013[22].
- CoRAP 2014-2016[23].
- CoRAP 2015-2017[24].

The documents contain the original CoRAP and the annual updates. All of the reports provide a table outlining the year the substance was added, the evaluating Member State, the EC No., CAS No. and public name of the substance, the initial grounds for concern, the source (whether it was added as an update or was already in the CoRAP) and the contact details of the evaluating Member State.

Comments

The last sentence on the page is potentially misleading as it indicates that the justification documents for the substances on the CoRAP are attached to the page. In fact the list of substances is not actually given on this page, rather a link to the list of substances (which takes you to Substance Evaluation – CoRAP [3]) is given, from which the justification documents can be obtained.

[7] – Community rolling action plan

http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan

Content

The webpage provides a brief basic but clear description of the CoRAP including the purpose of the CoRAP and the substance evaluation process, the role of the Member States, the timeline from publication of the final CoRAP update to the final decision from substance evaluation, the process for the annual draft update of the CoRAP and a brief mention of transitional measures for substances for which information has been requested under previous legislation.

The page provides links to the following webpages.

- Community Rolling Action Plan (CoRAP) lists [6].
- (About) Substance Evaluation [8].
- (About) The Community Rolling Action Plan [10].
- Opinions of the Member State Committee on ECHA's draft CoRAP [19].
- Draft CoRAP [17].
- Transitional measures: complementary part to the CoRAP [18].
- Community Rolling Action Plan Questions and Answers [9].

[20] http://echa.europa.eu/documents/10162/13628/corap_2012_en.pdf
[21] http://echa.europa.eu/documents/10162/13628/corap_2013_en.pdf
[22] http://echa.europa.eu/documents/10162/13628/additional_corap-substance-inclusion-2013_en.pdf
[23] http://echa.europa.eu/documents/10162/13628/corap_list_2014-2016_en.pdf
[24] http://echa.europa.eu/documents/10162/13628/corap_list_2015-2017_en.pdf

Documents

The following documents can be downloaded from the webpage.

- Selection criteria to prioritise substances for Substance Evaluation.
- CoRAP Factsheet.
- Leaflet - Substance Evaluation under REACH.

The selection criteria used to prioritise substance for Substance Evaluation are given in the following document: "Background document to the decision of the Executive Director of ECHA. ED/32/2011. Selection Criteria to prioritise substance for Substance Evaluation (2011 CoRAP Selection Criteria). 26 May 2011"[25]. This document gives background information on the process used by ECHA to prioritise substances for inclusion in the CoRAP. The process takes into account the legal (the REACH Regulation requires the process to take into account hazard information, exposure information and tonnage information) as well regulatory and practical aspects. The document explains how these aspects are taken into account in general terms.

The CoRAP Factsheet link leads to a document entitled: "Factsheet. Substance Evaluation. ECHA-11-FS-03-EN"[26]. This provides an easy to understand summary of the overall Substance Evaluation process starting from the CoRAP through to potential follow-up actions once the Substance Evaluation is complete.

The Leaflet – "Substance Evaluation under REACH is titled Substance Evaluation under REACH. Tips for Registrants and Downstream Users. ECHA-12-L-10-EN"[27] - is a very useful, short (4 page) document that highlights how registrants and downstream users of substances in the CoRAP can (and should) participate in the Substance Evaluation process.

Comments

In the third paragraph it could be considered to clarify here that when a Member State requests further information from the registrants this will be done via the final decision that will be published on the ECHA website. For example, the third paragraph could potentially be misinterpreted as the Member State informally requesting further information from the registrant during the substance evaluation rather than formally requesting it via the decision as a result of the substance evaluation. Although the paragraphs under the Timeline heading discus the draft and final decision there is no real explanation as to the legal role of the decision.

It could also be considered to include a short paragraph on what happens after the requested information has been provided by the Registrant.

The link to the Substance Evaluation Factsheet on this page is misleadingly labelled as CoRAP Fact Sheet. Although the fact sheet does cover the CoRAP, the same Fact Sheet is referenced as a Substance Evaluation Fact Sheet on other webpages.

[8] – (Understanding the) Substance evaluation

http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

Content

The webpage provides an overview of the substance evaluation process, giving details of the roles of the evaluating Member State and ECHA, and the timescale of the process. This covers:

- The overall objective of the substance evaluation – to request further information from the registrants of the substance to verify the suspected concern, if necessary.

[25] http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf
[26] http://echa.europa.eu/documents/10162/13628/fs_substance_evaluation_en.pdf
[27] http://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf

- The possible follow-on outcomes after the substance evaluation is complete, e.g. a conclusion that the risks are sufficiently under control with the measures already in place, or a proposal for EU-wide risk management measures (e.g. restriction, identification of substances of very high concern or harmonised classification), or a proposal for other actions outside of REACH.
- Clarification that the substance evaluation may be wider in scope that the initial concerns or reasons for selecting the substance for the CoRAP.
- The sources of information considered in the substance evaluation (all registration dossiers for all registrants of the substance and other available sources of information).
- Clarification that the evaluating Member State has 12 months from the publication of the CoRAP to decide on whether further information is needed from the registrants in order to clarify the concern and that the information requested may go beyond the standard information requirements of REACH.
- Agreement is reached between the other Member States and ECHA on the need for the further information before ECHA makes the final decision to request the further information if necessary.

There are links from the webpage to the following pages.

- What happens after Substance Evaluation? [14].
- Community Rolling Action Plan [10].
- Member State Committee [16].

Documents

The following documents can be accessed directly from the webpage.

- Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations.
- Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria). This is reviewed in relation to [7] – Community rolling action plan.
- Procedure on Substance Evaluation.
- Substance Evaluation fact sheet. This is reviewed under [7] – Community rolling action plan (where it is called the CoRAP Factsheet).
- Leaflet - Substance evaluation under REACH. This is reviewed under [7] – Community rolling action plan.
- Workshop proceedings – May 2014.
- Workshop proceedings – May 2013.
- Workshop proceedings – June 2012.
- Workshop proceedings – May 2011.

The document titled “Interaction between the evaluating Member State and Registrants under Substance Evaluation – Recommendations, ECHA-14-R-01-EN, January 2014”[28] provides recommendations on best practices for the informal interaction between evaluating Member State Competent Authorities and the registrant during the Substance Evaluation process. The aim of the document is to give guidance, to both evaluating Member States and Registrants, for a common approach to interactions and to create a level playing field. The report is based on proposals from a working group set up as a result of the Workshop in Substance Evaluation on 23-24 May 2013 (see below) and has been endorsed by the Competent Authorities for REACH and CLP (CARACAL). The recommendations are not legally binding and the report indicates that

[28] http://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf

although interaction between registrant and the evaluating Member State is recommended, the need and scope of any interaction will be specific to each evaluation and it is ultimately up to the evaluating Member State to decide.

The Substance Evaluation Procedure, PRO-0023.02, 20/10/2014[29] outlines the formal Substance Evaluation process, including decision making, as stated in the REACH Regulation.

The Workshop Proceedings cover the Workshops on Substance Evaluation held in Helsinki on 26th-28th May 2014 (ECHS-14-R-19-EN[30]), 23rd-24th May 2013 (ECHA-14-E-08-EN[31]), 4th-5th June 2012 (ECHA-12-R-07-EN[32]) and 23rd-24th May 2011 (ECHA-11-R-008-EN_INT[33]). Clarity of the Substance Evaluation process, particularly in relation to the availability of the Substance Evaluation Report to the Registrant, was a common theme to most of these workshops and this is considered further in Section 2 of the main report.

Comments

The document on interaction between evaluating Member State and the Registrant under Substance Evaluation provides much useful guidance on the informal interactions between the two parties during the process. It could be considered to better reflect the recommendations of this guidance on the webpage itself, particularly in relation to how to make initial contact, points of contact etc.

[9] - Q&A on CoRAP and substance evaluation

http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/corapandsubstanceevaluation

Content

The webpage contains general answers to the following questions at the time of the review (28th July 2015). The one marked with FAQ is a frequently asked question.

- When a substance is included in the CoRAP, are there any mechanisms by which a registrant can challenge the inclusion or provide input into the evaluation process? {FAQ}
- What is substance evaluation?
- Which Member States will evaluate the listed substances?
- What happens after the CoRAP is adopted?
- What is the difference between dossier evaluation and substance evaluation under REACH?
- What is the added value of substance evaluation?
- What is the difference between substance evaluation under REACH and evaluation under the Existing Substances Regulation ((EEC) No 793/93)?
- Why is a substance on the CoRAP list? Which criteria have been used? [Note: the answer to this provides a link to the 2011 CoRAP selection criteria document].
- Are the criteria for selection fixed?
- What does a known or suspected property mean in the grounds for concern in the CoRAP?
- When was the first CoRAP adopted?
- Is the CoRAP a new “black list” of chemicals?

[29] http://echa.europa.eu/documents/10162/13607/pro_0023_01_substance_evaluation_en.pdf
[30] http://echa.europa.eu/documents/10162/13628/sev_workshop_2014_en.pdf
[31] http://echa.europa.eu/documents/10162/13628/sev_workshop_2013_en.pdf
[32] http://echa.europa.eu/documents/10162/13628/ws_substance_evaluation_201207_proceedings_en.pdf
[33] http://echa.europa.eu/documents/10162/13628/ws_substance_evaluation_may+2011_proceedings_en.pdf

- What is the impact of substance evaluation on my business?
- Once adopted, is the CoRAP fixed?
- Is there any interaction between the evaluating Member Sate and the registrant/stakeholders?
- What is the outcome of substance evaluation?
- After adoption of the first CoRAP, when can a possible first decision requiring further information on a substance be expected? If further information is requested, when would this become available?
- What is the follow up of substance evaluation?
- Are substances in the (draft) CoRAP going to be included in the authorisation/restriction process?
- Where can I get more information on the CoRAP substances? [Note: the answer to this question provides a link to the registered chemicals webpage where the information on registered chemicals can be searched].

Documents

The answer to the question on why a substance is on the CoRAP list/which criteria have been used provides a link to the following document.

- "Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria)". This is reviewed in relation to [7] – Community rolling action plan.

Comments

The answer to the question on interaction between the evaluating Member State and the registrant/stakeholders may potentially be useful to many registrants. It could be considered to include some of this information on the relevant webpages, particularly Substance Evaluation [8]. This could include, for example, the following points.

- No formal interaction is foreseen during the 12 month evaluation process (before the possible draft decision is prepared).
- During the decision making procedure the registrants will be consulted on any prepared draft decision.
- The possibility for registrants/stakeholders to interact with the evaluating Member State during the evaluation process may differ between Member States.
- All relevant information available to the registrants of the substances should be included in the registration dossiers at the start of the evaluation (i.e. the beginning of March each year).

The answer to the last question on where sources of information on the CoRAP substances can be found currently provides a link to the registered chemicals webpage where the information on registered chemicals can be searched (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances). This then allows access to the registration dossiers within the dissemination database. It might be useful to also include a link to the CoRAP table itself [3] (http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table) in the answer to this question, as this provides more information on the substances specific to the CoRAP.

[10] - Community rolling action plan

http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Content

The webpage contains a clear, simple description of the CoRAP, the general criteria that are used in the selection of substances for the CoRAP and the process for establishing the CoRAP.

The webpage links to the following webpages.

- What happens after substance evaluation [14]?
- Evaluation Process [13].
- Evaluation Actors [16].
- Evaluation Steps [15].
- (Understanding the) Community Rolling Action Plan [7].
- CoRAP List of Substances [3].
- Questions and answers on Community Rolling Action Plan (CoRAP) [9].
- The Member State Committee [16].

Documents

The following documents are available from this webpage.

- Procedures on Substance Evaluation. This is considered under [8] – (Understanding the) Substance Evaluation.
- Draft Community Rolling Action Plan (CoRAP) List.
- Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP).

The Draft Community Rolling Action Plan (CoRAP) List document is titled “ECHA Proposal to the Member States: Draft Community Rolling Action Plan (CoRAP) update for the years 2015-2017, 30th October 2014”[34]. This is the draft Annual update of the CoRAP covering 2015-2017.

The document titled “Procedure: Substance Evaluation – Establishing updates of the Community Rolling Action Plan (CoRAP), PRO-0022.03, 01/12/14”[35] provides a description of the process used to establish updates of the CoRAP, with reference to the relevant Articles of the REACH Regulation.

Comments

It may be useful to include a link to the following document outlining the following specific criteria used to establish the CoRAP substances.

- Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection Criteria) - http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf [see 7].

[34] http://echa.europa.eu/documents/10162/13628/corap_2015_2017_en.pdf
[35] http://echa.europa.eu/documents/10162/13607/pro_0022_01_substance_eva_establishing_updates_of_corap_en.pdf

The draft CoRAP list available on this page has been superseded by the actual CoRAP list for 2015-2017[36]. This is potentially confusing. It may be better to consider putting either a link to the Annual Draft CoRAP webpage [11] itself or the actual CoRAP list document for 2015-2017.

[11] - (Annual) Draft CoRAP

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/draft-corap

Content

The webpage contains a clear, short description on the process used by ECHA for updating the draft CoRAP on an annual basis and producing the final CoRAP update. The text explains that the aim of publishing the update is to inform stakeholders of the progress made in substance evaluation and to help the involved registrants to communicate with the relevant evaluating Member State.

Links are given from the webpage to the following.

- About substance evaluation [8].
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [link not active].
- About the Community Rolling Action Plan [10].
- CoRAP list of substances [3].

Documents

The following documents can be accessed from the webpage.

- CoRAP update for years 2015-2017. This is considered in relation to [10] - Community Rolling Action Plan.
- Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP). This is considered in relation to [10] - Community Rolling Action Plan.

Comments

The link to the legal reference for the REACH Regulation is not active.

[12] - Transitional measures: complementary part to the CoRAP

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures

Content

The page explains the transitional measures for substances for which further information was requested in accordance with Article 16(1) of Directive 67/548/EEC (for Notified New Substances (NONS)) or Articles 10(2) or 12(2) of certain Commission Regulations adopted in application of Regulation (EEC) No 793/93 (for existing substances), and how this information is considered in substance evaluation.

Links to the following are given from the webpage.

- About substance evaluation [8].
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [link not active].

[36] http://echa.europa.eu/documents/10162/13628/corap_list_2015-2017_en.pdf

- About the Community Rolling Action Plan [10].
- Outstanding information requests for existing substances [20].
- Outstanding information requests for notified substances [21].

Documents

No relevant documents are available on the webpage.

Comments

The link to the legal reference for the REACH Regulation is not active.

[13] – Opinions of the Member State Committee on ECHA's draft CoRAP

http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee/opinions-on-draft-corap

Content

The webpage provides access to the Member State Committee Opinions on the draft CoRAP compiled by ECHA.

The webpage also provides links to the following.

- About substance evaluation [8].
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [link not active].
- About the Community Rolling Action Plan [10].
- ECHA's pages on Substance Evaluation [8 – duplicate].

Documents

The following MSC Opinions and Annexes (date of adoption) and documents can be downloaded from the page.

- 4 February 2015 (Opinion[37] and Annex[38]).
- 5 February 2014 (Opinion[39] and Annex[40]).
- 13 June 2013 (Opinion[41] and Annex[42]).
- 6 February 2013 (Opinion[43] and Annex[44]).
- 9 February 2012 (Opinion[45] and Annex[46]).
- Working procedures for the MSC in providing the opinion on the draft Community Rolling Action Plan. This document is reviewed under [18] – Member State Committee.

[37] http://echa.europa.eu/documents/10162/13578/final_msc_opinion_on_corap_2015-2017_en.pdf
[38] http://echa.europa.eu/documents/10162/13578/final_annex_to_msc_opinion_on_corap_2015-2017_en.pdf
[39] http://echa.europa.eu/documents/10162/13578/final_msc_opinion_on_corap_2014_public_en.pdf
[40] http://echa.europa.eu/documents/10162/13578/final_annex_to_msc_opinion_on_corap_2014_public_en.pdf
[41] http://echa.europa.eu/documents/10162/13578/msc_opinion_article45_addition_benpat_adopted_201306_en.pdf
[42] http://echa.europa.eu/documents/10162/13578/annex_msc_opinion_article45-5_notification_201306_en.pdf
[43] http://echa.europa.eu/documents/10162/13578/final_msc_opinion_on_corap_2013_public_en.pdf
[44] http://echa.europa.eu/documents/10162/13578/final_annex_to_msc_opinion_on_corap_2013_public_en.pdf
[45] http://echa.europa.eu/documents/10162/13578/final_msc_opinion_on_corap_2012_public_en.pdf
[46] http://echa.europa.eu/documents/10162/13578/final_annex_to_msc_opinion_on_corap_2012_public_en.pdf

The Opinion Documents outline the background to, and process used for adoption of the Opinion on the draft CoRAP, along with the Opinion on draft CoRAP. The Annexes to the Opinions provide a tabular summary of the opinion reached for each substance on the draft CoRAP.

Comments

The link to the legal reference for the REACH Regulation is not active.

The link to 'ECHA's pages on Substance Evaluation' is a duplicate of the link to 'About substance evaluation' [8].

Each of the Opinion documents contains a link to the background document: Selection Criteria to Prioritise Substances for Substance Evaluation which is reviewed under [7] – Community rolling action plan. However the link given in the document is not working. The correct link should be http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf.

[14] - What happens after substance evaluation?

http://echa.europa.eu/what-happens-after-substance-evaluation

Content

The webpage provides a short summary of the possible follow-up actions that may be undertaken by the evaluating Member State once the substance evaluation is completed, in particular outlining the options that Member States may take in order to address any identified concern (proposal for harmonised classification and labelling, proposal to identify the substance as a SVHC, proposal for a restriction or actions outside of the scope of REACH).

The webpage provides links to the following.

- Substance Evaluation [8].
- Community Rolling Action Plan [10].
- Member State Committee [16].
- CoRAP [10 - duplicate].

Documents

The following documents can be downloaded from the webpage.

- Workshop on Substance Evaluation (May 2011): Proceedings.
- Selection Criteria to prioritise substances for Substance Evaluation. This is reviewed in relation to [7] – Community rolling action plan.

The document "Summary Proceedings of the Workshop on Substance Evaluation, 23-24 May, ECHA-11-R-005-EN, 11th July 2011"[47] addresses many areas of Substance Evaluation in general terms.

Comments

Although the link to the 'CoRAP' is a duplicate of the link to the 'Community Rolling Action Plan' – [10] – the two links appear on different parts of the page (one in the main menu tree running down the left hand side of the page and one in the 'See also' box on the right hand side of the page). Therefore it is probably appropriate to have links to the same page in both places in this instance.

47 http://echa.europa.eu/documents/10162/13628/ws_on_substance_evaluation_may_2011_summary_proceedings_en.pdf

[15] – Evaluation process

http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

Content

The webpage contains a simple flow-chart giving an overview of the various evaluation processes (dossier evaluation and substance evaluation). A more detailed flow-chart of the processes can be downloaded from the page.

The webpage provides links to the following webpages.

- Evaluation actors [16].
- Evaluation steps [15].

Documents

The following document can be accessed from the page.

- Evaluation process detailed graph.

This is a diagram/flow chart outlining all the evaluation processes (Dossier and Substance Evaluation) that are carried out under the REACH Regulation. It outlines each step in the process and the bodies (e.g. ECHA, Member States, Registrants and European Commission) responsible for each stage.

Comments

None.

[16] – Evaluation actors

http://echa.europa.eu/regulations/reach/evaluation/actors

Content

The webpage outlines the main actors in the evaluation process (both dossier and substance evaluation) and provides a brief explanation of their roles (or where they can contribute) during the evaluation process. The following actors are considered.

- Registrants.
- Third parties.
- ECHA.
  - Secretariat.
  - Member State Committee.
- Member States.
- European Commission.

The webpage provides links to the following webpages.

- Evaluation process [13].
- Evaluation steps [15].
- Evaluation Directorate and Units [19].

- Committees Secretarial Unit [20].
- Member States Committee [16].

Documents

No relevant documents are available from this webpage.

Comments

The entry (and the box for related links on the right hand side of the page) for registrants mainly covers the responsibilities of the registrants in registering their substance. It may help clarity if a sentence is added indicating that the registrants may also have a role during substance evaluation (e.g. commenting on draft opinions, and possibly interaction with the evaluating Member State).

[17] – (Evaluation) Steps

http://echa.europa.eu/regulations/reach/evaluation/steps

Content

The webpage outlines the various steps in dossier and substance evaluation covering the following.

- Dossier preparation and submission.
- Registration.
- Dossier selection and evaluation.
- Substance evaluation.
- Results of evaluation (compliance checks and testing proposals).
- Draft decision requesting further information.
- Evaluation of comments/new information.
- No proposals for amendment of draft decision from Member States.
- Proposals for amendment of draft decision from Member States.
- Registrant's comments on Member States' Proposals for amendment.
- Member State Committee (MSC) meeting.
- MSC does not reach unanimous agreement – European Commission decides.
- MSC reaches unanimous agreement.
- Decision requesting further information.
- Follow-up to evaluation.

Each step is linked to the overall flow-chart for the evaluation process (which can be downloaded from the 'Evaluation Process' [15] page). The main actors (and their responsibilities) involved in each step are identified, along with the purpose and timeline for the step.

The webpage provides links to the following webpages.

- Evaluation process [13].
- Evaluation actors [16].

Documents

None.

Comments

The steps are intended to cover all the evaluation processes in REACH, including dossier evaluation and substance evaluation. Although in principle the steps are similar across all evaluation processes, some of the descriptions provided under some headings appear to be more specific to dossier evaluation rather than substance evaluation. This could potentially lead to some confusion for registrants/others looking for information on the substance evaluation process. For example, the steps "Results of Evaluation" and "Draft decision requesting further information" contain paragraphs/sections on compliance checks and testing proposals, but not substance evaluation.

The steps related to comments generally are more relevant to dossier evaluation/compliance checks than substance evaluation (for example reference is made to updating dossiers/dossier compliance which may not be relevant to a decision from substance evaluation).

The step on follow-up is again written mainly from the point of view of dossier evaluation: for example, the second paragraph indicates that the new information may be used for other processes such as substance evaluation; the third paragraph indicates that the new information may serve as the basis for identification as a candidate for the CoRAP; and the last sentence indicates how ECHA decides when dossier evaluation is complete). In order to make the steps clearer and more relevant to substance evaluation it could be considered to provide, where necessary, separate sub-headings for dossier evaluation and substance evaluation under each step as appropriate.

[18] – Member State Committee

http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee

Content

The webpage provides background information on the Member State Committee and information on the role of the committee in dossier evaluation, substance evaluation, authorisation and ECHA's Executive Director's requests. Meeting dates are also given.

Links to the following webpages are given.

- MSC opinions on draft CoRAP – Process [8].
- MSC opinions on draft CoRAP – CoRAP [10].
- Meetings (agendas and minutes) [21].
- List of MSC members with their CVs and Declarations of interest [22].

Documents

The following information/documents can be accessed from the webpage. The documents on this webpage are mainly factual/procedural documents and a brief summary of what is included in each document is given below.

- Closed and open sessions of the MSC plenary meetings[48]. This document outlines the main principles used by the ECHA secretariat when concluding on the need for closed sessions of the Member State Committee.

[48] http://echa.europa.eu/documents/10162/13578/Closed_and_open_sessions_of_msc_plenary_meetings.pdf

- Rules of procedure of the MSC[49]. This outlines the formal rules of procedure for the MSC as stated in the REACH Regulation.
- General principles and guidance for ECHA's Committees Members[50]. This provides principles and guidance for Members of ECHA's Committees in order to ensure their independent and impartial activity in the public interest.
- MSC General approach for admission of Accredited Stakeholder Organisation (ASO) observers[51]. Outlines the basic principles for admission of Accredited Stakeholder Organisations as observers to the work of the Member State Committee.
- List of the agreed MSC ASO observers[52]. This is a Table of ASO observers and their interests in ECHA's activities.
- Code of conduct for stakeholder observers at ECHA meetings[53]. This outlines the Code of Conduct expected of observers for stakeholders at ECHA meetings.
- ASO Workshop: Cooperating with ECHA through the Committees[54]. This is a background document which outlines the process by which Accredited Stakeholder Organisations can participate in the various ECHA Committees, including the Member State Committee.
- Code of conduct for case owners of evaluation draft decisions as observers at meetings of the MSC[55]. This outlines the code of conduct expected of case owners of draft decisions when attending meetings of the Member State Committee as observers. A case owner is defined as a concerned registrant or a representative of a group of concerned registrants in the case of joint submissions.
- MSC Working Procedure for processing of Substance Evaluation draft decisions[56]. This outlines the process used by the MSC in dealing with draft decisions from Substance Evaluation. It includes a description of the process and task involved. It also outlines how case owners' and stakeholders' participation in the process is organised and taken into account when draft decisions are being discussed.
- MSC Working procedures in providing opinion on draft CoRAP[57]. This outlines the workflow, tasks, possible procedures and communication when providing an opinion on the draft CoRAP.

Comments

None.

[19] –Evaluation Directorate and Units

http://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-e

Content

Brief details are given of the role and tasks of ECHA Directorate E – Evaluation.

A link is given to the following webpage.

- Member States Committee [18].

[49] http://echa.europa.eu/documents/10162/13578/msc_procedure_rules_en.pdf
[50] http://echa.europa.eu/documents/10162/13559/ed_decision_08_2013_en.pdf
[51] http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf
[52] http://echa.europa.eu/documents/10162/13578/list_aso_msc_observers_en.pdf
[53] http://echa.europa.eu/documents/10162/13559/conduct_code_stakeholder_observers_en.pdf
[54] http://echa.europa.eu/documents/10162/13587/aso_workshop_2012_bd_en.pdf
[55] http://echa.europa.eu/documents/10162/13578/code_of_conduct_msc_case_owners_en.pdf
[56] http://echa.europa.eu/documents/10162/13578/msc_working_procedure_for_processing_sev_draft_decisions_en.pdf
[57] http://echa.europa.eu/documents/10162/13578/wp_msc_community_act_plan_en.pdf

Documents

None.

Comments

None.

[20] – Committees Secretarial Unit

http://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-b

Content

Brief details are given of the role and tasks of ECHA Directorate B – Regulatory Affairs, including Unit B1: Committees Secretariat.

A link is given to the following webpage.

- Member States Committee [18].

Documents

None.

Comments

None.

[21] – Meetings of the Member State Committee

http://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee

Content

The webpage allows access to the Agenda and Minutes from all meetings of the Member State Committee.

Documents

The following documents can be downloaded from the page.

- Agendas of MSC meetings.
- Minutes of MSC meetings.

As is obvious from the titles, these documents contain the agendas and minutes of each MSC meeting.

Comments

None.

[22] – Members of the Member State Committee

http://echa.europa.eu/about-us/who-we-are/member-state-committee/members-of-the-member-state-committee

Content

The webpage lists the members of the Member State Committee, along with their CV and annual declaration of interests.

Documents

The following documents can be downloaded from the webpage.

- CVs of members.
- Annual declarations of interests of members.

The content of these documents is self-explanatory.

Comments

None.

[23] - Outstanding information requests from existing substances

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances

Content

Background information (legal) is given on the outstanding information requests for existing substances.

Links are provided from the webpage to the following pages.

- About substance evaluation [8].
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [link not active].
- About the Community Rolling Action Plan [10].
- Transitional measures: complementary part to the CoRAP [12].
- Consult the list of existing substances subject to transitional measures [25].
- ESIS database [external link – not working].

Documents

A link is provided to the following document.

- List of nominated MSCAs for Commission Regulation 465/2008[58].

This document gives the Substance Name, EINECs No., CAS No. and contact details for the Rapporteur Member State Competent Authority and the contact point for the Evaluation for existing substances with outstanding information requests resulting from Commission Regulation (EC) No 465/2008[59].

Comments

The link to the legal reference for the REACH Regulation is not active.

The link to the ESIS database should be removed as this database no longer exists (information formerly included is now available through the ECHA website).

[58] http://echa.europa.eu/documents/10162/13630/msca_subst_eval_en.pdf

[59] Commission Regulation (EC) No. 465/2008 imposing, pursuant to Council Regulation (EEC) No. 793/93, testing and information requirements on importers and manufacturers of certain substances that may be persistent, bioaccumulative and toxic and are listed in the European Inventory of Existing Commercial Chemical Substances. Official Journal of the European Union, L39, 29th May 2008, p8-9.

[24] – Outstanding information requests for notified substances

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-notified-substances

Content

Background information (legal) is given on the outstanding information requests for notified substances.

Links are given to the following webpages.

- About substance evaluation [8].
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [link not active].
- About the Community Rolling Action Plan [10].
- Transitional measures: complementary part to the CoRAP [12].
- Consult the list of notified substances subject to transitional measures [26].

Documents

None.

Comments

The link to the legal reference for the REACH Regulation is not active.

[25] – List of existing substances subject to transitional measures

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-existing-substances

Content

For each substance subject to transitional measures the page provides details of the rapporteur country, the relevant Commission Regulation which requested the information and the status. Links are also given to the conclusion documents.

Documents

The following documents can be downloaded for each substance (where relevant and available).

- Conclusion document.
- PBT report.
- Addendum to Risk Assessment.

In order to consider the contents of these documents for the current project, two examples of each type of document were randomly selected from those available, and the contents briefly reviewed. The type of document available depends on the nature of the initial concern that lead to the transitional measure (for example a PBT report is given for those substances for which the concern was over their PBT properties, whereas a Conclusion document, sometimes supported with an Addendum to the Risk Assessment where appropriate, is given where the concern was over other aspects of the risk assessment for the substance).

For the Conclusion Documents, the following two documents were considered.

> "Conclusion of Substance Evaluation for Transitional Dossiers: Substance concerned: 1) Dioctyltin dichloride. 2) Dioctyltin bis(2-ethylhexyl mercaptoacetate), 3. Octyltin tris(2-ethylhexyl mercaptoacetate). Date of Submission 07/08/2011"[60].

> "Conclusion of Substance Evaluation for Transitional Dossiers: Substance concerned: 5-Nonylsalicylaldehyde oxime. Date of Submission 04/09/2012"[61].

The documents give a summary of the conclusions reached for each substance, or group of substances, subject to the transitional measures. The documents provide a justification for the conclusion reached, a short summary of the information reviewed, a list of any supporting documents and a timetable for any proposed follow-up actions if necessary.

For the PBT reports the following two documents were considered.

> "Identification of PBT and vPvB Substances. Results of Evaluation of the PBT/vPvB Properties. Substance: 2,2',6,6'-Tetra-tert-butyl-4,4'-methylenediphenol"[62].

> "Identification of PBT and vPvB Substances. Results of Evaluation of the PBT/vPvB Properties. Substance: Bis(isopropyl)naphthalene"[63].

The documents provided a detailed evaluation of the data relevant to the PBT/vPvB properties of the substance.

For the Addendum to Risk Assessment documents, the following two documents were considered.

> "European Union Risk Assessment Report. Tertiary butyl hydroperoxide. Risk Assessment Addendum. December 2010"[64].

> "Risk Assessment Addendum for Nickel, Nickel sulphate, Nickel carbonate, Nickel dichloride, Nickel dinitrate"[65]. [This provides links to several laboratory test reports which are provided as Addenda to the Conclusion.]

These documents provide detailed background information to support the conclusions given in the Conclusion Documents. The content varies from substance to substance but can include for example, detailed evaluations of specific aspects of the risk assessment of the substance or, in some cases, test reports.

Comments

None.

[26] – List of notified substances subject to transitional measures

http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-of-notified-substances

Content

Provides a list of notified substances subject to transitional measures, including the country of notification.

Documents

None.

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[60] http://echa.europa.eu/documents/10162/72a56e4c-5f35-42ca-a61e-b5bb20a86406
[61] http://echa.europa.eu/documents/10162/8ac35c5d-12e7-4a2e-bbf0-191f52abcbcf
[62] http://echa.europa.eu/documents/10162/c69444d6-ffc8-46c0-888a-042b63f47fb2
[63] http://echa.europa.eu/documents/10162/b3644d5c-f66a-411c-9c42-0a05c5f138db
[64] http://echa.europa.eu/documents/10162/41cd59bf-4424-4047-b254-1d3434787fe3
[65] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-existing-substances/-/substance-rev/1138/term

Comments

None.

A2.4 Route B - regulations tab

Listed below is the approximate order that the webpages are encountered when looking for information starting from the “regulations tab”. The linkages between the webpages are summarised in the relevant map in the Appendix. Where webpages are encountered that have been considered under Route A, a reference is given rather than repeating the details again. Thus the sections below effectively consider the further webpages that are encountered in Route B other than those covered in Route A.

[27] – Regulations

http://echa.europa.eu/regulations

Content

The webpage provides a brief introduction to the various regulations within the compass of ECHA. A link is given to the following webpage.

- REACH – Read more [28].

Links are also given to other legislation that is outside the scope of the current review.

Documents

A link is given to appeals whereby appeals and results of appeals against decisions made under all aspects of REACH, including Substance Evaluation, can be obtained. The appeal documents provide a brief description of the legal basis of the appeal and, where available, provide a brief summary of the outcome of the appeal (see also [3] – Substance Evaluation – CoRAP).

Comments

None.

[28] – REACH

http://echa.europa.eu/web/guest/regulations/reach/

Content

The webpage provides a brief description of the various processes under REACH, including registration, evaluation, authorisation and restriction. A link is given to the following.

- Evaluation [29].

Documents

A link is given whereby appeal documents can be accessed (see Regulations [27]).

Comments

None.

[29] - Evaluation

http://echa.europa.eu/web/guest/regulations/reach/evaluation

Content

The webpage provides a brief paragraph on the three evaluation processes under REACH namely, compliance check and examination of testing proposals (both of which fall under dossier evaluation) and substance evaluation.

Links are given to the following webpages.

- Evaluation Process [15 – then as Route A].
- Evaluation Actors [16 – then as Route A].
- Evaluation Steps [17 – then as Route A].
- (Understanding) Substance Evaluation [8 – then as Route A].
- Requests for Further Information [30].
- Member States Committee [18 – then as Route A].

Documents

The following documents can be downloaded from the site.

- Evaluation Progress Reports (for 2008 to 2014).
- Evaluation Progress Reports - Facts & Figures.
- Title VI of the REACH Regulation (EC) No 1907/2006.
- Factsheet on substance evaluation. This is reviewed under [7] – Community rolling action plan.

The evaluation progress reports documents provide an update of the progress made each year in dossier evaluation (compliance checks, testing proposals) and substance evaluation. Reports are available for 2008[66], 2009[67], 2010[68], 2011[69] , 2012[70], 2013[71] and 2014[72]. The evaluation progress reports – facts & figures documents are essentially a short summary document of the progress report and are currently available for 2011[73], 2012[74] and 2013[75].

The link to Title VI of the REACH Regulation (EC) No 1907.2006 allows the legal text[76] of the REACH regulation to be downloaded.

Comments

Little practical guidance or information is actually given on this webpage but it effectively acts as a starting point whereby important information on the substance evaluation process can be accessed. The subsequent webpages include those accessible via Route A.

[30] - Requests for further information

http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information

66 http://echa.europa.eu/documents/10162/13628/progress_report_2008_en.pdf
67 http://echa.europa.eu/documents/10162/13628/progress_report_2009_en.pdf
68 http://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_report_2010_en.pdf
69 http://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf
70 http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf
71 http://echa.europa.eu/documents/10162/13628/evaluation_report_2013_en.pdf
72 http://echa.europa.eu/documents/10162/13628/evaluation_report_2014_en.pdf
73 http://echa.europa.eu/documents/10162/13628/evaluation_report_summary_en.pdf
74 http://echa.europa.eu/documents/10162/13628/evaluation_report_summary_2012_en.pdf
75 http://echa.europa.eu/documents/10162/13628/eval_report_2013_facts_figures_en.pdf
76 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2007:136:TOC

Content

The webpage contains relatively detailed background to the requests for further information that may result from an evaluation process, including substance evaluation. It covers draft decisions and final ECHA decisions, outlining the roles of ECHA, evaluating Member States and the Member State Committee in the process of agreeing the decision. The text also outlines the role of registrants in providing comments on the draft decision within a 30-day timeframe and how registrants can appeal against decisions. The follow-up actions that will be taken by evaluating Member States once the further information is received after substance evaluation are also described.

The webpage links to the following pages.

- Substance Evaluation [8 – then as Route A].
- Committees Secretarial Unit [20 – then as Route A].
- Member States Committee [18 – then as Route A].

Documents

None.

Comments

The information on this webpage is potentially useful for clarifying the process by which requests for further information (decisions) are produced as a result of substance evaluation. This webpage is not easily accessible via Route A, and it might be useful to consider linking this webpage to a relevant part of Route A (for example [8] – (Understanding the) Substance Evaluation).

A2.5 Route C - addressing chemicals of concern tab

Listed below is the approximate order that the webpages are encountered when looking for information starting from the “addressing chemicals of concern tab”. The linkages between the webpages are summarised in the relevant map in the Appendix. Where webpages are encountered that have been considered under Route A, a reference is given rather than repeating the details again. Thus the sections below effectively consider the further webpages that are encountered in Route C other than those covered in Route A.

[31] - Addressing chemicals of concern

http://echa.europa.eu/addressing-chemicals-of-concern

Content

The webpage provides an introduction to ECHA’s work on substances of concern. A small section is provided on substances of potential concern indicating, in very general terms, that substances with certain hazardous properties may be of concern for human health and/or the environment and that such substances may be identified and subsequently regulated to ensure that the risks are properly controlled.

Links to the following webpages.

Search for chemicals [2 – then as Route A].

Substances of potential concern [32].

Documents

None.

Comments

It is not entirely clear on this webpage which is the best way forwards to find information on substance evaluation. The relevant information can be found by following through the link to substances of potential concern and it may be clearer to consider expanding the text here to incorporate a few key words such as substance evaluation or CoRAP in order to signpost the way forwards a little more clearly. This is already done to some extent in the section on “Registry of Intentions” where certain key words (e.g. SVHCs, Restrictions, CLP, CLH) are indicated.

A search for chemicals can also be carried out from this page. This leads to the same webpages as for Route A.

[32] - Substances of potential concern

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

Content

A single sentence saying essentially the same as on the previous webpage: addressing chemicals of concern [31].

Links to the following webpages are given.

- Screening [33].
- PACT [34].
- SVHC Roadmap to 2020 implementation [35].

Documents

None.

Comments

Similar to the previous webpage on addressing chemicals of concern [31], it might be beneficial to provide links here to the relevant pages on the CoRAP and/or Substance Evaluation (e.g. a link to the webpage (Understanding) Substance Evaluation – CoRAP [8]). This will then provide a way into the webpages outlined in Route A (as can be done from the following webpage – screening [33]).

[33] – Screening

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

Content

This webpage provides some basic information on the common screening approach used by ECHA to screen REACH registration dossiers and other databases in order to identify potential candidate substances for a number of processes under REACH and CLP, including for the Community Rolling Action Plan (CoRAP). The process is linked to the SVHC Roadmap to 2020. No specific details of the process are given on the webpage but links to a number of relevant documents (see below) and other webpages are given, including the following.

- (Understanding) Substance Evaluation – CoRAP [8 – then as Route A].
- PACT [34].
- SVHC Roadmap to 2020 implementation [35].

Documents

The following documents can be downloaded from the webpage.

- A Common Screening Approach for REACH and CLP Processes.
- Screening definition document.
- SVHC Roadmap implementation plan.

The document titled "A Common Screening Approach for REACH and CLP Processes, March 2015"[77], outlines the systematic screening approach developed by ECHA. The approach is used to screen the available information in both REACH registration dossiers and other databases in order to identify candidate substances for the following processes under REACH and CLP.

- Compliance check under dossier evaluation.
- CoRAP under substance evaluation.
- Potential for further regulatory risk management measures such as harmonised classification and labelling, authorisation and restriction.

The document titled "Screening Definition Document: Logic and Strategy in Identifying Potential Substances of Concern for Substance Evaluation and Regulatory Risk Management, March 2015"[78], sets out the logic and reasoning behind the search criteria (screening scenarios) used to identify/select potential substances of concern.

The SVHC Roadmap implementation plan is outlined in the document titled "SVHC Roadmap to 2020 Implementation plan, ECHA-13-R-11-EN, 9 December 2013"[79]. The roadmap follows from a commitment to have all relevant currently known SVHC substances included in the candidate list by 2020, and the document outlines how this commitment is foreseen to be implemented. Key parts of the implementation plan include the following.

- Use of screening methods and risk management option analysis (RMOA) to identify all relevant SVHCs using information from the ECHA registration database, other REACH and CLP data bases and other relevant sources.
- Groups of substances to be covered by the implementation plan include CMRs, sensitisers, PBTs and vPvBs, endocrine disruptors and petroleum/coal stream substances with CMR or PBT/vPvB properties.
- Relevant SVHCs are to be identified by combining a series of screening (refinement) steps with RMOA.
- In some cases it may be necessary to carry out additional assessment of existing data or generation of further information. The available approaches for this may include further assessment by PBT or endocrine disruptor expert groups, information generated by dossier or substance evaluation, the harmonised classification and labelling processes and assessment of whether a substance is likely to be of an equivalent level of concern.

Comments

None.

[34] – PACT – RMOA and hazard assessment activities

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

[77] http://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf
[78] http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf
[79] http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf

Content

This webpage provides information on the Public Activities Coordination Tool (PACT). PACT provides a list of substances being considered under the SVHC Roadmap since February 2013. For these substances either a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB or endocrine disruptor properties is either under development or has been completed. At the time of this review (19th June 2015) the PACT list contained 288 substances, listed by name, EC number, CAS number and inclusion date.

Links are provide to the following webpages.

- Status and purpose of PACT [36].
- Substance evaluation – CoRAP [3 – then as Route A].
- Details for individual substances [37].

Documents

The following document can be downloaded from the webpage.

- Glossary - PACT technical details.

As the name indicates, the PACT Glossary[80] is a glossary to explain the technical terms in the PACT table.

Comments

None.

[35] – SVHC Roadmap to 2020 implementation

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

Content

The webpage provides a useful summary of the “Roadmap for SVHC and implementation of REACH Risk Management measures from now to 2020", also known as the SVHC Roadmap. The text outlines in general terms how the work under the implementation plan will be carried out, including screening to identify new substances of concern and analysing the risk management options appropriate to the particular substance. The implementation plan covers the following groups of substances. The progress made each year on the implementation plan is published in a progress report (see below).

- Carcinogens, mutagens, reprotoxicants (Categories 1A/1B).
- Sensitisers.
- PBT or vPvB substances.
- Endocrine disruptors.
- Petroleum/coal stream substances that are CMRs or PBTs.

Links are provided to the following webpages.

- Screening [33].
- PACT [34].

[80] http://echa.europa.eu/documents/10162/21743120/pact_glossary_en.pdf

Documents

The following documents can be downloaded from the webpage.

- SVHC Roadmap to 2020.
- SVHC Roadmap implementation plan. This document is reviewed under [33] – Screening.
- Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures 2013-2014.

The link to SVHC Roadmap to 2020 allows the following document to be downloaded: "Roadmap on Substances of Very High Concern. Council of the European Union 5867/13, 5th February 2013"[81]. This outlines the commitment to have all currently known SVHCs included in the candidate list by 2020.

The document titled "Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures, Annual Report, 23 March 2015, ECHA-15-R-04-EN"[82], is the first progress report on the implementation of the SVHC Roadmap 2020. The report outlines the progress made with the Public Activities Coordination Tool (PACT) and the activities planned for 2015 which include the following.

- Improving the common screening approach.
- Increasing transparency and predictability of activities, with a foreseen update of the PACT to include information on substances under assessment in the various ECHA expert groups.
- Developing an approach to address petroleum/coal stream substances.
- Continuing to build capacity with Member States to increase their involvement in the screening of RMOAs.

Comments

None.

[36] - Status and purpose of PACT

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/status-and-purpose

Content

The webpage provides useful information on the purpose of the PACT, which is to give advance notice of the substances for which ECHA or Member States are considering the potential for regulatory risk management. The inclusion of a substance on the PACT does not mean that a substance has the suspected properties or that there is need for regulatory risk management actions, although such actions may apply at a later date should the substance pass to other regulatory processes under REACH and CLP, such as harmonised classification and labelling, SVHC identification/authorisation or restriction.

Provides links to the following webpages.

- Screening [33].
- PACT [34].
- SVHC Roadmap to 2020 implementation [35].

Documents

None.

[81] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT
[82] http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf

Comments

It could be considered to add a sentence to the webpage indicating that, should a Member State consider that further information is needed in order to confirm the suspected concern, then the substance could be considered as a candidate for the CoRAP and then substance evaluation.

[37] – Details (for individual substances)

The link is substance specific.

Content

For each substance the following details of the work being carried out under the SVHC Roadmap.

- Name, EC Number and CAS Number.
- The Authority carrying out the work and contact details.
- The scope of the work (i.e. the area of concern being considered).
- The activity (i.e. hazard assessment or RMOA).
- The data the substance was included.
- The data the activity was finalised.
- The outcome.
- Any follow up actions recommended.
- The RMOA conclusion document or hazard assessment outcome document if available.
- The full RMOA document if available.

The webpage provides links to the following webpages.

- Status and purpose of PACT [36].
- Substance evaluation – CoRAP [3 – then as for Route A].

Documents

The following documents can be downloaded from the webpage.

- Glossary - PACT technical details.
- RMOA conclusion document/Hazard Assessment outcome document (where available).
- Full RMOA Document (where available).

In order to review the information available, the following representative documents were selected.

"Hazard Assessment Outcome Document for 3,7,11-trimethyldodeca-1,6,10-trien-3-ol, mixed isomers, 30th March 2015"[83]. This is a summary of the conclusions from the Member States and includes a statement of the hazard subject to assessment (in this case it was in order to clarify suspected PBT/vPvB properties), the outcome of the hazard assessment (using a tick box; in this case it was concluded that the substance does not have PBT/vPvB properties) and a summary of the basis/data used to reach the conclusion.

"Risk Management Option Analysis Conclusion Document for reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE), 29th August 2014"[84]. This document outlines the conclusions from the RMOA and includes an overview of

[83] http://echa.europa.eu/documents/10162/f7ef27e9-6313-4fb2-ab08-20606b87324c
[84] http://echa.europa.eu/documents/10162/95a89428-1dbc-4a20-97e5-c4b004977d3d

other regulatory processes/EU legislation, the conclusions of the RMOA (tick box), any follow-up regulatory risk management action needed at EU level (if appropriate) or whether no-follow-up is foreseen at EU level (if appropriate) and a tentative plan for any follow-up actions if necessary.

"Analysis of the most appropriate risk management option (RMOA), 1,3-propanesultone, 2n Feb 2015"[85]. This document contains the details of the risk management option analysis, including the justification for any proposed risk management measures.

Comments

None.

A2.6 Route D – support tab

Listed below is the approximate order that the webpages are encountered when looking for information starting from the "Support tab". The linkages between the webpages are summarised in the relevant map in the Appendix. Where webpages are encountered that have been considered under Route A, a reference is given rather than repeating the details again. Thus the sections below effectively considers the further webpages that are encountered in Route D in addition to those covered in Routes A and B.

[38] - Support

http://echa.europa.eu/support

Content

The support page provides a starting point for finding support on all aspects of REACH, CLP and the Biocidal Products Regulation.

Links to the following webpages are relevant for substance evaluation.

- Guidance Documents [39].
- Publications [40].
- Document library [41].
- Helpdesks [42].
- Q&As Support [43].
- Webinars [44].

Documents

None.

Comments

None.

[39] - Guidance

http://echa.europa.eu/support/guidance

[85] http://echa.europa.eu/documents/10162/3c6c3bce-c9d9-4b8a-8858-deeded78bfa7

Content

The webpage provides a brief summary of the various types of guidance provided by ECHA, including guidance documents, guidance factsheets, other factsheets, practical guides, guidance in a nutshell, consultation procedure table, a tool to identify your obligations, and formats.

Links to read more on the following are relevant for substance evaluation.

- Guidance Documents [45].
- Other Factsheets [46].
- Formats [47].

Documents

None.

Comments

None.

[40] - Publications

http://echa.europa.eu/web/guest/publications

Content

The publications webpage provides a brief summary of the various types of publications produced by ECHA, including guidance, practical examples, corporate publications, factsheets, questions and answers, manuals, and report.

Links to the following webpages are relevant to substance evaluation.

- Guidance Documents [45].
- Questions and Answers [43].
- Leaflets [48].
- Factsheets [46].

Documents

None.

Comments

None.

[41] - Document library

http://echa.europa.eu/web/guest/support/documents-library

Content

Provides a link to the publications webpage/catalogue from which keyword searches for specific documents can be carried out.

Documents

The documents located depend on the key words used in the search. An example of the search results is given below using “substance evaluation” as the key phrase and searching for factsheets and leaflets under the “type” field.

- Factsheet - Substance Evaluation.
- Leaflet - Substance evaluation under REACH.
- General report 2013 - facts and figures.
- Work Programme – Highlights for 2015.
- Leaflet - The Board of Appeal of the European Chemicals Agency: An independent review of ECHA decisions.
- Work Programme 2014 - facts and figures.
- Fact sheet - Guidance for identification and naming of substances under REACH and CLP.
- Fact Sheet - Substance Identification.

Comments

None.

[42] - Helpdesks

http://echa.europa.eu/web/guest/support/helpdesks/

Content

The webpage provides useful information on the national helpdesks and the ECHA helpdesk, including contact details of national helpdesks and a contact form for the ECHA helpdesk.

Provides links to the following webpages.

- Guidance [39].
- Q&As Support [43].
- Webinars [44].
- Publications [40].
- Public (ECHA) Procedures [49].

Documents

None.

Comments

None.

[43] - Q&As Support

http://echa.europa.eu/support/qas-support/qas

Content

The webpage allows keyword search of the common questions and answers on REACH in general. A search for “substance evaluation” gave 16 questions and answers (search carried out on 24th August). These are listed below.

- Do I have any data sharing obligation after the submission of my registration dossier?
- When a substance is included in the CoRAP, are there any mechanisms by which a registrant can challenge the inclusion or provide input into the evaluation process?
- How to use data submitted at least 12 years previously for my registration?
- What is substance evaluation?
- What is the difference between dossier evaluation and substance evaluation under REACH?
- What is the added value of substance evaluation?
- What is the difference between substance evaluation under REACH and evaluation under the Existing Substance Regulation ((EEC) No 793/93)?
- Why is a substance on the CoRAP list? Which criteria have been used?
- Are the criteria for selection fixed?
- Is the CoRAP a new "black list" of chemicals?
- What is the impact of substance evaluation on my business?
- Is there any interaction between the evaluating Member State and the registrants/stakeholders?
- What is the outcome of substance evaluation?
- What is the follow up of substance evaluation?
- Are substances in the (draft) CoRAP going to be included in the authorisation/restriction processes?
- Where can I get more information on the CoRAP substances?

The webpage also gives links to questions and answers under specific topics. One of the headings is “evaluation” however this did not lead to anything specifically relevant to substance evaluation (the questions relate to follow up to dossier evaluation decisions and targeted compliance checks).

It also provides links to the following webpages.

- Guidance [39].
- Webinars [44].
- Helpdesks [42].
- Publications [40].

Documents

None (other than the questions and answers).

Comments

It would be helpful if the relevant questions and answers for substance evaluation also appeared under the evaluation heading/link (or a separate substance evaluation heading) on the webpage. The relevant questions already appear on [9] - Q&A on CoRAP and Substance Evaluation.

[44] - Webinars

http://echa.europa.eu/web/guest/support/training-material/webinars

Content

The webpage lists the past webinars that are available to view, and provides access to the following relevant webinar.

- What should every registrant know about substance evaluation? Held on 5th October 2012.

The webpage also provides links to the following webpages.

- Guidance [39].
- Q&As [43].
- Helpdesk [42].
- Publications [40].

Documents

The agenda for the above webinar can be downloaded from the website[86].

Comments

None.

[45] - Guidance documents/guidance on REACH

http://echa.europa.eu/guidance-documents/guidance-on-reach

Content

This webpage lists the various guidance documents available. There is no actual guidance document under the “Guidance on Dossier and Substance Evaluation” heading on the webpage but rather a sentence is given indicating that the guidance document is now obsolete (and provides links to the relevant parts of the website – see below).

Provides links to the following webpages.

- Guidance [39].
- Formats [47].
- Q&As Support [43].
- Webinars [44].
- Helpdesks [42].
- Publications [40].
- Links to the following under both ‘Guidance on Priority Setting for Evaluation’ and ‘Guidance on Dossier and Substance Evaluation’:
  - Substance Evaluation [29 – then as Route B].
  - Public (ECHA) Procedures [49].

[86] http://echa.europa.eu/documents/10162/13628/substance_evaluation_webinar_agenda_en.pdf

Documents

None.

Comments

None.

[46] - Other factsheets

http://echa.europa.eu/web/guest/publications/fact-sheets

Content

The webpage provides access to the various factsheets produced by ECHA. There is a factsheet on substance evaluation (see below).

Provides a link to the following webpage.

- Publications [40].

Documents

The following factsheet can be downloaded from the webpage.

- Factsheet – Substance Evaluation. This is reviewed under [7] – Community rolling action plan.

Comments

None.

[47] - Formats

http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities

Content

The webpage provides access to the various formats issued by ECHA. Formats are given for both industry and authorities. For authorities it is noted that the format for substance evaluation has now been replaced by the ECHA integrated quality management system (IQMS) which describes the procedure for substance evaluation (see below).

Links are given to the following webpages.

- Guidance [39].
- Guidance Documents [45].
- Q&As Support [43].
- Webinars [44].
- Helpdesks [42].
- Publications [40].

Documents

The following document, aimed at the regulatory authorities, can be downloaded from the website.

- ECHA integrated quality management system (IQMS) document describing the procedure for substance evaluation. This is the document entitled “The Substance Evaluation Procedure, PRO-0023.02, 20/10/2014” reviewed under [8] – (Understanding the) Substance Evaluation.

Comments

None.

[48] - Leaflets

http://echa.europa.eu/web/guest/publications/leaflets

Content

The webpage provides access to the various leaflets produced by ECHA, including a leaflet on substance evaluation (see below).

Provides a link to the following webpage.

- Publications [40].

Documents

The following document can be downloaded from the website.

- Leaflet - Substance evaluation under REACH. This is reviewed under [7] – Community rolling action plan.

Comments

None.

[49] - ECHA procedures

http://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures

Content

The webpage provides access to the various ECHA procedures, including the procedure for substance evaluation and the procedure for establishing updates of the CoRAP (see below).

Provides a link to the following webpage.

- Publications [40].

Documents

The following procedure documents can be downloaded from the website.

- Substance Evaluation. This is the document entitled “The Substance Evaluation Procedure, PRO-0023.02, 20/10/2014” reviewed under [8] – (Understanding the) Substance Evaluation.
- Substance Evaluation – Establishing updates of the Community Rolling Action Plan (CoRAP). This is the document entitled “Procedure: Substance Evaluation – Establishing updates of the Community Rolling Action Plan (CoRAP), PRO-0022.03, 01/12/14” reviewed under [10] - Community Rolling Action Plan.

Comments

None

A2.7 Main routes of entry maps

Map A – chemical name

[1] EChA homepage
http://echa.europa.eu/web/guest
- Search for Chemicals via box on page

[1a] Information on Chemicals
http://echa.europa.eu/information-on-chemicals
- Search for Chemicals

[2] Search Results
- CoRAP webpage

[1b] Information on Chemicals
http://echa.europa.eu/information-on-chemicals
- CoRAP webpage

[3] Substance Evaluation – CoRAP
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
- Decision/detail
- Notes on substance evaluation table
- Any appeal documents (opens from link)
- Further information links on
  - Understand the Community Rolling Action Plan
  - Community Rolling Action Plan (CoRAP) lists
  - Understand the Substance Evaluation
  - Q&A on CoRAP and Substance Evaluation

[4] Decision/detail
Opens the substance evaluation table which provides links to the following documents where available:
- Justification documents
- Decision documents
- Appeal documents
- Evaluation documents
- Conclusion documents

[5] Notes on Substance evaluation table
- opens explanatory notes window

[6] Community Rolling Action Plan (CoRAP) lists
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
- Community Rolling Action Plan (CoRAP) List of Substances [3]
- (About) Substance Evaluation [8]
- (About) The Community Rolling Action Plan [10]
- Provides links to download the following documents
  - Download CoRAP 2012-2014
  - Download CoRAP 2013-2015
  - Additional inclusion to CoRAP list 2013
  - Download CoRAP 2014-2016
  - Download CoRAP 2015-2017

[7] (Understanding the) Community Rolling Action plan
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan
- Community Rolling Action Plan (CoRAP) lists [6]
- (About) Substance Evaluation [8]
- (About) The Community Rolling Action Plan
- Opinions of the Member State Committee on ECHA's draft CoRAP
- Draft CoRAP
- Transitional measures: complementary part to the CoRAP
- Community Rolling Action Plan Questions and Answers [9]
- The following documents:
  - Selection criteria to prioritise substances for Substance Evaluation
  - CoRAP Fact Sheet
  - Leaflet - Substance evaluation under REACH

[8] Understanding the Substance Evaluation
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
- What happens after Substance Evaluation?
- Community Rolling Action Plan [10]
- Member State Committee [18]
- The following documents:
  - Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations
  - Selection criteria to prioritise substances for Substance Evaluation
  - Procedure on Substance Evaluation
  - Substance Evaluation fact sheet
  - Leaflet - Substance evaluation under REACH
  - Workshop proceedings – May 2014
  - Workshop proceedings – May 2013
  - Workshop proceedings – June 2012
  - Workshop proceedings – May 2011

[9] Q&A on CoRAP and Substance Evaluation
http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/corapandsubstanceevaluation

[10] The Community Rolling Action Plan
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan
- What happens after substance evaluation? [14]
- Evaluation Process
- Evaluation Actors
- Evaluation Steps
- (Understanding the) Community Rolling Action Plan [7]
- CoRAP List of Substances [3]
- Questions and answers on Community Rolling Action Plan (CoRAP) [9]
- The Member State Committee [18]
- The following documents:
  - Procedures on Substance Evaluation
  - Draft Community Rolling Action Plan (CoRAP) List
  - Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

[11] Annual Draft of CoRAP
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/draft-corap
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- CoRAP list of substances [3]
- The following documents:
  - Download CoRAP update for years 2015-2017
  - Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

[12] Transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- Outstanding information requests for existing substances
- Outstanding information requests for notified substances

[13] MSC Opinion
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee/opinions-on-draft-corap
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- ECHA's pages on Substance Evaluation [8 – DUPLICATE]
- The following MSC Opinions and Annexes (date of adoption) and documents
  - 4 February 2015
  - 5 February 2014
  - 13 June 2013
  - 6 February 2013
  - 9 February 2012
  - Working procedures for the MSC in providing the opinion on the draft Community Rolling Action Plan

[14] What happens after substance evaluation?
http://echa.europa.eu/what-happens-after-substance-evaluation
- Substance Evaluation [8]
- Community Rolling Action Plan [10]
- Member State Committee [18]
- CoRAP [10]
- The following documents:
  - Workshop on Substance Evaluation (May 2011): Proceedings
  - Selection Criteria to prioritise substances for Substance Evaluation

[15] Evaluation Process
http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure
- Evaluation actors [16]
- Evaluation steps [17]
- Links to the following document:
  - Evaluation process detailed graph

[16] Evaluation Actors
http://echa.europa.eu/regulations/reach/evaluation/actors
- Evaluation process [15]
- Evaluation steps [17]
- Evaluation Directorate and Units
- Committees Secretarial Unit
- Member States Committee [18]

[17] Evaluation Steps
http://echa.europa.eu/regulations/reach/evaluation/steps
- Evaluation process [15]
- Evaluation actors [16]

[18] Member State Committee
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee
- MSC opinions on draft CoRAP – Process [8]
- MSC opinions on draft CoRAP – CoRAP [10]
- Meetings (agendas and minutes)
- List of MSC members with their CVs and Declarations of interest
- Provides links to the following information/documents:
  - Closed and open sessions of the MSC plenary meetings
  - Rules of procedure of the MSC
  - General principles and guidance for ECHA's Committees Members
  - MSC General approach for admission of ASO observers
  - List of the agreed MSC ASO observers
  - Code of conduct for stakeholder observers at ECHA meetings
  - ASO Workshop: Cooperating with ECHA through the Committees
  - Code of conduct for case owners of evaluation draft decisions as observers at meetings of the MSC
  - MSC Working Procedure for processing of Substance Evaluation draft decisions
  - MSC Working procedures in providing opinion on draft CoRAP

[19] Evaluation Directorate and Units
- Member States Committee [18]

[20] Committees Secretarial Unit
- Member States Committee [18]

[21] Meetings of the Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee
- The following documents:
  - Agenda's of MSC meetings
  - Minutes of MSC meetings

[22] Members of the Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee/members-of-the-member-state-committee
- The following documents:
  - CVs of MSC members
  - Annual declarations of interests of MSC meetings

[23] Outstanding information requests from existing substances
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- Transitional measures: complementary part to the CoRAP [12]
- Consult the list of existing substances subject to transitional measures
- ESIS database [EXTERNAL LINK – NOT WORKING]
- Link to the following document
  - List of nominated MSCAs for Commission Regulation 465/2008

[24] Outstanding information requests for notified substances
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-notified-substances
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- Transitional measures: complementary part to the CoRAP [12]
- Consult the list of notified substances subject to transitional measures

[25] List of existing substances subject to transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-existing-substances
- Details of the transitional measures for each substance from which the following documents can be downloaded (where available)
  - Conclusion document
  - PBT report
  - Addendum to Risk Assessment

[26] List of notified substances subject to transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-of-notified-substances

Map B – regulation

[1] EChA homepage
http://echa.europa.eu/web/guest
- Regulations Tab

[27] Regulations
http://echa.europa.eu/regulations
- REACH – Read more

[28] REACH
http://echa.europa.eu/web/guest/regulations/reach/
- Evaluation

[29] Evaluation
http://echa.europa.eu/web/guest/regulations/reach/evaluation
- Evaluation Process
- Evaluation Actors
- Evaluation Steps
- Substance Evaluation
- Requests for Further Information
- Member States Committee
- Links to the following reports:
  - Evaluation Progress Reports (for 2008 to 2014)
  - Evaluation Progress Reports - Facts & Figures
  - Title VI of the REACH Regulation (EC) No 1907/2006
  - Fact sheet on substance evaluation

[15] Evaluation Process
http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure
- Evaluation actors [16]
- Evaluation steps [17]
- Links to the following document:
  - Evaluation process detailed graph

[16] Evaluation Actors
http://echa.europa.eu/regulations/reach/evaluation/actors
- Evaluation process [15]
- Evaluation steps [17]
- Evaluation Directorate and Units
- Committees Secretarial Unit
- Member States Committee [18]

[19] Evaluation Directorate and Units
http://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-e
- Member States Committee [18]

[20] Committees Secretarial Unit
http://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-b
- Member States Committee [18]

[17] Evaluation Steps
http://echa.europa.eu/regulations/reach/evaluation/steps
- Evaluation process [15]
- Evaluation actors [16]

[8] Understanding the Substance Evaluation
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
- What happens after Substance Evaluation?
- Community Rolling Action Plan
- Member State Committee [18]
- The following documents:
  - Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations
  - Selection criteria to prioritise substances for Substance Evaluation
  - Procedure on Substance Evaluation
  - Substance Evaluation fact sheet
  - Leaflet - Substance evaluation under REACH
  - Workshop proceedings – May 2014
  - Workshop proceedings – May 2013
  - Workshop proceedings – June 2012
  - Workshop proceedings – May 2011

[30] Requests for Further Information
http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information
- Substance Evaluation [8]
- Committees Secretarial Unit [20]
- Member States Committee [18]

[18] Member State Committee
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee
- MSC opinions on draft CoRAP – Process [8]
- MSC opinions on draft CoRAP – CoRAP [10]
- Meetings (agendas and minutes)
- List of MSC members with their CVs and Declarations of interest
- Provides links to the following information/documents:
  - Closed and open sessions of the MSC plenary meetings
  - Rules of procedure of the MSC
  - General principles and guidance for ECHA's Committees Members
  - MSC General approach for admission of ASO observers
  - List of the agreed MSC ASO observers
  - Code of conduct for stakeholder observers at ECHA

[14] What happens after substance evaluation?
http://echa.europa.eu/what-happens-after-substance-evaluation
- Substance Evaluation [8]
- Community Rolling Action Plan [10]
- Member State Committee [18]
- CoRAP [10]
- The following documents:
  - Workshop on Substance Evaluation (May 2011): Proceedings
  - Selection Criteria to prioritise substances for Substance Evaluation

[10] The Community Rolling Action Plan (http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan)
- What happens after substance evaluation? [14]
- Evaluation Process [15]
- Evaluation Actors [16]
- Evaluation Steps [17]
- (Understanding the) Community Rolling Action Plan
- CoRAP List of Substances
- Questions and answers on Community Rolling Action Plan (CoRAP)
- The Member State Committee [18]
- The following documents:
  - Procedures on Substance Evaluation
  - Draft Community Rolling Action Plan (CoRAP) List
  - Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

[21] Meetings of the Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee
- The following documents:
  - Agenda's of MSC meetings
  - Minutes of MSC meetings

[22] Members of the Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee/members-of-the-member-state-committee
- The following documents:
  - CVs of MSC members
  - Annual declarations of interests of MSC meetings

[7] (Understanding the) Community Rolling Action plan
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan
- Community Rolling Action Plan (CoRAP) lists
- (About) Substance Evaluation [8]
- (About) The Community Rolling Action Plan [10]
- Opinions of the Member State Committee on ECHA's draft CoRAP
- Draft CoRAP
- Transitional measures: complementary part to the CoRAP
- Community Rolling Action Plan Questions and Answers [9]
- The following documents:
  - Selection criteria to prioritise substances for Substance Evaluation
  - CoRAP Fact Sheet
  - Leaflet - Substance evaluation under REACH

[3] Substance Evaluation – CoRAP (http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table)
- Decision/detail
- Notes on substance evaluation table
- Any appeal documents (opens from link)
- Further information links on
  - Understand the Community Rolling Action Plan [7]
  - Community Rolling Action Plan (CoRAP) lists [6]
  - Understand the Substance Evaluation [8]
  - Q&A on CoRAP and Substance Evaluation [9]

[9] Q&A on CoRAP and Substance Evaluation
http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/corapandsubstanceevaluation

[6] Community Rolling Action Plan (CoRAP) lists
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
- Community Rolling Action Plan (CoRAP) List of Substances [3]
- (About) Substance Evaluation [8]
- (About) The Community Rolling Action Plan [10]
- Provides links to download the following documents
  - Download CoRAP 2012-2014
  - Download CoRAP 2013-2015
  - Additional inclusion to CoRAP list 2013
  - Download CoRAP 2014-2016
  - Download CoRAP 2015-2017

[13] MSC Opinion
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee/opinions-on-draft-corap
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- ECHA's pages on Substance Evaluation [8 – DUPLICATE]
- The following MSC Opinions and Annexes (date of adoption) and documents
  - 4 February 2015
  - 5 February 2014
  - 13 June 2013
  - 6 February 2013
  - 9 February 2012
  - Working procedures for the MSC in providing the opinion on the draft Community Rolling Action Plan

[11] Annual Draft of CoRAP
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/draft-corap
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- CoRAP list of substances [3]
- The following documents:
  - Download CoRAP update for years 2015-2017
  - Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

[12] Transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- Outstanding information requests for existing substances
- Outstanding information requests for notified substances

[4] Decision/detail
Opens the substance evaluation table which provides links to the following documents where available:
- Justification documents
- Decision documents
- Appeal documents
- Evaluation documents
- Conclusion documents

[5] Notes on Substance evaluation table
- opens explanatory notes window

[23] Outstanding information requests from existing substances
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- Transitional measures: complementary part to the CoRAP [12]
- Consult the list of existing substances subject to transitional measures
- ESIS database [EXTERNAL LINK – NOT WORKING]
- Link to the following document
  - List of nominated MSCAs for Commission Regulation 465/2008

[24] Outstanding information requests for notified substances
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-notified-substances
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- Transitional measures: complementary part to the CoRAP [12]
- Consult the list of notified substances subject to transitional measures

[25] List of existing substances subject to transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-existing-substances
- Details of the transitional measures for each substance from which the following documents can be downloaded (where available)
  - Conclusion document
  - PBT report
  - Addendum to Risk Assessment

[26] List of notified substances subject to transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-of-notified-substances

Map C – chemical of concern

[1] EChA homepage
http://echa.europa.eu/web/guest
- Regulations Tab

[31] Addressing Chemicals of Concern
http://echa.europa.eu/addressing-chemicals-of-concern
- Search for chemicals
- Substances of potential concern

[2] Search Results
- CoRAP webpage

Then as chemical search map

[32] Substances of potential concern
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
- Screening
- PACT
- SVHC Roadmap to 2020 implementation

[33] Screening
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening
- Substance Evaluation – CoRAP
- PACT [34]
- SVHC Roadmap to 2020 implementation [35]
- The following documents
  - A Common Screening Approach for REACH and CLP Processes
  - Screening definition document
  - SVHC Roadmap implementation plan

[34] PACT – RMOA and hazard assessment activities
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact
- Status and purpose of PACT
- Substance evaluation – CoRAP
- Details for individual substances
- The following documents
  - Glossary - PACT technical details

[35] SVHC Roadmap to 2020 implementation
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation
- Screening [33]
- PACT [34]
- The following documents
  - SVHC Roadmap to 2020
  - SVHC Roadmap implementation plan
  - Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures 2013-2014

[8] Understanding the Substance Evaluation
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
- What happens after Substance Evaluation?
- Community Rolling Action Plan
- Member State Committee
- The following documents:
  - Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations
  - Selection criteria to prioritise substances for Substance Evaluation
  - Procedure on Substance Evaluation
  - Substance Evaluation fact sheet
  - Leaflet - Substance evaluation under REACH
  - Workshop proceedings – May 2014
  - Workshop proceedings – May 2013
  - Workshop proceedings – June 2012
  - Workshop proceedings – May 2011

[36] Status and purpose of PACT
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/status-and-purpose
- Screening [33]
- PACT [34]
- SVHC Roadmap to 2020 implementation [35]

[3] Substance Evaluation – CoRAP
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
- Decision/detail
- Notes on substance evaluation table
- Any appeal documents (opens from link)
- Further information links on
  - Understand the Community Rolling Action Plan
  - Community Rolling Action Plan (CoRAP) lists
  - Understand the Substance Evaluation [10]
  - Q&A on CoRAP and Substance Evaluation

[37] Details
- Status and purpose of PACT [36]
- Substance evaluation – CoRAP [3]
- The following documents
  - Glossary - PACT technical details
  - RMOA conclusion document/Hazard Assessment outcome document (where available)
  - Full RMOA Document (where available)

[14] What happens after substance evaluation?
http://echa.europa.eu/what-happens-after-substance-evaluation
- Substance Evaluation [8]
- Community Rolling Action Plan [10]
- Member State Committee [18]
- CoRAP [10]
- The following documents:
  - Workshop on Substance Evaluation (May 2011): Proceedings
  - Selection Criteria to prioritise substances for Substance Evaluation

[10] The Community Rolling Action Plan
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan
- What happens after substance evaluation? [14]
- Evaluation Process
- Evaluation Actors
- Evaluation Steps
- (Understanding the) Community Rolling Action Plan [7]
- CoRAP List of Substances [3]
- Questions and answers on Community Rolling Action Plan (CoRAP) [9]
- The Member State Committee [18]
- The following documents:
  - Procedures on Substance Evaluation
  - Draft Community Rolling Action Plan (CoRAP) List
  - Procedure on Substance Evaluation- Establishing updates of the Community Rolling Action Plan (CoRAP)

[18] Member State Committee
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee
- MSC opinions on draft CoRAP – Process [8]
- MSC opinions on draft CoRAP – CoRAP [10]
- Meetings (agendas and minutes)
- List of MSC members with their CVs and Declarations of interest
- Provides links to the following information/documents:
  - Closed and open sessions of the MSC plenary meetings
  - Rules of procedure of the MSC
  - General principles and guidance for ECHA's Committees Members
  - MSC General approach for admission of ASO observers
  - List of the agreed MSC ASO observers
  - Code of conduct for stakeholder observers at ECHA meetings
  - ASO Workshop: Cooperating with ECHA through the Committees
  - Code of conduct for case owners of evaluation draft decisions as observers at meetings of the MSC
  - MSC Working Procedure for processing of Substance Evaluation draft decisions
  - MSC Working procedures in providing opinion on draft CoRAP

[4] Decision/detail
Opens the substance evaluation table which provides links to the following documents where available:
- Justification documents
- Decision documents
- Appeal documents
- Evaluation documents
- Conclusion documents

[5] Notes on Substance evaluation table
- opens explanatory notes window

[7] (Understanding the) Community Rolling Action plan
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan
- Community Rolling Action Plan (CoRAP) lists [6]
- (About) Substance Evaluation [8]
- (About) The Community Rolling Action Plan [10]
- Opinions of the Member State Committee on ECHA's draft CoRAP
- Draft CoRAP
- Transitional measures: complementary part to the CoRAP
- Community Rolling Action Plan Questions and Answers [9]
- The following documents:
  - Selection criteria to prioritise substances for Substance Evaluation
  - CoRAP Fact Sheet
  - Leaflet - Substance evaluation under REACH

[6] Community Rolling Action Plan (CoRAP) lists
http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
- Community Rolling Action Plan (CoRAP) List of Substances [3]
- (About) Substance Evaluation [8]
- (About) The Community Rolling Action Plan [10]
- Provides links to download the following documents
  - Download CoRAP 2012-2014
  - Download CoRAP 2013-2015
  - Additional inclusion to CoRAP list 2013
  - Download CoRAP 2014-2016
  - Download CoRAP 2015-2017

[9] Q&A on CoRAP and Substance Evaluation
http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/corapandsubstanceevaluation

[15] Evaluation Process
http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure
- Evaluation actors [16]
- Evaluation steps [17]
- Links to the following document:
  - Evaluation process detailed graph

[16] Evaluation Actors
http://echa.europa.eu/regulations/reach/evaluation/actors
- Evaluation process [15]
- Evaluation steps [17]
- Evaluation Directorate and Units
- Committees Secretarial Unit
- Member States Committee [18]

[17] Evaluation Steps
http://echa.europa.eu/regulations/reach/evaluation/steps
- Evaluation process [15]
- Evaluation actors [16]

[19] Evaluation Directorate and Units
http://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-e
- Member States Committee [18]

[20] Committees Secretarial Unit
http://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-b
- Member States Committee [18]

[21] Meetings of the Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee
- The following documents:
  - Agenda's of MSC meetings
  - Minutes of MSC meetings

[22] Members of the Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee/members-of-the-member-state-committee
- The following documents:
  - CVs of MSC members
  - Annual declarations of interests of MSC meetings

[13] MSC Opinion
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee/opinions-on-draft-corap
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- ECHA's pages on Substance Evaluation [8 – DUPLICATE]
- The following MSC Opinions and Annexes (date of adoption) and documents
  - 4 February 2015
  - 5 February 2014
  - 13 June 2013
  - 6 February 2013
  - 9 February 2012
  - Working procedures for the MSC in providing the opinion on the draft Community Rolling Action Plan

[11] Annual Draft of CoRAP
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/draft-corap
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- CoRAP list of substances [3]
- The following documents:
  - Download CoRAP update for years 2015-2017
  - Procedure on Substance Evaluation- Establishing updates of the Community Rolling Action Plan (CoRAP)

[12] Transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT ACTIVE]
- About the Community Rolling Action Plan [10]
- Outstanding information requests for existing substances
- Outstanding information requests for notified substances

[24] Outstanding information requests for notified substances
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-notified-substances
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- Transitional measures: complementary part to the CoRAP [12]
- Consult the list of notified substances subject to transitional measures

[23] Outstanding information requests from existing substances
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances
- About substance evaluation [8]
- Legal reference REACH Regulation (EC) No 1907/2006 – Articles 44 to 48 [LINK NOT WORKING]
- About the Community Rolling Action Plan [10]
- Transitional measures: complementary part to the CoRAP [12]
- Consult the list of existing substances subject to transitional measures
- ESIS database [EXTERNAL LINK – NOT WORKING]
- Link to the following document
  - List of nominated MSCAs for Commission Regulation 465/2008

[26] List of notified substances subject to transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-of-notified-substances

[25] List of existing substances subject to transitional measures
http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures/outstanding-information-requests-for-existing-substances/list-existing-substances
- Details of the transitional measures for each substance from which the following documents can be downloaded (where available)
  - Conclusion document
  - PBT report
  - Addendum to Risk Assessment

Map D – support

[1] EChA homepage
http://echa.europa.eu/web/guest
- Support Tab

[38] Support
http://echa.europa.eu/support
- Guidance Documents
- Publications
- Document library
- Helpdesks
- Q&As Support
- Webinars

[39] Guidance
http://echa.europa.eu/support/guidance
Links to read more on the following:
- Guidance Documents
- Other Factsheets
- Formats

[40] Publications
http://echa.europa.eu/web/guest/publications
Links to following:
- Guidance Documents [45]
- Questions and Answers [43]
- Leaflets
- Factsheets [46]

[41] Document library
http://echa.europa.eu/web/guest/support/documents-library
- Publications

Allows keyword searches for specific documents to be carried out. See main report for examples.

[42] Helpdesks
http://echa.europa.eu/web/guest/support/helpdesks/
- Guidance [39]
- Q&As Support [43]
- Webinars [44]
- Publications [40]
- Public (ECHA) Procedures

[43] Q&As Support
http://echa.europa.eu/support/qas-support/qas
- Guidance [39]
- Webinars [44]
- Helpdesks [42]
- Publications [40]

Allows keyword search of Q&As. A search for "substance evaluation" gives 14 Q&A's. See main report.

[44] Webinars
http://echa.europa.eu/web/guest/support/training-material/webinars
- Guidance [39]
- Q&As [43]
- Helpdesk [42]
- Publications [40]
- Links to the following webinar:
  - What should every registrant know about substance evaluation?, held on 5th October 2012.
  - Agenda for the above.

[45] Guidance Documents/Guidance on REACH
http://echa.europa.eu/guidance-documents/guidance-on-reach
- Guidance [39]
- Formats [47]
- Q&As Support [43]
- Webinars [44]
- Helpdesks [42]
- Publications [40]
- Links to the following under both 'Guidance on Priority Setting for Evaluation' and 'Guidance on Dossier and Substance Evaluation':
  - Substance Evaluation
  - Public (ECHA) Procedures [48]

[46] Other Factsheets
http://echa.europa.eu/web/guest/publications/fact-sheets
- Publications [40]
- Links to the following factsheet:
  - Factsheet – Substance Evaluation

[47] Formats
http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities
- Guidance [39]
- Guidance Documents [45]
- Q&As Support [43]
- Webinars [44]
- Helpdesks [42]
- Publications [40]
- Links to the following document for authorities:
  - ECHA integrated quality management system (IQMS) document describing the procedure for substance evaluation

[48] Leaflets
http://echa.europa.eu/web/guest/publications/leaflets
- Publications [40]
- Links to the following document:
  - Leaflet - Substance evaluation under REACH

[49] ECHA Procedures
http://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures
- Publications [40]
- Links to the following documents:
  - Substance Evaluation
  - Substance Evaluation – Establishing updates of the Community Rolling Action Plan (CoRAP)

[29] Evaluation
http://echa.europa.eu/web/guest/regulations/reach/evaluation

Then follows the map for 'Regulation'.

Appendix B
Complete survey on SEv process

ECHA survey on Substance Evaluation

Welcome to ECHA survey on Substance Evaluation

A PDF version of this survey can be viewed and printed fromhere: (when you click a pop-up message will open asking you to sign in, just close it clicking on the cross and you will be able to see and download the pdf document)
Note that when you exit the survey, any changes will be saved. You can re-enter the survey at any time to update your responses as long as it is from the same IP address (your computer).

INTRODUCTION AND SCOPE OF THE STUDY

The European Chemicals Agency (ECHA) has launched a study to assess the functioning of the current substance evaluation process (SEv), comprising the effectiveness, efficiency, transparency and workability of the process.

The work is being undertaken by Amec Foster Wheeler Environment & Infrastructure UK Ltd and their partners Building Research Establishment Limited(BRE) and Peter Fisk Associates Limited (PFA). To carry out the study, a survey has been developed in co-operation between the consultants and ECHA to obtain evidence-based information and opinions on the functioning of the substance evaluation process under REACH. The survey is addressed to Member States Competent Authorities (MSCAs), Member State Committee (MSC) members, accredited observer stakeholder organisations of the Member State Committee, the Commission Services and a selected number of registrants that have been exposed to outcomes of substance evaluation and listing of their substances in the Community rolling action plan (CoRAP). The survey will be supported by selected interviews in cases where issues need further clarification or more detail.

Therefore we would like to invite you to complete this survey and provide any information to the consultant which may be useful in fulfilling his tasks. We encourage you to provide also free text responses with clear messages as this will assist with producing an assessment that fully explores the current functioning of the substance evaluation process.

The results of the survey will serve as evidence to ECHA for the continued improvement of the substance evaluation process. Moreover, the findings of the survey will feed into the coming substance evaluation workshop to be held in November 2015 in Helsinki and to the report on the status of implementation of REACH due in 2016.

COMPLETION OF THE SURVEY

The closing date for all responses isMonday the 7th of September 2015at 12pm Central European Time.

The survey is designed to have specific set of questions addressed to a) Member State competent authorities and members of Member State Committee of ECHA, b) Registrants and c) stakeholder organisations and the Commission. After filling in the contact details the survey will guide you to the relevant section of the survey.

Please complete all of the sections/ questions that you are able to. Where you are not able to answer a question – either through lack of data or because it is not relevant to your organisation – there is no need to provide a response. Where answers are uncertain, an estimate is more useful than no information at all. Where annual data are provided, please state the year and source.

Please note that you can go back to previous pages in the survey and update existing responses until the survey is finished or until you have exited the survey. You can re-enter the survey at any time to update your responses as long as it is from the same computer (IP address).

The report presenting the s

If you would like further information on this study or have any questions or concerns about completing the survey please contact Amec Foster Wheeler or ECHA as detailed below. We would also welcome any additional supporting documentation you are able to provide.

- Mrs. Araceli de Carlos (Amec Foster Wheeler), +44 (0) 7583691708 araceli.decarlos@amecfw.com

- Mrs. Pia Korjus (European Chemicals Agency), +358 (0) 9 6861 8470, Pia.KORJUS@echa.europa.eu or substance-evaluation@echa.europa.eu or Mrs Marta Sobanska (European Chemicals Agency), +358 (0) 9 6861 8428, Marta.SOBANSKA@echa.europa.eu.

We would like to thank you in advance for your efforts and cooperation on this work.

CONFIDENTIALITY AND PROTECTION OF COMMERCIALLY- SENSITIVE INFORMATION

Please be assured that the information provided will be treated confidentially. Specifically, any confidential information that you provide will not be passed on to third parties without your consent. Whilst the information provided is likely to be taken into account in the outputs (reports) from the work, the confidentiality of the data will be preserved by: making anonymous all information relevant to specific companies within our reporting; not using the information provided for any purpose other than for this project; presenting uncertainty ranges in reported data in order to avoid disclosing market-sensitive information; presenting aggregated data covering estimates for all companies and/or company average data, rather than data specific to individual companies; and excluding other information that you specify should not be included in the report.

As such, please indicate throughout the survey which, if any, data are confidential.

PROTECTION OF PERSONAL DATA

Your personal data will be processed as required by Directive 95/46/EC on the protection of personal data. You are entitled to access and rectify this data at any time by contacting us directly. Your contact details will not be shared with third parties other than ECHA.

For this purpose, indicate here if you oppose to revealing your identity to ECHA

ECHA
EUROPEAN CHEMICALS AGENCY

ECHA survey on Substance Evaluation

1. About your organisation

* Your contact details

Name	
Organisation/ authority you are representing:	
Job title:	
Telephone number:	
E-mail address:	
May we contact you for any clarifications?	
Preferred method of contact?	

Please select (as relevant for your stakeholder category) the Member State(s) you are reporting for/ represent at the MSC/ or where you carry out your activities:

	Yes
EU - level	○
Austria	○
Belgium	○
Bulgaria	○
Croatia	○
Cyprus	○
Czech Republic	○
Denmark	○
Estonia	○
Finland	○
France	○
Germany	○
Greece	○
Hungary	○
Iceland	○
Ireland	○

	Yes
Italy	○
Latvia	○
Liechtenstein	○
Lithuania	○
Luxembourg	○
Malta	○
Netherlands	○
Norway	○
Poland	○
Portugal	○
Romania	○
Slovakia	○
Slovenia	○
Spain	○
Sweden	○
United Kingdom	○

* Please tick which of the following apply to your organisation.NOTE: You will be directed to the section of the questionnaire containing targeted questions for your category stakeholder. If you wish to view questions addressed to other stakeholders please see the printed version.

- ○ Member State Competent Authority (MSCA) (including EEA countries)
- ○ Member State Committee (MSC) member
- ○ Registrant
- ○ Accredited observer stakeholder organisation
- ○ Commission services

ECHA
EUROPEAN CHEMICALS AGENCY

ECHA survey on Substance Evaluation

2. Questions for MSCAs/ MSC members

This section is structured in the following parts:

Questions on each of steps that form the Substance Evaluation process (SEv)

o Selection of substances to be listed by ECHA in the Community rolling action plan (CoRAP),

o Evaluation phase by the evaluating MSCA to decide whether there is a need to request further information from the registrants to clarify the concern (assessment and preparing the draft decision),

o Decision making phase (assessment of comments and agreement seeking at Member State Committee (MSC)),

o Follow up evaluation and taking the conclusions, and

o Interaction between eMSCA and registrants.

Questions covering horizontal and wider issues on SEv

2.1 Selection of substances

2.1.1 Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value? If relevant, please provide examples of substances where you disagree and your reasoning at the foot of the table.

- ○ Always
- ○ Most of them
- ○ Many
- ○ Few
- ○ No
- ○ Unknown/ do not have a view

Further detail/ commentary

2.1.2 In your role as evaluating MSCA/MSC-member, what are the main drivers or reasons for the selection of substances to be listed on CoRAP? Please tick all those which apply and provide further commentary at the foot of the table.

- [ ] In line with the CoRAP priority criteria
- [ ] National interests with particular substances
- [ ] Need for further information identified during risk management option analysis
- [ ] Other (please specify below at the foot of the table)
- [ ] Unknown/ do not have a view

Further detail/ commentary

2.1.3. Please indicate whether you agree with the following statements regarding the common screening approach recently developed to identify substances that matter most for various REACH/CLP processes including Substance Evaluation. If your answer is not YES to any of these, please provide further commentary at the foot of the table (see also question 2.1.7 for background information).

	Yes	Partly	No	Don't know
It has improved the selection of substances for which substance evaluation is needed to clarify the concern	○	○	○	○
It has improved transparency of substance selection for CoRAP	○	○	○	○
It has improved the collaboration between MSCAs during substance selection for CoRAP.	○	○	○	○
It has improved the linkages with other REACH and CLP processes, ensuring that substances that matter most are identified and, where necessary, processed via the most appropriate REACH or CLP process i.e. compliance check, substance evaluation or further regulatory risk management (Authorisation, Restriction, CLH)	○	○	○	○

Further detail/ commentary

2.1.4 Do you have any suggestions on how the selection of priority substances could be improved? How could you further contribute in your role as MSCA/MSC-member?

2.1.5 Do you think that inclusion of substances in the (draft) CoRAP has had an impact in the improved quality of dossiers i.e. was it a driver for the Registrants to provide better quality information in a dossier update? Please provide further commentary at the foot of the table to support your views.

- ○ Yes
- ○ Partly
- ○ No
- ○ Unknown/ do not have a view

Further detail/ commentary

2.1.6 In light of the experience so far, indicate how you think the future annual number of CoRAP substances should evolve (e.g. what is your capacity as an evaluating Member State to evaluate substances and contribute or what is your capacity as a MSC member to handle SEv cases at MSC level) . If you think it should be increased/decreased please indicate by how much and why at the foot of the table.

- ○ Keep the same as currently i.e. approximately 50 per year
- ○ Be increased
- ○ Be decreased
- ○ Unknown/ do not have an opinion

If you think it should be increased/decreased please indicate by how much and why:

2.1.7. Please indicate whether you agree with the following statements on information available about CoRAP and substance selection. Please provide further commentary at the foot of the table.
Note that relevant information in ECHA's website is available through the following links:
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

	Yes	Partly	No	Don't know
The information about CoRAP and substance selection on ECHA's website is sufficient to understand how the process works	○	○	○	○
The information about CoRAP and substance selection on the website of your national Member State Competent Authorities is sufficient to understand how the process works	○	○	○	○

Further detail/ commentary

ECHA
EUROPEAN CHEMICALS AGENCY

ECHA survey on Substance Evaluation

2. Questions for MSCAs/ MSC members

2.2 The Evaluation phase of substances

2.2.1 Whenever a Compliance Check in preparation for SEv is performed, ECHA informs the relevant MSCAs of any non-compliance on substance identity, human health endpoints and environmental endpoints. In your opinion, is the support provided by ECHA as part of Compliance Checks performed in support of SEv on each of these aspects appropriate in terms of timing, form and content? Please provide further commentary at the foot of the table to support your views.

	Yes	Partly	No	Not applicable/ Don't know
Is appropriate in terms of timing	○	○	○	○
Is appropriate in terms of form	○	○	○	○
Is appropriate in terms of content	○	○	○	○

Further detail/ commentary

2.2.2 In your role as evaluating Member State Competent Authority (eMSCA) or MSC member, what difficulties have you faced with the assessment of substances concerning the following aspects?

Substance identity

Human health endpoints

Environmental endpoints

Exposure

In general

2.2.3 In your role as the eMSCA what other sources of information do you use in the assessment of your substance in addition to the information in the aggregated registration dossiers? Please tick those which apply.

- [ ] Only information in the aggregated registration dossiers is used.
- [ ] Literature search
- [ ] Nationally available data e.g. monitoring information
- [ ] Requesting the information from other authorities and research institutes
- [ ] Informal contact with industry (e.g. performing a survey to collect exposure data)
- [ ] Other (please specify below at the foot of the table)

Further detail/ commentary

2.2.4 Have you contacted another evaluating Member State for a substance that you are not evaluating, but for which you have specific national interests i.e. providing input to the content and scope of the evaluation and expectations for the outcomes? If YES, please provide details at the foot of the table (e.g. in how many occasions).

- ( ) Yes
- ( ) No
- ( ) Not applicable/ do not have a view

Further detail/ commentary:

2.2.5 For each substance under evaluation ECHA has nominated a ECHA substance manager to facilitate the work of the evaluating MS. Has the support provided so far met your expectations? Please give suggestions for improvements at the foot of the table.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary:

2.2.6 Please respond to the following regarding the consistency screening of preliminary draft decisions (DDs) performed by ECHA. Please provide any comments and suggestions for improvement at the foot of the table. In particular if you decided not to change your preliminary draft decision in accordance with the suggestions from ECHA, please elaborate on the reasons:

	To a large extent	To some extent	To no extent	Not applicable/ Don't know
Was the feedback from ECHA useful to improve the quality of the DD?	○	○	○	○
Was the feedback clear?	○	○	○	○

Further detail/ commentary

ECHA survey on Substance Evaluation

2. Questions for MSCAs/ MSC members

2.3 Decision making phase

2.3.1 ECHA has noticed that in some cases it has taken long time from the preparation of the draft decision to the referral to the other MSCAs and ECHA to comment i.e. much longer than 12 months. What are the reasons behind this? Please tick all those which apply and provide further commentary at the foot of the table to support your views.

- [ ] We do not have the resources to handle Registrant comments and modify the DD
- [ ] Registrants' comments have been too complicated
- [ ] (Late) dossier update with considerable new information
- [ ] Difficulty to decide whether DD can be terminated and case concluded (parallel preparation of RMOA)
- [ ] The timeslots for MSC were not suitable
- [ ] Other (please indicate at the foot of the table)
- [ ] Not applicable/ do not have a view

Further detail/ commentary

2.3.2 The eMSCA may target the substance evaluation to focus only on the concerns identified by it. In the commenting period the other Member States and ECHA may however make a proposal for amendment (PfA) for a completely new endpoint. This leaves little time for the registrants and for the eMSCA to react on it. Please indicate how this situation could be improved in your opinion by selecting one option below. Please provide further commentary to support your response.

- ( ) There should be an agreement/policy that the scope of the evaluation is not widened to new concerns by a PfA.
- ( ) In case PfAs outside the original scope are made which require further analysis and rewording, the decision making should be aborted before the referral to the MSC, and evaluating Member State should start new round of consultation after thorough consideration of the proposal in discussion with the Member State making the PfA.
- ( ) No need to change the current practise.
- ( ) Other (please indicate at the foot of the table)

Further detail/ commentary

2.3.3 Are you examining the draft decisions referred to all Member States and ECHA in order to potentially make a Proposal for amendment:

- ○ Always
- ○ On a case by case basis (please specify criteria below)
- ○ Never as we trust in the work of other Member States
- ○ Never due to limited resources
- ○ Other (please specify below)
- ○ Not applicable/ do not have a view

Further detail/ commentary. In particular, if done on case by case basis what criteria do you apply in selecting the draft decision subject to examination?

2.3.4 Please provide your views on the challenges experienced with the following processes and on how you resolved them (in your role as eMSCA and eMSCA expert at MSC):

When answering the proposals for amendment (PfAs) received

When amending the DD following the receipt of the PfAs and submitting it within the deadline to the MSC

When incorporating the registrant's comments on the PfAs in the DD

Regarding the above tasks please indicate:

Was the webex with MSC and its timing helpful when amending the DD following receipt of PfAs?

What elements will you consider next time (or suggest) to facilitate this part of the SEv process?

2.3.5 Please respond to the following questions regarding the MSC meeting (in your role as eMSCA and eMSCA expert at MSC):

What were the main challenges that you were faced with e.g. during the redrafting of the DD, plenary discussions, negotiations etc., and how did you resolve them?

Did you feel that you should have had more national experts from your side in the meeting, but which you did not realise when you were preparing for the meeting?

Do you think that the support offered by ECHA has been appropriate (substance manager, endpoint expert, and legal expert support)?

What are the lessons learnt from MSC meetings?

2.3.6 For MSC members only: What is the average time you spend on the following in preparation for the MSC? Please provide further commentary at the foot of the table to indicate whether regarding the CoRAP update you have responded from the perspective of the rapporteur or a WG member.

	Assessment of a SEv-DD and the related background documents	Assessment of the MSC opinion on the draft CoRAP update
<15 minutes	☐	☐
15-60 minutes	☐	☐
1-2 hours	☐	☐
2-4 hours	☐	☐
> 4 hours	☐	☐

Further detail/ commentary

In the context of the above, please indicate if other persons in your organisation also spend time in helping you to prepare for the MSC:

- ○ Yes
- ○ No

Further detail/ commentary

2.3.7 What is your view on the following aids in preparation for decision making and opinion forming? (in your role as MSCA/MSC-member). Please provide further detail at the foot of the table to support your views.

	No view	Valuable - Continue as it is	Valuable - Continue with adaptation (please specify below)	No value added for me	Waste of time for all	Other (please specify below)
MSC Manual of Decisions and Opinions	○	○	○	○	○	○
Chairman's notes before the meeting	○	○	○	○	○	○
Written procedures	○	○	○	○	○	○
Webex	○	○	○	○	○	○
ECHA substance manager	○	○	○	○	○	○
ECHA legal support	○	○	○	○	○	○
Direct interaction between MSC members	○	○	○	○	○	○
MSC-S involvement in interactions between MSC members	○	○	○	○	○	○
Chairman's involvement in interactions between MSC members in the discussion groups	○	○	○	○	○	○

Further detail/ commentary

2.3.8 Please respond to the following questions regarding the written procedure (in your role as MSCA/MSC-member):

What is the average time you spend per case in preparation for written procedure voting?

Do you have suggestions for efficiency and/or effectiveness improvements of use of Written Procedures in MSC decision making?

2.3.9 In the MSC-meetings do you find the newly introduced structure of 10:00 – 17:00 for plenary timings, with separate discussion groups early in the morning or in the evening a good way for efficiently achieving unanimous agreement on draft decisions (in your role as MSCA/MSC-member)? If not, please provide suggestions for improvement at the foot of the table:

- Yes
- No

Further detail/ commentary

2.3.10 Please respond to the following questions regarding the organisation and role of the MSC (in your role as MSCA/MSC-member):

Do you have suggestions for improvements in the way the Chairman chairs the meetings?

In your experience what can/should be improved in drafting revisions on DDs at the MSC meeting?

What can MSC-S stop doing?

What may MSC-S start doing?

2.3.11 Do you have any suggestions on how to improve the transparency of the decision making process to Stakeholders?

2.4 Follow up evaluation and taking the conclusions

2.4.1 For eMSCA only: After the SEv decision registrants submit the requested information. What challenges do you envisage on the following

Before concluding on the substance?

In drafting the conclusions

2.4.2 Do you think that the new format for conclusion documents and reporting on the substance evaluation will improve efficiency (in your role as eMSCA)? If you think NOT, please explain the reasons.

- Yes
- No
- Not applicable/ do not have a view

Further detail/ commentary

2.5 Interaction between eMSCA and Registrants

2.5.1 Have you encountered problems in identifying the correct contact points for the SEv evaluation within the registrants? If YES please provide further commentary and suggestion for possible solution.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

2.5.2 Please specify if you have had informal discussions with the Registrants during the phases described below and the issues that these covered. Please tick all those which apply.

	Substance identity and hazard endpoints	Exposure	Substance evaluation procedure and obligations	Availability of further data and intentions to update a dossier	Other (please specify below)
Preparation of the CoRAP	☐	☐	☐	☐	☐
The evaluation of the substance	☐	☐	☐	☐	☐
Decision making	☐	☐	☐	☐	☐
Preparing the conclusions	☐	☐	☐	☐	☐

Further detail/ commentary

2.5.3 What means of interaction did you use and how frequently?

	Many	Some	None
Face to face meetings	○	○	○
Teleconferences	○	○	○
Videoconferences	○	○	○
Phone calls	○	○	○
E-mails	○	○	○
Letters	○	○	○
Other (please specify below)	○	○	○
Not applicable/ Don't know	○	○	○

Further detail/ commentary

2.5.4 If you reported interaction in the question above, please indicate did you consider this interaction useful and whether it helped you as the eMSCA to complete your tasks? In the comment field please reflect on whether there are any other elements you would like to comment regarding interaction with registrants? Do you have any suggestions to improve this process?

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

2. Questions for MSCAs/ MSC members

2.6 Horizontal/ general questions

2.6.1 The first substance evaluations started in 2012 and annually there has been an update to the CoRAP. In your opinion has the substance evaluation process improved from the setting up in 2012 to the present time in 2015? How?

2.6.2 Please identify if there are any barriers that hinder the efficiency of the substance evaluation process? Please tick all which apply and provide further comment at the foot of the table to support your views.

- [ ] Workload and resources available
- [ ] Procedural aspects and/or rigid rules
- [ ] Legal boundaries
- [ ] Expertise of evaluators and drafters (e.g. understanding the linkage to regulatory risk management)
- [ ] IT-related issues
- [ ] Confidential business information
- [ ] Collaboration with other Member States
- [ ] Collaboration with the Registrants
- [ ] Collaboration with ECHA
- [ ] There are no significant barriers
- [ ] Other (please specify below)

Further detail/ commentary

2.6.3 What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).

	1	2	3	4	5
Number of DDs/final decisions on data requests	○	○	○	○	○
Number of proposals for regulatory risk management	○	○	○	○	○
Number of clarifications of concern without needing a formal decision	○	○	○	○	○
Number of cases where SEv triggered changes in company level risk management, without need for EU wide regulatory risk management	○	○	○	○	○
Other (please specify below)	○	○	○	○	○

Further detail/ commentary

2.6.4 Few substances have been concluded so far. However, based on the experience so far, what is your expectation about the effectiveness of substance evaluation in relation to the following:

	High	Medium	Low	Don't have an opinion
Ability to clarify a certain concern.	○	○	○	○
Trigger of changes at company level to improve chemical safety	○	○	○	○
Creation of methodological reference cases (e.g. for addressing endocrine disruption properties)	○	○	○	○
Proposals for REACH regulatory risk management	○	○	○	○
Proposals for other EU legislative risk management	○	○	○	○

Further detail/ commentary

2.6.5 Please indicate whether there are any steps in the process where you find that instructions fall into the categories outlined below. Please tick all which apply. and provide further detail at the foot of the table.

- ☐ Instructions are sufficient for all steps in the process
- ☐ Instructions are missing for one or some steps in the process (please specify below)
- ☐ Instructions are not clear enough for one or some steps in the process (please specify below)
- ☐ Instructions are superfluous for one or some steps in the process (please specify below)
- ☐ Instructions are creating lots of additional (unnecessary) work for one or some steps in the process (please specify below)

Further detail/ commentary

2.6.7 Apart from contacting the competent authority do registrants or other stakeholders seek advice on substance evaluation in general or regarding particular substances through your national helpdesk? Can you provide information on the number and nature of the incidents/issues that have been raised?

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ECHA survey on Substance Evaluation

3. Questions for registrants

This section is structured in the following parts:

Questions on the profile of the registrant

Questions on each of steps that form the Substance Evaluation process (SEv)

o Selection of substances to be listed by ECHA in the Community rolling action plan (CoRAP),

o Evaluation phase by the evaluating MSCA to decide whether there is a need to request further information from the registrants to clarify the concern (assessment and preparing the draft decision),

o Decision making phase (assessment of comments and agreement seeking at Member State Committee (MSC)),

o Follow up evaluation and taking the conclusions, and

o Interaction eMSCA-registrants and between registrants

Questions covering horizontal and wider issues on SEv

3.1 Questions on the profile of the registrant

3.1.1 Please specify the size of your business. Please tick which applies and provide further details at the foot of the table, as necessary.

- ○ Micro firm (0-9 employees or ≤ € 2 m turnover)
- ○ Small firm (10-49 employees or ≤ € 10 m turnover)
- ○ Medium firm (50-249 employees or ≤ € 50 m turnover)
- ○ Large firm (over 250 employees or > € 50 m turnover)

Further detail/ commentary

3.1.2 How many substances from your company have been or are currently listed in the CoRAP?

Number of substances

3.1.3 Please indicate the number of your CoRAP substances where you act as a:

Lead registrant

Member

3.1.4 Have you or are you acting as a coordinator towards the evaluating Member State Competent Authority (eMSCA) and ECHA for your substance under substance evaluation?

- Yes
- No

Further detail/ commentary

ECHA
EUROPEAN CHEMICALS AGENCY

ECHA survey on Substance Evaluation

3. Questions for registrants

3.2 Selection of substances

3.2.1 Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value? If relevant, please provide examples of substances where you disagree and reasoning at the foot of the table.

- ○ Always
- ○ Most of them
- ○ Many
- ○ Few
- ○ No
- ○ Unknown/ do not have a view

Further detail/ commentary

3.2.2 Do you think that inclusion of substances in the CoRAP has had an impact in the improved quality of your dossiers i.e. was it a driver to provide further or better quality information (e.g. discussions on substance identity within the SIEF and submission of more details)? Please provide further commentary at the foot of the table.

- ○ Yes
- ○ Partly
- ○ No
- ○ Unknown/ do not have a view

Further detail/ commentary

3.2.3 Please indicate whether you agree with the following statements on information available about CoRAP and substance selection. If your answer is not YES to any of these, please provide further commentary at the foot of the table.

Note that relevant information in ECHA's website is available through the following links:
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

The information about CoRAP and substance selection on ECHA's website is sufficient to:

	Yes	Partly	No	Don't know
Understand how the process works	○	○	○	○
Reasons for inclusion of the substance in the CoRAP	○	○	○	○

Further detail/ commentary

The information about CoRAP and substance selection on the website of your national Member State Competent Authorities is sufficient to:

	Yes	Partly	No	Don't know
Understand how the process works	○	○	○	○
Reasons for inclusion of the substance in the CoRAP	○	○	○	○

Further detail/ commentary

3. Questions for registrants

3.3 Substance evaluation, decision making and follow-up phases

3.3.1 The time indicated in REACH for commenting on the draft decision (DD) and possible proposals for amendment is 30 calendar days. In addition according to REACH-IT rules, 7 days are added into it. Have you experienced any difficulties in the SIEF/consortia while preparing the comments? Please provide further detail at the foot of the table to support your response.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

In relation to the above, it is noted that ECHA has released an annual news alert in advance to indicate which substance will have a draft decision and by when the registrants may expect to receive it for comments. Does this facilitate making your comments in time? Please provide further detail at the foot of the table and indicate if you have any other suggestions that could further facilitate this.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

3.3.2 Was there a possibility to submit a dossier update agreed with the Member State after the DD was sent for your comments? If so, please indicate if it had an impact on the content of the draft decision at the foot of the table.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

3.3.3 Member States and ECHA can make additional proposals for amendment (PfA) to the draft decision that was issued to the registrant for comments. Have you experienced difficulties in commenting the Proposals for amendment from different Member States and ECHA? Please provide further detail to support your views.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

3.3.4 Are the draft decisions (DDs) and final decisions (FDs) clear enough to understand what is requested from you and the reasons behind them?

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

If you answered NO to question above, please indicate what issues are unclear or would benefit from further clarification. Please tick all those that apply and provide further detail to support your views.

- [ ] The procedure
- [ ] Tiered or conditional testing
- [ ] The scientific reasoning
- [ ] Exposure and use related requests
- [ ] The legal reasoning
- [ ] The test method to be used
- [ ] The deadline for submission of data
- [ ] Decisions should be more summarised and shorter in pages.
- [ ] Decisions should contain more details and potentially become longer in pages.
- [ ] Other (please specify below)

Further detail/ commentary

3.3.5 What difficulties have you faced when providing information in a dossier update for your substance concerning the following aspects?

Substance identity

Human health endpoints

Environmental endpoints

Exposure

In general

3.3.6 Please indicate below whether, upon receipt of a draft decision or final decision on SEv, you took action other than to comply with the decision. Please tick those which apply and provide further detail as necessary to support your response.

- [ ] Cease in manufacture/import
- [ ] Changes in registered uses
- [ ] Implementation of new risk management methods
- [ ] Other (please specify below)

Further detail/ commentary

3.3.7 If the conclusions on your substance are already published, do you think the conclusion derived fairly reflects the information available and helps the Registrants in establishing the safe use of the substance? If not, why do you think so?

- ( ) Yes
- ( ) No
- ( ) Not applicable/ do not have a view

Further detail/ commentary

3.3.8 Do you have any suggestions on how to improve the substance evaluation process?

3.4 Interaction between eMSCAs and Registrants and between the registrants themselves

3.4.1 Please specify if you have had informal discussions with the evaluating Member State during the phases described below and the issues that these covered. Please tick all those which apply.

	Substance identity and hazard endpoints	Exposure	Substance evaluation procedure and obligations	Availability of further data and intentions to update a dossier	Other (please specify below)
Preparation of the CoRAP	☐	☐	☐	☐	☐
The evaluation of the substance	☐	☐	☐	☐	☐
Decision making	☐	☐	☐	☐	☐
Preparing the conclusions	☐	☐	☐	☐	☐

Further detail/ commentary

3.4.2 What means of interaction with the Member State(s) did you use and how frequently?

	Many	Some	None
Face to face meetings	○	○	○
Teleconferences	○	○	○
Videoconferences	○	○	○
Phone calls	○	○	○
E-mails	○	○	○
Letters	○	○	○
Other (please specify below)	○	○	○
Not applicable/ Don't know	○	○	○

Further detail/ commentary

3.4.3 If you have reported interaction in the question above, please indicate below if this interaction was helpful and whether it helps you to understand your obligations and how to address the areas of concern for your substance(s). Please provide further detail to support your views and suggestions on how it could be improved.

○ Yes

○ No

○ Not applicable/ do not have a view

Further detail/ commentary

3.4.4 Have you encountered difficulties in deciding who of the registrants shall perform and submit the requested studies on behalf of the others? If YES please provide further detail to support your views.

○ Yes

○ No

○ Not applicable/ do not have a view

Further detail/ commentary

3.4.5 Are you in contact with downstream users when your substance is placed on the CoRAP in order to get more detailed information of uses and exposure? If YES, please indicate whether downstream users have supported you at the foot of the table.

- ○ Yes
- ○ No
- ○ Not applicable/ do not have a view

Further detail/ commentary

3.4.6 Are there any other elements you would like to comment or reflect upon regarding interaction with the evaluating MSCAs or with other registrants? Do you have any suggestions to improve these processes?

3.5 Horizontal/ general questions

3.5.1 Please identify if there are any barriers that hinder the efficiency of the substance evaluation process? Please tick all which apply and provide further comment at the foot of the table to support your views.

- ☐ There are no significant barriers
- ☐ Workload and resources available
- ☐ Procedural aspects and/or rigid rules
- ☐ Legal boundaries
- ☐ Expertise of evaluators and drafters (e.g. understanding the linkage to regulatory risk management)
- ☐ IT-related issues
- ☐ Confidential business information
- ☐ Collaboration with other Member States
- ☐ Collaboration with the Registrants
- ☐ Collaboration with ECHA
- ☐ Other (please specify below)

Further detail/ commentary

3.5.2 Apart from interacting with the evaluating Member State competent authority did you contact ECHA helpdesk and or national helpdesk for seeking advice on substance evaluation in general or regarding your substance in the CoRAP? If YES, please indicate at the foot of the table if the advice was helpful.

- ○ Yes
- ○ No

Further detail/ commentary

ECHA
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ECHA survey on Substance Evaluation

4. Questions for accredited observer stakeholder organisations and Commission Services

This section is structured in the following parts:

Questions on each of steps that form the Substance Evaluation process (SEv)

o Selection of substances to be listed by ECHA in the Community rolling action plan (CoRAP),

o Evaluation phase by the evaluating MSCA to decide whether there is a need to request further information from the registrants to clarify the concern (assessment and preparing the draft decision),

o Decision making phase (assessment of comments and agreement seeking at Member State Committee (MSC)), and

o Follow up evaluation and taking the conclusions.

Questions covering horizontal and wider issues on SEv

4.1 Selection of substances

4.1.1 Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value? If relevant, please provide examples of substances where you disagree and your reasoning at the foot of the table.

- ○ Always
- ○ Most of them
- ○ Many
- ○ Few
- ○ No
- ○ Unknown/ do not have a view

Further detail/ commentary

4.1.2 In light of the experience so far, indicate how you think the future annual number of CoRAP substances should evolve. If you think it should be increased/decreased please indicate by how much and why at the foot of the table.

- ○ Keep the same as currently i.e. approximately 50 per year
- ○ Be increased
- ○ Be decreased
- ○ Unknown/ do not have an opinion

If you think it should be increased/decreased please indicate by how much and why:

4.1.3. Please indicate whether you agree with the following statements on information available about CoRAP and substance selection. Please provide further commentary at the foot of the table.
Note that relevant information in ECHA's website is available through the following links:
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

	Yes	Partly	No	Don't know
The information about CoRAP and substance selection on **ECHA's website** is sufficient to understand how the process works	○	○	○	○
The information about CoRAP and substance selection on the **website of national Member State Competent Authorities** is sufficient to understand how the process works	○	○	○	○
The concern and reason for including a substance in the annual CoRAP update from the documentation that is made available during the opinion forming at **Member State Committee** (MSC) or upon publication of the annual CoRAP update is clearly presented.	○	○	○	○

Further detail/ commentary

4.1.4 Do you have any suggestions on the prioritisation and selection of substances subject to inclusion in the CoRAP updates?

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4. Questions for accredited observer stakeholder organisations and the Commission Services

4.2 Substance Evaluation, decision making and follow-up phases

4.2.1 What in your view is the most difficult aspect of the decision making process for SEv cases? How could this be improved?

4.2.2 Please indicate whether you agree with the following statements. If your answer is not YES to any of these, please provide further commentary at the foot of the table and suggestions of improvement.

	Yes	Partly	No	Don't know
The Member State Committee (MSC) is handling substance evaluation cases efficiently	○	○	○	○
The briefing sessions in the Member State Committee following agreement on SEV cases are giving you relevant information in order to help you fulfil your role	○	○	○	○
The substance evaluation decisions and conclusions published on the ECHA website are well understandable and transparent	○	○	○	○

Further detail/ commentary

4.2.3 Are there any other suggestions or elements you would like to comment or reflect upon regarding substance evaluation by the evaluating Member State or coordination by ECHA secretariat?

4.3 Horizontal/ general questions

4.3.1 The first substance evaluations started in 2012 and annually there has been an update to the CoRAP. In your opinion has the substance evaluation process improved from the setting up in 2012 to the present time in 2015? How?

4.3.2 Do you think there are any barriers that hinder the efficiency of the substance evaluation process? Please tick all which apply and provide further comment at the foot of the table to support your views.

- [ ] Workload and resources available
- [ ] Procedural aspects and/or rigid rules
- [ ] Legal boundaries
- [ ] Expertise of evaluators and drafters (e.g. understanding the linkage to regulatory risk management)
- [ ] IT-related issues
- [ ] Confidential business information
- [ ] Collaboration with other Member States
- [ ] Collaboration with the Registrants
- [ ] Collaboration with ECHA
- [ ] There are no significant barriers
- [ ] Other (please specify below)

Further detail/ commentary

4.3.3 What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).

	1	2	3	4	5
Number of DDs/final decisions on data requests	○	○	○	○	○
Number of proposals for regulatory risk management	○	○	○	○	○
Number of clarifications of concern without needing a formal decision	○	○	○	○	○
Number of cases where SEv triggered changes in company level risk management, without need for EU wide regulatory risk management	○	○	○	○	○
Other (please specify below)	○	○	○	○	○

Further detail/ commentary

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5. Other information

Please use the box below to provide any additional comments or information, including URL links to relevant documents/ information.

This is the end of the survey. Thank you very much for your time in completing this survey

Please note that you can go back to previous pages in the survey and update existing responses. After submitting the survey, you can re-enter the survey at any time to update your responses as long as it is from the same computer (IP address).

Appendix C
Detailed outcomes of survey on substance evaluation

C1 Introduction

C1.2 Purpose of this Appendix

This **Appendix** presents the detailed outcomes of the survey undertaken to gather information and views from Member State Competent Authorities and other relevant stakeholders across the EU-28 on the SEv process. The findings presented in this Appendix have been summarised in the main report (see section 3 on Task 2), and both documents should be jointly considered.

C1.3 Structure of the Appendix

The Appendix follows the structure of the survey and is divided into three sections according to the following groups of stakeholders:

- Member State Competent Authorities (MSCAs) and members of the Member State Committee (MSC) of ECHA.
- A selected number of stakeholders that have experience with the outcomes of substance evaluation and listing of their substances in the Community rolling action plan (CoRAP).
- Accredited observer stakeholder organisations of the Member State Committee and Commission Services.

Each of the sections is structured as follows:

- Overview of the profile of the respondents
- Question-by-question analysis following the numerical order established in the survey for each section. These were designed to cover the horizontal aspects and each of the stages of the SEv process, taking into consideration the level of involvement and role of each stakeholder type.

C1.4 Remarks

The following remarks are made:

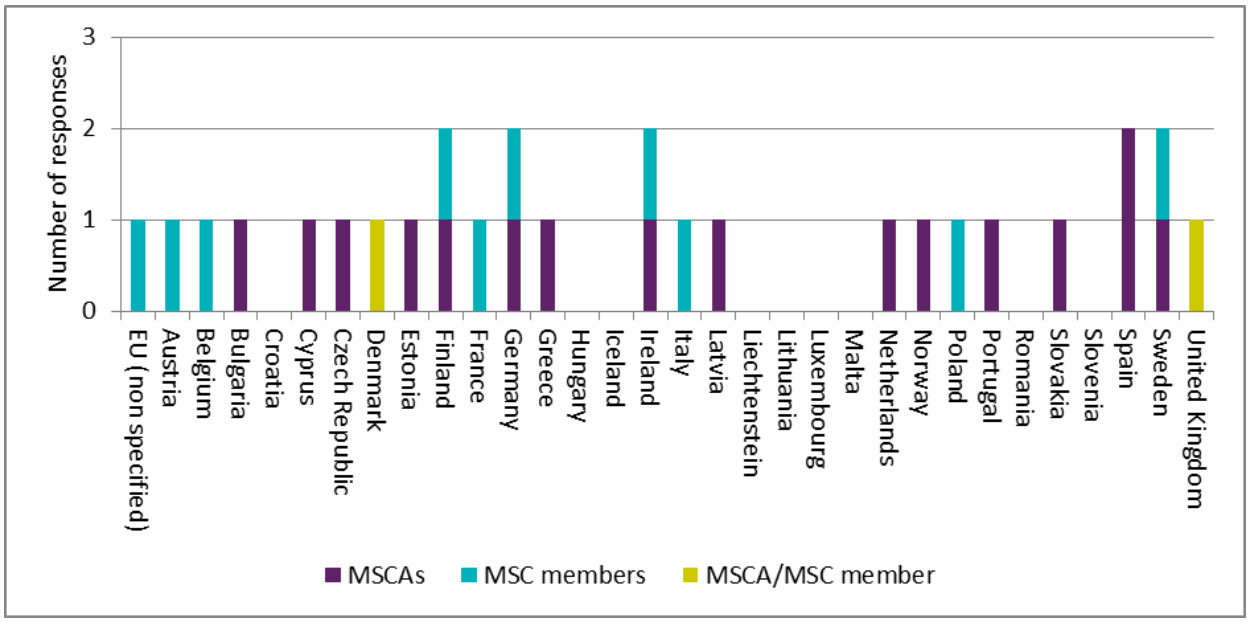
- The information included in this report is based solely on the data reported by the stakeholders consulted, and any subsequent clarifications.
- The questionnaires have been designed to strike a balance between multiple-choice and open questions to allow respondents taking part to express a full opinion. With regards to open ended questions the following is noted:
  - The general approach has been to disclose relevant comments in order to provide a comprehensive overview of the outcomes of the survey. However, the answers have been anonymised.
  - Where possible, recurring messages across responses have been highlighted and grouped together.
  - Where text has been quoted directly from the survey response, it is presented in italics.

C2 Analysis of responses to the survey provided by MSCAs and Members of the MSC

C2.1 Profile of the respondents

28 stakeholders provided relevant information via the submission of the survey. The responses included 16 from MSCAs and 10 members of the MSC, as well as two combined responses on behalf of the MSCA and MSC member (Denmark and the UK). Of note, one MSC member responded that it represents the EU rather than a particular Member State. The number and type of respondents per Member State is detailed in the figure below.

Figure C2.1 Number of consultation respondents by Member State

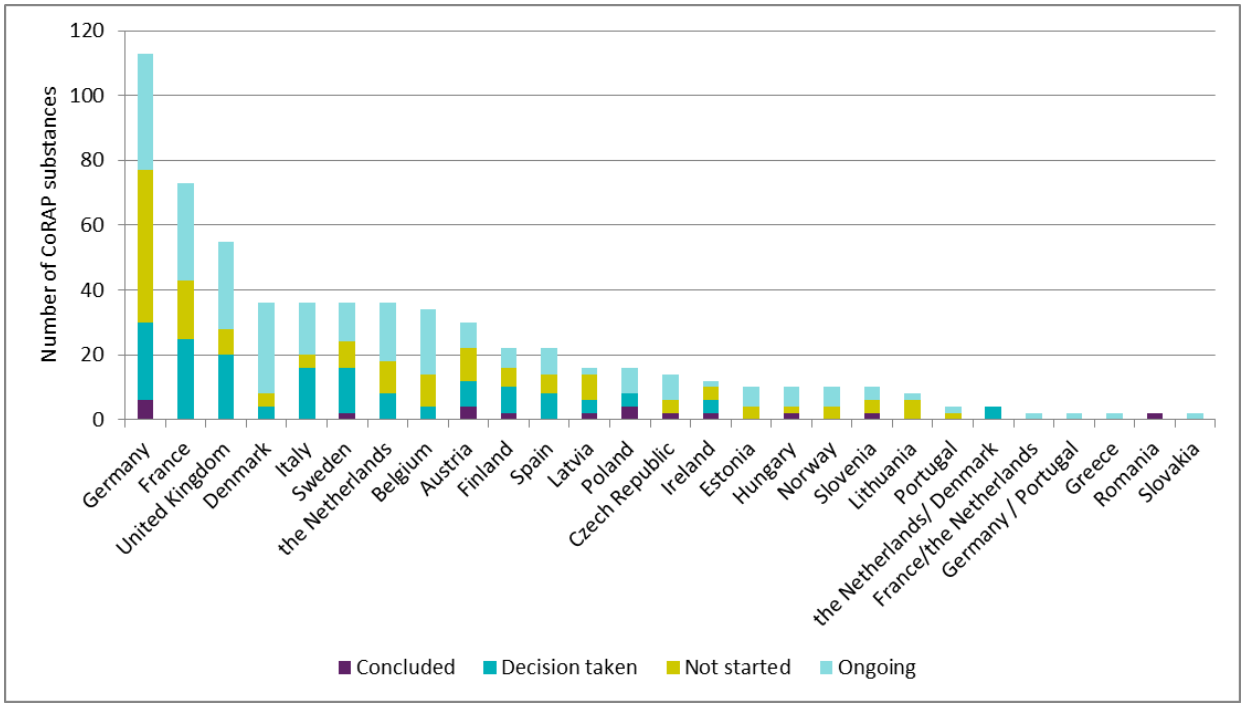


As demonstrated above (Figure C2.1), a good geographic coverage was attained through the consultation process with responses from either MSCAs or MSC members gathered for almost all of Member States (21 out of 28). In four cases (FI, DE, IE and SE), a separate response was provided by both the MSCA and the MSC member, and in the case of Spain, two MSCAs provided survey responses. Responses were not received from Croatia, Hungary, Lithuania, Luxembourg, Malta, Romania and Slovenia. Additionally a response has been provided by the competent authority in Norway; however, no feedback has been received from the other EFTA countries.

In this context, it is useful to assess the response rate by taking into account the level of involvement of the different Member States in the SEv process and the number of substances that have been assigned to each respectively. This information can be extracted from the complete CoRAP list of substances across all periods (2012-2017)[87]. The figure below presents the number of CoRAP substances assigned to each Member State and their current status (whether evaluation has started, is ongoing, has resulted in a decision, or has concluded).

[87] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances

Figure C2.2 Number and status of CoRAP substances assigned to each Member State



Source: CoRAP list from ECHA´s website (accessed on 11 September 2015)

Based on the figure above, it can be observed that respondents to the survey include the 14 Member States with the most experience in SEv, namely where some decisions are reported as having been taken or concluded (DE, FR, UK, DK, IT, SE, NL, BE, AT, FI, ES, LV, PL, IE). Furthermore, some of these Member States have experience in undertaking joint evaluations (PT, DK, NL and DE). Responses have been also provided by Norway, Estonia, Greece, Portugal and Slovakia, who also have some substances assigned or currently under evaluation. Among the Member States that do not have any substances assigned in the CoRAP list, responses have been received from Bulgaria and Cyprus.

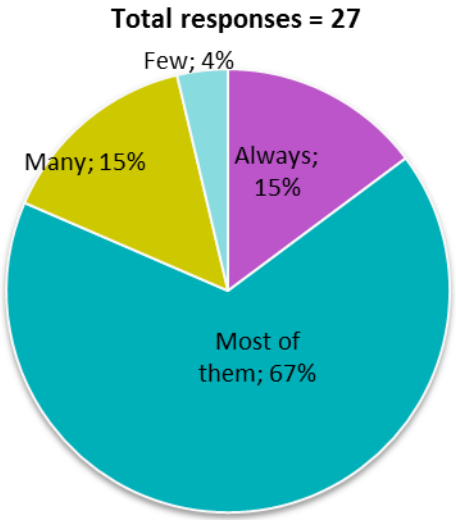
No responses were received by four Member States with substances assigned in CoRAP list, including Hungary (10 substances), Slovenia (10 substances), Lithuania (8 substances) and Romania (2 substances). In addition, the Czech Republic (14 substances) has provided a largely incomplete response with just a couple of questions filled in.

C2.2 Responses related to the selection of substances to be listed in CoRAP

2.1.1. Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value?

The majority of respondents consider that this is the case for most (67%) of the substances listed in CoRAP. The remaining respondents find that this is either the case for many of the substances listed in CoRAP (15%), or that this is always the case (15%). Lastly, one respondent considers that only a few of the substances should have been listed in CoRAP but offers no further details to support this statement. Responses to this question are shown in figure below:

Figure C2.3 Responses to question 2.1.1: Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value?



Several respondents have highlighted that a **better interplay between SEv and the process of compliance checks (CCH)** could improve the selection of CoRAP substances and increase the added value of SEv. For example, four Member States note that in some cases a compliance check could have been sufficient to clarify their highlighted concerns. One MSCA particularly notes that substances with non-compliant registration dossiers for several of the standard information requirements should be subject to a compliance check before they are added to the CoRAP list. This view is also shared by another competent authority which notes that due to the existence of many data gaps it is difficult to say if the SEv will give any added value without a full compliance check.

One Member State highlights that a common understanding and approach for the interactions between the CCH and SEV may be needed. In particular, an issue to explore would be how many of the CCH type requests should be included in SEvs and at what stage of the process these can be added.

In addition, other comments provided include:

- One MSCA notes that substances that are also under review as active substances under the Plant Protection Products Regulation or the Biocidal Products Regulation should not be listed in CoRAP if the initial grounds for concern to be clarified relate only to hazard.
- Another MSCA expresses a concern related to that lack of data on exposure used to prioritise some of the substances for SEv. They note that for one of their SEv substances the relevance decreased when it turned out to be an intermediate substance.

2.1.2. In your role as evaluating MSCA/MSC-member, what are the main drivers or reasons for the selection of substances to be listed on CoRAP?

The responses to this question generally show that a combination of drivers is used for the selection of substances. All MS responses to this question (21) indicate that the selection takes places according to the CoRAP criteria. In some of these Member States national interests on some specific substances can also play a role. Furthermore, substance selection as a follow-up to a risk management option analysis carried out has also been identified as a relevant driver by some Member. One MSCA further specifies that SEv could be used to clarify potential risks identified under other legislation (e.g. under the Water Framework Directive), and another MSCA also considers substances indicated as potential SEv candidates in the conclusions made after the completion of the Dossier Evaluation. In addition, one MSC member notes that the selection is based only on national interests but no further detail is provided.

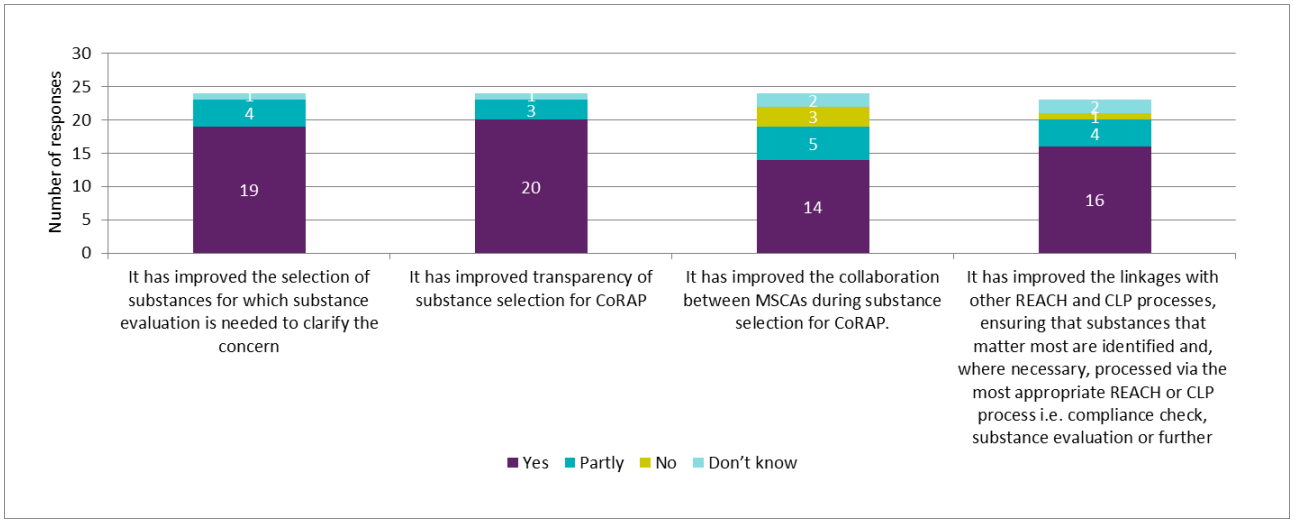
Table C2.1 Responses to question 2.1.2: In your role as evaluating MSCA/MSC-member, what are the main drivers or reasons for the selection of substances to be listed on CoRAP? Please tick all those which apply from the option below:

Number of MSs	In line with the CoRAP priority criteria	National interests with particular substances	Need for further information identified during risk management option analysis (RMOA)	Other
7	✓	✓	✓	
1	✓	✓	RMO based option has not been used so far by this MS, but theoretically it is a relevant driver.	Substances indicated as potential SEv candidates in the conclusions made after completion of Dossier Evaluation (REACH Article 42).
9	✓	✓		
2	✓		✓	
4	✓			
1		✓		

2.1.3. Please indicate whether you agree with the following statements regarding the common screening approach recently developed to identify substances that matter most for various REACH/CLP processes including Substance Evaluation.

Most respondents consider that the common screening approach has enhanced the previous situation, leading to improvements mainly in the selection of substances and the transparency of the process but also in the collaboration between MSCAs and in the linkages with other REACH and CLP processes.

Figure C2.4 Responses (number) to question 2.1.3: Please indicate whether you agree with the following statements regarding the common screening approach



Several respondents have provided comments to justify their responses with regards to each statement:

Table C2.2 Comments to question 2.1.3: Please indicate whether you agree with the following statements regarding the common screening approach

Statement	Comments
It has improved the selection of substances for which substance evaluation is needed to clarify the concern	• Better interplay needs to be achieved between CCH and SEv • Has optimised the internal prioritisation process, taking into account the total view of SVHC-candidates. • The refined criteria have improved the selection to some extent, however some of the triggers are quite sensitive and when the registration dossier is manually screened it turns out not to be an issue. • While they agree that the common screening approach has facilitated the identification of potential candidate substances for substance evaluation, in their experience (particularly from the 2015 manual screening round) very few "*good*" CoRAP candidates were identified. They would be interested to know how many of the substances for which CoRAP was identified as the "indicative process" on the screening shortlist were subsequently identified for CoRAP and also for those which were not identified for CoRAP, and what were the reasons they were considered to be not suitable. This information could facilitate further refinement of the shortlisting criteria.
It has improved transparency of substance selection for CoRAP	• Improved the transparency on the selection of CoRAP candidates within their organisation.
It has improved the collaboration between MSCAs during substance selection for CoRAP.	• Improved the overall thinking about the availability and use of capacity. • A proposal for joint SEv with 2 MSCAs should be legally described in order to save human resources. • No improvement regarding collaboration has been observed. They note that this year they screened fewer substances than last year and did not need to cooperate with other MSCAs. • In their experience the collaboration between MSCAs during CoRAP selection has not changed significantly (only contact when someone else selects a substance we have selected) and this is not an issue for the responding MS. • The manual screening process for the CoRAP update has shown many technical problems in relation to substance allocation both for screening and evaluation. However, the present (2015) template for justification document works well now. • In their experience the collaboration between MSCAs during CoRAP selection has not improved.
It has improved the linkages with other REACH and CLP processes, ensuring that substances that matter most are identified and, where necessary, processed via the most appropriate REACH or CLP process i.e. compliance check, substance evaluation or further regulatory risk management (Authorisation, Restriction, CLH)	• Although there is already some improvements, as the approach is very recent, a full assessment of the improvements on the linkages between processes cannot be made. • The linkage among processes has been partially improved by using the Portal Dashboard as the sole information platform for ongoing processes for a given substance. • They agree that the common screening approach has improved the linkages with other REACH and CLP processes but consider that further efforts are required to improve the tracking and follow up of substances following screening. For example, they find it difficult to follow substances for which CCH was identified as an outcome. They suggest that substances identified for CCH, where the screening MSCA indicates they wish to review the substance again following the CCH, should be included on the ACT tool to facilitate tracking of the progress prior to circulation of the draft CCH decision to MSCAs.
Other comments	• They value that all data for the screening activities is one tool, but note that the format of the master list 2015 (database schema) is not user friendly and consequently not fully available for use during the manual screening process.

2.1.4. Do you have any suggestions on how the selection of priority substances could be improved? How could you further contribute in your role as MSCA/MSC-member?

Responses to this question were open and are presented in table below.

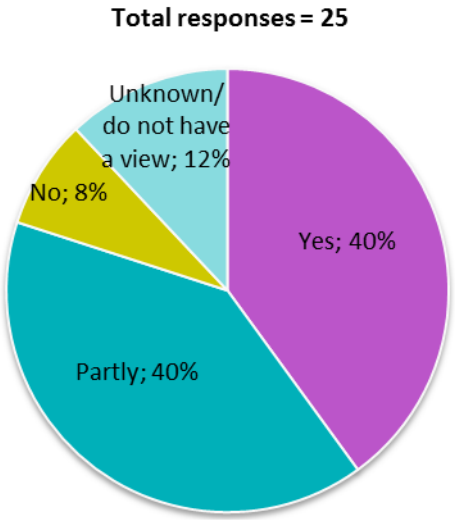
Table C2.3 Responses to question 2.1.4: Do you have any suggestions on how the selection of priority substances could be improved?

Comments
For the uses of the substance alternatives should be available, they should be from high volume range.
Find other information sources: monitoring, sectors of concern.
The CA considers substances with similar hazardous PC properties based on existing evaluations/classifications (e.g. particle and fibre dusts across unrelated substances). Reports from poison centres and information on "emerging risks" could be considered in addition, however, this depends on resources. One criterion for the Assessment Unit OSH to select substances is the hint from enforcement authorities that a problem at the workplace exists. This could be a proposal for closer collaboration between ECHA and FORUM in selecting priority substances. We are looking forward to the measures to be implemented with IUCLID6 which we assume will lead to an improvement of registration data and enable the more efficient researching of use and exposure related information from registrations.
The screening scenarios for identifying CoRAP Candidates are primarily based on information in the registration dossiers. Hence, poor quality dossiers may go undetected. It is important to ensure that also those substances are taken into consideration by e.g. including information from other sources in the identification step (and/or using e.g. QSAR estimates). The situation could also be improved by strengthening the completeness check at the time of registration.
Feedback from OSH regarding incidents at workplaces and feedback from the market surveillance projects.
may be other issues of concern should be considered, such as chemicals used in very high volume focused in one point and with potential environmental release (e. slags)
We have limited resources in this area and so for the moment we are relying on ECHAs IT mass screening results and screening shortlist to identify priority substances via manual screening.
To improve and to raise awareness on the existing tools e.g. a master table continuously updated with the available information on the substances with particular reference to the priority criteria. Screening substances for potential properties (e.g. using QSAR Toolbox)
The trickiest part is to select a substance for which further regulatory measures will have a high impact on health and safety. With the current candidates, information on exposure is often lacking to indicate if further regulatory measures will have a high impact in reality. Obtaining this information and using this information in the selection of substances would be of high added value. One of the activities MSCAs are undertaking is to prioritise the substances on the shortlist (for CoRAP, CLH or SVHC). Every MSCA wants to study each substance to select those substances that matter most to the individual MSCA. This costs significant resources. If there would be a way to avoid this, or at least not to duplicate these efforts for all MSCAs involved, we would win time by joining forces even further. We are not sure whether this would be accepted by the other MSCA.
There are some endpoints that are considered more difficult to evaluate and judge during the manual screening e.g. waiving based on grouping and read-across, exposure based waiving, exposure. Perhaps education or further guidance on those could be discussed?
More focus is needed on substances for which dossier evaluation is completed, particularly, in cases where ECHA flags them as potential candidates for SEv in their conclusions. As a MSCA we would appreciate if ECHA could highlight such cases with separate notifications via REACH-IT or e-mail. MSCAs then can further investigate and prepare a justification document for CoRAP inclusion, if appropriate.
We would welcome any improvements with regard to access and use of the master list that should be user friendly as manual screening activities, including selection of the substances for manual screening are performed by HH, ENV and Exposure experts not by the IT experts.
Including as much information from sources other than the registration dossiers e.g. factory inspections, epidemiology, research etc. - looking beyond the registration process to identify problems which could be improved by some form of action on chemical use. (We note that ECHA does use some information other than that in the dossiers when preparing the lists for manual screening) For human health exposure, it can be difficult to understand the true picture of how a chemical is being used based on the limited information that can be searched by the IT tools (e.g. tonnages and PROC codes). It would be useful if the scenario titles could also be provided. To date we have not had the resource to contribute in the groups developing the common screening so it is difficult to comment in detail on specific improvements.

2.1.5. Do you think that inclusion of substances in the (draft) CoRAP has had an impact in the improved quality of dossiers i.e. was it a driver for the Registrants to provide better quality information in a dossier update?

In general, the inclusion of substances in CoRAP is considered to improve, at least to some extent, the quality of dossiers, though it is noted that this will vary across registrants. Only two Member States responded negatively to this question based on their own experience with their substances.

Figure C2.5 Responses (number) to question 2.1.5: Do you think that inclusion of substances in the (draft) CoRAP has had an impact in the improved quality of dossiers?



Based on the additional comments provided, some MSCAs have experienced that the inclusion in CoRAP has prompted several registrants to update the dossier with better quality information, addressing or clarifying concerns identified, even before the SEv has started. As reported by one Member State, sometimes this has occurred when substances are listed on the draft CoRAP, and there was one substance for which SEv was no longer necessary after the updated dossier. However, as reported by two other Member States the quality of the updates at this phase is generally low.

In other cases, registrants have performed updates once the evaluation has started. Two Member States note that the impact on the quality of the dossier came only after an initial assessment of the dossier by the eMSCA (evaluating Member State Competent Authority), following first contact and informal questions from the MSCA regarding aspects of their dossier. Another respondent notes that the timing and content of any intended updates during this stage is discussed with the registrants to avoid the evaluation of any outdated information. However, it is noted that it can be challenging to deal with multiple updates during the year especially if these contain significant changes or come late in the process.

2.1.6. In light of the experience so far, indicate how you think the future annual number of CoRAP substances should evolve (e.g. what is your capacity as an evaluating Member State to evaluate substances and contribute or what is your capacity as a MSC member to handle SEv cases at MSC level)

Most respondents (65%) are in favour of maintaining the current situation of around 50 substances evaluated annually, compared to 23% that recommend a decrease in the annual number, and 8% that would support an increase. According to one MSCA, the current level has been workable to date and should continue to be flexible based on MSCA capacity. In general it is noted that the annual number should depend on the follow-up work from substances evaluated in earlier years 2012-2015, as well as the scale of the evaluations and on the resources ECHA will be able to allocate.

The comments from those respondents that would support a decrease are summarised as follows:

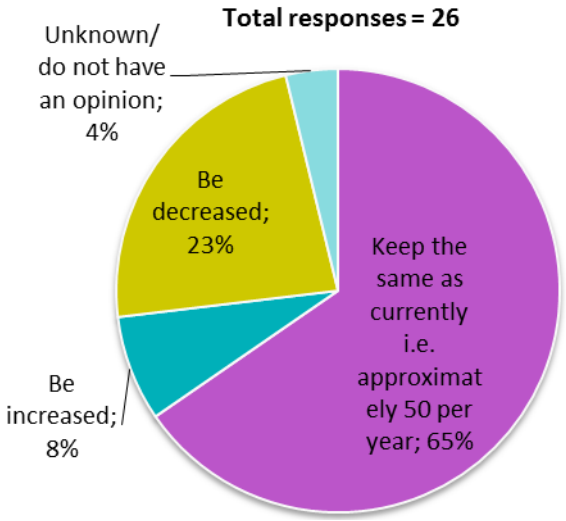
- One MSCA notes that a follow-up evaluation of the earlier substances and the fact that ECHA has decreased the fee it pays for a SEv has forced them to reduce the number of substances evaluated from 4 or 3 per year to 2 per year.

- Another Member State considers that the number of substances evaluated annually should decrease by 20% due to follow-up work.
- It is also noted by one Member State that some consideration should be given to the possibility of relocating resources from CLP/SVHC process to SEv if or when the pool of substances for those processes diminishes. It is noted that the provision of statistics, forecasts and communication to the MSCA in this regard would be valuable.
- In addition, one respondent also highlights that it is relevant to consider the workload associated with commenting on DD. Although the current level is considered reasonable, the MSCA notes that it would be useful to explore how the number of difficult cases going to a single MSC meeting can be reduced and resolved in written procedure instead.

The following observations were made by those respondents that would support an increase:

- A Member State notes that they could only increase their capacity from 3 to 4 substances due to the fact the funds foreseen for SEv are too low.
- Another MSCA expects to be able to undertake their first SEv after 2016.

Figure C2.6 Responses (number) to question 2.1.6: how do you think the future annual number of CoRAP substances should evolve?

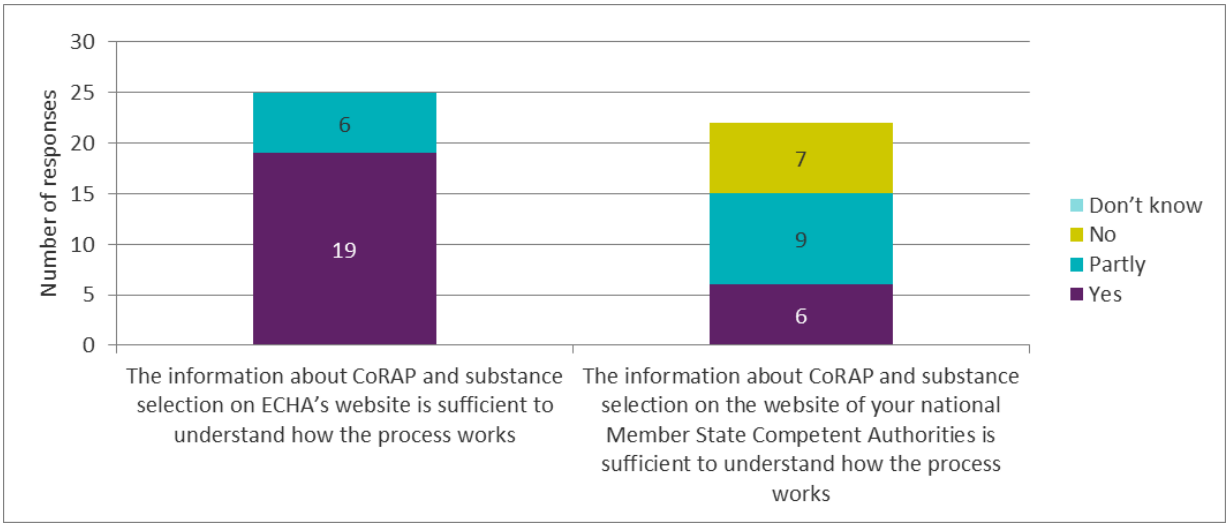


2.1.7. Please indicate whether you agree with the following statements on information available about CoRAP and substance selection.

As illustrated in the figure below, the information on ECHA´s website regarding substance selection is considered to be sufficient, with only 6 respondents out of 25 considering that available information could be enhanced to improve understanding. In particular, one respondent notes that some of this information can be difficult to find whereas according to another it could benefit from further clarification on the scope and the available selection methods (e.g. that SEv covers all registration dossiers and uses (other than OSII ref Art 49)).

In the case of the national MSCA websites, the information is generally considered partly or not sufficient to understand how the process works (16 responses out of 22). This is mainly explained by the fact that ECHA´s website is seen as the main source of information on CoRAP. Therefore national websites only contain a brief description of the process along with a link to ECHA´s webpage for detailed information. Nevertheless, three MSCAs have indicated that they intend to improve their content in the near future. In addition, one MSCA asks whether there is any recommendation from ECHA to MSCAs on the level of details that MSCAs should provide on their websites.

Figure C2.7 Responses (number) to question 2.1.7. Please indicate whether you agree with the following statements on information available about CoRAP and substance selection

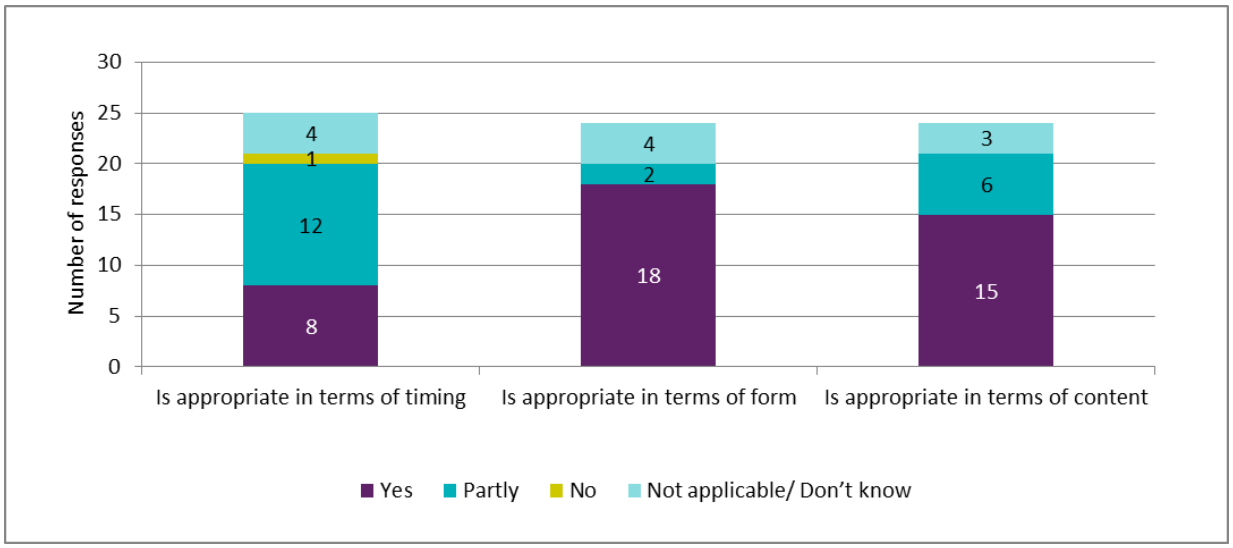


C2.3 Responses related to the Evaluation phase of substances

2.2.1. Whenever a Compliance Check in preparation for SEv is performed, ECHA informs the relevant MSCAs of any non-compliance on substance identity, human health endpoints and environmental endpoints. In your opinion, is the support provided by ECHA as part of Compliance Checks performed in support of SEv on each of these aspects appropriate in terms of timing, form and content?

Overall, respondents consider that ECHA´s support when a Compliance Check is performed is helpful, particularly in terms of form, with 18 out of the 20 respondents who have provided an opinion on the subject responding affirmatively on its appropriateness. The content of the information provided is also generally regarded as appropriate (15 out of 21 responded "Yes" and none negatively). Regarding the timing, the majority of respondents consider that this could be improved (12 consider it "partly appropriate" and 1 "not appropriate"). As such several respondents note that time available for MSCAs to comment is rather brief and that there is a need to improve the communication between ECHA and the MSCAs in terms of timing expectations and assigned responsibilities.

Figure C2.8 Responses (number) to question 2.2.1: In your opinion, is the support provided by ECHA as part of Compliance Checks performed in support of SEv on each of these aspects appropriate in terms of timing, form and content?



Comments provided by respondents to support their answers are provided in table below:

Table C2.4 Comments to question 2.2.1: Please indicate whether you agree with the following statements regarding the support provided by ECHA as part of Compliance Checks performed in support of SEv.

Statement	Comments
Is appropriate in terms of timing	• *There is a lack of structured information available on substances under CCH by ECHA for the MSCAs in terms of timing expectations. ECHA should ensure that assigned addressees/contact points in the MSCAs are in place who should receive relevant information related to CCH. Harmonised approach for communication is necessary.* • *The Compliance Check should start as early as possible and should be communicated timely (this works in many cases but for one substance we were surprised by a CCH running parallel to SEv).* • *Commenting time for SIDs CCH was quite brief. We had no problems with SID, but in complex cases more interaction (than just a notification in REACH-IT of the commenting possibility) between MSCA and ECHA might be beneficial during SIDs CCH.* • *The time available to comment is rather short.* • *After commenting these CCHs, it seems to take a long time still for the DD to be issued to the registrant. The DDs should be handled more as priority.* • *In some cases, improved communication is necessary to properly discern which authority will address which requests (e.g. an EOGRTS) in their respective decisions. The overview tables (DDxxx_MSCA_commenting_Period_xxx-xxx.xls) provided by ECHA are very helpful. The tables are the base of the administrative organization of processes and the IT-based processing.* • *We are not sure what timing you are referring to in the first question - Is it regarding the length of time a CCH takes or the amount of time we as an MSCA gets to comment on the outcome of the CCH? We have not had much experience as ECHA only fully compliance checks the substances on year 3 of the CoRAP and we have not been able to regularly select substances to completely populate each CoRAP update. Ideally we would prefer all CoRAP substances to have been through CCH prior to SEv and it would be appreciated if there was some flexibility to fast-track the process in these cases. For those substances that were checked ECHA provided useful information although the deadline for commenting was quite tight. It was helpful to be given contact details of a specific individual to discuss any issues arising. Where information is sent via REACH-IT we would prefer to also get an e-mail to alert us to the communication as we do not routinely check REACH-IT for messages.* • *It is difficult in terms of timing, when substances are selected for evaluation in the first or second year of the CoRAP list. This is difficult to avoid completely as we need to have some capacity to include e.g. nationally prioritised substances for evaluation within a shorter time frame than 3 years. We don't see how this problem could be solved.* • *It would be helpful if information on the status and timing of the stages of the compliance check of the substance before the referral of the draft decision to MSCAs could be communicated to the eMSCA, e.g. to indicate when the draft decision is sent to the registrants, if the registrant's comments result in a change in the scope of the draft decision, etc.*
Is appropriate in terms of form	• *In the excel file which lists the CCH draft decisions in each MSCA consultation round, we suggest for substance evaluation linked CCH draft decisions in addition to flagging the CCH type as "CoRAP", that the eMSCA could be also indicated. This would help to track CCH draft decisions.*
Is appropriate in terms of content	• *We consider that only endpoints that are relevant to the initial concerns could be included in the SEv. It is only after having performed the Substance evaluation that we will we know whether it is necessary to ask for more data on other endpoints.* • *The checking of exposure assessment during the compliance check by ECHA is highly supported.* • *In terms of content, we observe that compliance issues tend to be directed to the SEV's. We are not in favour of this practice because dealing with compliance issues during substance evaluation hampers the latter process. If compliance issues are still left to be addressed in a SEv, it will become a very long process, with likely multiple stages and decisions. For practical reasons we would like to see CCH issues dealt with as much as possible prior to the start of the SEv.* • *It is not obvious that ECHA performs CCH on substance ID, HH and ENVI endpoints during the SEv preparation process. However, such ECHA support would be very useful regarding the smooth SEv process.* • *In one case, while performing compliance check in preparation for SEv, ECHA asked us to assess the validity of a read-across in the dossier for a substance for which we are the eMSCA. In our opinion, it is*

Statement	Comments
	quite difficult for an eMSCA to allocate resources for such a time consuming task before actual substance evaluation begins.

2.2.2. In your role as evaluating Member State Competent Authority (eMSCA) or MSC member, what difficulties have you faced with the assessment of substances concerning the following aspects?

a) Substance identity (SID)

The difficulties expressed by respondents are presented in table below. Most of them identify as their key difficulty the SID of substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB substances). In such cases, the performance of Compliance Checks by ECHA is considered essential.

Table C2.5 Responses to question 2.1.4: What difficulties have you faced with the assessment of substances concerning their substance identity?

Comments
The substance ID with regard to nanoforms is unclear, partially because a proper legal definition is missing. The generic terms not always helpful (e.g. "graphite" for the highly diverse group of MWCNT)
Especially for UVCB's the SID is often insufficiently described. This also applies to impurities in mono constituents.
After the inclusion of the substance in the CoRAP, ECHA and the eMSCA noticed a discrepancy in the identifiers, and this led to postponing SEv and reincluding the substance in the next year's CoRAP.
Sometimes lack of expertise, especially with UVCBs or multiconstituent substances.
When a CCH was not performed before the start of the evaluation.
Currently we have no in house expertise or resources to address substance identity issues and therefore we rely on ECHAs compliance check of the lead registrant's dossier. This has an impact on our ability to evaluate certain substances, e.g. complex substances or groups of substances.
The identity of substance - change to UVCB. For the clarification of identity the long discussions was carried on and finally the decisions for clarification of identity was prepared.
Main difficulties with regard to SID were experienced with UVCBs. In these cases, the main issues were: - difficulties to assess whether the test substance in the studies was applicable to the registered substance - difficult how to cover all possible compositions - lack of data in general
UVCB - difficult to identify and challenging to find the correct CAS/EC No.
In one case of a UVCB substance in the first year of CoRAP update, for which substance identity (SID) compliance check was not performed, we had trouble confirming the SID with the Registrant(s). Due to time constraints ECHA experts could not provide feedback on our questions in this case.
We have had no major difficulties so far but there is a big difference in the quality of the analytical data provided to support substance identity. In some cases the same substances were identified as multi-constituent or UVCB in the same SIEF. Some registrants provide analytical information for a substance produced by a different manufacturing source.

b) Human health endpoints

Responses provided to this question were open and are presented in table below. There is a variety of aspects that have been raised by respondents.

Table C2.6 Responses to question 2.1.4: What difficulties have you faced with the assessment of substances concerning their human health endpoints?

Comments
Data gaps, invalid waivers, read-across without sufficient documentation, validity of tests, lack of reference to relevant public literature. Time consuming if lots of data outside the dossier available on the substance. Ongoing developments in science/test strategies (Mutagenicity, ED, ...)
ESR in the IUCLID datasets and the CSR are the basis of SEV. However, this information is very often insufficient because study summaries aren't robust and/or biased. Original study reports are required for reliable assessments which have to be separately requested by the eMSCA from the registrants. For the evaluation of nanomaterials, test guidelines and guidance are missing. Accordingly, valid toxicity studies are lacking. Often, toxicokinetic information in the registration is neglected or missing.
Lack of standard information requirements. In addition, existing studies are often not included (e.g. on endocrine disruption).
Not clear in the selection criteria whether sensitisation referred to skin or respiratory sensitisation. The driving reasons/ clues for selection not provided to eMSCA.
In some cases lack of clear description of toxicological effects or reporting in the registration dossier
We are CA for Env and do not evaluate HH endpoints
Lack of ED criteria
On respiratory sensitization since no test exist
We have limited toxicological resources and therefore we are unable to evaluate substances with large data sets or groups of substances.
Difficulties in defining deadlines when recently developed testing method are required (i.e. when no information on the presence of laboratories performing specific tests)
During MSCA/ECHA consultation of the DD, one MSCA PfA included an additional concern and the MSCA didn't have the expertise available to assess the PfA.
Challenges concerning implementation of: - EOGRTs; - COMET assay;
1. Complex read-across case. 2. Justification (including deadlines) in the Decision for sequential and conditional testing. 3. Justifying requests for non-guideline studies and non-standard endpoints in the guideline studies. 4. Poor quality dossiers (often the study summaries are not robust).
Information documented in the robust study summaries do not contain sufficient information for the SEv.
Our main issue is what to do with data gaps and the different views between MS lead that lead to additional requests to fill the gaps.

c) Environmental endpoints

Responses provided to this question were open and are presented in table below. There is a variety of aspects that have been raised by respondents.

Table C2.7 Responses to question 2.1.4: What difficulties have you faced with the assessment of substances concerning their environmental endpoints?

Comments
Commercial QSAR database used by the registrant which is not freely consultable, no experience with the database (transparency issue). Ongoing developments in test strategies (simulation testing, PBT guidance...).
Environmental hazards were not identified through the computerial selection.

Comments
Sometimes criteria regarding poor soluble substances, evaluation of enhanced tests for persistency
Lack of ED criteria
We have limited environmental expertise in house and therefore we are unable to evaluate substances which have an initial concern for the environment.
It is difficult to request exposure information if the Registrant uses an incorrect (too high) DNEL. In that case, the proportionality of the request is difficult to prove, since the SEV tool is not the appropriate tool to rectify incorrect DNELs.
UVCB - very complex and challenging to evaluate for PBT concerns.
Following a registrant comment to perform an Enhanced ready biodegradability test, it was verified that the PBT Guidance doesn't include criteria to accept the Enhanced ready biodegradability test for PBT assessment and further development is needed.
1. Justifying requests for non-guideline studies and non-standard endpoints in the guideline studies. 2. Poor quality dossiers (often the study summaries are not robust).
Information documented in the registration dossier are not sufficient for the SEv. Some important data are missing to confirm validity of the study. Justifications for waiving of the studies are missing or are not convincing. The registration dossier was not in compliance with REACH / Annex XIII.
A key issue is how the evaluation can address concerns when a substance is reacted during the life-cycle to form another substance but then that new substances degrades back to the parent substance in the environment. Similarly if the new substance produced (from the substance under evaluation) is considered to be a polymer the life-cycle of the polymer is not covered by REACH and thus any subsequent degradation is not considered. We would like to know how this type of concern can be addressed.

d) Exposure

Responses provided to this question were open and are presented in table below. There is a variety of aspects that have been raised by the respondents. One aspect that has been raised by three respondents is the difficulty to phrase a request for information related to exposure.

Table C2.8 Responses to question 2.1.4: What difficulties have you faced with the assessment of substances concerning their exposure?

Comments
Commercial QSAR database used by the registrant which is not freely consultable, no experience with the database (transparency issue). Ongoing developments in test strategies (simulation testing, PBT guidance).
Environmental hazards were not identified through the computerial selection.
Sometimes criteria regarding poor soluble substances, evaluation of enhanced tests for persistency
Lack of ED criteria
We have limited environmental expertise in house and therefore we are unable to evaluate substances which have an initial concern for the environment.
It is difficult to request exposure information if the Registrant uses an incorrect (too high) DNEL. In that case, the proportionality of the request is difficult to prove, since the SEV tool is not the appropriate tool to rectify incorrect DNELs.
UVCB - very complex and challenging to evaluate for PBT concerns.
Following a registrant comment to perform an Enhanced ready biodegradability test, it was verified that the PBT Guidance doesn't include criteria to accept the Enhanced ready biodegradability test for PBT assessment and further development is needed.

Comments
1. Justifying requests for non-guideline studies and non-standard endpoints in the guideline studies. 2. Poor quality dossiers (often the study summaries are not robust).
Information documented in the registration dossier are not sufficient for the SEv. Some important data are missing to confirm validity of the study. Justifications for waiving of the studies are missing or are not convincing. The registration dossier was not in compliance with REACH / Annex XIII.
A key issue is how the evaluation can address concerns when a substance is reacted during the life-cycle to form another substance but then that new substances degrades back to the parent substance in the environment. Similarly if the new substance produced (from the substance under evaluation) is considered to be a polymer the life-cycle of the polymer is not covered by REACH and thus any subsequent degradation is not considered. We would like to know how this type of concern can be addressed.

e) In general

Responses provided to this question were open and are presented in table below. There is a variety of aspects that have been raised by the respondents.

Table C2.9 Responses to question 2.1.4: What difficulties have you faced with the assessment of substances in general?

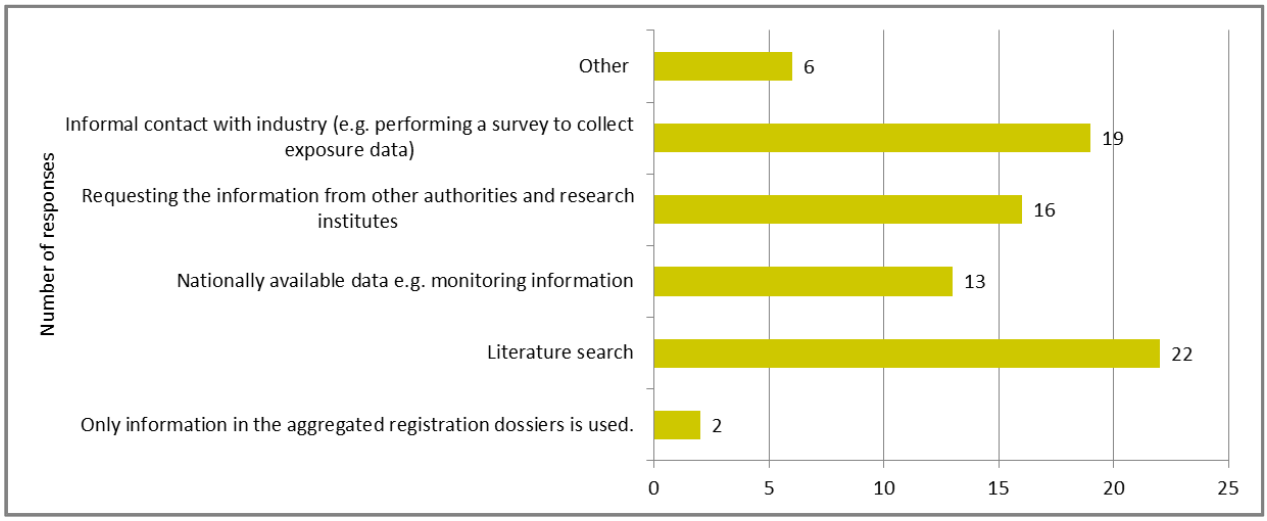
Comments
Bad quality dossiers (data gaps, invalid waivers, ongoing tests, read-across with other substances for which registration dossier is also available or evaluation focusses on degradation product. Overlap with other member states substances.
In some cases further exchange with the registrants on a specific test design for a requested study is required or desired by registrants after the final decision is issued.
Poor dossier quality. ECHA guidance too general for specific cases.
The cooperation with ECHA and the Industry has been proven sufficient and fruitful.
Sometimes we have to deal with PfA outside the scope of SEV in a short time
Lack of data due to waived information without clear justification.
Collaboration with other MSCA, since the time is really limited. Dealing with IUCLID
We have limited resources available for substance evaluation work and the available expertise is limited to human health hazard and exposure assessment. This has an impact on our ability to evaluate certain substances e.g. large data sets, groups of substances, substances with environmental risk focus.
In one case the study reports were submitted in non-EU language (possible Chinese), also summaries were not provided.
Problems / questions we face in the SEV process: - How to justify a concern that is actually a compliance issue? - How to deal with compliance issues in case there is no (SEV) concern? - How to justify a data request when there is no data to justify the concern (since therefore the request is raised)? - How to deal with informal data (e.g. derived my verbal communication with the registrant)? - How to deal with late updates of the registrant?
Identified uses are not up to date, making SEv difficult.
The drafting of the DD during MSC meeting due to time constrains is considered the most challenging step of the evaluation.
tired strategy (e.g. mutagenicity) to be included in one DD or several consecutive evaluations
Lack of resources to involve toxicokinetics experts in-house for SEv.
Low quality of registration dossier. Lack of experiences, lack of experts for specific endpoints.

Comments
In the first year of SEv (2012) the level of reimbursement was such that we could carry out full evaluations not just focussing on the initial concerns. In reducing the amount of reimbursement we have to be much more targeted in our evaluations. This is not necessarily a bad thing but we need to be clear about what this means, for example making PfAs on areas outside the scope if the evaluation. When considering OMS evaluations we sometimes find that the SEv report/draft decision does not contain all the critical information to allow an independent judgement of the request(s) to be made.

2.2.3. In your role as the eMSCA what other sources of information do you use in the assessment of your substance in addition to the information in the aggregated registration dossiers? Please tick those which apply.

This question has been answered by 25 stakeholders and it can be observed that most MSCAs use a combination of several information sources in the assessment of substances. Only two respondents report that the registration dossiers are the only source of information; however no further details are provided. Supplementary information is mainly obtained through a literature search and informal contact with industry.

Figure C2.9 Responses (number) to question 2.2.3: In your role as the eMSCA what other sources of information do you use in the assessment of your substance in addition to the information in the aggregated registration dossiers?



Comments provided by respondents to support their answers are provided in table below:

Table C2.10 Comments provided to support responses to question 2.2.3: In your role as the eMSCA what other sources of information do you use in the assessment of your substance in addition to the information in the aggregated registration dossiers?

Comments
Registration dossiers of other substances (i.e. read-across substances or dossiers of the constituents of a substance, similar substance). QSAR data email exchange with US scientific institute Collaboration with Swiss competent authority Info requested from other EU member state (related substances)
Single registration dossiers in ECHAs IUCLID-database especially for assessment of IUCLID section 3. (In some cases) additional surveys are conducted to contribute to substance evaluation. National data bases such as SPIN, Technical rules for hazardous substances (TRGS) Original study reports used in CSR/IUCLID Case studies and dossiers from international programmes (e.g. OECD Working Party on Manufactured nanomaterials)
E.g. national data bases, full study reports, dossiers from international programmes
We check any source of information available. Until now we have used registration data, data from literature search and informal contact with industry.

Comments
QSAR data and modelling.
Publicly available literature, publicly available QSAR-like tools for hazard and exposure estimation and expert judgments were taken into account. Information from registration data from structurally similar substances.
We have and will continue to use a combination of the above as necessary depending on the substance/concerns. NOTE – we have some reservations with the example given above regarding exposure data. Whilst we contact industry regarding the evaluations and may ask if they have any monitoring data available we would not ask them to produce new exposure information informally. This should be possible only as part of the decision making process.

2.2.4. Have you contacted another evaluating Member State for a substance that you are not evaluating, but for which you have specific national interests i.e. providing input to the content and scope of the evaluation and expectations for the outcomes? If YES, please provide details at the foot of the table (e.g. in how many occasions).

7 MSCAs respond affirmatively to this question, compared to 12 which responded that this has not taken place. In addition 2 respondents note that this question was not applicable or that they had no opinion.

Among the responses, only the following provide further detail, as summarised below:

- Information on methanol was provided to the eMSCA of Poland;
- When the assessment concerns substances which belong to a same category, they establish informal contact to have a common approach or know the outcome of the SEv; and
- Information has been provided on environmental monitoring data, but no further detail is provided.

2.2.5. For each substance under evaluation ECHA has nominated an ECHA substance manager to facilitate the work of the evaluating Member State. Has the support provided so far met your expectations?

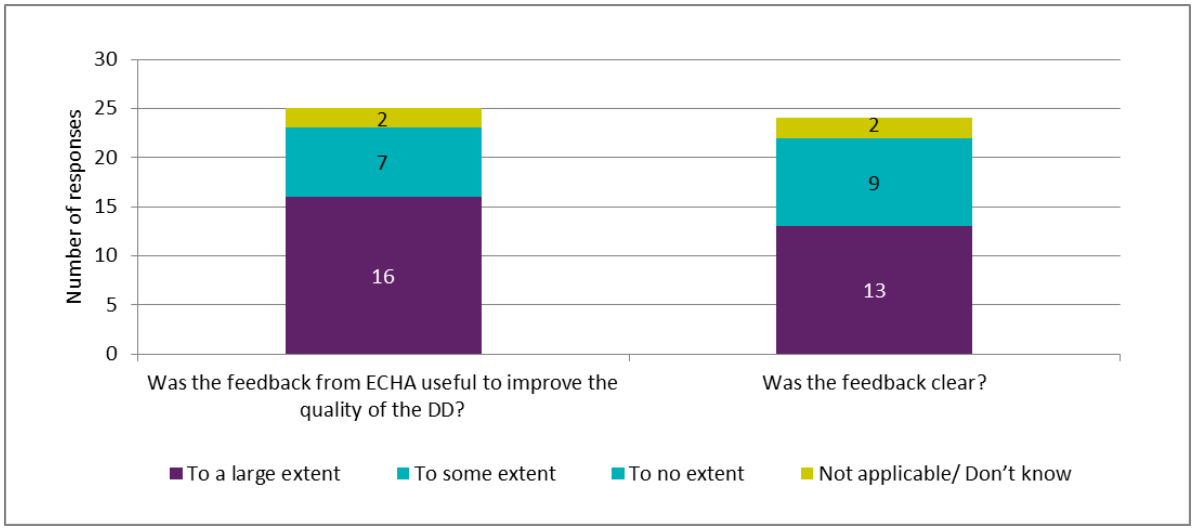
Most respondents (20/23 or 87%) consider that the support provided by ECHA´s substance manager has facilitated the work and met expectations. Based on additional comments provided, the role of the ECHA substance manager is generally highly valued, though a few have noted that the cooperation will depend largely upon the appointed substance manager. In addition, one MSCA notes that whereas the support provided during the evaluation was very good, they were expecting a more proactive role from the manager during the decision making discussion and as such there were several cases under discussion at the MSC meeting but the support was limited.

Only one MSC member considers that this support has not met the expectations; however no further details are provided. In addition, 2 respondents note that this question was not applicable or that they had no opinion.

2.2.6. Please respond to the following regarding the consistency screening of preliminary draft decisions (DDs) performed by ECHA. Please provide any comments and suggestions for improvement at the foot of the table. In particular if you decided not to change your preliminary draft decision in accordance with the suggestions from ECHA, please elaborate on the reasons:

Overall, respondents consider that ECHA´s support during consistency screening has been useful, with 16 out of 25 respondents finding that this contributed to a large extent to the improved quality of DDs. Furthermore, most respondents also consider that the feedback provided was clear to a large extent (13 out of 24 respondents).

Figure C2.10 Responses (number) to question 2.2.6: Please respond to the following regarding the consistency screening of preliminary draft decisions (DDs) performed by ECHA.



Comments provided by respondents to support their answers are provided in table below:

Table C2.11 Comments provided to support responses to question 2.2.6: Please respond to the following regarding the consistency screening of preliminary draft decisions (DDs) performed by ECHA:

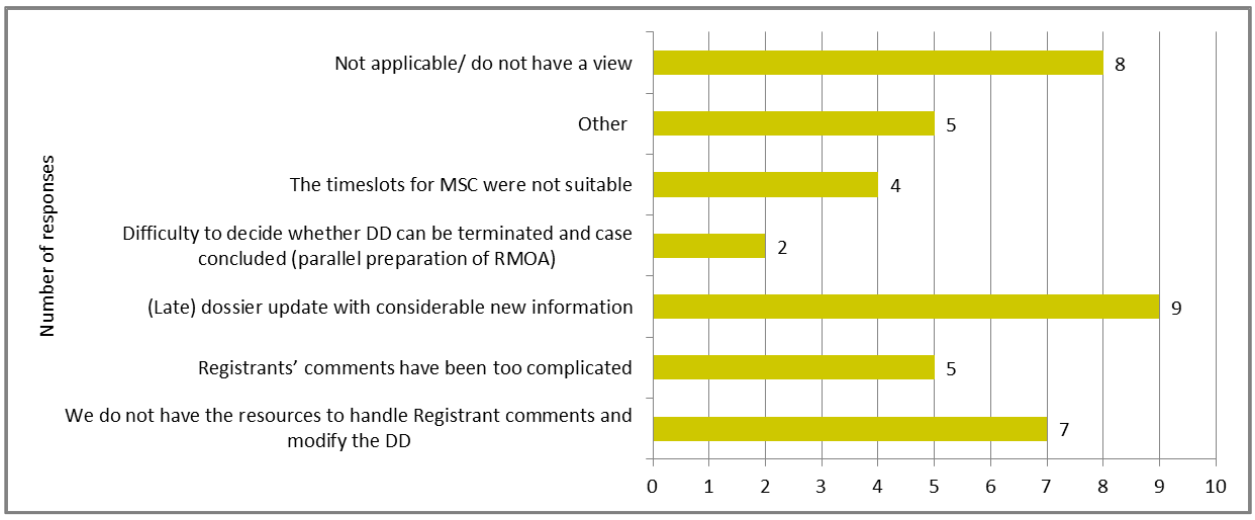
Comments
In general, ECHA's feedback is highly welcome. However, sometimes suggestions are made to adhere to regulatory frameworks/guidance, although the framework is not yet effective (e.g. RAAF). The reasoning for some recommendations could be improved, e. g. by referring to other (draft) decisions that address a concern more appropriately or which are otherwise relevant for the case at hand.
Feedback is highly welcome,
No draft decision was prepared, but a conclusion document, which has been reviewed by ECHA staff in a very satisfactory and fruitful way.
We have only submitted one draft decision for consistency screening by ECHA and it was a reasonably straightforward case. For our subsequent case we decided not to submit the draft decision for consistency screening as we felt that the feedback received from ECHA on the first case was also relevant for the second case. Overall we found the process useful, particularly for non-standard information requests.
To us, ECHA's role in the process is not always completely clear. Is the role of ECHA of procedural nature of also of with regard to scientific input?
Some of the comments were not integrated in the DD since we didn't clearly understand the proposal, therefore we consider that the comments during consistency screening should include the drafting proposal in order to allow better comprehension or having a contact point to clarify any doubts.
ECHA support during consistency screening was very useful.
It has helped to get an understanding of what ECHA want the DD to look like and it has been very useful getting a legal viewpoint of the requests as we don't consult with legal experts within our organisation. Generally we have been happy to make the changes suggested although in some cases ECHA have suggested we request additional data. In some cases we have not incorporated such requests at this stage as we feel they would be better addressed by ECHA formally submitting a PfA. We have received conflicting advice on the level of detail that we should expect registrants to provide when describing any required PPE, for example whether to request information on glove material/breakthrough times. It would be useful if ECHA could provide some updates for specialists on what they have learned and the future direction of their thinking.

C2.4 Responses related to the decision making phase (assessment of comments and agreement seeking at Member State Committee (MSC))

2.3.1. ECHA has noticed that in some cases it has taken long time from the preparation of the draft decision to the referral to the other MSCAs and ECHA to comment i.e. much longer than 12 months. What are the reasons behind this?

This question has been answered by 23 stakeholders. The main reasons provided to explain the delay of the submission of DDs to the other MSCAs and ECHA are related to the late update of dossiers with large volumes of information and limited resources to handle this new information. As well there have been issues where comments given by the registrants were found to be too complicated (as noted by 5 stakeholders), time consuming or even result in a change of the focus of the evaluation. The fact that the timeslots for the MSC meeting are not suitable is also mentioned by 4 stakeholders, one noting that having the meeting in September is not suitable as the MSCA consultation period before this runs during the vacation period for most authorities.

Figure C2.11 Responses to question 2.3.1: ECHA has noticed that in some cases it has taken long time from the preparation of the draft decision to the referral to the other MSCAs and ECHA to comment i.e. much longer than 12 months. What are the reasons behind this?



Comments provided by respondents to support their answers above are provided in table below:

Table C2.12 Comments provided to support responses to question 2.3.1: ECHA has noticed that in some cases it has taken long time from the preparation of the draft decision to the referral to the other MSCAs and ECHA to comment i.e. much longer than 12 months. What are the reasons behind this?

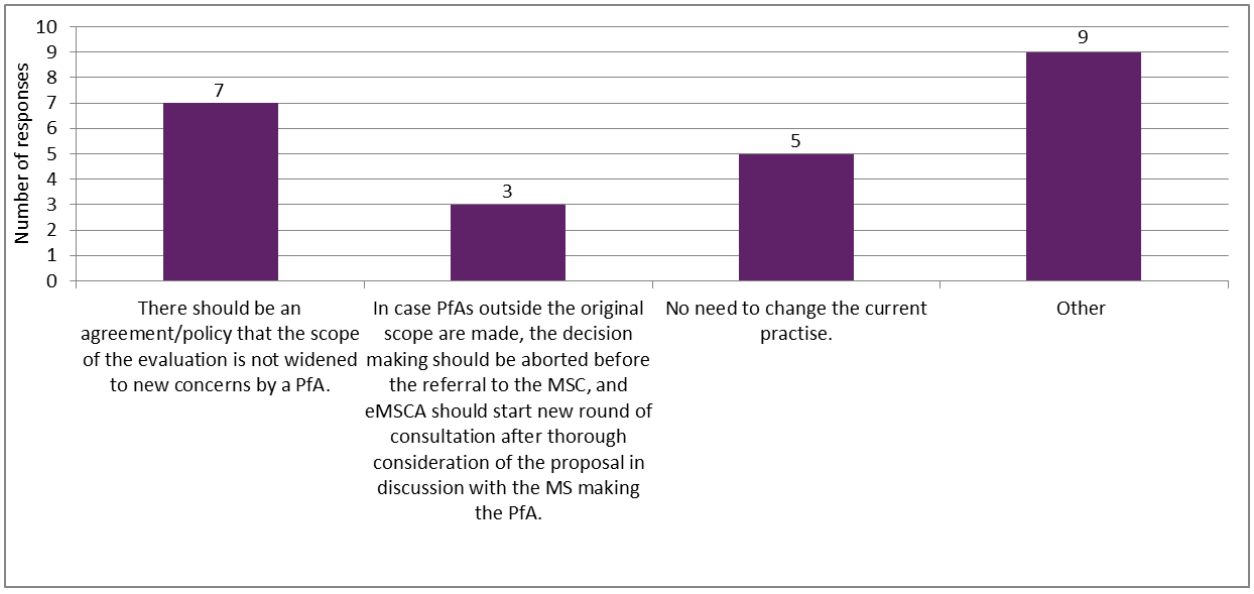
Comments
Timing issues: Comments come in when experts are busy evaluating new substances. Once a date for MSC is chosen, strict deadlines apply and experts need to be available for each step of the process. Responding to the registrant's comments can be time consuming (preparing the RCOM). New information is to be evaluated.
Not so much because the registrants comments have been complicated but because they can be very time consuming and in some cases completely change the focus of the evaluation (e.g. changing substance ID, providing new studies, etc.)
Lack of human resources is a general problem
So far we have been able to process the decisions without delay. However, we can see that in some cases it might be useful to wait for instance for results from a TPE decision etc.

Comments
In our previous evaluations the registrants comments were not extensive and there were no (late) dossier updates which significantly influenced the draft decision. However, we have limited resources to handle such extensive comments on draft decisions and (late) dossier updates, in particular where this is likely to overlap with other REACH work areas e.g. manual screening, start of a subsequent substance evaluation. In such instances this could result in a delay in the referral of the draft decision to other MSCAs/ECHA.
For some of our SEV substances, there were several updates with drastic changes, resulting in a high workload to update the SEV, at various phases of the process. Furthermore in one case the registrant changed the status of the registration to 'intermediate', but it was questionable whether the use was indeed in conformity with this declaration. We have asked another MSCA to look into it and are waiting for the outcome of that before we are able to conclude on the DD.
September MSC meeting is not suitable as the MSCA consultation period before this runs during the vacation period for most.
We adjust timetable to our personnel capacities and workload.
We have only had one case where we have delayed referral to the OMS for comment. This was previously agreed with ECHA as we were evaluating similar substances in the following year. Our approach is to get the draft decisions out for commenting as soon as possible but this depends on the following factors; We may have agreed with the registrant to accept some new information following their commenting and need to wait to take this into account • Logistics – e.g. the availability of key staff for a specific MSC meeting and the key steps leading up to that meeting (e.g. time to produce RCOM etc.) We would hope to get all the previous year's substances through the decision making before the next years evaluations are in full swing although this is not always possible.

2.3.2. The eMSCA may target the substance evaluation to focus only on the concerns identified by it. In the commenting period the other Member States and ECHA may however make a proposal for amendment (PfA) for a completely new endpoint. This leaves little time for the registrants and for the eMSCA to react on it. Please indicate how this situation could be improved in your opinion by selecting one option below.

Based on the responses provided there is no clear or simple option to address this issue, and a few have expressed that this would need further discussion and flexibility, dependent on each case. Nevertheless, it appears that having a kind of agreement or policy not to widen the scope of the evaluation following a PfA is the preferred option of the three that have been proposed. A few stakeholders have further expressed that some legal and practical concerns would need to be considered if this was the option to be chosen.

Figure C2.12 Responses to question 2.3.2: In the commenting period the other Member States and ECHA may however make a proposal for amendment (PfA) for a completely new endpoint. This leaves little time for the registrants and for the eMSCA to react on it. Please indicate how this situation could be improved in your opinion by selecting one option below.



Comments provided by respondents to support their answers are provided in table below:

Table C2.13 Comments provided to support responses to question 2.2.3: In the commenting period the other Member States and ECHA may however make a proposal for amendment (PfA) for a completely new endpoint. This leaves little time for the registrants and for the eMSCA to react on it. Please indicate how this situation could be improved in your opinion by selecting one option below.

Comments
We don't see a legal solution for restarting the consultation process. Also the registrant should be included in a possible new consultation process, but as said before, there is no legal process foreseen for such cases. Deadlines are too short for informal consultations after MSCA commenting period. Further thought is indeed needed on a solution but none of the above seems possible.
This is a serious problem especially in countries with lack of resources since you have to react in 15 days to an endpoint that have not been deeply addressed. In addition you can lack the needed expertise. For instance we only choose substances with human health concern and we are not competent to evaluate environmental issues. If the PfA is related with environment we would not be able to assess the issue.
It will have to be studied case by case, but in general, the process takes time enough and should not be delayed if possible.
MSCAs/MSC should be active when substances are selected to CoRAP and comment if they feel that the scope (initial grounds of concern) should be widened. The current practise of manual screening is quite comprehensive covering in principle all endpoints on a screening level.
The above selection represents our initial view on this issue but we consider that this is an important topic which requires further discussion at a workshop. We note that the options available will be limited by legal considerations regarding substance evaluation decision making process.
To leave more time to the eMSCA (and consequently to the registrant) when a PfA is proposed due to an additional concern
Completely new endpoints should be raised in different way for example, substance inclusion in the next CoRAP list with indicated new concern.
If the new endpoint is important for clarifying possible concern regarding the substance, it seems reasonable to give the eMSCA more time before referral to the MSC.
We consider that the solution for this situation should be decided on a case by case basis. We consider appropriate that if PfA outside the original scope are made which require further analysis and rewording, the decision making could be aborted before the referral to the MSC; this should be decided by the eMSCA.
Difficult to decide on one option. Further discussion needed and perhaps some flexibility at the end.
PfAs should be detailed and sound enough scientifically, also considering the practical and legal boundaries.
At present there is no possibility to make PfAs for SEv cases concluded without draft decision. The MSCAs should have the possibility to review the SEV cases for which eMSCA intend to conclude SEV without DD. The process requires sufficient time. Time limitation decreases the quality of evaluation. Modification of REACH is needed.
We agree that this is an issue that does need further discussion especially as the reduction in reimbursement will lead to more targeted evaluations. However, we think there is no simple, single solution and the best option will depend on each case. Initial thoughts are that it will depend on the PfA and the opinion of the eMSCA. Consideration should be given whether the PfA relates to a data gap that could be filled via compliance check or whether a true, substance specific, concern has been identified that can only be clarified via substance evaluation. Having an informal agreement/policy not to widen the scope of the evaluation is certainly a simple solution and our preferred one but one should consider the legality of this - a MSCA has a right to make a PfA. Additionally how would this fit in with Article 47(1) and relisting a substance on the CoRAP. Aborting the decision making and having another commenting round would be a good solution for more complex cases. Consideration should also be given to whether the eMSCA has the resource/expertise to evaluate the additional information requested. It could be an option for the MSCA making the PfA to provide support in that respect. Ideally all potential issues should be flagged at the common screening phase but the manual screening is not a detailed evaluation and new issues nay emerge. Discussing the evaluations at relevant technical groups either during the evaluation or before the commenting by MSCAs could also be useful in flagging potential issues that may be raised in PfAs allowing more time for them to be dealt with.

2.3.3. Are you examining the draft decisions referred to all Member States and ECHA in order to potentially make a Proposal for amendment?

More than half of the respondents (54%) note that the examination of DDs takes place on a case by case basis. Three MSCAs report that this is done always on a general basis, while five MSCAs report that this is never done. The reasons provided are that they trust the work done by other MSCAs (in one case), and due to lack of resources (five Member States). However, two Member States note that there might be cases where based on national priority criteria, a DD may be reviewed.

Explanations on the criteria and approach used to decide upon the review of DDs provided by respondents are presented in table below. Generally MSCAs will tend to focus on similar substances or similar endpoints to their CoRAP substances, for the purpose of harmonisation and learning.

Figure C2.13 Responses (%) to question 2.3.3 Are you examining the draft decisions referred to all Member States and ECHA in order to potentially make a Proposal for amendment?

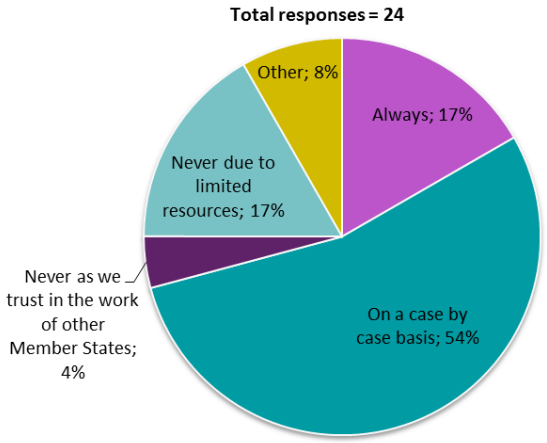


Table C2.14 Comments provided to support responses to question 2.3.3: Are you examining the draft decisions referred to all Member States and ECHA in order to potentially make a Proposal for amendment?

Comments
In cases our MS is somehow concerned
Very limited resources, focus on similar substances or similar endpoints than our CoRAP substances
Only if there is special national interest
Due to our lack of resources we focus on specific substances. We first screen the DD looking for difficult cases. If we consider that it is a clear case we do not follow with the examination.
We select draft decision for review based on our available internal expertise at the time of the MSCA consultation. We also review draft decisions where we feel we can learn from the approach taken by the eMSCA to improve our own SEv decision drafting.
In particular when the case is considered of national (health) relevance
It depends on our resources available, on the endpoints addressed, and on the Member State responsible for the SEV dossier. Tricky in the SEV process is that if the evaluating Member State concludes that there is no concern, other Member States are not having the opportunity to check this conclusion.
We examine the DDs for substances of National priority.
Substances of national interest; endpoint - reprotoxicity, endocrine MoA; significant exposure to consumers or professionals

Comments
Subject to resources availability, we tend to focus on substances with endpoint requests concerning reproductive toxicity and endocrine disruption.
We would welcome the renewal of the earlier practice when it was possible to send comments and not only PfAs.
We initially look at the spreadsheet listing the information being requested and have a quick screen of the draft decision. We will focus on requests for vertebrate testing to ensure we agree with the justification. We will also look for opportunities to propose a tiered approach to any requests.

2.3.4. Please provide your views on the challenges experienced with the following processes and on how you resolved them (in your role as eMSCA and eMSCA expert at MSC):

a) When answering the proposals for amendment (PfAs) received

Responses provided to this question were open and are presented in table below. Most of them identify their key difficulties as the short deadlines involved at this stage, and the fact that PfAs can sometimes be unclear, not properly justified or contradictory which takes time in the preparation of the "Response to comments" (RCOM). In the latter case it is mentioned that initiating informal contact with the Member State who submitted the PfA was helpful, even though time limitations and the fact that this occurs during the summer period are highlighted as a problem for such contacts.

Table C2.15 Responses to question 2.3.4: What challenges have you experienced when answering the proposals for amendment (PfAs) received?

Comments
If PfA is not completely clear, informal contact was initiated with the MS who submitted the PfA (but problem with limited time available)
The challenge is the level of detail for the replies.
It can be difficult to fully harmonize the answers in the RCOM with the amendments in the draft decision if the documents are not prepared in parallel. It is difficult for experts to be always aware which documents are available for the registrants and to answer accordingly.
Very case specific and not possible to generalize.
Lack of time to answer some amendments and to decide on the test required. This problem is bigger if the amendment is outside the scope of the DD
Usually the PfAs are focused on the issue of concerns; in those cases it is grateful to receive comments. A problem raised when comments from human health are provided regarding the PBT and expertise in HH are needed.
The lack of time (10 days is not enough, especially during summer time or when there are national holidays) - Due to lack of time, prefer to send the RCOM alone and postpone the submission of the amended DD to after answering the comments from registrant(s) on PfAs. But if this is done this way due to lack of time, it means that the response to comments are actually not finalized and that the DD may evolve from what was said in the RCOM. - What should MSCA and ECHA do when RCOM from eMSCA are uploaded on CIRCA BC? On the contrary to what is established with registrant(s), there is no commenting period for MSCA/ECHA on PfAs. It seems that exchanges with MSCA/ECHA (such as trilateral discussions) are not expected in the procedure before the MSC to try to reach an agreement and close open points. Note: trilateral discussion would need guidance (should eMSCA contact MSCA/ECHA, or the opposite), more time and a template to record discussions. And please note that we found it difficult to know which documents need to be submitted before the 30-days period for MSCA/ECHA to provide PfAs. Maybe need to clarify the guidance (SEv Instructions for MSCAs (v1.2))?
Sometimes the PfA is not clear or the rationale for the proposed amendment is not clear. In this case we have contacted the MSCA who provided the PfA to clarify it. This worked for us.
It is really important to contact the Member States submitting the comments to make the process run more smoothly in particular when conflicting PfA are given.

Comments
To have the relevant experts available in the specific short period.
It is challenging to fully understand the arguments supporting the PfA and to confirm that all PfA/comments were answered. It would be helpful to have the proposals numbered.
1. Meeting short-deadline has been a great challenge. 2. PfAs without complete justification are difficult to include in the DD.
As eMSCA we received PfAs with different opinion, so it was not possible to avoid discussion at MSC. We investigated / analysed the PfAs received and accepted / not accepted accordingly. The challenging experience was when we received the contrary PfAs on the same issue from different MSCAs. That phase of SEv process is very time-stress.
Sometimes it was not clear what the PfA was. We would reflect this in the RCOM. It can be time consuming building up an argument against a PfA – especially when we do not think the request is justified and may be politically driven rather than based on substance specific scientifically sound concerns.

b) When amending the DD following the receipt of the PfAs and submitting it within the deadline to the MSC

Responses provided to this question were open and are presented in table below. Similar to what has been outlined in question above, short deadlines are highlighted as a key challenge. In addition, it is noted that there is lack of suitable instructions and guidance on the level of detail needed in the DD concerning PfA.

Table C2.16 Responses to question 2.3.4: What challenges have you experienced when amending the DD following the receipt of the PfAs and submitting it within the deadline to the MSC?

Comments
When addressing the PfAs in the draft decision, the level of detail needed in the DD is not always clear.
The tight deadlines are always a challenge, especially if several expert units are involved.
See above It´s always a challenge to find the right level of details to reflect PfAs and registrants 'comments in the draft decisions.
Very case specific and not possible to generalize.
This process is linked to the previous question so there is short time to decide and proceed.
Phone meetings for previously agreement, before the MSC meetings, are very helpful.
PfAs and comments on PfAs from registrant(s) may trigger important changes, difficult to do it properly due to lack of time - Difficult to know to which extent the PfAs/comments on PfAs need to be reported in the DD. Considering that the DD is amended with track changes, is it sufficient to add the sentence "PfAs were submitted from MSCA X and the DD was amended/but the DD was not amended" in the concluding paragraph of the corresponding endpoint? Or should all modifications be introduced by a sentence on the corresponding PfA/comment on PfA?(the second option may dilute the information). Need more guidance? - If the numbering of the requests in the DD is changed following PfAs, should the numbering also be changed in the RCOM?
The main challenge is the short time frame to amend the DD. We have tried to ensure the required internal resources are available to complete any required amendments to the draft decision.
Very short deadline when amending the DD for WP
If a PfA is not sufficiently comprehensive/detailed it is difficult to include the proposal in the DD.
1. Short-deadline. 2. Lack of suitable instructions/guidance.
We acknowledge the PfAs from MSCa and ECHA for improvement of DD. See also answer above.
If the PfA is simple and/or we agree with it the amendments are relatively simple. If we disagree with the PfA we would not amend the DD at this stage, just complete the RCOM. We agree the deadlines are tight and a problem could be availability of key staff but we consider the timeline and take this into account when booking a specific MSC meeting. We

Comments
do question the need to include details of the PfA and how it was taken into account in the DD when we have already produced the RCOM document that could be appended to the decision.

c) When incorporating the registrant's comments on the PfAs in the DD

Responses provided to this question were open and are presented in table below. Similar to what has been outlined in questions above, short deadlines are highlighted as a key challenge, particularly in cases where decision in written procedure is envisaged. The challenge is to decide to what extent the comments should be reflected in the DD, especially when these are numerous, contradictory and complex as this can make the DD non-readable. Further guidance on the level of detail needed would be welcomed.

Table C2,17 Responses to question 2.3.4: What challenges have you experienced when incorporating the registrant's comments on the PfAs in the DD?

Comments
Very limited time available if the written MSC procedure is targeted. Level of detail needed is not always clear.
Level of detail: When numerous and voluminous comments were made it was sometimes difficult to maintain a clear and readable decision.
Very challenging timeline if decision making in written procedure is envisaged. See above
Very case specific and not possible to generalize.
Since there is no limit of time we consider it less challenging.
Sometimes additional information is included with no very much time to inform on the modification of the DD, without possibility to inform the MSC on the changes.
We have agreed to take into consideration registrant's comments after the dead-line, and need to balance on to what extent comments that do not bring crucial information to the decision need to be reflected in the decision.
We have agreed to receive registrant's dossier updates after the deadline and need to balance on to what extent data that do not bring crucial information to the decision need to be reflected in the decision.
Difficult to report the registrant's comments when he merely repeated the comments already provided in the first commenting period. - Difficult to report the registrant's comments when he comments endpoints rather than PfAs. - Registrant(s) have 30 days to comment the DD then again 30 days to comment PfAs. And MSCA/ECHA have less time (only 30 days)!
We understand the importance to incorporate clearly and transparently the comments of the registrant and the reason for agreement or no agreement since the do not have access to the RCOM.
The challenge is to decide to what extent the comments should be reflected in the DD
The extension of the text needed to respond to the registrant's comments is difficult to determine, especially if the registrants have made long comments on the PfA.
1. Short-deadline. 2. Lack of suitable instructions/guidance.
It depends on the PfA. Sometimes the decision can get very cumbersome if there are differences of opinion.

d) Regarding the above tasks please indicate:

Was the Webex with MSC and its timing helpful when amending the DD following receipt of PfAs?

Ten of the Member States that have provided their views on Webex agree that it can be a useful tool for the preparation of an upcoming MSC meeting as it enables a better understanding and an opportunity to discuss

member's positions and the reasoning behind PfAs. This is particularly useful when the eMSCA and the MSCA who wrote a PfA disagree.

Nevertheless the following observations were also made:

- Two MSCAs have argued that it would be preferable if the date of the Webex was prior to the deadline to send the amended DD to ECHA, in order to allow time to amend the DD based on the PfA explanation provided in the Webex.
- One MSCA notes that that Webex is only needed when there is disagreement between the eMSCA and the MSCA who wrote a PfA and the DD will only get amended at the MSC meeting following further discussion. In these cases the Webex might be good to explore acceptable compromises and work on amendments before the meeting.
- To be useful, the MSCA submitting the PfA's should always participate in the Webex and this is not always possible. Therefore participation in the Webex of MSCAs should be encouraged by ECHA. In particular it is suggested to set the date or time well in advance (maybe built into the timeline) to help planning and ensure maximum availability of the key parties.
- Another MSCA notes that both open and closed questions should be clearly defined in the Webex. *Sometimes silence regarding the acceptance of a response to a PfA makes the eMSCA have to be prepared for the meeting and this is unnecessary and a waste of time*.

What elements will you consider next time (or suggest) to facilitate this part of the SEv process?

Most respondents have interpreted this question as related to how to facilitate and improve the Webex (these have been integrated in the above analysis). Additional suggestions are summarised below:

- *RCOM should be made available to the registrant and more time available before written procedure.*
- *The actual assessment of a substance is recorded as clearly and comprehensibly as possible so that the answers to PfAs or registrants' comments can be taken from there*.

2.3.5. Please respond to the following questions regarding the MSC meeting (in your role as eMSCA and eMSCA expert at MSC):

a) What were the main challenges that you were faced with e.g. during the redrafting of the DD, plenary discussions, negotiations etc., and how did you resolve them?

Responses provided to this question were open and are presented in table below. There is a variety of aspects that have been raised by the respondents. One recurring aspect is the time pressure during the meeting, which can be particularly challenging when there are contradictory PfAs or new comments are raised, making it difficult to achieve an agreement. Another challenge appears to be related with the fact that many of the specific experts for the discussed requests cannot attend the meeting or only some of the discussions (i.e. just stay a few days), thus making it difficult to provide immediate feedback or to reach agreements if the discussion extends in time. With regards to this, it is suggested that it could be useful to limit the discussion and the agreement on specific cases to a few days in order to ensure the presence of experts.

Table C2.18 Responses to question 2.3.5 (a): What were the main challenges that you were faced with e.g. during the redrafting of the DD, plenary discussions, negotiations etc., and how did you resolve them?

Comments
Many changes in the draft decisions within the meetings, discussions with experts have to be reflected in the meeting
Many of the experts who have been involved in the evaluation are not present at the meeting. Hence, it can be difficult to provide immediate detailed feedback when discussions become very technical.

Comments
The eMSCA prepared a detailed list of requirements and sent it to the Industry in the first 2 months after the beginning of SEv. Industry fully conformed with the eMSCA requests. Therefore no DD was prepared and a conclusion document was developed.
It is a challenge to discuss with countries responsible from the PfAs, that have each other different views and sometimes the lack of flexibility makes negotiations stressful. It is very difficult sometimes to get an agreement.
It is very difficult to cope with the task if only one expert attend to the meeting, since there are many activities to do at the same time (including comments, attend the meeting, redrafting, discussions...)
First a remark: The detailed explanations from ECHA MSC secretariat at each step, reminding us the working procedure (including informal one) and timeline, is really helpful. Thank you! Much appreciated. It is really challenging to follow the discussions and redraft at the same time. The MSC week is really tiring with a never-ending discussion until the last day. Very difficult to deal with very late comments from an MSC member (like on the last day, or after everything has been already agreed). Nevertheless we are gaining more experience...
As eMSCA expert, we have no experience since our previous decision was agreed by written procedure/decision making was terminated due to cease manufacture in accordance with Article 50(3).
The discussion on SEV cases is diluted throughout the meeting and is difficult to have the specific experts for more than two days. It could be useful to concentrate the discussion and the agreement for the specific case
You cannot predict which point will arise for discussion during the MSC meeting. Then you should always be ready.
- Dealing with comments from Member States that had not provided a PfA - Legislation versus science - time pressure during the meeting (it might take until day 2 of MSC before it is clear whether the DD has to be changed and in which direction
The main challenge during MSC meeting was the negotiation since we had contradictory PfA and several MSCA making PfA for the same endpoint. The redrafting of the DD was also difficult due to time constrains and because it was dependent on the negotiation.
Drafting of extensive new text under time pressure e.g. related to justification of rejection of grouping and read-across - we resolve this with ECHA extensive involvement but late in the process. Brief standard text on how to deal with such "endpoint" could be included in the guidance for MSCAs; - dealing with different views on how to request data on mutagenicity in the tired approach (all in one DD or consecutive evaluations) - we resolved this by preparation of options with pros and cons for discussion. Again some proposed standard approach could be discussed and included in the guidance.
Comments based on less science and more conjecture create difficulties and had to be resolved with unintended compromises.
Main challenges during redrafting of the DD - time-stress phase of SEv, some PfAs were contradictory (e.g. different opinions regarding requirement on PNDT study on the second species).
One of our issues in the past was poor management of the breakout meetings and not knowing when the substance was going to be discussed in plenary however, there have been changes made and the sessions are now much better managed. The discussions are often between a small number of MSCAs only and they can have a disproportionate influence on the final agreement. Many MSCAs do not take part in the plenary discussions or breakout groups and so it is difficult to gauge which way a vote would go. It can be quite difficult to calmly explore possible solutions when there are extreme differences of opinion, particularly if one is adamant there is no room for compromise. Having good mediation is often necessary and the involvement of the chair and legal team in these discussions has helped agreements to be reached. Sufficient time should be available for discussion between the MSC member and the expert to react to any new proposals and agree an approach.

b) Did you feel that you should have had more national experts from your side in the meeting, but which you did not realise when you were preparing for the meeting?

15 respondents have provided their views on the subject. Of these, only three respondents agree with this statement and affirm that they felt they should have brought more national experts to the meeting when they were already there. In addition there are four Member States that note that it would have been better to have more experts present at the meeting, particularly in some cases, but that it is not possible to bring all involved experts to ECHA. Finally, five MSCAs indicate that this was not an issue for them. In particular, one notes that they would plan to have the appropriate experts available – either at the meeting or by phone.

Another one responds to this question by noting that it is necessary that the experts for the discussed requests can follow the meeting but does not specify if they had any problems.

In addition, one respondent notes that *a Memorandum of Understanding is needed with national experts, especially on the occupational exposure issues, as well as other research institutes.*

c) Do you think that the support offered by ECHA has been appropriate (substance manager, endpoint expert, and legal expert support)?

Of the 15 respondents with a view on this question, almost all (14) have confirmed that the support provided by ECHA has been appropriate and essential to complete the work, with most of them saying that it is highly valued. In particular, the legal support provided by ECHA is very appreciated by respondents to improve the consistency of the DD, as this is an area where they have less relevant experience. Only one stated that the appropriateness of the support depends on the specific case.

d) What are the lessons learnt from MSC meetings?

Responses provided to this question were open and are presented in table below. There is a variety of aspects that have been raised by the respondents. One recurring aspect is the importance of having a text prepared beforehand, considering different options for the DD already identified based on the PfAs to allow a more efficient redrafting at the meeting. Informal communications with the MSCAs submitting PfAs before the meeting is also recommended by several respondents.

Table C2.19 Responses to question 2.3.5 (d): What are the lessons learnt from MSC meetings?

Comments
More than 1 expert needed (plus MSC member). Good and detailed preparation needed + informal contact before the meeting with PfA submitters can be useful. The presentation should focus on the main issues and these should also be presented during the Webex as preparation for the meeting.
It is important that the lessons learned in the meeting discussions are communicated to all experts for future discussions, that´s often challenging due to the DE structures
Good preparation is essential. Don't expect much sleep....
When concerns are scientifically substantiated, cooperation is more easily achieved.
When you are an eMSCA, MSC meetings can be really extenuated. There is a big pressure of time to get an agreement between quite different opinions. It is also important to draft properly the DD and sometimes it is done without enough time to reflect on it.
Legal issues, and consistency of the document, are also relevant for the DD. It is a very intensive and hard work.
It's a very challenging and tricky part.
It is always possible to find compromise between different parties.
It may only become clear at the MSC meeting what the reason behind a certain PfA was. E.g. because there was no prior contact between the eMSCA and the CA that submitted the PfA. It helps to have contacts established in the very early phase of the MSCA consulting round.
The importance of the negotiations with other MSCA during the meeting but also prior to it. Additionally it was important to have a text prepared beforehand, considering different options for the DD already identified according to the PfA to allow a more efficient redrafting. In addition of the support provided by substance manager, endpoint expert and legal expert support it was relevant the support provided by the MSC Chair and Secretariat.
Prepare several options in line with different PfA (present pros and cons) to facilitate discussion and conclusion; - clarify views of other MSCAs and their PfA before the meeting (before and after WEBEX)
1. Based on the PfAs, it is good to be ready with alternate text that can be used in redrafting the DD at the meeting. 2. Informal communications with the PfA submitting MSCAs before the meeting are of great help.

Comments
The MSC agenda is large and complicated. The better, more precise preparation work on possible alternatives of DD before the MSC meeting the more effective discussion during the MSC
Unless there is only a minor issue to be resolved, as the eMSCA we have found that it is necessary to have a specialist attend the meeting specifically for the substance discussions and for drafting any amendments and appreciate that ECHA pay for this person. In some cases it may be possible to explore the potential outcomes of the discussions beforehand and have prepared some possible text for inclusion in the DD. It would be easier if certain issues could be closed off prior to the meeting – for example in a written procedure which would not get discussed further. This would increase efficiency and potentially reduce the need for multiple experts. However consideration would have to be given to the current ECHA policy of not inviting registrants to attend the MSC if their substance has gone to WP but then is stopped. It would also be useful to close particular issues during the meetings once resolution on them has been reached; our experience is that certain MS persist in raising issues even though it seemed that they had been decided.

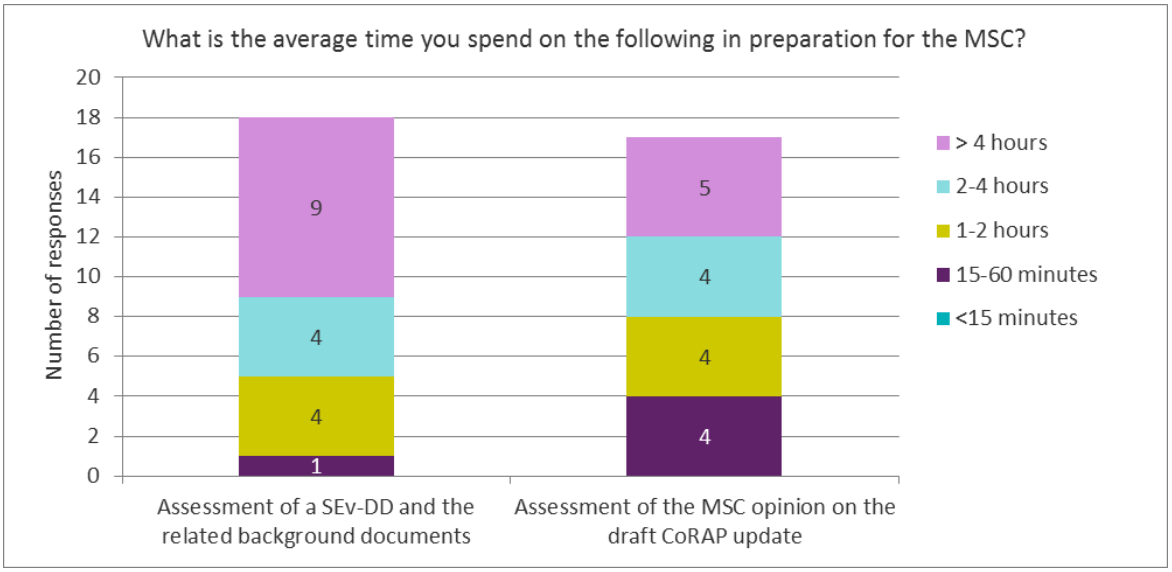
2.3.6. For MSC members only: What is the average time you spend on the following in preparation for the MSC? Please provide further commentary at the foot of the table to indicate whether regarding the CoRAP update you have responded from the perspective of the rapporteur or a WG member.

Although this question was addressed to MSC members only it has been also responded by some MSCAs, totalling 18 respondents.

Assessment of a SEv-DD and the related background documents generally takes on average more than 4 hours as reported by half of the respondents (50%). Only in one case this exercise is reported to take less than one hour. One Member State notes that the time spent will depend on a number of aspects including the number of substances on the agenda and the related PfAs and the level of involvement of the MSC in any of them.

On the time spent on the assessment of the MSC opinion on the draft CoRAP update, answers have been balanced with an equal number of respondents (4) indicating that this can take between 15-60 minutes, 1-2 hours or even 2-4 hours, and five stating that more than 4 hours are needed. Clarification on whether this answer was provided from the perspective of the rapporteur or the WG member is only provided by one WG member and one Member State with both perspectives.

Figure C2.14 Responses to question 2.3.6: What is the average time you spend on the following in preparation for the MSC?



This question also asks if other people in its organisation spend time helping the MSC member to prepare for the MSC meeting. Almost all respondents (18/19 or 95%) respond affirmatively that the MSC member is aided by relevant experts with specialist knowledge (i.e. endpoint specific experts, or previously involved in the DD). These can be internal staff and external scientific advisors (as reported by one MSCA). Only one

Member State responds that the MSC member is not supported by other people within his organisation but no further details are provided.

2.3.7. What is your view on the following aids in preparation for decision making and opinion forming? (in your role as MSCA/MSC-member).

The survey indicates an overall positive view among the MSCAs/MSC members regarding the different aids provided by ECHA for decision making. In particular, ECHA´s legal support and the role of the substance manager seem to be the most appreciated, with 22 respondents out of 24 indicating that it should continue as it is. Also the Chairman's notes and its involvement in discussions as well as the written procedures are highly valued. Some respondents have made some suggestions to improve some of these aids, particularly concerning the Webex and the direct interaction between MSC members, which are summarised in table below.

It is of note that none of these have been identified as being a waste of time for everyone. Only a few have noted that certain tools were not relevant for them.

Figure C2.15 Responses (number) to question 2.3.7: What is your view on the following aids in preparation for decision making and opinion forming?

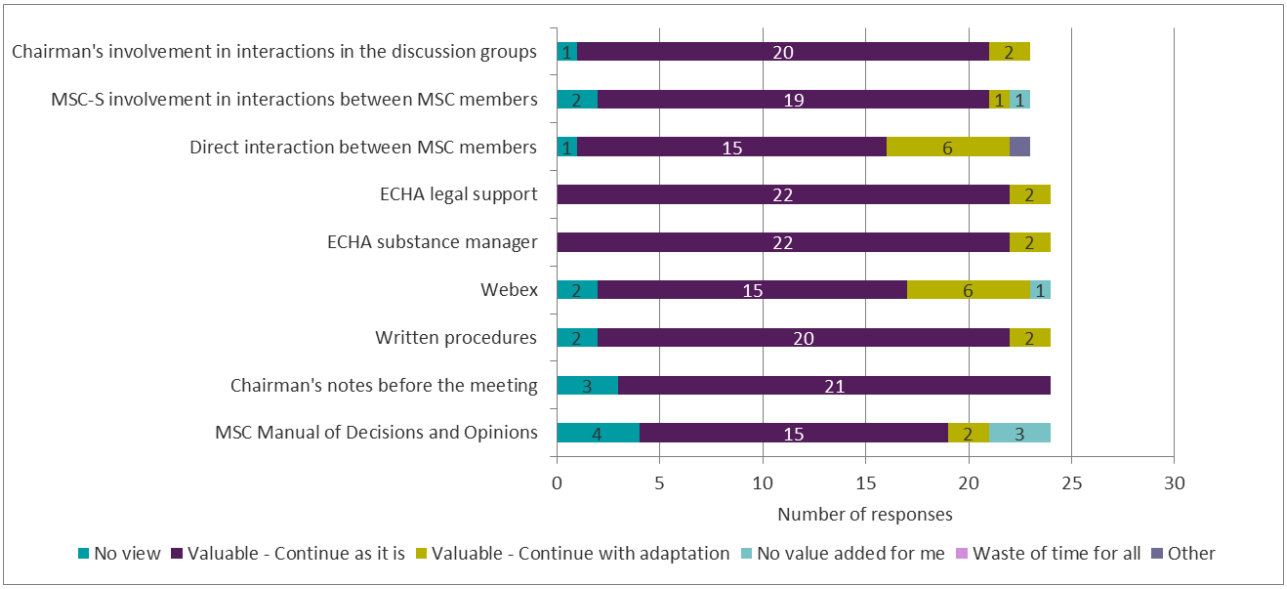


Table C2.20 Comments to question 3.3.7: What is your view on the following aids in preparation for decision making and opinion forming?

Statement	Comments
Webex	• *The Webex helps in understanding the reasoning behind a PfA. If an MSCA has additional information that it will use in either the Webex or its intervention in MSC it could be useful if it would share this prior to the Webex (e.g. literature, data, graphs etc.).* • *The Webex date should be communicated very early in order to allow MS experts to look f they are available and to decide which meeting can be envisaged for decision making.* • *Please indicate well in advance the times for Webex meetings (in preparation for the MSC meetings).* • *Aim of the Webex presentation should be clear: Is it to inform members of the main issues or is a detailed discussion and a way forward already expected? If PfA submitting MS is not present, then the Webex discussion is not very useful.* • *Sometimes the Webex can seem like a waste of time. There are times when no real debate takes place and MSCA simply re-state the positions in their PfA however, information gained here can be a sense of how strongly a PfA will be fought for at MSC. Additionally there could be benefits for MSCAs that have not been involved in the case to hear the issues. Occasionally those MSCA making a PfA cannot be present and in these cases the debate should be cancelled or curtailed.*

Statement	Comments
	• *Clear results from the Webex should be achieved to discuss in the meeting only remaining concerns and to know when the MS responsible form the PfA accept the RCOM.*
Chairman's involvement in interactions between MSC members	• *Do not accept very late comment/disagreement i.e. when the discussion/redrafting of the DD are almost over.*
Written procedures	• *The written procedure is really important to avoid unnecessary discussion at the MSC and to allow the discussion of other cases. However when a MS would like to propose a WP for a SEV case there is really little time available for drafting the DD and includes all the details in a transparent mode.* • *It would be useful to have some criteria for selection of substances for WP. Currently it seems to be down to the eMSCA's ability to amend the DD, taking into account the registrants comments on the PfAs within the tight timeline set. Where PfA have been made and the eMSCA agree, then this is an obvious candidate for WP. However, other MSCA may not agree with the PfA and stop the process in order to have a debate at the MSC. In order to potentially increase efficiency at the MSC meetings all SEv decisions could be put to WP to allow issues to be closed before the meeting. Obviously consideration should be given to allowing registrants to take part in MSC discussions on these substances, which is not currently the case. This would increase transparency.*
ECHA legal support	• *In general the ECHA legal support is excellent; it has improved over time and continues to learn. However there can be times when they fail to grasp the science or complexity of an issue and their interventions serve only to confuse the issue. A better appreciation of the science is needed.*
Direct interaction between MSC members	• *Interaction between MSC members and national expert is supported and important, but should be based on members´ and experts´ suggestions.* • *Direct interaction between MSC members - more focus on preparatory exchange of views before the meeting to make the meeting discussions limited to not resolved issues, more predictable and better prepared;* • *Only one MSC member responded on informal communication initiated by eMSCA.* • *Secretariat should promote the interaction. Sometimes there is no response from the contacted member.*
MSC Manual of Decisions and Opinions	• *MSC manual of decision could be very valuable but needs updates with entries that have been well discussed. Perhaps some working document listing the endpoints under discussion and the reference to the relevant cases could facilitate inclusion of entries to MoD?* • *Regarding the MoD, greater use with more entries could be valuable.* • *This has the potential to be of use in the future as it captures more of the key decisions and precedents* • *We note that the MSC manual of decisions currently contains only one entry relating to substance evaluation. While we could support the more frequent update of the manual of decisions with respect to substance evaluation, we consider that the ongoing work by SEV DD working group to establish best practice for SEv draft decisions may be more useful for eMSCAs.*

2.3.8. Please respond to the following questions regarding the written procedure (in your role as MSCA/MSC-member):

a) What is the average time you spend per case in preparation for written procedure voting?

Information on the periods of time provided by the Member States is summarised in the table below. The majority of Member States reported that the mean period of time for the preparation of the written procedure voting ranges from between 15 and 30 minutes to up to 4 hours. Two Member States indicated that this process could last up to 1 working day, depending on the complexity of the dossier, and one reported a period of 7 days for the rewriting of DD, though only 3 hours of this time would be spent by the MSC member on preparing for the vote. A few Member States note that this will depend on the specific case.

Table C2.21 Responses to question 2.3.8 (a): What is the average time you spend per case in preparation for written procedure voting?

Comments
30 minutes
7 days (rewriting of the DD) as MSCA 3 hours as MSC member (vote on other dossiers)
0,5 - 2 hours, it depends very much from the PfAs and the expertise necessary
One working day (including downloading the docs and spotting/reviewing the issues and as appropriate making comments (PfAs or comments to WP)
Case-by-case, not measured so far.
More than one day per substance depending on the complexity of the dossier.
It depends on the number of cases and their difficulty. It could be 3-4 hours.
1 - 4 h
Max 2 hours
30 minutes
It depend from the complexity of case
1-2 h
ca. 1 hour
ca 15-30 minutes for cases relatively easy to understand from the Chairman notes; ca 1-2 h for very limited number of cases when there is a need to read DD/RCOM or seek internal consultation;
It depends on the case.

b) Do you have suggestions for efficiency and/or effectiveness improvements of use of Written Procedures in MSC decision making?

Some respondents had made a variety of propositions for the efficiency and/ or effectiveness improvement of the use of written procedures. All the proposals are listed below except where suggestions have already been provided in response to question 2.3.7 above.

A suggestion proposed by several respondents refers to the fact that Chairman's note for written procedure could be further elaborated with even more details to help efficiency. Also a few stakeholders consider that it would be useful to have some criteria for the selection of substances for written procedure.

Table C2.22 Responses to question 2.3.8 (b): Do you have suggestions for efficiency and/or effectiveness improvements of use of Written Procedures in MSC decision making?

Comments
Chairman notes should highlight the topics where the DD was reviewed and summarize the rational.
No suggestions for improvement, except perhaps try to make as much use of the WP as possible.
More time for drafting the DD should be given to the eMSCA
It is not clear what the selection criteria are for the WP. Sometimes very difficult cases are referred to the WP and easy ones to the plenary meeting. It might help to communicate about or discuss the selection criteria with MSC.

Comments
Chairman's note to written procedure is important. Could be further elaborated with even more details to help efficiency.
The WP is a useful tool for SEV decision making. However the deadline given to eMSCA to decide to use the WP is very short (5 days) and in some cases is shortened for calendar constraints, and therefore its use is very limited.
For some cases the Chairman notes for WP could be slightly more detailed but difficult to give a specific example right now.
Use of Written Procedures in MSC decision making for most of DDs and to focus discussion on problematic points at MSC meeting.

2.3.9. In the MSC-meetings do you find the newly introduced structure of 10:00 – 17:00 for plenary timings, with separate discussion groups early in the morning or in the evening a good way for efficiently achieving unanimous agreement on draft decisions (in your role as MSCA/MSC-member)?

All of the 21 respondents that provided a view on this question agree that the newly introduced structure of 10:00 – 17:00 for plenary timings is a good way for efficiently achieving unanimous agreement on draft decisions. In addition some respondents have provided further insight and suggestions on the subject, as follows:

Table C2.23 Responses to question 2.3.9 (a): Do you find the newly introduced structure of 10:00 – 17:00 for plenary timings a good way for efficiently achieving unanimous agreement on draft decisions?

Comments
A definitive agenda would be welcome to be able to arrange one day-participations of experts.
My experience has been that it can be problematic with several working group meetings going on in parallel when I´m alone representing our MSCA because more than one case may be of importance/interest for us (e.g. of principal nature) and because it´s impossible to be at two places at the same time. But I also realize that as long as ECHA pays for possible attendance of also an expert this is perhaps more a critical remark to our MSCA than to ECHA.
There is now a clear time slot available for a more in-depth discussion of a case, without risking missing the plenary debate on another subject.
Having the discussions structured to make sure all the key players can attend the relevant discussions is a big improvement however in some cases just having 30 minutes is not sufficient to make progress in the resolution of issues. Perhaps there should be more effort put into arranging informal discussions prior to the meeting to try to explore potential compromises. Where there is a need to have experts on the phone consideration should be given to the time difference and where possible discussions involving them should not be scheduled for the morning slots. A downside of this structure is that although the members not taking part get a brief verbal update they do not necessarily appreciate how the discussions have evolved and what options have been proposed and dismissed.

2.3.10. Please respond to the following questions regarding the organisation and role of the MSC (in your role as MSCA/MSC-member):

a) Do you have suggestions for improvements in the way the Chairman chairs the meetings?

In general there is a very positive view among the MSCAs/ MSC members regarding the way in which the Chairman chairs the meetings, with 10 out 14 respondents responding that they have no suggestions, and most responding with a positive view on his job. Only a few suggestions were made as presented in the table below:

Table C2.24 Responses to question 2.3.10 (a): Do you have suggestions for improvements in the way the Chairman chairs the meetings?

Comments
If same arguments are repeated, then the discussion in plenary should be closed, it is more efficient then to work in break-out groups. Positions of different members should be requested earlier (to know about majority view).
It would be beneficial to stop earlier some discussions
In general all is fine. Could possibly limit the discussion time of some members, but acknowledge that can be difficult and the discussions are often needed. It can be difficult for MSC members whose MSCA did not submit PfAs to participate in discussions, but not sure that much can be done about that.
Discussions based on hypotheses not backed by valid reasoning should not be encouraged.

b) In your experience what can/should be improved in drafting revisions on DDs at the MSC meeting?

Some respondents had made a variety of suggestions on how to improve the drafting revisions on DDs at the MSC meeting. These are presented in table below.

Table C2.25 Responses to question 2.3.10 (b): In your experience what can/should be improved in drafting revisions on DDs at the MSC meeting?

Comments
No redrafting in the plenary!
Perhaps we participants - and also ECHA-S -. should try to develop clearer structure for discussing "hot issues" at WG meetings outside plenum, i.e. the first evening for going through all vital issues and presenting all arguments pro et contra with alternative solutions - and then the second evening the eMSCA (SEV cases) or ECHA-S (DEV cases) should go through the case step by step summarizing the sub-groups previous discussion argument by argument / topic by topic and then making conclusions on how they based on each intend to come to a final draft decision text to be presented to the whole MSC. ECHA should instruct MSC to participate in WG meetings if they have particular interest in the case with the purpose to clarify all controversial issues before returning to plenum. If a MSCA is only represented by one participant who cannot participate in parallel on-going WG meeting ECHA should before plenum consult with that MSC participant who did not participate in the WG meeting (because of his attendance in another WG meeting).
The separate discussion groups have reduced the need for on the spot drafting. This has been an improvement and should continue. The process could be speeded up a little, as some decisions can take 3-4 days to agree with a small amount of progress reporting during that time.
The current practice is that members that expressed a clear interest in a case are informally consulted before a new version is uploaded to circabc. This works quite well in practice and could be continued.
ECHA should continue to give legally and scientific advice regarding the drafting the revised DD during the MSC meeting.
Should be drafted in small group consisted of interested parties.
Please consider discussion on the SEV DD searchable via endpoint database that format has been proposed and tested for several cases by the SEV DD working Group. This could be a useful tool for drafting as it would facilitate finding "reference" cases. Even development of standard structure or text for some requests would facilitate drafting of revisions. The drafting based on PfAs should be discussed and optional texts prepared before the meeting.
Members suggesting revisions could also help with providing the text to be used in DD.
All activities are performed according to REACH. Existing REACH time-limits prevent the improvement of evaluation activities.
Often new drafts are uploaded onto CIRCABC overnight and there is no time to look at in detail. Experts at home may not be at work when agreement is needed. Sometimes it is difficult to keep up if there have been a number of revisions although it is improving.

c) What can MSC-S stop doing? What may MSC-S start doing?

Only two respondents have provided a suggestion with regards to actions of the MSC-S, with most responding that they have no suggestions on what should be done.

- *In the past there were quite a number of presentations which were informative but not always very urgent (e.g. about the status of SEV, DEV, etc.). These are now usually submitted as 'information document'. That saves valuable meeting time. It could be explored if the presentations given as an introduction before the start of a debate are shortened too, by leaving out the 'administrative' info such as timeline, history etc.*
- *To improve interaction between MSCAs.*

2.3.11. Do you have any suggestions on how to improve the transparency of the decision making process to Stakeholders?

Only a few stakeholders have made suggestions on how to improve the transparency of the decision process. These include the possibility of sharing with the registrants the RCOM to PfAs (two respondents) as well as limiting closed sessions as much as possible (another two respondents). One Member State notes that the transparency of the process could be improved by informing registrants of the start of the consultation of the DD to the MSCA/ ECHA, so that they are aware of the start of the 30 day period for the registrants to comment on the PfA beforehand.

In addition, a couple of stakeholders have explicitly indicated that the level of transparency is enough and should be kept as it is.

C2.5 Responses related to the follow up evaluation and taking the conclusions

2.4.1. For eMSCA only: After the SEv decision registrants submit the requested information. What challenges do you envisage before concluding on the substance and in drafting the conclusions?

Very few respondents (12) report difficulties drafting the conclusions for substances and drafting the decision after registrants have submitted the requested information. In this sense, most note that they have little or no experience yet on this stage of the process. Six of the respondents that provided further detail to their answer identified as a key challenge the fact that delivered information is not what was requested. Comments elaborating on problems to both aspects are displayed in the following table.

Table C2.26 Responses to question 2.3.11 (a): What challenges do you envisage in concluding on the substance after registrants submit the requested information? And in drafting the conclusions?

Comments
Before concluding: *No automatic warning that the update has been received. Delivered information is not what was requested --> problems with enforcement. Timing of updates, if the deadline is not respected it is very difficult to plan the work within the MSCA (too early or too late can both pose problems regarding planning).*
Before concluding: *Currently, there is still too little experience to answer this question. Nevertheless, first impressions show that a direct meeting with registrants is necessary because the missing information is not submitted as requested. Apart from that, the same comment as under 2.2.2 applies. The updated information may - in case of toxicological studies - be biased as no original study reports will be available. General workload for SEV due to possible piling-up of new and old SEV cases might be a problem. If information on uses and exposure is provided by some registrants only, it will be difficult to assess the risks from the uses that are supported by the other registrants.*
Before concluding: *To evaluate whether the submitted information is - in accordance with the request - sufficient to clarify the concern or whether new information is required - the nature of the required new information* ***In drafting the conclusions:*** *explaining each step mentioned above!*
Before concluding: *Enough time to evaluate the new data provided.* ***In drafting the conclusions:*** *Ways to incorporate the new data that may be confidential.*

Comments
Before concluding: *Sometimes the information requested is not provided by all the registrants* ***In drafting the conclusions:*** *Additional information has to be requested to clarify the provided information*
Before concluding: *If people who assess the substance are no more there/if there is a need for new information*
Before concluding: *We can envisage the following challenges: - Time/ resource constraints due to overlapping processes and deadlines. For example, even within substance evaluation work area a new substance evaluation (substance C) could be ongoing, decision making phase for a different substance (substance B) and evaluation of the requested information on another substance (substance A). In addition, our experts are also involved in other work areas. - Evaluation of an adaptation/waiving arguments submitted by the registrants to address the requested information requirement in the final decision. - Where additional concerns are identified or where there is an obvious change in circumstances following submission of the requested information which requires further evaluation and a possible second draft decision.*
Before concluding: *Informal contact should be maintained*
Before concluding and in drafting the conclusions: *Time limits and human resources.*
Before concluding on the substance: *If the DD as agreed in the MSC includes an information request for a new concern for which the eMSCA don't have the necessary resources, it will be challenging to evaluate this information and conclude about this concern.*
Before concluding: *1. Dossier updates not fully compliant with the information required by a Decision. 2. Several deadlines, e.g. for a substance with Decisions addressed to all the Registrant(s) and the Decisions addressed to individual Registrant(s).*
Before concluding: *Update of SEV report with new information will be time consuming.*
Before concluding: *Dealing with registrants that have not done exactly what was requested – if they have made unanticipated adaptations. How to incorporate information from new registrations into the evaluation – although this may not be an issue once the 2018 phase -in deadline has passed and the registrations completed. If there has been a complete rewrite of the CSR it may sometimes need to be completely re-evaluated which would need a lot of resource. We should consider how to minimise this activity.* ***In drafting the conclusions:*** *How best to include the additional information in to the existing SEv report. For human health exposure even though the calculated RCRs may be >1 the conclusion of the specialist may be that the way the substance is used doesn't actually constitute a risk or concern. It may be difficult to explain this.*

2.4.2. Do you think that the new format for conclusion documents and reporting on the substance evaluation will improve efficiency (in your role as eMSCA)?

Of the 15 respondents with a view on this question, most of them (12 or 60%) agree that the new format for conclusion documents and reporting will improve efficiency. Only three of them disagree with this statement and provide the following arguments:

- *It duplicates the work. May be it should be practical for new substances, but there is no need to re-write the SEv in a new format for those substances written in the old template.*
- *Efficiency has not been improved in our opinion, since the new format appears to simply be a fusion of the old formats for the SEv report and the conclusion document.*
- *It is difficult to say at this point. The actual format of the SEv report part has not changed significantly and it is flexible enough for the eMSCA to include as much or as little information as they like. It is important for all the relevant information to be reported and if this can be done in a concise way that is fine. We are however concerned that there may not be sufficient information included for us to make a judgement on whether requests made by another eMSCA are sufficiently founded. Efficiency will not be improved if we have to look at the registration dossiers to make our own assessment of the data or ask questions of the eMSCA.*

C2.6 Responses related to the interaction between eMSCAs and Registrants

2.5.1. Have you encountered problems in identifying the correct contact points for the SEv evaluation within the registrants?

More than half (70% or 14/20) of the respondents to this question noted that they have not encountered problems in identifying the correct contact points. One respondent notes that usually the lead registrant steps up to the task of acting as the contact point during SEv. The further comments supplied by the Member States where problems have been experienced (five respondents) note that these generally occur when the dossier is submitted as a joint submission and registrants are part of a consortium. It was also noted that where large numbers of registrants are involved in the process, a lot of manual searching in REACH-IT to obtain contact details is required. More detailed comments are listed below.

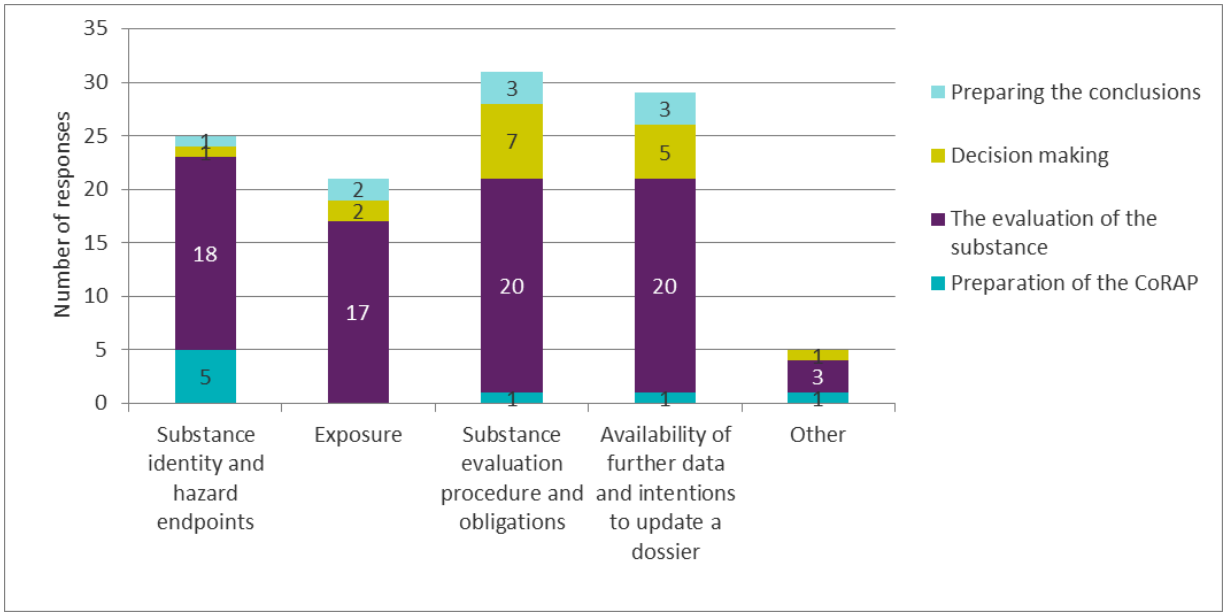
Table C2.27 Responses to question 2.5.1: Have you encountered problems in identifying the correct contact points for the SEv evaluation within the registrants?

Comments
In some cases registrants have been slow to respond and there has been suspicion of wrong contact information. REACH-IT alert does not work properly with us.
In the first instance we have generally contacted the lead registrant to request they act as the contact point for all registrants, in particular where there are a large number of registrants and the registrants are all part of the same joint submission. However, where some of the registrants within the joint submission are part of a consortium this can result in some difficulties. Also, large numbers of registrants requires a lot of manual searching in REACH-IT to obtain contact details.
In case if dossier is submitted as joint submission, not easy to find which registrant submitted particular information and therefore which of them we need to contact.
In general we have no problems. However, it is not always clear who is in the lead (joint submission, consortium, only representative).
Although we have not had problems identifying an e-mail address from REACH-IT &/or the registration dossiers it can be time consuming especially if there are a large number of registrants (we send an e-mail to all registrants at the start and ask that they agree to a single contact point). It would be useful if ECHA could send a communication (a letter written by the eMSCA?) to all registrants via REACH-IT.

2.5.2. Please specify if you have had informal discussions with the Registrants during the phases described below and the issues that these covered. Please tick all those which apply.

The eMSCAs appear to have had informal discussions with the registrants throughout all stages of the process, according to the 20 respondents who answered this question. The greatest number of informal discussions with eMSCAs were held during the evaluation stage according to 20 respondents. Thematically, the answers indicate that the four proposed issues seem quite equally frequent during those informal discussions at the evaluation stage. Discussions during decision making seem fairly common as well as they were experienced by almost half of the respondents (9). At this stage these discussions mainly covered procedural and obligational aspects and the potential availability of further information or dossier update. The results are displayed in more detail in the figure below.

Figure C2.16 Responses (number) to question 2.5.2: Please specify if you have had informal discussions with the Registrants during the phases described below and the issues that these covered.



Further comments by some respondents explain other issues that have been covered as part of these informal discussions:

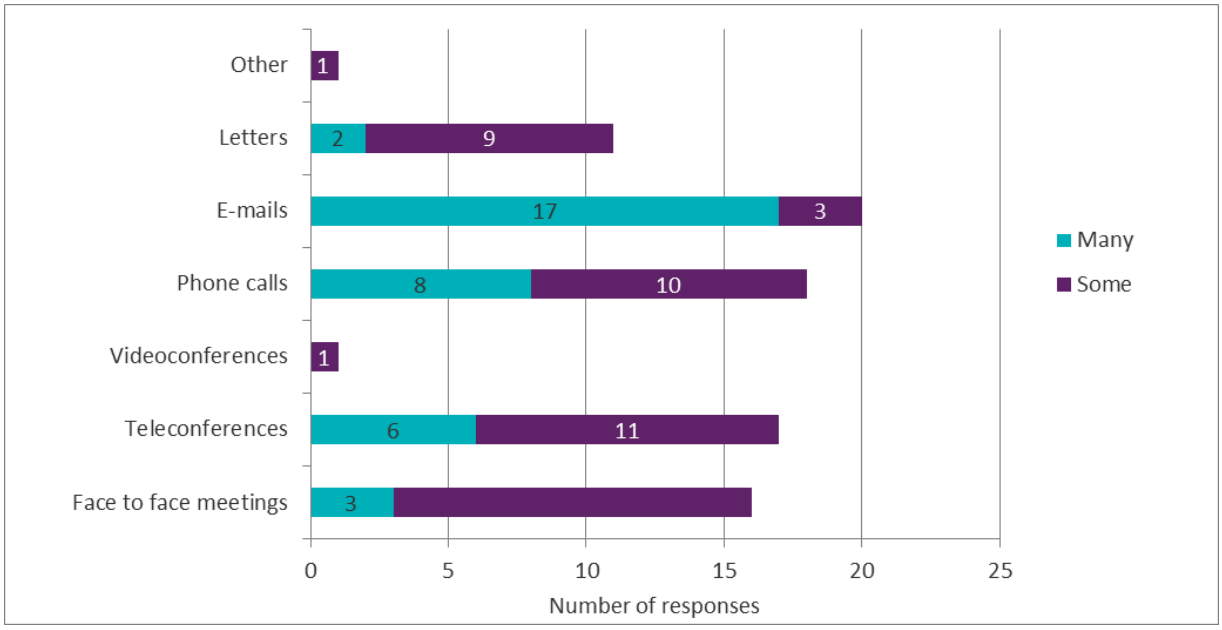
Table C2.28 Responses to question 2.5.1: Have you encountered problems in identifying the correct contact points for the SEv evaluation within the registrants?

Comments
Where we amended the CoRAP justification document for a substance which is already on the published CoRAP, we emailed the affected registrants to bring this to their attention so they could consider completing any planned dossier updates before the evaluation started.
Other: Clarification of comments sent by the registrant
During the evaluation of the substance the eMSCA asked the registrants for original study reports, which were kindly, provided.
We don't normally contact registrants during the preparation of the CoRAP. We have been contacted by registrants once the CoRAP has been published but postpone any detailed discussion until the start of the evaluation. We would discuss any of the above during the evaluation and decision making as appropriate. We have limited experience in preparing conclusions but have so far had informal discussions in both cases.

2.5.3. What means of interaction with the registrants did you use and how frequently?

The figure below shows the experiences of the respondents regarding frequent means of interaction with the registrants. Email is the most commonly used means of communication between registrants and MSCAs (20 respondents), with 17 respondents qualifying the number of emails as "many". Other common forms of interaction include telephone calls (18), teleconferences (17) and face to face meetings (16). However, fewer of these respondents claimed having "many" of such interactions.

Figure C2.17 Responses (number) to question 2.5.3: What means of interaction with the registrants did you use and how frequently?



In addition, two Member States provide further insight on the interaction process, as follows:

- *Registrants are offered a meeting to discuss procedural aspects of substance evaluation at the beginning of the evaluation year. Video conferences will be implemented if feasible. Further meetings in which specific questions which arise (from both sides) may be arranged if necessary. Exchange via phone, e-mail or letters during the evaluation year before or after the meetings to answer specific questions are used on a regular basis. In some cases, distributing questionnaires with further substance-specific questions among registrants has proven beneficial.*
- *We contact the registrants by e-mail at the start of the evaluating year and offer a meeting/telephone conference to discuss the evaluation. We outline what the evaluation will cover (especially if it is targeted), our timeline and the process in general. We give the registrants the opportunity to ask questions and we find out whether there are any updates planned, studies ongoing, imminent changes etc. that might impact on our evaluation. We will then communicate by phone &/or e-mail as necessary. In the first year we shared the draft report with the registrants during the evaluation period and at that point offered a second meeting/call to discuss. Following an informal agreement between MSCAs/ECHA not to share the whole report during this period we have changed to offering a discussion during the 30 day commenting period where we clarify the requests in the draft decision and share the main conclusions of the evaluation.*

2.5.4. If you reported interaction in the question above, please indicate did you consider this interaction useful and whether it helped you as the eMSCA to complete your tasks? In the comment field please reflect on whether there are any other elements you would like to comment regarding interaction with registrants? Do you have any suggestions to improve this process?

Almost all (19/20 or 95%) of the respondents agreed that the interaction with the registrants was helpful and aid the evaluation by providing additional information. Only one MS disagreed by noting that some uncertainties in the study report were discussed with the testing laboratory based on communication and approval with the registrant. A number of other respondents had provided feedback and suggestions for improvement. A selection of comments providing more detailed information is listed in the table below.

Table C2.29 Responses to question 2.5.1: Have you encountered problems in identifying the correct contact points for the SEv evaluation within the registrants?

Comments
The registrants usually are helpful and try to aid the evaluation by providing additional information. It has been shown that only limited information can be gained from downstream users in this way, mainly due to time constraints during the evaluation year and reservations of the industry to asking for and gathering confidential business information on behalf of the evaluating member state.
It would be helpful if ECHA could provide a list of the contact points for all registrants from the registration dossiers for each substance as currently we have to obtain this information from REACH-IT for each registrant. Also it would be helpful if ECHA could send the first correspondence on substance evaluation to all registrants via REACH-IT. As the functionality is not available in REACH-IT for MSCAs to communicate with registrants via REACH-IT, this could be facilitated by the development of a template letter which could be amended as necessary by the relevant eMSCA. This correspondence could also include general information on the substance evaluation process.
Both we and the registrants find this interaction important and it is useful to clarify issues informally. The registrants appreciate the openness and the opportunity to be involved in the process. We think this could be improved by sharing the report at this early stage and also the RCOM document that we produce for ECHA/OMS.

C2.7 Responses related to horizontal and general questions

2.6.1. The first substance evaluations started in 2012 and annually there has been an update to the CoRAP. In your opinion has the substance evaluation process improved from the setting up in 2012 to the present time in 2015? How?

All the respondents providing their view (18) have answered that the substance evaluation process has improved from the setting up in 2012 to the present time. As such it is noted that involved parties have a better understanding and are gaining experience in the process with procedures evolving and improving accordingly.

In particular aspects that have been mentioned to be improved include:

- More streamlined procedures, better formats, better timing, and improved instructions guidance and templates (seven Member States). For instance, one respondent noted that the new SEv report template should result in less time and resources for the preparation of the final published version.
- Communication with different stakeholders (four Member States). For instance, one Member State valued the publication of the guidelines for informal interaction between registrants and eMSCAs.
- The manual screening procedure for the selection of the substances for CoRAP and the process for booking candidates after the manual screening (five Member States). One respondent further notes that the development of the manual screening process has increased the availability of CoRAP substances where the eMSCA is also the screening MSCA as this ensures that the eMSCA is already familiar with the substance before substance evaluation begins.
- Dealing with the decision making phase and with IUCLID (one respondent).
- Support on IT-related issues (one respondent).

In addition one respondent notes that whilst the process is evolving and improving, there are still certain issues that need to be addressed and discussed, potentially at the annual workshop, which is seen as very useful. These include *1) the overlap with compliance checks and the scope of the evaluations; 2) more discussion by appropriate specialists in technical expert groups would be helpful to avoid unexpected PfAs and minimise discussion needed at MSC meetings; 3) reduction in the level of reimbursement is restricting the amount of resources available for each evaluation and consequently the scope of each requires increasingly careful consideration resulting in more targeted evaluations.*

2.6.2. Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?

Regarding barriers hindering the efficiency of the evaluation process, workload and resources available is the most recognised barrier according to the survey (according to 24 respondents, 92%). Confidential business information and the expertise of evaluators and drafters (54% respectively of respondents) appear as the next most commonly encountered problems. The full list of responses can be seen in Figure 3.5.

Figure C2.18 Responses (number) to question 2.6.2: Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?

A number of respondents also specified the issues they encountered. The relevant comments are collected in the table below. The main points of concern refer to procedural barriers and/ or rigid rules, legal boundaries, or the increased workload on the authorities (particularly due to the piling-up of new and old SEv cases i.e. CoRAP selection combined with the evaluation of new substances plus the follow-up work from previous evaluations).

Table C2.30 Comments to question 2.6.2: Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?

Comments
During in depth evaluation new hazards can be identified for which expertise is lacking. Collaboration with other MSs can be difficult due to time limitations, differences in dealing with certain issue. Introducing dossiers to ECHA can pose problems (business rules check failures due to aggregated dossiers).
Sometimes, the preparation of MSC discussion and spontaneous decisions in MSC is complicated due to last minute preparation of commenting experts. Legal boundaries: There should be more efforts to solve unclear situations, e.g. when requesting exposure information. CBI: Differences between single CSR's are difficult to evaluate and cannot be easily addressed in draft decisions or SEV report due to confidentiality. Procedural barriers and/or rigid rules: During the amendment of DDs from MSCAs and ECHA: Adaptations of the draft decision in the process are currently not communicable to the registrants. Very tight timeline for the "Written procedure" which prevents choosing it more often Workload and resources available: In general due to possible piling-up of new and old SEV cases. IT-related issues: Sometimes very slow access to ECHA IUCLID (MS access). Collaboration with MS: When there is a joint SEV of two MS for one substance coordination is difficult and very time consuming.
Our available resources and expertise is a limiting factor in the substances we can evaluate and also the number of evaluations we can undertake in any one year.

Comments
The amount of funds assigned for SEV to MSCA doesn't reflect the amount of work. The resources directly depend on the funds given
Some cases legal time limits are too tight.
Compliance issues - The lack of definition of proportionality - To date almost all of our SEV decisions were challenged before the BoA and to date the BoA has not ruled yet in any of these cases. This makes the SEV process very slow, certainly if the request(s) are beyond what would be standard information. Therefore the SEV process has not (yet) delivered what we expected of it.
Collaboration with registrant(s): It was a problem that it took very long time to get access to full study reports. Other: Error in the registration. We found in the end of the evaluation that the substance was imported as polymer.
The crucial issue of our MSCA is that our capacity for SEv process is limited. We have also problem with access to MSCA IUCLID and practical use of dtb. Evaluation should be a scientific process. However, legal barriers negatively influence the evaluation.
As the process becomes more established the workload involved with substance evaluation is increasing, not only do we have the new evaluations but we need to plan resource for manual screening /CoRAP updates, taking the previous year's substances through decision making, evaluating any information requested from previous decisions and preparing conclusions. With reduced reimbursement we have to carefully manage the resource allocated with all these parts of the process. Although some of procedures are onerous we appreciate that they are needed to make sure that the legal text is complied with, however as mentioned elsewhere in this survey we think that appending the RCOM to the decision would be more efficient and lead to a shorter more understandable decision. As mentioned in 2.2.2 one of the issues we have found is how to deal with degradation of polymers due to the legal boundaries. We think some requests could be avoided if the system encouraged evaluators to only request further studies as a measure of last resort and instead focussed on developing better ways of dealing with uncertainty. Having to create an IUCLID dossier and submit it via REACH-IT can be very time-consuming especially where there are business rule issues. Given tight resources it would be much more efficient just to submit the documents. It can be difficult, particularly with non-disseminated exposure information, to give a meaningful discussion of the information in the non-confidential body of the report. We question how useful the publication of these reports is if most of the detailed discussion is contained in the unpublished confidential annex.

2.6.3. What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).

22 respondents have provided their views on which are the most important indicators for the effectiveness of the SEv process. However it is noted that most of them only selected which one they considered to be the most important, with less selecting which other indicators would follow in level of importance, in second place (19 respondents), third and fourth place (17 respondents each) and fifth (4 respondents). In addition, it is noted that six respondents have expressed some concerns about the way in which this question has been formulated. In particular they note that all these indicators give some measure of the effectiveness of the SEv process as a means to clarify an identified concern (i.e. consideration of all is what determines success) and that care should be taken when ranking them.

Looking at the responses provided, as illustrated in the figure below, it appears that the indicators that have been more highly ranked are the number of proposals for regulatory risk management followed by the number of cases where SEv triggered changes at company level risk management. Less support is given to the indicator based on numbers of DDs or FDs on data requests, with three stakeholders noting that this indicator should not be taken as the only measure of success. The relevant comments are collected in the table below.

Figure C2.19 Responses (number) to question 2.6.3: What do you think is the most important indicator for the effectiveness of the substance evaluation process?

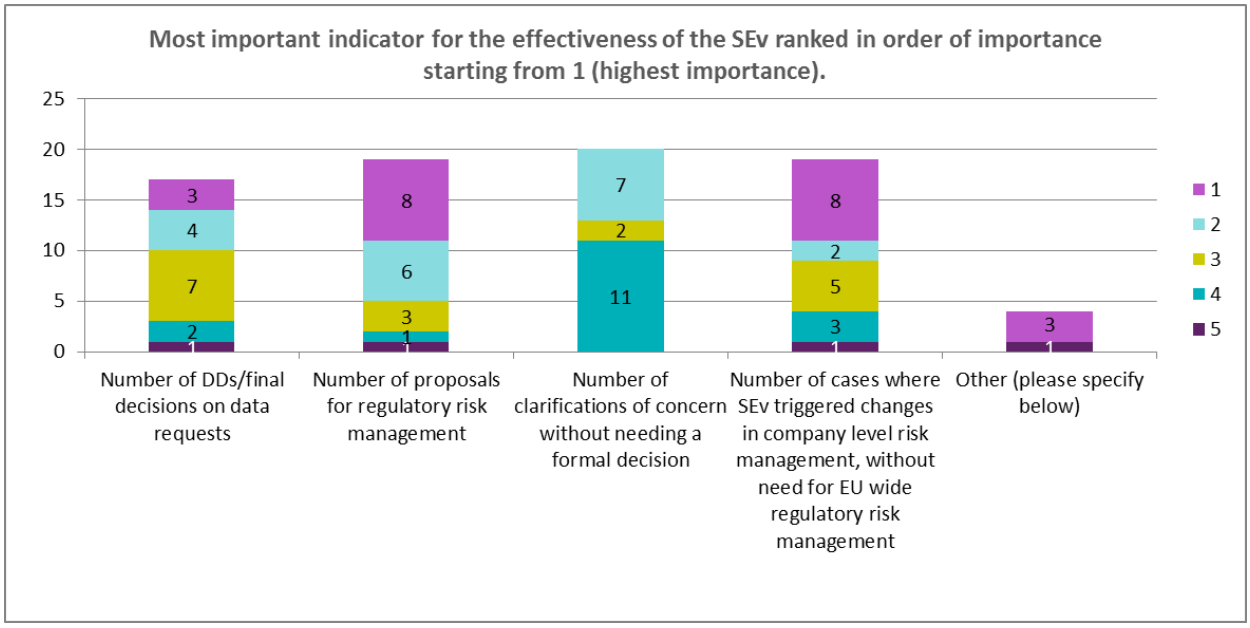


Table C2.31 Comments to question 2.6.3: What do you think is the most important indicator for the effectiveness of the substance evaluation process?

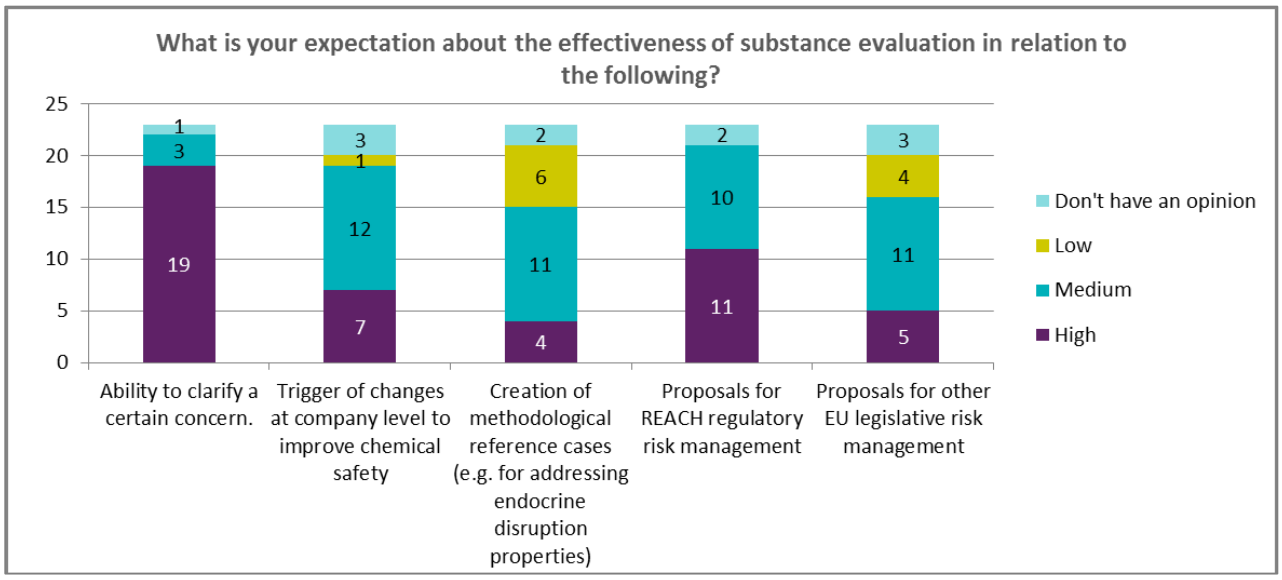
Comments
It is the sum of all the above that determines the effectiveness. Also spontaneous dossier updates, improvement of data quality. Number of DDs is not important if afterwards, the requested data is not of high quality or irrelevant or not delivered.
Other: The overall number of clarifications of concern (with or without a formal decision) is an important indicator for effectiveness of the SEV process. As recital (20) states: "If … there are grounds for considering that a substance constitutes a risk to human health or the environment, the Agency should … ensure that this substance is evaluated." The value of SEV is that those concerns are either cleared out or confirmed, so that in the latter case RMM can be triggered. The clarification of concerns is the core value of SEV.
Re.: "SEv triggered changes in company level risk management, without need for EU wide regulatory risk management ": this is an issue we - regrettably - do not know much about. Our knowledge on this relates mostly to "hear say" We do not think it is relevant to rank these indicators - they can all be important for the effectiveness of the process
This question does not represent the most effective way in determining upon the effectiveness of the substance evaluation process.
We have not ticked any box as we consider all the above indicators are relevant to some degree. All of the indicators above give some measure of the effectiveness of substance evaluation as a means to clarify an identified concern, either by confirming a concern exists or by confirming a concern does not exist. Substance evaluation is a complex process and care should be taken when selecting indicators as these need to be representative of the whole process and all possible outcomes of success. For example, to base indicators of effectiveness only around numbers of draft decisions would not provide any information on the number of cases where the concern could be clarified without a draft decision and may result in unnecessary draft decisions if these are deemed the only "measure of success". We consider that this point requires further discussion.
This is case dependent. The ultimate goal is the safe use of chemicals and dependent on the situation one of the above issues will apply
Some thoughts: This is a difficult question and linked to what extent it is the "best" candidates that are chosen for CoRAP. CCH should be done first. No.1: High ranking, means that more information was needed (beyond data requirements) and hence SEv was correct process. No. 2: Assume this is one of the options wanted as outcome, and in light of this high rank. But for some substances, if no DD, SEv was maybe not necessary for coming to this conclusion (then lowering the rank)? No.3: This covers both concl. "RRM needed" and "no concern". Since no DD, was SEv really needed? Could one have gone directly to RRM or seen that the substances were not good SEv candidates? No.4 (rank

Comments
low): This could be (better) achieved by other means than SEv (enforcement, campaigns)? Result important for workers covered.
The most efficient/effective outcome would be if the company takes the responsibility informally to ensure any risks are managed effectively without the need for formal action by authorities. These changes may be made during the evaluation meaning a formal decision is not needed. Consequently the number of proposals for formal risk management should be low. The number of decisions requesting further information is not as important and should not be the main indicator. It should always be clear how the requested information is going to be used and why it is necessary. It should be possible to deal with uncertainty and make regulatory decisions without resorting to asking for new information. Perhaps an additional measure could be the number of decisions that are not appealed. This would indicate whether the registrants found the requests fair and proportionate.

2.6.4. Few substances have been concluded so far. However, based on the experience so far, what is your expectation about the effectiveness of substance evaluation in relation to the following outcomes.

23 respondents have provided their views about the effectiveness of the SEv process in relation to a number of outcomes. As illustrated in the figure below, it appears that SEv is expected to be most effective in clarifying a concern (19 respondents or 83%). As noted by one MS, the clarification of concerns (with or without decision) is considered to be the core value of SEv, so that in cases this concern is confirmed risk management measures can be triggered. As such, the SEv is expected to be also effective in leading to proposals for REACH regulatory risk management by almost half of respondents (48%).

Figure C2.20 Responses (number) to question 2.6.4: What is your expectation about the effectiveness of substance evaluation in relation to the following outcomes?



2.6.5. Please indicate whether there are any steps in the process where you find that instructions fall into the categories outlined below.

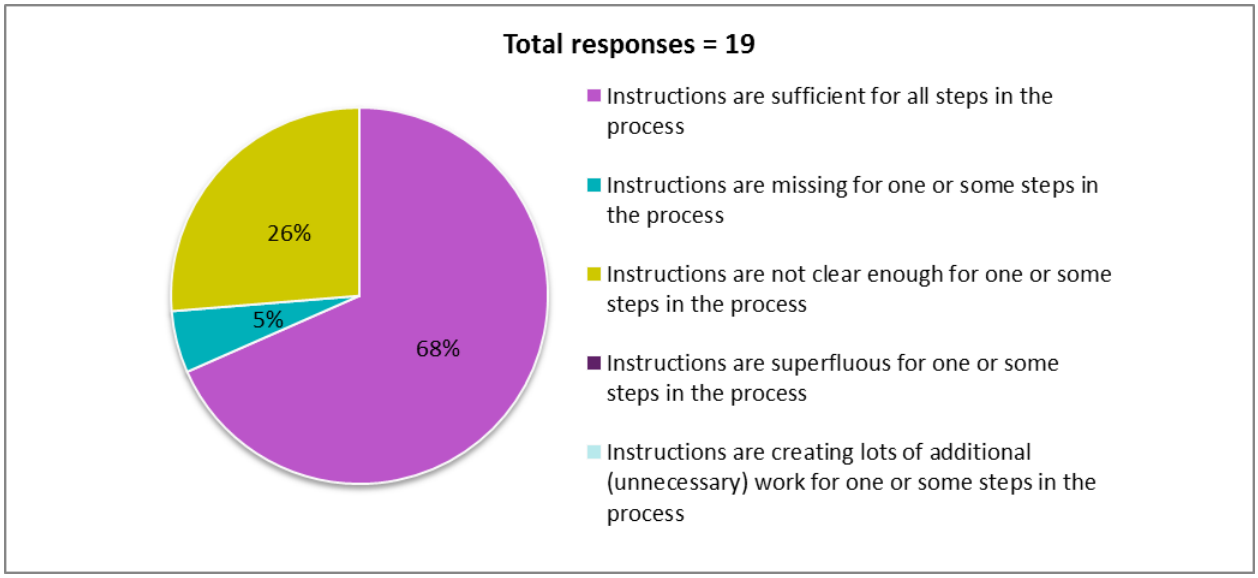
The majority of respondents to this question (68% or 13/19) consider that instructions on SEv are sufficient for all steps in the process. None of them have identified the instructions as being superfluous or as creating lots of additional (unnecessary) work for one or some steps in the process. Only some have indicated that they find that the instructions fall into the categories outline below, as follows:

- Are not clear enough for one or some steps (26% or 5/19). Based on additional comments provided these refer to the following:
  - Enforcement options

- *The SEv instructions (guidance) for the eMSCA do not outline the need to acquire aggregated dataset prior to creating SEV dossier.*
- *Difficult to know which documents need to be submitted before the 30-days period for MSCA/ECHA to provide PfAs. Maybe need to clarify the guidance (SEv Instructions for MSCAs (v1.2).*
- *The policy regarding inclusion of data gaps has changed, different signals have been given. The best would be that CCH is performed before SEv starts. IUCLID-dossier for sending: Struggled with this.*
- *Instructions are not clear enough on how to reflect PfAs and the RCOMs in the DD.*

- Are missing for one or some steps. This is only reported by one MSCA, but in the comment field it is only noted that instructions and templates change very frequently.

Figure C2.21 Responses (number) to question 2.6.5: Please indicate whether there are any steps in the process where you find that instructions fall into the categories outlined below.



In addition, one MSCA notes that *one potential problem under REACH is that if the eMSCA concludes that no further information and no further action is required this conclusion is not tabled for EU discussion between MSCAs - and could only be challenged by another MSCA by proposing a new substance evaluation initiated e.g. on the same subject - and this will for sure be seen as controversial because it demonstrates a deficiency /lack of effectiveness of the REACH process in that case.*

2.6.7. Apart from contacting the competent authority do registrants or other stakeholders seek advice on substance evaluation in general or regarding particular substances through your national helpdesk? Can you provide information on the number and nature of the incidents/issues that have been raised?

Eight Member States (57% of the Member States taking a position on this question) stated that they have received questions on SEv or particular substances through their national helpdesks, though in most cases these were rather occasional or rare and mainly related to the general or procedural aspects of SEv (i.e. CoRAP selection). As such it is noted that questions on SEv are usually received directly by the SEv team. Comments explaining the nature of these requests are collected in table below. Additionally, five Member States explicitly indicate that they have not received such requests through their national helpdesks.

Table C2.32 Comments to question 2.6.7 Do registrants or other stakeholders seek advice on substance evaluation in general or regarding particular substances through your national helpdesk? Can you provide information on the number and nature of the incidents/issues that have been raised?

Comments
The national helpdesk receives a moderate amount of (general) questions on the CoRAP and SEV process by registrants or other stakeholders (private individuals, researchers etc.), i.e. mostly procedural questions or questions on the outcome of substance evaluations and the follow-up. Specific questions on the country's CoRAP substances during or before the evaluation year are usually handled and answered by the CA directly.
All communication on SEV is done through national SEV contact point.
Yes. Questions on the testing methods for endpoints are addressed, on the enforcement penalties that may arise from the SEv process and the involvement of the national CA in the SEv process carried out by another CA (other country).
Advises on CLH, laboratory requesting information regarding the implementation of tests,
We do not classify questions coming to our national helpdesk in respect to substance evaluations. Occasionally we get general questions on the SEV process related to specific substances.
Our national helpdesk has responded to 8 queries relating to "evaluation": 4 in 2015, 2 in 2014 and 2 in 2012. The queries covered the following areas: the inclusion of particular substances on the CoRAP, the effect of CoRAP on cosmetics, the evaluation of intermediates, the evaluation of a particular substance for which IE was not the eMSCA and how it affects use in IE, and the role of SIEFs in filling data gaps noted under SEv.
Very few. Questions concerning CoRAP in general.
Now and then we get questions from Brussels-based consultants about substances on CoRAP and which substances we think will be added in the coming years.
The national helpdesk is rarely contacted about specific substance evaluations. This is likely to be because our SEV team liaise directly with those involved from industry. We do answer general questions about the DEV and SEV process, but will generally use our leaflets and the ECHA website to answer such questions. In the time available we cannot provide details of the number of queries on this subject.

C2.8 Additional comments or information

Two further specific comments had been made by respondents in this concluding section. These are listed below.

Table C2.33 Comments to question 5: Please provide any additional comments or information.

Comments
Just a couple of technical remarks: 1) We have repeatedly difficulties with the IUCLID MSCA connection (could be problems with Java - difficult to say -we do not have sufficient resources at IT help). Therefore, we would appreciate if the possibility to order IUCLID dossiers via REACH-IT would be maintained. Thus we can, when needed, read dossiers in the stand alone IUCLID version. 2) Please remember to enable the email notifications when you upload documents on CircaBC. This is very helpful. Thanks.
As common screening, CoRAP development, substance evaluation and risk management processes have evolved over recent years, we think that it might be timely to review how information on the status of substances in the various REACH/CLP processes is recorded and communicated to MSCAs. Currently this information is stored in various locations (e.g. Circabc, Portal Dashboard, ECHA dissemination site) and in multiple formats. For example we note that: • ***In Circabc, information is saved in different interest groups and within different libraries within the same interest group. While we appreciate the need to maintain different interest groups which represent the different work areas, we think an overall central database would be useful to track substances and avoid overlapping processes/interest.*** • ***The Portal Dashboard (V1.0) includes (limited) information on the status of substance evaluation and risk management (RMOA) activities but no information dossier evaluation (other than to indicate "Y" or "N" as to whether a substance is under dossier evaluation). We note that the status of CCH and TPE can be found on the relevant progress excel files on Circabc. However, this does not provide information on CCH cases identified from common screening for which ECHA has not yet started the CCH. For example, the screening MSCA has no information on when ECHA plans to open the CCH or if ECHA decides not to open a CCH. It would be useful if***

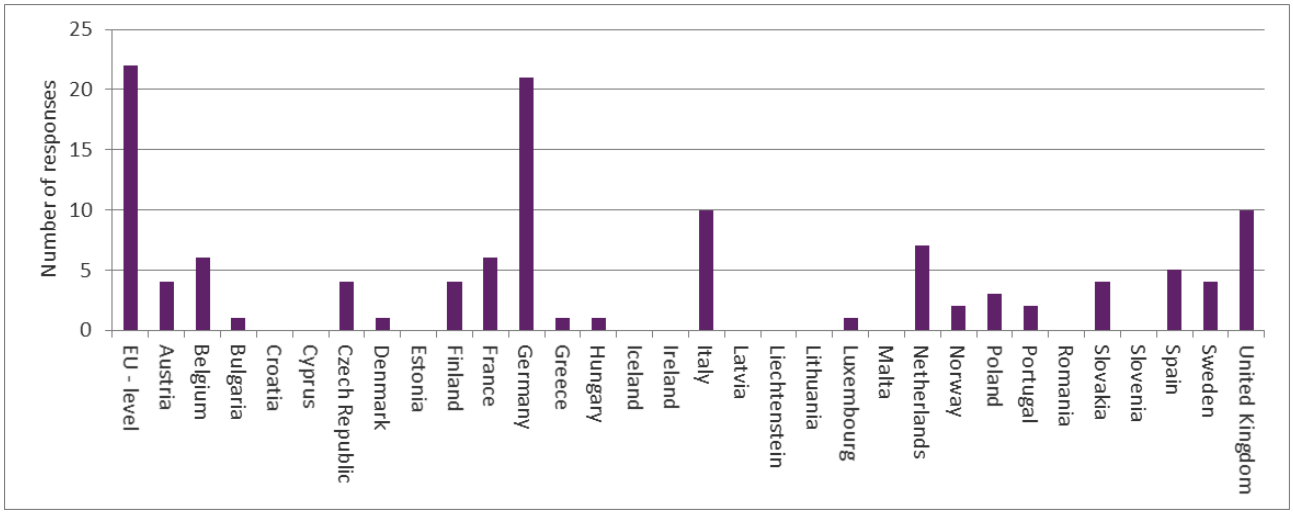
Comments
the status of dossier evaluation could be included also in the Portal Dashboard, e.g. whether ECHA reviewed the case following screening and chose not to open a CCH, at what point of the DEv process a substance is, whether a final decision has been issued etc. • ***There appear to be some discrepancies between information included on the Portal Dashboard and that published on the PACT and CoRAP lists. For example, we note that 2017 CoRAP substances are not included in the list of substances under evaluation in the Portal Dashboard but are included on the published CoRAP; the status of some substances under RMOA appears to be more up to date on the PACT than on the Portal Dashboard. We consider that a single consolidated method of tracking a substance through all REACH/CLP processes would greatly assist MSCAs in their work and would reduce the potential for unnecessary overlapping activities on substances.***

C3 Analysis of responses to the survey provided by registrants

C3.1 Profile of the respondents

56 registrants provided relevant information via the submission of the survey. The majority (52) of the respondents indicated the geographical range of their activities. The number of respondents carrying out activities in each Member State is detailed in the figure below. Precisely half of the respondents indicated that they see their activities constrained to or concentrated in one Member State, while the rest claim to be active either at an EU-wide level or across a number of Member States. The dominant geographical areas of activity of the respondents are EU-wide (22 respondents) and Germany (21), followed by Italy and the UK (10 each).

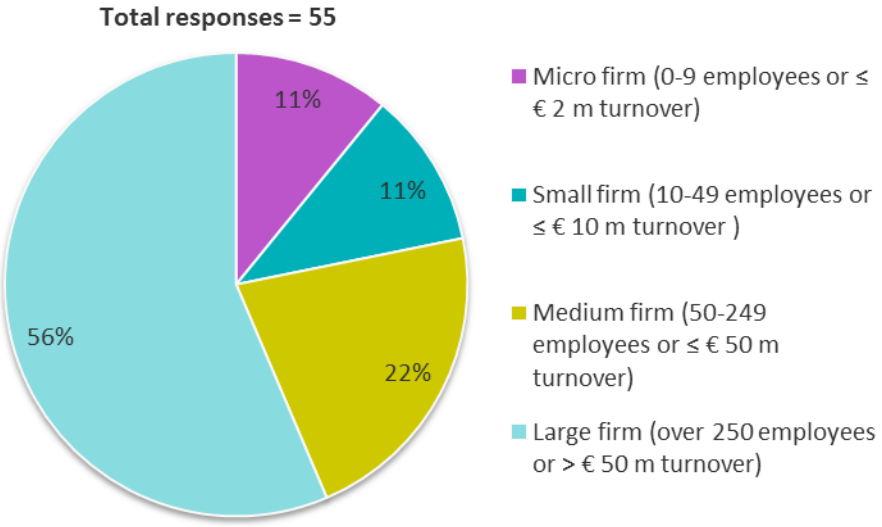
Figure C3.1 Number of consultation respondents by Member State



Furthermore, the profile of the respondents is characterised by the large number of large firms. More than half of the 55 respondents had specified the size of their firm as large with more than 250 employees or €50m turnover. This is illustrated in Figure C3.2. Large firms also exhibit the highest number of substances listed in the CoRAP with an average of 9.1 listed substances. Smaller firms have lower average numbers of between 1.0 and 1.5 substances listed per firm, with the exception of a small consulting company that is concerned with 31 listed substances while representing a number of registrants.

Similarly, it is the respondents from large firms that predominantly act as lead registrants. Amongst large firms, in 35% of the CoRAP listed substances, the registrant acts as lead, whereas small or micro firms acts as lead registrant for three CoRAP listed substances. 14 out of 55 (25%) of the respondents have acted or are acting as coordinator towards the evaluating Member State Competent Authority (eMSCA) and ECHA for their substance evaluation. These firms too are predominantly (12/14) large firms.

Figure C3.2 Number of respondents by firm size

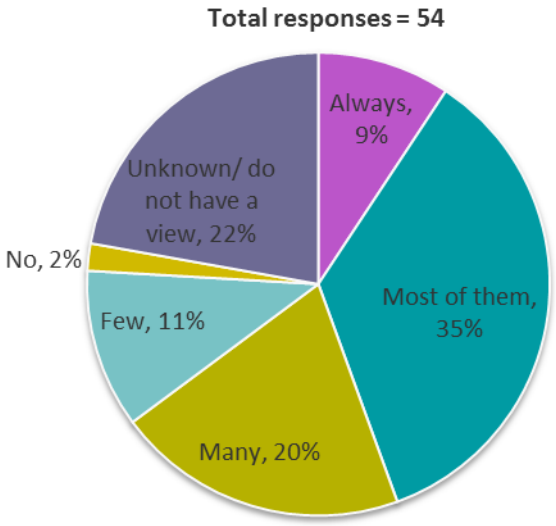


C3.2 Responses related to the selection of substances to be listed in CoRAP

3.2.1. Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value?

Most respondents expressed a positive view regarding whether CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value. As shown in the figure below, almost two thirds (64.9%) of respondents agree that this is the case for many, most, or all of the substances. 11.1% however responded that only few substances listed require evaluation and one respondent completely disagrees. 22.2% of respondents don't have a view.

Figure C3.3 Responses (number) to question 3.2.1: Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value?



Several respondents report examples of concerns that are not convincingly argued. They criticise the prioritisation of substances with small market sizes, low exposure possibilities, or very low risk at high exposure, as well as questionable calls for studies. Furthermore, there are concerns of redundancies within

parallel processes, such as the dossier evaluation or evaluations of another substance of the same category and for the same concerns, as well as pre-existing regulations and decisions. Some of the given examples are listed below.

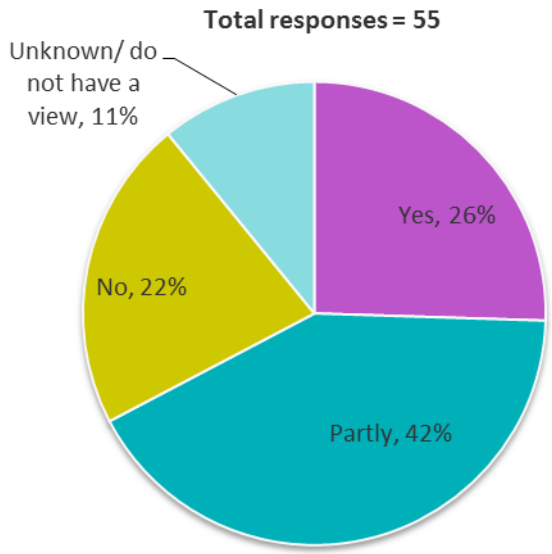
Table C3.1 Selected comments to question 3.2.1: Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value?

Comments
Ex DHTDMAC is included in CORAP whereas it has been evaluated in 2002 and RAR concluded that no further investigation is needed.
Some substances are already regulated since a long time and even already under restriction (formaldehyde, methanol, xylene, cresol). Other substances are managed under strictly controlled conditions and it would not be of importance to refine hazard information. Finally there are some substances which are obviously selected to "train" the member states (dimethyl glutarate). Also there is a great focus on possible ED properties whereas final criteria are not available.
TiO2 is used in food or toothpaste since long. Wide use should not be enough to be suspicious.
Incorporation of one simple ester (diisotridecyladipate) into CORAP seems not to be correct while all the other adipate or sebacate esters are not covered by CORAP. Why is propylacetate selected but all the other acetates are not covered?
E.g., reasons to justify the concern for listing synthetic amorphous silica (nanoparticles) not convincing. We expect that RMOA will form a better basis for future inclusions in CoRAP.

3.2.2. Do you think that inclusion of substances in the CoRAP has had an impact in the improved quality of your dossiers i.e. was it a driver to provide further or better quality information (e.g. discussions on substance identity within the SIEF and submission of more details)?

The respondents had provided a rather balanced range of views on the impact of CoRAP listing as a driver for a better quality of information. 42% stated it partly did, with just slightly more respondents agreeing (26%) than disagreeing (22%). This is reflected in the figure below.

Figure C3.4 Responses (number) to question 3.2.1: Do you think that inclusion of substances in the CoRAP has had an impact in the improved quality of your dossiers?



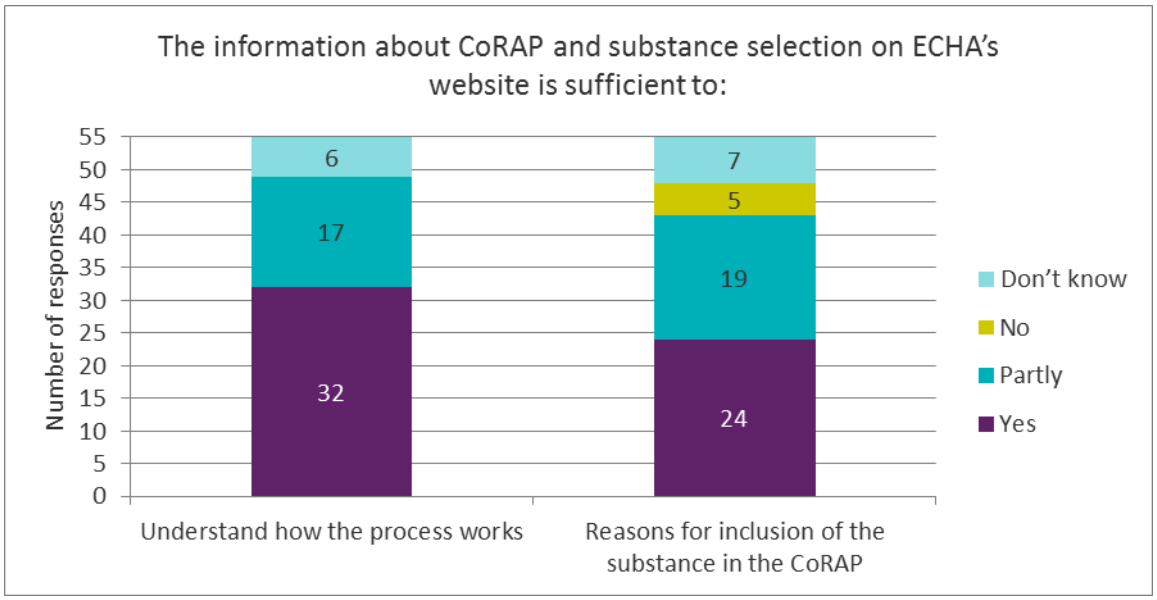
Some respondents had provided comments on the issue. While most of them reflect agreement that CoRAP generally fosters review of the dossiers and the collection of further information, concerns about redundancies as in the previous question were once again pointed out. This includes parallel compliance checks and substances on which there already is a vast amount of data available. One respondent stated

that *"a CSR generated by Chesar and IUCLD is not sufficient for MSCAs for identification of CoRAP substance, SVHC and Restriction. Again, it would be most optimal for us if we had a chance to provide that sort of information prior to entering to the official process of CoRAP."* A severe issue mentioned are gaps in some CoRAP entries which do not include all substances in the same category, thus including some substances but not other similar ones by competitors, leading to competition issues for the different manufacturers.

3.2.3. Information about CoRAP and substance selection on ECHA's and the MSCA's website

The information about CoRAP and substance selection on ECHA's website is viewed in a predominantly positive light. It is sufficient to understand how the process works according to 58% the respondents, and at least partially sufficient according to the rest of the respondents. The statements are slightly more critical regarding the information on the reasons for inclusion of the substance in the CoRAP. Five respondents (9%) consider the information not sufficient, 35% partly sufficient and still 44% sufficient. The figure below displays the number of responses agreeing with each of the statements.

Figure C3.5 Responses (number) to question 3.2.3: Information about CoRAP and substance selection on ECHA's website



The respondents had also made a number of comments on their answers, most of which relate to the reasons for inclusion of a substance in the CoRAP, once again underlining the slightly higher controversy regarding that issue. Comments indicate that the information on reasons are unclear or vague and lack technical detail. However, there are also various comments concerning the information on how the process works. They are shown in the table below.

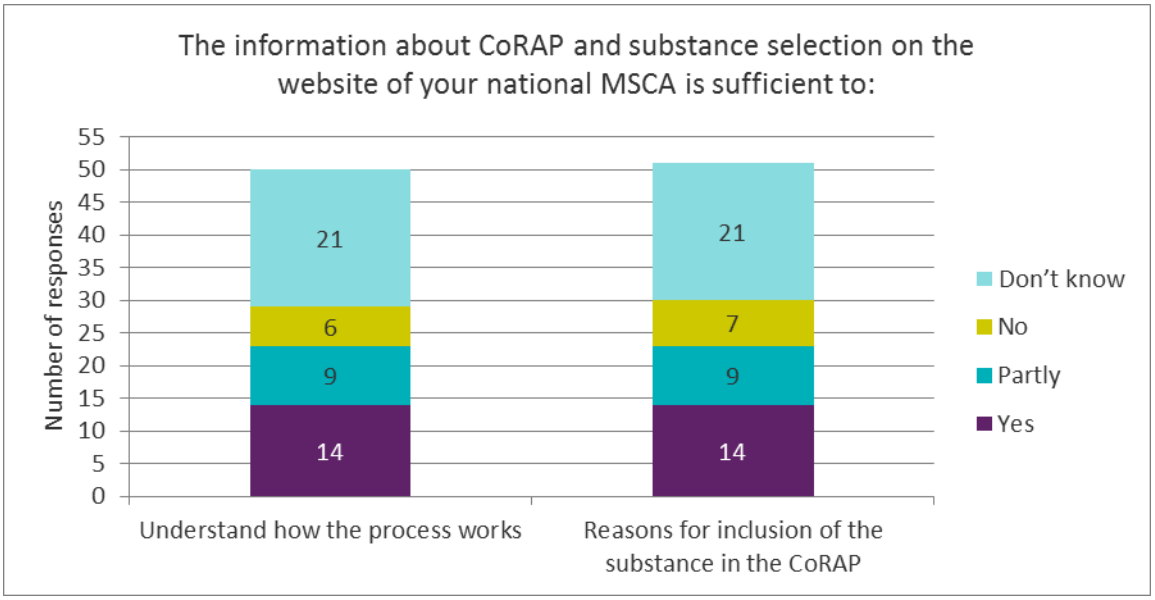
Table C3.2 Selected comments to question 3.2.3: Information about CoRAP and substance selection on ECHA's website

Comments regarding the information on the ECHA's website on the substance evaluation process
Still unclear about when we can expect the draft decision, and the time-line to get the final decision, or potentially another draft decision. It is the same issue for the testing proposals.
The process is very complex as there are now additional steps for screening purpose. Also the first screenings are automatic processes and are leading to selection of substances which are not relevant.
Processing of DD: clear rules for timing of PfA, MSC meeting (early warning) lacking. ***Closure of evaluation process: rules for availability of final evaluation report lacking.***

Comments regarding the information on the ECHA's website on the substance evaluation process
Process seems to differ between difference member states, there is no unified approach.

A similar picture had been drawn by the respondents for the information on their respective national MSCA's website, though a much larger share of respondents stated they didn't know. The comments provided indicate that the respondents in question mostly used the ECHA website, and some indicate that they didn't know the MSCA's website or that it offered little to no information on the matter. The following table shows the distribution of the responses.

Figure C3.6 Responses (number) to question 3.2.3: Information about CoRAP and substance selection on the MSCA's website



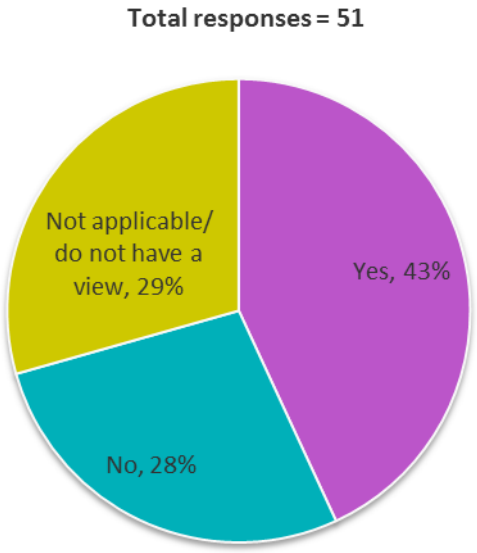
The comments provided here also raised some additional issues whereby some respondents were unclear as to why the information is divided between the two sources (ECHA and MSCA) or duplicated on both sites. One stated that the flow of information should be direct and not via the website and another one urged to take into account that the registrants may not speak the local language of the MSCA.

C3.3 Responses related to evaluations, decision making and follow-up phases

3.3.1. The time indicated in REACH for commenting on the draft decision (DD) and possible proposals for amendment is 30 calendar days. In addition according to REACH-IT rules, 7 days are added into it. Have you experienced any difficulties in the SIEF/consortia while preparing the comments?

As seen in the figure below, the majority of respondents (43%) experienced difficulties during the preparation of comments on the draft decision (corresponding to over 60% of respondents that have a view on the matter). The main problem experienced by respondents (17/22, 77%) is that the given timeline is too short. Several reasons for this had been mentioned, the most frequent ones being interference with vacation periods and the difficulty of reaching agreements with other registrants, especially in large consortia. Other stated reasons include the burden of involvement in multiple processes regarding various substances, and the high expenditure of time when testing is involved or when industry needs technical discussions with the MSCA.

Figure C3.7 Responses (number) to question 3.3.1: Have you experienced any difficulties in the SIEF/consortia while preparing the comments?



In relation to the above, it is noted that ECHA has released an annual news alert in advance to indicate which substance will have a draft decision and by when the registrants may expect to receive it for comments. Does this facilitate making your comments in time?

59% of the respondents have a view on the facilitating effect of the information regarding when a draft decision is to be expected in the yearly news alert. Responses are in part positive with 37% confirming that the alert facilitates the timely preparation of comments on the draft decision. Some respondents expanded their answer with comments which are displayed in the table below. In sum, some respondents are unaware of the alert, some consider it useful for improving organisation, and others see only a limited value considering it does not include enough information of the DD to allow a timely preparation.

Table C3.3 Comments to question 3.3.1: Does the annual news alert facilitate making your comments in time?

Comments
We received the draft report of the evaluation done by the MSCA before we received the draft decision. It is really nice but at the same time, the process does not allow the Industry to comment this report. Then, the Industry cannot anticipate what will be in the draft decision, and it is really frustrating not to be able to formally comment the report, that is a huge work done by the MSCA. But of course, it is better to have it.
The additional transparency is appreciated, but there are too many processes running in parallel. It appears that there is no clear indication that the listed substance will be selected for a compliance check. It was also noted that sometimes substances are listed that are already in work triggered by other requirements from REACH or other regulation (e.g. biocides).
The advance indications of which substances may be selected for compliance check is very welcome and helps us plan and prioritise our work.
It is only a clarification, but does not change the deadline. The most important is to get the information about the report in addition to the DDL.
ECHA should notify that in REACH it. The list is based on chemical name and EC number and sometimes only the common name is known
As we do not know the information of the draft decision upfront we cannot prepare ourselves for such a DD.
This clearly helps in preparing the organisation of discussions between registrants, but it doesn't facilitate discussions themselves if it is not known before what to discuss about.

3.3.2. Was there a possibility to submit a dossier update agreed with the Member State after the DD was sent for your comments? If so, please indicate if it had an impact on the content of the draft decision.

Of the 17 respondents that responded to this question, 9 state that it was possible to submit a dossier update after the DD and 8 state that it was not. The experiences regarding the impact on the content of the draft decision appear rather sceptical. Three respondents are unsure of the impact, another three see no impact, while two respondents state that in some cases there was, for example one respondent notes: "*Happened in exceptional cases (strongly depending on eMSCA)*".

3.3.3. Member States and ECHA can make additional proposals for amendment (PfA) to the draft decision that was issued to the registrant for comments. Have you experienced difficulties in commenting the Proposals for amendment from different Member States and ECHA?

Of the 12 respondents with a view on this question, 4 experienced difficulties commenting on the proposals for amendment from the Member States and ECHA. A few comments provide insight on the variety experiences had when commenting on the proposals for amendment. They are displayed in the table below. A reoccurring issue in the comments is the short timeline.

Table C3.4 Comments to question 3.3.3: Have you experienced difficulties in commenting the Proposals for amendment from different Member States and ECHA?

Comments
No difficulty in commenting during MSCA / MSC Committee, but comments are not taken into account finally
We wish the comments by the different MS were transparent for the registrant
Your commenting period is quite short
PfA come as a surprise (both timing and content), very tight and stringent timeline for answering. Time for consultation with co-registrants also needed.
Process closely monitored in order to timely prepare for commenting.
The process of commenting (on decisions as well as on PfA) gives a strong feeling of unfairness. ECHA and MSCA are given much more time (resources) to prepare initial comments and final comments - the registrant only has one opportunity. We experience that we receive completely new arguments / comments based on the comments we submitted, sometimes many months later, where we have no opportunity to discuss. I would strongly suggest to organize a final call with all parties between commenting and writing final decision, allowing for final clarification.

3.3.4. Are the draft decisions (DDs) and final decisions (FDs) clear enough to understand what is requested from you and the reasons behind them?

The survey indicates an overall positive view among the registrants regarding the clarity of the decisions and the reasons behind them. Half of the respondents found the DDs and FDs clear enough, whereas 22% disagreed. However, the details provided by some of the respondents reveal various specific issues and show that some opinions vary regarding the clarity of the decision and the clarity of the reasons. The respective comments are listed below.

Table C3.5 Comments to question 3.3.4.: Are the draft decisions (DDs) and final decisions (FDs) clear enough to understand what is requested from you and the reasons behind them?

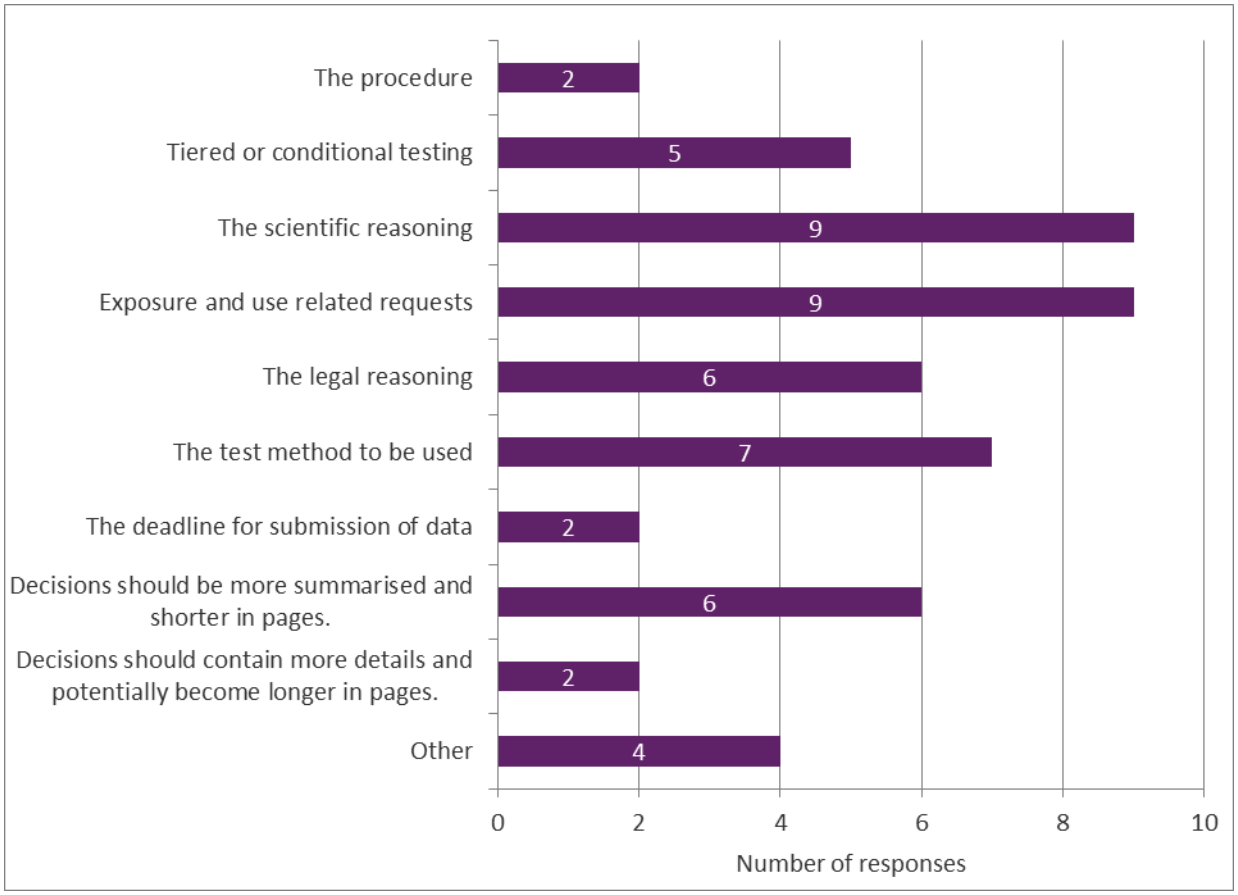
Comments
In some cases, difficulty to understand mainly where FD is not dealing with study requests.
Considering the draft decision we received, we have highlighted some issues with the tests proposed and the conditions of testing to apply, that could drastically impact the timing, and the results. We had also some lack of clarity about the substance to test, because our substance evaluation is a very difficult case.

Comments
When we have a step by step testing approach, then a long-term testing plan, it is very difficult to discuss about the technical aspect of tests to be conducted three or four years after, at the very last stage of the evaluation. This approach conducts to a lack of clarity about the DDL. We would prefer to have an intermediate evaluation step, rather than having 5 years plan of tests.
In some cases it appeared to be difficult to discuss alternative approaches, in particular when using read-across based on metabolic pathways. UVBC vs. multi-constituent
In most cases the draft decisions are clear, however in some instances we have been required to make use of consultants to interpret them. The opportunity to discuss the draft decision with ECHA officials in a short conference call (which is however not always provided) is very useful. It is in the interest of all parties that the registrant is able to interpret the DD without misunderstandings.
In case of complex substances and different status (intermediates / full dossier) the draft decision is definitely unclear on which registrant should provide which information. For example the CoRAP asks for exposure information, whereas this information is not mandatory for SCC intermediates. For one dossier the test methods are sometimes not available (ED, fate and behaviour for PBT). In addition test conditions are requested to be different (temperature issue for degradation) without any scientific rational for that.
In general they are clear, but is it difficult to understand if the information has to be provided individually for each registrant, or in some cases can be part of the Joint Submission. Should be better clarified in the decisions.
The reasons are well explained, but it doesn't mean we always agree with the conclusions.
Decisions are sometimes unclear if eMSCA did not interact with Registrant before issuing DD
I am a chemist but not a toxicologist. The draft decisions why some studies have to be conducted are very hard to understand, I have to rely on good communication from the lead registrant to understand why the additional studies are necessary.
Very clear on the what, not always clear on the why, especially in FD.

If you answered NO to question above, please indicate what issues are unclear or would benefit from further clarification.

This follow-up question further specifies the unclarities percieved by the registrants in the DDs and FDs. As can be seen in the figure below, scientific reasoning as well as exposure and use related requests had been rated the most commonly by the respondents as unclear. The least commonly identified issues are procedure and the deadline for submission of data. Regarding the length and detail of the decisions, the survey shows a clear preference for more summarised and shorter decisions (6 respondents), rather than more detailed and longer decisions (2 respondents).

Figure C3.8 Responses (number) to question 3.3.4: Please indicate what issues in the draft decisions (DDs) and final decisions (FDs) are unclear or would benefit from further clarification.



The detailed comments provided by a number of respondents show varying concerns. Topics addressed in multiple comments are above all testing as well as a lack of participation in the decision process. Relevant comments are listed in the following table.

Table C3.6 Comments to question 3.3.4.: Please indicate what issues in the draft decisions (DDs) and final decisions (FDs) are unclear or would benefit from further clarification.

Comments
Final decision does not always comply with technical guidance. ***What will happened if tiered testing and first results leads to another option than those mentioned in the FD?***
The conditions of tests are sometimes very clear (temperature for soil tests) and sometimes the substance to be tested, or the need for radio-labelling and purification is not mentioned, even if it could seriously impact the timing for the DDL.
Decisions should be complemented by the opportunity to discuss their content with ECHA officials. This would be the easiest way to avoid misunderstandings.
Conditional testing will have an impact on timeline; there are several tests that are still under research development and authorities are not aware / keen for using them although they are the most relevant ones. ***Long decisions with conditional testing should be avoided. Rather than this conditional testing, short decisions with a different deadline would be easier to manage. The decisions for several kinds of substances (with different status) are not well manageable. Requests for degradation products are unclear.***
Any waiving is not allowed. ***Either you have a test or you have to perform an additional test whether scientific reasonable or not.***

Comments
Clarification only after meeting with eMSCA: what was required from a registrant of a transported intermediate vs. non-intermediate? ***Tiered or conditional testing should be applied more frequently to avoid extensive requirements.***
We do not see that any of our comments or updates are taken into account.
The deadlines are really tight, have to be adjusted to amount of requested amendments.
Should be understandable for non-expert personnel.
The process of commenting (on decisions as well as on PfA) gives a strong feeling of unfairness. ECHA and MSCA are given much more time (resources) to prepare initial comments and final comments - the registrant only has one opportunity. We experience that we receive completely new arguments / comments based on the comments we submitted, sometimes many months later, where we have no opportunity to discuss. I would strongly suggest to organize a final call with all parties between commenting and writing final decision, allowing for final clarification.

3.3.5. What difficulties have you faced when providing information in a dossier update for your substance concerning the following aspects?

The relevant difficulties mentioned by the respondents have been listed in the following table concerning each of the following aspects: Substance identity, human health endpoints, environmental endpoints, exposure, and any other general points.

Table C3.7 Responses to question 3.3.5: What difficulties have you faced when providing information in a dossier update for your substance concerning the following aspects?

Aspect	Difficulties faced when providing information in a dossier update
Substance identity	▶ *Too detailed (purity/impurities): discussion within SIEF impossible for confidentiality reasons* ▶ *Not enforced during the dossier evaluation. It is an issue especially when intermediates (not analytical report submitted), because the identity of the substance has not been fully checked.* ▶ *UVCB and category approach* ▶ *Substance ID was not well checked. Then there are unclear requests for each type of substance. The intermediate status was not well checked for some registrants. In addition the substance ID is not in line with the substances on which models are applied (QSARs).* ▶ *Purity/Impurity* ▶ *It is well known that this is a major issue; prior to REACH, substance identity was a non-issue. It seems that totally unambiguous substance identity has become an end in itself rather than a means to an end under the REACH process.* ▶ *Unpractical requirements of 3 spectra for hydrocarbons (especially gases) as GC-MS is the one of real value. The same problem applies for inorganic substances.* ▶ *Some problems with NONS, because previous substance identity was not as detailed as it is today an very often there important differences.* *I've also found a substance with clearly wrong structure.*
Human health endpoints	▶ *New tests not well known by the authorities. Differences of interpretation of those tests. No possibility to present our interpretation to the other member states.* ▶ *A Lead Registrant dossier update is always needed for this. This takes time especially where there are many registrants.* ▶ *Derived from the complexity of the section.* ▶ *Study required which cannot be performed by any testing facility worldwide so far (special administration route).* ▶ *Additional info to be collected or generated*

Aspect	Difficulties faced when providing information in a dossier update
Environmental endpoints	▶ *Risk assessment is a stepwise process, whereas FD do not really allow flexibility in testing strategy.* *Sharing of confidential data (Tonnage)* ▶ *The DDL mentions testing conditions not mentioned in the OECD guidelines. When the industry proposes alternative method or conditions, we have the feeling that it is not well accepted.* ▶ *Temperature issue: asking 12°C for degradation tests is not scientifically based. Use of new approaches: the authorities are reluctant to use up to date scientific methods. The right compartment of concern is not enough investigated: only aquatic studies seem to be considered whereas in some cases there is not exposure in the aquatic column.* ▶ *A Lead Registrant dossier update is always needed for this. This takes time especially where there are many registrants.* ▶ *Very difficult to obtain detailed tonnage information and uses along the supply chain.* ▶ *Derived from the complexity of the section* ▶ *Difficult to convey a weight of evidence approach in a dossier without discussion between industry and CA experts. Sometimes CA's are lacking the experience on the substance and/or the specific endpoint.* ▶ *Additional info to be collected or generated*
Exposure	▶ *Sharing of confidential data (Uses)* ▶ *This data can be either generic and common for all, or alternatively registrant and site-specific. Therefore, it may take even more time to achieve.* ▶ *Very difficult to obtain detailed tonnage information and uses along the supply chain.* ▶ *Relevance and structure* ▶ *Derived from the complexity of the section* ▶ *Information required which needs cooperation of downstream users who are not addressed by decision and thus not obliged to support registrants* ▶ *Additional info to be collected or generated* ▶ *Various uses and a lot of different users; scenarios cannot be as detailed as requested, since users do not want to give too much details on their use away and number of scenarios will be uncountable.*
In general	▶ *We don't know if the technical arguments and the alternatives we proposed in term of testing and life cycle analysis are well understood and/or acceptable for the MSCA.* ▶ *When the structure of IUCLID is changed, the old decisions/selections are no more valid, but would need a completely new setup* ▶ *Difficulties to get the LoA to existing studies. Sometimes impossible, sometimes too expensive* ▶ *Realistic timelines for required information are essential* ▶ *waivers; read-across; risk assessments when not hazardous*

3.3.6. Please indicate whether, upon receipt of a draft decision or final decision on SEv, you took action other than to comply with the decision.

According to the survey responses, the predominant actions taken by registrants upon receipt of a draft decision or final decision on SEv, are to change the registered uses or implement new risk management methods with nine responses each (Figure C3.9).

Figure C3.9 Responses (number) to question 3.3.6: Please indicate whether, upon receipt of a draft decision or final decision on SEv, you took action other than to comply with the decision.

12 respondents also listed other reactions, some of which they specified in further comments, as follows:

- Active search of replacement,
- Lodging an appeal (named twice),
- Ceasing manufacture,
- Review and update of exposure scenarios, and
- Completing additional studies.

3.3.7. If the conclusions on your substance are already published, do you think the conclusion derived fairly reflects the information available and helps the Registrants in establishing the safe use of the substance? If not, why do you think so?

Of the 12 respondents that responded, 8 note that the conclusions on their substances fairly reflect the information available and help them to establish the safe use of the substance. Four respondents disagreed. Unfortunately, little detail was provided by the respondents. One of them stated that "*each conclusion is very specific to the substance and its exposure*".

3.3.8. Do you have any suggestions on how to improve the substance evaluation process?

Respondents proposed a number of improvements relating to the substance evaluation process. All the proposals are listed in the table below. In brief, those addressed by multiple respondents are as follows:

- The flow of information between the authorities and the registrants is criticised several times. Responses suggest, that more timely information about imminent steps of the process (above all the decision) and more details about the reasons of the decision have to be communicated to the registrants. Also a more direct contact between authorities and registrants as well as more openness for updated information from the registrants during various stages of the process is sought after. Also various uncertainties in communication are named.
- A second reappearing topic is the selection and prioritisation of substances, which according to some respondents should become more precise and focused.

Table C3.8 Responses to question 3.3.8.: Do you have any suggestions on how to improve the substance evaluation process?

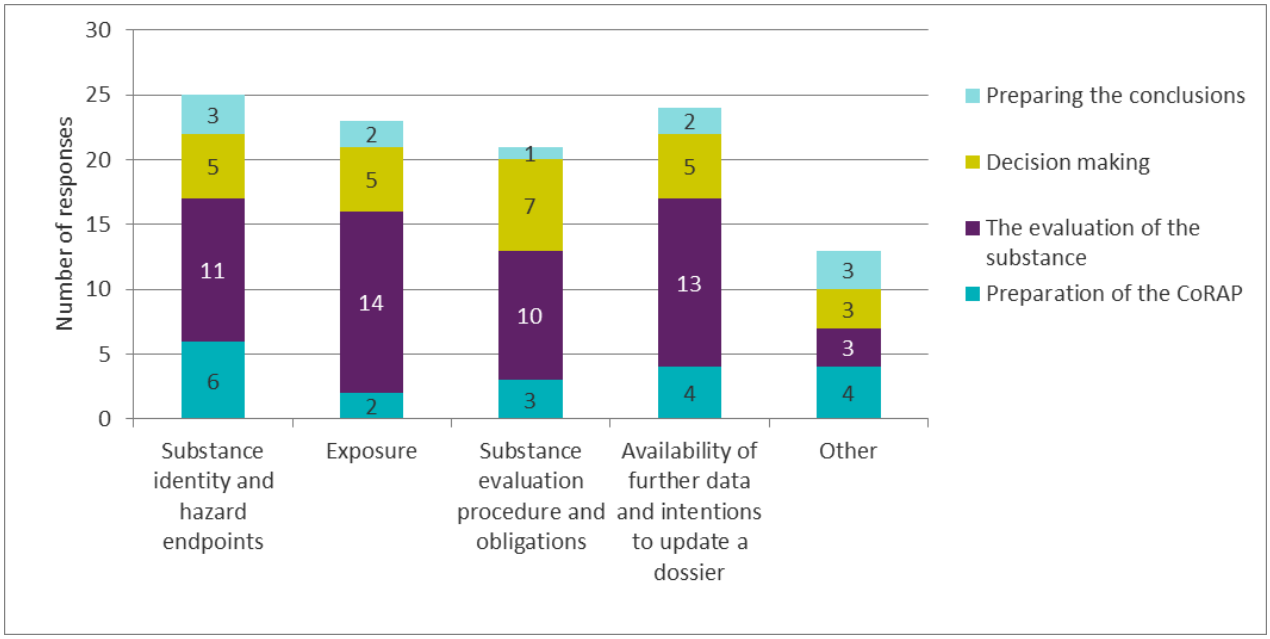
Comments
As the 30 days commenting period is too short after DD is received, we suggest that evaluating MS give informal conclusion before the formal reception of the DD. Improve communication with authorities during FD execution to take into account new information generated in order to adapt if needed.
There is often focus on substances with a lot of data available, used in industrial settings with no consumer exposure. These should have low priority.
Direct contact to MSA is required, but there appear to be differences amongst member states
Focus on real hazard substances
Intense dialogue between eMSCA and registrants to avoid inefficiencies and costs on both sides. Avoid parallel processes (e.g., CCh vs. SEv). Stick to Roadmap process. Early indication of relevant MSC meeting to facilitate registrants' preparation.
Better selection of priority substances
1. Make more clear as to why the substances have been picked. 2. For joint submission members the process should be explained simpler, as they do not have the expert personnel as the lead registrant has. 3. For joint submission members, it´s totally unclear under which tonnage band the new studies will fall.
Sufficient discussion between evaluating MS and registrants is necessary to ensure mutual understanding of the issues and the characteristics of the substance/registration dossier. In cases where the evaluating MS is not the same as the one who prepares the draft proposal for inclusion in the CoRAP, it will be impossible to have a preliminary discussion on the justification of the inclusion and the concerns about the substance.
The process of commenting (on decisions as well as on PfA) gives a strong feeling of unfairness. ECHA and MSCA are given much more time (resources) to prepare initial comments and final comments - the registrant only has one opportunity. We experience that we receive completely new arguments / comments based on the comments we submitted, sometimes many months later, where we have no opportunity to discuss. I would strongly suggest to organize a final call with all parties between commenting and writing final decision, allowing for final clarification.

C3.4 Responses related to interaction between eMSCAs and Registrants and between the registrants themselves

3.4.1. Please specify if you have had informal discussions with the evaluating Member State during the phases described below and the issues that these covered.

Registrants have reported that informal discussions with the eMSCAs were held throughout all stages of the process (according to the 22 respondents who responded to this question). Respondents note that the greatest number of informal discussion with eMSCAs occur during the evaluation stage (20). Discussions during decision making (13) and preparation of the CoRAP (11) seem fairly common as well, as they each were experienced by at least half of the respondents. Thematically, the answers show that the four proposed issues are all commonly referred to during those informal discussions. The number of answers range between 25 for substance identity and hazard endpoints, and 21 for substance evaluation procedure and obligations. The results are displayed in more detail in the figure below.

Figure C3.9 Responses (number) to question 3.4.1: Please specify if you have had informal discussions with the evaluating Member State during the phases described below and the issues that these covered.



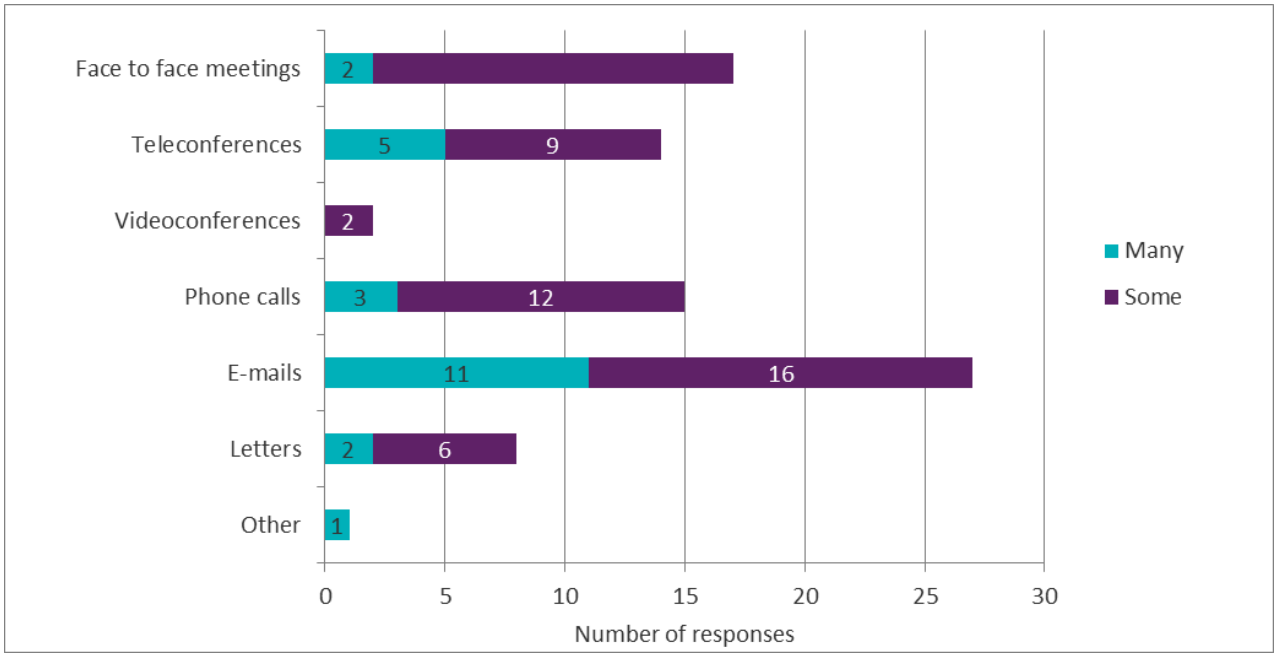
Further comments by the respondents indicate that these types of discussions are mostly undertaken by the leading registrants only. Furthermore, some respondents note that despite the discussions, the impact of their comments is unsure, particularly as not all eMSCAs are sufficiently open to such discussions.

3.4.2. What means of interaction with the Member State(s) did you use and how frequently?

The figure below reveals the experiences of the respondents regarding frequent means of interaction with the Member States. According to the responses given, email is the most commonly used means of communication between registrants and MSCAs (27) with 16 respondents qualifying the number of emails as "many". Other common means of interaction reported by respondents include face to face meetings (17), phone calls (15) and teleconferences (14). Only a few respondents claim to have "many" of such interactions, as follows: face to face meetings (2); phone calls (3); and teleconferences (5).

Commenting on the question further, one respondent noted that "[…] *there are no minutes of the meetings coming from the member states. This would be useful to get some minutes for the later process*."

Figure C3.10 Responses (number) to question 3.4.2: What means of interaction with the Member State(s) did you use and how frequently?



3.4.3. If you have reported interaction in the question above, please indicate below if this interaction was helpful and whether it helps you to understand your obligations and how to address the areas of concern for your substance(s).

57% of the respondents find that the interaction with the Member States was helpful with regards to the obligations and means of addressing the concerns for the respective substances. Only 9% disagreed, while the rest (34%) did not take a position.

A number of respondents provide feedback and suggestions for improvement. Many registrants stress the importance of frequent interaction between the MSCAs and the registrants. A selection of comments providing more detailed information is listed in the table below.

Table C3.9 Comments to question 3.4.3.: Please indicate if the interaction with MSCAs was helpful and whether it helps you to understand your obligations and how to address the areas of concern for your substance(s).

Comments
Interactions are always useful. It is mandatory to help the MCSA to better understand the chemistry, the uses, and also the concerns on how to conduct the testes, the technical issues for testing, as an example.
The interaction was very much depending on the members of Member States. With certain Member States no interaction was possible at all.
Interaction should actively be sought by all eMSCAs.
eMSCA contacted us before we received the draft decision via REACH-IT to provide background to the draft decision. This gave us more time to prepare the comments and has been very much appreciated.
It would be great to receive a time table from the eMS. DD was sent in April 2014. After sending our comment and preparing an update of the dossier nothing happened. We still do not know when evaluation will continue.

3.4.4. Have you encountered difficulties in deciding who of the registrants shall perform and submit the requested studies on behalf of the others?

Very few respondents (13%) report difficulties deciding who of the registrants perform and submit the studies, while 62% have not encountered such problems and 25% did not have a view. Five of the respondents that provide further detail to their answer state that the lead registrant usually took on those tasks, or should do so. Comments elaborating on these problems are displayed in the following table.

Table C3.10 Comments to question 3.4.4.: Have you encountered difficulties in deciding who of the registrants shall perform and submit the requested studies on behalf of the others?

Comments
Different strategies between the leaders: data access and data sharing issue for supporting study and read-across purpose.
We have already some data-sharing issues within the SIEFS (data used without any compensation, that is not an entry for the check of the IT compliance check of the REACH registration dossiers, really difficult to get the money back through local legal actions), the costs are clearly an issue during the substance evaluation process, because the competitors do not want to spend extra money of the substance dossier.
It is very difficult to understand which registrant needs to perform which study and how the studies could be shared between the registrants. It is a critical issue and it does not seem with this aspect that animal welfare is taken into account.
Some co-registrants did not respond, some registrants of transported intermediates do not want to share costs (topic to be clarified in detail, including situation of latter registrants).
It was impossible to agree on this issue, so that ECHA eventually decided who should perform the studies.

3.4.5. Are you in contact with downstream users when your substance is placed on the CoRAP in order to get more detailed information of uses and exposure? If YES, please indicate whether downstream users have supported you.

Half of the respondents replied yes to this question with 32% reporting that they have not been in contact with downstream users, and 18% that they have no view. Where provided by respondents, the additional comments indicate that the process is complicated and lengthy, but in most cases there is a supportive attitude by downstream users. The helpfulness of downstream users was reiterated by a few other registrants (although no further comment was provided). More detailed comments are listed below.

Table C3.11 Comments to question 3.4.5.: Are you in contact with downstream users when your substance is placed on the CoRAP in order to get more detailed information of uses and exposure? If YES, please indicate whether downstream users have supported you.

Comments
Contact with DUs is part of many REACH process and especially in the registration process. In some cases, SEV can enhance these contacts but it is not always the case. For ex we encounter the case where MSCA have access to DU reports and request us to modify our CSR accordingly but we cannot since the DU does not provide us the information and prefer make a DU report to ECHA.
Downstream users want to know very quickly how the business could be impacted. We are under a lot of pressure for the defence of the product but up to now no specific support was provided.
Supply chain communication takes a lot of time and effort, and needs consolidation of the responses. It is therefore not applicable means to do in a strictly deadlined regulatory process.
Most of them support us, However if the supply chain is long with many members from registrant to final user, it is really difficult to get the information.
Our downstream users have been very supportive. However it required us thorough communication with the downstream users and their trade associations to gain their understanding and establish trustworthy collaborations for CoRAP.

Comments
Very limited support. Exposure data missing.
Large DUs are supportive
Some DU are only worried about the fats that the substance is evaluated. ***Some DU gave additional information about their uses.***
Limited experiences in SEv, in general downstream users tend to be quiet.
As registrant of a TII, the substance is fully consumed in our plants
It is difficult to work with DU's in the early phases as the precise concern/impact is not yet known. DU's or their organizations are contacted once the requirements are clarified (draft or final decision stage).
Yes and No; contacting downstream users is a large exercise, especially in case of commonly used substances. There is simply not enough resources to do this. So, typically a selection of representable DUs is chosen
We talked to all of our customers. It was very hard to get the necessary information. Large companies did not want to give detailed information away or did not have time to work on it. Smaller companies (especially in countries such as Italy, Spain, Poland) hadn't even heard from REACH and do not know what to do.

3.4.6. Are there any other elements you would like to comment or reflect upon regarding interaction with the evaluating MSCAs or with other registrants? Do you have any suggestions to improve these processes?

According to three of the respondents that elaborated with further comments and suggestions for interaction with the eMSCAs, the experiences vary strongly between different Member States. Although one of them states that the "*CORAP process should be equal in all MSs*". Another comment made is that "*interaction should actively be sought by all eMSCAs*".

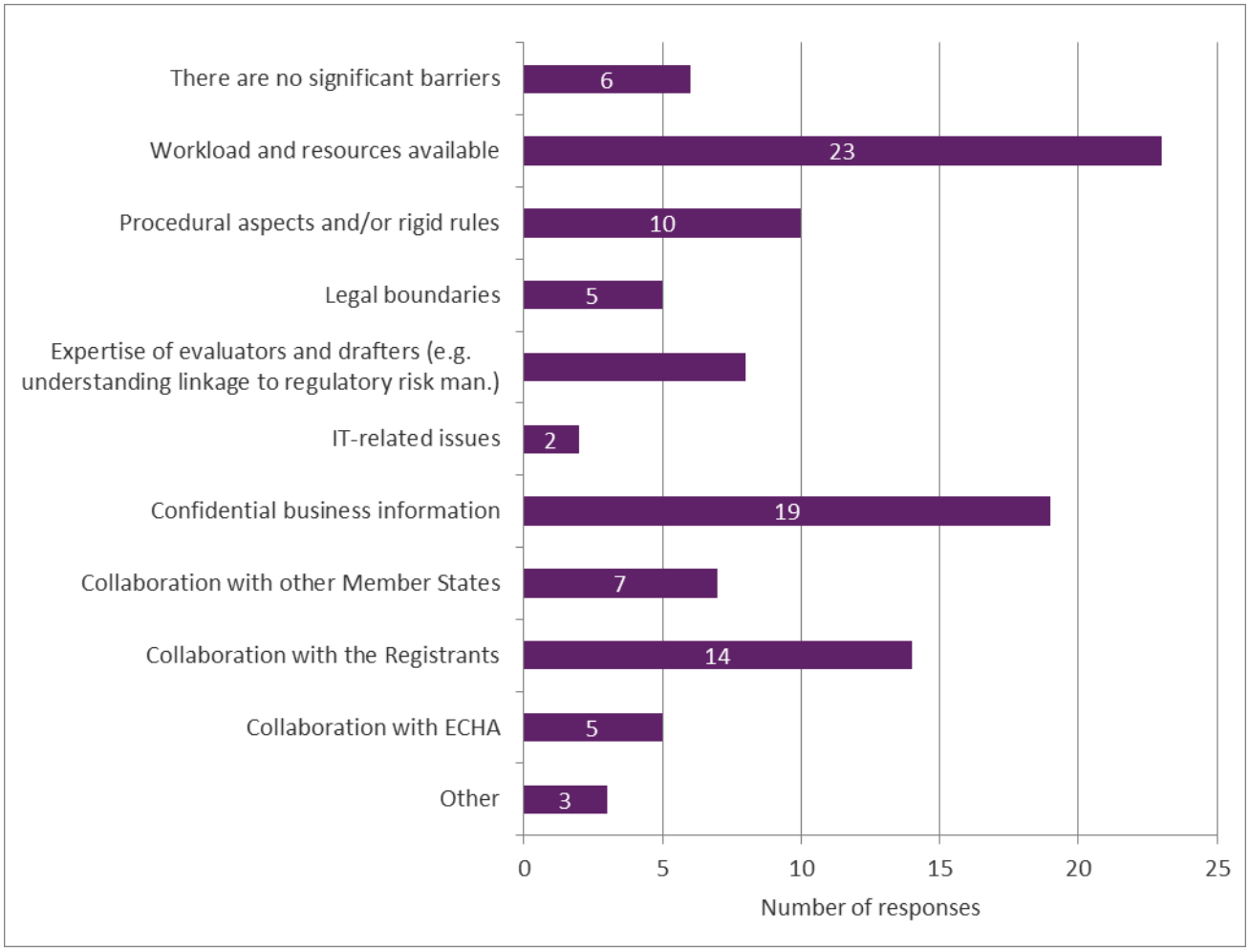
Suggestions made by registrants include the possibility to comment prior to the CoRAP becoming final as well as allowing the participation of registrants in the Member State meetings regarding their respective dossier. This latter suggestion would, according to the respondent, enable registrants to provide the Member State with their interpretation and to discuss scientific issues directly.

C3.5 Responses related to horizontal and general questions

3.5.1. Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?

Regarding barriers hindering the efficiency of the evaluation process, workload and resources available is the most recognised barrier according to the survey. More than half of the respondents (55%, corresponding to 23 respondents) identify this barrier. Confidential business information (19 respondents) and collaboration with the registrants (14 respondents) are the next most commonly encountered problems. The full list of responses can be seen in the figure below.

Figure C3.11 Responses (number) to question 3.5.1.: Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?



A number of respondents also specified the issues they encountered. The relevant comments are collected in the table below. Main points of concern refer to either the flow of information (openness of the authorities to new information, confidentiality, complicated communication between registrants and with downstream users) or the burden on the business, particularly due to the resulting work load.

Table C3.12 Comments to question 3.5.1.: Please identify if there are any barriers that hinder the efficiency of the substance evaluation process?

Comments
It seems that MSCAs do not have access to the latest dossier update and to the dossier (CSR) of non-lead/co-registrants.
It is difficult to share with MSCA & ECHA regarding the technical points and to reach an agreement.
Communication with downstream users / impact on business even in situations of uncertainty.
The information which has to be submitted is often very specific and difficult to understand for non-specialists. Furthermore there is a lot of discussion within the consortium to decide just to follow the Member State request or to follow the own opinion. In combination with the daily workload this costs a lot of effort.
Availability of confidential use and exposure data is a challenge. A lead registrant cannot legally acc. to competitiveness legislation consolidate the volumes nor exposure information (unless via the use of a trustee, which takes time). Could ECHA somehow be available to act as such a trustee? ***Also the responsibility of the aggregated exposure assessment should be allocated to the independent authorities,***

Comments
not to a Lead Registrant who is one of the market players and thus never an independent party. Would one possibility be that the overall exposure and risk assessment be made only at the substance evaluation phase by the authorities?
It is certainly resource-demanding. Some data is specific to certain customers e.g. specific exposure scenarios, so we have to check contracts/security agreement with downstream users. Collaboration with other registrants can be an issue, especially if CoRAP leads to new cost sharing.
Exposure data from DU
Language barriers
Many registrants are OR that do not participate in the discussion
Co-registrants depend on the willingness of the lead registrant to keep others up to date on ongoing discussions with the eMSCA. Data and cost sharing rules are not clear with regard to the addressees of the CoRAP decision (e.g., actual and future registrants of the substance: will the CoRAP tests be mandatory for future registrants to have a compliant dossier?)
The process of commenting (on decisions as well as on PfA) gives a strong feeling of unfairness. ECHA and MSCA are given much more time (resources) to prepare initial comments and final comments - the registrant only has one opportunity. We experience that we receive completely new arguments / comments based on the comments we submitted, sometimes many months later, where we have no opportunity to discuss. I would strongly suggest to organize a final call with all parties between commenting and writing final decision, allowing for final clarification.

3.5.2. Apart from interacting with the evaluating Member State competent authority did you contact ECHA helpdesk and or national helpdesk for seeking advice on substance evaluation in general or regarding your substance in the CoRAP? If YES, please indicate if the advice was helpful.

Ten respondents, 23% of the respondents taking a position on this question, state that they have contacted the ECHA or national helpdesks. Five of them confirm in further comments that the advice was at least partly, if not mostly helpful. No respondent made a comment to the contrary.

C3.6 Additional comments or information

Three further specific comments were made by respondents in this concluding section. One addresses the banning of CoRAP-listed substances by other players irrespective of the results of the evaluation process, another one the difficulty of breaking volumes down to various uses and the third one the proportionality of information requirements. The comments are listed below.

Table C3.13 Comments to question 5. Please provide any additional comments or information.

Comments
In many cases, retailer, NGOs, ECO-label, etc. put substances mentioned in CoRAP-process on their restricted substances lists independently from the results of the evaluation process. In most cases this leads to a complete ban of the concerned substances and does not follow the systematic of a risk assessment.
Breakdown of volumes between various uses is currently not possible to get. Therefore, risk assessments of the substances unfortunately need to remain on a general level.
We are deeply worried about proportionality - there seems to be no boundary in information requirements that can be requested in the CoRAP process which in our opinion are not proportional to any perceived risk.

C4 Analysis of responses to the survey provided by accredited observer stakeholder organisations of the MSC and Commission Services

C4.1 Profile of the respondents

Representatives of three observer stakeholder organisations (STOs) as well as two representatives from the European Commission (EC) (the Environment Directorate-General Chemicals) responded to the survey. The respondents of this category cannot be assigned to specified countries, they are all associated with organisations that operate at an EU-level. However, the STOs represent certain groups of stakeholders that can be specified in more detail. The STOs involved in this survey represent very diverse groups, namely the metals industry, non-EU manufacturers of chemical substances and preparations thereof, as well as crafts, trades and SMEs. Thus, despite the limited number of respondents, a wide range of stakeholders are reflected in this survey.

C4.2 Responses related to the selection of substances

4.1.1. Do you agree that CoRAP includes substances for which substance evaluation is needed to clarify the concern and has potential regulatory added value? If relevant, please provide examples of substances where you disagree and your reasoning.

All respondents, except one abstention from an EC representative, agreed to some degree that CoRAP includes substances for which substance evaluation is needed. One respondent accredited this regulatory added value to all CoRAP included substances (one to most of them and two to many of them). The EC representative abstaining from voting noted that for the substances known to the respondent, in several cases substance evaluation was not the appropriate tool to address the concern. Another respondent stated that the “focus should if possible be on concerns that passes the capacity of a single registrant” and that a CCH dossier could have resolved many substance evaluations. The respondent also provided two concrete examples:

- *ZnPO4 case by Romania: unclear intention at the start of the assessment.*
- *GaAs case by Lithuania: case was covered by an ongoing harmonised classification. So unclear what the added value of listing this on CoRAP was.*

4.1.2. In light of the experience so far, indicate how you think the future annual number of CoRAP substances should evolve. If you think it should be increased/decreased please indicate by how much and why.

While only one respondent decided to make a definite statement, namely to keep the annual number of CoRAP substances the same as currently i.e. approximately 50 per year, some additional views had been expressed in the comments by the other respondents. One EC representative remarked that “a political commitment made by our previous Commissioner for the environment suggested about 100 substances.” Two respondents, the latter of which an EC representative, stressed the low importance of the number itself compared to the importance of having an appropriate selection criteria as well as the application of the evaluation where most appropriate:

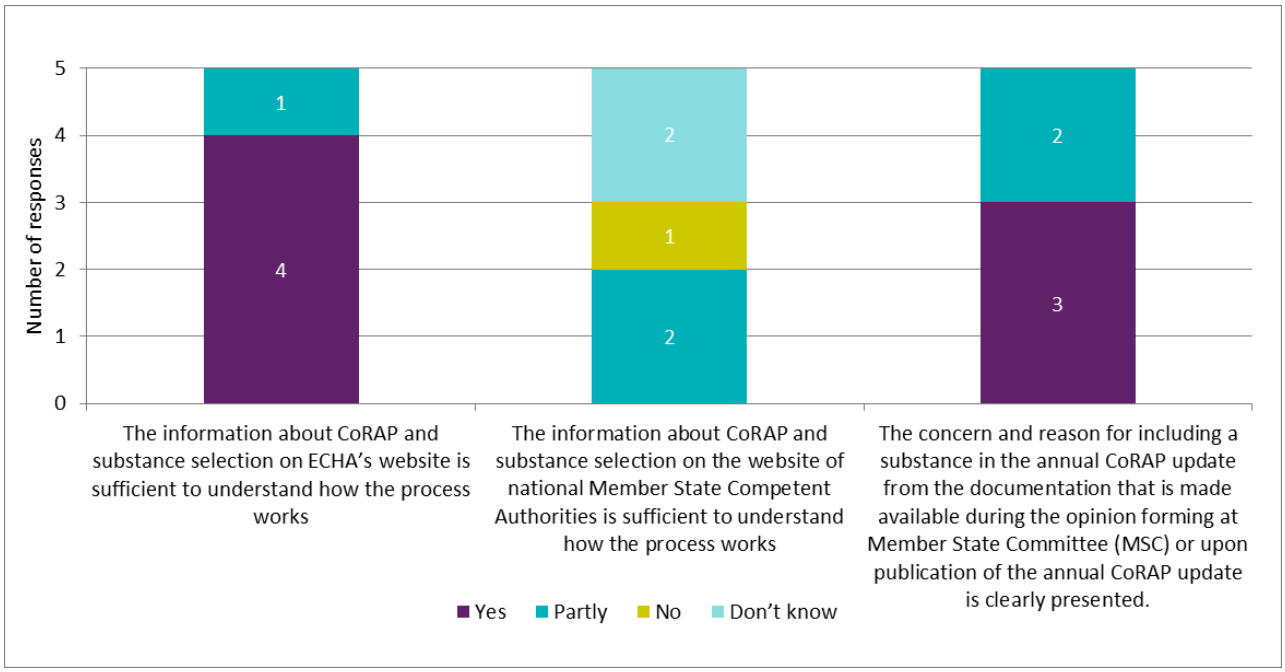
- *The number is not so relevant and depends on the selection criteria used for ACROSS. What is probably more relevant and important is that the cases selected are potentially relevant for common concerns/issues/case so that a reported Substance Evaluation can cause a "catalytic or domino effect" to improve the quality of the registration dossiers and the understanding by authorities.*

- *I think that rather than searching for a number of substances with largely varying information requests, substance evaluation can be used as a targeted instrument to address uses of concern or certain exposures of potential concern and then find the substances which fit. Examples are substances in textiles, plastic softeners, monitoring programme for PBTs or near PBTs, etc. Of course the option to have individual priority substances nominated from MSs must also remain.*

4.1.3. Please indicate whether you agree with the following statements on information available about CoRAP and substance selection.

The answers to this question are displayed in the figure below. Regarding the information about CoRAP and substance selection available on the ECHA website[88], the responses are very positive. Four of the five respondents agreed that the information is sufficient to understand how the process works, while one respondent stated it partially does. However, information regarding the Member States Authorities' websites was evaluated more critically by the respondents. Two of them judged it partially sufficient to understand how the process works, one judged it insufficient and two respondents abstained from voting. Clarity of concern and reason for CoRAP listing during opinion forming at Member State Committee (MSC), or upon publication of the annual CoRAP update, are regarded rather positively by the respondents (Three yes, two partially). One respondent noted the following to elaborate on the last question: "*The publication of the reasons why a substance is selected improved with the increased transparency of the CoRAP and ACROSS selection criteria and reporting. However, a member states sometimes has other parallel concerns than openly omitted/published during the CoRAP listing (clear examples exist)*."

Figure C4.1 Responses (number) to question 4.1.3.: Please indicate whether you agree with the following statements on information available about CoRAP and substance selection.



4.1.4. Do you have any suggestions on the prioritisation and selection of substances subject to inclusion in the CoRAP updates?

The EC representatives proposed a more targeted approach of applying substance evaluations or a grouping of similar substances. Another respondent suggested replacing subject evaluations with CCH

[88] A link to the relevant website was given to the respondents: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screeninghttp://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

where appropriate. Nanomaterials and substances where the RMOA shows data-gaps were proposed as concrete examples for selection and prioritisation. The answers are displayed in detail in the table below.

Table C4.1 Responses to question 4.1.4.: Do you have any suggestions on the prioritisation and selection of substances subject to inclusion in the CoRAP updates?

EC/STO	Responses
STO	*Better consider if a concern can be resolved in a CCH rather than an SE. The latter concerns should in principle go beyond the capacity of the registrants.*
EC	*[…] Substance evaluation can be used as a targeted instrument to address uses of concern or certain exposures of potential concern and then find the substances which fit. Examples are substances in textiles, plastic softeners, monitoring programme for PBTs or near PBTs. Of course the option to have individual priority substances nominated from MSs must also remain.*
EC	*Could similar substances be grouped such as to increase efficiency of the process?*
STO	*1) (potential) nanomaterials, instead of changing annexes of the REACH-regulation* *2) Where the RMOA shows data-gaps and before taking other regulatory measures (e.g. authorisation, restriction...)*

C4.3 Responses related to substance Evaluation, decision making and follow-up phases

4.2.1. What in your view is the most difficult aspect of the decision making process for SEv cases? How could this be improved?

The respondents expressed a variety of different views on the decision making process for substance evaluation, as listed in the following.

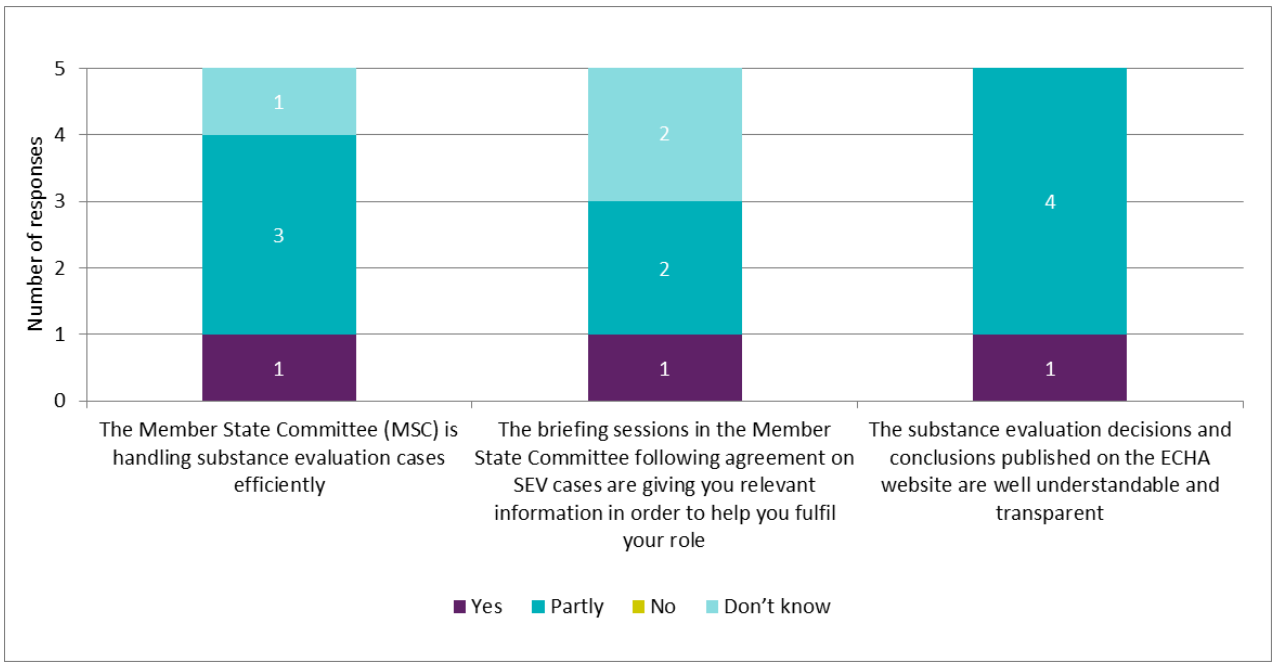
Table C4.2 Responses to question 4.2.1.: What in your view is the most difficult aspect of the decision making process for SEv cases? How could this be improved?

EC/STO	Responses
STO	*We have more than one issue in this respect:* *- Ensuring consistency between the SEs.* *- Enabling registrants to resolve the issue proactively given this aims for the aimed improved chemicals management level.*
STO	*Which substances to select with available resources. Should be exposure driven.*
EC	*The fact that substantial exposure information is being requested which is very difficult for the registrant to obtain OR is in fact lacking from the CSR (and hence not compliant). It can be improved by no longer attempting to get such information and having the CA, after a consultation of the registrants on the same points, develop a restrictions proposal based on default values. The work put into the substance evaluation seems considerable.*
EC	*Difficulty of agreeing on the exact level of information needed. Especially for the exposure part, information needs are harder to define than for hazard ID questions.* *SEv process was designed to clarify concerns rapidly. The recently advocated tiered process may significantly delay a final conclusion.*
STO	*Communication between dossier-submitter(s) and evaluating authority - this should be an open discussion between partners and not opponents trying to prove that the other is wrong.*

4.2.2. Please indicate whether you agree with the following statements. If your answer is not YES to any of these, please provide further commentary and suggestions of improvement.

The efficiency of the substance evaluation and the relevancy of information during briefing sessions by the Member State Committee, as well as the transparency and clarity of SEv decisions as published by ECHA are rated separately by the respondents. As shown in the figure below, the majority of respondents agreed partly to all of the questions. It is notable however, that no respondent fully disagreed with any of the statements.

Figure C4.2 Responses (number) to question 4.2.2.: Please indicate whether you agree with the following statements.



One STO and an EC representative made very detailed comments on the matter.

Table C4.3 Comments to question 4.2.2.: please provide further commentary at the foot of the table and suggestions of improvement.

EC/STO	Comments
STO	*The way how the outcome of the SE is reported to STO is often too administrative and could benefit from a discussion/identification of the horizontal learning lessons that would allow improving the generic chemicals management level based on the SE as "an indicative example".* *There is no possibility to draw horizontal learning lessons from cases that are closed without a decision (e.g. Be).* *Picking up horizontal learning from SEs that are closed by written procedure is very difficult, thereby missing lots of potential to improve the chemicals management level of registrations for comparable substances or comparable situations/cases.*
EC	*Q1: MSC discussions not always efficient or factual, as similar issues and arguments are being repeatedly played.* *Q2: Can't comment as COM also follows closed session.* *Q3: Some decisions appear rather lengthy and too detailed regarding procedural points. Information requests for exposure data are not in all cases fully clear and hence ambiguous to implement.*

4.2.3. Are there any other suggestions or elements you would like to comment or reflect upon regarding substance evaluation by the evaluating Member State or coordination by ECHA secretariat?

The main improvements regarding substance evaluation by the evaluating Member State or coordination by ECHA secretariat suggested by the respondents are:

- Stronger interaction between eMSCA and registrants.
- CCH in advance of an SE.
- Improving SE reports.
- Involvement of external experts early on in complex cases.

The comments are listed in detail below.

Table C4.4 Responses to question 4.2.3.: Are there any other suggestions or elements you would like to comment or reflect upon regarding substance evaluation by the evaluating Member State or coordination by ECHA secretariat?

EC/STO	Responses
STO	*Some member states see SE as a case to resolve internally for an individual substance while at the other side of the spectrum, some MSs see this as a case to interact with industry to improve the assessments on a given issue. The latter may request more energy but creates much more added value in respect to the generic aims of REACH. A better interaction with registrants during the MSs SE assessment could help improve the relevancy of the assessment. It is understood that this initiative should come from the eMS when the assessment has been launched.* *A CCH in advance of an SE has many benefits and should always be strived for, given more efficient.* *The lack of an insight in the SE-report makes it often difficult for registrants to define what has been reviewed (scope), to what extend (depthness) and what was felt OK. More openness is requested here given the SE-report may provide exactly the messages that could create the added value for the registrant to motivate further improving his/her registration dossier but also define learning cases for other substances.*
EC	*When a draft decision is shared with MSC, it is not always very clear how much the eMSCA has already involved ECHA experts or other MS in the evaluation. Complex cases might benefit from early involvement of others.*

C4.4 Responses related to horizontal and general questions

4.3.1. The first substance evaluations started in 2012 and annually there has been an update to the CoRAP. In your opinion has the substance evaluation process improved from the setting up in 2012 to the present time in 2015? How?

According to the respondents, the SEv process clearly improved since 2012. Particularly the STOs commented positively. Especially increased transparency was mentioned as a concrete example of how the process improved. The below table lists the responses.

Table C4.5 Responses to question 4.3.1.: The first substance evaluations started in 2012 and annually there has been an update to the CoRAP. In your opinion has the substance evaluation process improved from the setting up in 2012 to the present time in 2015? How?

EC/STO	Responses
STO	*Yes it did. It became in particular more transparent. Alternatively it lost some transparency/value due to the increased use of the written procedure whereby the learnings are partially lost. We believe that it is relevant to explore a better reporting solution for substances that closed under WP.*
STO	*Yes, more efficient and MSCAs are more transparent and easier to Approach from industry.*
EC	*As not all elements of the process have been active from the beginning, it is difficult to compare. As processes kicked-in, challenges were successfully addressed.*

EC/STO	Responses
STO	*It became more transparent. The cooperation between evaluating authorities and registrants tends to improve.*

4.3.2. Do you think there are any barriers that hinder the efficiency of the substance evaluation process?

As shown in the figure below, the workload as well as the collaboration with registrants are the barriers most commonly named by the respondents. Further comments made by two respondents support this, as they address the same issues. They are listed in Table C4.6.

Figure C4.3 Responses (number) to question 4.3.2.: Do you think there are any barriers that hinder the efficiency of the substance evaluation process?

Table C4.6 Comments to question 4.3.2.: Are there any other suggestions or elements you would like to comment or reflect upon regarding substance evaluation by the evaluating Member State or coordination by ECHA secretariat?

EC/STO	Comments
STO	*There is still too much diversity in how MSs communicate with registrants. Defining a minimum level and a best practice level based on cases could probably help to improve. Collaboration with registrants can certainly further improve (e.g. allowing/stimulation the eMS to pose questions for clarification or detail during the SE process, or to review the draft DD with the registrant before starting the formal review procedure given this may clarify misunderstandings).*
EC	*It seems that substance evaluation is a very resource intensive activity, implemented with quite a high resource implication in ECHA. The legal boundaries also exist, though not in Art 46(1), but through the fact that the information must be obtainable for the registrant and be the registrants responsibility. Hence given the resource*

EC/STO	Comments
	intensity and the clear limitations a discussion on the efficiency of which information can easiest be obtained, based also on an assessment of what information has been submitted as a result of substance evaluation, would be useful.

4.3.3. What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).

Two respondents considered the number of cases where SEv triggered changes in company level risk management without need for EU wide regulatory risk management as the most important effectiveness indicator for SEv. While that is more than any other proposed indicator, three other indicators have also been considered the most important by one respondent. This reflects the similar importance of multiple indicators, which also varies by case as the comment of one respondent suggests. Interestingly, the number of clarifications of concern without needing a formal decision was ranked the second most important indicator by almost all respondents. The detailed results are shown in the figure below and the comments which include proposals for other indicators in the table below.

Figure C4.4 Responses (number) to question 4.3.3.: What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).

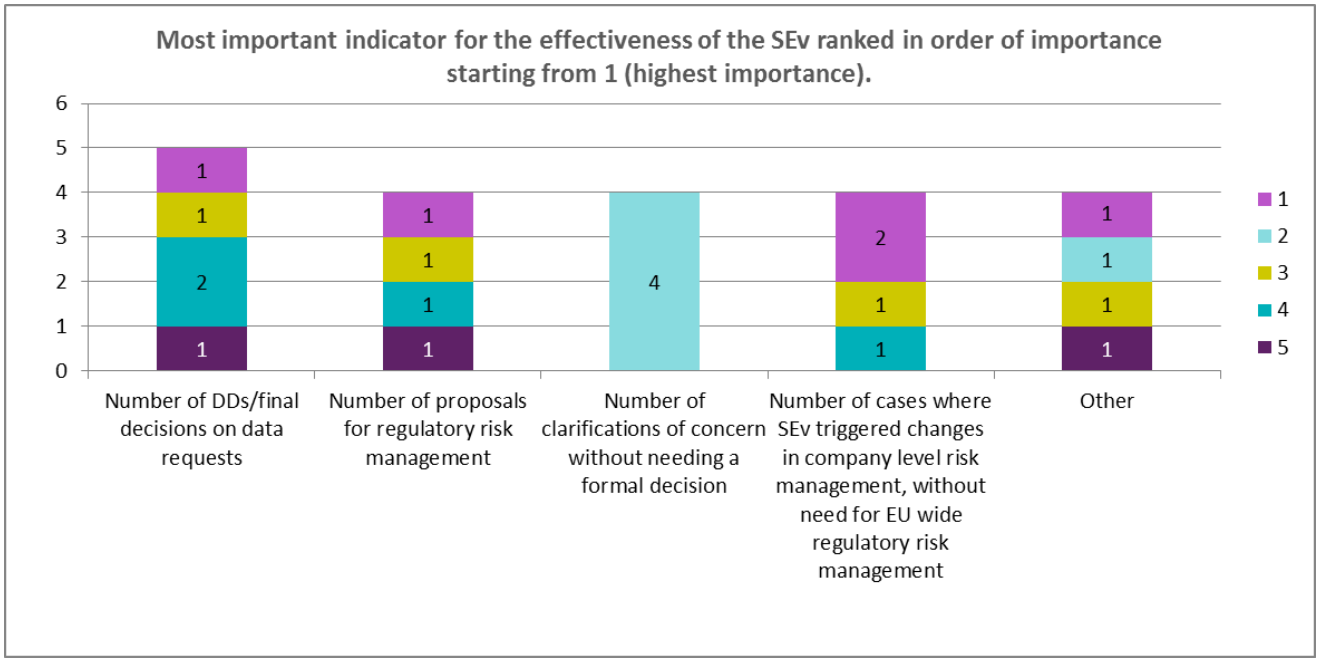


Table C4.7 Comments to question 4.3.3.: What do you think is the most important indicator for the effectiveness of the substance evaluation process? Rank these in order of importance starting from 1 (highest importance).

EC/STO	Comments
STO	*Other: the number of cases whereby a SE outcome/conclusion influenced / triggered the update of other registration dossiers stimulating improvement of the chemicals management level.*
EC	*The question is 'effectiveness'. Clearly the stats listed are interesting for various reasons, but effectiveness means meeting the goals of substance evaluation. For that a goal needs to be set - at the moment the goal seems to be 'for the MS to request the registrant to update the CSR to meet the standard they wish'. For that purpose the number of DDs is the best measure. However, this is in my view not the appropriate goal of substance evaluation.*

EC/STO	Comments
EC	*First 3 are equally important, depending on the case at hand. Alternative indicators: a) number of clarified issues (regardless how - effectively CORAP) and b) number of cases where RMM has been modified based on it (regardless which) c) if possible, estimation of multiplier effects of a) and b) compared to number of cases picked*
STO	*[Other:] No action - That would mean that registrants are fully understanding their obligations and have submitted exactly the data that authorities expect from them. That again would mean that obligations and authorities-expectations are clearly communicated.*

C4.4 Additional comments or information

Two further specific comments had been made by respondents in this concluding section. An STO representative recommended early communication between eMSCA and registrants so that they can anticipate the needs of the authorities. An EC representative noted the following:

The SEv process appears to suffer or be delayed due to several aspects in REACH that have not been sufficiently defined yet. Examples: Criteria for requesting EOGRTS cohorts; exposure information - which use or foreseeable use scenarios should be included; what information a registrant needs to include when waiving studies.