ECHA
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SVHC Roadmap to 2020 Implementation Plan

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List of abbreviations

Abbreviation	Description
ACT	Activities Coordination Tool
Art.	Article
CCH	Compliance Check under Dossier Evaluation
CLH	Harmonised Classification and Labelling
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogen, Mutagen, Toxic for Reproduction
CG	Coordination Group
CoRAP	Community Rolling Action Plan
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert Group
ENV	Environment
ELoC	Equivalent Level of Concern

GHS	Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
HH	Human Health
IARC	International Agency for Research on Cancer
ID	Identification
IUCLID	International Uniform Chemical Information Database
IPCS	International Programme of Chemical Safety
PBT	Persistent, Bioaccumulative and Toxic
OECD	Organisation of Economic Co-operation and Development
(Q)SAR	(Quantitative) structure-activity relationship
PACT	Public Activities Coordination Tool
PETCO	Petroleum and Coal Streams
POP	Persistent Organic Pollutant
REACH	Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	Information Technology system for REACH
RESP SENS	Respiratory Sensitiser
RoI	Registry of Intentions
RMOA	Risk Management Option Analysis
SKIN SENS	Skin Sensitiser
SEv	Substance Evaluation
SVHC	Substance of Very High Concern
UVCB	Unknown or Variable Composition, Complex Reaction Products and Biological Materials
vPvB	Very Persistent and Very Bioaccumulative
WHO	World Health Organisation

1. Introduction

Based on the commitment made by Vice-President Tajani and Commissioner Potočnik to 'have all relevant currently known Substances of Very High Concern (SVHCs) included in the candidate list by 2020', the Commission developed a 'Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020'[1] (in the following: SVHC Roadmap to 2020), which found widespread support from the Member States at meetings of the Competent Authorities for REACH and CLP (CARACAL, November 2012 and March 2013) and at the Competitiveness Council (February 2013) and the Environmental Council (March 2013) meetings. This document outlines how the SVHC Roadmap to 2020 is foreseen to be implemented. The main elements of the implementation presented in this document have been developed in close cooperation between the Member State Competent Authorities, the European Commission and ECHA.

The SVHC Roadmap to 2020 foresees the use of screening methods and of Risk Management Option (RMO) analyses to identify the relevant SVHCs using information from the ECHA registration database, other REACH and CLP databases and further available relevant sources. The SVHC Roadmap to 2020 lists as groups of substances to be covered by the implementation plan CMRs, sensitisers, PBTs and vPvBs, endocrine disrupters and petroleum/coal stream substances with CMR or PBT/vPvB properties.

Both screening and RMO analysis contribute to establishing which substances are 'relevant SVHCs' in the context of the implementation of the SVHC Roadmap to 2020. In Section 2 it is outlined how 'relevant' SVHCs are identified by combining a series of screening (refinement) steps with RMO analysis.

In the screening phase it is possible to pick from the registration (and other REACH/CLP) databases substances which have or are likely to have the necessary intrinsic properties to be SVHCs substances.

In some cases there is a need for **additional assessment of existing information and/or to generate further information** to have sufficient basis to conclude that the substance is likely to meet the Art 57 criteria. How this is done in practice depends on the substance group and on the case; available approaches include further assessment by the PBT/ED Expert Groups, information generation via dossier or substance evaluation, the harmonised classification process and assessment whether the substance is likely to be of equivalent level of concern. These additional working steps to support the conclusion that a substance is likely to meet Art 57 criteria[2] require clear and well-functioning interfaces to the evaluation and harmonised classification and labelling (CLH) processes.

The screening activities and the links to the further information generation are elaborated in *Section 2.1* and in the substance group specific *Annexes 2 - 6*.

In the **RMO analysis** phase, case-by case assessment is needed to conclude on the remaining aspects which define whether a substance is a 'relevant SVHC' in the context of the SVHC Roadmap to 2020. According to the roadmap these aspects cover i) whether registrations include uses within the scope of authorisation[3], ii) that the known uses are not already regulated by specific EU legislation that provides a pressure for substitution and iii) that there is no need or basis for a restriction and no overarching reasons as to why substitution is not the desired outcome for the substance. The RMO analysis phase is further described in *Section 2.2*.

1 http://register.consilium.europa.eu/pdf/en/13/st05/st05867.en13.pdf

2 It is in the remit of the Member State Committee or the European Commission to finally decide whether a substance meets the SVHC criteria set out in REACH Article 57.

3 I.e. other uses than as isolated intermediate and uses exempted from the authorisation requirement under Articles 2, 56 or 60(2).

Screening activities will cover all substances in the REACH and CLP databases and will be of an iterative nature. The Commission made a preliminary worst-case estimation of 440 substances to be RMO assessed between 2013 and 2020. Hence, achieving the SVHC Roadmap to 2020 objectives will require considerable resources and agreement on how to share the work between Member States, the Commission and ECHA. Also, further intensification of co-operation amongst the actors involved on the regulators' side for a more efficient use of resources appears necessary. Co-operation and co-ordination is reflected in Section 3 and in substance group specific *Annexes 2 - 6*.

Progress indicators are needed to allow monitoring the progress in achieving the policy objectives set by the Commission and Member States and provide basis to identify any needs for refocusing the activities or changing the allocation of resources. The development of such indicators is reflected in *Section 4*.

Communication towards stakeholders and the public in general is another element considered important in the 2020 SVHC Roadmap as transparency on the objectives and activities will support the acceptability of the implementation work and increase its predictability. Clarity on the aim of the authorities' work and openness on the status of the substance in the process should also help avoiding the "black-list" effect for substances under scrutiny. Communication aspects are outlined in *Section 5*.

2. Identification of 'Roadmap relevant' SVHCs

The SVHC Roadmap to 2020 foresees the use of screening methods and risk management option (RMO) analysis to identify the relevant SVHCs using information from the ECHA registration database, other REACH and CLP databases and other available relevant data. Both screening and RMO assessment contribute to establishing which substances are 'relevant SVHCs' in the context of the implementation of the SVHC Roadmap to 2020.

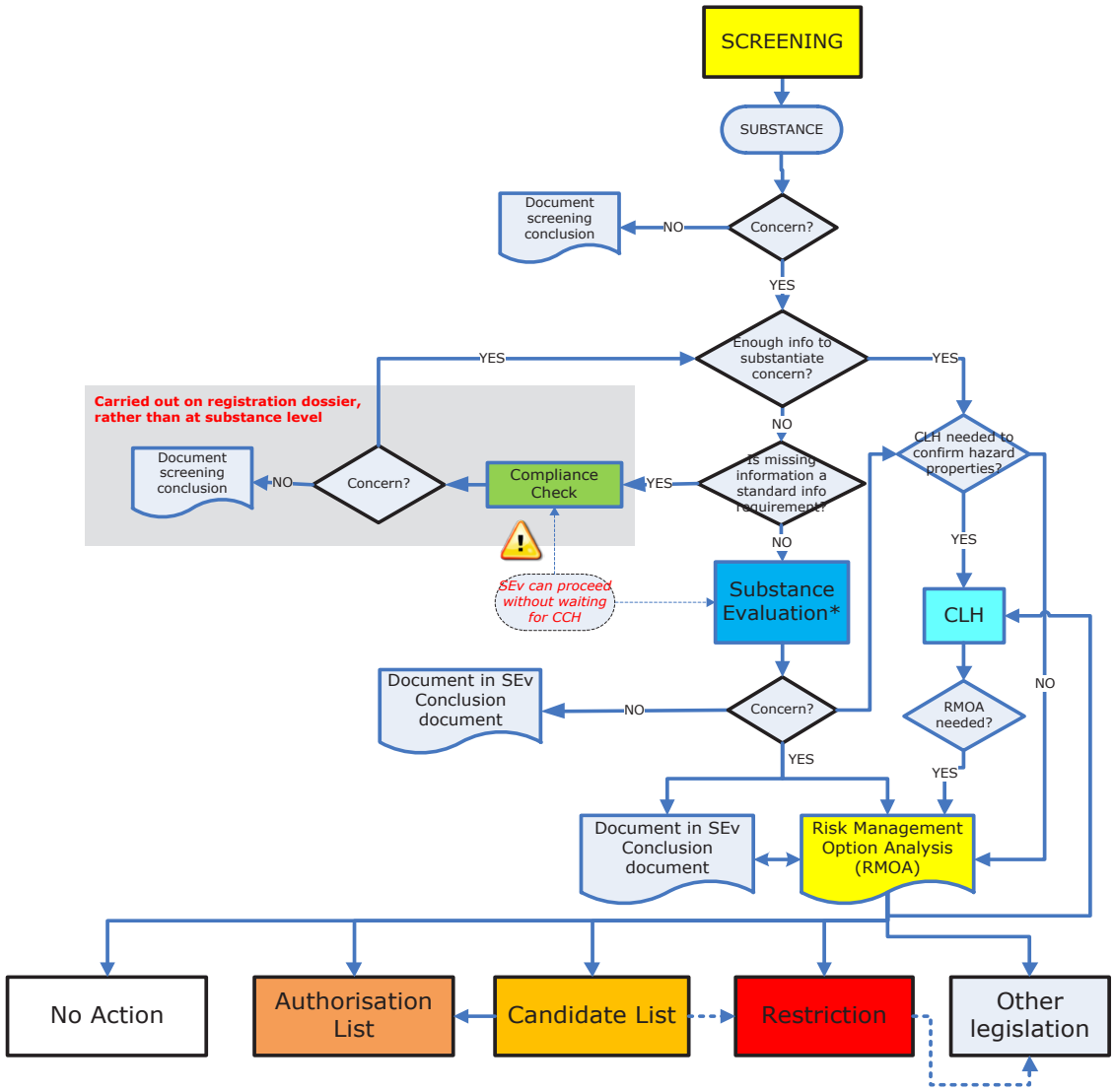
2.1 SCREENING FOR SUBSTANCES OF CONCERN

2.1.1 General context

Part of the authorities' work is to identify substances of concern likely requiring further regulatory risk management action and cases where further information is required to conclude on the hazard properties of a substance or the risk its use(s) may pose to human health or the environment. The screening for identifying potential Roadmap relevant SVHCs is therefore to be seen in a wider context of screening intended to enable on the basis of the available information substance selection for different REACH and CLP processes (e.g. CoRAP listing, Harmonised Classification and Labelling proposals). *Figure 1* illustrates the inter-links between the different REACH and CLP processes.

The term "screening" is here used to cover all identification and investigation of substance (and dossier) specific information, en mass, to make a preliminary assessment to support conclusion on how to proceed with the substance. The screening may result in identification of substances (or dossiers) for which further information is required before it is possible to conclude on the need for further regulatory risk management actions. For some substances there may be need for further assessment of the relevant hazard properties either via the formal harmonised classification process under the CLP Regulation (in particular, CMR and respiratory sensitisers) or informally by expert groups (PBT/vPvB and endocrine disruption properties). Where no further information is needed, the substance will be subject to RMO analysis.

Figure 1: SVHC Screening in wider context: inter-linkages between the REACH and CLP processes.



There may be alternative ways to get missing information, besides using Substance Evaluation (e.g. direct informal contact with industry or enforcement activities)

2.1.2 Screening for SVHCs

In this section the SVHC screening approach foreseen to be applied to the substance groups addressed in the SVHC Roadmap to 2020 is outlined.

2.1.2.1 Purpose

The purpose of screening for SVHCs is to find potential SVHCs which subsequently may be further assessed

to informally conclude on their likely SVHC properties. If it is informally concluded that SVHC properties[4] are likely met the substance is taken forward to RMO analysis.

2.1.2.2 Scope

The SVHC Roadmap to 2020 gives priority to substances with SVHC properties which are registered for non-intermediate uses within the scope of authorisation. The (main) substance groups for which screening activities need to be planned and carried out are:

- CMRs (cat 1A/1B),
- Sensitisers (& subst. with other human health related hazard profiles, which may give rise to equivalent level of concern)[5],
- PBT/vPvBs,
- Endocrine disrupters (EDs) and
- Petroleum/coal stream substances which are CMRs or PBTs[6].

For all these groups of substances screening activities have to be planned and carried out following the same basic approach. Priority will be given to substances that have been fully registered for non-intermediate uses. Screening of these registered substances is considered (and will be referred to) as **"Core Activities".** In addition, so called **"Supplementary Activities"** will be carried out with the aim to identify further (potential) SVHC substances similar to the SVHCs with registrations for non-intermediate uses (and therefore may be taken forward together with these latter substances during RMOA development) but with registration(s) as intermediate only or not being registered. The focus of screening will in the starting phase be on the core activities for each substance group but will, as the substances falling under the core activities have been progressively dealt with, shift towards the supplementary activities. Nevertheless, also in the starting phase flexibility is foreseen on a case by case basis. For instance, it might be relevant in the case of CMRs to bring forward screening work on some supplementary tasks such as registered self-classified CMRs for which relevant properties need to be clarified by Substance Evaluation and harmonised classification achieved in accordance with Article 37 of the CLP Regulation.

Some of the **supplementary activities** are based on screening for substances that are similar to those SVHCs already on the Candidate List, included for SVHC identification in the Registry of Intentions, or identified as potential SVHCs and earmarked for RMO analysis. A (substance group specific) approach to search for similar substances will need to be developed (the draft approach outlined in *Annex 1* may be used as starting point).

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4 In cases where information is insufficient to recognise that obviously SVHC criteria set out in REACH Article 57 are met (e.g. criteria for classification as CMR 1A/1B in accordance with Annex I of the CLP Regulation (EC) No. 1272/2008 or PBT/vPvB criteria in accordance with Annex XIII of the REACH Regulation (EC) No 1907/2006) an informal preliminary assessment may be carried out by qualified staff of the authorities involved in the screening, supported as necessary by the substance group specific coordination or expert groups. Similarly, an informal preliminary assessment may be carried out for substances potentially giving rise to an equivalent level of concern to those addressed by REACH Article 57 (a – e)). Formal conclusion that SVHC criteria set out in REACH Article 57 are met is in the remit of the Member State Committee or the European Commission (in case the MSC cannot find unanimous agreement).

5 Also substances with human health related hazard properties other than sensitisation may be considered, if they may qualify as SVHCs because they appear to give rise to equivalent concern in accordance with REACH Art. 57 (f) (does not include endocrine disrupters, which are dealt with in their own substance group).

6 Petroleum stream substances will for practical reasons be kept as a separate set of substances / work package even though it can be foreseen that they also would fall under the CMR or PBT substance groups.

Further details on the different core and supplementary screening activities to be undertaken for each substance group are provided in *Annexes 2 to 5*.

2.1.2.3 SVHC search and selection criteria

Search criteria define the specific pieces of hazard and fate information that can be used to retrieve potential SVHC substances in each substance group (e.g. classification as a respiratory sensitiser, criteria hinting at potential PBT properties).

Depending on the search criteria (that can be) used, the screening exercises may result in a large number of potential SVHC candidates, requiring more in depth assessment (e.g. potential PBT/vPvBs, potential CMRs cat 1A/1B or potential endocrine disrupters). This more in depth assessment may, for example, need to be carried out in order to clarify hazard properties or to decide whether more data is needed (e.g. through compliance check, substance evaluation) before a conclusion on the SVHC properties of the substance concerned can be drawn.

Selection criteria need therefore be applied to help identifying those substances of higher priority[7] on which work should focus on in the time period planned for. To the extent possible, such selection criteria should facilitate the identification of substances which obviously seem to be of no or low relevance (e.g. because all uses of the substance are outside the scope of authorisation). It is foreseen to base the selection criteria only on information that can be easily extracted from the registration dossiers during screening.

Selection of substances of higher priority may need to take place (and is foreseen in the screening workflows, see *Figures A2.1 – A5.1* in *Annexes 2 - 5*) at the following stages:

- When deciding which substances on the mass screening outcome lists are of high relevance for **further assessment of PBT/vPvB, ED or CMR properties**.
- When selecting substances **for further clarification of their PBT/ED/CMR properties** (e.g. via Compliance Check or Substance Evaluation) in cases where there is not enough information available to conclude.

In addition, for substances with endocrine disrupting or with sensitising properties, it is envisaged to support already in the selection stage the equivalent level of concern assessment. In that specific case suitable selection criteria could be used to de-select substances for which it is easy to recognise that they are not of equivalent level of concern and therefore do not need to be considered further. For instance, selection in that case could be based on easily available information on intrinsic properties such as fate data.

As for search criteria, selection criteria need to be defined at a conceptual level defining which information could help in selecting substances for further assessment or clarification of properties. Examples of criteria which could be used to support substance selection:

- High volume
- Uses in the scope of authorisation
- Highest potential of being concluded to fulfil the PBT/vPvB/ED/CMR properties. This could be defined based on the search criteria agreed for screening (e.g. log Kow of 5 would have a higher priority than a log Kow of 4.5 for PBT/vPvB substances).

7 E.g. substances used in high annual volumes for uses in the scope of authorisation and/or uses with a significant potential for exposure; substances that are more likely to fulfil the Article 57 SVHC criteria etc.

- Time needed to obtain the missing information when selecting substances for clarification of properties. At this stage of the process it may be clear that there is not enough information to make a decision on the hazard properties of the substance and therefore there may be a need to obtain further information. The exact nature of this further information may already be known. Based on this it should be possible to identify in which case the missing information will be easier (e.g. no need for substance evaluation or compliance check) or quicker (e.g. duration of the test required) to obtain.

- Structural similarity to substances on the Candidate List, to substances for which there is an intention to identify them as SVHC (i.e. in the Registry of Intention (RoI)) or to substances in the pool for RMO analysis.

2.1.2.4 Overview of the screening activities for Roadmap relevant SVHCs

Screening for Roadmap relevant SVHCs includes the following generic activities:

- Definition of scope and planning of screening

  Time plan and assignment of tasks.
  For each screening activity, a schedule and a list of tasks needs to be agreed in the planning phase as well as a clear assignment of the different tasks to be carried out.

  Definition and development of search and selection criteria.
  Definition and development of search and selection criteria is a stepwise process. Once these criteria are defined and agreed at a conceptual level, specific IT algorithms corresponding to these criteria will be developed, validated and if needed refined, to ensure that they reflect the agreed search and selection criteria. It will be important to document all specifications for the sake of transparency and for later review of the work carried out in the context of each particular screening activity.

  Search and selection criteria will normally be applied concomitantly in the mass screening runs. By this it can be ensured that for all potential SVHCs on the mass screening outcome list (resulting from the application of the search criteria) the information required for the subsequent application of the selection criteria is also available.

  Determination of information sources (databases, etc.).
  The information to be used for a particular screening activity can come from different sources. For each substance group, the core activity will consist of the screening of the registration database (covering, as soon as possible, also the 2013 (and 2018) registration deadlines). Therefore the registration database will be the main source of information. However it is clear that for supplementary activities further databases (or lists) will be considered and screened (e.g. Annex VI, C&L inventory). In addition, it is foreseen that (for some groups of substances) supplementary information such as (Q)SAR estimates may be used to support the screening (e.g. screening for endocrine disrupting substances where experimental information relevant for assessment of potential ED properties will be scarcely available in the registration database). Other databases and information will be considered as well. These external sources may comprise the databases available at the eChem Portal but as well evaluations, reports, monographs, data from (inter)national bodies and chemical regimes such as OECD, WHO, IPCS, IARC, etc.

- Conduct and analysis of screening

  The result of the automatically carried out screening (using IT tools) will be a pool of substances of potential concern(s). These substances meet the search criteria. The selection criteria are then applied

subsequently to identify substances of highest potential interest. (A sub-set of) these substances will be selected for further manual screening and assessment. The manual screening will consist of a targeted assessment per substance of the information provided in the registration dossier(s) in relation to the search criteria. This manual screening is intended to scrutinise the outcome of the automated screening and to verify and better define the identified SVHC proper(ty/ties). This manual screening needs to be documented.

- Reporting of screening results

  Once the outcome of the screening is analysed the results need to be documented in a report specifying for instance the scope of the screening, the methodology used, and the main results.

- Regular re-iteration of screenings

  Screening re-iteration plans need to be set up in order to account after a certain period of time for new information on uses and properties and by that ensure that new potentially relevant SVHCs are identified not too long after they meet the criteria.

2.1.3 Organisation/coordination of work

The screening work comprises many activities for which coordination and organisation of tasks among the involved MSCAs, ECHA and the Commission is needed in order to adhere to agreed plans and tasks and to avoid duplication of work.

Depending on the substance group, planning and coordination of the screening work will be supported by:

- A substance specific coordination group (CMR, sensitisers) or
- An Expert group (PBT Expert Group, future ED Expert Group)

The role of the CMR or Sensitiser specific coordination groups at the level of screening will be mainly to organise and coordinate the screening activities of the Member States and ECHA, to contribute to the further development of the screening approaches and to support progress reporting. The PBT expert group (PBT-EG) and the future Endocrine Disruptor expert group (ED-EG) are anticipated to mainly focus on supporting the assessment of PBT/vPvB and ED properties of substances, including development and improvement of the assessment methodology[8].

Development and refinement of screening and selection criteria, and of the similarity approach will be handled by ECHA in close cooperation with the coordination and expert groups.

2.2 RISK MANAGEMENT OPTION (RMO) ANALYSIS

2.2.1 Purpose

The purpose of the RMO analysis is to clarify whether risk management activities are required for a

8 In order to be transparent in terms of complex assessment issues and to benefit from respective experience of experts from accredited stakeholder organisations, the ED expert group, as is already practiced by the PBT EG, will include nominated experts from industry organisations and other "public interest" NGOs. For the CMR and Sensitiser coordination groups such stakeholder involvement is not foreseen as these groups concentrate on practical co-ordiantion of authorities' work and do not deal with assessment, respectively Classification and Labelling related issues (assessment of the CMR or sensitising properties is carried out in the CLH process in accordance with the provisions set out in Art. 37 of the CLP Regulation).

substance and to identify the most appropriate instrument to address a concern. In the context of the Roadmap implementation, the RMO analysis should facilitate the conclusion on whether a substance (likely) fulfilling the criteria set out in Article 57 is relevant under the Roadmap and, therefore, the authorisation process should be initiated through proposing this substance for the Candidate List, or to initiate/ recommend a different risk management route (e.g. restriction, action under other legislation).

Documenting the RMO analysis and sharing it with other MSs and the Commission will promote early discussion and should ultimately lead to a common understanding on the action pursued. Consideration of the views of different MSs early enough can facilitate and speed up the actual process to establish the new legal provision. However, it should be noted that preparing and discussing the RMO analysis is not a legally required step in REACH but is a voluntary action.

In this section the main principles of the RMO analysis are described.

2.2.2 Scope

In relation to the role of the RMO analysis, the Roadmap gives priority to substances with SVHC properties which are registered for non-intermediate uses. The authorisation process under REACH was specifically created to deal with SVHCs, and the ultimate objective of REACH with regard to SVHCs is substitution when technically and economically viable alternatives are available. Until this ultimate aim is achieved the authorisation process provides an additional level of scrutiny to ensure control of risks with the possibility for setting further conditions and/or monitoring arrangements[9]. The Roadmap takes as a starting point that the authorisation requirement is used as a regulatory instrument for SVHCs registered for uses within the scope of authorisation.

Thus, the main purpose of the RMO analysis would be to either document that the authorisation route is suggested for an (potential) SVHC or that there are specific reasons for an SVHC which would overrule going the authorisation route to achieve its substitution. The latter conclusion could instead lead to recommending a different risk management route (e.g. restriction or action under a different legislation) or to the conclusion that at that point in time no action is envisaged.

Unless particular conditions apply, the RMO analysis can be straightforward, documenting the conclusion that the authorisation process is the appropriate risk management route for the substance and the basic information used to achieve this conclusion. Such particular conditions may apply if, based on available information, there is a need and sufficient basis for a restriction that provides pressure for substitution, or if there are overarching reasons as to why substitution (even in the longer term) is not considered (for the time-being) as the wished outcome for a particular substance. If there are reasons why substitution would not be the objective for a particular SVHC, then the RMO analysis should document these reasons and assess if there is a need for a different risk management route (e.g., restriction, other legislation) or if there is no action envisaged. A public conclusion of the main results of each finalised RMO analysis will be made available.

9 The registration obligation requires industry to identify, recommend and implement measures which control the risks. In comparison, the authorisation application and decision making process involves also a systematic scrutiny of applications. This scrutiny by the ECHA Committees covers also the risk management measures and the resulting exposure levels as identified and estimated by the applicant. Furthermore, the Commission can impose additional conditions, including monitoring requirements, as part of the authorisation decision and these authorisation decisions are subject to a review.

3. Coordination of activities between authorities

3.1 PURPOSE

The SVHC Roadmap to 2020 aims to have all relevant currently known Substances of Very High Concern (SVHCs) included in the Candidate List by 2020. To achieve this goal, numerous screening activities and RMO analysis work will need to be conducted by the different Member State Competent Authorities (MSCAs), ECHA and the Commission (COM).

Coordination will help to optimise the efficiency of this work, avoid overlapping or duplicate work and to close any gaps which may materialise. It will lead to MSCAs, ECHA and the Commission benefitting from the combined knowledge that exists in the area of screening and RMO analysis, which will increase the overall effectiveness of the work being carried out.

Coordination will help to increase the common understanding and acceptability of work on single cases / groups of substances, as well as to enhance the common understanding on new issues. It is also hoped that effective coordination of activities will encourage more MSCAs to get involved in the implementation of the Roadmap, to facilitate the inclusion of all relevant substances on the Candidate List by 2020.

3.2 SCOPE

The scope of the coordination of work under the SVHC Roadmap to 2020 will be two-fold:

1. The overall coordination of the screening and RMO activities (ECHA) and

2. Coordination of the screening and RMO work being carried out by MSCAs and ECHA on the following groups of substances: non petroleum CMRs (cat 1A/1B), sensitisers, PBT/vPvBs, Endocrine Disrupters (EDs) and petroleum stream substances which are CMRs and/or PBTs.

Responsibility for the overall coordination of the implementation of the Roadmap on the technical level, in particular with respect to the screening and RMO activities lies with ECHA whereas the Commission will be responsible for the policy related issues in the context of the SVHC Roadmap to 2020 implementation.

In the case of CMRs and sensitisers, the established coordination groups will be responsible for the coordination of the activities in relation to these substances. In the case of the PBT and ED expert groups, ECHA will be responsible for coordinating activities in relation to these substances. Further details on the coordination tasks applicable to these substance groups can be found in *Section 2.1* and *Annexes 2 – 5*.

4. Progress monitoring

Indicators are needed to monitor the progress in implementing the SVHC Roadmap to 2020, i.e. to "have all relevant currently known Substances of Very High Concern (SVHCs) included in the Candidate List by 2020". Such indicators should allow monitoring the progress in achieving the policy objectives set by the Commission and Member States and provide basis to identify any needs for refocusing the activities or changing the allocation of resources.

Indicators need to reflect both screening and RMOA activities. Such indicators should tell whether the substances placed on the EU market have been sufficiently and effectively covered. It would also be desirable to get an indication whether the screening activities support the authorities in identifying pertinent substances for further scrutiny and ultimately the most relevant substances first for further regulatory action. In other words, it should be possible to monitor that the further work is not overburdened and rendered ineffective with a too high number of false positives. On the other hand, achieving the objectives should not be compromised by unacceptably high number of false negatives and the system should be sensitive enough to select the more relevant before the less relevant.

The indicators could be qualitative, semi-quantitative and/or quantitative, and could be measured and reported at different time intervals and points in the process (e.g. annual and cumulative measurements until 2020 and, where relevant, thereafter). They should demonstrate that the work undertaken serves the overall objective of the Roadmap to identify by 2020 all relevant SVHCs.

Examples of quantitative indicators of progress in the context of screening could be related to the types, numbers and shares of hits and misses of substances screened per year. This would help to optimise the screening approaches and criteria and therefore would increase the probability of having identified all relevant SVHCs. For RMOAs, the number of substances RMO assessed each year (for which indicative numbers are already given in the Roadmap) could be used. Not only quantitative indicators will have to be developed as those will only reflect that work is actually done but not necessarily that the work done is of such quality that it ensures to identify the relevant SVHC and to develop the proper RMO for those identified substances.

It is expected that a first set of progress indicators will be developed during 2014, with the intention to apply these indicators for annual reporting for 2014.

5. Communication towards stakeholders and the public

5.1 PURPOSE AND SCOPE

The SVHC Roadmap to 2020 requests to consider publication of certain information to document activities carried out in order to achieve the Roadmap's targets. Transparency around the implementation will help to understand the objectives and scope of the SVHC Roadmap to 2020 implementation and will increase the predictability how substances with certain hazard/fate and use profiles will be dealt with by the regulatory authorities. Moreover, clarity on the aim of the authorities' work and openness on the status in the Roadmap process should help to avoid "black list" effects for the substances under scrutiny.

This section deals with communication on SVHC Roadmap to 2020 related issues towards stakeholders (i.e. industry and other NGO interest groups) and the general public. A summary overview is provided in *Table 1*. Aspects considered cover what to communicate on the roadmap itself, on the (status of the) substances in the Roadmap process and on the (interim) results of the assessment in the different process steps. Further aspects addressed are information on coordination and allocation of work to be carried out, and reporting on planned and carried out activities in the context of the SVHC Roadmap to 2020.

5.2 SVHC ROADMAP SECTION OF THE ECHA WEBSITE

Effective communication towards stakeholders and the general public requires the availability and easy accessibility of relevant Roadmap related information via a centralised platform. A dedicated section of the ECHA Website can be used as such a platform. At this dedicated section all Roadmap related information and data will be provided for stakeholders and the general public.

5.3 WHAT TO COMMUNICATE AND WHEN

5.3.1 SVHC Roadmap to 2020 and Roadmap implementation plan

The SVHC Roadmap to 2020, as drafted by the Commission is already available publicly and can be accessed via the Commission's website[10]. This Roadmap and a public version of the SVHC Roadmap Implementation Plan will be made available via the SVHC Roadmap section of the ECHA website (see *Section 5.2*).

5.3.2 Annual reports

Annual reports on the implementation of the SVHC Roadmap to 2020 will be made available via the SVHC Roadmap section of the ECHA website (see *Section 5.2*). The annual report will consist of the two parts, which will be accessible via the SVHC Roadmap webpages:

Part 1) Summary of activities carried out in the previous year and

Part 2) Outline of activities planned for the following year

The annual reports will not provide substance specific information but will provide generalised technical level information on the progress made in implementing the Roadmap.

The annual report will indicate the planned screening and RMO analysis activities, which will be undertaken

10 Accessible at: http://register.consilium.europa.eu/pdf/en/13/st05/st05867.en13.pdf

by ECHA, the substance specific coordination or expert groups, and the MSCAs. These screening activities will be described in a generic manner e.g. the substance groups subject to screening[11] and the objectives of the screening exercises[12].

Public versions of the (generic) screening approaches used to identify SVHCs could also be made available, either as stand-alone documents or as part of the annual report.

The annual report could be published in March each year starting from 2015. This will allow for adequate time to report on the previous years' activities, whilst also outlining the plans for the coming year.

5.3.3 Information on substance specific activities

All activities will continue to be tracked using the 'Activities Coordination Tool' (ACT) available for MSCAs and COM/ECHA. A public view of the ACT (PACT) will be established at (or linked to) the SVHC Roadmap section of the ECHA website, which will contain publicly available information about all substances being considered for regulatory action in the frame of REACH and CLP, specifying the actual process and status and, where already possible, the envisaged risk management process.

The PACT will provide information on substance specific activities, which are coordinated by the coordination and expert groups for the specific relevant substance groups (CMRs, sensitisers, PBTs/vPvBs, endocrine disruptors). The status and conclusion of the RMO analysis and status of assessment of PBT properties of a substance will be communicated via the PACT. This PACT will also be used as a data source for generating the summary information and statistics required for the annual reporting foreseen in the context of the Roadmap. ECHA will coordinate the input of information and data into the ACT (as done currently) and subsequently the PACT.

With regard to RMO analysis, the SVHC Roadmap to 2020 foresees the publication of a list of all substances which will be RMO analysed (including indication of the reporting MSCAs). In addition, as envisaged in the SVHC Roadmap, a public version of the conclusions of the RMO analysis will be made publicly available.

Substance specific information on the substances RMO analysed, the reporting MSCAs, and the RMO outcomes is foreseen to be communicated via the PACT accessible on ECHA's website.

It is to be stressed that the provision of this activity information in the PACT is for the purposes of openness and transparency. All substance specific information that should and can be in registration (and other REACH and CLP) dossiers should be provided to the authorities via these channels. This will be emphasised in relevant areas of the website and other communication with stakeholders. It is important to continue to stress and communicate to the stakeholders the importance and role of public consultations included in the formal processes (CLH, SVHC identification, Annex XIV recommendation, application for authorisation, restrictions). The information on activities provided in PACT should not be seen as another 'public consultation'. That being said, there could be merit in MSCAs/ECHA receiving relevant information (e.g. regarding alternatives) which is not to be found in the registration dossiers.

The conclusions of the RMO analyses communicated via the PACT will already provide an indication of the potentially appropriate and envisaged risk management actions. The foreseen follow-up regulatory

11 But rather not refer to lists of individual substances to be screened.

12 For example "It is intended to screen the ECHA registration database [in the period from … to …] in order to find respiratory sensitisers listed in CLP Annex VI, which are registered for non-intermediate uses" or "screen the ECHA registration database to find substances with classification as respiratory sensitiser in CLP Annex VI, which are registered for intermediate uses only but are structurally similar to classified respiratory sensitisers registered for non-intermediate uses (and therefore potentially can be used as replacement for fully registered respiratory sensitisers)".

actions in the REACH and CLP context (e.g. SVHC identification / authorisation, restriction, harmonised classification and labelling) will continue to be notified in the Registry of Intentions on ECHA's website.

5.4 DEVELOPMENT NEEDS

SVHC Roadmap section of the ECHA website
Creation and technical implementation of a section on ECHA's website at which all SVHC Roadmap related public information can be made available. Planning and establishment of such a section of the ECHA website is an ECHA task. The section should be up and running before the end of 2013.

PACT
A public view of the 'Activities Coordination Tool' (PACT) needs to be developed and linked to the dedicated SVHC Roadmap section of the ECHA website. Planning and establishment of the PACT is to be further considered with the aim of being operational by Q2 2014.

Annual Report
For the annual report on the SVHC Roadmap to 2020 implementation, a report format and progress indicators (see *Section 4*) need to be developed and agreed.

Table 1: Elements to enable communication on SVHC Roadmap to 2020 related issues towards stakeholders and the general public

Means of communication	Content
Website	Sub-section on ECHA's website dedicated to SVHC Roadmap related information, including public version of implementation plan and annual reports
Public Activities Coordination Tool (PACT)	Substance specific activities relating to regulatory action
Annual report on SVHC Roadmap implementation	Public report on: 1. Progress made on implementation of the SVHC Roadmap (including summary of results and statistics of screening and RMO analyses results) and on impact of the RM implementation and 2. Planned activities in implementing the SVHC Roadmap for the coming year
Description screening approaches *	Public description of the screening approaches used to identify SVHCs
Follow-up risk management actions	Registry of Intentions: notify intended risk management actions

* These could be developed as stand-alone documents or considered as sections of the "results part" of the annual report on the Roadmap related activities

Annexes

Annex 1: Considerations on how to 'group' substances based on similarity

A1.1 INTRODUCTION

The Roadmap to 2020 foresees to *"consider grouping of substances for RMO analysis based on properties and uses*[13]*"*. The Roadmap requests also to consider grouping of substances with (potential) SVHC profile that currently are not registered, produced or used in Europe, if they might be used as an alternative to another relevant SVHC(i.e. grouping with this latter substance).

On this basis, when implementing the SVHC Roadmap it appears to be necessary to consider "grouping" of substances based on structural similarities both at the screening and the RMOA level. In addition, at the level of the RMO analysis, further refinement of "grouping" based on similarity of uses could be considered, if appropriate. This is reflected in the flowcharts in *Annexes 2 – 5*, in which the screening for and RMO analysis of different groups of SVHCs relevant under the Roadmap 2020 is mapped. These flowcharts are described in detail in the referred to annexes.

Therefore the definition of "grouping" of substances in the context of the Roadmap 2020 considers on the one hand grouping of structurally similar substances (mainly at the screening level) and potential supplementary grouping based on similarity of uses (at the RMOA level).

A1.2 CORE ACTIVITY

Under the SVHC Roadmap to 2020 the core activity of identifying relevant SVHCs (as mapped in the flowcharts and further described in the corresponding substance group specific descriptions of screening activities in Annexes 2 – 5) is on substances that:

- Are classified as CMRs 1A/1B or as sensitisers in Annex VI of the CLP Regulation, meeting the criteria for PBT/vPvB substances set out in Annex XIII of REACH or meeting (future) criteria for Endocrine Disrupters (ED); and
- Have been registered for non-intermediate uses.

These substances constitute, respectively, the "CMR pool", the "sensitiser pool", the "PBT/vPvB pool" and the "ED pool" of substances for RMO analysis (see flowcharts in Annexes 2 – 5).

In order to support the grouping of substances within each substance group specific "pool of substances for RMO" as defined above, the following is envisaged:

- At the **screening level**, the substances will be grouped based on structural similarities. First it could be considered whether there are structural similarities among the substances on the mass screening outcome lists (clustering of similar substances). Then, it could be considered further whether the new (clusters of) potential SVHCs identified in mass screenings are structurally similar to substances already on the Candidate List, to those notified for SVHC identification in the registry of intentions (RoI) or to those in the pools for RMOA.
- At the **RMO level** available information from the registration dossiers on uses could be used to refine

13 http://register.consilium.europa.eu/pdf/en/13/st05/st05867.en13.pdf (p. 13)

the primary grouping based on structural similarities. For instance, if structurally similar substances would be used in very different uses, this could indicate that the substances cannot be used as mutual substitutes or that their potential for replacement is at least limited. Information on the technical function of each structurally similar substance in its uses, when available in the registration dossiers, would be particularly helpful for carrying out this kind of use based refinement of grouping.

A1.3 SUPPLEMENTARY ACTIVITIES

The SVHC Roadmap to 2020 gives priority to Annex VI CMRs 1A/1B, Annex VI sensitisers, PBT/vPvB substances and Endocrine Disrupters (ED) that are registered for non-intermediate uses, as mentioned under the core activity section. In addition to this core activity, potential supplementary activities have been identified for each substance group as detailed in the flowcharts and further described in *Annexes 2 – 5*.

The substances to be screened and reviewed in the supplementary activities are either not registered, registered as intermediates only or registered but not included in Annex VI (for CMRs and sensitisers). Substances registered only as intermediates or not registered but structurally similar to the substances in the pool of substances for RMOA, on the Candidate List or in the registry of intentions for SVHC identification will be considered for grouping with the substances in the pools for RMO analysis or addition to these pools (if similar to substances on the RoI or on the Candidate List). Substances registered only as intermediates or not registered which are not structurally similar to the substances in the pools for RMOA, on the RoI or on the Candidate List will not be processed further.

Annex 2: Screening for potentially relevant SVHCs - CMRs

A2.1 OVERVIEW AND OBJECTIVE

The objective is to develop and implement a strategy and tools that ensure the systematic screening of registration dossiers and the development of RMO analyses for SVHC Roadmap relevant substances with CMR 1A/1B properties.

For CMR 1A/1B substances, the roadmap work consists of (i) a **core activity** and (ii) **supplementary activities**. Both activities comprise **screening** steps, which result in a pool of relevant substances for which **RMO analyses** may be carried out.

The activities are described more in detail in the following sections. A flowchart setting out the key steps in screening and identifying CMR (cat 1A/1B) substances is provided in *Figure A2.2*. For the co-ordination of screening activities around the CMR substances, a coordination group has been established and it is envisaged that this group will be the main channel of cooperation between the MSCAs, COM and ECHA with respect to identifying CMRs relevant in the context of the SVHC Roadmap but as well for other REACH and CLP processes such as substance evaluation (SEv) or harmonised classification and labelling (CLH).

A2.2 SCREENING

A2.2.1 Core activity

Aim: Identification of CMR cat 1A/1B substances in Annex VI to CLP, registered for non-intermediate uses. Once identified, these are added to the "CMR Pool for RMO analysis" and RMO analysis is carried out.

In addition to the finalisation of the work on CMR cat 1A/1B substances registered for non-intermediate uses with unique combinations of EC and CAS numbers in Annex VI, the **core activity** will also comprise:

- To identify (not yet scrutinised) CMR substances which have harmonised classification due to group entries of Annex VI or due to constituents, impurities or additives which are in Annex VI
- To deal with new CMR entries to Annex VI or
- To revisit CMR substances, which have already been screened but not taken further to date (i.e. in time intervals to be agreed on, consider whether the "relevance" of these substances has been changed due to new information on their uses).

A2.2.2 Supplementary activities

A. Identification of CMR cat 1A/1B substances in Annex VI to CLP, which are similar to the substances already included in the Candidate List or identified in the 'CMR Pool' under the core activity, but which have only been registered for intermediate uses. If such substances are identified and similarity to the 'CMR Pool' substance(s) is verified using the approach (to be developed, see *Annex 1*), these would be added to the CMR Pool also.

B. Identification of Annex VI CMR cat 1A/1B substances, which are similar to the substances already included in the Candidate List or identified in the 'CMR Pool' under the core activity, but which have not been registered at all. These substances could be used as potential substitutes for the 'CMR Pool'

substances. If such substances are identified and similarity to the 'CMR Pool' substance(s) is verified, these would be added to the CMR Pool also.

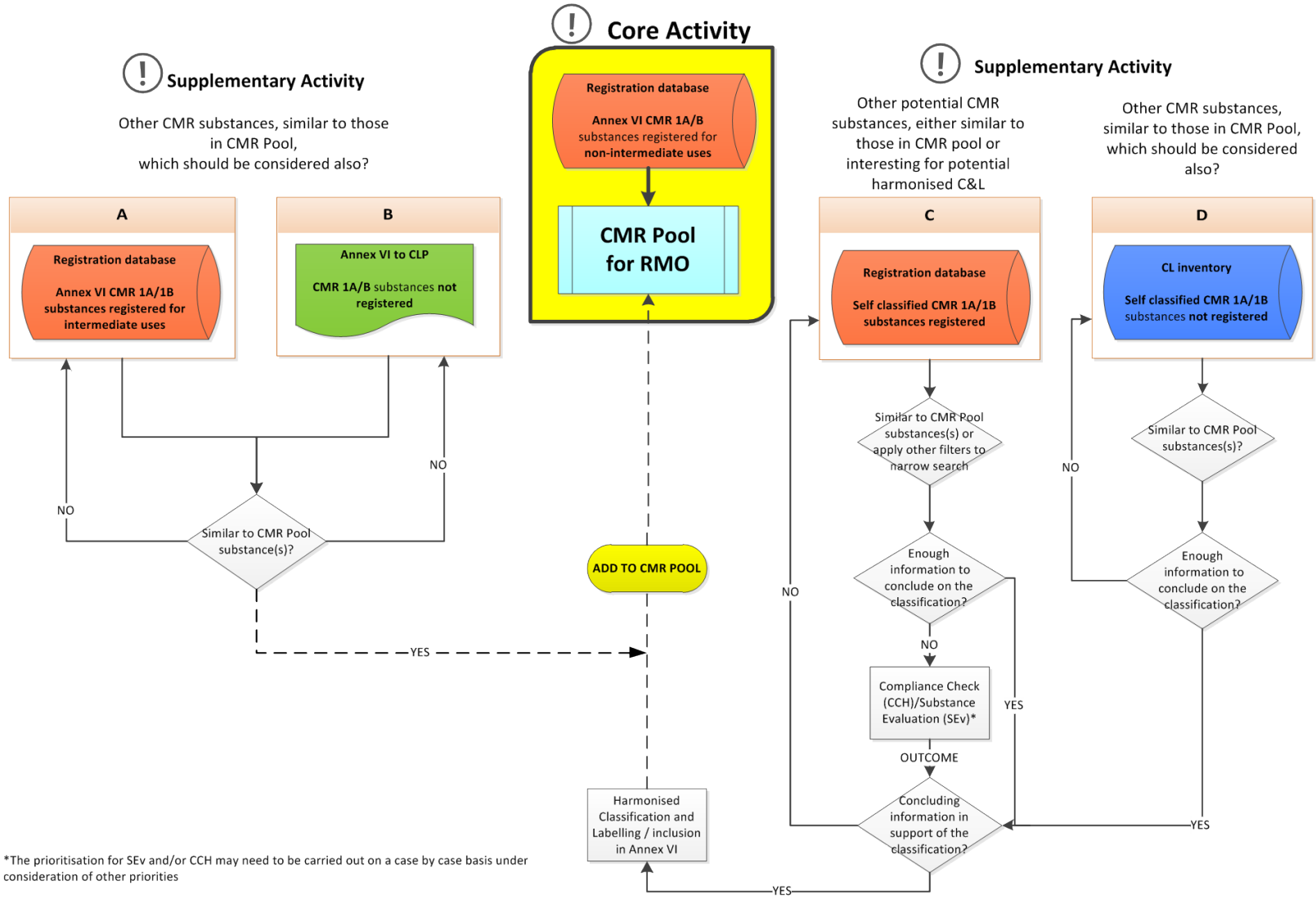
C. Self-classified CMR cat 1A/1B substances registered for non-intermediate use, which are identified because they are similar to the substances already in the 'CMR Pool' under the core activity or because they merit further assessment and verification of their CMR hazard potential for other reasons (to be developed; e.g. high tonnage within scope of authorisation). If such substances are identified and similarity to the 'CMR Pool' substance(s) is verified or the substance is chosen for another reason, harmonised C&L would be the next step. First, it would need to be considered whether there is enough information to conclude on the classification. If this is the case, a CLH proposal for inclusion of the substance in Annex VI to CLP should be made. If there is not enough information to conclude on the classification, compliance check or substance evaluation[14] could be carried out to obtain the necessary information. Any newly harmonised CMR substances would then be added to the CMR Pool also.

D. Focus on self-classified CMR cat 1A/1B substances in the C&L inventory, which are not registered but are similar to substances already identified in the 'CMR Pool' under the core activity. These substances could be used as potential substitutes for the 'CMR Pool' substances. If such substances are identified and similarity to the 'CMR Pool' substance(s) is verified, harmonised C&L should be the next step. First, it should be considered whether there is enough information (e.g. from IARC reports, studies in USA, Canada or Australia) to conclude on the classification. If this is the case, a CLH proposal for inclusion of the substance in Annex VI to CLP should be made. It may however be difficult to obtain the necessary information to make a CLH proposal. Any newly harmonised CMR substance would then be added to the CMR Pool also.

E. Re-iteration of activities A – D at time intervals to be agreed on.

14 Other routes to receive the required information, such as informal communication with and voluntary action by the registrant(s) or enforcement could as well be considered.

Figure A2.1: Key steps in screening and identifying CMR substances



Annex 3: Screening for potentially relevant SVHCs - Sensitisers

A3.1 OVERVIEW AND OBJECTIVE

The objective is to develop and implement a strategy and tools that ensure the systematic screening of registration dossiers and the development of RMO analyses for SVHC Roadmap relevant substances with sensitising (cat 1/1A/1B) properties[15].

For sensitising substances, the roadmap work consists of (i) a **core activity** and (ii) **supplementary activities**. Both activities comprise **screening** steps, which result in a pool of relevant substances for which **RMO analyses** may be carried out.

The activities are described more in detail in the following sections. A flowchart setting out the key steps in screening and identifying sensitising substances is provided in *Figure A3.1*. For the screening of sensitising substances, a coordination group has been established and it is envisaged that this group will be the main channel of cooperation between the MSCAs, COM and ECHA with respect to identifying sensitising substances relevant in the context of the SVHC Roadmap but as well for other REACH and CLP processes such as substance evaluation (SEv) or harmonised classification and labelling (CLH).

A3.2 SCREENING

A3.2.1 Core activity

Aim: Identification of sensitising substances listed in Annex VI to the CLP Regulation and registered for non-intermediate uses. Once identified, they are preliminarily assessed for equivalent level of concern to CMRs and those deemed to be (or have the potential to be) ELoC are added to the "Sensitiser Pool for RMO analysis" An RMO analysis is foreseen to be carried out subsequently.

In addition to the completion of the work on sensitising substances registered for non-intermediate uses with unique combination of EC and CAS numbers in Annex VI to CLP, the **core activity** will also comprise:

- identifying sensitising substances which have harmonised classification due to group entries of Annex VI or due to constituents, impurities or additives which are in Annex VI,
- dealing with new sensitiser entries to Annex VI or
- re-visiting sensitising substances, which have already been screened but not taken further to date (i.e. in time intervals to be agreed on, consider whether the "relevance" of these substances has been changed due to new information on their uses).

A3.2.2 Supplementary activities

A. Identification of Annex VI sensitiser substances, which are similar to the substances already included in the Candidate List or identified in the 'Sensitiser Pool' under the core activity, but which have only been registered for intermediate uses. If such substances are identified and similarity to the 'Sensitiser Pool' substance(s) is verified using the approach (to be developed, see Annex 1), these would be added to the Sensitiser Pool also.

15 Also substances with human health related hazard properties other than sensitisation may be considered, if they may qualify as SVHCs because they appear to give rise to equivalent concern in accordance with REACH Art. 57 (f) (does not include endocrine disrupters, which are dealt with in their own substance group).

B. Identification of Annex VI sensitiser substances, which are similar to the substances already included in the Candidate List or identified in the 'Sensitiser Pool' under the core activity, but which have not been registered at all. These substances could be potential substitutes for the 'Sensitiser Pool' substances. If such substances are identified and similarity to the 'Sensitiser Pool' substance(s) is verified, these would be added to the Sensitiser Pool also.

C. Self-classified sensitiser substances registered for non-intermediate use, which are identified because they are similar to the substances already identified in the 'Sensitiser Pool' under the core activity or because they merit further assessment and verification of their sensitiser hazard potential for other reasons (to be developed; e.g. high tonnage within scope of authorisation). If such substances are identified and similarity to the 'Sensitiser Pool' substance(s) is verified or the substance is chosen for another reason, harmonised C&L would be the next step. First, it would need to be considered whether there is enough information to conclude on the classification. If this is the case, CLH proposal for inclusion of the substance on Annex VI to CLP should be made. If there is not enough information to conclude on the classification, compliance check or substance evaluation[16] could be carried out to obtain the necessary information. Any new harmonised sensitiser substances would then be added to the Sensitiser Pool also.

D. Focus on self-classified sensitiser substances in the C&L inventory, which are not registered but are similar to substances already identified in the 'Sensitiser Pool' under the core activity. These substances could be used as potential substitutes for the 'Sensitiser Pool' substances. If such substances are identified and similarity to the 'Sensitiser Pool' substance(s) is verified, harmonised C&L should be the next step. First, it should be considered whether there is enough information (e.g. from IARC reports, studies in USA, Canada or Australia) to conclude on the classification. If this is the case, CLH proposal for inclusion of the substance on Annex VI to CLP should be made. It may be difficult to obtain the necessary information to make a CLH proposal. Any new harmonised sensitiser substances would then be added to the Sensitiser Pool also.

E. Re-iteration of activities A–D at time intervals to be agreed on.

A3.2.3 Equivalent level of concern (ELoC) assessment

Sensitising substances need to be assessed on a case-by-case basis to determine whether there is enough evidence to support them being considered as equivalent level of concern (ELoC) to CMRs. For further information on this "equivalent level of concern' comparison, please refer to ECHA's generic approach paper entitled "Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example" [17].

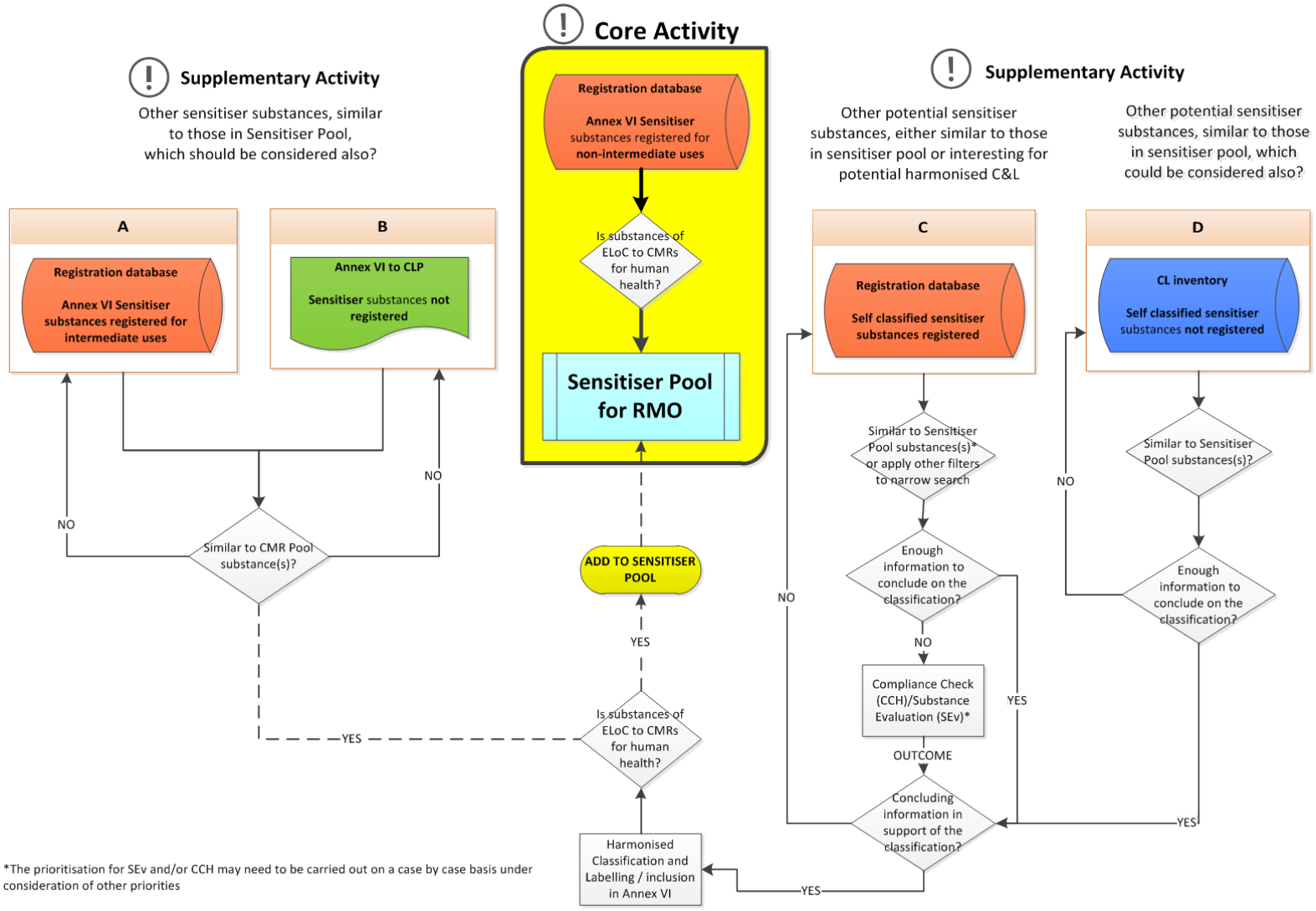
As part of the planned core and supplementary activities, each sensitising substance that is identified as part of the screening exercise, should undergo a **preliminary**[18] ELoC assessment, in order to decide if it merits being added to the "Sensitiser Pool for RMO" or it should be withdrawn from further consideration. Any substances deemed to be (or to have the potential to be) of equivalent level of concern to CMRs for human health will end up in the 'Sensitiser Pool' for RMO analysis.

16 Other routes to receive the required information, such as informal communication with and voluntary action by the registrant(s) or enforcement could as well be considered.

17 http://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf

18 The final conclusion on whether a substance is of equivalent level of concern is the responsibility of the Member State Committee (MSC) or the Commission.

Figure A3.1: Key steps in screening and identifying sensitising substances



Annex 4: Screening for potentially relevant SVHCs - PBTs /vPvBs

A4.1 OVERVIEW AND OBJECTIVE

The objective is to develop and implement a strategy and tools that ensure the systematic screening of registration dossiers and the development of RMO analyses for SVHC Roadmap relevant substances with PBT/vPvB properties, including substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCBs) and multi-constituent substances.

The SVHC Roadmap to 2020 aims to have all currently known relevant SVHCs included in the Candidate List by 2020. The Roadmap gives priority to substances which are registered for non-intermediate uses (i.e. "fully" registered in accordance with REACH Art. 10). Therefore it is foreseen that priority of the work on PBTs/vPvBs will be given to those substances which have been fully registered.

For PBT/vPvB substances, the roadmap work consists of (i) a **core activity** and (ii) **supplementary activities**. Both activities comprise **screening** steps, which result in a pool of relevant substances for which **RMO analyses** may be carried out.

The activities are described more in detail in the following sections. A flowchart setting out the key steps in screening and identifying PBTs and vPvBs is provided in Figure A4.1. For screening and assessing of PBT/vPvB substances, the already established PBT Expert Group provides the main channel of cooperation between the MSCAs, COM and ECHA with respect to identifying PBT/vPvB substances relevant in the context of the SVHC Roadmap but as well for other REACH and CLP processes such as substance evaluation (SEv) or harmonised classification and labelling (CLH). If relevant, consideration will also be given to the question whether a substance may be likely to fulfil the POP criteria.

A4.2 SCREENING

A4.2.1 Core activity

The PBT Expert Group, as foreseen in its mandate, is expected to have a central role in the screening for and assessment of potential PBT/vPvB substances.

The **core activity** will be screening of the registration database (covering the 2013 and 2018 registration deadlines) for potential PBTs/vPvBs with registrations in accordance with REACH Art. 10 for non-intermediate uses in the scope of authorisation. This may require (further) development/revision of screening algorithm(s) based on the PBT/vPvB (screening) criteria.

The screening work itself may yield a considerable number of potential PBTs/vPvBs. Therefore it is likely that in a first step selection (i.e. reduction of number) of substances for further PBT assessment in the period planned for will be required. This selection could be based on factors such as e.g. tonnage within scope of authorisation and also be carried out by the PBT-EG.

If the PBT-EG, respectively the reporting MSCA who have referred the case to the PBT EG, considers that there is enough information to make a decision on the PBT/vPvB properties for a substance and that the information supports identification of a substance as a PBT/vPvB (i.e. the Annex XIII criteria are deemed to be met), this substance will be added to the pool of substances for RMO analysis. Alternatively, if the PBT-EG, respectively the reporting MSCA, considers that there is not enough information to conclude whether certain substances have PBT/vPvB properties, it is likely that a second selection (prioritisation) of

substances for clarification of their properties (i.e. through generation of further data) will be required. This selection could be based on factors such as tonnage, nature of properties to be clarified etc.

PBT or vPvB properties may be clarified through compliance check / substance evaluation[19]. Subsequently, if the PBT-EG, respectively the reporting MSCA, considers that the further information collected supports the identification of a substance as a PBT/vPvB, this substance will then be added to the pool of substances for RMO.

A4.2.2 Supplementary activity

The **aim** of the supplementary activities is to find additional PBT/vPvB substances similar[20] to those in the PBT/vPvB pool, which should also be considered.

Supplementary activities could be carried out with a view to identifying potential PBTs/vPvBs which are similar to those in the pool of PBT/vPvB for RMOA, on the Candidate List or in the registry of intentions for SVHC identification and therefore could potentially be used as replacement for the PBT/vPvB substance they are similar to. This supplementary activity could involve screening of the registration database for potential PBTs/vPvBs with uses as intermediate only and of the notified but not registered substances in the C&L inventory for potential PBTs. Substances not structurally similar to the substances in the pools for RMOA, on the RoI or on the Candidate List will not be processed further. In the following, the activities are described roughly. A more detailed work plan may be developed later in the process of screening for (potential) PBT/vPvB substances.

A. *Identification of PBT/vPvB substances which have been registered for intermediate uses only and are similar to the registered substances already included in the pool for RMOA under the core activity*: The same agreed screening criteria/algorithms as those used for the fully registered substances[21] could be applied in order to identify potential PBT/vPvBs. However, as the amount of hazard information might be limited for substances with intermediate dossiers, it is proposed to first look for structural similarity to substances in the PBT/vPvB pool and then to apply the agreed screening criteria.

If the PBT/vPvB concern is confirmed for a similar substance with uses as intermediate only then it can be added to the "PBT/vPvB pool" of substances for RMO analysis and grouped / assessed together with the similar fully registered substance(s) in the pool.

As hazard information in intermediate dossiers is expected to be rather limited it is envisaged to use the information on classification available in the C&L inventory for the same substance or for similar ones as supporting information (e.g. consistent self-classification in hazard classes for PBT substances).

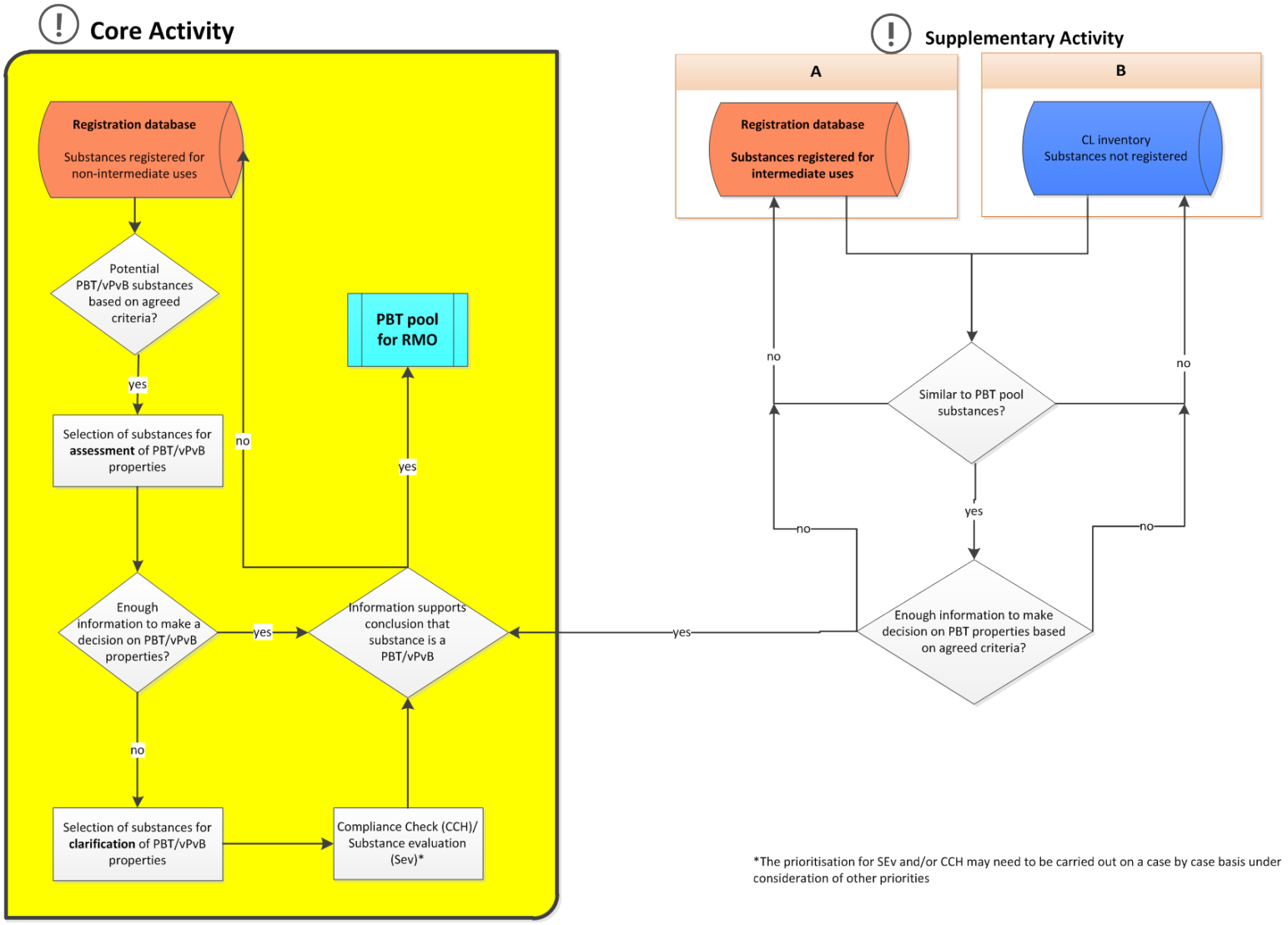
B. *Identification of potential PBT/vPvB substances in the C&L inventory, which are not registered but are similar to substances already identified in the PBT/vPvB pool under the core activity*: Similarity of the substances in the C&L inventory to the substances in the "PBT/vPvB pool" for RMOA (see Figure A4.1) should be assessed and it should be considered whether there is enough information to conclude on the PBT/vPvB properties of the substances notified in the C&L inventory. As the substances in that group are not registered it may be more difficult to obtain the necessary information to confirm the PBT/vPvB properties.

19 Other routes to receive the required information, such as informal communication with and voluntary action by the registrant(s) or enforcement could as well be considered.

20 See Annex 1

21 i.e. those substances registered in accordance with REACH Art. 10

Figure A4.1: Key steps in screening and identifying PBT/vPvB substances



Annex 5: Screening for potentially relevant SVHCs -Endocrine Disruptors

A5.1 OVERVIEW AND OBJECTIVE

In the EU, endocrine disruptors (EDs) are addressed by a number of legal instruments, e.g. REACH, Plant Protection Products Regulation, Biocidal Products Regulation. The European Commission (COM) is currently developing criteria for the identification of such ED-substances that require regulatory action.

Under REACH, substances – such as those having endocrine disrupting properties – may be identified on a case-by-case basis as Substances of Very High Concern (SVHC), where there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to CMR Cat 1A/1B or PBT/vPvB substances (Art 57(f)).

The SVHC Roadmap to 2020 aims to have all currently known relevant SVHCs included in the Candidate List by 2020. The Roadmap gives priority to substances which are registered for non-intermediate uses (i.e. "fully" registered in accordance with REACH Art. 10). Therefore it is foreseen that priority of the work on EDs will be given to those substances which have been fully registered.

In relation to implementation of the Roadmap, the aim is to develop and implement a strategy to ensure systematic screening of registration dossiers and development of RMO analyses for relevant substances with ED properties, including UVCBs and multi-constituent substances. The screening work is broken down into a "**core activity**" and "**supplementary activities**".

ECHA has developed a flowchart setting out the key steps in the screening and identification of endocrine disruptors, which may subsequently be taken forward for Risk Management Option (RMO) analysis (see Figure A5.). It has been agreed at the ad hoc CA meeting on 2/3 July 2013 in Helsinki that an Endocrine Disruptor Expert Group (ED-EG) will be established which will, inter alia, provide the main channel of co-operation and advice on the screening, assessment and identification of endocrine disruptors between MSCAs, COM, ECHA and other stakeholders.

A5.2 SCREENING

A5.2.1 Core activity

The ED-EG is foreseen to have a central role in the screening, assessment and identification of EDs.

The **core activity** will involve screening of the registration database (covering also 2013 (and 2018) registration deadlines) for potential endocrine disruptors with non-intermediate uses. As currently there is limited information available in the registration database on the endocrine disrupting potential of substances, it is proposed that initially the focus would be on assessment of the endocrine disrupting potential of registered substances which are listed on the EU database (Endocrine Active Substances Information System) as Category 1 and Category 2 EDs (link to EU ED database: http://ec.europa.eu/environment/endocrine/strategy/short_en.htm) The ED-EG may also consider registered substances on other ED databases (e.g. The Endocrine Disruption Exchange (TEDX) database).

In addition, it is proposed that an appropriate screening algorithm(s) be developed by the ED-EG based on the forthcoming Commission ED criteria and its usefulness in screening for potential ED substances from the

registration database be investigated. In the event that this screening exercise would yield a considerable number of potential EDs, it is possible that selection (i.e. reduction) of substances for further ED assessment for a given planning horizon would be required.

If a MSCA/ED Expert Group considers that there is enough information to make a decision on the ED properties for a substance and that the information supports identification of a substance as an ED, this substance may then be subject to equivalent level of concern assessment (see *Section A5.2.3*).

If a MSCA/ED Expert Group considers that there is not enough information to conclude that certain substances have ED properties, it is likely that selection of substances for clarification of ED properties (i.e. though generation of further data) will be required. This selection could be based on factors such as volume, nature of properties to be clarified etc.

ED properties may be clarified through substance evaluation (SEv) (or in some cases compliance check (CCH)[22]. Subsequently, if a MSCA/Expert Group considers that the further information collected supports identification of a substance as an ED, this substance may then be subject to equivalent level of concern assessment (see *Section A5.2.3*).

A5.2.2 Supplementary activities

Supplementary activities could be carried out with a view to identifying potential endocrine disruptors which are similar[23] to those in the pool of EDs for, on the Candidate List or in the registry of intentions for SVHC identification and therefore could potentially be used as replacement for the ED substance(s) they are similar to. This supplementary activity could involve screening of the registration database for potential endocrine disruptors with uses as intermediate uses only and of the non-registered substances which have been suggested as potential EDs (e.g. from the Commission list of potential EDs). Substances which are not structurally similar to the substances in the pools for RMOA, on the RoI or on the Candidate List, will not be processed further.

A. *Identification of ED substances which have been registered for intermediate uses only and are similar to the registered substances already included in the "ED pool" for RMO analysis under the core activity*: The same criteria (to be agreed) as those used for the registered substances could be applied in order to identify potential EDs. However, as the amount of information on endocrine disrupting properties might be particularly limited for substances with intermediate dossiers, it is proposed to first look for structural similarity to substances in the ED pool and then to apply the screening criteria.

If the ED concern is confirmed for a similar substance with uses as intermediate only then it can be added to the "ED pool" of substances for RMO analysis and grouped / assessed together with the similar fully registered substances in the pool.

As information on endocrine disrupting properties in intermediate dossiers is expected to be very limited it is envisaged that information on classification available in the C&L inventory for the same substance or for similar ones could potentially be used as supporting information (e.g. consistent self-classification in hazard classes relevant for ED substances). Other sources of information on potential ED substances may also need to be explored.

B. *Identification of potential ED substances which are not registered but are similar to substances already identified in the ED pool under the core activity*: Similarity of non-registered substances,

22 Other routes to receive the required information, such as informal communication with and voluntary action by the registrant(s) or enforcement could as well be considered.

23 See Annex A1.1

which have been identified elsewhere as potential EDs (e.g. Commission list of EDs), to the substances in the "ED pool for RMO" could be assessed and it could be considered whether there is enough information to conclude on their ED properties .

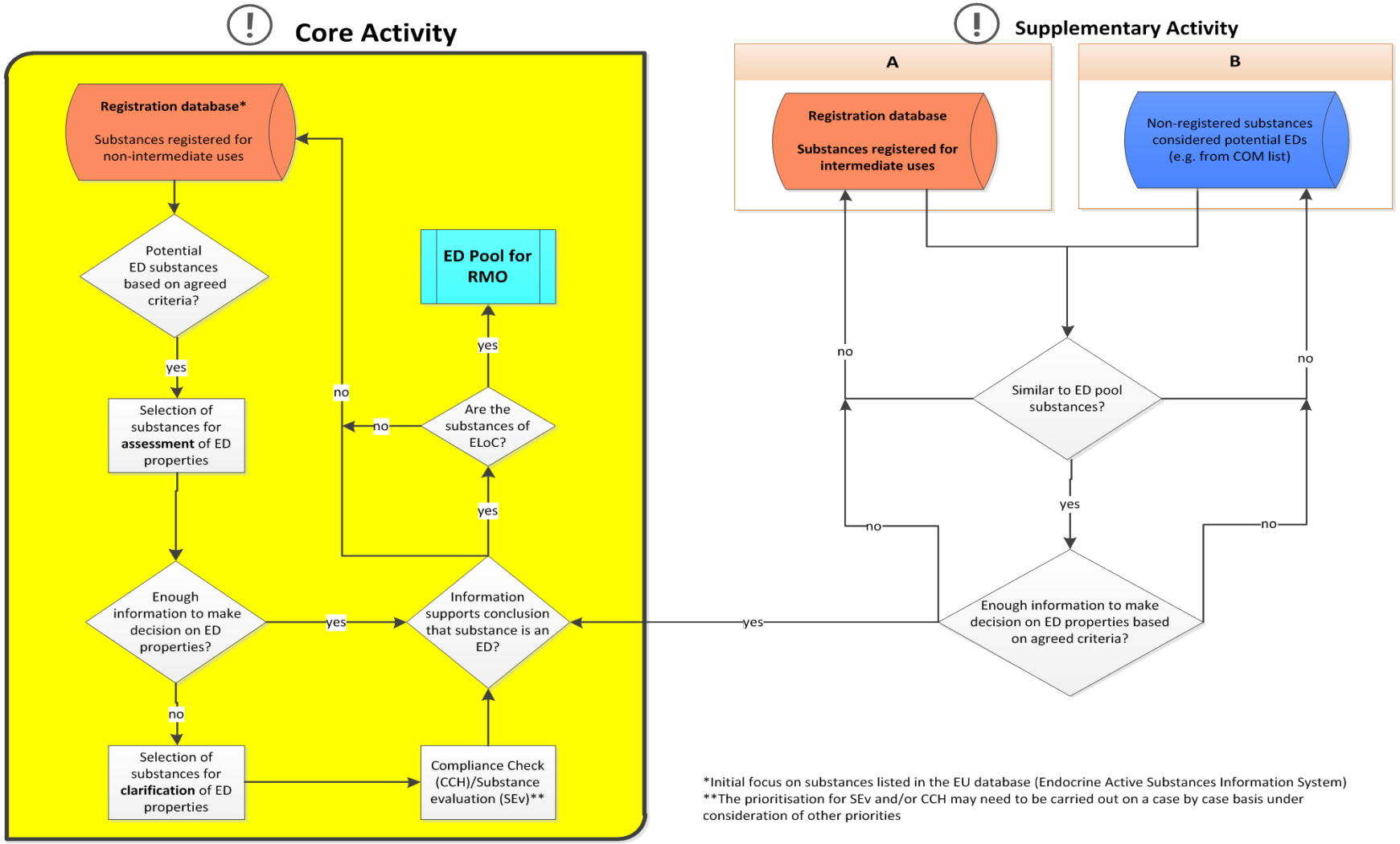
A5.2.3 Equivalent level of concern (ELoC) assessment

Equivalent level of concern assessment is required for identification of ED substances as SVHC under Art 57(f) and this should be undertaken on a case-by-case basis. In this context, it is worth further developing what aspects should be taken into account when making the equivalent level of concern assessment (e.g. use of exclusion criteria).

As part of the planned core and supplementary activities, each ED substance that is identified as part of the screening exercise, should undergo a preliminary[24] ELoC assessment, in order to decide if it merits being added to the "ED Pool for RMO" or if it should be withdrawn from further consideration. Any substances deemed to be (or to have the potential to be) of equivalent level of concern will end up in the 'ED Pool' for RMO analysis.

24 The final conclusion on whether a substance is of equivalent level of concern is the responsibility of the Member State Committee (MSC) or the Commission.

Figure A5.1: Key steps in screening and identifying endocrine disruptors



Annex 6: Screening for potentially relevant SVHCs - petroleum/coal[25] stream substances

A6.1 INTRODUCTION

Petroleum stream substances are substances of very complex and variable/partly undefined composition. Crude oil or any specific refinery stream obtained by one or more processes, are used as starting materials for these substances, which are considered as a specific group of UVCB substances (Chapter 4.3.2.2 of the Guidance for identification and naming of substances under REACH and CLP).

Petroleum stream substances are specifically mentioned in the SVHC Roadmap to 2020, however so far this group have been omitted from many screening exercises e.g. Trade Union Priority List for REACH Authorisation (June 2010) and SIN list (version 2.0). The SVHC Roadmap to 2020 highlights the need to start working on regulatory risk management (RRM) for petroleum stream substances.

For the purpose of finding in the context of the Roadmap all relevant SVHCs it is suggested **to understand the term "petroleum stream substances" so that it encompasses UVCB substances originating from both crude oil and coal refining, transformation or extraction processes.**

The main reason why it is felt these substances need to be considered from a RRM perspective is the potential concern regarding human and environmental health due to their CMR and/or PBT properties. These substances are very high volume chemicals and there are indications from the registration data that these substances are not just used in fuels but also in other uses.

A6.2 PRELIMINARY PROPOSED APPROACH FOR PETROLEUM STREAM SUBSTANCES UNDER SVHC ROADMAP

The following is a preliminary proposed approach to initiate work to define a RRM approach for petroleum stream substances, in line with the SVHC Roadmap to 2020.

Scope: Non-fuel uses of petroleum/coal stream substances

Starting point: REACH Registration database

Aim: To obtain a better understanding of non-fuel uses

Interactions with CMR coordination group and PBT expert group: As the concern is based on possible CMR or PBT properties of the petroleum substance (or of one or several of its constituents), a collaboration between the groups working on petroleum substances and those working on CMRs and PBTs is envisaged.

Plan to be developed on how to:

- Screen for relevant petroleum stream substances
- Select substances for further regulatory action
- Identify the action

25 This work is foreseen to cover both petroleum and coal stream substances having CMR and/or PBT/vPvB properties

In parallel to any screening exercises, ECHA and interested MSCAs will strive for ways to *improve the characterisation of substance identity and hazard information* given in the registration dossiers. There will be a need to link and co-ordinate with the improvements on dossier quality.

The priority of these substances versus other roadmap substances is yet to be determined.

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