EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

January 2016

Guidelines for an Industry Risk Management Options Analysis (RMOA)

COPYRIGHT

DISCLAIMER

INTRODUCTION

1. Purpose of an Industry Risk Management Options Analysis approach

Initially aimed at helping the industry to identify and address the risk management challenges it may have to consider under REACH *and other EU regulatory regimes*, this document has proven useful in a broader context. It is a valuable instrument to help explore and develop risk management options (**RMO**), including alternatives to the Authorisation or Restriction processes under REACH for industry as well as authorities.
The RMO exercise presented here will contribute to focus the minds of Industry stakeholders on potential risks and risk management needs and to prioritise and structure the data collection and analysis. It should also help Industry to contribute credibly in the RMO Analysis (**RMOA**) and decision processes at EU level.
More than a "shadow RMOA" used to counter an official RMOA, the exercise should be an "enriching RMOA" where Industry makes use of its expertise to contribute to the discussion and help find the most effective and acceptable risk management measure.
The general advice is to conduct the RMOA screening for all substances that meet the SVHC 2020 Road Map criteria or even broader and to get started as early as possible in the current screening process of substances by ECHA and Member States (MS), so as to have enough time to develop a coherent view and a realistic solution for when one's substance is scrutinized.

2. Words of caution

The exercise described in this paper has been designed in such a way that it can be performed efficiently when relevant data and expertise are at hand to go through the different steps of selection and justification of an appropriate risk management measure (RMM). Its outcome will allow Industry experts and consultants to proceed to a targeted collection of additional data and to develop the arguments, thus "putting flesh on the bones" of a solid RMO that will reflect the views and interests of the value chain.
The involvement of downstream users is critical to define appropriate RMMs. However, this may be a challenge given that they may not be acquainted with the assessment of risk management measures and the exchange of confidential business information may constitute a hurdle for them.

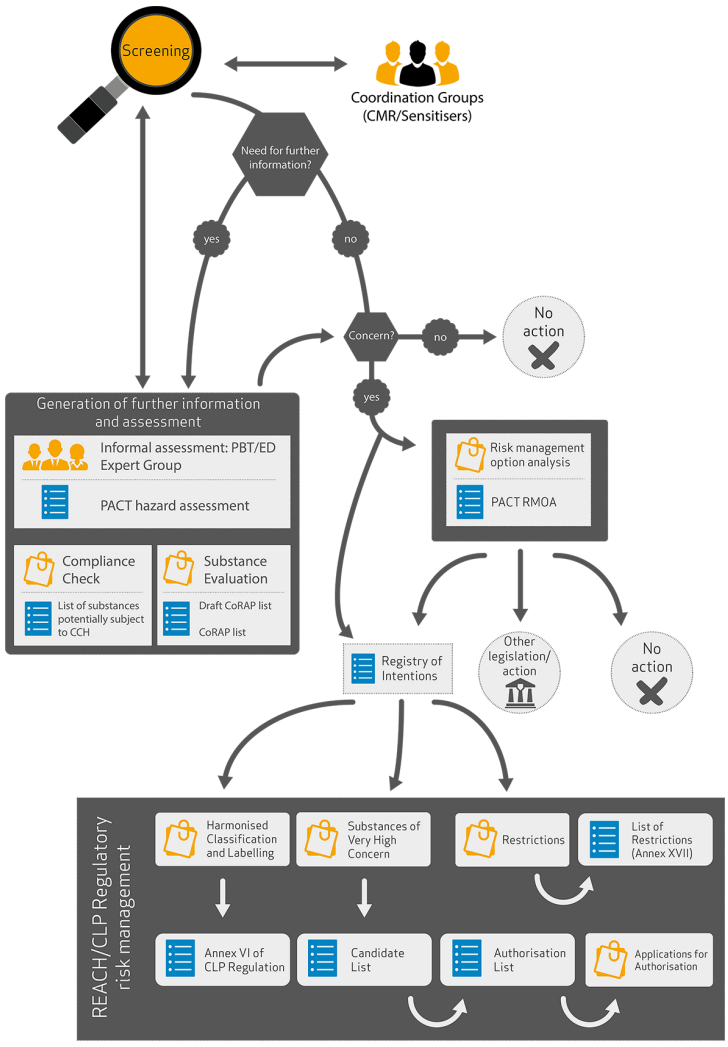
PART 1 - Short introduction to RMOA under REACH & first Industry action points

1. RMOAs in the REACH context

Initially focused on SVHC selection and thus *eventually* Authorisation or on Restriction, the risk management policy under REACH has started opening up to other risk management options. The realisation has come that the identification of so-called 'Substances of Very High Concern" (SVHCs) (and thus at one stage prioritisation and Authorisation) appears not to always be the best Risk Management Option (RMO) and that each relevant regulatory option should be considered earlier in the process.
The process initiated by the SVHC Roadmap 2020 involves different steps starting from the screening of relevant substances, as shown in Figure 1 below:

Figure 1: SVHC screening following the introduction of the SVHC Roadmap to 2020 Implementation Plan[1]

The process initiated by the SVHC Roadmap 2020 involves different steps starting from the screening of relevant substances, as shown in Figure 1 below:



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

We will consider the following steps:

2. Step 1: Screening of relevant substances

The screening process is mainly based on the REACH registration dossiers although there might be cases when non-registered substances can be selected (entry in CLP without being registered). It allows identifying substances that have a 'profile' that is relevant or about which there is insufficient information in the Registration dossier.

The screening focuses mainly on the following information:

- Physico-chemical properties and hazard profile
- Volumes or Tonnage
- Uses, Exposure and monitoring data (environment and workplace, and if relevant consumers)
- Risk Characterisation Ratios (RCRs)
- Recommended risk reduction measures.

This process is unavoidable and **Industry is highly encouraged to take some *proactive* actions. Industry should consider to provide or complete some key data provided in the Registration dossiers,** in particular:

	Recommended Actions from Industry
Hazard profile	Is it up-to-date? Identify which endpoints are most relevant? Have any of the companies opted out for a specific endpoint? Are there any impurities of relevance for the hazard profile?
Tonnage	The Dossier screeners have access to the tonnages indicated by the registrants. **Figures in Registration dossiers tend to inflate the significance of a substance as both intermediate and final production are added up and as only imports are reported, not the exports**. As a first step, it is recommended that the tonnages of intermediate vs. non-intermediate uses be reported. Regarding the trade balance, one has to consider that in many cases, Eurostat statistics are not available (if not unreliable) because of the grouping of different substances under the same nomenclature heading.
Uses and Exposure	Are all uses covered? Some uses may not be relevant any more, or have been added to cover all possibilities whilst new uses or minor uses may not have been identified. Do you know the exact volumes per use? Which use-sectors are most significant in terms of potential for exposures (e.g. dispersive, consumer, etc.)? Are the exposure scenarios up-to-date and still relevant? What about the monitoring data provided? Do they allow for drawing a conclusion regarding potential exposures? What are the chances of for example, a DNEL being challenged?
Risk Characterisation Ratios (RCRs)	Are these still robust? Are there scenarios where they could be challenged? Have sensitivity analyses looked at sensitivity of RCR and DNEL values?
Recommended risk reduction measures	Do these need to be reconsidered?

The quality of the assessment discussed in this guidance document will to a large extent depend on the thoroughness of these proactive actions and it cannot be emphasised enough how useful they will prove to be.

No substance that fits within the criteria for SVHC selection as set in the REACH Regulation, should be overlooked (PBT, CMR as well as Equivalent Concern such as endocrine disruptors, STOT-RE, sensitizers).

Such proactive actions from Industry will already involve significant sectors of the value chain, although not the final industrial users of articles. They will yield both data and useful value chain contacts for the Industry RMOA. Furthermore, weaknesses identified should be addressed as soon as possible, if not in time for the screening, then for the benefit of those conducting the RMOA.

Priorities: while all substances fitting with the Road Map criteria should be recommended for RMOA review, some prioritisation may be relevant. Substances that are listed for CoRAP or focussed by in the ECHA Soft Letter campaigns or PACT (see further) could be priority candidates for RMO assessment.

3. Step 2: Risk Management Options Analysis (RMOA) for substances of concern

ECHA or any MS may decide to conduct a RMOA based on an initial concern regarding hazard properties and/or potential exposure. The purpose of an RMOA is to clarify whether risk management activities are required for a substance based on existing hazard and / or risk information and to identify the most appropriate instrument to address a concern. If needed, available risk management measures include:

- **Evaluation** (although not apparent in the figure above, the SVHC Roadmap indicates that the RMOA may still come to a conclusion that additional information needs to be generated)
- **Harmonised classification and labelling (CLH)**
- **Restriction under REACH**
- Inclusion on the **Candidate list** (i.e. selection as SVHC), the first step toward prioritisation for **Authorisation under REACH**
- Other regulatory options, such as **Occupational Exposure Limits** (**OEL**)[2]**, Environmental Quality Standards (EQS), etc.**

A useful tool for Industry is the Public Activities Coordination Tool (PACT) on ECHA's website that lists the substances for which an RMOA is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013[3] (http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact)

As soon as an Authority has initiated an RMOA, Industry should engage with this Authority and share the additional data it may have collected on uses, tonnages, etc. Simultaneously Industry will have to make sure that effective communication channels are open with its supply chain, down to the final industrial users.

Rumours are difficult to control and, in a competitive market, the launch of an RMOA may be presented as foreboding bad times ahead for the substance, triggering first precautionary measures of substitution or reshaping of the supply line. However, the RMOA is supposed to dig deeper into the specifities of each risk management option, as well as into the data about the substance, tonnages and levels of exposure.

To be able to weigh on the discussions early enough, Industry should consider other types of preparatory work, hence the concept of "**metals RMOAs**" discussed at Eurometaux[4], which is explained further in this document.

[2] For example: BAUA, the German Member State Competent Authority (MSCA), has submitted an RMO Analysis conclusion document on Acrylonitrile, recommending the introduction of a Europe-wide OEL (28 August 2014)

[3] Note that some Member states will have initiated work on some substances before communicating on it

[4] For the policy dimension of this issue, please read "**To a vision on REACH RMM by the metals sector- Thought starter on a Eurometaux strategy**", a strategy paper developed by Eurometaux (December 2014)

PART 2 - RMOA Check-list

Building on the key structure and main elements of a 'standard' RMOA, an RMOA in line with this Guidance should contain the following elements, which as indicated in Part 1 should be collected as early as possible so as to 'inform' the exercise.

1. The Substance

1. Regulatory status in the EU (REACH, Water Framework Directive etc.), processes (use sectors), articles containing the substance.
2. Non-regulatory product stewardship schemes involving the substance. Examples of such schemes are the Voluntary Emissions Control Action Programme (VECAP) which is to reduce potential emissions of flame retardants to the environment through the promotion of manufacturing best practice throughout the value chain[5]. Some of those systems are the result of an agreement between government and Industry, such as BEBAT (collection and recycling of batteries in Belgium).[6]
3. Hazard profile from the Registration dossier
   Note: Of major importance may be the threshold nature (or not) of a substance *as this may impact the risk management measures*
4. Particular properties of the substance: What about substances entering the supply chain and industrial processes as impurities contained in natural resources (e.g. arsenic)? Is the substance present in materials that are later recovered for recycling?

2. Uses, Volumes and Potential Exposures throughout the Life Cycle

1. Uses, volumes (tonnages per Use), and identification of (potential) exposures.
2. Risk characterisation for the different exposure scenarios (Registration dossier). The Risk characterisation scenarios (RCR) should be discussed and an uncertainty analysis performed so as to refine or qualify some of the assessments (Is the RCR over conservative? What does a reality check provide as feedback? Is there a possibility that an authority carrying out the RMOA would set aside the DNEL in the dossier and recalculate the RCRs based on an alternative exposure limit value?) This introduces an analysis of the uncertainties about the existing RCRs. If on the basis of a more conservative exposure limit, the recalculated RCRs remain significantly below 1, then there should be no need for risk management. This Guidance suggests an approach on this, taking into consideration the fact that authorities may want to proceed further with their analysis on the basis of the intrinsic properties of the substance.
3. Physical form of the substance, and how it may change at each step of the life cycle: a substance may go through different physical forms (liquid, powder, massive as such or in an alloy e.g.) each of these forms having a different exposure or emission potential.
4. Production of articles (i.e. volumes involved), and potential for release of the substance from articles during use.
5. Material flows – for each step of the substance and product life time; starting from raw materials, manufacturing, down the supply chain. This will allow to illustrate how the substance enters the EU market (import and production including refining and recycling). The "first uses" can then be sketched out (for example a metal compound being used for catalyst manufacturing, surface treatment, batteries, pigments etc.) and the end uses should be identified as well. This is often where the substance is integrated into an article that will find its use in an end-use sector such as the automobile sector. Even if the end-users are not legally concerned by an Authorisation process, they may be critically impacted, hence the importance to identify them and possibly involve them in the process if and when needed. An example of

[5] VECAP is run by BSEF, an international bromine production association (http://www.bsef.com/product-stewardship/)
[6] http://www.bebat.be

such an involvement has been the heavy involvement of the aeronautics industry in the Authorisation process for chromium trioxide.

6. End-of-Life. What is the final fate of the substance? Will the substance be recycled? Do the concerns materialise into risks that might justify a Restriction e.g.?

3. Alternatives per (Identified) Use

The Analysis of Alternatives (**AoA**) starts with describing the functional contribution of a substance to a process or an article so as to be clear on what is expected from an alternative. At the RMOA phase, the AoA may be more generic in the identification and discussion of alternatives than in the case of individual applications for an Authorisation, but it should reflect the state-of-the-art to avoid future challenges such as during public consultations. Following issues will come up during the AoA:

1. Identification of key functional requirements may force to split the analysis into different functionality groups.
2. Among the questions to address:
   a. Drivers for substitution: potential exposure, cost (relative prices), and market pressure.
   b. Drivers for continued use: could be the cost of the alternative (unit price, performance-related cost), technical considerations related to functionality, process complexity or the production of additional impurities/waste and market conditions (technical specifications or consumer preference)
   c. Likelihood of an alternative becoming available: ongoing trials (from most likely to yield success to 'plan B alternatives', at a less mature stage) and timeframe
   d. Other criteria such as
      - Hazard profile of the alternative (an issue for metals because alternatives have often similar hazard profiles)
      - Operational constraints linked to the process e.g.
      - Sustainability criteria (resource availability or depletion, energy and carbon leakage)
      - Life cycle (displacement of problem to a later stage?)
      - Key economic elements (e.g. cost of the alternative substance, process implications, etc.)
   e. Credibility: An AoA should stand the test of a peer review.

The Analysis of Alternatives may bring to light that the use of the substance has already been limited to processes or products that are difficult to substitute, i.e. that the markets have already made an 'arbitration'.

4. Socio-Economic Assessment per Use

In the context of REACH, socio-economic assessments (SEA) are conducted applying quantitative methods to both describe economic events and trends and to bring various impacts (e.g. health, environmental, social or societal as well as economic) of a RMOA under a common denominator (i.e. Euros).

- The key aspect of a SEA is the identification of the critical elements or pivotal factors that trigger the socio-economic consequences.
  It is important to be cautious with the key arguments that one may consider bringing forward. Let's imagine a substance used as a pigment providing a specific colour:
  - *Absence of alternatives: How to put a value on a colour*, e.g. when that is the key functionality provided by a substance? The Analysis of Alternatives may have indicated that no alternatives were available to provide exactly the same colour but will this conclusion be acceptable from a political point of view? Regulators tend to believe that the market and consumers will adapt to the loss of a particular colour shade unless it has

proven a particular efficiency (road marking, signalling, safety lights etc.) that provides a societal benefit. The SEA should therefore critically take up the conclusions of the AoA.

- *Market impacts:* On top of economic and technical feasibility, the SEA may identify consumer preferences that will drive the market response (price elasticity, opt for imports if the articles affected are not available anymore) or loss of competitiveness, etc. These aspects are particularly interesting to explore when alternatives have already been made available to consumers for some time.
- *Loss of jobs*: Can the SEA identify a serious risk of net loss of jobs and plant closures in the EU?"

- SEA refinement at the RMO stage will vary according to the RMO type, for example:
  - Indicative OEL: requires few if any socio-economic arguments
  - Binding OEL: involves examination of compliance costs
  - Restriction: socio-economic impact, preferably via a Cost-Benefit Analysis
  - Authorisation: socio-economic impact via a Cost-Benefit analysis based on likely scope and duration of Authorisation

A broader perspective - societal rather than socio-economic - may be brought in at this stage:
The criterion of sustainability or resilience may be interesting to explore, especially in the EU where there are several regulatory initiatives and policy targets aimed at stimulating economic growth and job creation, or to protect the environment (e.g. climate change, circular economy, etc.).

5. Synthesis: The Risk Management Options that could be considered and conclusion on the most adequate option

1. Identification of options, including an inventory of their possible benefits/drawbacks

Options will have to be considered in view of the EU policy objectives, such as protection of man and the environment, therefore favouring 'risk removal' (i.e. substitution of the problematic substance), to 'risk reduction' (exposure reduction).
This hierarchy has to be built into the risk management option selection and discussion.
Furthermore, three main criteria shall be assessed: effectiveness, practicality and regulatory consistency. These criteria can be assessed according to yes/no, or graduated (low/medium/high) or even scored, weighted and ranked (see Part 3.4.).

2. Proportionality assessment of the options

A number of criteria will be discussed such as effectiveness, practicality and regulatory consistency in a way that can be binary (yes/no) or graduated (low/medium/high) or even scored, weighted and ranked.
It has to be taken into consideration that the EU jurisprudence employs the notion of proportionality as an overall assessment concept that covers the following three steps:

a) **Suitability**: Is the risk management measure appropriate to achieve the objective that is pursued?
b) **Necessity**: Is there no other risk management option considered suitable to achieve the objective that is less cumbersome, costly or restrictive whilst equally effective in achieving the objective?
c) **Proportionality** stricto sensu: Is the risk management option considered suitable and necessary, while not too excessive? Hereby the balance between the different interests at stake (Industry & society e.g.) needs to be considered.
One has to take into consideration that the precautionary principle has as consequence that arbitration between uncertainties may lead to favouring the more maximalist approach…

3. Conclusions and recommendations

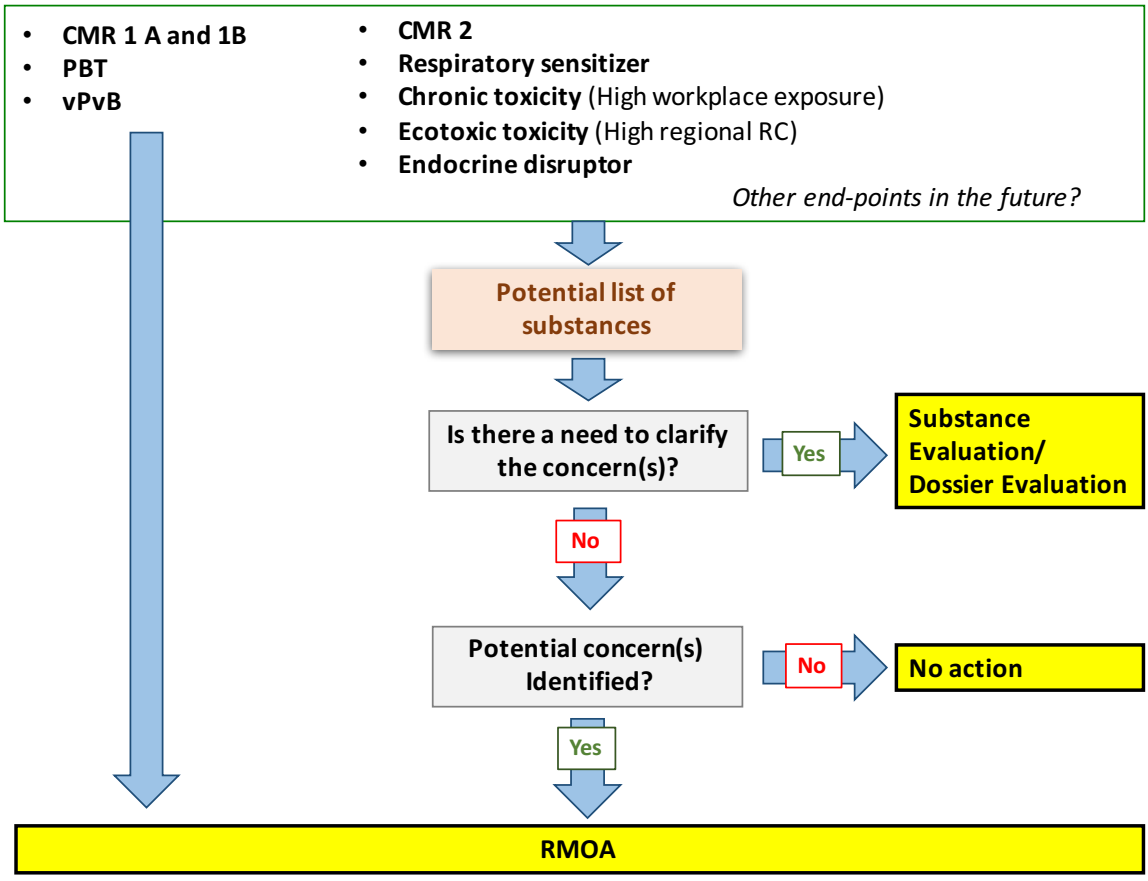
PART 3 - Approach for an Industry RMOA

The approach developed by Eurometaux has been divided into several main steps.

1. Preparatory steps: Identification of the substances and of the risk(s)

In this step, the substances that may be potentially concerned are identified. For each of them, one then establishes whether or not there is a need to clarify the concern(s) linked to the substance profile and whether there is a potential concern related to the use of the substance. At this stage, one may identify needs for further data gathering to clarify a potential risk (Figure 2).

Figure 2: Preparatory steps to decide on performing an Industry Risk Management Options Analysis



Note that ecotoxicity is also taken up as endpoint in this framework as the metals Industry Risk Management Options Analysis suggests taking a broader look at the substances than what is defined in the specific context of Authorisation, and in particular Article 57 of the REACH Regulation.

2. The various filters of an RMOA

The RMOA should consider all possible RMOs and the most adequate RMO should be selected by applying a series of filters.

1. 1st filter: Mapping the areas of concern and identification of need to address a risk

Aim: Demonstrate that all possible areas of concern have been considered and that the selection of the areas of concern for further discussion is justifiable.

The possible areas of concern can be considered, according to the life cycle stages for the metal substance:

- Raw materials (e.g. ores and concentrates)
- Industrial and Professional use;
- Environment, and man via environment;
- Articles/consumers; and
- Recovery/recycling and end-of-life (EOL).

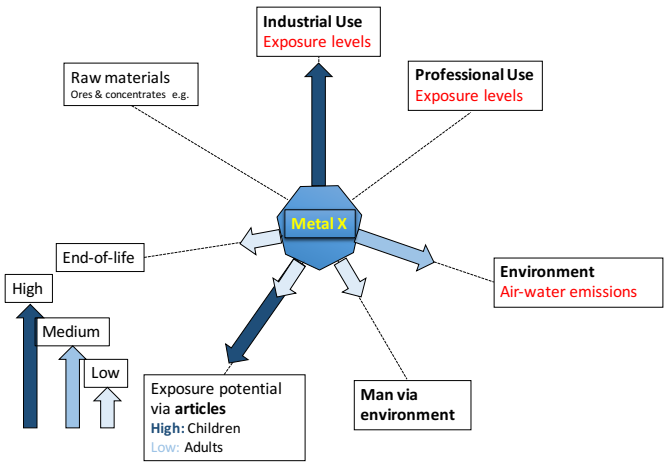
Approach: A first overview can be obtained by consensus between industry experts. The exercise is then to build consensus on where **all** the potential concerns may arise.

During a Eurometaux workshop, a group of industry representatives (i.e. REACH Consortia Managers and member companies) came up with a description of all potential areas of concern they were aware of for **manufacturing and use of a specific substance**. Participants were asked to rate the level of concern (from low to high).

This type of group exercise has already proven to be a very useful way of focusing the minds of those who will have to support or perform the more in-depth work afterwards.

The possible areas of concern for manufacturing and use of the substance are shown in Figure 3, below, looking at its entire life cycle. In this example, potential concerns were identified and ranked according to significance at occupational level (industrial and professional uses), in the environment (air and water emissions) as well as with articles that could create exposure.

Figure 3: Example of how to present the areas of concern in manufacturing and use of a substance (life cycle approach)



To be more in line with the type of assessment that will be performed by a Member State or ECHA and to facilitate communication, the areas of concern may also be considered more closely in order to confirm whether there is a risk that should be addressed. For that purpose, the RCRs in the Registration Dossier can quickly provide

precious indications (ANSES proceeded this way in its RMOAs on Nickel Sulphate and Nickel Oxide). However, this may require preparatory work to conduct sensitivity and uncertainty analyses looking at the RCRs and other factors as well as a discussion on the grey zone close to a RCR close to 1 (see Figure 4).
Some concerns feature higher on the scale of societal concerns than others, for example children's' health. If such a concern is encountered, it will be difficult not to take it up in the further RMOA. Societal concerns that are not immediately related to the environment or human health (such as coherence with other EU policies) may be part of the analysis but at a later stage, when the proportionality of the different Risk Management Options is discussed.

Figure 4: Risk Characterisation Ratios to see whether a risk has to be addressed

Risk Characterisation Ratio (REACH Registration dossier)		
< 0.7	**Between > 0.7 and < 1**	**> 1**
Provided data are robust, concern may not have to be considered in an RMOA	**Grey zone to be discussed because of its proximity to an RCR of 1**	**RMOA necessary to consider a risk management measure**

In essence, this comes to apply the following line of reasoning:

1. If the RCRs , even based on the most conservative exposure limit value that an authority may choose remain (considerably) below 1, then in principle the exercise could stop here.
2. If the RCRs, or the most conservatively recalculated RCRs, are equal to 1 or higher, the exercise should continue for the relevant uses.
3. As there is an uncertainty whether the authority carrying out the RMOA would do the step of identifying a risk (some authorities may proceed simply on the basis of the intrinsic properties of the substance) it is recommended that the exercise is also carried forward for uses where the (possibly recalculated) RCRs are below 1.

2. 2nd filter: Identification of possible Risk Management Options

The second filter consists in the identification of **all** the possible risk management options that may be considered, starting from the least demanding "no action required").

Aim: Explore all possible risk management options and describe to what extent and how they might address the risk(s) considered relevant at the end of the previous step

Approach: Company experts should be involved in this step as they may come up with possible solutions, which people in charge of regulatory affairs may not yet be aware of (upcoming technologies e.g.). Depending on the substance and its value chains, it might also be worthwhile to involve downstream users (first use sectors).

One should start to identify a list of possible RMOs for the substance, per area of potential concern (see illustrative list in Annex I).
If action is required:

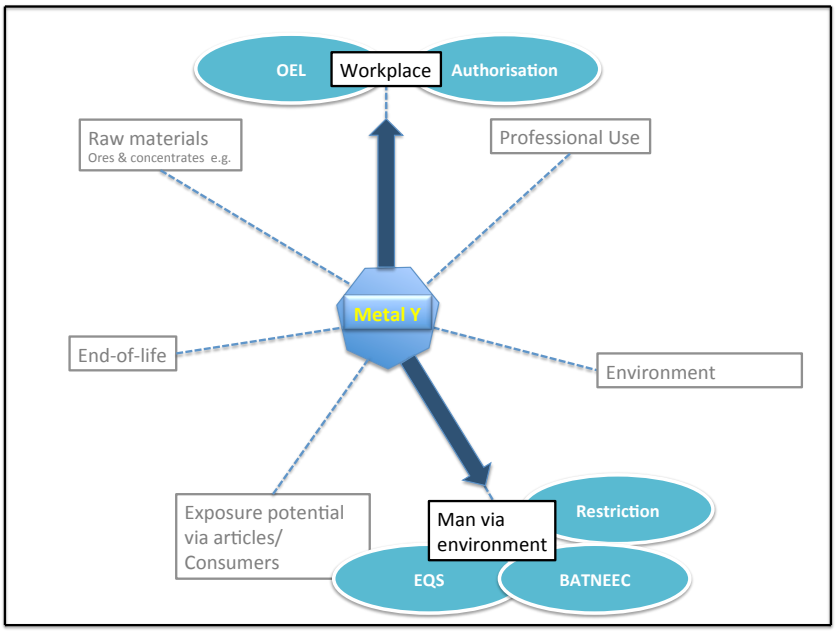
- Substitution (Industry initiative)
- Existing legislation that may be related to workplace Directives (Occupational Exposure Limits (OEL)), the Industrial Emissions Directive (Best Available Technologies Not Entailing Excessive Costs (BATNEEC), the water Framework Directive (Environmental Quality Standards (EQS)), etc.)
- Harmonised Classification under CLP
- Substance Evaluation under REACH
- Restriction under REACH
- SVHC selection and Candidate Listing

- Authorisation under REACH
- Restriction under RoHS, etc.
- Water Framework Directive
- Other EU legislation
- Other Risk Management Measures?

The initial exploration of the potential risk management options may lead to an opinion that an option may not be workable in the timeframe set by regulators or be extremely difficult to implement (too diverse sector, too many actors etc.). However, none of the identified options should be excluded and the participants of the exercise need to remain objective and unbiased at this point, as the next steps in the exercise will be to compare the options in terms of feasibility and other factors.

This may lead to a listing of "potentially relevant or feasible RMOs", as shown in Figure 5 below for an example of a substance where concerns were identified (and possibly confirmed in terms of risk) in the workplace and in the man via environment endpoints. For the other areas, there may be, for example, no concerns or these may already be addressed adequately:

Figure 5: Example of possible RMOs for a metal/compound where two areas of potential concern were identified



3. 3rd filter: Identification of need for use-tailored Risk Management Options

The third filter to apply will consider whether the potential RMOs are equally valid for all the sub-sectors that are concerned.

Aim: Identify what might be the most efficient RMO considering substance- or sector-specific characteristics. It is important that, if Restriction is a possibility (e.g. an EU-wide risk is proven), one should also consider the possible scope and content of such a Restriction, otherwise the discussion may end up being too hypothetical, and few conclusions can be reached in an "it-depends" situation…

Approach: Three approaches may be taken into consideration to consider whether the substance or its uses justify one of the following approaches:

- **Simple – or Non-integrated approach: The risk management measure can be limited to the substance and its use(s).** This is the simplest approach, and will be the favoured approach when there are no cross-substance issues such as the use of other SVHCs in same processes as illustrated in Figure 6.

  Regulators may tend to focus on substitution or non-use of the substance, i.e. Authorisation or Restriction. A Restriction may address some conditions of use or some particular uses whilst Authorisation would allow – at least in the eyes of the authorities- to help sort out the uses between those for which there is a case for continued use and those for which there is no case for avoiding phasing out.

  However other substance-specific regulatory or technological solutions (OEL, EQS, BATNEEC) may also be considered.

  An example of a simple approach where a Restriction or an Authorisation may be considered is shown in Figure 6. It may reflect a case where the risk can not be efficiently addressed by an alternative risk management measure such as an OEL.

Figure 6: Example of an RMO for a Simple - or Non-integrated Approach

	Use of Substance X
Decisive criterion	*No cross-substance issues related to process and no satisfactory approach identified through other legislation*
Simple – Non-integrated approach	• **Restriction** • **Authorisation**

- **Combined – or Integrated Approach:**
  - **The potential risk is recognized as being linked to a process that may be common to other substances and value chains**, and therefore one should try to address it in an integrated way. For instance, the use of a substance in surface treatment would lend itself to such an integrated approach.
  - **It is felt that a combination of risk management measures could lead to an optimal solution of challenges identified.** There might be imports of the substances through articles and a Restriction could complement an Authorisation**.**

Figure 7 reflects a case where the substance was identified as having critical uses, which may be linked to other substances (e.g. in plating) where a disruptive approach such as an Authorisation per substance could be ideally replaced by the introduction of a technological solution for the entire sector (BATNEEC).

Figure 7: Example of an RMO for a Combined – or Integrated Approach

RMO	Substance X		Use of Substance Y in same process	Use of Substance Z in same process
Decisive criterion	*Critical use in a process with cross-substance issues. Alternatives and /or other substances used in the process have similar hazard profile Would a combination of RMMs be increasing the effectiveness of the approach on the substance?*		*Same/similar hazard profile*	*Same/similar hazard profile*
Combined – Integrated approach	• **BATNEEC** 			

- **Specialised – or Mixed Approach:** The approach is a mixed one. In some cases, industry characteristics may justify a combination of a substance-based and a process-based approach, for example if there needs to be different solutions sought for large scale versus small scale processes (i.e. proportion of SME vs. non-SME).

  One could imagine a combination of Restriction for a Use 1 (consumer use), or a Use 2 (professional use) for which no realistic worker protection can be implemented, compared with a BATNEEC for a Use 3 (use in industrial settings) where potential worker exposure can be controlled by a technological solution (Figure 8).

  Figure 8: Example of RMOs for a Mixed Approach compared to a Simple/ Non-Integrated Approach

RMO	Use 1	Use 2	Use 3
Decisive criterion	*Leads to consumer exposure*	*Professional use and exposure*	*Occupational exposure in industrial settings & technological solution identified*
Simple approach	• **Restriction** • **Authorisation**	• **Restriction** • **Authorisation**	• **Restriction** • **Authorisation**
Specialised – Mixed approach	• **Restriction**	• **Restriction**	• **BATNEEC**

Here again, it is important that the approach identified is justified so as to make sure that it is a realistic view. Industry is the best equipped to develop a set of approaches that would be more suitable than a problematic one-size-fits-all measure. One has to be aware of the fact that this fit-for-purpose approach requires an investment in time and expertise. The pay-off may however be worth the effort.

4. 4th filter: Fitness test of the RMOs

The analysis will now have tog come to a conclusion (i.e. identify the best RMO) that fits with the key criteria that have been used in the RMOAs.

Aim: The objective is to test the different potential RMOs against four key criteria. The level of expertise required at this stage may be less technical. However, policy, legal and economic considerations come into play.

Approach: The criteria to be considered are the following:

- **Effectiveness;**
- **Practicality;**
- **Consistency**
- **Broader impact (economic, human health, environmental)**

So as to be able to conclude on Overall Proportionality of the different RMOs considered.
The following pages outline this approach.

- **EFFECTIVENESS**: Is the RMO able to reduce possible risks and will its effects be measurable? What is the availability of proven and affordable technology? What is known about alternatives?
  Here is where the expertise developed in previous steps (filter 2 and 3) has to be synthesised into a couple of sentences per Risk Management Option considered for the final comparison.
  Any **data and expertise on alternatives** will be a valuable input into the discussion.
  Figure 9? provides an example of a scoring of different RMOs in two types of approaches as illustrated in Figure 8.

  Overall effectiveness may be discussed as a combination of the following criteria:

  - **Ability to reduce risk**, especially compared to the desired outcome. This will contain in itself the consideration of whether there is an alternative available.
  - **Measurability** (tonnage of substance known to be used in the EU represented by companies submitting an application for Authorisation e.g.) or **monitorability** (testing or sampling of articles or of emissions)
  - **Proven technology available**. This suggested criterion is to encourage an assessment of the technologies that are needed to implement the different potential risk management measures (including the technological implications of using alternative substances) or that may constitute BATNEECs.

In the example simulated in Figure 9, assessors have decided to **score the criteria from 0 to ++++** depending on ability to satisfy the criterion to obtain a view of overall effectiveness by adding up the scores. Depending on the uses, the scoring may vary and a decision must be taken on what the average is. It is important to note that the choice of the scoring system and of the criteria should be left to the assessors who can take into consideration specific dimensions related to the use of the substance. These choices should be duly documented.

Figure 9: Example of a comparison of the effectiveness of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) approach

RMO	Ability to reduce risk	Measurability / Monitorability	Proven technology available	Overall effectiveness
Simple – Non-integrated approach				
Restriction (based on assumptions made on scope and content of Restriction)	++ (between + and +++ due to doubts on workability for some uses)	++	+	+++++
Authorisation	+ (between 0 and ++ depending on use, some being intermediates)	++ (between + and +++ depending on use)	+ (between + and ++ depending on use)	++++
Specialised – Mixed approach				
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+++	++	+	+++++ +
BATNEEC For Use 3	++	+	+++ (some participants claim ++++)	+++++ +

- **PRACTICABILITY**: Can the RMO be implemented easily?
  Practicability may be considered from a variety of angles:
  - **Ease to implement by Industry:** One considers if actions to be undertaken to implement the RMO are clear and implications in terms of obligations and responsibilities. Another parameter is the availability of tools (technology e.g.) needed to implement the RMM
  - **Ease to implement by Regulators**: Under which conditions and at what cost can enforceability be assured?
  - **Time to implementation:** If action is considered urgent by regulators, there are RMOs that have less chances of being agreed to. If a technological solution is not yet mature, the process of validating it and adopting it as a BAT may take too much time than acceptable by society.

In the following hypothetical illustration (Figure 10), the authors of the RMOA may have found that a targeted Restriction would be more practical than an overall Restriction and that compared to the other options, there may be disadvantages from a policy-maker point of view with BATNEECs.

Figure 10: Example of a comparison of the practicability of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Ease to implement by Industry	Ease to implement by Regulators	Time to implementation	Overall practicability
Simple – Non-integrated approach				
Restriction (based on assumptions made on scope and content of Restriction)	+ (between 0 and ++ due to doubts on workability for some uses)	++	+++	+++++ +
Authorisation	0 (between 0 and + depending on use, some being intermediates)	+++	++ (between + and ++ depending on use)	+++++
Specialised – Mixed approach				
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+ (between 0 and ++ depending on use, some being intermediates)	+++	+++	+++++ ++
BATNEEC For Use 3	+	+	0 (timing concern for most participants)	++

- **CONSISTENCY**: How do the RMOs being considered perform in terms of a level playing field and coherence.

  - **Regulatory consistency**: Is the RMO consistent with a level playing field across the EU? Is there a risk of distortion of competition through differences in implementation at national level?
  - **Consistency with existing EU legislation**: Are there any potential regulatory overlaps with existing regulations?
  - **Consistency with previous EU initiatives**: How does the conclusion of the RMOA fit with the conclusions of previous EU Risk Assessments?
  - **Consistency with other EU policy objectives**: If, for example, the substance can not be substituted in processes that contribute to achieving EU air quality standards, a ban may negatively affect air quality and associated public health objectives. There is an abundance of EU policies that could be considered in this respect and not only related to human health or environmental objectives (energy, resource efficiency etc.)

Figure 11: Example of a comparison of the regulatory consistency of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Regulatory consistency	Consistency with existing EU legislation	Consistency with previous EU initiatives	Consistency with other EU policy objectives	Overall consistency
Simple – Non-integrated approach					
Restriction (based on assumptions made on scope and content of Restriction)	++++	+	++	++	+++++ ++++
Authorisation	++	+	+	+	+++++
Specialised – Mixed approach					
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+++	+++	+++	++	+++++ +++++ +
BATNEEC For Use 3	0	+++	++	+++	+++++ +++

In the same hypothetical case, the regulatory consistency considerations might be clearly in favour of a mixed approach, for example if a previous risk assessment/EU risk reduction strategy identified uses or sectors of concern, thus justifying a more specific set of measures.

- **BROADER IMPACT**: To come to an overall proportionality test, it may be good to consider the broader impacts on the value chain or on society.
  Here, one may consider value chain impacts at sector-level, company-level (SMEs and non-SMEs), but also possible collateral impacts on unsuspected value chains through e.g. alloys, product impacts (loss of functionality), market impacts (impacts on market shares, trade balance), monitoring costs and administrative consequences.
  Figure 12 provides an example of how to look at broader impacts but those performing an RMOA may decide on another set of criteria. The hypothetical case described in Annex IV shows an example of how the broader impacts can be considered with a more in-depth analysis of impacts at company level and value chain level. The Annex IV case splits the consideration of the economic impacts from the analysis of the human health and environmental considerations (see page 40 and following pages). The templates in Annex V also consider them separately. The choice is left to those performing the exercise and will depend on the substance.

  Figure 12: Example of a comparison of the broader impact of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Value chain impact				Societal impact		Overall broader impacts
	Neutrality vs. supply disruption	Neutrality vs. sustainability of SME business	Neutrality in terms of Impact on investments	Neutrality in terms of cost to value chain	Socio-economic benefits	Additional Human health and/or environmental benefits?	
Simple – Non-integrated approach							
Restriction (based on assumptions made on scope and content of Restriction)	+	+	++	+	0	+	+++++ +
Authorisation	+	0	0	+	+	0	+++
Specialised – Mixed approach							
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	++	++	++	++	0	+	+++++ ++++
BATNEEC For Use 3	+++	++	++	0	0	++	+++++ ++++

Annex II provides further detail on some of these impacts (value chain disruption, societal impacts etc.).

3. The synthesis of the RMO exercise: overall proportionality

The following illustration shows how the fitness test could be synthesised, as an indication of overall proportionality, for the case where an EU-wide (potentially) unacceptable risk has been identified that would justify discussing a Restriction or an Authorisation.
In this hypothetical example, the initiative to try and improve the regulatory outcome through a mixed approach has proven useful, altering dramatically the proportionality dimension. This comparison of rankings of the RMOs can also be examined further by applying "weightings" on the proportionality score that consider the respective views of the participants.

Figure 13: Example of a synthesis of comparison of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Overall effectiveness	Overall practicability	Overall consistency	Broader Overall Impacts	Overall proportionality
Simple – Non-integrated approach					
Restriction (based on assumptions made on scope and content of Restriction)	5	6	9	6	26
Authorisation	4	5	5	3	17
Specialised – Mixed approach					
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	6	7	11	9	**33**
BATNEEC For Use 3	6	2	8	9	**25**

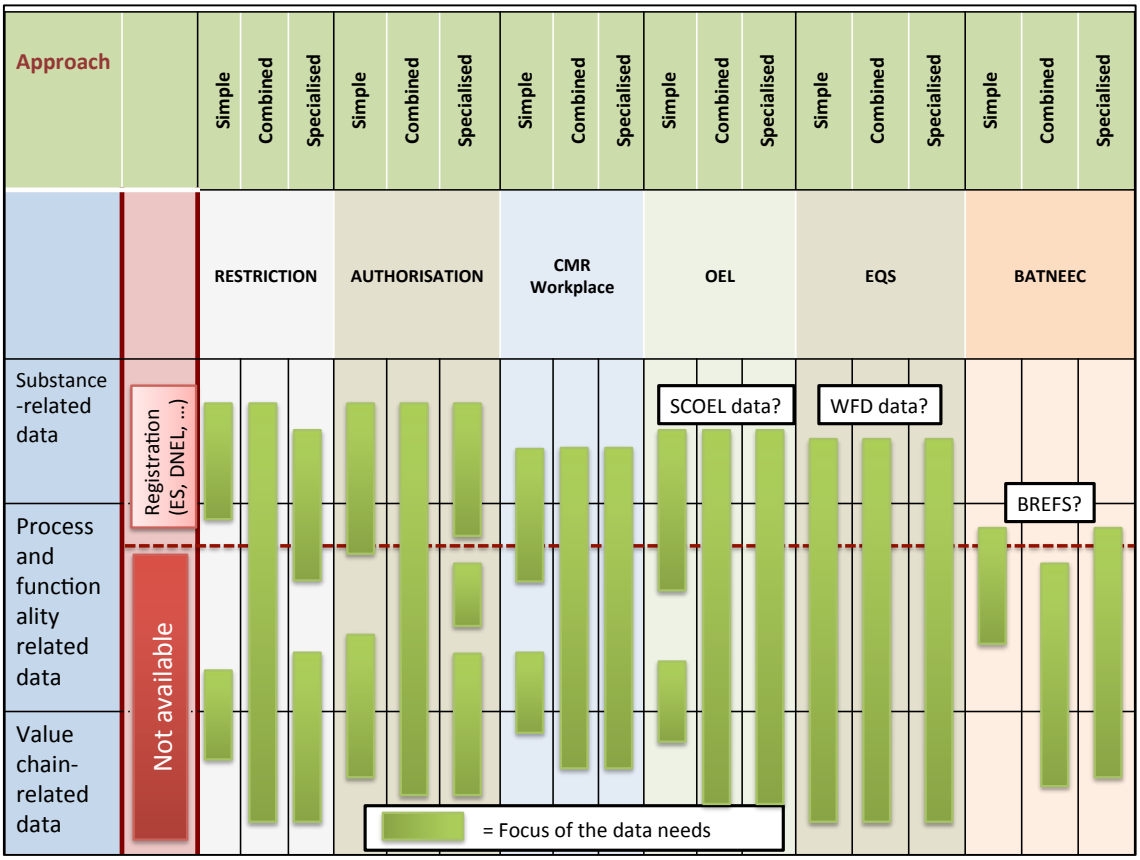
Any conclusions drawn from this synthesis can therefore be presented in a transparent manner, using the above table as a summary overview, which is then supported by explanatory comments. See further in Annex IV and its templates more information on scoring systems and their weighting.

The overall transparency in the approach is important to prevent the introduction of any bias. It is also important to capture and document the reasoning applied in the assignment of the scores, and in the selection and application of any weighting.

Part 4 - Data Collection Requirements according to RMO

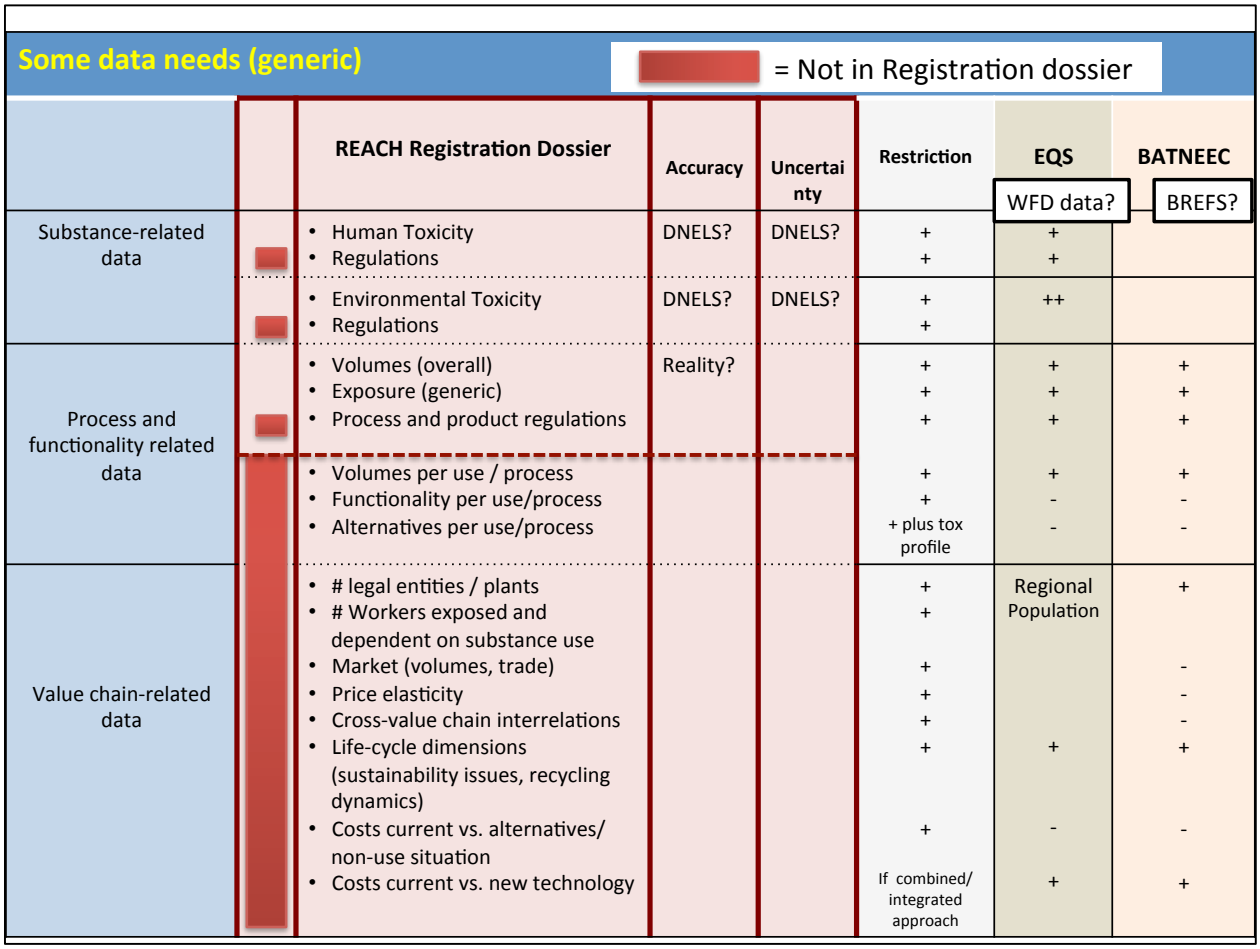
Registration dossiers constitute the main starting point for ECHA and the MS. Therefore, Industry should also start with the Registration dossier of the substance of concern, and conduct a review of the hazard properties, as well as of the current exposure scenarios. However, depending on the RMO, additional information will also be required, which will need to be collected through separate studies (e.g. use-volumes, supply chains, alternatives, socio-economics, etc.). This additional work will require considerable time/effort, and additional costs, illustrations of this are provided in Figures 14 and 15.

Figure 14: Illustration of possible data gaps in function of the RMO approaches to assess



The above figure is an illustration of the fact that some options are more demanding in terms of data than others but also and foremost it serves to highlight that information on process and functionality-related data and value chain-related data, is not readily available, especially to regulators, as not contained in registration dossiers
The Industry RMOA exercise may thus serve to collect and process data that could be shared with regulators when they decide to initiate their own RMOA or during public hearings and consultations.

Figure 15: Illustration of key data needs for three Risk Management Options



		REACH Registration Dossier	Accuracy	Uncertainty	Restriction	EQS WFD data?	BATNEEC BREFS?
Substance-related data		• Human Toxicity • Regulations	DNELS? 	DNELS? 	+ +	+ +	
		• Environmental Toxicity • Regulations	DNELS? 	DNELS? 	+ +	++ 	
Process and functionality related data		• Volumes (overall) • Exposure (generic) • Process and product regulations	Reality? 	 	+ + +	+ + +	+ + +
		• Volumes per use / process • Functionality per use/process • Alternatives per use/process	 	 	+ + + plus tox profile	+ - -	+ - -
Value chain-related data		• # legal entities / plants • # Workers exposed and dependent on substance use • Market (volumes, trade) • Price elasticity • Cross-value chain interrelations • Life-cycle dimensions (sustainability issues, recycling dynamics) • Costs current vs. alternatives/ non-use situation • Costs current vs. new technology	 	 	+ + + + + + + If combined/ integrated approach	Regional Population - +	+ - - - + - +

ANNEX I - List of RMOs and their Strengths and Weaknesses

This is a ***non-exhaustive list of existing Chemicals Management Legislation*** as there might be product- or substance-specific regulations that are relevant to the analysis e.g.

- Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation 1272/2008)
- REACH Regulation (1907/2006) with a particular focus on Authorisation and Restriction
- Transport of dangerous goods (Directive 2008/68)
- Import and export of dangerous chemicals (re. Rotterdam Convention (Regulation 649/2012))
- Biocidal Products (Regulation 528/2012)
- Plant protection (Regulation 1107/2009)
- Consumer protection regulation such as Toys Safety Directive (2009/48)
- Occupational Safety and Health Legislation:
    - Risks related to Chemicals at Work (Directive 98/24) and Directives on indicative occupational exposure limit values (Directive 2009/161)
    - Carcinogens or Mutagens at work (Directive 2004/37)
- Environmental legislation
    - Waste management
        - Basel Convention on transboundary movements of hazardous wastes and their disposal (Council decisions 93/98 and 97/640)
        - End-of-Life Vehicles (Directive 2000/53 and amending acts)
        - Batteries and accumulators and waste batteries and accumulators (Directive 2006/66 and amending acts)
        - Waste electrical and electronic equipment
            - Waste electrical and electronic equipment WEEE Directive 2002/96 and amending acts)
            - Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65)
    - Water
        - Water Framework Directive (Directive 2000/60)
        - Environmental Quality Standards (Directive 2008/105) – priority substances
        - Quality of water intended for human consumption (Directive 98/83)
    - Air
        - Ambient Air Quality (Directive 2008/50)
        - Arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons (Directive 2004/107)
    - Industrial Emissions
        - Industrial Emissions Directive (2010/75)
        - Waste Incineration Directive (200/76)

Policies to consider in the assessment of the pros and cons of the different RMOs:

- Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP) Action Plan (Communication SEC (2008) 2110 & 2111)
- Roadmap to a Resource Efficient Europe
- Integrated Product Policy (Green Paper COM 2001/68)
- Thematic Strategy on the Sustainable Use of Natural Resources (Communication COM 670/2005)
- Substance-specific strategies such as for mercury (export ban Regulation 1102/2008) and storage as waste (Directive 2011/97)
- Circular Economy Package adopted on 2 December 2015 which among other objectives and measures, includes ambitious waste management and recycling targets by 2030 and the promotion of re-use and industrial symbiosis.

The following table provides a schematic and incomplete overview of strengths and weaknesses of the different RMOs.
It will be regularly updated on the basis of feed-back of practitioners.

RMO	Strengths	Weaknesses	Possible target conflicts (with other EU policies	Notes
SVHC selection	- Quick process - Allows to send a message to the market that the use of the substance should be reconsidered	- As such, no immediate beneficial effect because no direct impact on emissions/exposure - Risk of stigmatisation of substance and uses that may appear later (during Authorisation process) to be of high societal benefit	- May discourage use of substances for R&D purposes in the EU, thus diverting innovation investments and knowledge development away from the EU	(1)
Authorisation	- Strong instrument to push for substitution and/or to make sure that uses that are technically and economically 'fit' for phasing out are effectively banned - Allows Industry to make its case: society is informed on state of the art and on the real use of substances	- Complex dossier preparation, including discussions in the value chains between actors with different stakes and understanding of the issue - Business uncertainty: - Uncertainty of the decision process - Review times may be difficult to match with business planning (long-term contracts, investments) - Consistency concerns for processes using different SVHCs - Resource-intensive (Industry but also reviewers and assessors) - Intermediate uses are not covered which reduces potential Human Health and Environmental benefits	- Business uncertainty may - weaken the competitiveness of EU value chains - divert flows of critical raw materials from EU to other production areas in the world - Sub-optimal substitution may reduce appeal of EU products, lead to off-shoring production or impact on recycling chain efficiency and profitability - Difficulty to factor in the sustainable use of natural resources or natural elements	
Restriction	- Based on an established risk that justifies an EU-wide measure - Clarity of the rules which apply to all	- Complex to prepare for a Regulator (scoping, technical aspects, alternatives, socio-economic dimension) - Enforcement can be challenging (testing of imported articles e.g.) - Does not cover isolated on-site intermediates which may reduce effectiveness in terms e.g. of Human Health protection (workers)	- Difficulty to factor in the sustainable use of natural resources or natural elements	
OEL	- Allows to address all occupational exposures (irrespective of the regulatory status of the substance, i.e. intermediate or not) - Business certainty once implemented	- Potential disparity of implementation at national level (depending on whether indicative or binding) - Science is evolving and OELs may be difficult to establish and agree on. - Potentially (over-)conservative assessment factors in setting the OEL may have a huge impact on companies		
EQS (Water Framework Directive)	- Allows a holistic assessment and approach of the concerns (surface, ground and coastal waters with management of water bodies based on river basins or catchments and interlinks with Industrial emissions Directive etc.)	- Slow in adopting new understandings on e.g. bio-availability of elements in the water bodies		
BAT (Industrial Emissions Directive)	- Based on Industry expertise and on in-depth understanding of technical and economic feasibility	- Lengthy process which makes it inadequate to address issues that are considered urgent to address		

Comments:
(1): Opinions are divided on whether SVHC selection could be considered an RMM in and of itself.

ANNEX II - Economic approach to the concept of proportionality

Value Chain impacts

The discussion on the economic dimension of the proportionality of each RMO may include the following aspects:

- Disruption of value chains due to shortages of supply or the disappearance of a segment of the value chain (closure of activities etc.).
- Loss of turnover/profit in one or more of the segments of the value chain.
- Loss of production in the EU and increased imports.
- Rearrangement of the value chain (new supply loops or new outsourcing circuits in the EU or outside the EU).
- Relocation of one or more parts of the value chain.
- Loss of confidence in the future of the value chain (loss in stock value, higher interest rates, higher insurance premiums etc.)

But possibly also:

- Introduction of innovative technologies
- Productivity and competitiveness gains
- If planning security is offered: regained confidence in the value chain with positive impact on investment planning and cost

Such arguments should be used parsimoniously and only when they can be substantiated (qualitatively or quantitatively) to avoid being suspected of trying to bias the assessment by, for example, inflating negative impacts and ignoring the positive ones. It is also not realistic to expect a value chain to be able to accurately estimate impacts across other value chains (substitute substances).

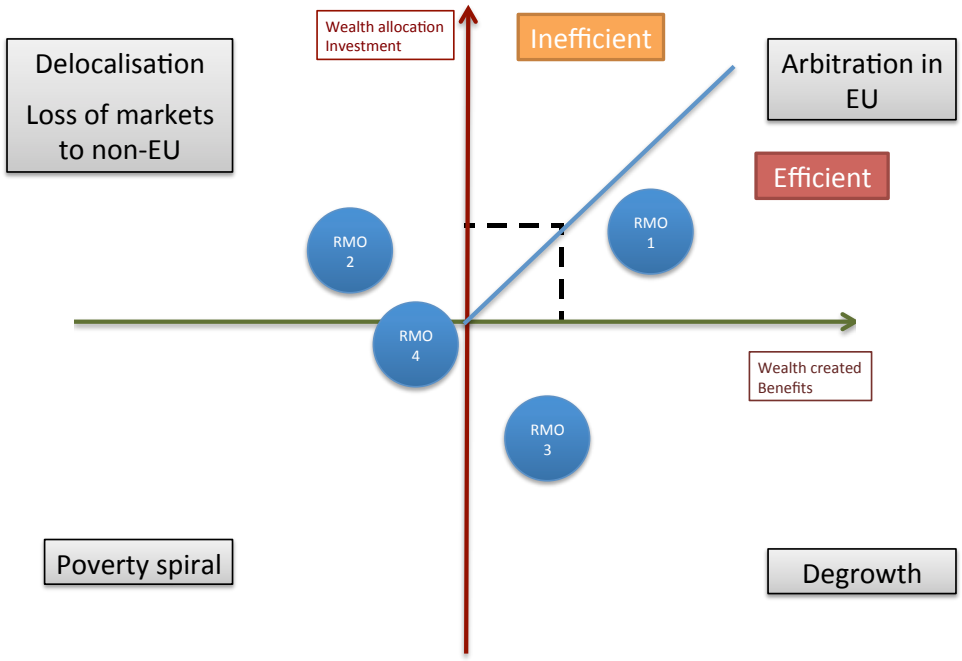
In a first stage, experts in the value chain may provide a qualitative assessment of the expected impacts, which may be confirmed and quantified later if and when required.

Societal impacts

It may be valuable to put the value chain impacts in a broader perspective that includes the direct and indirect benefits of the RMOs considered as well as the possible drawbacks.
An indirect impact of relocation to the rest of the world might, if of sufficient magnitude, be social disarray, health challenges and lower education standards in regions already affected by high unemployment.

Such an exploration allows to develop another view on how, from a societal point of view, costs compare to benefits. However, enough solid data should be available to draw a credible conclusion (see illustration in Figure 16).
Note that the concepts used in this example are subject to controversy but they may help structure a broader discussion.

Figure 16: Possible positioning of RMOs on a Societal Impacts scale



1. **Society benefits from RMO 1**
   RMO 1 requires a certain allocation of wealth (investment) but produces a higher level of wealth (benefits).
   Ideally, and provided all costs can be accurately estimated (including impact on shares value e.g.) and all benefits can be valued, society would be satisfied with an outcome along or under the blue line. In that case the investment might be worth doing.
   If it can be proven that the RMO leads to an outcome above the blue line, the RMO can be said to be inefficient from an overall societal point of view.

2. **Society looses with RMO 2**
   The costs to Industry (relocation, loss of business to non-EU competitors etc.) are not matched by a net benefit (because of higher net health costs due to unemployment, fiscal challenges for the government, reduced care of the environment etc.). One may qualify this option as 'contra-economic' growth.

3. **Society 'looses' with RMO 3**
   The net positive effect for society results from an increase in essentially 'monetised' qualitative improvements (less noise from transport, reduced air pollution etc.) due to a reduction of the size of the activity. The economy is said to lose financially even if there might be greater benefits on the long run, for instance, due to enhanced sustainability.

4. **Society looses with RMO 4**
   The reduction of activity leads to a net loss of benefits that may be a loss in well-being (unemployment leading to poverty e.g.). The more the net effects of policies hint towards this quadrant, the more one can say that society risks falling into a spiral of poverty.

ANNEX III - Learning lessons from RMOA exercises and practical advice, including role play

This section will be updated regularly as learning lessons come in from different RMOA exercise performed by Industry

Issue identification

1. It has proven useful to **first hold an internal (commodity/consortium) preparatory exercise** to go through the Industry tasks and check-list (see PARTS 1 and 2).

2. It is very important that in the early phase of the RMOA exercise, **the participants consider how a regulator may look on the issue**!
   What will a regulator base his assessment of the concern on?
   - Own data
   - Registration dossier and what are the points that may 'stick' (calculation of exposure and of DNELs e.g.) views on RCRs
   - NGO reports and academic research
   - Free accessible data on the Internet

   Confronting that point of view with the Industry view may lead to uncover risks of misunderstandings and may orient the data collection.
   It may also affect the Industry view of the concern.

3. **It may be recommended to hold a role play with those participating in the first meeting**.
   a. Purpose: familiarise participants with an exercise where they will be invited to not only defend their company's interests (and imagine a path forward) but to adopt a holistic view, taking into account concerns of the value chain(s) and of regulators and society)
   b. Role play organisation:
      i. Organise small groups (6 to 7 people maximum) that will discuss one or several parts of the value chain.
      ii. Ask participants to play the role of a company representative defending the interests of a particular segment of the value chain.
      iii. Have a moderator – familiar with the RMOA tool - who starts the discussion and challenges the views expressed by the participants, such as "Regulator X has stated to be concerned that there is an unacceptable risk or concern"
      iv. Provide participants with a small briefing note with 'imaginary' company objectives such as "Company is very close to having an alternative available but doesn't want the competitors to know" for example.
      v. Let them consider, during half an hour, how they would address the concerns voiced by regulators, i.e. the substance has a profile that would qualify it for consideration as SVHC or for other RMOs.
   c. Conclusion: In plenary, moderators provide feed-back on interesting elements of the discussion such as issues ignored (on purpose?), on the level of understanding between value chain actors etc. This proves to be an interesting introduction to the complex assessment of the issues across value chains.

4. Following up on point 2, i.e. the regulators' point of view, it may be useful to **assess this identification of concerns**
   a. **Relevance?** Is the assessment of the risk i.e. respiratory sensitizer as the main/only focus point to consider, in the life cycle stages/uses described, a good reflection of the reality of risks for a policy-maker to suggest a conclusion?

b. **Credibility?** How likely will this assessment be accepted by regulators / other stakeholders as being honest and unambiguous?
c. **Acceptability**? To what extent will this risk identification be accepted and supported in the companies and the value chain?
d. **Easy to validate?** Is this assessment of risks easy to check and validate by external experts/regulators?
e. **Robust?** Are these conclusions able to stand the test of time? Could they be put into question by the resolution of existing uncertainties or ongoing research?

5. As the main policy aim of dealing with SVHCs is to substitute, **do take up "substitution" as the first RMO on the list**.

6. Different **RMOA approaches are possible, depending on when the assessment is made vs. SVHC Roadmap screening process**:

a. **Explore and prepare by <u>improving the understanding of the issue</u>** (risk or not?) through development of data (measurements) so as to be able to better describe what is at stake
   - May remove the concern
   - May bring to light issues that were not visible at first glance (risk may be elsewhere than what was initially thought or estimated)

And then proceed with the RMO analysis proper when considered opportune.

b. <u>RMOA as such</u>
Challenges to address:
   - ***Too few participants or too different or too sensitive:***

The exploratory exercise may show that there is a limited number of sites and/or different technologies, or that there are business considerations that are difficult to 'reconcile'. It is then advised to divide the exercise into a generic part (understanding the potential concerns related to e.g. risk characterisation in the RCRs) and more specific parts that will be discussed separately.
Depending on the findings, a common conclusion or recommendation may be suggested.
This is time- and resources consuming, but it offers the potential to yield much more information than with a common exercise, especially when exploring substitution, socio-economic feasibility etc. These separate discussions may be useful to companies when they consider their own options later on.

   - ***Too many participants (huge value chains):***

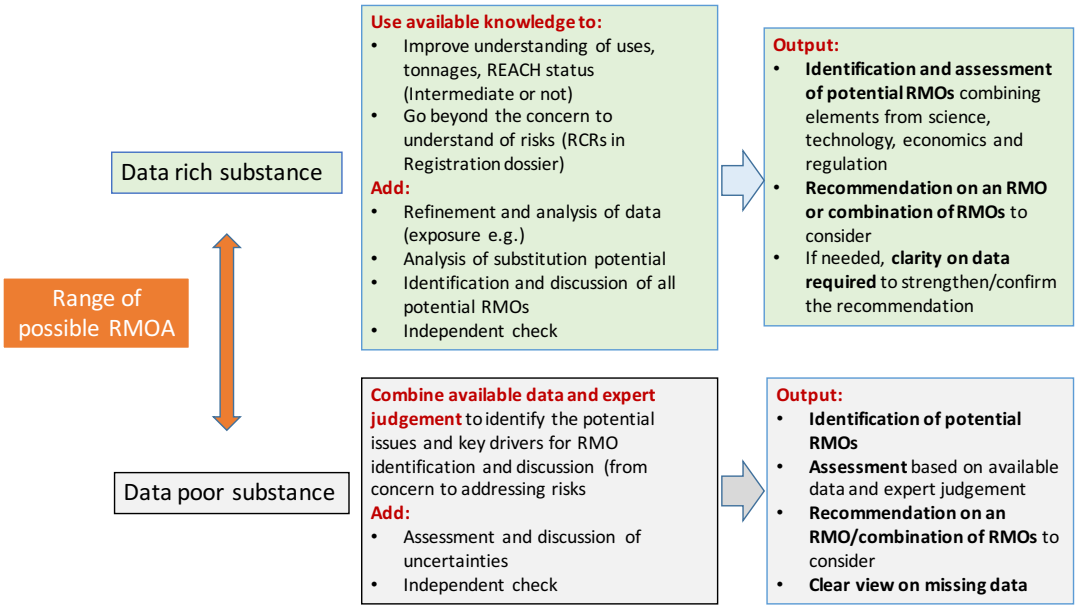
The suggestion is to consider working in a modular way with, with preferably a champion per module (a company a step ahead of the other companies and thus a useful support to the process moderator)

   - ***Criteria for estimating overall proportionality may vary, depending on the substance, its use, policy context:***

Flexibility is allowed.

7. It may be advisable to **differentiate between gaps in data** that are relevant to come to a credible conclusion. Initially, in the identification of the RMOAs, one will tend to rely more on expert judgment than when considering input into Public Consultations and beyond (ultimately Authorisation e.g.).
So, in order not to discourage participation and clogging the system with irrelevant information, it is important to be selective (what is relevant at what time?).
So ideally, map the gaps according to their relevance vs. the stage of the process.

8. **Data rich substances** will allow a much easier **analysis of the concern so as to whether there is a risk that needs to be addressed.** For example, an EU-wide risk may lead to explore the possibility of a Restriction.



9. It has proven of high value and therefore highly advisable to submit the report and its conclusions to an **external review**. An independent view on the proceedings may bring to light logical flaws, weaknesses in the argumentation etc.

ANNEX IV - RMOA – Illustration with hypothetical substance X

Introduction

RMOA Process description:
This is an exercise that refers to a theoretical substance X used as a stabiliser in plastics.
The process consisted in:

a) Preparatory data gathering
b) Meeting of companies to identify all possible RMOs and agree on data that should be collected
c) Companies individually discussed and scored the different RMOs
d) Bringing together of the company evaluations and proposal of synthesis
e) Consensus on outcome and agreement on next steps

At each of the different stages, notes are provided with learning lessons from other similar RMOA exercises.

Hypothetical substance:
Substance X: metal compound
Hazard profile: fits with SVHC criteria (reprotoxicity)
Exposure through humans occurs via migration from plastic materials

Caution:
The discussions and outcome of this RMOA are purely hypothetical, although they do reflect the logic in the discussions and the types of findings in several groups and consortia.
This overview provides a flavour of a RMOA. Depending on the complexity of the substance and of its uses, the RMOA may be much more elaborated and rich in data.

Meeting to start the RMOA: Agreeing on potential concerns and potential RMOs

Setting the scene

PARTICIPANTS

Several companies using substance X for producing **articles made of plastics**
Facilitator: REACH Consortium / consultant

PURPOSE

a. Check agreement and data gaps/uncertainties on
   - Substance use (so as to be sure of life cycle and REACH status)
   - Exposure (to look for potential issues along the life cycle)

b. Discuss potential Risk Management Options for further analysis.

Discussion

USES

Uses as in the Registration dossier:

Use	REACH status
Formulation	Not an intermediate
Production of plastics	Not an intermediate

Questions:

I. Is the Registration dossier up-to-date on uses?

a. Potential uses identified (Google search, analysis of patents, commercial websites and catalogues etc.)

Note: In other RMOAs, preparatory research, meetings and subsequent consultations led to discover an increasing interest for the substance and potential new uses in the future, for example:

- **R&D in catalyst:** a substance appeared to be a favourite compound in the development of new chemistries for new applications. This information came from companies and was confirmed by literature search as well a scan of recent patents.
- **Inclusion in new rechargeable battery chemistries** for electric vehicles. One of those chemistries is not yet produced in the EU but investment by a non-EU car manufacturer in a European battery production site might change the picture.

The group was of the opinion that such possible developments should be taken into account in a RMOA. It could be done by checking the outcome if the evaluation by companies (scoring and discussion of the potential RMOs) is compatible with potential future developments.

II. Is the Registration dossier up-to-date regarding tonnages? Double counting?

No reliable trade statistic is available to Industry which might be helpful to identify the net use in Europe as substance X is taken up in a broader category of compounds.

A tentative tonnage allocation (based on estimates from companies) provides:

Use	Intermediate	Non-intermediate
Formulation (In EU, includes exports but excludes imports of ready to use mixes)	0	110-200 tons
Downstream use		
Production of plastics	0	210-250 tons
Total used in EU	**200-400 tons**	**320-450 tons**

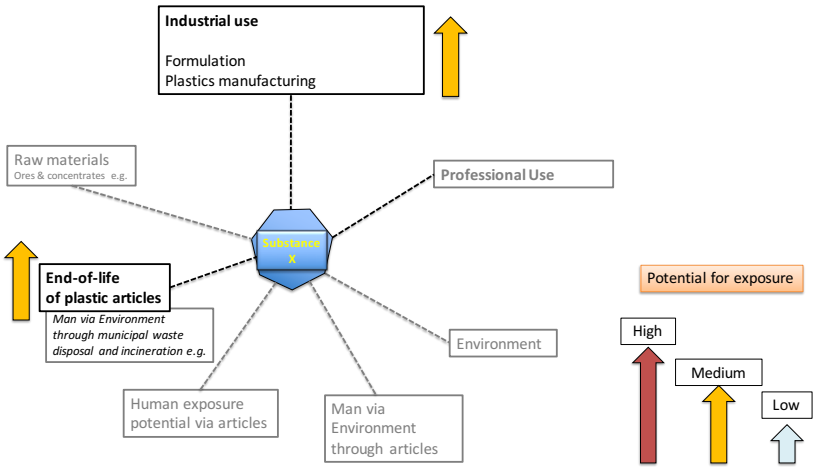
Overall, the tonnage used in the EU was estimated at around 400 to 500 tons.

Decisions:

1. Check **uses** with commercial departments and if needed update Registration dossier
2. Check **tonnages** so as to be able to get a clear picture of the real use (excluding double-counting etc.)

EXPOSURE

The potential for exposure was discussed and considered from a life cycle point of view:



	Number of manufacturing sites / legal entities	Number of potentially exposed workers
Formulators	5	50- 80 (tbc)
Plastics manufacturers	45	880 - 1450 (tbc)

Potentially exposed workers number 1500 maximum.
Man via environment exposure is still under investigation to confirm existing studies but companies agreed that the potential for exposure exists at end-of- life

SUBSTITUTION

	Substitution potential
Formulators	Alternatives exist and move to them would not lead to business disruption, provided that the market is not taken up by competitors who do not substitute
Plastics manufacturers	Substitution is possible. Concern about the continued presence of substance X in granules produced from recycled articles Concern about import of articles still containing substance X (commercial handicap and end-of-life concerns)

Substitution appeared both technically and economically feasible.
Participants indicated that they would be prepared to consider voluntary substitution provided that there are no free-riders.

IDENTIFICATION OF POTENTIAL RMOS

The group discussed the different options that could be identified and were discussed.
Interesting is that the group found that a combination of approaches may be necessary, especially to address the risk of free-ridership and issues of end-of-life management of articles containing substance X (including imported articles).
The following table was agreed upon as a conclusion of the meeting with the request to the participants to assess and score the options individually.

Potential RMO	First discussion	A priori relevance
Substitution (Industry initiative)	Possible approach. Concern for market disruption by free-riders	High
Existing legislation (e.g. OEL, BATNEEC, etc.)	Possible approach. Benefits may not be worth the investment	Medium to High
Harmonised Classification under CLP	Done	No relevance hence no further discussion
Substance Evaluation under REACH	Last uncertainties on exposure levels are being addressed	Low
Restriction under REACH	Possible approach. Maybe useful combination with an industry initiative to address potential end-of-life mismanagement (man via the environment)	High
SVHC selection (Candidate List)	Participants had difficulty identifying SVHC selection as an RMO as such and not as only the antechamber to Authorisation. The market signal function was considered to be weak	Depends on discussion of Authorisation
Authorisation under REACH	Would be a means to accelerate substitution and avoid free-riders	High

Note: It has to be stressed that each substance may, due to its profile, end up with a different set of potential risk management options.
Participants were invited to consider **all** potential options and to try and imagine how a regulator may consider defining them (e.g. possible scope of a Restriction).
Participants had also to try and look beyond their immediate business activity. In this case, they discussed the end-of-life of articles and the fate of the articles (including imported articles) containing substance X (from municipal waste dumps, over incinerators to recycling). The concerns identified and discussed were the potential risk of exposure (man via environment) and the delay in phasing out of the presence of substance X in plastics due to recycling.

Individual company exercise: scoring of potential RMOs

The following tables summarize the contributions made by the different companies.
Note that the choice was made to rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion. Annex V of this Guidance shows such tables where ranking is suggested.
The weights that were suggested for the criterion range from 0,5 (low importance) over 1 (neutral) to 1,5 (high) but this is open for debate and, often companies have suggested a different weighting.

1. Effectiveness of the RMOs

Formulators		Ability to reduce risks	Weight	Measurability / Monitorability	Weight	Proven technology available	Weight	Overall EFFECTIVENESS score	Ranking
Substitution (Industry)		5	1,5	7,5	1	0	1	**15**	**5**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	8	1,5	8	1	7,5	1	**27,5**	**2**
	BAT	8	1,5	8	1	7,5	1	**27,5**	**2**
Restriction under REACH		6	1,5	10	1	0	1	**19**	**4**
SVHC selection		1	1,5	0	1	0	1	**1,5**	**6**
Authorisation under REACH		8	1,5	9	1	7,5	1	**28,5**	**1**

Plastic producers		Ability to reduce risks	Weight	Measurability / Monitorability	Weight	Proven technology available	Weight	Overall EFFECTIVENESS score	Ranking
Substitution (Industry)		10	1,5	7	1	10	1	**32**	**3**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	8	1,5	8	1	5	1	**25**	**4**
	BAT	8	1,5	8	1	5	1	**25**	**4**
Restriction under REACH		9	1,5	10	1	10	1	**33,5**	**1**
SVHC selection		1	1,5	0	1	0	1	**1,5**	**6**
Authorisation under REACH		9	1,5	10	1	10	1	**33,5**	**1**

Formulators ranked OEL and BATs higher than the plastics producers because the exposure situation is less complex and difficult to manage than the plastics producers. The viewed SVHC selection, when considered as an RMO per se, thus independently from Authorisation, as the least relevant option.

Note: In other RMOAs performed with this scheme, one could identify a definite divide between sectors where the use could be easily or foreseeably substituted and those where substitution is a no-go.
Those who are set on a path of substitution indicated that Authorisation or Restriction might provide a safeguard against unfair competition, feeling that these instruments could "rubber-stamp" their efforts.
For those who will continue to depend on the substance under scrutiny, the main challenge is to identify a path that will allow business planning and continuity whilst optimising operational conditions in terms of potential exposure of man and the environment.

2. Practicability of the RMO

Formulators		Ease of implementation by Industry	Weight	Ease of implementation for regulators	Weight	Time to result	Weight	Overall PRACTICABILITY Score	Ranking
Substitution (Industry)		5	1,5	0	1	5	1,5	**15**	**4**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	6	1,5	9	1	7,5	1,5	**29,25**	**1**
	BAT	4	1,5	1	1	2,5	1,5	**10,75**	**5**
Restriction under REACH		5	1,5	9	1	8	1,5	**28,5**	**2**
SVHC selection		0	1,5	0	1	0	1,5	**0**	**6**
Authorisation under REACH		8	1	9	1	6	1,5	**26**	**3**

Plastics manufacturers		Ease of implementation by Industry	Weight	Ease of implementation for regulators	Weight	Time to result	Weight	Overall PRACTICABILITY Score	Ranking
Substitution (Industry)		10	1,5	7	1	7	1,5	**32,5**	**1**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	6	1,5	9	1	5	1,5	**25,5**	**3**
	BAT	4	1,5	2	1	3	1,5	**12,5**	**5**
Restriction under REACH		8	1,5	7,5	1	8	1,5	**31,5**	**2**
SVHC selection		0	1,5	0	1	0	1,5	**0**	**6**
Authorisation under REACH		7	1	9	1	6	1,5	**25**	**4**

The relatively easier implementation of an OEL at formulator level is reflected in the outcome of their scoring, potentially coupled with a Restriction.
Plastics manufacturers, because of the ease to substitute, favoured the voluntary substitution option, possibly backed by a Restriction. They found the Authorisation not so 'practicable'.

Note: The ability to push through an industry initiative depends on where an industry actor is situated in the value chain. One of the merits of such an RMOA approach is that it allows early in the process to bring around the table different actors and to identify the conditions for success of an industry initiative (substitution, BATNEEC in particular).

3. Regulatory consistency

Formulators		Regulatory consistency across the EU	Weight	Consistency with existing EU regulations and policies	Weight	Overall REGULATORY CONSISTENCY score	Ranking
Substitution (Industry)		0	0,5	2	1,5	**3**	**6**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	7,5	1,5	9	1,5	**24,75**	**2**
	BAT	1	1	7,5	1,5	**12,25**	**5**
Restriction under REACH		10	1,5	6	1,5	**24**	**4**
SVHC selection		10	1,5	10	1,5	**30**	**1**
Authorisation under REACH		9	1,5	7,5	1,5	**24,75**	**2**

Plastics manufacturers		Regulatory consistency across the EU	Weight	Consistency with existing EU regulations and policies	Weight	Overall REGULATORY CONSISTENCY score	Ranking
Substitution (Industry)		3	0,5	9	1,5	**15**	**5**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	8	1,5	9	1,5	**25,5**	**4**
	BAT	1	1	7,5	1,5	**12,25**	**6**
Restriction under REACH		10	1,5	10	1,5	**30**	**1**
SVHC selection		10	1,5	10	1,5	**30**	**1**
Authorisation under REACH		10	1,5	10	1,5	**30**	**1**

Companies from both use groups understood that an initiative carried only by industry has less 'regulatory weight' and carries a risk of unsanctioned free-ridership.
From a purely regulatory point of view (consistency with the texts of the law), SVHC selection came out as the option with the highest score and, depending on the characteristics of the industry, followed by either OELs or Authorisation.

Note: In other cases, companies identified risks of policy inconsistencies. If they agreed that in purely regulatory terms an identification as SVHC appears logical, they questioned the relevance of such a move. The 'eventual' prioritization for Authorisation may lead to subjecting to a costly and potentially disruptive process uses of a substance for which there is no alternative or which are necessary to contribute to the realisation of EU objectives in the field of energy, human health or environment.
In such cases, the scoring for SVHC selection is either very high (when seen independently) and Authorisation is scored low. Other sectors have opted, from the beginning to not separate the discussion of SVHC selection and Authorisation and scored both options low.

4. Economic impacts

CAUTION! Scores are from 10 to 0 (10 for most positive impact to 0 most negative impact)

Formulators		Value chain impacts								Company-specific impacts				Overall economic impact	Ranking
		Supply disruption	Weight	SME-specific impacts	Weight	Costs	Weight	Invest-ment	Weight	Costs	Weight	Business model and continuity	Weight		
Substitution (Industry)		8	0,5	7,5	0,5	5	0,5	10	0,5	5	0,5	10	1	**27,75**	**1**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	10	0,5	2,5	0,5	2,5	0,5	5	0,5	2,5	0,5	7,5	1	**18,75**	**5**
	BAT	10	0,5	5	0,5	2,5	0,5	5	0,5	2,5	0,5	10	1	**22,5**	**4**
Restriction under REACH		7,5	0,5	5	0,5	6,5	0,5	7,5	0,5	5	0,5	7	1	**22,75**	**3**
SVHC selection		7,5	0,5	7,5	0,5	10	0,5	2,5	0,5	10	0,5	5	1	**23,75**	**2**
Authorisation under REACH		7	0,5	5	0,5	5	0,5	5	0,5	2,5	0,5	5	1	**17,25**	**6**

Plastics manufacturers		Value chain impacts								Company-specific impacts				Overall economic impact	Ranking
		Supply disruption	Weight	SME-specific impacts	Weight	Costs	Weight	Invest ment	Weight	Costs	Weight	Business model and continuity	Weight		
Substitution (Industry)		10	0,5	7,5	0,5	7	0,5	8	0,5	6	0,5	6	0,5	**22,25**	**2**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	10	0,5	2,5	0,5	2,5	0,5	5	0,5	2	0,5	7,5	0,5	**14,75**	**6**
	BAT	10	0,5	5	0,5	2	0,5	5	0,5	1	0,5	10	0,5	**16,5**	**5**
Restriction under REACH		7,5	0,5	8	0,5	7	0,5	8	0,5	7	0,5	6	0,5	**21,75**	**3**
SVHC selection		9	0,5	7,5	0,5	10	0,5	8	0,5	10	0,5	5	0,5	**24,75**	**1**
Authorisation under REACH		8	0,5	5	0,5	6	0,5	6	0,5	6	0,5	5	0,5	**18**	**4**

Logically, considering the consensus in favour of substitution, companies considered that SVHC selection will have the least economic impact as no harmful stigmatisation should be feared.
Investing in OELs or new technologies didn't seem to make sense.

Note: In all cases discussed in industry, companies gradually developed a more holistic view of the economic impacts, looking at how to optimize risk management along the value-chain.

5. Human health and environmental benefits

CAUTION! Scores are from 10 to 0 (10 for most positive impact to 0 most negative impact)

Formulators		Human health impacts				Environmental impacts				Overall Human Health and Environmental impact	Ranking
		Improvement of affected population (workers, etc.)	Weight	Other health impacts (benefits)	Weight	Specific benefits	Weight	Other environmental benefits	Weight		
Substitution (Industry)		7	1,5	5	1	2	1	1	0,5	**18**	**2**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
	BAT	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
Restriction under REACH		7,5	1,5	5	1	2	1	1	0,5	**18,75**	**1**
SVHC selection		1	1,5	0	1	0	1	0	0,5	**1,5**	**6**
Authorisation under REACH		7,5	1,5	5	1	2	1	1	0,5	**18**	**2**

Plastics manufacturers		Human health impacts				Environmental impacts				Overall Human Health and Environmental impact	Ranking
		Improvement of affected population (workers, etc.)	Weight	Other health impacts (benefits)	Weight	Specific benefits	Weight	Other environmental benefits	Weight		
Substitution (Industry)		8	1,5	5	1	2	1	1	0,5	**19,5**	**1**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
	BAT	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
Restriction under REACH		7,5	1,5	5	1	2	1	1	0,5	**18,75**	**2**
SVHC selection		0	1,5	0	1	0	1	0	0,5	**1,5**	**6**
Authorisation under REACH		7,5	1,5	5	1	2	1	1	0,5	**18,75**	**2**

From a human health or environmental impact point of view, the different options are very close (with the exception of SVHC selection for the reasons of non-effectivity already indicated).
Companies estimated that positive environmental impacts could not be excluded but would be minimal.

6. Synthesis

The point of view of the ***formulators***:

Formulators		Overall effectiveness	Overall practicability	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality ranking	Final ranking
Substitution (Industry)		5	4	6	1	2	18	4
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	2	1	2	5	4	14	2
	BAT	2	5	5	4	4	20	5
Restriction under REACH		4	2	5	3	1	15	3
SVHC selection		6	6	4	2	6	24	6
Authorisation under REACH		1	3	1	6	2	13	1

The ranking by the formulators of the OEL, Restriction and Authorisation options are very close which is confirmed when looking at the sum of scores in the following table.
Having taken full consideration of regulator's concerns, formulators ended up ranking Authorisation first as they felt that regulators had a case for wanting to force Industry to abandon the use of substance X and that Authorisation might allow to bring to light very specific uses, not generally known, that could still get an Authorisation. Looking at their business, they didn't see the benefit of going through the process of Authorisation as substitution looks the most straightforward option.
The participants in that use group indicated that the apparent lack of clarity or indecisiveness of this synthesis reflects their more neutral position vis-à-vis the continued use or not of substance X.

Formulators (sum of scores)		Overall effectiveness	Overall practicability	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality scoring	Final ranking
Substitution (Industry)		15	15	3	27,75	18	78,75	5
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	27,5	29,25	24,75	18,75	16,25	116,5	1
	BAT	27,5	10,75	12,25	22,5	16,25	89,25	4
Restriction under REACH		19	28,5	24	22,75	18,75	113	3
SVHC selection		1,5	0	30	23,75	1,5	56,75	6
Authorisation under REACH		28,5	26	24,75	17,25	18	114,5	2

The point of view of the ***plastics manufacturers***:

Plastics manufacturers		Overall effectiveness	Overall practicability	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality ranking	Final ranking
Substitution (Industry)		3	**1**	**5**	2	3	14	2
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	4	**3**	**4**	6	1	18	4
	BAT	4	**5**	**6**	5	1	21	6
Restriction under REACH		1	**2**	**1**	3	3	10	1
SVHC selection and Candidate Listing		6	**6**	**1**	1	6	20	5
Authorisation under REACH		1	**4**	**1**	4	5	15	3

Plastics manufacturers (sum of scores)		Overall effectiveness	Overall practicability	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality scoring	Final ranking
Substitution (Industry)		32	32,5	15	22,25	19,5	**121,25**	**3**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	25	25,5	25,5	14,75	16,25	**107**	**4**
	BAT	25	12,5	12,25	16,5	16,25	**82,5**	**5**
Restriction under REACH		33,5	31,5	30	21,75	18,75	**135,5**	**1**
SVHC selection and Candidate Listing		1,5	0	30	24,75	1,5	**57,75**	**6**
Authorisation under REACH		33,5	25	30	18	18,75	**125,25**	**2**

The ranking by the plastics manufacturers reflects the consensus in favour of substitution, supported by a regulatory 'fire-wall' against free-riders (i.e. restriction).
Closer to the markets and their expectations – including societal concerns – they favoured a set of initiatives, with a voluntary phase-out by industry backed-up by regulatory initiatives that would prevent free-riders at use-level and mismanagement at end-of-life stage (incineration) where a concern was identified of man-via-environment exposure.

Final meeting: agree on conclusions and path forward

A consensus-finding meeting was held with the participants of the RMOA exercise. Such a meeting is of particular interest when participants may have a different stake (formulators and plastics manufacturers, in this case). It may be that the participants agree to reconsider their first conclusions or identify further gaps in knowledge or data.

At the meeting, participants opened a discussion on issues they had felt difficult to address during their internal exercise or were not directly of their field of expertise. One example was the trade dimension (import of articles still containing substance X which would lead to continued contamination of the end-of-life flows.

1) The participants discussed the synthesis of the scoring exercise and explained the reason of some of the scores.

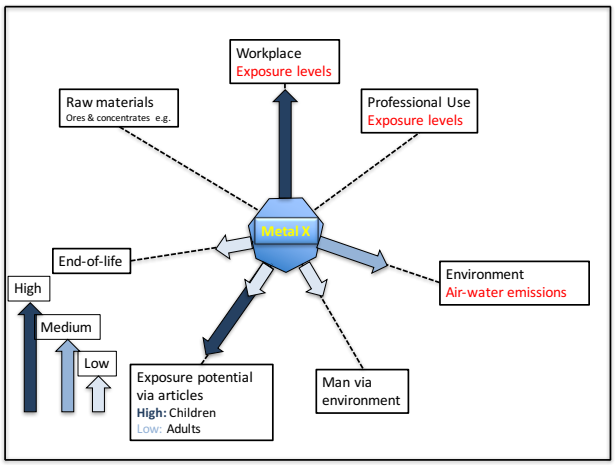
2) They examined whether a common conclusion could be identified and what to do with this conclusion.
    a. There was agreement that there was:
        i. no technical or economical obstacle to substitution of substance X and that substitution was an economically better option than technical risk reduction measures such as the implementation of OELs
        ii. a concern regarding the possibility for some to delay or relinquish phasing out substance X which may create an economic disadvantage for the adopters of the substitutes. Participants indicated that they would not resist a call for Authorisation as that would affect those not wanting to phase-out the use of substance X
        iii. a concern that needed to be addressed related to the possibility of continued import of articles containing substance X. Some further work would be needed to scope and define the content of a possible Restriction and consider its costs and benefits. It was felt that it that might complement Authorisation
        iv. a concern at the end-of-life management stage of the substance that may be addressed with a Restriction related to issues such as incineration
    b. A plan for communication and broader debate within industry was established. A second plan concerned future communications with other stakeholders, i.e. article users, national competent authorities for REACH, waste management authorities etc.

3) They finally agreed on a path forward regarding the collection and updating of data needed to substantiate the conclusions and to better understand the impacts. A particular attention was devoted to the update of the Registration dossier.

ANNEX V - Templates for the RMOA Exercise

This is an example of templates one can use. Tables can be used as such or copied and pasted in Excel but the Excel workbook can be obtained from Eurometaux.

Identification of the potential issues to be addressed



- What end-points should be considered?
- Have all uses been identified and described?
- Where is the exposure occurring?

Discussion:

- **UNCERTAINTIES:**

What are the uncertainties in this assessment?
- Share between intermediate and non-intermediate uses?
- Number of workers exposed?
- Uses not accounted for?
- Trends in some uses?

- **How would you assess this identification of risks?**

Relevance? Is the assessment of the risk i.e. respiratory sensitizer as the main/only focus point to consider, in the life-cycle stages/uses described, a good reflection of the reality of risks for a policy-maker to suggest a conclusion?
Credibility? How likely will this assessment be accepted by regulators / other stakeholders as being honest and unambiguous?
Acceptability? To what extent will this risk identification be accepted and supported in the companies and the value chain?

Easy to validate? Is this assessment of risks easy to check and validate by external experts/regulators?
Robustness? Are these conclusions able to stand the test of times? Could they be put into question by the resolution of existing uncertainties or ongoing research?

Basically, consider the elements in the Check-list discussed in Annex II:

- **The substance**
- **Uses, volumes and potential exposures throughout the life cycle**
- **Alternatives per (identified) use** (at a level relevant at this stage of the analysis)
- **Parameters for later Socio-Economic Assessment, per Use**

Identification of all the potential Risk Management Options that may be considered

Step 1: Identification / listing of potential RMOs		
RMO	**What are the conditions that are required to make an RMO feasible and ensure it can be implemented**	
Substitution (Industry initiative)		

Discussion:

Step 2: Feasibility requirements of potential RMOs		
RMO	**Relevancy**	**Description/ scope / justification / comment**
Substitution (Industry initiative)		

NOTE: Among the prerequisites for an RMO to be feasible, it may be important to consider elements such as **data**, **resources**, **time to implementation**, **type of stakeholder involvement** (public-private 'partnership' for a BAT e.g.) on top of regulatory requirements (cf. EU-wide risk for a restriction or scoring for Authorisation after selection as SVHC).
Another political prerequisite is likely to be that the RMOs are proposed with clear and monitorable objectives, hence the importance of providing a scope of the RMO, i.e. an idea of how it key objectives might be worded.

Discussion:

Synthesis:

Possible approaches	Potential RMOs
Simple approach (no technology-driven integration or use-specific options)	
Combined approach (i.e. integrated approach, combining with other substances of same profile used in same process or a combination of RMOs to ensure full efficiency)	
Specialised approach (i.e. a mix of RMOs based on use-specific characteristics)	

Analysis of the potential Risk Management Options

The following templates assume, for the sake of completeness, that different approaches may be considered.

EFFECTIVENESS:

Is the RMO able to reduce possible risks and will its effects be measurable?
What is the availability of proven and affordable technology? What is known about alternatives?
The elements developed in previous steps have to be synthesised into a couple of sentences per RMO considered for the final comparison.
In function of the options chosen and of the approaches tested, a table will be built to discuss the possible effectiveness of the different RMOs.

RMO	Ability to reduce risk	weight	Measurability / Monitorability	weight	Proven technology available	weight	Overall effectiveness	Ranking
Simple – Non-integrated approach								
Combined – Integrated approach								
Specialised – Mixed approach								

Scoring choice: One may rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion)
The **weights** suggested are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

PRACTICABILITY:
Can the RMO be implemented easily?

RMO	Ease of implementation by Industry	weight	Ease of implementation by Regulators	weight	Time to result	weight	Overall effectiveness	Ranking
Simple – Non-integrated approach								
Combined – Integrated approach								
Specialised – Mixed approach								

Scoring choice: One may rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion)
The **weights** suggested are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

CONSISTENCY:

Is the RMO consistent with a fairly level playing field across the EU? Is there a risk of significant differences between national implementation? Are there any potential overlaps with existing regulations?

RMO	Regulatory consistency across the EU	weight	Consistency with existing EU regulations and policies	weight	Consistency with previous EU initiatives	weight	Consistency with other EU policy objectives	weight	Overall REGULATORY CONSISTENCY	Ranking
Simple – Non-integrated approach										
Combined – Integrated approach										
Specialised – Mixed approach										

Scoring choice: One may rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion)
The **weights** suggested are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

OTHER IMPACTS: ECONOMIC AND HUMAN HEALTH /ENVIRONMENTAL

The impact categories taken up here will depend on the nature of the substance and its use in value chains.

ECONOMIC IMPACTS:

The criteria will have to be chosen in agreement with the participants. Depending on the substance and the value chain characteristics, it may be that downstream user-specific impacts are considered.

RMO	Value chain impacts								Company-specific impacts				Overall REGULATORY CONSISTENCY	Ranking
	Supply disruptions	weight	SME-specific impacts	weight	Costs	weight	Impact on Investments (production and R&D)	weight	Costs	weight	Business model and continuity	weight		
Simple – Non-integrated approach														
Combined – Integrated approach														
Specialised – Mixed approach														

Scoring choice: One may rank the option from 10 to 0 (from 10 no impact to 0 maximum impact)

The **weights** suggested here are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

HUMAN HEALTH AND ENVIRONMENT:

The criteria will have to be chosen in agreement with the participants, depending on the substance properties and production situation.

RMO	Human health impacts				Environmental impacts				Overall Human Health and Environmental Impact	Ranking
	Improvement of affected population (workers etc.)	weight	Other health impacts	weight	Specific benefits	weight	Other environmental benefits	weight		
Simple – Non-integrated approach										
Combined – Integrated approach										
Specialised – Mixed approach										

Scoring choice: Here one again ranks the option from 0 to 10 (from 0 no positive effect to 10 maximum positive impact)

The **weights** suggested here are also debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

Synthesis

It may be good to perform the sum of scores as well as the sum of rankings.

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health and environmental impact	Overall proportionality	Final ranking (based on scoring)
Simple – Non-integrated approach							
Combined – Integrated approach							
Specialised – Mixed approach							

Discussion:

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health and environmental impact	Overall proportionality	Final ranking (based on rankings)
Simple – Non-integrated approach							
Combined – Integrated approach							
Specialised – Mixed approach							

Discussion: