Eurometaux

Industry-Risk Management Options Analysis

Explanatory documents

This is the third in a series of explanatory sheets:

1. RMOA: Definitions and Concepts
2. Preparatory steps for an I-RMOa: strategy and practical preparations
3. Performing the I-RMOA: from Simple to Integrated-RMOa and the three pillars of the analysis
4. Templates for I-RMOa

# Performing the I-RMOA: from Simple to Integrated-RMOa and the three pillars of the analysis

# Content

## Introduction

The I-RMOa approach as developed in Part 3 proposes to cover ground beyond the regulatory scope of an RMO Analysis in the SVHC Roadmap 2020 context, sensu stricto, as there is, with the Green Deal, a need for integrating the manifold of green priorities into the Risk Management measure discussions so as to achieve a holistic and effective approach for metals and inorganics.

It will be presented as a three-pillar exercise consisting in:

- Pillar 1: The I-RMO analysis in the chemicals management sphere which can be split between a reactive exercise (responding to a regulatory management options analysis initiative) and a more holistic approach (pro-active or even strategy-oriented)
- Pillar 2: When relevant, the Circular Economy dimension is considered, and the risk management options considered under pillar I will be put to the test of circular economy priorities.
- Pillar 3: Also, when relevant, the Climate Change dimension will be considered and the risk management options under pillar I will be looked at from the Climate policy perspective.

The guidance will start from the REACH context while additionally suggesting new approaches that will help extend the analysis beyond what is currently considered a standard Regulatory Management Options analysis.

# PILLAR 1: CHEMICALS MANAGEMENT

Pillar 1 describes the Industry-Risk management Options analysis from a 'purely' chemicals management point of view, although it will gradually integrate broader considerations (socio-economic mainly).

Initially focused on SVHC selection and thus eventually Authorisation or 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 a later stage prioritisation and Authorisation) may not always be the most adequate Risk Management Option and that all relevant regulatory option should be considered earlier in the process.

Industry has the opportunity to contribute to the exploration of a broader spectrum of risk management options and this Guidance aims at facilitating this. Moreover, this Guidance has already proven useful in a broader context, beyond REACH.

And finally, the I-RMOa may also be a tool for industry to assess the quality of its data so as to prepare for regulatory reviews. It may be used as a tool by a single company to perform its own risk management assessment. The key elements of a 'standard' I-RMOa, are to be structured along the following generic scheme. This scheme reflects a broad consensus on what is needed to make an informed decision. It is built on data should be collected as early as possible so as to 'inform' the exercise.
Of course, if the substance has been identified for assessment – has been put on the PACT list e.g. – some identification steps described hereunder can be overlooked.

In the following pages, the different phases of the I-RMOa are described.

## 1. The Substance

The definition of the substance to consider will depend on the regulators' selection criteria or on an industry strategic consideration as outlined in Explanatory Sheet 2: '**Preparatory steps for an I-RMOA: strategy and practical preparations.'**
It is important to consider the regulator's views of substances that matter most (extended to the substances now also considered by the Chemicals Strategy for Sustainability) and understand the principles of substance screening. In practice, the challenge consists in identifying in a 'neutral' way, substances for which an RMOa may be useful or required in view of the current regulatory environment and prospects of evolution. This allows to get a view on the likelihood that the substance may be considered for a regulatory assessment/RMOa. The following checklist will help:

CHECK-LIST: SUBSTANCE SELECTION

1. What does the Registration dossier say about the hazard profile vs. criteria in the REACH Regulation or the selection criteria of the screening system put in place at ECHA or even upcoming concerns in society?
2. Is the picture of hazards complete?
    1. Do we have all relevant endpoints covered? Is the quality of the assessments satisfactory or are there still some endpoints under scrutiny? What is being done about it such as substance evaluation by a regulator or a testing proposal by Industry?
    2. What is the possible impact of remaining uncertainties?
3. Do we have an unambiguous picture of hazards to be checked along the supply chain or will the analysis (also) cover a potential issue due to societal trends?
4. Is there a need or is it relevant to consider the presence of/exposure to/hazardousness of the substance in a broader context? A more holistic view considering natural background, direct and indirect anthropologic input may help put the risks into perspective and identify the most adequate risk management option

## 2. Understanding potential risks through Uses, Volumes and Exposures throughout the Life Cycle

Once the substance that may fall under a regulatory scrutiny identified, its fate along the supply chain, actually its entire lifecycle should be mapped in view of establishing whether there is a (potential) risk.

**CHECK-LIST: FATE OF SUBSTANCE IN SUPPLY CHAIN AND LIFECYCLE AND IDENTIFICATION OF POTENTIAL RISK**

### 1. Uses

1) Is the Registration dossier complete in the description of uses and are these descriptions relevant for understanding exposure?

2) Do these descriptions provide indications of the functionality of the substance?

### 2. Volumes (tonnages per Use)

3) Material flows (ideally)

   For each step of the substance and product lifetime; 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 has been the heavy involvement of the aeronautics industry in the Authorisation process for chromium trioxide.

4) Specific aspects related to the nature/fate 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?

5) 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.

6) Check if the substance doesn't change speciation during its uses or some of its uses (cf. from a metal salt to the metal during surface treatment, substance changes formula etc.). This has implications on the life-cycle assessment (cradle-to-cradle approach) as the fate of the substance would stop there.

7) Production of articles (i.e. volumes involved), and potential for release of the substance from articles during use.

8) 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. Exposure

9) Identification of (potential) exposures/risks.

10) 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.

**PRACTICAL ILLUSTRATION:**

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.

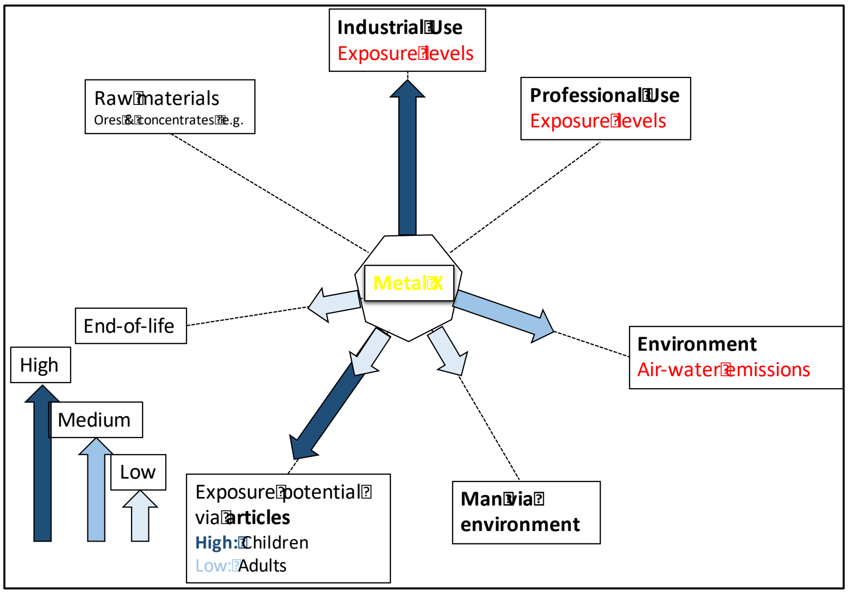
During a Eurometaux workshop, a group of industry representatives (i.e. REACH Consortia Managers and member companies) came up with a description of all potential areas of concern they were aware of for manufacturing and use of a specific substance. Participants were asked to rate the level of concern (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 **1**, below, looking at its entire life cycle. In this example, potential concerns were identified and ranked per 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 1: 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 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

Table **1**)

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.

TABLE 1: RISK CHARACTERIZATION RATIOS TO IDENTIFY POTENTIAL RISK TO ADDRESS

| 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 |

This leads to applying 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 considered for uses where the (possibly recalculated) RCRs are below 1.

## 3. Mapping current management environment and regulatory status of the substance

At this stage and before risk management measures are developed, it is useful to understand whether regulators or Industry have already put in place instruments to manage the (potential) risk.
That overview of regulatory or voluntary instruments will be useful in the assessment of the need for additional measures to efficiently manage risks.
The review may highlight shortcomings in existing measures, the causes of which can be diverse: incomplete geographical coverage, divergence of scope and severity, not up to date with scientific knowledge, weak enforcement and reporting etc. It will inform the listing and discussion of any RMO.

**CHECK-LIST: CURRENT MANAGEMENT ENVIRONMENT**

1. *Existing regulatory framework:* What are the regulatory schemes in place at national and EU level? This will cover REACH, the Water Framework Directive, the waste framework directive and many other schemes regulating the substance, the processes in which it is used, or articles containing it.

   This overview may have to be refined later on, with the further analysis of the fate of the substance as there may be uses that will be discovered or better understood.

2. *Regulatory status of the substance regarding the REACH regulation*. This will be important for the further discussion of possible risk management. A substance used only as an intermediate will not qualify for authorisation and another regulatory approach may be required, such as restriction or occupational exposure limits.

3. *Non-regulatory management schemes*: A product stewardship on the substance is an example of such a scheme. Other 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[1]. Some of those systems are the result of an agreement between government and Industry, such as BEBAT (collection and recycling of batteries in Belgium)[2] whilst others may consist in social dialogue-type of approaches involving employee and employer associations as for example NEPSI, the European Network for Silica.

4. *Assessment and discussion of the existing regulatory and non-regulatory schemes:* Prior to designing possible new risk management measures, the existing ones should be assessed so as to establish whether they are suited to address the possible and/or remaining issues identified. This assessment of strengths and weaknesses of the existing measures will be critical in the further RMOa discussions.

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

[2] http://www.bebat.be

## 4. Identification of risk management options

Options will have to be considered in line with 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 will play a role when trying to identify the most adequate RMO.

CHECK-LIST: RISK MANAGEMENT OPTIONS

1. All potential options should be listed, irrespective of the perception one may have of their pertinence. Assumptions on workability or acceptability may be discussed later in the exercise, but the purpose of the listing is to force those performing the RMOa to consider the views of other stakeholders as well as to explore/discover the merits of counter-intuitive approaches.

2. All potential options should be clearly defined in scope and content, i.e. their content (scope, basic definitions) should be clear in the minds of the assessors.
   This requires a careful approach that may encounter several difficulties:
   - There could be different ways of approaching a Restriction, either on its own or in combination with an Authorisation.
   - The option of Substitution is likely to be approached differently by a company or by a substance consortium. Experience has shown that it will be a case-by-case decision on how to proceed with this.

**In practice, one may proceed in two steps in the listing of RMOs:**

1) First list: Listing of the regulatory/risk management options per area of potential concern.

2) Second list: Processing of the first list to produce a refined set of RMOs for the analysis

## Step 1: First List of RMO's

If action is required, one should per area of potential concern, consider the following options (see also list in Annex I):

- Substitution (Industry initiative / mandatory through a regulatory measure)
- Existing legislation related to workplace safety and industrial settings (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 possible?

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

**PRACTICAL ILLUSTRATION:**

To assist in the listing and discussion of “potentially relevant or feasible RMOs”, a graphical illustration as shown in Figure 2 may help. In the example shown, 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 no concerns, or they may already be addressed adequately.

FIGURE 2: EXAMPLE OF POSSIBLE RMOS IN THE CASE OF CHROMIUM VI WHERE TWO AREAS OF CONCERN WERE IDENTIFIED

Concern was qualified as of medium level, justifying a further RMO analysis. The assessment also allowed to highlight that the absence of concern in other areas was resulted from the fact that the substance had been transformed into a non-toxic form (Cr metal).

Figure **3** illustrates the speciation challenge when considering the fate of some substances.

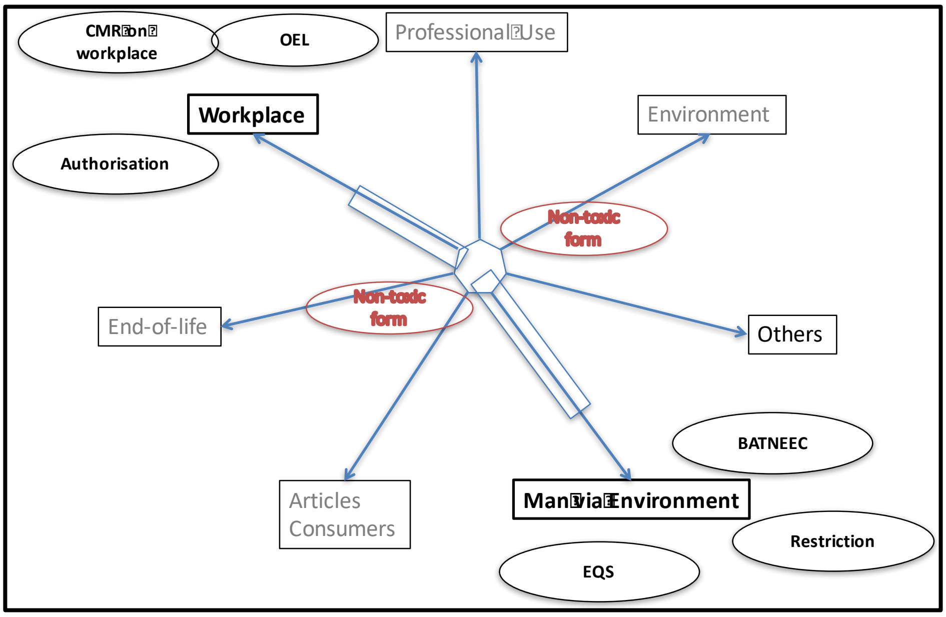
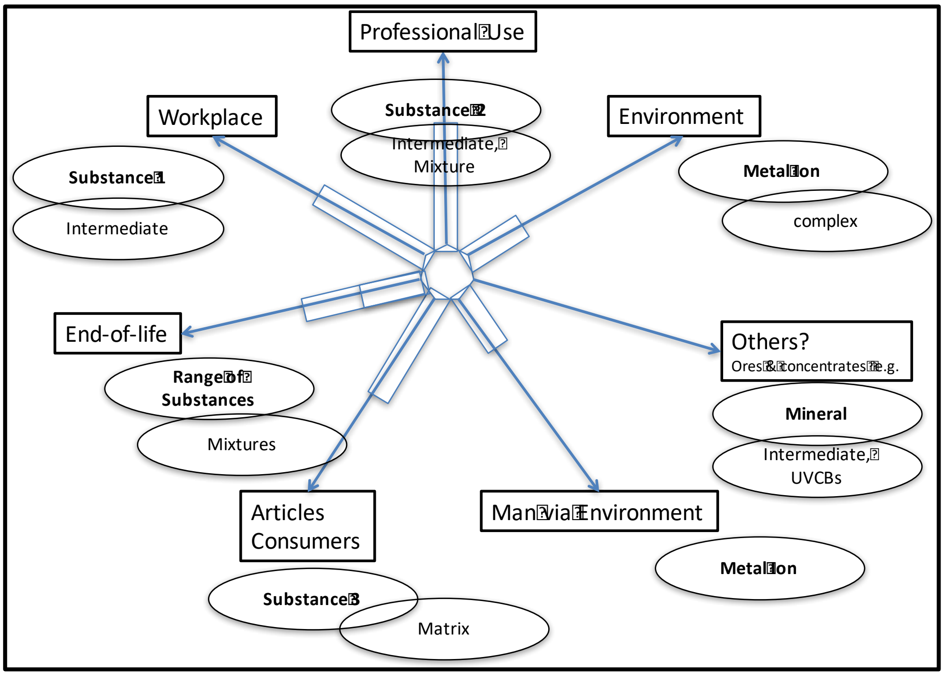



FIGURE 3: SPECIATION ANALYSIS IN CONCERN ASSESSMENT

One may encounter quite complex situations where the initial substance (called here ‘substance 1’) changes speciation, is found in mixtures or in matrixes. Depending on the boundaries of the analysis, the life-cycle overview may highlight potential risks not linked to ‘substance 1’.

## Step 2: Refined RMO list for discussion

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.

Approach: The refinement will consider whether:

a) A single Risk Management Measure may suffice to address the potential risk. For example, can the issue identified be addressed with a restriction?
b) A combination of Risk management Measures needs to be considered. Would a single risk management measure be efficient to address the potential issue? The situation in different use sectors may be so different that e.g. a restriction with exemptions may not be desirable. A combination of measures may have to be put in place potential RMOs are equally valid for all the sub-sectors that are concerned.
c) An integrative approach to Risk Management may be advisable. Here, the assessment goes beyond the single substance and is more holistic. It may consist in

DISCUSSION AND PRACTICAL ILLUSTRATIONS

## A. SINGLE RISK MANAGEMENT MEASURE:

The risk management measure can be limited to the substance (and its use(s)) and will be limited to one measure. Typically: Restriction, Authorisation, Occupational Exposure Level. This is the simplest approach, which will be the favoured one when there are no cross-substance issues such as the use of other SVHCs in same processes or complex issues requiring other ad-hoc measures such as a specific restriction.

Regulators may want 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 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 Table 2. It may reflect a case where the risk cannot be efficiently addressed by an alternative risk management measure such as an OEL.

TABLE 2: EXAMPLE OF AN RMO FOR A SIMPLE NON-INTEGRATIVE APPROACH

| Use of Substance X | |
|---|---|
| Decisive criterion | No cross-substance issues related to process and no satisfactory approach identified through other legislation |
| Simple | • Restriction<br>• Authorisation |

### B. COMBINATION OF RISK MANAGEMENT MEASURES:

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.

Table **3** reflects a case where the substance is present in different types of exposures and could be addressed through a mix or combination of risk management measures.

TABLE 3: EXAMPLE OF AN RMO FOR A COMBINED 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 | • Restriction | • Restriction |
| | • Authorisation | • Authorisation | • Authorisation |
| Combined approach | • Restriction | • Restriction | • BATNEEC OEL |

### C. INTEGRATIVE APPROACH TO RISK MANAGEMENT:

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 example, the use of a substance in surface treatment would lend itself to such an integrated approach.

One could imagine an Authorisation per substance, which would be a long and complex process and highly disturbing for the companies concerned (uncertainty - what guarantees of equality of treatment? - consistency?)
However, a creative approach may focus on acid mist, the carrier of the various substances as particulates, and the introduction of a technological solution for the entire sector (BATNEEC) could help solve the problems (see Table 4).

TABLE 4: EXAMPLE OF RMOS FOR AN INTEGRATIVE 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<br>This approach allows to address the issue with the substance and similar substances through the process | | Same/similar hazard profile | Same/similar hazard profile |
| Integrative approach | BATNEEC → | | | |

Here again, it is important that the approach identified is justified and realistic. 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 should know that this fit-for-purpose approach requires an investment in time and expertise. The pay-off may however be worth the effort.

## 5. Discussion of risk management options: fitness test

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.

Notes:

- As will be discussed later in the Guidance, some other criteria may be added, depending on relevance and availability of data. It may, for example, be interesting to explore indirect human or environmental benefits or drawbacks. A closed system may reduce the exposure to other substances, improve productivity etc.
- The precautionary principle has as consequence that arbitration between uncertainties may lead to favouring the more maximalist approach…

IN PRACTICE:

Possible risk management options having been identified and defined, the next step of the analysis is to come to a conclusion (i.e. identify the best RMO) that fits with the key criteria that have been used in the RMOas.

The 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.

The main criteria to be considered are the following:

1. Effectiveness
2. Efficiency
3. Consistency
4. Broader impact (economic, human health, environmental)

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

## 1. Effectiveness

The question is: "Has the measure under consideration the capacity to produce the desired effect?" One will in particular discuss its capacity to reduce possible risks in a measurable way. Effectiveness is synonym of efficacy. Among the aspects to be considered is the availability of proven and affordable technology and what is generically known about alternatives. Here is where the knowledge gathered in previous steps comes to use. It will be necessary for the final comparison between options to discuss the respective effectiveness (pros and cons) of each RMO considered.

Table 5 provides an example of a scoring of different RMOs in two types of approaches (simple and combined) as identified and presented in previous tables.

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 applying 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 Table 5, assessors have decided to score the criteria from 0 to ++++[3] 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.

[3] ANNEX III discusses scoring approaches

TABLE 5: EXAMPLE OF A COMPARISON OF THE EFFECTIVENESS OF THE DIFFERENT RMOS IN BOTH A NON-INTEGRATED (OR SIMPLE) AND A MIXED (OR SPECIALIZED) APPROACH

| RMO | Ability to reduce risk | Measurability / Monitorability | Proven technology available | Overall effectiveness |
|---|---|---|---|---|
| Simple | | | | |
| Restriction * | ++<br><br>(between + and +++ due to doubts on workability for some uses) | ++ | + | +++++ |
| Authorisation | +<br><br>(between 0 and ++ depending on use, some being intermediates) | ++<br><br>(between + and +++ depending on use) | +<br><br>(between + and ++ depending on use) | ++++ |
| Combined | | | | |
| Restriction *<br><br>For Uses 1 and 2 | +++ | ++ | + | +++++<br><br>+ |
| BATNEEC<br><br>For Use 3 | ++ | + | +++<br><br>(some participants claim ++++) | +++++<br><br>+ |

- Based on assumptions made on scope and content of Restriction

## 2. Efficiency

The question to answer is: "Can the RMO be implemented in a manner that its outcome compares favourably with the efforts invested in it?." An efficient RMO will first have to be practicable. This criterion is more process-oriented (administrative or technical) as it compares the results of the management measure to the means needed for its implementation.
Efficiency may be considered from a variety of angles:

- *Ease to implement by Industry:* One considers if actions to be undertaken to implement the RMM are clear and implications in terms of obligations and responsibilities. Another parameter is the availability and type of tools (technology e.g.) and processes (organisation e.g.) needed to implement the RMM. The costs associated with the implementation of the different options will not be estimated, only qualitatively compared in the discussion.
- *Ease to implement by Regulators:* Under which conditions and at what cost can enforceability be assured? Here too, the options will only be qualitatively compared in the discussion.
- *Time to implementation:* If action is considered urgent by regulators, there are RMOs with 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 (Table 6), one 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.

TABLE 6: EXAMPLE OF A COMPARISON OF THE PRACTICABILITY OF THE DIFFERENT RMOS IN BOTH A NON-INTEGRATED (OR SIMPLE) AND A MIXED (OR SPECIALIZED) APPROACH

| RMO | Ease to implement by Industry | Ease to implement by Regulators | Time to implementation | Overall efficiency |
|---|---|---|---|---|
| Simple | | | | |
| Restriction * | +<br>(between 0 and ++ due to doubts on workability for some uses) | ++ | +++ | +++++<br>+ |
| Authorisation | 0<br>(between 0 and + depending on use, some being intermediates) | +++ | ++<br>(between + and ++ depending on use) | +++++ |
| Combined | | | | |
| Restriction *<br>For Uses 1 and 2 | +<br>(between 0 and ++ depending on use, some being intermediates) | +++ | +++ | +++++<br>++ |
| BATNEEC<br>For Use 3 | + | + | 0<br>(timing concern for most participants) | ++ |

- Based on assumptions made on scope and content of Restriction

## 3. Consistency

The question to address is: "How do the RMOs being considered perform in terms of a level playing field and regulatory coherence?"

Table 7 illustrates four dimensions chosen for discussing consistency.

- 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, especially in the field of resources preservation and efficiency (Circular Economy, Climate Change and other parts of the Green Deal): If, for example, the substance cannot be substituted in processes that contribute to achieving EU air quality standards, a ban may negatively affect air quality and associated public health objectives. Similarly, a measure may impact the operations of a well-functioning recycling loop and thus impact the EU Circular Economy ambitions.

Table 7: Example of a comparison of the regulatory consistency of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialized) Approach

| RMO | Regulatory consistency | Consistency with existing EU legislation | Consistency with previous EU initiatives | Consistency with other EU policy objectives | Overall consistency |
|---|---|---|---|---|---|
| Simple | | | | | |
| Restriction * | ++++ | + | ++ | ++ | +++++ ++++ |
| Authorisation | ++ | + | + | + | +++++ |
| Combined | | | | | |
| Restriction * For Uses 1 and 2 | +++ | +++ | +++ | ++ | +++++ +++++ + |
| BATNEEC For Use 3 | 0 | +++ | ++ | +++ | +++++ +++ |

- Based on assumptions made on scope and content of Restriction

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.

## 4. 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),
- Circular economy impacts
- 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.

Table 8 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. The templates in Annex V also consider them separately. The choice is left to those performing the exercise and will depend on the substance.

TABLE 8: EXAMPLE OF A COMPARISON OF THE BROADER IMPACT OF THE DIFFERENT RMOS IN BOTH A SIMPLE OR COMBINED 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 | | | | | | | |
| Restriction * | + | + | ++ | + | 0 | + | +++++<br>+ |
| Authorisation | + | 0 | 0 | + | + | 0 | +++ |
| Combined | | | | | | | |
| Restriction *<br>For Uses 1 and 2 | ++ | ++ | ++ | ++ | 0 | + | +++++<br>++++ |
| BATNEEC<br>For Use 3 | +++ | ++ | ++ | 0 | 0 | ++ | +++++<br>++++ |

- based on assumptions made on scope and content of Restriction.

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

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

The outcome of the different scorings can be presented in an overall proportionality synthesis table as the one shown in Table 9.

Table 9: Example of synthesis table

| RMO | Effectiveness | Efficiency | Consistency | Broader impacts | Overall proportionality |
|---|---|---|---|---|---|
| Simple | | | | | |
| Restriction * | 5+ | 6+ | 9+ | 6+ | 26+ |
| Authorisation | 4+ | 5+ | 9+ | 3+ | 21+ |
| Combined | | | | | |
| Restriction * For Uses 1 and 2 | 6+ | 7+ | 11+ | 9+ | 33+ |
| BATNEEC For Use 3 | 6+ | 2+ | 8+ | 9+ | 27+ |

- Based on assumptions made on scope and content of restriction

The synthesis of the exercise, the basis for internal communication and decisions or outreach, will basically highlight:

- The potential risks in the context defined by the scope (can range from REACH registration dossier uses to more holistic view of the presence and fate of the substance)
- The potential RMOs and the discussion of their relevance and proportionality
- The conclusions drawn and recommendations

Possibly, and depending on scope and context, the report may contain several add-ons such as

## 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 AoA 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'.

## 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 as well as economic) of a RMOa under a common denominator (i.e. Euros).

1. *Key determinant in the analysis:* The key aspect of an 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 for which one claims that there is no alternative: 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.

2. *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.

3. *Employment effects:* 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 also be brought in at this stage:

The criterion of sustainability may be most relevant 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.).

## In short

An I-RMOa is a systematic process which can be summarized as follows:

- **1st : Setting the Scene**
    - Substance to discuss is given by a regulatory process or needs to be selected in function of a set of criteria - Areas of possible concern are mapped – Significance of concern is defined - Need for Risk Management is established
- **2nd : Identifying RMOs**
    - All possible Risk Management Options are listed and defined
- **3rd : Fitness test of RMOs**
    - RMOs are discussed and most proportionate is/are identified

The practical approach described in the guidance is based on a set of steps that help narrow down the analysis. Once risks are identified and described one can consider a broad set of risk management measures which may be a combination of measures, in function of the uses.

Among the many advantages of the approach presented, one can mention that it allows

- *Screening for all potential concerns:* The screening means the identification and investigation of substance specific information to make a preliminary assessment on whether there are concerns, or potentially remaining concerns, that may need to be addressed by means of risk management measures. This screening may go beyond the notion of 'concern' as considered in the context of the REACH Regulation (Substance of Very High Concern)..
- *Putting the potential concerns in context:* A series of analyses are at hand (described in Annexes) to assess the relevance of the potential concerns, through e.g. a source analysis, a tool that may be particularly useful in the case of naturally occurring substances.
- *Identifying the data needed for selecting RMMs:* This may be specific to the regulatory environment (EU-REACH, chemicals management legislation in other jurisdictions, …). The outcome may be also the setting of a pathway for collecting these data.
- *Discovering and comparing all potentially relevant RMMs:* The comparison may look at RMMs in terms of efficiency and overall proportionality; may highlight stumbling blocks (time constraints, credibility issues etc.)
- *Presenting an industry view on possible risk management approaches or deciding on measures to implement (company analysis)*

# PILLAR II: Circular Economy

The Circular Economy Assessment is closely related to the Materials Mass Flow Assessment. It focusses on whether the lifecycle includes a closure of loop and what its characteristics and significance are.

The recycling dimension is complex to analyse in two ways:

a) it includes the main materials’ recovery and often also minor substances added during the manufacturing processes as well as potentially unwanted materials like impurities
b) it requires an understanding where the substances referred to in point a) will end up and if uses could create a potential for risk

The Circular Economy assessment is of high relevance as it may help identify management measures (regulatory or not) that may benefit both Industry and Society (address risks related to exposure to substance, preservation of resources, protection against the release of impurities which may be substances that are undesirable from a risk to man or environment, economic or technical point of view).

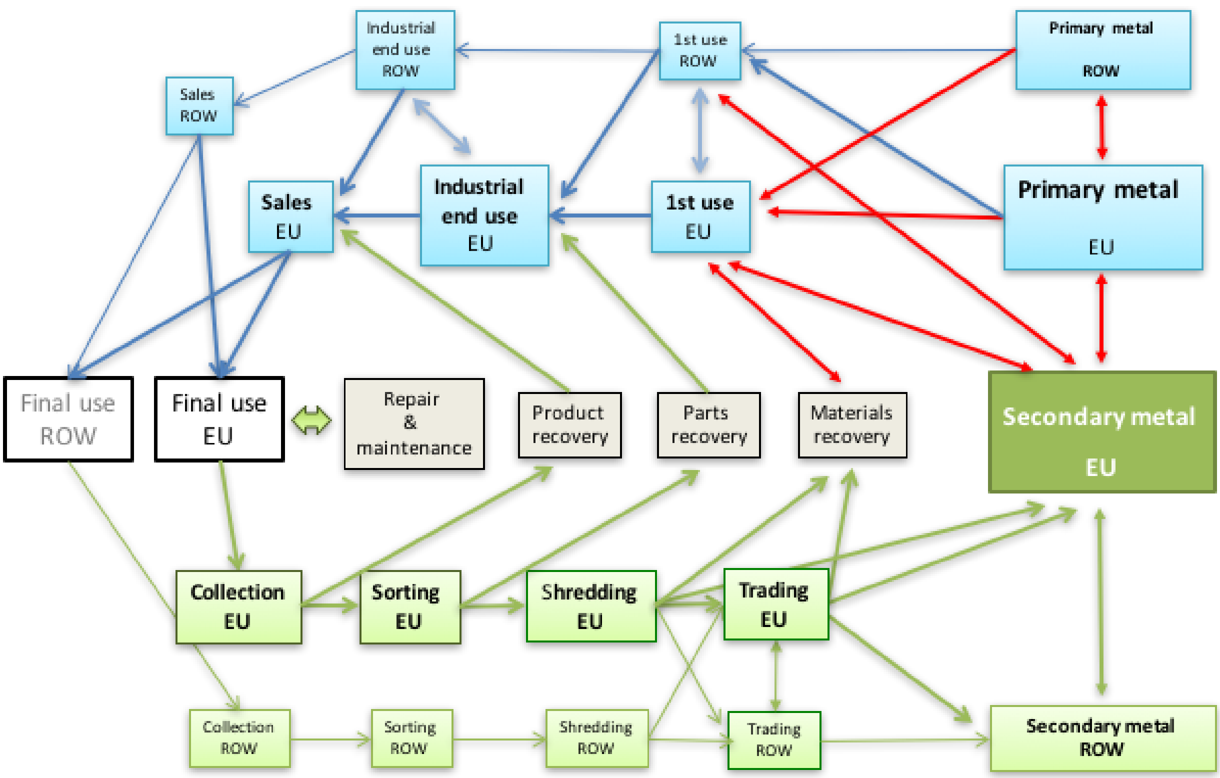
## 1. Outline of the analysis

The suggested Circular Economy approach considers the lifecycle of an element and its compounds from a materials flow perspective. Such a perspective is complex and may be represented like a spiderweb as presented in Figure 10. The ambition is to optimize the overall materials flow from manufacturing over user steps, end-of life until recycling. This approach, particularly suited for an integrative I-RMOa approach, allows a discussion of measures that may go beyond the strict risk management of an individual substance or use. It applies a cradle-to-cradle approach rather than a cradle-to-grave, thus considering closing the materials loop.

When relevant, the analysis de facto considers the substance as a resource. It presupposes that the availability of materials for the economy cannot be considered as granted any more due to increased global competition to access finite resources: losses of materials are losses for the economy.

Figure 4 provides a generic scheme with the different dimensions of a circular economy, seen from a metal's perspective. The scheme can be refined per metal to take into account the characteristics of the supply chain.

FIGURE 4: THE CIRCULAR ECONOMY DIMENSION IN A METALS CONTEXT




For an EU primary and/or secondary metal manufacturer or user, the Circular Economy dimension is of the utmost importance as its company objectives match to a large extent those of the Circular Economy package.

Companies aim at optimising their operations in a way that coincides with the Circular economy objectives as shown by the following elements at production level:

- Optimisation of yields and of energy consumption
  This has several dimensions such as:
  - Optimisation of extraction/manufacturing of metals (base metals, precious metals, minor metals e.g.) and optimisation of recovery of metals from new scrap (DU manufacturing waste) and old scrap (EOL, materials becoming available from the 'stock of metals' accumulated as articles in society),
  - Minimisation of waste and ensuring, e.g., that final slags can be of such a quality they can have a useful further life (building industry, infrastructure) rather than ending in landfill sites,
  - Minimisation of unwanted elements in input materials (impurities) and optimal processing (concentration in by-products or in waste material or managed re-circulation)
- Operational optimisation may mean
  - Optimisation of material mixes (primary & secondary materials) in the metallurgical process loops,
  - Specialisation in the processing of materials (by-products, often UVCBs) that others cannot treat in a resource -efficient manner (too small quantities, too complex process etc.). This is also a way to ensure a better performance in circular economy terms.

The circular economy dimensions along the supply chain may include the following functionalities (see Table 10):

1) *Industrial Ecology:* Eco-efficiency, industrial symbiosis, technically, economically and environmentally sustainable loops… The materialisation of all these concepts requires a regulatory framework that allows durable supply chain commitments, that favour economies of scale, long-term planning comfort. These are based on and grow out of what is technically and economically favourable to all parties, in a context where the interests of society at large are fully considered.

2) *Economy of functionality:* The migration towards service-based relationships may potentially contribute to a sustainable economy. Recycling of products that are not sold and remain property of their manufacturer can greatly facilitate the establishment of efficient recycling loops.

3) *Repair and maintenance:* This is classically considered as part of the overall Circular Economy system, but actually more an issue at the consumer-end of the supply chain, facilitated by adapted (eco-) design. However, the quality of the articles will depend on the quality of their components, which relates to upstream in the supply chain, up to the alloy manufacturers.

4) *Reuse:* This concept can be seen broadly from community-scale initiatives to the organised reuse of electric vehicle batteries for home energy storage.

5) *Recycling:* Ultimately, the efficiency of the end-of-life stage will determine whether a virtuous circular economy loop could be established at local, regional, national or EU level.

TABLE 10: CIRCULAR ECONOMY DIMENSION ALONG THE SUPPLY CHAIN

| | Industrial Ecology (1) | Economy of Functionality (2) | Repair (3) | Reuse (4) | Recycling (5) |
|---|---|---|---|---|---|
| Refiners | X | | | | X |
| Alloy/ compound manufacturers | X | | | | X |
| Semi-manufacturers/ chemical processers | X | | | | X |
| DUs/OEMs | X | X | X | | X |
| Final product manufacturers | X | X | X | X | X |
| Consumers | | | X | X | X |
| Collectors etc. | X | | | | X |

As can be seen in Table 10, the most critical elements in terms of circular economy for those metal industries at the high end of the supply chain will be recycling and industrial ecology and a number of key questions will have to be considered in an I-RMOA:

- How to ensure a steady/reliable flow of secondary materials?
- Will the future regulatory Risk Management Measure impact the flow of secondary materials?
- Will the regulatory measures allow the current diversity of materials to continue to be collected and processed in the EU?
- If the materials mix is to change, what will be the implications?
- What about elements appearing in streams where they might have a detrimental effect as a consequence of forced material choice (substitute) or phasing out (becoming unwanted element)?
- Will the measure(s) impact the viability of the existing industrial ecology, such as complex non-ferrous metals refining circuits?

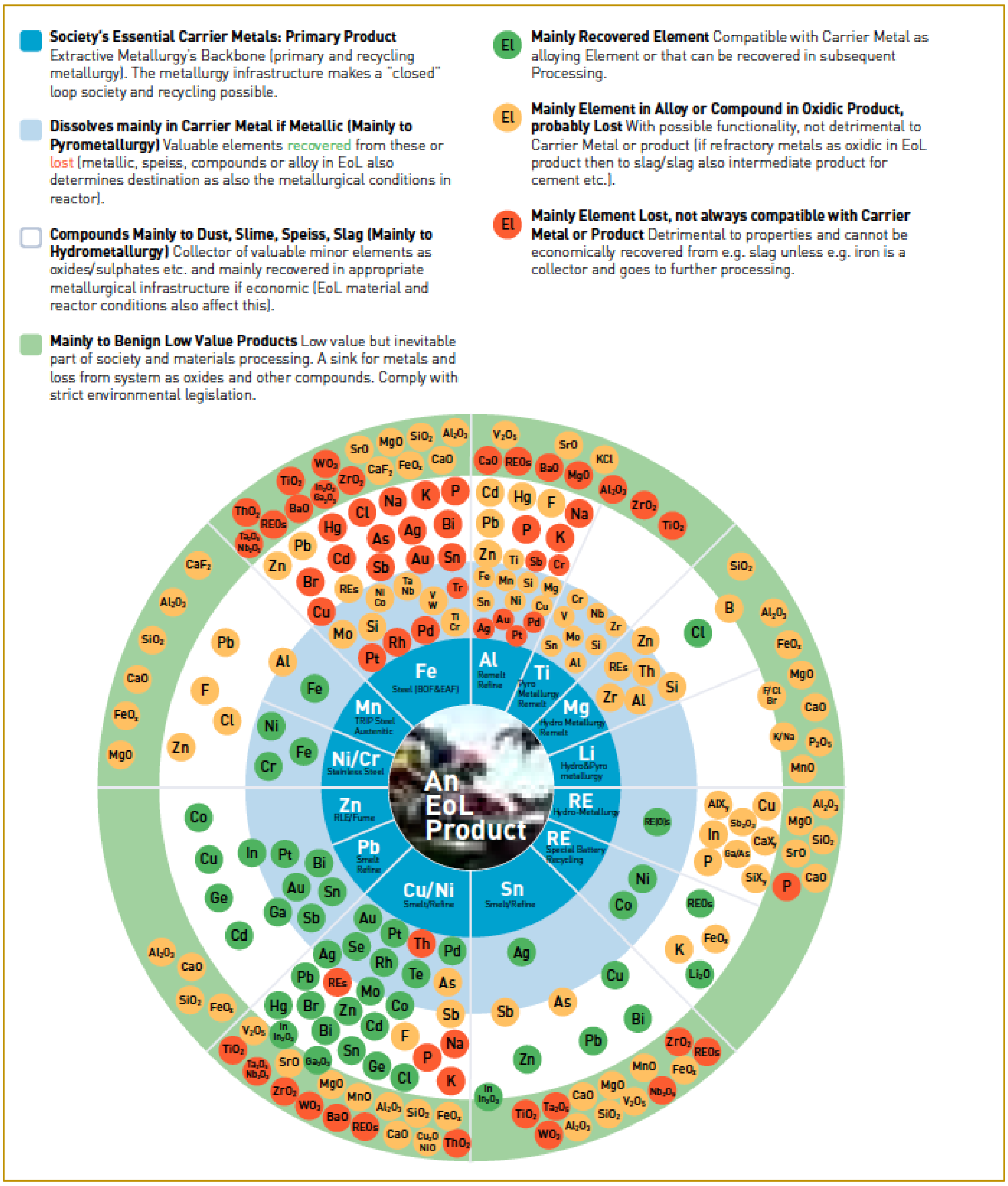
Metal supply chains are not closed loops per metal: there is a strong link between them as shown "Metal Wheel" of the 2013 UNEP report "Metal Recycling – Opportunities, Limits, Infrastructure" where the authors depict the destination of different elements in base-metal minerals as a function of interlinked metallurgical process technology (

Figure **5**)

Each of the slices represents the complete infrastructure for base- or carrier metal refining and constitutes a factor in any discussion on the circular economy impacts of regulation.

The authors of the UNEP report indicate that the "complexity of consumer product mineralogy requires an industrial ecological network of many metallurgical production infrastructure to maximize recovery of all elements in end-of-life products." (Reuter and van Schaik, 2012a&b; Ullmann's Encyclopaedia, 2005 as quoted in UNEP report)"

FIGURE 5:UNEP METAL WHEEL




From Metal Recycling – Opportunities, Limits, Infrastructure (UNEP – report 2b of the Global Metal Flows Working Group of the International Resource Panel of UNEP – 2013), page 30

## SPECIAL POINT OF ATTENTION:

### Unwanted materials as impurities or minor constituents of UVCB's?

With a growing diversity of primary and secondary material sources, a continuous increasing number of substances used in articles, the industry has to face the exposure potential and risk management of unwanted hazardous materials like some unwanted impurities and minor constituents.

Impurities, metals that have no functional role in the 'parent' metal containing them, and minor constituents, raise other types of questions and discussions on possible trade-offs:

- If hazardous, can they be separated safely and given a safe use on their own?
- If not, can they be kept safely in the 'parent' substance/material and recirculate with them without risk (dilution effect)? (recuperation as a material)
- If the hazards and risks differ from the mother material, impurities or the minor constituents may need to be handled in a specific I-RMOa
- Or requiring specific risk management in case they need to be removed as a waste or as a filler in other materials such as slags

The discussion on the management of impurities in hazardous elements becomes increasingly relevant for industry and society require data on what the releases and risks may be as discussed in the next points. However, the I-RMOa concepts as developed for main substances apply in an equal way to impurities.

## 2. Presentation for the I-RMOa discussion

The relevance to Circular Economy policies may be discussed by situating the substance under scrutiny in a scale of relevance as shown in Table 11 and Table 12 in the following pages.

TABLE 11: DEFINITION OF RELEVANCY DISCUSSION IN RELATION TO THE CIRCULAR ECONOMY POLICY

| Relevancy Category related to the Circular Economy dimension | Very Relevant (negative) | Relevant (negative) | Neutral | Relevant (positive) | Very relevant (positive) |
|---|---|---|---|---|---|
| Definition | • The substance is not or barely recycled or recyclable at end-of-life.<br>• There are very significant known drawbacks to the substance and its use in terms of the Circular Economy. | • The substance is poorly recycled or poorly recyclable.<br>• There are known drawbacks to the substance and its use in terms of Circular Economy. | • One cannot identify a direct or indirect contribution to the Circular Economy of the substance.<br>• The Circular Economy dimension is not relevant | • Is recycled / can be recycled<br>• Used in or researched for applications that allow recycling.<br>• May display properties that make its use relevant from Circularity perspective<br>• Considered a candidate for (improved) recycling efforts<br>• Recycled material does not achieve same performance as the primary product<br>• There may be economic constraints to recycling (energy input and cost e.g.) | • A high percentage of the substance is recycled at end-of-life.<br>• May display properties/potential that make its use very relevant or even critical from a Circular Economy point of view. |

TABLE 12: EXPLANATION AND EXAMPLES OF RELEVANCY DISCUSSION IN RELATION TO CIRCULAR ECONOMY POLICY

| Relevancy Category related to the Circular Economy dimension | Very Relevant (negative) | Relevant (negative) | Neutral | Relevant (positive) | Very relevant (positive) |
|---|---|---|---|---|---|
| Explanation and examples | The use of the substance goes counter to the spirit of the Circular Economy.<br><br>Example:<br>Relevant to the discussion: specific uses in which the substance is lost for what would be more 'circular' uses. (ZnO in tyres, for example, remains an issue in recycled uses) | Substance and/or use constitute a challenge in terms of the Circular Economy (technically or economically difficult to collect and recycle)<br><br>Example:<br>Circular Economy Difficulties: An alloying element that technically disrupts (poisons) established recycling circuits (Bismuth, for example, blocks the recycling of Copper) | Used in such a way that it is difficult to identify a circular economy dimension.<br><br>Example: a substance used as an intermediate in chemical processes, a fertiliser, a molecule used in over-the-counter drugs, substances such as oxygen for which the concept of circular economy is not relevant (at least not on the Earth surface). | The substance is recyclable and there are recycling circuits established for it.<br><br>Example: some plastics recycled in lower tier applications or metals that are recycled but cannot be used to the same quality level as the primary material | One or more of the following conditions are met:<br>• Highly valuable<br>• High recycling performance<br>• Strategic resource for the EU economy and its availability depends on recycling performance<br>• Very significant benefit in terms of resource use (including energy) to achieve circularity<br>• ...<br>Example: Recycled base and minor metals that can be introduced in equivalent uses as primary use |

Once the relevance established, the Circular Economy dimension will influence the proportionality discussion according to the relevancy category as illustrated in Table 13 :

TABLE 13: TYPES OF RISK MANAGEMENT MEASURES IN FUNCTION OF CIRCULAR ECONOMY RELEVANCY

| Relevancy category related to the Circular Economy dimension | Very Relevant (negative) | Relevant (negative) | Neutral | Relevant (positive) | Very relevant (positive) |
|---|---|---|---|---|---|
| Impact on RMO selection and analysis | < ----------------------------------------------------------------------------------------- Growing pressure towards avoidance, substitution to correct the lack of contribution to the Circular Economy<br><br>-----------------------------------------------------------------------------------------> Growing relevancy to place the Circular Economy as one of the RMO-defining elements | | | | |
| Type of measures | Targeted Restriction(s)/possibly authorisation to phase-out uses | Push for more restrictive/corrective measures which may be restriction/authorisation) | Unlikely to impact proportionality discussion and focus will be on other aspects (toxicity etc.)<br>In some instances, an OEL will be considered neutral in terms of Circular Economy | Measures that would aim at striking a balance between addressing risks and exploring potential for greater contribution to the Circular Economy | Use-specific approaches (combined and integrative approaches)<br>Such as, in some cases: BAT, OELs, EQS, …<br>Targeted Restriction (selected uses)<br>Industry initiatives |

The above-mentioned relevancy discussion may be critical for the selection of potential Risk Management Options in the final proportionality analysis.
In that analysis, the Circular Economy dimension plays an important role in the overall proportionality of the selection and weighting of RMOs.

The assessment of the Circular Economy impact can be tested using the following set of 3 Circular criteria: "reusability/recyclability", "preservation of functionality of the concerned substance allowing utilisation for the same use" and "Longevity of use".

An assessment of the RMOs regarding their performance in terms of these 3 criteria leads to a qualitative proportionality scoring such as --, -, 0, +, ++.

Table **14** provides an illustration on how such a scoring can be applied for a substance that has been considered negatively relevant because of wide-dispersive professional uses that are the source of human health concerns and the production of articles that are technically and economically difficult to collect and recycle.

TABLE 14: EXAMPLE OF PROPORTIONALITY SCORING OF THE CIRCULAR ECONOMY DIMENSION OF A SET OF POTENTIAL RMOS

| Scoring of the Circular Economy dimension | Preservation of resource: Reusable/ Recyclable | Preservation of properties / functionalities (Same use possible ?) | Circularity over time: Longevity of use | Relevancy and proportionality from Circular Economy point of view |
|---|---|---|---|---|
| RMO 1 Authorisation aiming at total phase-out | 0 | 0 | 0 | 0<br>The scoring group considered that considering the poor relevancy of the substance in terms of Circular Economy, a phasing-out would not impact its Circular Economy performance |
| RMO 2 Restriction aiming at limiting the uses to those where not only the human health risks could be addressed but recyclability could be improved | + | + | 0 | ++<br>The scoring group expected that the focus on recyclable uses would allow a more efficient collection and improved recycling processes leading to a better-performing recycled substance |

| | | | | |
|---|---|---|---|---|
| RMO 3<br>OEL | 0 | 0 | 0 | 0<br>The scoring group considered that the OEL would not influence the 3 criteria considered for the analysis and thus not the Circular Economy performance of the substance. |

# PILLAR III: Climate Change

## 1. Purpose

The objective of discussing the Climate dimension of the substance is

a) To assess whether the Climate dimension – linking to the various Climate policy aspects – will be relevant to discussing the RMOs.
b) To discuss, when that dimension is relevant, the relative performance in terms of Climate policy of the RMOs considered.
c) To include Climate aspects in the RMOa proportionality assessment.

Even if the RMOa consist in a scanning of the fate of the substance throughout its life cycle, it does not equate to a Life-Cycle Assessment (LCA) looking at the overall resource and energy performance. Indeed, in an RMOa we look at these aspects relatively to alternative substances and technologies. The discussion of the Climate dimension will thus be qualitative at this stage whereby the assessment will have to be justified, acknowledging that it is difficult to set the boundary of the discussion.
Another critical aspect is to consider the Climate (energy consumption and/or CO2 emission) impact over the substance life cycle. Indeed, a substance may be energy-intensive in its production but may contribute to sustainability if it provides durability to articles and or allows the energy to be recuperated during the recycling phase. In essence it is the energy / functional use from the life cycle perspective of the substance that counts. The detail of this discussion goes beyond the scope of an RMOa and is in the remit of an LCA as mentioned earlier. Alternatively, in an RMOa assessment different options can be qualitatively compared to their positive or negative contributions to climate aspects during manufacturing/use/EOL and recycling.

## 2. In practice:

The relevancy to Climate Change policies may be discussed by situating the substance under scrutiny in a scale of relevance as shown in Table 15 below:

TABLE 15: SUBSTANCE RELEVANCY IN RELATION TO CLIMATE POLICIES

| Relevancy Category related to the Climate dimension | Very Relevant (negative) | Relevant (negative) | Neutral | Relevant (positive) | Very relevant (positive) |
|---|---|---|---|---|---|
| Definition | There are very significant known drawbacks to the substance and its use in terms of resource conservation, energy use and or climate change.<br>It can be said to directly or indirectly impact in a negative way on the Climate challenges.<br><br>(e.g. disbanding the use of borates as a flux material increases the temperature of the melt in metal processes) | There are known drawbacks to the substance and its use in terms of resource conservation and energy use.<br><br>It can be said to directly or indirectly impact in a negative way on the Climate challenges. | One cannot identify a direct or indirect contribution or potential contribution of any significance in terms of addressing the Climate challenges | The substance is used in or is researched for applications that are directly or indirectly related to addressing the Climate challenges.<br>The substance may display properties that make its use very relevant in terms of energy conservation etc.<br><br>(e.g. metals used in energy carriers but for which the manufacturing energy is not recuperated) | The substance is used in or researched for applications that are known to address the Climate challenges.<br><br>(e.g. metals used in energy carriers that allow for recuperating the manufacturing energy during recycling) |

| Relevancy Category related to the Climate dimension | Very Relevant (negative) | Relevant (negative) | Neutral | Relevant (positive) | Very relevant (positive) |
|---|---|---|---|---|---|
| Explanation and examples | The substance and its use constitute a significant challenge in terms of the Climate objectives (energy intensity, energy efficiency, overall emissions, sustainability, durability etc.). Its use negatively impacts the Climate.<br><br>Example: Fluorinated gasses (hence the EU F-gas regulations) | The substance and its use constitute a challenge in terms of the Climate challenges (energy intensity, energy efficiency, overall emissions, sustain-ability, durability etc.).<br><br>It is of no use in addressing the Climate challenges.<br><br>Example: Substance used for a short life, throw-away packaging without any recycling of the energy<br><br>A substance that can be recycled but requires more energy than for primary use | The substance is not used in energy production/storage/transport etc.<br>There is no significant difference in its energy-performance (consumption etc.) compared to its known alternatives.<br><br>Example: a molecule used in pharmaceuticals | Energy transport systems (cables etc.)<br><br>A Substance that, compared to its alternatives allows significant savings in energy use (thus also emissions)<br><br>Example: a metal used for energy transport or a solvent/flux that allows fibre/metal production at lower temperatures | Clean/renewable energy production and storage (solar, wind etc.).<br><br>Example: windmill components, constituents of rechargeable (and storage) battery systems of outstanding energy performance and the substance is/can be recycled to recover most of the energy to produce it. |

Once the relevance established, the Climate dimension will influence the proportionality discussion according to the relevancy category as illustrated in Table 16 hereunder:

TABLE 16: SUBSTANCE RELEVANCY AND PROPORTIONALITY IN RELATION TO CLIMATE POLICIES

| Relevancy Category related to the Climate dimension | Very Relevant (negative) | Relevant (negative) | Neutral | Relevant (positive) | Very relevant (positive) |
|---|---|---|---|---|---|
| Impact on RMO selection and analysis | < ------------------------------------------------------------------------------------------<br>Growing pressure towards substitution (authorisation, restriction)<br><br>------------------------------------------------------------------------------------------><br>Growing pressure to address human health and/or environmental issues without jeopardising use of the substance | | | | |
| Type of measures | Push for more restrictive measures (restriction/ authorisation) | Push for more restrictive measures (restriction /authorisation) | Unlikely to impact proportionality discussion and focus will be on other aspects (toxicity etc.) | Will impact proportionality discussion and influence the choice of measures (less push for restrictive measures/overall substitution) | Use-specific approaches (combined and integrative approaches)<br>Such as:<br>BAT<br>OELs, EQS<br>Targeted Restriction (selected uses)<br>Industry initiatives |

The above-mentioned relevancy discussion may be critical for the selection of potential Risk Management Options for the final proportionality analysis. In that analysis, the Climate dimension can play an important role as the overall proportionality of the RMOs can also be tested for their impact on a suggested set of 3 Climate criteria that are "impact on energy cost during manufacturing", "impact on energy use at use phase (energy consumption per functional use)" and "recuperation (or not) of the intrinsic energy during recycling".

A qualitative assessment of the RMOs regarding their performance in terms of the 3 criteria mentioned above may lead to a proportionality scoring such as --, -, 0, +, ++. Table 17 provides an illustration of such a scoring. The hypothetical case in Table 7 is one of a substance with human health concerns at manufacturing stage and in professional uses which in the Climate relevancy discussion has been considered positively relevant (substance used in energy transport).

TABLE 17: EXAMPLE OF PROPORTIONALITY SCORING OF THE CLIMATE DIMENSION OF A SET OF POTENTIAL RMOS

| | Impact on energy cost during manufacturing | Impact on energy use at use phase (energy consumption per functional use) | Recuperation (or not) of the intrinsic energy during recycling | Relevancy and proportionality from Climate point of view |
|---|---|---|---|---|
| RMO 1 Authorisation aiming at total phase-out with only known substitute being less energy-efficient | - | - | -- | - - - -<br>The scoring group considered that a forced substitution with less energy-efficient substance would lead to an overall negative Climate impact |
| RMO 2 OEL | - | 0 | 0 | -<br>The scoring group considered that the OEL would impact on the Climate performance at manufacturing stage due to the need for the installation of additional equipment to collect and treat gases |

## Overall Conclusion of the Integrated I-RMOa

The conclusions of a ‘purely’ chemicals management-oriented analysis have been discussed in the section on Pillar I.
This section will explore the way to reach conclusions when Pillar II (Circular Economy) and/or Pillar III (Climate Change) are added to Pillar I (Chemicals Management sensu stricto).
Several situations are possible:

- The analysis covered two pillars: Pillar I and Pillar II or Pillar III)
    - The conclusions of the separate pillar analyses are convergent
    - The conclusions reached in the separate pillars diverge or there are options that are too closely ranked for an easy conclusion
- The analysis covered the three pillars

## 1. Presentation of outcomes of the Analysis in the Pillars

This section will explore the way to reach conclusions when Pillar II (Circular Economy) and/or Pillar III (Climate Change) are added to the I-RMO analysis.
For the purpose of illustrating the approach, a fictitious case and scoring is considered for a set of possible 4 types of RMOs. So as to avoid any interference of individual opinions on a practical example, the RMOs are not described.
The discussion will start with putting together the conclusions of the analysis of the three pillars, starting with Pillar I (Chemicals management):

### PILLAR I:

The outcome of the RMO discussion and the scoring (in this case a scoring between -2 and +2) is represented in Table **18**:

TABLE 18: PILLAR I PROPORTIONALITY SYNTHESIS

| Pillar I: Chemicals Management | | | | | |
|---|---|---|---|---|---|
| | Effectiveness | Efficiency | Consistency | Broader Impacts | Conclusion Pillar I |
| RMO 1 | 1 | 1 | 1 | 1 | 4 |
| RMO 2 | -1 | 1 | 1 | -2 | -1 |
| RMO 3 (combination) | 2 | 1 | 1 | 0 | 4 |
| RMO 4 (combination) | 1 | 2 | 2 | 1 | 6 |

Discussion: In this case, the first conclusion will be that RMO 2 is not considered as being proportionate. RMO 4 scored best but the other options are very close so that they all three may qualify for further discussion or a more quantitative SEA/impact assessment.

### PILLAR II:

The conclusion of the Pillar II discussion can be presented as shown in Table 19.
TABLE 19: PILLAR II PROPORTIONALITY SYNTHESIS

| Pillar II: Circular Economy | | | | |
|---|---|---|---|---|
| | Reusable /recyclable | Preservation of properties / functionalities | Longevity of use | Conclusion Pillar II |
| RMO 1 | 1 | 1 | 0 | 2 |
| RMO 2 | -2 | -2 | 0 | -4 |
| RMO 3 (combination) | 1 | 1 | 0 | 2 |
| RMO 4 (combination) | 1 | 1 | 0 | 2 |

Discussion: In this case, the conclusions of Pillar I are confirmed or even strengthened for RMO 2 but do not provide a conclusion regarding the three other options.

If the analysis consisted only of Pillars I and II, the overall conclusion would not be much influenced by Pillar II and RMO 4 would probably be selected as the most adequate/proportionate risk management option, pending possible confirmation as discussed above.

## PILLAR III:

The conclusion of the Pillar II discussion can be presented as shown in Table 20.

TABLE 20: PILLAR III PROPORTIONALITY SYNTHESIS

| Pillar III: Climate Change | | | | |
|---|---|---|---|---|
| | Impact on energy cost during manufacturing | Impact on energy use at use phase | Recuperation of intrinsic energy during recycling | Conclusion Pillar III |
| RMO 1 | 0 | 1 | 1 | 2 |
| RMO 2 | 0 | 0 | 0 | 0 |
| RMO 3 (combination) | -1 | 0 | -1 | -2 |
| RMO 4 (combination) | -1 | 0 | 0 | -1 |

Discussion: In this case, RMO 1 comes out as the most favourable one in terms of Climate Change objectives.
RMO 3 which would have been further considered in a classical chemicals' management RMOa would now be difficult to consider further considering its negative scoring for the Climate Change dimension.
If the analysis consisted only of Pillars I and III, the Pillar III conclusion would tip the overall balance in favour of RMO 1.

Eurometaux

## PILLARS I, II & III:

The synthesis of the scorings of the 3 pillars is presented in Table 21 below.

TABLE 21: SYNTHESIS OF SCORING OF 3 PILLARS

| Overall Conclusion of the 3 Pillars | | | | |
|---|---|---|---|---|
| | Pillar I | Pillar II | Pillar III | Overall |
| RMO 1 | 4 | 2 | 2 | 8 |
| RMO 2 | -1 | -4 | 0 | -5 |
| RMO 3 (combination) | 4 | 2 | -2 | 4 |
| RMO 4 (combination) | 6 | 2 | -1 | 7 |

Discussion: RMO 1 and RMO 4 lead the scoring whilst RMO 2 and RMO 3 are disqualified. The final choice seems now between RMO 1 and RMO 4

A multiple pillar analysis offers the following advantages:

- It introduces nuances to the analysis and forces the assessors to consider nuancing their views.
- It broadens the context of the analysis, introducing new elements to consider
- By possibly modifying the ranking of RMOs along the process, it may call for a refinement of the analysis
- It calls on new expertise to be involved (energy, life cycle, recycling etc.) which adds value to the exercise. Multi disciplinarity increases the chances of optimisation of risk management through creativity and out-of-the-box thinking
- It strengthens the case for ex-post re-assessment of the RMO decision and implementation.

Possible drawbacks of a multiple pillar RMOa one needs to keep as points of attention:

- The method presented here can be biased by pure mathematical reasons such as the number of criteria selected in a pillar (Here four criteria in Pillar I vs. three in the two other pillars)
- Scoring criteria must be rigorously defined and scoring must be explained so as to reduce the risk of biases (cf. aversion for authorisation e.g.). Experience has proven that an as objective as possible presentation of the RMOs helps their discussion and scoring.
- The closer the scoring the greater the advantages of presenting the strengths and weaknesses of the options considered the most suitable for political/strategic decision taking. The greater the chances also that an SEA may help decide between the options.

## 2. Discussion of outcome

The outcome of the three-pillar analysis may be complex to present to the ultimate decision-takers and may require a synthesis table presenting the findings in a SWOT-type of reasoning. This may allow a better understanding of the compromises a decision ultimately may have to make compared to what might be considered an ideal solution.

In some cases, the outcome may be so clear that no further discussion is needed but the RMOa outcome is mainly a decision aid for regulatory or industry strategies. The outcome of the analysis could be summarised in a table considering the positive and negative impacts (cf. Table 22).

TABLE 22: SUMMARY OF ANALYSIS OF 3 PILLAR ANALYSIS

| | Pillar I: Chemicals Management | | Pillar II: Circular Economy | | Pillar III: Climate Change | |
|---|---|---|---|---|---|---|
| | Strength<br>Opportunity | Weakness<br>Threat | Strength<br>Opportunity | Weakness<br>Threat | Strength<br>Opportunity | Weakness<br>Threat |
| Options considered overall suitable for addressing the risk(s) identified | | | | | | |
| RMO 1 | Effective because<br>Efficient because…<br>Consistent because…<br>Positive broader impacts expected because… | | Positive impact in terms of recyclability…<br>Properties preserved… | | Neutral in terms of energy use during production because…<br>Positive impact on energy use at use phase because…<br>Positive impact in terms of recuperation of intrinsic energy during recycling because… | |
| RMO 4 (combination) | Effective because<br>Very efficient because…<br>Very consistent because …<br>Positive broader impacts because… | | Positive impact in terms of recyclability…<br>Properties preserved… | | | Negative impact on energy cost during production because… |
| Options not considered overall suitable for addressing the risk(s) identified | | | | | | |
| RMO 2 | Efficient because…<br>Consistent because… | Not effective because…<br>Negative broader impacts on… | | Implementation would seriously hamper recyclability of… because of…<br>Properties would not be preserved under the following conditions… | Climate neutral impact | |
| RMO 3 (combination) | Very effective because…<br>Efficient because…<br>Consistent because<br>No broader impacts because… | | Recyclability promoted because<br>Functionality preserved because… | | | Negative impact on energy cost during production because…<br>No recuperation of intrinsic energy during recycling because… |