Chemical Risk Management Option Guidance

Structure outline and content mapping

Eurometaux

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Disclaimer

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Document evolution

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About this document

This document presents a proposed structure and content mapping for a potential future revision of the Industry Risk Management Options Analysis (I-RMOA) guidance. It is not a completed guidance document, but a structure that outlines how a revised version could be organised and what content it may include.

Rather than providing a one-to-one mapping of the existing guidance, this document sets out a new structure that identifies where existing material may need to be updated, removed or expanded – and where entirely new content may be required. If a full revision is undertaken, the revised guidance would include material not currently covered and remove outdated or redundant sections.

Each section includes a brief description of its intended purpose, along with a reference table showing where related content can currently be found in both the *existing I-RMOA guidance* and the *Overarching Principles and Method* document. This mapping provides a single, coherent reference point that brings together material from both documents.

This document is intended to support discussion on whether and how the guidance should be revised, and to provide a foundation for future development.

Recommendations

This section summarises key recommendations to inform a future revision of the I-RMOA guidance, based on a proposed new structure and mapping exercise.

Overarching

- Generalise the guidance to make it applicable beyond industry. Recent examples show that regulatory RMOAs can be comprehensive and may significantly differ from what the existing guidance indicates. There is no clear rationale for why a regulator's RMOA should follow a different approach than industry, as the main differences would typically be data and resources available.
- Integrate the 4Cs – chemical management, climate change, circularity, and criticality pillars – into a single analysis rather than treating them separately. Segmenting the analysis risks obscuring linkages between these aspects and could make it more difficult to visualise trade-offs. The issues represented by each pillar can still be captured through designing a set of attributes and associated assessment criteria.
- Clearly state that all RMOAs – whether conducted by industry or authorities – are to be approached from a societal perspective. Regulatory decisions are made with consideration for impacts on all actors in society, not just individual companies or supply chain segments. Aligning the analysis with this broader view ensures that the outputs are more realistic, balanced, and relevant to decision-makers. It also enhances the credibility and usefulness of the RMOA for all stakeholders involved in or affected by the regulatory process.
- Clarify that the process undertaken by authorities to decide which substances should be subject to an RMOA is a separate step that should be undertaken prior to commencing the RMOA and is therefore out of scope of any future guidance.
- Establish well-defined and consistent terminology that is relevant for all practitioners, both regulators and industry actors.

New content

- In the current guidance, information on how to define the baseline scenario is spread across various parts, making it difficult for practitioners to develop a clear and consistent frame of reference. The revised guidance should include a dedicated section that explains the purpose of the baseline, outlines what it contains (e.g. substance functions, use patterns, emissions, and exposure levels), and provides practical steps for constructing it. A clearly defined baseline is essential for comparing the performance and impacts of different RMOs.
- Provide a structured approach for developing and applying a transparent methodology throughout the RMOA process. This should include a step-by-step guide on the selection of attributes and assessment criteria, how to carry out qualitative and/or quantitative assessments, and how to apply scoring and weighting systems where appropriate.
- Include a dedicated section on stakeholder and expert engagement that explains why this is essential to the quality and legitimacy of the RMOA process, who to involve, when, and how. The

guidance should also reflect that RMOAs can be used in different ways depending on the stakeholder context – for example, submitted to authorities to support a regulatory process or informing supply chain communication. Including clear, practical examples of stakeholder engagement – both during and after completion of the RMOA – would improve the relevance and usability of the guidance. Furthermore, the guidance should include a short discussion on the potential consequences of weak of ineffective stakeholder consultations.

- Currently, the guidance refers to Analysis of Alternatives (AoA) only briefly as a potential add-on during the RMOA process. Given the importance of AoA in regulatory processes, the revised guidance should include a dedicated section outlining how to approach a fit-for-purpose, early-stage AoA, covering aspects such as technical feasibility, performance, economic feasibility, availability, hazards and exposure, and lifecycle aspects of alternatives. The AoA may be a high-level assessment but should nevertheless be part of the RMOA.
- The existing guidance does not include a section on assumptions, despite their critical role in shaping the outcomes of an RMOA. It could be improved by detailing how to identify, document, and justify assumptions. This would enhance the transparency and robustness of the analysis.
- The revised guidance should include a discussion on grouping of substances within an RMOA. For example, conducting an RMOA on a group of structurally or functionally similar substances, rather than on individual substances, can improve efficiency, consistency, and policy relevance.

Inclusion of data sources

- Reference a wider and more current set of data sources for substance-related information. This would include signposting practitioners to relevant sources for physiochemical and hazard data, such as peer-reviewed literature, OECD and ECHA databases, PubChem, and regulatory substance evaluations. It should also highlight sources linked to other topics, for example, Prodcom and Eurostat . Any known caveats associated with these sources should be flagged, for instance, risks data presented in registration dossiers may be inaccurate where modelling has been relied on instead of monitoring data.
- Offer clear advice on how to handle low-confidence or incomplete data, including how to assess its reliability, document associated uncertainties, and decide whether further data collection is necessary.

Next steps

- Use the below proposed structure and content mapping as the foundation for conducting a complete revision of the RMOA guidance. The complete revision should include engagement with representatives from industry, regulators, and NGOs, to test the usability and relevance of the revised guidance before it is finalised. This will help ensure the guidance is practical, well-aligned with practitioners' needs, and fit for purpose.

Contents

Proposed RMOA guidance structure and content mapping

Abbreviations & Acronyms

A revised guidance will include a table which defines abbreviations and acronyms.

1. Introduction

1.1 About the guidance

Brief introduction of the purpose and structure of the revised guidance, and the intended users.

1.2 What is an RMOA?

An RMOA is a type of socio-economic assessment. This section will explain what an RMOA is and how it fits into the wider family of socio-economic assessments.

A key difference from the current guidance is that it will not divide the types of RMOAs into industry RMOAs, regulators' RMOAs, nor use the terminology integrated-RMOA and pre-RMOA. Instead, it will highlight how RMOAs can differ in terms of level of detail, data gathering, stakeholder engagement etc. – using neutral terminology. Section 1.3 will further explain the purpose and timing of different types of RMOAs.

This approach would replace the majority of "PART 1" of the existing guidance, aligning the recommended approach across all actors (both industry and authorities).

Reference document	Pages	Content mapping
Existing guidance	12	Explains how RMOAs fits into a wider policy context but not to other types of socio-economic assessments.
	13 – 17	Contains information on different types of RMOAs, but the information is split between industry, authorities, integrated, simple and pre-RMOAs. A revised guidance will take a more systemic approach.
Overarching principles and method	7 – 8	Provides an overview of what constitutes an RMOA and how it links to other socio-economic appraisal tools

1.3 Why and when to undertake an RMOA

Following on from the explanation of different types of RMOAs in Section 1.2, the purpose and timing of RMOAs will be explored. The sections will describe in what ways an RMOA can be a useful tool for both industry and authorities, notably to identify data gaps and allow for sufficient time to address them, and how it can inform different regulatory and policy process. These sections will also help highlight how an RMOA exercise differs from an impact assessment as well as emphasise the importance of pro-active and anticipative RMOAs carried out by industries.

Reference document	Pages	Content mapping
Existing guidance	13 – 17	Contains relevant information on the purpose and timing of RMOAs. The information is split between industry and authorities/regulators approach on RMOA, and integrated and simple RMOAs.
	19	Discussion of the purpose of an RMOA, differentiating between simple and Integrated RMOAs, in the context of project scoping.

20 – 21	The question of "when" an RMOA should be undertaken is embedded in the discussion within the Authorities approach to chemicals regulation. The section discusses the substances that matter most according to the EU/ECHA policies and priorities as well as some contextual regulatory information that helps to understand why and when an RMOA should be undertaken.
26	Discusses the timing of Simple RMOAs within the context of regulatory processes, with a focus on generation and collection of data.
31	**Table 8** describes the "Principles for an Integrated RMOA" and provides information on purpose and use of an RMOA.

1.3.1 What happens afterwards?

Different steps that may follow the completion of an RMOA will be outlined, including direct use by industry and input into regulatory processes. It will also cover potential needs for additional analyses, for example, carrying out more a more in-depth socio-economic analysis to underpin the results of the RMOA.

Reference document	Pages	Content mapping
Existing guidance	15	Describes steps after the RMOA is completed and how it can feed into various regulatory processes.
	27 – 29	The last row of the tables in each of these pages addresses "Next steps" after completion of the RMOA from Companies, Commodity Organisations and Consortia point of views, both before the regulatory review or initiative and during the regulatory process.
	Annex II, 108 – 110	This annex discusses the types of conclusions and actions that the RMOA can lead to, including an example from the Cadmium industry (**Table 38**).
	Annex VI, 141	As part of the worked example with a hypothetical substance, this page describes a "consensus-finding meeting" to discuss the conclusions of the RMOA and path forward.

2. Scoping and data gathering

This part will focus on practical aspects of an RMOA project that are not part of the analysis itself. It is intended to help the user through the planning, scoping and data gathering stages.

2.1 Project scoping

2.1.1 Define the objective(s) of the RMOA

Users will be guided in clearly defining why the RMOA is being undertaken and what it aims to achieve. Although most RMOAs serve a similar general purpose, i.e. identifying and defining which RMO(s) may be the best for addressing the risk in question, there can be nuances in the specific objectives each RMOA tries to achieve. For example, some might focus on the screening of RMOs, while others on identifying data gaps or increasing industry awareness and preparation in anticipation of future regulatory developments. As such, an explanation of why clear objectives is important will be provided alongside representative examples.

Reference document	Pages	Content mapping
Existing guidance	15	**Figure 1** situates the RMOA process in the wider continuous chemicals risk analysis context, thereby highlighting its regulatory purpose.
	16	**Table 2** compares a regulatory approach under REACH with an Industry RMOA. It outlines the difference in purpose between a regulatory RMOA and a simple or integrated industry RMOA.
	19	The "*Defining the purpose*" section provides examples and explanation on the purpose and objective of an RMOA, differentiating a simple RMOA with an Integrated RMOA.
	30	**Table 7** provides guidance on how to decide between a simple and integrated RMOA based on the aim of the RMOA.
Overarching principles and method	9	Discusses the importance of having a well-defined objective and focus of the RMOA, with examples of how this influences the selection of attributes and assessment criteria.

2.1.2 Setting the scope

This guidance will explain how RMOAs can be carried out with differing depths of analysis and stakeholder engagement. They can range from high-level "screening RMOAs" with limited stakeholder engagement, to in-depth appraisals with multiple stages of consultations with stakeholders and (external) experts. The type of assessment depends on factors such as where in the regulatory process the substance is (e.g., hazard testing vs CLH proposal), whether subsequent assessments are envisaged (e.g., impact assessment of the most likely/best option(s)), perceived severity of the 'problem' (e.g., if risks are potentially high), the resources available, and data availability. In some cases, an authority may take the initiative to launch a 'screening RMOA' with the primary aim of identifying the scope of a concern and the data gaps that would need to be addressed before a more in-depth RMOA can be launched.

If the organisation carrying out the RMOA has a portfolio of multiple substances of concern, a prioritisation exercise may be needed to identify which substance should be assessed first. This exercise may entail grouping substances and/or compounds together to avoid performing separate RMOAs for similar substances. This is considered a preliminary step that comes before the steps of the RMOA process outlined in this document.

Reference document	Pages	Content mapping
Existing guidance	16	**Table 2** compares a regulatory approach under REACH with an Industry RMOA. It outlines the difference in scope between a regulatory RMOA and a simple or integrated industry RMOA.
	20 – 25	The "Setting the scope" section mentions the screening process for selecting substances to analyse, which can help refine the scope of the analysis once the substance is identified and selected. It covers the REACH classification process and provides guidance on whether to choose a simple or broad RMOA.
	26	The "*Timing considerations*" section includes an implicit scope discussion by linking the resource burden of generating and collecting data with the regulatory process timeline.
	30	**Table 7** discusses RMOA approaches in function of the assessment, linking the specific aim of each assessment step with its associated scope depending on the choice of either a simple or integrated RMOA.
	119	Describes how the RMOA analysis and depth will differ depending on data availability

2.1.3 Plan for stakeholder and expert engagement

This section will guide practitioners in how and when to engage relevant stakeholders and experts throughout the RMOA process to ensure the baseline and analysis are robust, representative, and grounded in reliable evidence. It will help identify key stakeholder groups, such as industry actors, regulators, downstream users, technical experts, academics, and potentially NGOs, and define their roles at different stages (i.e. selection of RMOs, baseline development, analysis of alternatives, scoring and verification). The guidance will emphasise the importance or early engagement to improve the acceptance of the RMOA's outcomes and to improving the RMOA timeline.

Reference document	Pages	Content mapping
Existing guidance	27 – 29	Discusses 'Who performs the RMOA' and the role of companies, commodity organisations and consortia in the RMOA process. Specifically, it considers how, in which type of activities, and when they should be involved.

2.2 Data gathering

This section will guide practitioners through the process of gathering the data needed to carry out the RMOA. It will outline how to identify what data is needed at each stage (e.g., defining the baseline,

characterising risks, evaluating alternatives, and assessing RMOs), and distinguish between what data is likely to be obtained from primary vs secondary sources. The section will also provide an overview of potential secondary data sources, such as REACH registration dossiers, regulatory databases, scientific literature and industry reports. Guidance will be given on aligning data collection with stakeholder engagement and verifying data quality to ensure the analysis is evidence-based and fit for purpose.

Data source associated with specific parts of the analysis (e.g., market data or use volumes) will also be highlighted under respective sections in the analytical guidance (Chapter 3).

Reference document	Pages	Content mapping
Existing guidance	Annex IV, 115 – 116	Presents two tables (**Table 40 & 41**) that highlight the possible data gaps and needs as well as potential secondary data that may complement the information found in registration dossiers.

2.2.1 Mapping of existing data and data gaps

Data availability typically determines the type and depth of analysis it is feasible to carry out, as well as the expected robustness of the results. Practitioners will be supported in reviewing existing data and mapping it against key information needs, including identifying critical data gaps, and determining where reasonable assumptions or less detailed information may be sufficient. It will also outline how to assess whether the available data is sufficiently reliable and relevant and determine which data gaps can be addressed through secondary data gathering and which will likely require stakeholder input.

Reference document	Pages	Content mapping
Existing guidance	Annex IV, 115 – 116	Presents two tables (**Table 40 & 41**) that highlight the possible data gaps and needs as well as potential secondary data that may complement the information found in registration dossiers.

2.2.2 Review of secondary sources

This section will explain how to identify, review, and evaluate secondary data sources. It will provide guidance on reviewing relevance and reliability of available data, and how to use it to complement and guide primary data collection.

Reference document	Pages	Content mapping
Existing guidance	Annex IV, 115 – 116	Presents two tables (**Table 40 & 41**) that mention secondary data sources that can complement REACH registration dossier data (i.e. Scientific Committee on Occupational Exposure Limits, Water Framework Directive, BAT reference documents (BREFs)).

2.2.3 Gathering of stakeholder data

This section will provide guidance on how to engage stakeholders in providing primary data to fill key

information gaps identified earlier in the RMOA process. It will outline various methods for data collection, such as targeted surveys, questionnaires, interviews, or workshops, and help users identify which stakeholders are best placed to provide certain data. To reduce the risk of consultation fatigue, the guidance will recommend designing the process to capture the necessary data in as few rounds as possible, ideally in a single round. The section will also emphasise the importance of building stakeholder confidence, ensuring confidentiality, and communicating the purpose and value of the data request.

Reference document	Pages	Content mapping
Existing guidance	Annex V, 117 – 118	Provides guidance on how to conduct a role play exercise with industry stakeholders in the early stages of an RMOA to help identify the issue

3. Step-by-step approach to the analysis

3.1 Defining the baseline

The baseline is a key part of any economic assessment, as it represents the 'do nothing' scenario against which RMOs are assessed. It is also needed to identify and define the problem the RMOs aim to solve, and for the subsequent RMO screening and selection process.

This guidance will explain how to define the baseline scenario. It will provide guidance on identifying the substance(s) subject to the RMOA, describing their uses and functions, calculating use volumes per market sector, and characterising exposure and risk.

3.1.1 The substance

This section will indicate the type of information about the substance that should be assessed, focussing on intrinsic properties, such as physiochemical properties and hazards.

Reference document	Pages	Content mapping
Existing guidance	36	Provides an overview of hazard information that should be checked and presented when selecting and defining the substance.

3.1.2 Uses and functions

This section will provide guidance on how to identify and document the uses of a substance across its life cycle, including its technical functions in different applications. It will outline how to map use patterns, clarify whether the substance remains present in final products (i.e. articles), and describe the potential for exposure.

Reference document	Pages	Content mapping
Existing guidance	37	Describes how the REACH registration dossier can be used for descriptions of substance uses and functions, as well as providing considerations on the physical form and speciation of the substance at each step of its life cycle.
	Annex I, 97 – 99	Presents the 'I-RMOA tools set' – It illustrates how to perform a life-cycle scan to document all possible life-stages and exposure possibilities of the substance. It also presents a material mass flow assessment which can be used to show how the selected substance is used and moves through industrial processes, including changes in forms, emissions, and losses, including a topical example with Hexavalent chromium.
	Annex VI, 129	As part of the 'Illustration with hypothetical substance x', it provides a practical example of how to obtain the uses for a substance and make sure the information is complete.

3.1.3 Markets and use volumes

Users will be guided in identifying the key market sectors where the substance is used and estimating the volumes associated with those uses, helping to differentiate between high-volume and niche applications.

It will also address how the substance moves through the supply chain – from production or import to end-use – including where it is transformed, reformulated, or incorporated into products. Consideration will be given to material flows, reuse or recycling routes, and any by-products or waste streams generated. The guidance will cover how to assess the number and type of companies and employees involved in the substance's use across the supply chain, as this is important not only for understanding the potential economic and social impact of risk management options, but also for informing later assessments of potential population exposure.

The section will also explain how to develop forward-looking projections such as estimating future use volumes, market development, or economic dependence on the substance. This may involve the use of market forecasts, demographic or employment trends, expected regulatory or technological developments, or other factors likely to influence future demand and use patterns.

Reference document	Pages	Content mapping
Existing guidance	37	Provides a checklist of points to consider when determining use volumes (tonnage per use) of the substance, ideally at each stage of the substance lifetime.
	Annex I, 97 – 98	Presents the 'I-RMOA tools set' – It illustrates how to perform a life-cycle scan to document all possible life-stages and exposure possibilities of the substance. It also presents a material mass flow assessment which can be used to show how the selected substance is used and moves through industrial processes, including changes in forms, emissions, and losses. An example of a material flow assessment for cadmium is provided.
	Annex VI, 130	Provides a practical example of how to obtain total tonnage of a hypothetical substance in the EU.

3.1.4 Exposure and risks

Building on the previous section, this part of the guidance will emphasise the close links between exposure, risk, and the markets and volumes in which the substance is used. It will provide guidance on identifying where and how human and environmental exposure may occur throughout the substance's life cycle – covering production, formulation, use, and end-of-life stages. The guidance will outline how to assess both actual and projected levels of exposure, identify relevant exposure pathways, and compare predicted environmental concentrations (PECs) with hazard thresholds. It will also support a mapping of who bears which risks – such as workers, consumers, or the general population – and how those risks arise under different use scenarios.

The section will explain how to assess both direct and indirect exposure routes across occupational, consumer, and environmental contexts, and how to interpret existing hazard and risk data. It will help practitioners determine whether the available information is sufficient or whether further assessment is needed.

Finally, the section will address how projections can be used to estimate future exposure levels, taking into account potential changes in use volumes, market trends, technological developments, or regulatory drivers. It will also highlight how uncertainties and societal concerns may influence the overall risk profile

and decision-making on risk management options.

Reference document	Pages	Content mapping
Existing guidance	37 – 39	Provides a checklist of aspects to consider when determining exposure, such as nature, fate, and form of the substance, presence in articles, and end-of-life treatment. Outlines how to interpret existing Risk Characterisation Ratios (RCRs) from REACH registration dossiers, and how to perform sensitivity and uncertainty analyses to test the robustness of these assessments. Mentions the approach authorities might apply to calculating risk, such as alternative exposure limits, focusing on intrinsic hazard and societal concerns.
	43	Provides a practical example for illustrating exposures of concern and how changes in speciation can affect risk.
	Annex I, 100 – 105	Provides case study examples with cadmium and nickel, showing how to perform an assessment of sources of exposure and release over a substance's lifecycle and utilise mass balance and diffuse sources analyses.
	Annex VI, 131	Provides an example of how to obtain the potential number of exposed workers for a hypothetical substance after the exposure analysis was undertaken from a life cycle point of view.

3.1.5 Summary of baseline and problem definition

Practitioners will be supported in summarising the baseline scenario – that is, the current situation in the absence of further regulatory action – against which the need for intervention and the impacts of RMOs can be assessed. It will explain how to clearly define the problem the RMOA seeks to address, such as unacceptable risks to human health or the environment. The summary should bring together key elements from earlier steps in the RMOA, including the substance's uses, volumes, exposure pathways and affected population groups (e.g. workers, consumers). The guidance will also highlight how the baseline can incorporate projected future developments, where relevant, to support a more robust comparison of potential RMOs.

Note that the existing regulatory landscape is covered in Section 3.2 below, as it is more practical – from an analytical perspective – to address regulatory mapping and initial screening of RMOs in a single step.

Reference document	Pages	Content mapping
Overarching principles and method	9	Explains the importance of having a clearly defined baseline prior to assessing RMOs and what should be included in the baseline definition.

3.2 Regulatory landscape and screening of RMOs to assess

This section will provide guidance on mapping the existing regulatory and non-regulatory landscape for the substance(s), identifying how risks are currently controlled and whether any regulatory gaps or

shortcomings exist. It will outline a two-step process. The first step involves identifying and screening all potentially relevant risk management options (RMOs), based on the areas of concern identified earlier in the RMOA. This includes mapping existing regulatory measures (e.g. REACH, sector-specific legislation), screening relevant legislation, and identifying any applicable non-regulatory or voluntary initiatives. The second step focuses on refining this longlist into a shortlist of the most relevant RMOs by considering substance- and sector-specific characteristics, feasibility and likelihood of implementation, and the extent to which the options address the identified concerns.

Note that outlines the RMO screening and selection step and is not a full assessment of the RMOs.

Reference document	Pages	Content mapping
Existing guidance	40 – 41	Explains explain the importance of undertaking regulatory and non-regulatory mapping and outlines a process for identifying potential RMOs, taking into account EU policy objectives, the strengths and shortcomings of existing measures, and the practical scope of each RMO.
	42	Outlines the first step in the selection of RMOs, which is creating an initial list of potential RMOs. It provides a longlist that includes a range of regulatory and non-regulatory measures, excluding national options.
	43	Provides a practical illustration of finding relevant or feasible RMOs given specific areas of concern, using chromium VI as an example.
	44 – 46	Explains how to refine the initial list of RMOs to identify the most appropriate ones for analysis. These pages introduce three possible approaches: a single RMO (simple I-RMOa), combination of RMOs (integrated I-RMOa), and integrative approach to risk management (integrated I-RMOa). These sections encourage thinking beyond the substance alone and consider the practicality, scope, and sector-wide implications of each approach.
	Annex III, 111 – 113	Provides a long "non-exhaustive list of existing Chemicals Management Legislation", as well as the strengths and weaknesses for the main ones.
	Annex VII, 143 – 145	Provides a table template for RMOs identification and shortlisting, including an assessment of their feasibility requirements and a synthesis.

3.3 Analysis of Alternatives (AoA)

This section will outline how to assess and present information on the availability and suitability of alternatives for each identified use of the substance. While a fully detailed analysis of alternatives (AoA), such as those included in Applications for Authorisation (AfA), is not expected at the RMOA stage given time constraints and limited access to confidential business information (CBI), the guidance will help practitioners identify and evaluate key aspects of potential alternatives – including their technical feasibility, performance characteristics, market availability, economic feasibility, exposure and hazard profiles, and lifecycle aspects. The aim is to support a preliminary comparison of alternatives to inform the assessment of RMOs and to indicate where more detailed analysis may be required at later stages.

Reference document	Pages	Content mapping

Existing guidance	54 – 55	Highlights the importance of understanding the substance's functional role and evaluating key factors driving either substitution or continued use of the substance(s), including technical feasibility, cost, hazard profiles, sustainability, and market readiness and pressure.

3.4 Define the methodology

This section will explain how to clearly and transparently define the methodology to be used, provide best practise principles and examples.

In the current guidance, the analysis of impacts of the RMOs are split into different categories, and the associated methodology is described in different places of the guidance. A key aspect of the new guidance will be to integrate all impacts into one overarching analysis, and the method will be described in full in one section.

3.4.1 Define the attributes and associated assessment criteria

The guidance will help practitioners break down the overall objective(s) into key performance aspects (e.g., effectiveness, practicality and implementability) and use this to develop a list of attributes. It will also support identification of the different types of impacts RMOs could have, which in turn inform the development of assessment criteria under each attribute.

The section will introduce key principles for defining a clear and consistent assessment criteria, such as completeness, clarity, non-redundancy, operationality, mutual independence, and avoiding double counting. Examples and best practice will be provided to illustrate how attributes and associated assessment criteria can be used in practice to compare RMOs.

Reference document	Pages	Content mapping
Existing guidance	48 – 53	Provides an overview of attributes and assessment criteria related to chemical management. It covers effectiveness, efficiency, consistency and broader impacts. **Table 17** provides an overview of attributes assessed.
	57 – 65	Describes how to assess circularity impacts. **Table 20** presents examples of assessment criteria.
	66 – 70	Describes how to assess climate change impacts. **Table 24** presents examples of assessment criteria.
	78 – 81	Describes how to assess impacts associated with material criticality. **Table 32** provides examples of assessment criteria.
	142 – 165	Provides further examples and table templates for assessing various impact categories.
Overarching principles and method	14 – 18	Provides an overview of how to develop bespoke attributes and assessment criteria. It also sets out key principles and realistic examples.

3.4.2 Description of general assumptions

Clear articulation of key assumptions will be emphasised, including those related to expected policy developments, enforcement capacity, behavioural responses, implementation timelines, or other contextual factors. Documenting these helps ensure consistency and transparency across the assessment. The guidance will also encourage practitioners to test the sensitivity of key assumptions – particularly where they may significantly affect how the feasibility or impact of an RMO is interpreted.

Where appropriate, key assumptions can be validated through consultation with relevant experts and stakeholders to ensure they reflect real-world conditions and are fit for purpose.

Reference document	Pages	Content mapping
Overarching principles and method	11 – 12	Explains the importance of clearly setting out general assumptions prior to the analysis.

3.4.3 Define the scoring methodology

This section will describe different approaches to scoring Risk Management Options, including both qualitative methods (e.g. simple "+" / "–" scales) and more structured quantitative systems that apply numerical scores (e.g. 0–10) and weighting to reflect the relative importance of each criterion. It will outline the strengths and limitations of each approach, and how the choice of scoring method can affect the overall workload, transparency, and usability of the final analysis. The guidance will also cover how to interpret the selected scoring scale and emphasise that scoring systems should be developed iteratively, adapting as the RMOA progresses and new information becomes available.

Reference document	Pages	Content mapping
Existing guidance	Annex V, 123 – 124	Discusses different scoring methods, the importance of documenting and applying the chosen method consistently, and provides an example of how to define points along the scoring scale.
Overarching principles and method	17 – 19	Explains what needs to be considered when choosing an appropriate scoring scale and highlights the benefits of developing the scoring method iteratively, with flexibility to adjust it as the analysis progresses.

3.5 Assessment of each RMO and sub-options

3.5.1 Detailed definition of RMOs and sub-options

Practitioners will be guided on how to define each RMO and any sub-options in sufficient detail to enable a meaningful assessment. This includes clearly describing the scope of the RMO, the specific uses it targets, the actors affected across the supply or value chain, and any direct obligations the measure would place on those actors. The aim is to establish a consistent and transparent basis for assessing the relevance, feasibility, and potential impacts of each option.

Reference document	Pages	Content mapping
Overarching principles and method	10 – 11	Discusses the differences between RMOs and sub-options and describes the level of detail required to allow them to be analysed meaningfully

3.5.2 Additional assumptions specific to RMOs and sub-options

This section will provide guidance on documenting any option- or sub-option-specific assumptions that are critical to their assessment. These assumptions go beyond the general methodological assumptions set out in Section 3.4.2 and relate directly to how a particular RMO or sub-option is expected to function in practice. Examples include assumptions about enforcement mechanisms, implementation timelines, stakeholder compliance, supporting legislation, or the availability of required technologies. Clarifying these assumptions supports consistency in scoring and helps identify where uncertainty may influence the comparison of options.

Reference document	Pages	Content mapping
Overarching principles and method	11 – 12	Explains the importance of clearly setting out option or sub-option-specific assumptions prior to the analysis.

3.5.3 Actors, triggers and behavioural responses

Practitioners will be supported in identifying and categorising the different types of actors affected by each RMO – such as manufacturers, importers, formulators, downstream users, consumers, and authorities. For each actor group, the guidance will focus on identifying what element of the RMO acts as the trigger for a behavioural response. Triggers may include legal obligations, compliance costs, reputational pressure, or other incentives or constraints introduced by the measure.

The section will then outline how to assess the most likely behavioural response from each group, including substitution, process changes, product reformulation, market withdrawal, or continued compliance. Understanding these trigger–response dynamics will help inform the assessment of how each RMO performs against the defined attributes and associated criteria.

Reference document	Pages	Content mapping
Overarching principles and method	13 – 14	Explains how to identify affected actors of an RMO and what aspects of the RMO will trigger a different behavioural response.

3.5.4 Qualitative assessment of each attribute using assessment criteria

This section will provide guidance on how to conduct a qualitative assessment of each RMO's performance against the defined assessment criteria. It will outline how to use descriptive summaries and expert judgement to evaluate the option or sub-option under each attribute, particularly where quantitative data are limited or unavailable.

The guidance will emphasise the importance of a systematic and transparent approach, with clear reasoning and supporting evidence documented for each assessment. It will also encourage consistency in language, structure, and level of detail to support fair and balanced comparison across RMOs.

Reference document	Pages	Content mapping
Existing guidance	51	Discusses the Efficiency attribute and how it can be qualitatively assessed.
	65	Provides a proportionality scoring example of the Circular Economy dimension for selected RMOs based on a qualitative assessment.
	70	Provides a proportionality scoring example of the Climate dimension for selected RMOs based on a qualitative assessment.
	79	The "Assessment step" bullet point discusses qualitative assessment regarding the Criticality Assessment.
	89 – 90	Example/template of discussion and qualitative assessment of RMOs performance, with a focus on criticality.
	Annex V, 120	Mentions the qualitative assessment of the economic dimension, including different costs and benefits that should be considered.

3.6 Scoring of risk management (sub) options

3.6.1 Refinement of scoring methodology

This section will provide guidance on how to refine the scoring methodology during the course of the RMOA. It will highlight that definitions for points on the chosen scoring scale (e.g. 1 to 10) are often developed iteratively, as evidence evolves and expert judgement is applied. The guidance will emphasise that allowing for flexibility – rather than fixing scoring definitions in advance – can help avoid early assumptions biasing the results and ensure that scoring remains grounded in the available evidence

Reference document	Pages	Content mapping
Overarching principles and method	18	Discusses the advantages of developing the scoring interpretations iteratively.

3.6.2 Scoring of assessment criteria and attributes

This section will provide guidance on how to conduct the scoring in a way that promotes transparency and draws on appropriate expertise. As scoring in RMOAs often involves assessing economic, social, environmental, and regulatory impacts, the process is closely aligned with socio-economic impact assessment methods. The analysis should be led by those with relevant experience in impact assessment, while input from other disciplines – such as toxicology, environmental science, policy, or legal experts – can

enhance the robustness and credibility of the results.

The guidance will outline how to develop scores collaboratively, encourage structured discussion, and provide advice on how to proceed when consensus on scoring cannot be reached. It will also describe how to present scoring outputs, including the use of scoring matrices that consolidate results across criteria and RMOs or sub-options. These outputs help ensure comparability between options and support transparent consideration of trade-offs.

Reference document	Pages	Content mapping
Existing guidance	50	Provides an example of a tabular format for presenting the scoring of different RMOs.
	70	Provides an example of proportionality scoring of the climate change dimension using a '+' and '-' scoring system.
	Annex V, 123 – 124	Provides an example of scoring with different weights applied to different criteria.
	Annex VI, 133 – 138	Provides scoring tables, but by attribute/assessment criteria and for each RMO
	Annex VII, 146 – 150	Provides scoring templates for each attribute.
Overarching principles and method	17 – 19	Discusses how to interpret intervals on the scoring scale, approaches to scoring (including anchoring scales to the best / worst-performing RMO, and recommendations for conducting the scoring in a collaborative setting what makes use of multidisciplinary expertise.

3.7 Comparison of RMOs and scenario analysis

An approach for comparing and ranking RMOs and sub-options, based on their performance across all assessment criteria, will be outlined. It will guide practitioners in constructing a scoring matrix to support side-by-side comparison, highlight trade-offs, and identify key strengths, weaknesses or redundant criteria that may dilute the analysis. The guidance will cover both unweighted and weighted approaches – starting with simple additive methods and progressing to weighted models that reflect differing stakeholder priorities (e.g. policymakers, regulators, industry).

Practitioners will be encouraged to test multiple weighting scenarios to explore how the ranking of RMOs changes when different criteria are assigned different levels of importance. This can help assess the robustness of the comparison and support more informed decision-making where priorities differ or uncertainty is high.

The section will also exemplify how to summarise key strengths and weaknesses that drive each RMO's performance, using clear and concise language. Where two RMOs perform similarly overall, the guidance will encourage a short narrative discussion of contextual factors that may inform a preference. Visual tools – such as bar charts, ranking tables, or radar plots – will be recommended to support effective communication of the results.

Reference document	Pages	Content mapping
Existing guidance	50 – 54	Presents tables which score each attribute and present a comparison between each RMO for that specific attribute.
	71 – 75	Presents a synthesized discussion of the outcomes of the analysis, comparing the scoring of each RMO and attribute as well as providing general strengths and weaknesses.
	89 – 90	Example/template of discussion and qualitative assessment of RMOs performance, with a focus on criticality.
	Annex VI, 139 – 140	Presents scoring summary tables across all attributes and RMOs, distinguishing and comparing the Formulators and Manufacturers points of view.
	Annex VII, 151 – 152	Provides table templates to synthetise results and ranking the RMOs.
Overarching principles and method	20 – 23	Discusses how to rank RMOs by aggregating scores with and without weights.

3.8 Synergies and RMO design

This section will provide guidance on how to identify weaknesses in the design of the assessed RMOs that drive low scores and how the RMO design could be adjusted to improve performance. It will also highlight how performance can sometimes be improved by implementing RMOs alongside one another, and how to identify and document these synergies.

Reference document	Pages	Content mapping
Existing guidance	44	Mentions combination of RMOs as an approach to consider when developing the refined list of RMOs.
	46	Table 11 provides an example of using multiple RMOs to address different risks.
	145	Provides example of potential combination of RMOs
Overarching principles and method	23	Discusses the importance of identifying weaknesses in the design of RMOs that are driving low scores and identifying potential synergies to improve the performance of RMOs.

3.9 Summary and conclusions

This section will provide guidance on how to bring together the key findings of the RMOA in a clear and

policy-relevant manner. It will describe how to summarise the comparative performance of the RMOs and sub-options assessed, and identify which options appear most favourable based on the evidence and criteria used.

The section will also highlight the importance of reflecting on the limitations of the RMOA – including data gaps, methodological uncertainties, or lack of stakeholder consensus – and discussing the impact these may have on the outcomes of the RMOA. It will encourage practitioners to identify areas for further work or analysis, such as where additional data collection, refinement of assumptions, or stakeholder engagement may be needed.

Finally, the guidance will cover how to draw out key insights that are relevant for policy development, including potential next steps, areas for improvement, or considerations that may support future regulatory decisions.

Reference document	Pages	Content mapping
Existing guidance	75 – 76	Illustrates a summary of the analysis across all attributes, as well as main strengths and weakness, for each RMO.
	91 – 92	Template of synthesis and conclusions/recommendations.
	Annex VI, 141	Conclusions of the RMOA and path forward as part of the worked example with a hypothetical substance.

Appendix 1 Long list of RMOs

This annex will provide an overview of regulatory and non-regulatory risk management options (RMOs) that can be considered when developing the longlist of potential measures. It is intended as a reference resource to support the initial screening and selection of relevant RMOs during the RMOA process.

A1.1 Existing EU chemical legislation

This section will present a reference list of existing EU chemical legislation and the RMOs available under each framework. The legislation will be categorised by their scope and policy area – for example, environmental protection, consumer safety, occupational health and safety, and waste management.

Reference document	Pages	Content mapping
Existing guidance	42	Provides an example longlist of RMOs falling under EU chemical legislation
	111	Provides a non-exhaustive list of existing chemical legislation
	112 – 113	Provides a list of RMOs falling under selected existing EU chemical legislation

A1.2 Non-EU chemical legislation and non-regulatory measures

This section will provide a reference list of relevant national legislation outside the EU, as well as international frameworks and non-regulatory initiatives. It will include examples of RMOs that fall under these measures. As in A1.1, the content will be categorised by scope and area of focus to support systematic consideration during the screening process.

Appendix 2 Worked example

This appendix will present a worked example of an RMOA following the structure and steps set out in the new guidance. The example will illustrate how the different elements of the methodology – such as problem definition, data mapping, screening of RMOs, and scoring – can be applied in practice.

The purpose of the example is to support users in understanding how to operationalise the guidance, particularly where professional judgement and structured reasoning are required. Where possible, templates or suggested formats for key steps (e.g. scoring matrices, attribute–criterion tables, or summary sheets) may be included here to support consistency and streamline the RMOA process.

If parts of the example are better placed alongside the relevant methodological sections, these may be integrated directly into the main text. The remainder of the worked example will be retained in this annex as a full end-to-end illustration of the approach.

Reference document	Pages	Content mapping
Existing guidance	Annex VI, 127 – 141	Provides an example RMOA process with a hypothetical substance

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