Eurometaux
European Association of Metals

Risk Management Option analysis

A relevant tool for industry to anticipate and define the need and choice for RMM

Risk Management Option analysis was only recently introduced by member states as a "non-regulatory tool" *helping to define the need for and best Risk Management choice.* The tool was originally mainly applied for authorisation but later on broadened its scope by exploring other RMMs including non-REACH related tools. An RMOa intention by a Member State or ECHA is usually pre-announced on the PACT list.

While not foreseen in the REACH regulation ***an RMOa assessment*** is, in Eurometaux's view ***a very significant*** *(efficiency and efficacy)* ***improvement of REACH*** given it helps to decide for RMM in a more structural and transparent way. Moreover, and contrary to what is often thought, it helps shorten the application and effective implementation of an appropriate RMM through initiating relevant data gathering early on in the RMM process and prevents RMM options being "stalled" because they are found to not be relevant later in the prioritisation process.

The RMOa assessments industry is being aware, have often shortcomings due to different delivery levels by member states, despite a template being made available by ECHA. Whilst an RMOa isn't a legal tool this is of concern given that the outcome and selection of an RMOa option can differ depending on the level of scrutiny applied by the member state. As such it challenges somewhat the principle of equal treatment or level playing field. Additionally RMOa relevant information to a large extent is not part of the available information in the registration dossiers. An RMOa announcement on PACT therefore often requires further data gathering needs by the member state that took the initiative for the RMOa.

Recognizing the value of the RMO tool and the concerns listed, Eurometaux took the i***nitiative to develop a RMOs guidance and template*** aimed for Industry to:

- Anticipate RMOa assessments for substances that meet the criteria of the SVHC Road Map
- Develop a broad and open view on RMOa selection based on potential efficiency and efficacy of the RMM
- Anticipate additional data needs beyond information in the registration dossier that could help define the best RMOa option
- Help align manufacturers and their supply chains on relevant RMOa needs, information required and implementation

In general it would help industry to contribute credibly and in a transparent way to the RMO analysis and Risk Management selection process at EU level by collecting and providing suitable additional information relevant for the RMOa but not part of the Registration dossier.

While mainly developed for industry the guidance may also ***be potentially relevant for member states and ECHA*** given:

- It provides a structural and robust assessment technique and template to define the best RMOa option
- Industries that implemented the RMOa guidance would normally have conducted an in-depth assessment of suitable Risk Management options and relevant RMO information available for the member state that conducts the RMOa assessment

The RMO guidance attached to this letter was developed by Eurometaux based on the experience of the last 3-4 years with RMOas. It provides ***a tiered approach*** based on available information to define the potentially best RMM option(s) and to structure the data collection needs.

The proposed technique builds on a series of logical ***elements*** including:

1. Substance information on hazards and regulatory status in the EU
2. Uses, volumes and potential exposure throughout the Life Cycle of the substance
3. Alternatives per (identified) use
4. Initial Socio-economic information by use
5. And a synthesis on the Risk Management Options that could be considered

All this helps concluding on relevant or potentially efficient RMM options.

Additionally the guidance contains a ***checklist of potential RMOs*** under existing Chemicals Management information.

The draft guidance was piloted in several cases each of them emphasizing particular aspects. Based on this experience the guidance includes in Annex V "a*n illustration with a hypothetical substance* " that combines most of the learning lessons.

It is most relevant to emphasize that developing a credible and robust RMOa ***takes time and efforts*** and can't hardly be considered as a "desk exercise" that can be conducted by a registrant. The experience shows that the robustness of the exercise increases with the users' involvement, the broadness of the view and review on relevant risk management options and the tiered information gathering for any lack of relevant RMO information. Additionally it is most pertinent to properly understand relevant stakeholders' interests (manufactures, importers, formulators, users, workers, regulators, consumers, …), which can be a difficult exercise. It is in this respect that Eurometaux also developed a complementary role play to encourage recognizing these different views from the start of the exercise.

Experience by industry **shows** that conducting an RMOa according to the guidance aiming at preparing industry on critically reviewing the need and best option for RMM, as well as identifying outstanding important information needs:

- Takes 4 to 6 months
- Requires 2 to 3 meetings with manufactures and users
- Is best followed/complemented by an external independent reviewer to keep the mind-set as open as possible
- Sometimes requires a mechanism to handle confidential information (e.g. the existence or development of suitable and feasible alternatives)
- Results in a conclusion scheme that identifies further information needs as well as an indication as to which information is most relevant.

- Somewhat depending on the additional needs, such additional data development usually takes at least 2 to 3 months

Recognising that the PACT list pre-announces RMOa activity usually only a couple of weeks and at best some months in advance, Eurometaux recommends the metals sector to consider launching RMOa activity on a voluntary basis for all substances that potentially fulfil the SVHC road map criteria (CMRs, potential Endocrine disruptors, potential respiratory and skin sensitizers, and other hazards of equivalent concern).

Added to this, member states and ECHA are encouraged to list interests on PACT as soon as possible. Industry would therefore rather plead for a continuous updated PACT tool rather than a tool with a low frequency update.

Whilst the guidance was developed with primarily the metals and the inorganic sector in mind, the tool, including its structure and templates, are probably as relevant for other types of chemicals (e.g. organics). Although, Annex I (list of RMOs-Existing Chemicals Management legislation) may need broadening to cover organics.

Finally, Eurometaux would provide occasional training on the RMO tool as well as a service to its members to act as an external peer reviewer of the assessment made to help increase the independence and credibility of the assessment. The latter would further help as a mechanism to update and further improve the guidance developed.

The latest version of the RMOa guidance*, the templates[1]* as well as the role-play material, can be downloaded from a specific hyperlink: http://www.reach-metals.eu/index.php?option=com_content&task=view&id=211&Itemid=319

Further information, comments and suggestions to improve the tool can always be submitted to a specific e-mail address (infoRMOa@eurometaux.be) that has been created for this purpose.

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[1] *The RMOa tools and templates are made freely available for non-commercial use. Consultants and commercial users/uses would require to sign contractual terms and a license.