

Outline of Maltese-Slovenian Proposal concerning an alternative approach to the registration and evaluation of low volume substances (1-10 tonnes)

Why is a new approach necessary?

Malta and Slovenia support the general principle in the Commission proposal that priority should be given to high volume substances, as these substances account for, by far, the greatest proportion of total potential exposure.

Substances in the 1-10 tonne range represent a potentially huge number of substances, although exposure to many of these substances is often minimal. On the other hand, it is necessary to put into place an appropriate mechanism for being able to deal with those low volume substances for which significant exposure may occur, such as substances used in consumer products intended for frequent use, as well as to ensure the availability of information that is necessary for the purposes of risk management.

The mechanisms employed must also ensure that the system that will be established by REACH is workable. There are major concerns with the existing Commission proposal in this respect, as it is highly improbable that sufficient attention and resources could be devoted to low volume substances, taken as a group. Clearly, some kind of prioritisation mechanism should be built into the system in order to ensure that substances of concern can be rapidly identified and targeted for more detailed attention.

In this context, it is also important to clearly distinguish between substances for which we have the benefit of historical experience and those about which we know very little. It is clear that a 'one size fits all' policy will not work and would probably create an indirect risk through diverting resources into the examination of substances posing only a limited risk to health and the environment to the exclusion of more significant risks.

In order to be able to deal with all possible scenarios, the mechanism adopted must be flexible and cost effective, ensuring that substances of concern in this tonnage bracket can be selected for priority attention. Such an approach would ensure the greatest possible protection of health and the environment, as it would also include an appropriate prioritisation of resources.

Broadly speaking, two categories of substances can be distinguished in this tonnage bracket. The first group consists of speciality chemicals. These chemicals are generally found only in the low tonnage bracket and are often manufactured by not more than a few registrants, often only one. The number of uses is also limited. The second group of low volume substances are chemicals manufactured or imported by SMEs, but which are also manufactured or imported at higher tonnages by other registrants. A relatively common situation is that of downstream users occasionally importing chemicals for their own use, or chemicals manufactured as by products during the production of other substances.

The distinction made above is an important one, and was a key consideration during the formulation of the new approach to the registration of low volume substances being proposed by Malta and Slovenia. In cases where registration at higher tonnages is also expected, it is clear

that data sharing can be a significant means for reducing registration costs for smaller businesses. At the same time, however, it must also be recognised that manufacturers / importers of substances in low volumes generally cater for specific clients or applications and may not necessarily benefit from joining a consortium formed between users with more general interests. It could well turn out, for example, that the low volume manufacturer / importer services a specialist market that would not interest a consortium made up of much larger manufacturers / importers. It is also generally true that specific applications, for example in the use of speciality chemicals, will result in a limited number of specific exposure scenarios, thus making extensive risk assessments unnecessary. In most cases, all that is required for the safe management of chemicals in this tonnage bracket is a targeted or even a preliminary or qualitative risk assessment.

For many speciality low volume chemicals, uses are limited. Exposure scenarios are therefore often highly specific and of interest mainly to the user. A distinction should therefore be made between access to hazard data and information on use / exposure that is required for the purpose of a chemical safety assessment (CSA). Data on the intrinsic properties of a substance is not subject to confidentiality, as it forms the basis of classification and labelling requirements, as well as of the material safety data sheet. In many cases, sufficient hazard information may already be available through publicly accessible databases, including the one that will be established by the Agency under REACH. It is therefore clear that this information can be made available to subsequent applicants, provided an appropriate compensation mechanism is integrated into REACH. On the other hand, information relating to uses is often highly confidential, as it may relate to proprietary processes or innovative applications and technologies. In the case of low volume substances, the number of identical applications of the same chemical registered by different manufacturers/importers will not be high. Manufacturers / importers in this bracket will often cater for the requirements of specific downstream users and not for the general market. It is therefore probable that there will be a very limited scope for the formation of consortia for the purpose of sharing use information, and very little to be gained in practice from such an arrangement. It would therefore be appropriate to require hazard data to be made available. The confidentiality of use data, on the other hand, should be protected. In the case of second or subsequent registrations, registrants should be able to make reference to information already submitted, while submitting detailed information on use and exposure. Later registrants would of course be able to fill in information gaps in cases where the hazard data submitted previously was incomplete or required refinement. It is also conceivable that manufacturers / importers submitting registrations for the same substance simultaneously at the same tonnage bracket could arrange among themselves to individually submit different endpoints, thus dividing the cost of the whole data set. This would be a simpler form of consortium formation, as it would not be necessary to reach agreement on individual endpoints.

The Commission proposal would require registration of these substances 11 years after the entry into force of REACH. It is therefore clear that, at that point, an extremely large number of substances (20,000+) would enter the system. This gives rise to grave concerns as to workability. On the one hand, it is probable that the Agency and the Member States would, at that time, still be heavily involved in regulating substances previously registered in the prioritised higher tonnages. This can be foreseen, given the complexity of the authorisation and restrictions procedures and the lack of resources available for simultaneously dealing with more

than a certain number of substances at a time. It is clear that, for the foreseeable future following the entry into force of REACH, the spotlight will have to be kept on the high volume substances, particularly on those with PBT, vPvB or other undesirable characteristics. There is therefore a clear risk that the arrival of a large new wave of low volume substances at the 11 year mark could mean that resources might need to be diverted from areas of primary concern. On the other hand, if the agreed prioritisation scheme is maintained, and few resources are dedicated to low volume substances, this would imply that industry, and SMEs in particular, would have dedicated precious resources to the compilation of data without any obvious benefit to health or the environment, particularly if Member States and the Agency cannot dedicate sufficient resources in order to ensure the quality of the information provided and the efficacy of the risk management measures employed. The resources available within industry would also be more fruitfully spent on refining production processes so as to reduce potential exposure and risk and looking into possible alternatives for the more hazardous substances, in addition to simply compiling data for the purposes of registration. In the case of low volume substances, where undesirable effects are most likely to be local, the emphasis should be mainly on controlling exposure and reducing emissions to the environment, as this would give an immediate and direct benefit, apart from optimising the use of the chemical itself. The compilation of extensive hazard data where this is not necessary as part of this process has little added value in itself.

It is also clear from various impact assessments carried out that the costs of REACH are proportionately highest in the 1-10 bracket. There is therefore a serious risk that this sector in particular may suffer from a markedly decreased competitiveness, leading, *inter alia*, to possible withdrawal of substances. The reasons that may lead to the withdrawal of substances have been extensively dealt with in a number of studies. It is highly probable that withdrawal would be driven by purely economic reasons and not on considerations of risk. There is also the possibility that withdrawal of low volume substances may drive downstream users to increase the use of substitutes produced at higher volumes, where the direct and indirect costs of registration are lower in relation to the value of the chemical. Such a process may actually hinder substitution and alternative technologies, and would definitely hinder innovation.

Finally, the Maltese-Slovenian proposal seeks to further elaborate the concept of a review of information requirements for low volume substances, already envisaged in the Commission proposal. This review clause could be developed into a complete mechanism for ensuring that demands for further information requirements could be based on clearly defined prioritisation criteria, enabling a flexible response to changing priorities and taking full benefit of the experience gained in the first years of REACH. The Maltese-Slovenian proposal therefore proposes regular review cycles for low volume substances.

Key elements of the Maltese-Slovenian proposal

The proposal is based on the premise that the key to successfully managing such a large number of substances is first to ascertain the real state of affairs in this sector. This would be accomplished by first establishing an inventory of substances in the 1-10 tonne bracket, together with all relevant information currently available to the registrants. In this first wave of registrations, it is possible that duplicate information may be submitted for some substances.

However, as this would be information already available to the registrants, no extra costs would be incurred. If substantial inconsistencies in the information submitted are subsequently picked up during the evaluation phase, these could be resolved at a later stage. If hazard data is made available to all directly interested parties, the highlighting of such inconsistencies could alert downstream users to this fact, making recourse to the precautionary principle advisable. As explained earlier, use data would remain strictly confidential.

Since, as a first step, only information that is already available to the registrant will be requested, a pre-registration period as such is not required under this proposal. By the registration deadline for low volume substances (11 years after the entry into force of REACH), data would already have been submitted for substances in the high volume brackets (100 tonnes +). Should any of these high volume substances appear as repeat registrations in lower tonnage ranges, suitable mechanisms should be put into place in order to ensure that basic hazard data submitted when registering at higher tonnages is made available to registrants of the same substance at lower tonnages, while at the same time ensuring adequate compensation for the owner of the studies from which the data is derived, as well as protection of the studies themselves. This could be achieved by ensuring access to the hazard database to all subsequent registrants, on payment of the registration fee. It is also being suggested that registrants submitting complete data sets at this initial inventory phase, should benefit through a reduced Agency fee.

It is however recognised that the majority of substances registered at low tonnages will consist of speciality chemicals that will not appear in higher brackets, and especially not in the prioritised bands (100 tonnes +). For this reason, Malta and Slovenia, while supporting the principle behind the United Kingdom / Hungary ‘one substance one registration’ (OSOR) proposal, namely the avoidance of duplicate testing, whether carried out on vertebrate animals or not, consider that OSOR would only offer a partial solution, at best, to the problem faced by registrants in the lowest tonnage bracket. Furthermore, registrants in the 1-10 tonne bracket will require only basic hazard data, as their main responsibility is to produce a Material Safety Data Sheet that effectively communicates practical risk management measures down the supply chain. It might therefore be excessive to expect low volume registrants to incur the costs inherent in the formation of consortia for the sharing of studies and study summaries. A more appropriate and specific solution is required for this bracket. In the case of low volume speciality and fine chemicals, one would in any case expect a closer relationship between producer and downstream user. In such a niche market, it is hoped that there will be a greater flow of information along the supply chain. This factor may well turn out to be more relevant for low volume substances than any possible collaboration between competing producers / importers. For the same reason, it is considered unlikely that small volume producers would suggest unrealistic risk management measures that could not be successfully implemented by their clients.

Nevertheless, the adoption of OSOR in the higher tonnage brackets could offer an indirect benefit to subsequent registrants at lower volumes by ensuring a higher consistency of hazard data submitted at higher tonnages, as well as possibly an agreed classification. It should however be stressed that the Maltese-Slovenian proposal is limited to the lower volume brackets and is to be regarded as independent from any final decision on the adoption of OSOR.

Under the Maltese-Slovenian proposal, registrants in the 1-10 tonne bracket would be required to submit information about their substances that was readily available, during an initial inventory phase. It would be in the registrant's interest to submit all data that was available, in order to minimise the possibility of the dossier being selected for evaluation. Market considerations would also enter into play, as poorly supported substances could be at a competitive disadvantage compared to alternatives for which more comprehensive risk management information was available. Again, as only available information would be requested, no additional costs would be incurred at this stage. The concept of a core data set would be retained, but this would be considered as an eventual objective and not as a firm legal requirement. However, a basic set of physico-chemical data should already be submitted during this initial phase. This is necessary in order to permit the successful application of available quantitative structure-activity relationship ((Q)SAR) models, as well as in order to calculate relevant emissions and exposures, particularly to environmental compartments. Registration would still be possible in the case of an incomplete data set, as the aim at this stage is to gather information on what was known about the chemical. In order to partially compensate for the absence of precise data, the registrant could submit other relevant information, for example historical data, similarity to other substances whose properties are known, (Q)SARs, estimates from epidemiological data and so on. A conservative approach should be adopted in such cases. Also, given the specialised use of many low volume substances, it is expected that it should also be easier to put forward arguments for not presenting certain parts of the core data set on the basis that they are rendered unnecessary through effective and documented control of exposure or through the fact that only certain exposures are plausible. Evidence from risk management / monitoring should be used to support such assertions.

As a second compensation mechanism, all registrations of substances classified as dangerous in the low volume brackets would require a periodic review, unless the core data set had already been completed, or the substance had already been selected for evaluation and supplementary information had already been requested for this purpose. Five year review intervals would seem appropriate. During that review period, registrants should seek to update the dossier through actively searching for new or updated information, or possibly by generating more precise data. This review should be documented as a duty on the part of these registrants. The existing Commission proposal does include a requirement to update the registration dossier whenever new or updated information becomes available, but this would appear difficult to enforce in the absence of a fixed review cycle. The introduction of a review requirement would provide a measure of flexibility to industry, while at the same time maintaining the overall objective of REACH. Finally, it could also be argued that a regular review of chemicals, based on a concept of continuous improvement and refinement, would in itself enhance the competitiveness of SMEs in particular, by acting as an incentive for process optimisation and gaining greater knowledge of the chemical and its properties, while ensuring that costs can be kept proportional to the market value of the substance. In order to optimise use of resources and provide a degree of certainty for registrants, provision should be made in the Regulation for the establishment, through comitology, of criteria for prioritisation of dossier review. These criteria could take the form of lists of substances subjected to review, or they could also be general criteria, for example requiring a review of all substances used in a particular application, with the aim of encouraging substitution, for example.

Registrants of substances meeting these criteria would be expected to take active measures to review and update the registration dossier.

When first registering a substance, registrants would be required to submit comprehensive information about supported uses that is uses that are known to the producer and which the producer could support. In such cases, the producer should supply sufficient risk management information to enable the substance to be used safely by the downstream user. Alternatively, the downstream user could utilise hazard data supplied by the producer to formulate his own risk management strategy. This option would be utilised in cases where the downstream user wishes to keep the use confidential.

The following general scheme for registration of low volume substances could therefore be considered:

- a) Registrants would submit all available hazard data during the inventory phase. A basic set of physicochemical data should always be submitted.
- b) Registrants would also submit uses that are known to them and which they could support. These would either be uses communicated to them by downstream users or uses that they would wish to use a basis for marketing the substance.
- c) A preliminary exposure assessment should be carried out for all identified uses. The producer should carry out this exposure assessment where the nature of the use is known to him. If this is not the case, the preliminary exposure assessment should be performed by the user.
- d) Following the exposure assessment, a preliminary safety assessment should be carried out by the producer in the case of supported uses, or by the downstream user in all other cases. Only a targeted safety assessment would be required, covering exposures considered to be significant. In other cases, suitable argumentation should be provided.
- e) In carrying out the preliminary safety assessment, use shall be made of hazard data available to the producer / downstream user as well as of any other relevant information. Wherever a quantitative approach is not possible, a qualitative assessment should be performed, with the aim of establishing whether the risk management measures being recommended still give rise to an element of uncertainty as to the risk. In such cases, further refinement of the assessment may be necessary at a later stage.
- f) If, following the preliminary safety assessment, a conclusion can already be reached as to appropriate risk management measures, no further action is necessary for those uses. Where a conclusion cannot be reached, this fact should be highlighted. In such cases, the notifier may:
 - i) present a proposal for further information gathering, to be completed by the next review period;
 - ii) recommend a precautionary approach, aimed at minimising exposure;
 - iii) present a case for safe management of the substance on the basis of proven historical experience or monitoring data;
 - iv) withdraw support for that particular use.

Options ii) and iii) would not be available to the registrant if the substance / use falls within the criteria for prioritisation of dossier review established under the REACH Regulation, as is being suggested later in this document .

- g) In the case of substances where two or more registrations are submitted, each registrant could utilise hazard data submitted by other registrants during the next review of the registration.
- h) The material safety data sheet would contain information on hazards and on uses supported by the manufacturer/importer on the basis of this preliminary safety assessment.

In order to compensate registrants who submit a complete core information set, the proposal would also develop the Agency fee as an incentive system. Thus, registrants submitting a complete core information set would pay a lower registration fee than those submitting incomplete data sets. Similarly, if an information set is completed at a subsequent review point, the registrant could possibly be refunded the appropriate portion of the registration fee. Complete information sets would be evaluated by the Agency prior to any such compensation. Summaries of information on intrinsic properties would be made available by the Agency to other and subsequent registrants, but use data would remain confidential.

It is important at this stage to keep in mind that the Commission REACH proposal distinguishes between 4 types of information, namely:

- a) the full study report, which is kept by the registrant;
- b) a robust study summary, required for the chemical safety assessment (Annex I);
- c) a summary of the study, required for the registration of all substances under the Commission proposal;
- d) results (hazard data), often freely available on the MSDS and on the internet.

Whereas these distinctions are appropriate for high volume substances, it may be possible to simplify further for low volume chemicals. In the case of substances in the 1-10 tonne bracket, a quantitative chemical safety assessment is not required. As there is no need to submit a robust study summary, it should also be possible to eliminate the study summary as a registration requirement during the inventory phase. Study summaries should only be required if the substance falls under one of the prioritisation criteria for dossier review triggering a request for supplementary or more detailed information. This simplification would greatly reduce the problems associated with the sharing of data, as only non-confidential hazard data would be required to be made available for most substances.

In establishing the fee structure for the Agency, two elements should be included. The first is the compensation element referred to previously. This part of the fee could be paid for 'in kind' through the provision of a complete data set during the inventory phase. The second component of the fee would cover the operating costs of the Agency. As it is expected that the main focus of the Agency's work will be on high volume substances, this second component should be a nominal one for low volume registrations.

It is also being suggested that this principle should be extended to other tonnage brackets in such a way that basic hazard information would be made available to subsequent registrants in

lower tonnage brackets, subject to compensation as outlined above. The robust study summaries and the studies themselves would however remain the property of the owner of the study. Particularly in the lowest tonnage level, it is envisaged that a level of detail comparable to a complete material safety data sheet, i.e. basic physico-chemical and hazard data, would be sufficient to carry out a basic safety assessment for the purposes of REACH when coupled with detailed information on use, as well as with a degree of historical experience. The exception to this assumption is in the area of new substances (non-phase-in), where very little might be known. Even in such cases, however, enough information will be available to enable appropriate use and exploitation of the properties of the substance. As most new chemicals are destined for highly specialised applications, use and exposure scenarios will also be generally limited, facilitating a targeted approach.

To summarise, at the end of this process, the following would have been achieved:

- a) a comprehensive inventory of substances marketed at the 1-10 tonne bracket;
- b) the supported and known uses of these substances;
- c) a compendium of information available on the properties of these substances, including more hazard information available to the general public;
- d) complete information sets would be available for a number of substances,;
- e) partial information sets would be available for the remaining substances;
- f) by inference, it should also be possible to identify data gaps and areas where further information is required.

It might also be worth considering requesting submission of data sheets during the inventory phase. A database of data sheets would facilitate monitoring their quality, as well as their accessibility to interested parties.

The second key element of the Maltese-Slovenian proposal is a prioritised review and evaluation of dossiers. Following the initial registration, the Agency would carry out a study of the information submitted and submit a report to the Member State Committee of the Agency, including also recommendations for priority dossier review (by registrants) and priority dossier evaluation (by Member States). This study would include observations on the quality of the information submitted, possibly following evaluation by Member States of a sample of registration dossiers. Such an exercise could highlight areas that merit closer examination, as well as gauging the extent to which industry was meeting its obligations and whether further investment in guidance material and development of alternative methodologies was advisable. These recommendations would also cover areas where closer scrutiny of dossiers would be considered advisable, taking into account the availability of resources. The Member State Committee would be able to add to or modify these recommendations, prior to formulation by the Commission of a proposal for further prioritisation criteria to be adopted by comitology.

In summary, it is therefore being proposed to expand on the evaluation process already included in the Commission proposal. The aim of this exercise would be to propose two sets of criteria for prioritisation to further work, namely:

- a) prioritisation criteria for the selection of dossiers for evaluation by Member States; and
- b) prioritisation criteria addressed to industry, indicating substances or situations where a specific review of the registration dossier would be requested.

The final criteria would be decided through regulatory comitology and included in an appropriate Annex. It might also be possible to establish at least some of these criteria a priori, ensuring that complete information sets are submitted for those low volume substances clearly falling within these prioritisation criteria.

Possible criteria for prioritisation of further elaboration of the dossier by industry could include:

- a) 'data-poor' substances where less than a certain proportion of the core data set had been submitted following a completeness check or where specific combinations of information points were missing;
- b) substances with significant exposure patterns, e.g. substances used in consumer products where exposure may not be so easily controlled;
- c) substances for which substantial concerns have been identified following enforcement activities.

These are only possible examples. Other prioritisation criteria could be envisaged. The prioritisation criteria adopted would be included in an Annex of the Regulation. Industry would thus be aware of these priorities and could consequently focus its resources accordingly. This translates into a higher degree of cost-effectiveness, besides acting as an incentive for substitution of substances likely to be prioritised according to these criteria. Member States' authorities would identify dossiers meeting these criteria and request appropriate updates within the review period.

Suitable criteria for dossier evaluation by Member States could include:

- a) structural similarity with substances already identified as substances of high concern in higher tonnage brackets, or already subjected to authorisation or restrictions;
- b) possible substitutes for substances subject to authorisation or restrictions, so as to speed up a possible knowledge-based substitution and facilitate eventual production at higher tonnages;
- c) results obtained from screening (Q)SARs and other alternative approaches, even if not validated for confirmatory purposes.

At the end of this second stage, the following would have been accomplished:

- a) a number of dossiers would have been comprehensively evaluated and their degree of reliability evaluated;
- b) cases where direct recourse to authorisation/restrictions procedure was advisable would have been identified;
- c) dossiers requiring updating or review as a priority during the next 5 year review period would be identified;
- d) in some cases, specific requirements for further information or testing, for the purposes of filling in data gaps and refining the safety assessment;
- e) identification of areas where greater effort in the development of alternative methodologies was required, for example, identifying endpoints for which conventional testing was proving to be particularly challenging for SMEs, or where the availability of an affordable alternative method could result in improvements in a substantial number of dossiers.

It should also be stressed that a targeted evaluation might also be possible. For example, it might be possible to focus on just one endpoint for certain applications, such as data on acute toxicity for substances likely to be used in certain industrial applications, if such areas are considered as being of concern by Member States. In this case, only this aspect of the selected dossiers would be evaluated and any supplementary information requirements would be limited to completing this targeted evaluation. Another possibility would be to evaluate a range of substances having identical or similar applications.

Dossiers requiring updating or submission of more detailed information would require resubmission at the end of the next 5-year review period. When compared to the Commission proposal, this is still a substantial improvement, as industry will be aware of the prioritisation criteria and would be expected to also prioritise its efforts in the same way, through generating information that was actually required.

A substance would no longer be legally on the market if updating/review was not carried out by the end of the prescribed review period, or where further information requested was not submitted by that time.

Averaging of tonnages

One disadvantage of the Commission approach is that it relies heavily on inflexible thresholds. This reduces flexibility for SMEs, which may only exceed the threshold momentarily or occasionally. The significance of this is particularly high in the 1 t and 10 t thresholds, which are easily exceeded. It also places expanding companies at a disadvantage, as they have to incur higher registration costs before their market is actually established.

The Maltese-Slovenian proposal would introduce a 3-year average for the calculation of tonnages, calculated on the basis of the preceding three years. This would ensure that only manufacturers / importers regularly exceeding a tonnage threshold are subject to registration requirements for that tonnage bands. An added benefit would be that downstream users would be able to source speciality chemicals outside the EU in the event of withdrawal or temporary shortage of substances, thus maintaining a higher degree of flexibility when sourcing. This is essential in cases where the market may take some time to recover equilibrium following withdrawal of a substance or manufacturers rationalising their portfolio.

Conclusion

The approach illustrated in this paper seeks to ensure that resources within industry, the Member States and the Agency are primarily utilised in the regulation of substances posing a potential risk to health and the environment. In view of the large number of substances falling within the 'low volume' category, some kind of prioritisation mechanism for this category is necessary. In our opinion, the two main criteria driving prioritisation of work in this area should be significant exposure, particularly to consumers, as well as the existence or otherwise of at least basic information about the substance's inherent properties. The latter could be qualitative and not necessarily quantitative, as long as the indication available permits a basic characterisation of risk. The importance of historical experience should not be underestimated.

The approach illustrated would ensure that the attention of industry was drawn to the need to look more closely at certain substances where the possible risk was considered significant. It would then be the responsibility of industry to fill in the existing 'knowledge gaps'. At the same time, it is important to avoid useless waste of resources in generating data of no practical significance.

At a later stage, it will be necessary to elaborate further on the links between registration and evaluation (dossier and substance). It is our belief that the adoption of suitable criteria for evaluation, indicating also where a greater level of detail was required in registration would also provide the best possible link with the remaining components of REACH (authorisation and restrictions), as these components are primarily driven by information on risk.

Malta and Slovenia are also considering ways in which certain elements of the scheme outlined above for substances in the 1-10 tonne bracket could be further extended and applied to substances in the 10-100 tonne bracket, given that similar arguments could generally be applied for both tonnage brackets.