SRU German Advisory Council on the Environment

Chemicals Registration under REACH: Priority Setting and Data Requirements

Executive Summary and Recommendations

October 2005

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1 Introduction: Improving Knowledge on Chemicals

1. Technological advancement involves broad use of chemical substances. There are very few areas of public and private life that do not involve the use of technical equipment containing plastics, surface coatings, paints, liquid crystals and equally so cooling agents, lubricants, fire-extinguishing and flame-proofing agents. Chemicals are also widely used in securing food supplies, for example as pesticides and in the treatment of livestock. Without the use of synthetic pharmaceuticals, the detection, treatment and prevention of disease is unthinkable. Depending on the field of application, available knowledge on how chemicals affect human health and the environment differs considerably. In the case of pharmaceuticals and plant protection products, tests carried out during product development provide broad-based knowledge on chemical effects and their mechanisms. This knowledge serves in justifying intended uses and helps identify substance risks. For other types of chemicals, those that are used primarily on account of their technical properties, economic viability, chemical reactivity and physicochemical stability, available knowledge is less comprehensive. In many cases, use on humans or introduction into the environment is not the primary intention and, rather than focusing on biological impact, available knowledge on many such substances concentrates on other parameters. There is thus an urgent need to improve knowledge on chemicals.

2. Since the entry into force of Germany's Chemicals Act in 1982 and the EU Regulation on the evaluation and control of the risks of existing substances in 1993, an obligation has existed whereby data on existing chemicals must be systematically generated, collected and evaluated. Evaluation of the data and the workability of the implementation process has shed light on a series of new informational deficits. These largely involve substances that are not covered by the EU's Existing Substances Regulation and downstream users of chemical substances not yet included in the implementation process. Despite the advancements made so far in assessing the safety of chemicals used in the workplace, the consumer sector and the environment, the existing information is nowhere near adequate due to the vast range of uses and the large number of chemical substances involved. Protection gaps still exist in terms of human health and the environment.

The existing regulation strategies are based on a division of responsibility for data generation and interpretation on the one hand, and for evaluation and risk assessment on the other. They also concentrate on substances with a production and import volume in excess of 1,000 t/a. The procedures for these substances are therefore thorough and substance assessment takes in a range of different issues. What the procedures are unable to do, however, is unleash the capacity needed to remedy the recognised deficits in chemicals legislation. The existing regulation strategies are

clearly limited in terms of overcoming identified barriers and accordingly expanding the responsibilities of those involved.

3. The EU's new chemicals regulation, REACH (Registration, Evaluation and Authorisation of Chemicals), provides for a workable and transparent process that places responsibility for product safety with chemicals producers and downstream users. REACH will improve available knowledge on chemicals and the basis for substance assessment. And at least in the medium and longer term, it will give EU producers, importers and downstream users a competitive advantage over non-EU competitors in terms of product safety.

In addition to the EU Commission's proposal of October 2003 on chemicals registration under REACH, a number of alternative proposals have since been put forward. For the most part, these focus on the procedures for priority setting and determining the scope of the data required.

The full Statement thus compares the various proposals on chemicals registration under REACH with regard to their potential for achieving the aims of the Regulation. It is available on the website of the German Advisory Council on the Environment under: www.umweltrat.de/03stellung/downlo03/stellung/Stellung_REACH_Okt2005.pdf.

The following short version only contains an executive summary of the comparative assessment and the recommendations.

2 Executive Summary of the Comparative Assessment

4. Compared with alternative proposals, the EU Commission's proposal of October 2003 concerning the structure of the REACH Regulation offers a number of crucial benefits:

- A schedule for the processing sequence of the registration of different groups of phase-in substances is based upon well-defined and simple criteria. Registration is linked to deadlines and thus provides for overall enforcement certainty. The limited processing and negotiation capacities of the competent authorities are thus spared, leaving them free to concentrate on other responsibilities involved in the registration process. This is of key importance, particularly as regards implementing REACH and structuring the information base within the value chain.
- Compliance with registration deadlines is simplified in that responsibility for providing documentation lies solely with producers and there is no need for coordination with other actors in the supply chain during the registration process. Failure to meet the deadlines is subject to sanction in line with the 'no data, no

market' principle. This gives producers a strong incentive to meet the deadlines and so provides for enforcement certainty.

- As a general rule with the possibility for exemptions the amount of information required is linked to production volume. A comprehensive testing programme is prescribed for substance volumes in excess of 1,000 t/a and between 100 and 1,000 t/a. This top-down approach is to be welcomed in that by setting out the scope of assessment, it defines a requirement for information that encompasses the potential harmfulness of a substance when handled and the risk to consumers and the environment from repeated exposure. Further, the burden of proof and justification is clearly placed with registrants and REACH will significantly broaden the chemicals knowledge base as a result. Exceptions from fulfilling the testing matrix are possible, but are subject to justification; the reasoning must be verifiable using the information contained in the chemical safety report.
- In principle, the Commission proposal, like its alternatives links the probability of exposure to the amount of information required (data requirements) and the processing sequence. However, the criteria for allowing to reduced testing requirements based on exposure-related reasoning while maintaining a constant high degree of safety are not yet clear enough. It is thus impossible to assess the resource-saving potential of this option.
- The top-down approach is largely independent of knowledge on patterns in chemicals use and on distribution streams within the production chain. This is a relatively robust approach to dealing with existing informational deficits. Considerable deficits exist when it comes to information on estimating exposure within the value chain and the associated opportunities to delineate different sources of consumer exposure.

5. Nevertheless, the Commission's proposal requires a number of improvements. These include:

- The basic data set for substances is too limited to allow the priority setting process to pick out the type of information that could illustrate probable impacts on the environment and effects on human health.
- The processing sequence for registration based on production volume should provide an option for substances to be exempted from early registration and be assigned a lower priority (opt-out). The available processing capacity should then be focused on assessing substances whose classification indicates a high risk and assigning them a higher priority in the processing sequence (opt-in).
- Sequential priority should not only be given to substances classified as carcinogenic, mutagenic or reprotoxic for reproduction (CMR substances), but to

other substances with properties of concern that are potential candidates for the authorisation process – substances which are very persistent and very bioaccumalative (vPvBs) and substances which are persistent, bioaccumalative and toxic (PBTs), for example.

- Procedures for quality assurance of information and interpretation by registrants are too weak or are not provided for. This aspect is, however, of extreme importance and in consequence, the measures for observing quality assurance must be greatly improved.
- The criteria and the procedures for allowing exposure-based exemptions from the testing requirements are still not precise enough and must be better defined.
- For substances with a tonnage of less than 100 t/a, substance assessment and risk classification is the sole responsibility of the producer. The hesitance on the part of the authorities to participate in primary interpretation, generation of overviews and data archiving is unacceptable. Instead, they must actively support and help to shape the desired expansion of the knowledge base to ensure that its structure and the quality of the data available can actually be used to achieve the further goals of REACH legislation – for example risk assessment within the production chain.
- For substances with a tonnage in excess of 100 t/a, the procedural barriers for national authorities requesting data themselves have been set too high.

3 Further Development of the EU Commission's Approach: Recommendations

6. The German Advisory Council on the Environment recommends that the EU Commission's proposal be made the basis for a priority-setting strategy and for risk-focused data requirements in chemicals registrations. Structuring the REACH Regulation in accordance with the Commission's proposal of October 2003 has the following benefits:

- A clear processing sequence for chemicals registration
- Binding deadlines
- Scaled data requirements
- Resource-savings by means of reduced assessment effort
- Robust procedures
- Clear division of responsibilities (burden of proof placed on industry).

Nevertheless, there are a number of areas in which the Commission's proposal needs to be improved:

- The sub-goals of the REACH Regulation – (1) substance classification, (2) defining safety measures, (3) developing an information structure, (4) improving the knowledge base, and (5) strategies for risk assessment and risk limitation – are not adequately delineated.
- The processing sequence allows no room for flexibility.
- In some cases, the volume of data required is insufficient to enable achievement of the REACH objectives.
- Focusing the testing requirements on exposure and exposure categories has yet to be finalised.
- Quality assurance for data is inadequate.
- The (Q)SAR models are not sufficiently matured to allow existing resource-saving expectations to be met.
- The burden of proof and division of responsibility must be tightened.

3.1 Sub-Goal Delineation

Classification

7. One aspect of substance assessment involves using a catalogue of criteria to assess the potential risks to human health and the environment, and also the development of safety measures to protect people. The established concepts for classifying substances into categories allow no delineation between no effect and weak effect. Greater delineation as regards weak effects is, however, desirable because classification in the no effect category is of importance in assessing potential substance uses.

Information Structure

8. The information supplied to customers by chemicals producers and importers should primarily be provided using a safety data sheet. Alongside substance data, the sheet should contain details of the analysis methods used, the exposure assessment and instructions for safe handling. Further development and enhancement of safety data sheets must be addressed and closely monitored during the REACH implementation phase because in all probability it can be assumed that users will have different questions to those addressed by the safety data sheet format and the various uses will give rise to a need for exchange on sheet contents.

Producers and importers are required to produce a comprehensive chemical safety assessment (CSA), conduct a hazard assessment and describe the effectiveness of their safety measures. A full chemical risk assessment is only required for substances with hazardous properties (see Annex I of the REACH Regulation). However, a chemical safety report (CSR) is the primary form of communication with the authorities. The report contains standardised and in some cases comprehensive details of the results of the chemical safety assessment. Under certain circumstances, it also contains a robust summary of the findings of individual tests performed during toxicological assessment. In this phase of REACH, it is assumed that the substance-based chemical safety reports generated by the expected multiple registration of single substances will provide conflicting information that can only be resolved at peer review level. On the whole, the Commission's proposal on REACH does not appear to provide a framework for interactive exchange and does not, therefore, give adequate recognition to the complexity of substance data exchange and assessment.

Improving the Knowledge Base

9. Systematic identification of substances produced in the last twenty years has shown that a remarkably broad use of single substances can occur within the value chain. The existing strategies for chemical safety assessment have failed to give sufficient consideration to this aspect and there is a need to develop an integrative assessment strategy for multiple substance sources. In the consumer sector, this means systematic description of the distribution paths in order to identify substance sources from products and regulate protection of human health.

10. Despite the advancements made in identifying the distribution and fate of substances in the environment, the existing assessment models remain deficient. REACH addresses this problem. The obligation to generate information must be further tightened, however, because the data sets required under the current approach will not be sufficient to allow science-based classification of the effects from the release of substances into the environment and therefore to develop strategies to reduce substance release.

11. Identification of substance risks will only be possible for some of the substances registered. Also, the procedures for risk identification are not sufficiently enshrined to provide adequate assurance that the assessment of the substance risks involved is scientifically founded. The risk assessment criteria that must be met are not well enough delineated and the expected results do not meet the intended purposes. There is thus an urgent need for the REACH implementation phase to encompass this responsibility as a yet-to-be-defined area and to support its development.

3.2 Processing Sequence

12. The provisions for a processing sequence based solely on production volume and substance properties should be made more flexible through the incorporation of exemption provisions. Flexibilisation is deemed necessary because during the REACH implementation phase, combinations of substance properties and use patterns could occur that were not recognised or not known during conception of at the time the Regulation was drawn up but have either a negligible or excessive impact on time and processing capacity during registration. It is thus recommended that the processing sequence be supplemented by opt-out and opt-in provisions without endangering the timeline of the entire process. These should be structured as exception rules for justified cases and thus call for the formulation of restrictive criteria. This approach would open up the opportunity to tighten the link with substance-based problems during assessment but without weakening the REACH strategy.

Opt-out Provision

13. Given its clear criteria and automated procedures, the EU Commission's approach to the processing sequence spares the capacities of both the European Chemicals Agency and national authorities. It is, however, inflexible. The Commission's proposal provides for priority processing even for substances that are clearly not of high concern and to which no priority has been assigned on grounds of acknowledged harmless properties and easily demonstrated negligible exposure probability. An opt-out provision could be applied when dealing with those cases that come to light during pre-registration. A waiver on early registration for such substances would free up capacity for assessment of other substances and uses that must be registered as priority substances on account of their risks. This applies in particular to other potential candidates for the authorisation process that are not systematically covered during the first years of registration. If an exemption rule of this type remains restricted to clear-cut cases, it should be easier to implement administratively than a general exposure-based list to which less clear-cut cases must also be assigned.

This type of approach should not be structured as a general rule, as is called for in the industry associations' proposals, but as a more restrictive exemption rule. The national authorities should be authorised to use their discretion to reprioritise a substance on the basis of additional information submitted during pre-registration. This discretionary power should not be made subject to the appeal process under Article 85 ff of the REACH Regulation because that could paralyse the entire process. It should thus be used only to handle cases that, for the most part, are undisputed.

Opt-in Provision

14. Administrative and assessment capacities, made available by the opt-out rule, should primarily be used to assess substances with properties of high concern to effect the earliest possible identification of candidates for the authorisation process. Neither the Commission's proposal nor the proposals submitted by the industry associations have introduced procedures that could contribute to the earliest possible identification of substances with properties of high concern. Under Article 54 of the REACH Regulation concerning substances for inclusion in the authorisation process, this applies to CMR substances, PBTs and vPvBs, and to endocrine disrupters in particular. At the present stage of the debate, CMR substances are only treated as priority substances when they have been classified and recognised as such. This is a barrier for getting CMR-substances prioritised. Therefore CMR substances in category 3 (substances having possible CMR properties) should also be processed as priority substances.

Clarification is still needed as regards the criteria for inclusion of substances having possible PBT or vPvB properties. They must be better defined and explained to allow as seamless an implementation as possible. The criteria for PBTs should also focus on the progress made in the OSPAR debate. In Annex XII of the REACH Regulation, which sets out the criteria for PBTs and vPvBs, the only criterion on bioaccummulation is the requirement for a bioaccummulation study. It should also include the log Pow already required in Annex V. Concerns regarding the reliability of log Pow data should be used to further develop quality assurance for the accuracy of archived data and for recommendations on opportunities for its further application in the modelling of secondary data.

Testing the Process

15. Experience gained in the authorisation of pharmaceutical preparations invites the assumption that, on the whole, the assessment of substances with less serious effects will be easy provided that all relevant substance testing information is made available that could have led to the detection of any potential serious effects. As this will not be the case with chemicals registration under REACH, due, for example, to deficient information on chronic and carcinogenic effects, the reliability of registration data can generally be seen as doubtful. It is thus recommended that during the early phase of registration, substances be selected which, due to their low production volumes, would not ordinarily be candidates for priority registration but would have a great impact when it comes to testing the process because, for example, their distribution within the production chain is well documented. Another interesting aspect would be a clear effect mechanism with the absence of metabolism, whereby these

substances might be good candidate substances for (Q)SAR modelling or a special status as regards their technical use where well-documented exposure in specific sectors or consumer groups exists. This can, however, only be achieved by reducing the level of effort elsewhere. Particularly in the early phase, the processing capacities of all involved will be exhausted because all the strategies assume that the start-up phase will involve registrations of substances that entail the most intensive assessment effort and the greatest number of multiple registrations. At a time when available experience within the European Chemicals Agency will be in relatively short supply, an immense amount of effort will be involved in resolving discrepancies in basic data sets and assessments of multiple registrations. Thus, prior to taking on the difficult task of processing the large number of substances to be assessed, existing cooperation networks and a broad knowledge base could be used to establish new REACH procedures which would then be structured in line with practice in the field.

3.3 Data Requirements

16. The Commission proposal requires that, depending on their assignment within a production and import volume range, substances for registration must meet a scaled list of testing requirements. This is essentially system of rules with exemptions that takes a top-down approach. It places the burden of proof and justification clearly with the registrant and is thus to be welcomed. However, to avoid an influx of data that could paralyse the entire system (see the following paragraphs), the approach must ensure that the data requested is limited to that actually required and necessary to guarantee safe chemicals handling.

Improving the Basic Data Set

17. From a professional perspective, the basic data set in Annex V of the Commission proposal must be supplemented. The basic data set should be structured to provide initial indications of human toxicity and environmental risk. This means expanding the basic data set to include tests on biodegradability in the environment and on mammalian toxicity. An assessment that at minimum provides information about substance properties and identification of candidate substances of high concern cannot be achieved without a minimum canon of test results. While (Q)SAR processes provide a good illustration of hazardous properties like corrosive effects and skin irritations, they – at least at present – provide a less than adequate guarantee for other endpoints that are relevant for classification.

Exposure as a Means to Reduce Testing Requirements

18. To ensure that information needed for substance assessment is collected in as targeted a manner as possible, the option contained in the Commission's proposal to

omit specific components from the testing requirements is essential in cases where additional information on assumed exposure levels supports the omission. The criteria under which such exposure-based exemptions could be made require further definition. The criteria must be transparent and allow clear classification of exposure with regard to its relevance for human health and the environment. This is the only way to make the process enforceable and reliable for all concerned. In case of doubt, compliance with the original testing requirements should be required and particularly where it provides for the first opportunity to close information gaps in areas such as identification of chronic toxicity.

19. For each assessment-relevant sector in which contact with chemicals occurs (workplace, consumers, environment protection), cut-off criteria must be defined as regards safety and acceptance of a potential exposure when handling substances and products. The German Advisory Council on the Environment recommends that the following be taken into account when defining the criteria:

- Only in exceptional cases should a purely exposure-based justification suffice (for example, a 'closed facility' in the case of industrial uses and workplace safety). Instead, the intrinsic properties of a substance must be included as a general rule. Among other things, this includes the possibilities for release of substances included in a matrix, the persistence of substances in the environment, the formation of problematic metabolites, multiple sources of substances and repeated substance exposure.
- If the risk reduction strategy is justified on the basis of safety measures, it must be ensured that the safety measures are robust and that they can be realistically implemented and monitored.
- If general cut-off values are applied to safety in the workplace, the justifications for maximum allowable concentrations (MAC) for known hazardous workplace chemicals should be taken into account. This option is, however, only possible for substances for which MAC levels and an associated justification have been defined. Thus, substances thought to have carcinogenic effects and those for which information is lacking are excluded.
- There are two ways in which the transfer of knowledge from MAC substance evaluation can provide certainty: the intrinsic substance properties of substances with largely unknown properties would probably be exaggerated because MAC classification focuses particularly on hazardous substances. The same applies for estimated length and frequency of exposure. The existing uncertainties regarding the transferability of MAC level justifications to the consumer situation could be dealt with by introducing an additional safety margin.

– No general cut-off values should be defined for substances and substance groups whose group classification or suspected structure give rise to assumed high mammalian toxicity, higher accumulation or carcinogenicity.

20. Exposure estimation can initially focus solely on intended substance uses. However, a range of unintended uses will also come to light during the REACH implementation phase. The European Chemicals Agency should identify the expected discrepancy between assumed and actual substance use within the value chain and integrate it into the process.

3.4 Data Quality

Enhanced Quality Assurance

21. A workable quality assurance system for the data and knowledge obtained is indispensable in terms of data interpretation, safety management and risk communication. Effective quality assurance mechanisms for data and their interpretation must therefore be enshrined in the REACH Regulation and its implementation process. Also, the conditions under which these data will be used to derive secondary data must be clearly defined. In line with the shifting of responsibility to producers and importers, data should be certified and different producers of the same chemical substance should vote jointly on the quality of the archived data. Furthermore, in the course of dossier evaluation and substance evaluation under Article 38 ff of the REACH Regulation, the competent authorities should have the explicit option to conduct random checks to ensure that data generated and interpreted by registrants meets generally accepted standards. The development of data interpretation guidelines should be made an integral component of the work performed by the European Chemicals Agency under Article 73 or the Committee on risk assessment under Article 81 of the REACH Regulation.

The experience gained so far in substance evaluation and subsequent implementation activities allows a clear definition of the conditions under which quality assurance of the accuracy of reference data must be guaranteed. Compliance with these conditions is a vital prerequisite for the scientific reliability of subsequent decisions on risk assessment and risk reduction measures. Taken as a whole, it is also urgently recommended that a clear definition be given as to which additional issues the data can reliably be used for and which of the mostly complex issues can be answered solely on the basis of aggregated and verified data sets. Available knowledge from existing substance assessment programmes overwhelmingly underlines the importance of these requirements. It is also recommended that data be archived and the matrix structured not solely on the basis of a list of criteria but using a yet-to-be-developed catalogue of

criteria that takes adequate account in objective terms of the assessment-related decision trees used in achieving the innovative objectives of the REACH system.

Further Development of SAR and QSAR

22. Given their current developmental stage, SAR and QSAR systems cannot be deployed as robust and reliable methodes for substance evaluation during the first phase of REACH. The conditions that would allow their reliable deployment must be further explored. The training data sets must be improved in a determined way and the data set relationship matrix adapted to meet REACH requirements. This appears possible only in respect of high quality substance-based basic data sets. On the whole, modelling systems are the working level at which the greatest development potential exists for substance processing capacity. Science-based further development of the existing system is thus urgently recommended. With the (Q)SAR systems, greater delineation is needed between systems of ecotoxicological and human toxicological relevance because the prognosis systems for both areas of application will have different effects. Also, close linkage is needed between the modelling processes for substance transport, distribution in environmental media and resulting overall exposure.

3.5 Division of Workload and Responsibility

23. Both the Commission proposal and the existing consensus among EU Council working groups place the workload and responsibility with registrants as regards gathering information on chemical substances and using this information to assess the safety of chemicals and to select appropriate risk management measures. In exceptional cases registrants may prove safe use by proving effective substance release prevention or adequate control of substance use. The associated principle of placing the burden of proof with producers is vital and thus to be welcomed.

24. The competent authorities' negotiating position must be strengthened as regards insisting that this producer responsibility be implemented in the registration process. Articles 39 and 40 of the REACH Regulation govern the opportunities to review test proposals and registration dossiers for compliance with REACH requirements. The Commission's proposal places high procedural barriers for authorities to overcome in cases where they consider a producer's test proposal to be inadequate as an aid to further assessment of substance risks. These procedural barriers in the evaluation process should be significantly lowered in order to lessen the information gaps in cases involving justified suspicion of risk and inadequate test strategies. Under Article 39, however, the authorities are only authorised to reject proposals involving animal tests that they deem unnecessary. While the right to request

further information (and so the performance of animal tests) in order to close information gaps is enshrined in Article 40, it can only be enforced in long and drawn-out proceedings that serve as a considerable deterrent. Conversely, if the test proposals submitted appear inadequate because it is suspected that a hazardous substance property could occur when the substance is used in the consumer sector and/or the effectiveness of the safety measures is doubtful, the authorities must be allowed to require animal testing without having to engage in a rejection process that goes through a range of different instances.

Producers must employ cost-saving measures as a matter of economic necessity. Hence, not everywhere economic incentives for adequate risk classification are sufficiently strong and the results of substance data assessments can diverge between producers/importers and the authorities. The option to request test data in cases where there is justified concern is an important factor in ensuring that risk potential is not underestimated. There is thus an urgent need for the restrictive provisions contained in Article 48 (4) of the Commission's proposal of October 2003, which set outs registrants' rights, to be relaxed and to allow additional information to be requested if the competent authorities come to the conclusion that a substance poses a potential risk to human health or the environment.

3.6 Conclusions

25. The Commission's proposal of October 2003 provides an important basis on which to take a new approach to the regulatory framework for chemicals assessment. It provides the best solution to the problems experienced in implementing the EU Existing Substances Regulation as regards achieving a sufficiently timely procedural flow given the prescribed division of responsibilities between the various actors. The Regulation previously failed to cover a number of significant substance groups and did not include downstream users of chemicals. Assigning to industry the sole responsibility for substance evaluation and risk assessment, including drawing up use patterns and providing effective safety measures to protect human health and the environment from the effects of hazardous substances, makes use of industry's informational advantage and does away with complex coordination and approval processes between the parties.

The declared and innovative goal of the REACH Regulation is to improve the knowledge base on all chemicals with production and import volumes in excess of 1 t/a per company and so to allow adequate assessment of chemicals safety and harmlessness. Greater effort must be made to avoid the success of the REACH system being stymied by a system that overwhelms registrants with requirements that can rarely be fulfilled because for most substances that are to be assessed for the first time

under REACH, a balance has yet to be found between adequacy, necessity and general desirability regarding the assessment data required. There is thus an urgent need for constructive monitoring of the implementation process and a review of the catalogue of measures. A structural framework must be developed for the purpose.

With implementation of the REACH Regulation, downstream users will be drawn in as new actors who will share responsibility for substance assessment. This will highlight new problem areas that were not recognised when drafting the Regulation because it is impossible to chart the range of substances and substance uses and the problems they involve. There will also be a need for substance risk advisory services for downstream users and consumers. Distribution of information and communication of risks to the interfaces between downstream users and/or consumers is an essential layer. It will play a significant role in determining the success of the REACH Regulation and thus requires very careful planning and monitoring.

26. While the incentives for early, proactive assumption of the new responsibilities involved under REACH are too weak, they could provide the preemptive spark for the more inexperienced actors and, of course, for the success of the REACH system overall. Some areas of responsibility prescribed in the REACH Regulation cannot be fulfilled by industry, however. These include the identification and summarised assessment of substances within the processing chain, the further development of testing and assessment processes, and effecting the shift from substance-centric evaluation to product-centric evaluation. These responsibilities can in all probability only be performed by the competent national authorities or their subordinate committees.

The experience gained with existing substance evaluation programmes has proven vital in achieving scientifically sound results in data quality assurance, careful design of dossier formats and their contents, and early peer review of data which includes balancing conflicting information. The necessary and irreplaceable expertise needed to conduct well-founded chemicals assessment can really only be developed at cooperative working levels and these are largely lacking in the Commission's proposal on REACH.

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