

**ROYAL SOCIETY OF CHEMISTRY SUBMISSION TO THE
UK CONSULTATION PAPER ON THE NEW EU CHEMICALS STRATEGY – REACH**

16 June 2004

The Royal Society of Chemistry welcomes the opportunity to make the following submission to Department for Environment, Food and Rural Affairs, together with the Department of Trade and Industry and the Devolved Administrations for Scotland, Wales and Northern Ireland. This submission has been prepared under the aegis of the Environment, Health and Safety Committee [EHSC] of the Royal Society of Chemistry. Members of the EHSC serve the RSC as individual experts and not as representatives of their employer.

The RSC's Royal Charter obliges it to serve the public interest by acting in an independent advisory capacity and we are happy for this submission to be put into the public domain.

The RSC finds the latest version of the EU Chemicals Legislation setting out the proposed regulations to be more balanced and more pragmatic than earlier versions. However, we still have significant concerns about the workability of some aspects of the proposal, and we believe that more information and guidance is required if it is to achieve its intended objectives. The Society is also aware that the process of developing the proposals into legislation may jeopardise the latest improvements and these changes will need to be monitored during the passage of this proposal.

The current EU system is fragmented and cumbersome. In principle The Royal Society of Chemistry would welcome a single harmonised regime for assessing and controlling the effects of chemicals on health and the environment.

The Royal Society of Chemistry only wishes to respond to those questions which fall within its area of its concerns.

Q 2. Do consultees agree with the Government approach to limit the scope by excluding lower priority chemicals such as certain intermediates and polymers in the first stages of REACH as outlined in the European Commission proposal?

The Society agrees with the Government approach to limit the scope by excluding certain intermediates and polymers in the first stages of REACH.

Q 3. The Government would welcome views on whether the exemptions from registration outlined in Annex II and Annex III under this Regulation are appropriate.

Exemptions are appropriate for the type of material outlined in Annex II (i.e. the list from the Existing Chemicals Regulation), that are describable as 'generally regarded as safe'. Annex III substances should continue to be exempt from registration as these are currently on the standard list of 'automatically exempt' substances used for EINECS reporting. The RSC would also recommend extending the 'postcard' registration requirement to all lower priority

chemicals similar to those substances that are in Annex II. Such exemptions are important to prevent unnecessary resource utilisation and costs being incurred. However, there does not appear to be any systematic procedure for determining the substances that should be included in Annex II (that was derived from substances on the ECR list). Furthermore, to ensure transparency, such a list should be produced by a defined (although flexible) process and subjected to independent peer review. A fair and transparent process for recommending substances for inclusion in Annex II and III needs to be developed, as does a decision tree, or similar tool, to ensure consistency of approach.

Q 4. Is the proposal for substances contained in articles workable and likely to provide adequate protection from chemicals in articles? If not, what alternative approach could be used?

This is an important issue for industry. The current proposal for substances contained in articles is unworkable and not likely to provide adequate protection from chemicals that may be released from articles under a range of foreseeable and unforeseeable conditions. One option may be to adopt the US approach, which is commonly used in other chemical schemes, whereby the definition of an article could be enhanced to include chemicals contained in articles so that these can be regulated as appropriate (if there is evidence that these chemicals may be released to the environment).

Q 6. The Government would welcome comments on the European Commission proposal for registration and views on the workability of the ‘one substance, one registration’ approach and ways it could be improved.

In principle the Royal Society of Chemistry would welcome the proposal for ‘one substance, one registration’ but has concerns about its workability. In addition, this proposal appears to have limited support outside the UK. There are potential complications over data protection, e.g. the same substance may have several different suppliers with different registration data trigger levels, so it would be complex to decide how the cost of data generation should be shared. Also there would need to be arrangements to allow subsequent suppliers to join the registration, e.g. data compensation for the original data holders.

Q 8. The Government seeks views on the European Commission proposal for registration to be phased in based on tonnage bands and welcomes views on other approaches to registration that could improve on this.

Using tonnage to trigger the REACH process is not ideal although it offers a pragmatic solution for new substances. Production and importation levels are not ideal indicators of potential harm or exposure. Therefore testing thresholds should, where practicable, take account of estimated actual exposure and potential impact. There is a need for improved prioritization procedures for existing substances. The Society would have preferred prioritisation (to identify and deal with substances of high concern) on the basis of risk to be built in at the Registration stage. Exposure scenarios required for registration could be used to differentiate between chemicals on the basis of use. This will have a key impact on the risk that a chemical (substance) poses. By focusing on the volume of chemical produced or imported, the danger exists that effort may be misdirected on high volume but low toxicity substances such as sodium chloride – common table salt, rather than on substances of high concern used in smaller quantities. It also may be miss-directed to high volume-low exposure chemicals which, because of the containment measures associated with their production and use, do not pose a threat to human health or the environment. In this regard it may also be appropriate to revise Annex II which provides for exemptions from the obligation to register (in accordance with article 6(a)).

It is vitally important that prioritisation is based on risk with the risk category determined from a combination of production data, estimated release (based on use categories) and toxicity or surrogate QSAR. A system has already been developed by ECETOC for this purpose and we recommend that a system such as this could be used to improve the registration process.

The RSC would also welcome a move away from detailed examination of individual substances of concern. The RSC would like to see chemicals substances grouped on the basis of similar uses rather than on the basis of similar chemical properties because this would facilitate discussion on alternatives and comparisons of risk and need. Chemical substances within each group should be prioritised according to patterns of use and exposure.

Q 9. The Government would be interested in views on whether the European Commission proposals for data sharing are workable. It would also welcome views on how they could be improved to address remaining questions of avoiding duplicate animal testing.

The Society recognises that the revised proposals also make provision for data sharing between enterprises but it is not clear on how this will be achieved in practice without excessive bureaucratic interference.

Commercial enterprises should only have an obligation to declare hazardous components of mixtures and articles that could have public safety implications. However this should not extend to providing detailed commercially sensitive information that would impact on competitiveness without providing any useful benefit. Commercially sensitive information would include the intermediates used in pharmaceutical syntheses, or details of formulations that would allow competitors to copy mixtures or articles (finished products). Although there is a perception that modern analytical science enables the reverse engineering of any formulation or mixture to be undertaken simply and cheaply, this is a myth; the majority of formulations cannot be analysed in sufficient detail without the availability of supporting evidence, such as a list of ingredients.

The RSC believes that REACH should only require data that has real value. This is particularly true for 'existing chemicals' that have been in use for many years with no apparent adverse effects. As there tends to be more information about chemicals of high concern, data waivers should be allowed where there are good surrogate measures. Provision is made for this in Annex IX (rules for adaptation of standard testing regime) which also covers the need for additional standard information requirements for substances in excess of 100 tonnes (Annexes V to VII); these provisions must not be rendered ineffective through too strict an application of the criteria set out in Annex IX. Furthermore, there should be greater acceptance of scientifically reliable historical data gathered for other toxicological assessments required under other regimes.

There is also a need for European Chemicals Agency guidance on using read across toxicity data and advice on what level of information is required at the Registration stage to enable a move away from a tick box approach. There is concern that if dossiers will only be checked for completeness, prior to being placed on the database, that this will encourage registrants, who wish to guarantee a successful registration, to generate comprehensive datasets and thus the use of experimental animals for toxicity testing is likely to increase unnecessarily.

Testing on animals should be minimised. It would be unethical to require animal testing simply to complete a bureaucratic box ticking exercise.

For low volume chemicals (1-10 tonnes/year/ manufacturer or importer) the European Commission has recognised the need to avoid animal testing as far as is possible. For higher volumes animal testing may be necessary if existing information and validated alternative methods are not sufficient. Even though the Commission is proposing to allow maximum use of existing non-animal test methods and encourage the development of new tests that do not use animals, this may not reduce the use of experimental animals in the short and medium term. New test methods will take time to develop, validate and gain acceptability by regulators. The regime should also be flexible enough to adapt to developments in toxicology, such as those resulting from the fast developing area of genomic science. In general companies prefer to use test methods that don't involve animals. However a company cannot use alternative tests until legislators and regulatory agencies have confirmed that they will accept the results. In the past it has taken many years of international validation studies before legislators and regulatory agencies would accept the results from alternative test methods.

Q.10 The Government would welcome comments on the proposal for a single pre-registration phase to encourage data sharing at all tonnages.

Unless such a pre registration phase occurs, it is difficult to see how duplicate animal testing will be avoided. Although an added complexity, such a step would have a number of benefits additional to the avoidance of duplicate animal testing. Firstly, it would provide an early indication of the paucity or otherwise of the pre-existing data, and hence the likely cost of the registration step. This would, in turn, minimise the number of substances lost to the market because of lack of (or at least perceived lack of) data.

Q 11. The Government would welcome views on whether the use of safety data sheets to convey risk information downstream is appropriate.

Safety data sheets are particularly suited for transferring data between chemical manufacturers, but have less utility the further the customer is down the supply chain. The RSC finds the use of safety data sheets problematic because of the ability of many downstream users to understand the contents and take appropriate action. A more flexible approach is needed which fits the information and its delivery system to the purpose of the user.

Q 16. The Government would welcome comments on the criteria for authorisation and the proposed procedure for identifying those substances.

The RSC is concerned that authorised substances are being selected solely on the basis of hazard. This means that all CMRs will require authorisation such as the use of benzene in petrol. Furthermore, some suggested classes have no rules for identification (test methods and criteria against which to judge the results of the tests) e.g. Endocrine Disruptors.

Q 18. The Government would welcome views on the measures proposed to encourage substitution.

The guiding principle should be to reduce the overall risk to man and the environment from exposure to chemicals. We recognise that in many cases, replacing (substituting) one

chemical by another can make an important contribution to producing a lower overall risk. However, this is a complex issue which cannot be reduced to an automatic process and should therefore be seen as a tool to reduce risk rather than as an end in itself. The Society believes that it is only through 'risk based' substitution that the lowest reasonably practicable level of acceptable risk can be achieved. Substitution involves comparisons between different end points (e.g. cancers against greenhouse effects) and there is a clear need for a consensus within society as to how to trade-off different end points and societal valuations. For human health one trade-off may be in the form of quality assessed life years, there appears to be no satisfactory metric available for trade-offs for environmental damage or between environmental damage and human ill-health.

Substitution must be set within a proper legislative framework which identifies the conditions in which substitution is required and identifies who is responsible for selecting an appropriate substitute. The Society therefore recommends the Health and Safety at Work Act 1974 [HSWA] as a suitable legislative model for the control of substitution. The principle of reasonable practicability by which the Act operates also involves complex judgments about risk and would provide a suitable test by which to assess the need for substitution. The test of reasonable practicability would allow appropriate balances to be made between costs and benefits, including the costs of modifying existing plant and equipment. By analogy with the HSWA the onus to initiate substitution would rest with the user but would be goal oriented rather than prescriptive. It would also allow the development of guidance and approved codes of practice on difficult issues such as how to balance environmental risks against workplace health and safety risks.

There is also concern that although substitution can lead to environmental benefits it is unlikely to lead to truly innovative articles (products) which contribute to the economic profits needed to underpin sustainable development.

Q 23. The Government welcomes comments on the European Commission's proposal for the harmonisation of classification and labelling.

Harmonisation of classification and labelling is very important and the Global Harmonisation System of UNECE should be integrated into the EU classification and labelling system.

**ANNEX B
CONSULTATION ON THE TESTING PROPOSALS OUTLINED IN ANNEXES V TO IX**

Q (ii). Comments are sought on whether the testing Annexes should be indicative of testing requirements at each tonnage level but that the Technical Guidance Document should be referred to as part of the Regulation's to guide registrants through a complex testing procedure.

The testing strategy is contained in Annexes V to IX. The actual tests are (sometimes) in Annex X. Annex X needs updating substantially. In particular the mouse local lymph node assay test method must be included in Annex X if the test is being requested in Annex V. Updating of Annex X to take in new scientific knowledge must be considerably faster than it has been for the 'new substances' scheme.

The testing strategy is based on slightly outdated knowledge. The development of new testing strategies may become necessary within ten years. It should be born in mind a massive change in the philosophical approach to testing could well be required as more

becomes known about the human responses to chemicals through, in particular, human toxicogenomics.

Additionally there is considerable unevenness in presentation. Tests and a partial testing strategy are contained in the Regulation and Annexes; further guidance on testing strategies is presumably to be presented in a new edition of the 'Technical Guidance Document' used for the current legislation on chemicals and biocides. These all concentrate on using hazard characterisation to drive testing. Exposure and use information should also be used to drive testing (including driving the lack of need for testing). That exposure/use information should be similarly split between Annexes to the Regulation and Technical Guidance. The Annexes are not even handed.

Q (iii). Comments are sought on whether it would it be helpful to include in the regulation some examples of the 'intelligent testing' approach.

It would not be helpful to include in the Regulation some examples of the 'intelligent testing' approach. This properly belongs to Technical Guidance.

Q (iv). Comments are sought on the adequacy or otherwise of the data requirement at the 1 tonne level as set out in Annex V.

The Annex V data set might be more closely based on the existing reduced notification data (i.e. Annex VIIB of Directive 92/32/EEC). In particular some of the physico-chemical properties data seem unnecessary at this first stage of registration, as they are not needed for hazard identification or risk assessment and simply characterize the substance.

Furthermore it may be possible to use literature data, non-GLP 'in house' measurements or predictions for some physico-chemical properties data, depending on the particular substance, the endpoint and the value of the parameter. This is because for some results there can be considerable uncertainty in the value of the parameter without affecting the outcome of the hazard or risk assessment. An intermediate solution, if the option of deferring some of the current Annex V physico-chemical properties tests to Annex VI is unacceptable, might be to allow literature or non-GLP data or calculations to be used for these non-essential endpoints. Our suggestions are:

Melting/freezing point, needed mainly to characterize the substance should be kept in Annex V but the use of non-standard test data should be allowed but not the calculation as this may be unreliable.

Boiling point, needed mainly to characterize the substance, should be kept in Annex V but the use of calculation or non-standard test data should be allowed.

Relative density, needed mainly to characterize the substance should be deferred to AnnexVI.

Vapour pressure, used for environmental fate estimation, in estimating workplace exposures and to help select the exposure route for the acute toxicity studies should be kept in AnnexV.

Surface tension, used to help select the correct method for the partition coefficient and adsorption studies and in estimating the environmental effects should be kept in Annex V, but this test is often omitted, i.e. for poorly-water soluble substances.

Water solubility, used for environmental fate estimation, to decide if data waivers for the surface tension and hydrolysis tests are applicable and for environmental classification of poorly-water soluble substances) should be kept in Annex V.

Partition coefficient, used for environmental classification and as a predictor of bioaccumulation should be kept in Annex V.

Flash point or flammability, which depends on the physical state of the substance is needed for classification and should be kept in Annex V, perhaps with the option to use UN transportation tests.

Explosivity is needed for classification should be kept in Annex V (the result is often predicted negative without testing), and perhaps with the option to use UN transportation tests.

Oxidising properties are needed for classification and should be kept in Annex V (the result is often predicted negative without testing), and perhaps with the option to use UN transportation tests.

Granulometry used to help decide the exposure route for the acute toxicity studies and for occupational exposure assessment should be kept in Annex V.

It would be useful to bring forward the *ready biodegradation* test from Annex VI to Annex V, as this is essential for classification regarding 'dangerous for the environment' and for environmental fate estimation for environmental risk assessment. Furthermore, it may be beneficial to bring forward the *hydrolysis* test from Annex VI to Annex V, as this information often helps with the water solubility, surface tension, partition coefficient and acute *Daphnia* toxicity tests and it may be needed for prediction of environmental fate.

Some studies could be deferred to Annex VI. The modified Annex VI data would include the studies transferred from Annex V. In addition it may be that the toxicology information could be deferred to Annex VII.

Q (viii). Comments are sought on whether the OECD 422 test provides the information needed on reproductive and developmental function.

The general belief is that the pre-mating dosing is inadequate and does not cover all of the cycle of male development. However, if that test has been done to comply with the OECD programme, then doing a one-generation study is not desirable on animal welfare grounds. It would be useful not to create unnecessary transatlantic differences. Ideally the OECD422 study should be updated to remove these problems – i.e. to become a proper combined repeated dose/reproductive toxicity study.

It seems unnecessary to routinely require both the reproductive/developmental toxicity screening test (OECD 421) and the full developmental study (OECD 414), especially in addition to a 28-day repeat-dose study. An option might be to follow the OECD/ICCA strategy of using a 28-day repeat-dose study plus the combined reproduction / developmental toxicity study (OECD 421) or to conduct only a combined repeat-dose / reproduction/developmental toxicity study (OECD 422). However, some toxicologists do not favour this latter study (OECD 422) on scientific grounds, so it is important to give registrants the option to choose the first strategy, even though this uses more experimental animals and costs a lot more. In any case, it seems unnecessary to require both a screening developmental toxicity study (i.e. OECD 421, or OECD 422 if the above suggestion is accepted) and a full study (OECD 414), so perhaps the full OECD 414 study could be deferred to Annex VII.

Q (ix). Comments are sought on whether 2 or 3 *in vitro* mutagenicity screening tests (i.e. information for 2 or 3 genetic endpoints) should be provided as standard at the 10 tonne level.

The present technical guidance for chemicals has been a long time in development and should not be changed without good cause. Both an *in vitro* cytogenicity study and a gene mutation study in mammalian cells are listed in Annex VI in addition to an Ames test as part

of Annex V. Under the current notification testing requirements (see the revised 2003 risk assessment TGD), the second *in vitro* mammalian cell test is normally only needed at Level 1 and then only if the Ames and *in vitro* chromosome aberration tests are both negative. If either test is positive, further testing is required, but this may be either *in vitro* or *in vivo* depending on the results and other information on the substance. Therefore it seems adequate to require one *in vitro* mutagenicity test in mammalian cells in Annex VI, and defer the second to Annex VII.

Q (xiii). Comments are sought on taking a case-by-case 'intelligent testing' approach for higher tonnage substances rather than going through a 'tick-box' approach.

The UK has always preferred having the ability to apply intelligence. A 'tick box' approach has the advantage of uniformity and the disadvantage that, generally, the maximum number of tests results. There are clear animal welfare problems with a 'tick box' mentality.

We hope the above comments are of assistance. Please do not hesitate to contact us should you wish us to expand on any of these points.

Yours sincerely,

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Notes:

The Royal Society of Chemistry is the UK Professional Body for chemical scientists and an international Learned Society for the chemical sciences with 46,000 members world-wide. It is a major international publisher of chemical information, supports the teaching of the chemical sciences at all levels and is a leader in bringing science to the public.