

RESPONSE OF THE UK ROYAL SOCIETY OF CHEMISTRY

REACH REGULATION PUBLIC INTERNET CONSULTATION

A - Contact details

(Please enter your contact details)

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B - Confidentiality

- I would like my identity to be kept confidential**
(please leave this box blank if you agree that your name and organisation will be identified on the Commission's website for public access)

C - SME

- Are you a small or medium sized enterprise?** ([EC legal definition](#))
please specify the number of members:

Approx 300 staff
Approx 45000 members

D - Description of your primary activities

(please select only one of the following)

Industry

- Manufacturer**
 Importer
 Downstream user
 Distributor
 Trade association
 Other

NGO

- Environmental group**
- Animal welfare group**
- Trade union**
- Consumer organisation**
- Other : Learned and Professional Society**

Public authorities

- EU Member State government
- Other national government
- International organisation
- National or regional authority

Other

- Academic or technical institute
- Worker in chemicals or downstream industry
- EU citizen
- Other

Please structure your response according to the following topic areas and provide comments or proposals for amendments to the legislation. Please comment on those topics that are relevant to you.

When finished, please send your document to the following address:
entr-env-ec-reach@cec.eu.int.

Thank you in advance for your contribution.

E - Topics :

1. Duty of care
2. Chemical safety assessment
3. Information flow
4. Registration procedure
5. Polymers
6. Intermediates
7. Data requirements
8. Data sharing/consortia formation
9. Procedures for downstream users
10. Evaluation procedure
11. Authorisation procedure
12. Restrictions procedure
13. The Agency
14. Other

RESPONSE OF THE UK ROYAL SOCIETY OF CHEMISTRY

We are concerned that the complexity of the proposals could lead to restrictions based on hazard rather than on risk. Chemical risk assessment is a skilled task and this expertise is unlikely to be available in the bulk of smaller organizations. There's a need for simplified risk assessment procedures, and the 'COSHH Essentials'

TOPIC 2 – Chemical Safety Assessment

The proposals are based on twentieth century toxicity testing and are likely to be overtaken by developments in toxicology within 10 to 20 years. The regime should be flexible enough to adapt to such developments, eg those resulting from the fast developing area of genomic science. For example it will be necessary to adapt to the massive change that is likely in the philosophy and approach to

chemical safety away from testing regimes to the use of SAR and biomarkers for early signs of disease which will occur within the time span of the proposals. An ATP Committee should be established to ensure that these changes are included in the regulatory system far more quickly than is currently the case for single new tests.

The lack of pre-Registration consultation opportunities will mean a conservative approach to the conduct of toxicity studies (particularly at the 10 tpa level) in order to avoid dossier rejection because QSAR/read across, etc., may not be accepted by the Agency or Competent Authorities. Thus apart from testing costs there appears to be little incentive to minimise animal testing - in fact quite the opposite. Possible incentives to minimise animal testing could include prescriptive testing guidelines, a charge per animal, and allowing greater use of pre-existing data from within or outside the EU. Possible solutions include clear technical guidance and opportunities to consult the appropriate regulator (eg the ECA or the rapporteur Competent Authority).

In addition validating 'in vitro' alternatives is a slow process and this also inhibits reductions in animal testing. With the present state of knowledge [Q]SARs are primarily a priority setting tool. Particular gaps in 'in vitro' testing include skin sensitization, skin irritation, endocrine disruption, and reproductive toxicity. Possible solutions include extra EU resources for developing and validating alternative tests.

TOPIC 7 – Data requirements

Only data that has real value should be required. It is totally unethical to require the use of animal testing simply to complete a bureaucratic box-ticking exercise. This is particularly true for those 'existing chemicals' that have been in use of many years with no apparent adverse effects. Thus the approaches set out in Annex IX must be interpreted liberally in order to minimise testing. It must be made clear in guidance to industry that the Competent Authorities will expect the full flexibility offered in Annex IX to be fully implemented. Also there needs to be a more open debate between the Competent Authorities and Industry and where appropriate a willingness to accept a less than perfect dataset. Further, there will need to be a device (possibly a suitably set up technical committee with experts from a wide range of sources, and particularly from professionals working in industry) to guide the Competent Authorities in their decision making concerning the acceptability of Annex IX explanations for omitting tests. This should be a risk-based process. In other words low exposure would justify less hazard data but again technical guidance is needed to ensure transparency and consistent decision-making.

Testing should be carried out by approved laboratories in accord with approved methods and quality control systems. However the regime should also ensure that the sections of Annex IX that allow use of historic data that may have been produced in other ways are fully utilised if the data are judged reliable.

The implication seems to be that applications will go to the Competent Authorities in different EU member states in rotating order. If so there is a clear need to ensure consistency across the EU. This could be achieved by issuing detailed technical guidance notes to the Competent Authorities. Alternatively there could be a single EU-wide Competent Authority. However to ensure confidence in the system the best solution may be the technical committee proposed above.

Overall the proposals have been constructed from a range of 'building blocks'. They require careful editing to provide consistency and remove ambiguity. For example it would be helpful if all the exemptions were included in Section 1 which defines the scope.

TOPIC 8 – Data sharing/consortia formation

There are workability issues that need to be resolved around submissions by consortia. For example it is not entirely obvious what will trigger the data

requirements. Is it the tonnage manufactured or imported into the EU per company? Or if the tonnage criteria are exceeded by a consortium but not by each member would this also trigger the data requirements? This needs to be made absolutely clear because it could lead to 'controls' that are based on administrative factors rather than on actual risk to the environment. A related area which would benefit from clarification is how to deal with multiple importers of a substance made by the same non-EU manufacturer. Under the current system the non-EU manufacturer can nominate a sole-representative notifier to cover all the importers (but in this case the tonnage is intended to be aggregated, as the notification testing is based on EU supply per manufacturer). Where an existing substance (eg glycerol) has a wealth of downstream users the relatively short time available and the relative lack of information and technical expertise among many downstream users is likely to mean there will be problems in setting up the consortia.

An appeal procedure needs to be available for those substances where consortium formation is a particular problem and is hampered by an excessive multiplicity of downstream users. That appeal procedure must be to a body that is separate from the regulatory authority. A 'stakeholder' committee might be a useful forum for deciding on the appropriateness of any extension.

TOPIC 12 – Restrictions procedure

We are concerned that the complexity of the proposals could lead to restrictions based on hazard rather than on risk. Chemical risk assessment is a skilled task and this expertise is unlikely to be available in the bulk of smaller organizations. There's a need for simplified risk assessment procedures, and the 'COSHH Essentials' approach developed by the UK Health and Safety Executive might provide a suitable model, though it would probably be difficult to extend beyond workplace assessment. There is an apparent paradox between the CSR which requires simplified risk assessment and the technical guidance which requires full assessment. There is also a danger that the burden of risk assessment will fall on those further down the supply chain who are least able to do it. Indeed it seems likely that the ability of small and micro businesses throughout the EU to deal with information on hazards and risks has been greatly overestimated. This view is confirmed by recent work on the comprehension of substance related information that was sponsored by the UK Health and Safety Executive. The transfer of information within the supply chain will be further hampered by the different languages involved.

Stakeholders should be involved in developing detailed guidance that is not too complex for the intended users. This guidance should lead to common forms that show the information and process required. The emphasis should be on simplicity and EU-wide consistency. This will prevent the waste of considerable effort and expense among SMEs, micros, and other organizations. It will also prevent unnecessary transfer of information within the system – noting that when organizations are unclear about the information required they usually overcompensate by generating extra data.

Production levels can be a poor indicator of potential harm. Even if tonnage/toxicity thresholds are used it seems likely that they could be better designed to reduce the number of new chemicals to be considered and hence make the process more workable.

It is essential that the proposals ensure that any chemicals that are withdrawn are those that are least desirable for health, safety or environmental reasons. As presently drafted there is a danger that in some cases the 'best' or 'safest' substances may be withdrawn simply because they generate insufficient profit to cover testing costs.

TOPIC 14 – Other

- (a) The Chemical Safety Report seems to be required before anyone other than a customer can use any substance, regardless of the registration status. If academic laboratories are considered to be downstream users this would be unworkable because of the very large number of substances involved. We assume that the R&D exemption from the REACH proposals will be extended to the chemical safety report requirements of the duty of care provisions. This can be justified because the R&D community already has in place satisfactory provisions to protect the health and safety of its workforce and the quantities of material involved pose no significant risk to the environment. Chemical Safety Reports should be proportional. Current Safety Data Sheets can be unnecessarily alarming especially for small-scale users such as school laboratories. The information provided should enable precautions to fit the scale of use.
- (b) There does not seem to have been a proper assessment of the need for, and available supply of, people with the skills and expertise to generate and interpret data required by the proposals. For example there may be insufficient toxicologists and eco-toxicologists to properly apply the REACH testing requirements. Without such expertise SMEs in particular may find it difficult to prepare and understand chemical safety reports, especially those SMEs that use a large number of materials. Also chemists and regulatory affairs professionals will be required in order to carry out chemical safety assessments and registrations, and in particular for risk assessments. It could require years to build up a suitable body of expertise to meet the requirements of the new system. The needs for different professionals within the various timescales relating to the proposals should be properly assessed. Once this has been done professional organizations and teaching/training bodies can plan accordingly.
- (c) The regime should be transparent. Transparency is one way in which public confidence can be improved. In principle we support open access to REACH data wherever possible. However information about formulation and intermediates is often a commercially sensitive issue for industry. The public access database should contain a 'robust summary' and in general data made available to the public should be presented in such a way that its not open to misunderstanding.
- (d) There is a danger that the proposals will inhibit innovation. Innovation is essential to achieving sustainable development. Chemical innovation should be seen primarily as part of the 'solution' to sustainable development rather than as part of the problem.
- (e) The criteria for 'articles' are too vague. Consumers generally encounter products and preparations rather than 'raw' chemicals. While this is a generic issue far more clarity and support will be required to help downstream users to engage with the process of gathering information for risk assessments on substances in articles.
- (f) To help downstream organizations prepare, both financially and technically, for the introduction of the new system, there should be a clear set of criteria for what constitutes a 'downstream user'. There should also be practical examples of where this classification ends.