REACH- Outcome and implementation aspects

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Role of the DG-SANCO Scientific Advisory Committees.

* To provide expert, independent advice to Commission Services on the risks to human health and to the environment from chemical, biological and physical agents and processes
* The focus is on risk assessments, the committees are not involved in risk management issues

Scientific committees- range of current activities.

- SCHER (formerly CSTEE) – ECB risk assessment reports, indoor air quality, endocrine disrupting chemicals.
- SCCP- Cosmetics including hair dyes, fragrances, preservatives. Other consumer products.
- SCENIHR- nanotechnology, medical devices, smokeless tobacco products.

REACH- Some of the issues of concern to the scientific committees.

i) Is prioritisation based on tonnage appropriate to achieve a high level of protection of public health and the environment?

ii) Is the proposed methodology adequate for the purpose?

REACH- some of the issues of concern to the scientific committees contd.

iii) How will the data from REACH be used?

iv) What will the role of independent expert scientific advice be?

v) Is the required expertise in risk assessment likely to be available?

REACH – i) concerns on the use of tonnage for prioritisation purposes

Issue.

A key aspect of risk is exposure of humans/environment. Tonnage is an unreliable surrogate for exposure. A prioritisation system is mentioned but its nature is very unclear.

Conclusion.

A transparent scientifically validated algorithm needs to be developed that takes into account uses that will inevitably result in human/environmental exposure, structural alerts and physical chemical properties.

REACH- ii) is the proposed methodology suitable?

Position of the Committees on alternatives.

‘The committees fully encourage the continued development of improved risk assessment methodologies. To be clear when validated, as being as effective for the assessment of chemical safety as currently accepted methods, alternative methods should be used to replace animal experimentation’.

REACH- ii) Is the proposed methodology suitable?

Principle.

There is a widespread confusion between hazard and risk. A distinction must be made between:

a) tests that are suitable to identify acute and chronic hazardous properties

b) tests that enable acute and chronic hazard characterisation (eg dose response relationships).

REACH – Issues ii) suitable methodology

- Information on physico-chemical properties, acute toxicity, local irritation, sensitisation and mutagenicity is important but it can only be used to identify hazard
- For the foreseeble future findings from animal/human studies will also be necessary to enable risk assessments to be performed.

REACH- issue ii) conclusion

A flexible, tiered approach to risk assessment is required that is scientifically valid rather than a prescribed battery of tests. Further work is needed to identify this ‘intelligent testing strategy’.

REACH- issue iii) How will the data be used

It is unclear:

whether data obtained under REACH will be able to be used for other purposes eg cosmetics

- how issues such as exposure to chemicals in particular physico-chemical forms eg as nanoparticles will be addressed.

REACH- iii) data use contd

It is unclear whether the data will be available and in what form:

- to set up/ further develop a SAR/QSAR data base
- To the scientific committees considering the risk from the same or related chemicals
- To scientific researchers seeking to improve the methodology.

REACH-Issues iii) Conclusion

The REACH process should be a learning one where previous data/experience is used to improve the quality and scope of the risk assessment process. It is vital therefore that the data is available to:

* develop an SAR/QSAR
* for methodology development purposes

REACH- Issues iv)

- ***Areas where the SC's could contribute <u>prior</u> to the establishment of the Chemicals Agency eg.***

  a) development/evaluation of the prioritisation framework

  b) review of new TGD proposals

  c) development/evaluation of a framework for comparing the risks of possible substitutes

REACH- Issues iv)

- ***Areas where the SC's could contribute <u>after</u> the establishment of the Chemicals Agency eg***

  a) arbitrating where there is conflict on the interpretation of data on particular chemicals

  b) auditing risk assessments on random/key chemicals

  c) cooperation to ensure no unnecessary duplication of effort or conflicts in data interpretation

REACH Issues v) Availability of expertise

- REACH will only be credible if the standard of evaluation is high and the process is seen to be objective.
- Industry, Member States and the Agency will require many risk assessors. However there is a progressive shortage of the requisite expertise and an increasing demand for the requisite skills.

REACH- Issues v) expertise

A coordinated effort by commission services, industry, higher education establishments and member states is embarked on to ensure that the requisite expertise is available when it is needed.

REACH- Conclusions on a scientific committee perspective

- REACH is potentially a significant advance in ensuring a high level of human health and environmental protection in respect of existing chemicals.
- A transparent scientifically sound algorithm must be developed for prioritisation purposes.
- It is important that the potential application of particular methodologies are properly assessed
- Work needs to start promptly in a number of areas including: building an SAR data base, the identification of priorities for better tests and the training of risk assessors