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TEXTILES INDUSTRY ADVISORY COMMITTEE

New European Chemical Strategy (REACH) – Current developments

Issue

- 1 To decide on TEXIAC's position and its contribution to the future of the debate.

Timing

- 2 The EC is likely to publish the final text of the draft legislation by the end of October. TEXIAC will then have the opportunity to advise the HSC on the implications for occupational health and safety in the industries it represents.

Recommendation

- 3 To note developments and if agreed, to provide comments to the Health and Safety Commission to feed into HSC/E's response to DEFRA.

Background

- 4 On the 7 May DG's Environment and Enterprise, jointly published a draft proposal for the new REACH system. At the same time, they launched an eight-week Internet consultation on the 'workability' of the system. Annex A summarises the main aspects of the proposal.
- 5 The EC received 7,000 responses including a response from the UK Government. These can be found on DG Enterprise's web site <http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/contributions.htm>
- 6 The European Commission is currently holding an internal debate before publishing the final text of the draft legislation. This is likely to be at the end of October 2003.
- 7 Once the final text has been adopted by the European Council and Parliament, Member States have the opportunity to negotiate and suggest amendments before it is finally agreed by the Parliament.
- 8 DEFRA are the lead department on REACH and they will co-ordinate UK responses in formulating the line to be taken in UK negotiations on the legislation.

Discussion

- 9 At present, thousands of chemicals that have never been tested for their impact on human health are being sold and used in the EU because they were already in use when current legislation was introduced. The REACH proposal is to remove the distinction between new chemicals, that have been tested, and existing chemicals, about which there is varying knowledge.

- 10 The registration and evaluation exercise determines whether the chemical is of sufficient concern to require authorisation. Authorisation entails approval for every use before it can be sold for that purpose, or authorised nationally. It follows that authorisation for certain uses could be withheld. Businesses would have to 'make a case' for using substances, rather than at present, relying on regulators to control or ban the use. Elimination or substitution would therefore come more to the forefront.
- 11 Although there are likely to be significant implications for downstream users of chemicals, the Committee can only consider the impact in health and safety terms. Although there may be positive benefits, the present proposals also contain some negative aspects. There is the potential for overlap between the new proposals and existing health and safety legislation which could lead to confusion and present an extra layer of requirements. There is also some concern about the competence of small downstream users to contribute to the Chemical Safety Report on how the chemical is used. This would have to be repeated for each substance and for every manufacturer that the user buys from. There could also be language difficulties to contend with. In addition, downstream users could face a huge volume of information in each of the CSRs subsequently supplied to them by the manufacturer/importer of each substance.
- 12 Comments on these aspects were made in consultation and may well be addressed in the final text.

Next steps

- 13 It is proposed that one or more members are given responsibility for assessing the final text once it is produced and briefing members. Any comments from the Committee will then go forward to the HSC.

The New European Chemical Strategy - REACH

The main themes of the new REACH system are:

- **Registration** of all substances manufactured or imported into the European Union in quantities above 1 tonne per year.

Completed registration dossiers must be submitted to the Central Agency and include:

- A Chemical Safety Report (CSR) for 90% of all intended uses including downstream uses
- Chemical Safety Assessment (CSA) – assessment of the risks posed to human health and environment from the use(s) of the substance
- Any proposed additional testing strategies
- Risk Reduction Measures to address the risks identified in the CSA
- Authorised uses for the chemical (for substances subject to authorisation)
- Classification and Labelling of the substance

(Inadequate dossiers will be rejected and manufacture cannot then take place)

- **Evaluation**: two types are proposed:
 - standard - evaluation of all substances manufactured or imported into the EU over 100 t per year. (Competent Authorities in the Member State where the registrant is based will be required to assess and agree any testing proposals put forward by the registrant.)
 - priority – evaluation of any carcinogens, mutagens, or reproductive toxins (CMRs), irrespective of tonnage. (A Member State (MS) with a concern over any part of the CSR may evaluate its contents and ask for supplementary data/information it considers necessary to complete the CSR and satisfy its concerns.
- **Authorisation** scheme for substances considered to be of most concern – CMRs, Persistent Bioaccumulative Toxins (PBT), very Persistent very Bioaccumulative (vPvB) and substances of equal concern to MS or Commission.

In order to gain an authorisation for specific use(s) Manufacturers, Importers or Downstream Users (M/I/DU) must submit:

- A Risk Assessment to the Agency or in cases where the substance is not placed on the market to the Member State that demonstrates the risks are adequately controlled. Where this is not possible the M/I/DU should provide;
- a Socio Economic Analysis (SEA) that shows the benefits of continued use outweigh the risks

Applicants must have considered substitution of an alternative as part of their SEA

- **Restrictions** scheme for substances that Member States or the Commission consider propose a risk to Human Health (workers, consumers and Members of the Public) or to the environment.

Either the MS proposing the restriction or the Commission must prepare a Risk Assessment and SEA to justify the restriction.

- **Duty of Care** provision that applies, regardless of the quantity of the substance being manufactured or used. M/I/DU must:
 - Manufacture or use their substance(s) in such a way that Human Health or the Environment is not adversely affected;
 - Ensure that their substance(s) are placed on the market in such a way as that Human Health or the Environment is not adversely affected;
 - Undertake a Chemical Safety Assessment, identify and apply appropriate measures to reduce the risks.
- **Central Agency** is proposed to undertake the central administrative duties of the system including:
 - Receiving, logging and assigning a number to the Registration dossiers;
 - Undertaking a completeness check of the dossier and communicate its findings to the Competent Authorities;
 - Maintain the database of registered substances
 - Recommend substances for authorisation
 - Appoint Risk Assessment and SEA committees
 - Prepare Community restriction dossiers
 - Maintain a publicly accessible databases for Authorisation decisions, SEA opinions and the Classification and Labelling of substances
- The full proposal and explanatory information can be obtained from:
- <http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/consultation.htm>