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HEALTH AND SAFETY COMMISSION

UPDATE ON THE EUROPEAN COMMISSION'S 'STRATEGY FOR A FUTURE CHEMICALS POLICY'

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Issue

1. The European Commission's (EC) Strategy for a Future Chemicals Policy – Adoption of a proposal for new EU Chemical Legislation – REACH and proposals for handling essential briefing.

Timing

2. Routine.

Recommendation

3. That you:

- note the imminent publication of the adopted text.
- note the practical arrangements for handling including the role of the chair in clearance and the use of your Advisory Committee on Toxic Substances (ACTS) and its subgroup SCHIP.

Background

4. The EC published its White Paper a 'Strategy for a future Chemicals Policy' in February 2001. The paper proposed a new scheme of Registration, Evaluation and Authorisation of Chemicals (REACH) to manage their manufacture, importation and supply. More detail is attached at Annex A.

5. In May 2003 DGs Environment and Enterprise jointly published a draft proposal for an EU Regulation to introduce the new REACH system. MISC paper 03/22 provides more information. The EC decided that for this complex proposal a Stakeholder check on system workability would be appropriate. This launched an 8 week public Internet consultation on 16 June 2003. Following cross-Government consultation Defra drafted and sent a UK response. The co-authors of the proposal

DG's Environment and Enterprise, received some 7000 responses on the workability of the proposal. These have been published on DG Enterprises website.

6. Following the Internet consultation a significantly revised proposal was developed and adopted by the Commission on 29 October and will now be forwarded to the European Parliament and the EU's Council of Ministers for adoption under the co-decision procedure. Pending publication in the Official Journal an 'unofficial' version of the proposal is available from the DG Enterprise website:

<http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm>

HSE officials have made an initial analysis of the text. A summary is at Annex B.

Argument

7. Concern about the environment and public health from the environment was the principal driver for the REACH proposal. It was never intended to address explicitly issues relating to occupational health and safety (OHS). Despite this the text does provide opportunities for OHS gain, for example, through better information on the chemicals used at work. There is also the potential for damage, for example, if existing finite OHS resources are diverted in to work on REACH, or unacceptable risk management advice is promulgated.

Consultation

8. Following publication of the official text, the UK will develop an Explanatory Memorandum (EM) setting out broad negotiating positions for the scrutiny committees. The protocol is to clear the EM at Ministerial level within 10 days. Defra will coordinate this procedure as the lead department for REACH.

9. We expect the text to be published officially by 11 November, which does not coincide with the timetable for HSC meetings. We therefore propose to draft a submission for Des Browne (which will largely be based on the UK position Statement and 'workability' response (MISC 03/04 and MISC03/22)). We will clear this through the Chair and involve the Advisory Committee on Toxic Substances and its sub committee the Standing Committee on Hazard Information and Packaging as much as is practicable.

Presentation

10. DWP Ministers have been briefed on REACH and formally agreed the UK 'workability' response to the EC. DEFRA and DTI Ministers have taken an active interest in this dossier, which is considered the most important legislative proposal affecting the viability of the chemical industry for many years.

Costs and Benefits

11. The EC had originally estimated the EU-wide costs of the proposals to be in the region €18-32billion over a period to 2020 taking into account both direct and indirect costs. The EC now claim this figure has been reduced by 80% to €2.8-5.2 billion over an 11 year period as a result of the changes made following the Internet draft.

An extended impact assessment produced by the EC anticipates the benefit to the environment and human health in the order of €50 billion over a 30 year period. We are studying the report findings in more detail to establish the extent of their validity. However our emerging position is to have serious reservations over any claims for major OHS benefits.

Financial/Resource Implications for HSE

12. Defra have commissioned a Regulatory Impact Assessment on the proposal; this work is at an early stage. The financial/resource implications for HSE/UK government remain highly uncertain. Much will depend on the practical arrangements for the delivery of REACH . This is not seen as a function for HSE.

Environmental Implications

13. Defra have the policy lead on REACH, which covers environment and human health via the environment.

Action

14. HSE officials will continue to work with DEFRA and OGDs on the development of the new system. In addition, we will continue to up date the HSC on progress with REACH and the development of the UK negotiating line.

The New European Chemical Strategy - REACH

Background to the proposal for a EU Regulation on Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH)

1. The European Commission (EC) published a White Paper for a 'Strategy for a Future Chemicals Policy' in February 2001. The Strategy resulted from an EC review of four pieces of chemical legislation that currently form the basis of chemical human health and environmental hazard, and risk identification:
 - Directive 67/548 on classification, packaging and labelling of dangerous substances (HSE responsibility)
 - Directive 88/379 on classification, packaging and labelling of dangerous preparations (recently replaced by 1999/45/EC) (HSE responsibility)
 - Directive 76/769 on marketing and use (Defra responsibility); and,
 - Existing Substances Regulation (793/93) (joint HSE and Defra responsibility)
2. The White Paper recommended the establishing of a single system for reducing risks to the environment and human health by a new scheme, mainly via the Registration, Evaluation and Authorisation of CHemicals (REACH).
3. In May 2003 DG's Environment and Enterprise jointly published a draft proposal (not yet formally adopted by the EC) for an EU Regulation to introduce the new REACH scheme. The draft proposal is based on the White Paper and takes into account the results of EC working groups (Member States, NGOs and business), Environment Council conclusions and European Parliament recommendations.
4. The main themes of the new REACH system are:
 - **Duty of Care** This broad provision requires all those manufacturing, importing or using substances to carry out a chemical safety assessment and take appropriate risk reduction measures to address any risks identified. The requirement applies regardless of the quantity of the substance being manufactured or used.
 - **Registration** A requirement on industry to collect, collate and submit data on the hazardous properties of all substances manufactured or imported into the EU in quantities above 1 tonne per year. In addition, industry should prepare risk assessments and provide safety information to downstream users.
 - **Evaluation** There are two types of evaluation.
 - Standard evaluation covers all substances manufactured or imported into the EU over 100 tonnes per year. It requires Member States to assess and agree any testing proposals put forward by industry as part of their registration package.

- Priority evaluation provides a mechanism for Member States to review registration packages and consider whether more information is required.
- **Authorisation** Industry will need to gain authorisations for the use of substances considered to be of very high concern. These are substances that are identified as carcinogenic, mutagenic or toxic to reproduction (CMRs); persistent, bioaccumulative and toxic substances (PBTs); substances that are very persistent and very bioaccumulative (vPvBs); and substances demonstrated to be of equivalent concern, such as endocrine disruptors.
- **Restrictions** The provisions enable risk reduction measures to be introduced across the European Community where this is shown to be necessary. Member States or the Commission prepares proposals for restrictions.
- **European Chemicals Agency** The provisions create an agency for managing the technical and administrative aspects of the REACH system at Community level.

Proposal for a Regulation of the European Parliament and of the Council – REACH – Overview of the changes following ‘Workability’ Internet Consultation.

1. REGISTRATION

- The Agency now has sole responsibility for the registration process.
- Requirements have been simplified for the 1-10 tonne level. Chemical safety reports (CSR) do not have to be submitted. However, Chemical Safety Assessments (CSA) will need to be produced and the information kept available.
- Polymers (including the monomer constituents) have been exempted but may still be subject to authorisation & restriction.
- Limited form of registration for certain isolated intermediates. Requirements for transported intermediates under strict control have been reduced.
- For Downstream Users (DU) the requirement to undertake CSAs and produce CSRs has been limited.

2. TESTING REQUIREMENTS

- Acute toxicity has not been included in 1-10 tonne data requirement.
- The in vitro cytogenicity study in mammalian cells has been moved from Annex V (1-10te) to Annex VI (10-100te)
- Text clarifies that data sharing is obligatory.
- The information required at the 1-10 tonne level will be reviewed 6 years after the establishment of the Agency (NB: before registration is required at this level).
- There are also several changes to the environmental information requirements in the Annexes.

3. INFORMATION EXCHANGE

- Manufacturers and Importers CSRs should cover known uses. DUs should provide details of their uses. In cases where DUs decide not to disclose this information, they need to produce the CSR.
- The primary tool for transfer of information through the supply chain is now the safety data sheet (SDS). The SDS should reflect the conclusions of the CSA. (New guidance is provided in Annex 1a)
- The proposal now allows for the production of a single CSA for a preparation, instead of having multiple CSRs associated with the preparation (new guidance is provided in Annex 1b).

4. EVALUATION

- Dossier & Substance evaluation replace Standard and Priority evaluation
- Dossier evaluation requires authorities to examine proposals for testing & allows them to check that dossiers are compliant.
- Substance evaluation allows authorities to consider whether industry should be required to obtain more information for CSA.
- Both forms of evaluation are required to be carried out by the same Member State to which the dossier was allocated.
- Agency has greater responsibility for the smooth running of the system and monitoring decision-making.
- Agency to develop criteria for prioritisation of Dossier Evaluations based on a risk based approach – criteria will include hazard data, exposure data and tonnage.

5. AUTHORISATION

- Clearer reference to substitution.
- Companies encouraged to present substitution plans that will influence the authorisation decision.
- Definition of adequate control – authorisations shall be granted if the risk to human health and/or the environment is considered adequately controlled in accordance with risk characterisation requirements of Annex 1 section 6
- Proposal for national authorisation by individual Member States removed.

6. CONFIDENTIALITY/INFORMATION ABOUT CHEMICALS

- Stricter protection of confidential business information
- All information that is non-confidential will be available on request.

7. THE AGENCY

- An Appeal Board has been included in the Agency.
- Agency has boosted powers with regard to data sharing. It is empowered to make information available to subsequent registrants if no deal has been reached with previous registrants of the same substance.

8. CLASSIFICATION & LABELLING

- A proposal for a new Directive to amend Directive 67/548/EEC in the light of REACH is included in the document. A helpful explanatory memorandum is included.

- The amendments are required to delete the paragraphs related to notification of new chemicals & transfer test method Annexes to the REACH Regulation.
- The Commission intend to propose the inclusion of the globally harmonised system on the classification and labelling of chemicals (GHS) in EU law as soon as possible. The Memorandum states that because GHS has only recently been formally adopted, it is too early to put forward an implementation proposal. However, the Commission intends to come forward with the necessary proposal to adopt GHS at the same time as the final adoption of the REACH legislation.

9. ARTICLES

- Registration of substances in articles only if the substances are classified as dangerous, are intended to be released from the product and are present in the 'article type' in quantities over 1 tonne per year. In addition, specified information (not a registration) must be notified to the Agency if the release is associated with a function of the article that is not intended.