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HEALTH AND SAFETY COMMISSION
ADVISORY COMMITTEE ON TOXIC SUBSTANCES
New European Chemical Strategy
A paper by Graham Tompkins

Issue

1 The New European Chemical Strategy (NECS): update and forward look to legislative proposals.

Timing

2 Routine.

Recommendation

3 That ACTS notes:

- recent developments on the NECS;
- the most recent HSC MISC paper - MISC/02/19 (Appendix 1) updating the Health and Safety Commission (HSC) on the NECS;
- a paper by UK 'Officials' setting out their understanding of the priorities and objectives for the UK in relation to the NECS (Annex 1 of Appendix 1).

Background

4 The European Commission (EC) published its White Paper for a future chemicals policy in February 2001 that proposed a system called REACH, which requires chemicals manufactured in quantities of greater than 1 tonne to be registered, those manufactured at greater than 100 tonnes to be evaluated and certain substances of high concern to be authorised.

5 Annex1 (HSC MISC paper) gives more background and information on recent developments.

Argument

6 The EC intend to finalise its legalisation by 2004, with legislative proposals produced by the end of this year. The EC are considering a possible informal consultation process during

the autumn but are anxious about whether this would lead to delay. DEFRA intend to consult within the UK to formally respond to the proposals.

7 There is still some uncertainty over the content of the legislation and its impact on Occupational Health and Safety. It is however clear that REACH will bring major change to the way chemicals are regulated in the UK. In an attempt to influence the EC and other member states, UK Government officials have been developing a UK position for Ministerial agreement.

Communication Plan

8 Not Relevant

Evaluation Plan

9 Not Relevant

Relevant Control Systems

10 Not Relevant

Consultation

11 DEFRA have the UK Government lead on the NECS and have established a 'rapid reaction sounding board' with a wide stake holder base for informal consultation.

12 HSE has consulted its own 'rapid response group' to contribute to HSE thinking as negotiations have progressed.

Presentation

13 DEFRA and DTI Ministers have been actively involved in the review.

Costs and Benefits

14 The cost of implementing the requirements of the new system are estimated to be between 1.7 – 7 billion euros depending on the number of chemicals to be registered and the level of testing required. This does not, however, take account of the impact on downstream users and seems to take as the baseline predictable costs to industry such as the ICCA initiative.

Environmental implications

15 The new system should provide the information necessary to control substances of concern (starting with the most harmful) because of their effect to human health and the environment.

European implications

16 The legislation will be far reaching effecting the legal base and the control regimes of all member states. It will additionally impact, to an unknown extent, on other European matters such as occupational exposure setting.

Devolution

17 Not Relevant

Other implications

18 Not Relevant

Action

19 Following legislative proposals we will consult ACTS members on the development of the HSE position.

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EU CHEMICALS REVIEW: OFFICIALS' WORKING PAPER APRIL 2002

Introduction

This paper sets out the working level understanding of the priorities and objectives in relation to the Commission's forthcoming legislative proposals for an EU chemicals policy.

Following the publication of the European Commission's White Paper for a future chemicals policy in February 2001, a comprehensive set of conclusions that gave clear directions for the shaping of new legislation were adopted by the Environment Council in June 2001. The European Parliament then adopted a report on the White Paper in mid-November 2001. In it, Parliament stated that authorisation should be limited to carcinogenic, mutagenic and reproductive toxins (CMR) and to persistent organic pollutants (POPs). This position differs from that of the Council Conclusions, which include persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances, and a call to study adding sensitisers. The Commission subsequently held a series of technical working groups to help inform it's thinking.

The time-scale for the process of developing new legislation is still unclear. Whilst the Commission has been asked by the Council to develop proposals by the end of 2001, the magnitude of the task and the different opinions of Council and Parliament have made this not possible. It is anticipated that publication of proposals is likely to occur at the end of the Summer this year, though there may be an informal consultation process earlier.

Overarching Objectives

Our overarching objectives in this area are to:

- Speed up process of testing, screening and assessing chemicals, whilst minimising animal testing to that necessary to protect human health and the environment.

- Be credible by being transparent (including a transparent process) and enforceable.

- Ensure that the competitiveness of the EU chemicals industry is enhanced, or at least maintained.

- Ensure an effective system for providing information to users about chemicals in products, which they buy and use.

- Ensure that as far as possible industry assumes full responsibility for managing the risks from chemicals.

More specifically, the following sections outline our position in particular areas.

A simplified and transparent system

We believe that the new EU chemicals strategy should be a streamlined, transparent and, where possible, simplified system that effectively identifies and prioritises chemicals of concern and takes early risk management action. This should ensure that risk assessment is used in a targeted way to deal swiftly with identified uses of concern. It is therefore, essential that implementation follows a realistic and achievable timetable.

We also believe that recommendations made in and lessons learned from recent initiatives such as the SLIM report of the Dangerous Substances Directive should be enshrined into the new legislation. This will ensure the resources required by MS authorities are used where they will have the greatest effect, and minimise the demands on business.

A simplified and transparent system is also important, from a competitiveness perspective, such that REACH and other key components of the new regulatory regime conform to UK regulatory best practice.

Scope of the EU Chemicals Strategy

We believe, in principle, that all substances should be subject to new EU Chemicals legislation, with appropriate ways of dealing with, for example, polymers and chemicals of minimal exposure (e.g. intermediates). However, we recognise the need to avoid unnecessary duplication of any existing legislation for substances subject to positive approval.

We further believe that there should be a phased approach to the scope of the legislation to ensure the new system does not suffer the fate of previous schemes. This move to the new system could include:

- piloting of the new system (ESR was never piloted) using a limited number of priority substances in the first year of its operation,
- progressive integration of new substances (keeping a modified new substances system for a few years, allowing concentration on existing substances for the first few years of the system),
- making best use of the resources spent on existing programmes (using chemicals assessed under ESR to pilot authorisation and rapid risk management, putting to one side chemicals that have been previously assessed in great detail e.g. lead).
- for the environment, a phased approach that should prioritise substances that have a wide dispersive use and, for authorisation, should initially focus on chemicals of most concern (e.g. PBTs),

- for health concerns, for example in the workplace, a phased approach alongside the environment priorities as the highest exposures to chemicals are likely to be to workers.

Minimisation of animal testing

We strongly believe that vertebrate animal testing should be kept to the absolute minimum, whilst ensuring that sufficient information is available for decision-making, for health and environmental protection. Reducing the need for animal testing will ensure that the EU strategy will not lead to an excessive burden on industry. In addition, where alternative, validated test methods are available they should be used.

Data sharing should be strongly encouraged by promoting a preregistration stage that will allow companies that manufacture the same chemical to form consortia, and work towards one registration for each manufactured substance. This could be further encouraged by incentives such as reduced fees and longer time periods for registration.

We believe that animal testing can be minimised by having a registration system that is sufficiently flexible to allow waiving of certain animal tests if other information is available which allows decision making. The registration system should also offer the opportunity for decision making by authorities and make use of scientifically appropriate *in vitro* tests and computer models for health and environmental hazards. Any additional information should only be required where it is needed to ensure adequate control of the substance, not merely to complete a data set.

For substances produced/imported in quantities less than 10 tonnes we believe that where suitable methodology is available, testing for registration purposes should be confined to *in-vitro* methods only (and *daphnia*) - sufficient to identify environmental and human health hazards. In addition, we believe that testing above the base-set or its equivalent, should be based on intelligent strategies to gather relevant information (e.g. focussing on endpoints of concern, grouping of chemicals) to limit the amount of testing. It is essential that the system deal with chemicals in a intelligent way, for example, positive results in *in vitro* screening tests not automatically leading to *in vivo* testing when the information to hand is sufficient to determine the risk management strategy required.

We also believe that validated *in-vitro* test methods for endocrine disrupters should be introduced into the basic information package for substances over 10 tonnes (for screening purposes) as soon as they are available.

Chemicals in products

We believe that the EU policy on products is workable and that it does not impact adversely on industry. In particular, we believe that:

a) future EU legislation should have clear definitions of product and article;
b) chemicals should be prioritised according to risk posed as opposed to relying totally on tonnage use;
c) REACH should have adequate resources to ensure a workable system and not to raise consumer expectations unnecessarily; and
d) consumers should have access to relevant and meaningful information on risks of chemicals.

Provision of Information

We believe that there should be a greater provision of useful information (e.g. on risks of chemicals) to the public and workers, not only via a central database, but also by manufacturers, importers, and formulators themselves. Consumers should have access to relevant and meaningful information but such information sharing should recognise issues of intellectual property rights.

In addition, there is a need for an effective system for providing information to downstream users about chemicals in products which they buy and use, so that they can take responsibility for managing the risks to the environment and to human health for their part of the life-cycle.

WTO and international commitments

We believe that the EU should work closely with wider international fora and activities (e.g. fully utilise information gathered under ICCA initiative), and should ensure that its proposals are consistent with WTO rules and other international undertakings. The EU should also seek to negotiate a global approach to managing chemicals as rapidly as possible.

The EU chemicals strategy should be consistent with commitments under the Stockholm Convention (i.e. concerning POPs and transport through the environment), the Rotterdam Conventions (i.e. concerning chemicals banned or severely restricted in two or more regions) and OSPAR agreement. It should also contribute to work under the OECD Programmes on Chemicals (e.g. Chapter 19, Agenda 21 targets and Test Guidelines).

We also believe that REACH should recognise and make maximum use of data and assessments produced under the OECD Programme, whilst investigating the use of bilateral agreements with other major trading blocks to bring forward mutual recognition of tests, data and good practice, in advance of agreement through other international fora, in order to maximise resource efficiencies and reduce the need for animal testing.

Innovation and the competitiveness of the chemicals industry

We believe the new EU chemicals strategy should encourage innovation and maintain or enhance the competitiveness of the EU chemicals industry whilst

addressing the urgent need to obtain information on existing chemicals. REACH must be streamlined, workable and place the minimum regulatory burden on industry necessary to ensure the adequate protection of human health and the environment. It should ensure a level playing field is maintained with non-EU producers and should not result in a disproportionate impact on discrete sections of industry, particularly SMEs.

We believe that the new legislation must guard against the scope for companies to 'piggy-back' on testing and registration carried out by other companies under REACH, whilst at the same time avoid the creation of undue barriers to market entry and prevent the consortia envisaged under REACH, acting in an anti-competitive manner (e.g. by forming cartels). Furthermore, the new EU chemicals strategy must avoid creating an incentive for 'environmental dumping', with companies moving manufacturing out of the EU to avoid the new controls.

In addition, adequate controls on access to commercially sensitive, shared date are essential to avoid stifling innovation. The system must respect IPR arrangements, as a vital element of competitiveness.

Occupational Health and Safety (OHS)

We believe that the new EU chemicals strategy should, where possible, build on the current OHS system, whilst sensibly dovetailing with existing requirements. Industry should be required, as part of their registration package, to propose 'Occupational Exposure Limits' which then can be prioritised by DG Employment for harmonisation.

In addition, we believe that sensitisers should be in the scope of the EU strategy, as this would provide a major benefit for OHS. The REACH system should identify and control them appropriately - including rapid risk management and/or authorisation for the most potent.

A pragmatic authorisation system

We believe that transparent and pragmatic criteria should be set for the authorisation of PBT, vPvB, CMR, and other identified substances of high concern (e.g. potent sensitisers). These should be based on sound science and be consistent with the criteria for taking action, developed by the EU Marine Technical Guidance Document (TGD) for PBT and vPvB substances, and the latest TGD for substances of concern to human health. Furthermore, the authorisation system should allow for the inclusion of other chemicals for authorisation (e.g. a safety net procedure for future priorities) where there is equivalent or greater concern than that for those meeting the criteria for authorisation (i.e. a flexible prioritisation mechanism for substances for authorisation, based on scientific review).

In addition, a pragmatic prioritisation process for authorisation should be established, subject to regular reviews, which enables chemicals of highest

concern to be dealt with in a manageable way first. For the environment PBT substances should be the first priority followed by vPvBs. Health concerns, such as category 3 mutagens and sensitisers, should also receive a high priority. Chemicals already controlled under Directive 76/769 on Marketing and Use should be a lower priority than unregulated chemicals. The authorisation of carcinogens and mutagens should take account of the requirements in the Carcinogens Directive.

DEFRA rapid reaction sounding board' members:

- Melvyn Whyte - Whyte Chemicals Ltd
- Tony Bingham - National Starch & Chemical Limited
- Tony Newbould - British Coatings Federation,
- Dr Peter Donnelly - Akzo Nobel (Akcros Chemicals
- John Moore - Avecia Limited
- John Bailey - Procter & Gamble
- Helen Lynn - Women's Environmental Network
- Malcolm Bassett - Research and Testing Laboratory
- Lynn Duggan - Institute of Consumer Affairs
- Nigel Bryson – GMB
- Susan Murray - TGWU
- Mary Taylor – FOE
- Stuart Dobson - CEH
- Nigel Smith – BRC
- Dr Phil Stubbs - Boots Co. PLC
- Gwynne Lyons - WWF
- Mike Barry - Marks & Spencer PLC
- Prof. Kevin Chipman - School of Biosciences, The University of Birmingham
- Dr Gill Langley - Dr Hadwen Trust
- Dr A. Michael Warhurst - WWF European policy Office
- Dr Barry Phillips - RSPCA