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HEALTH AND SAFETY COMMISSION

Proposals for Control of Substances Hazardous to Health (Amendment) Regulations 2003

A Paper by John Thompson and Bill Macdonald

Advisors: Mike Reeves, Carole Sullivan and Simon Mundy

Cleared by Sandra Caldwell on 17 February 2003

Issue

1. The results of consultation on proposals for Control of Substances Hazardous to Health (Amendment) Regulations 2003, and agreement to submit draft Regulations to the Minister.

Timing

2. Urgent. The Amendment Regulations include provisions for implementing into GB legislation a requirement in EC Directive 1999/38/EC that must be implemented by 29 April 2003. Approval of the draft Regulations will help implement the Directive by that date.

Recommendation

3. The Commission is invited to:

- (a) note the responses received to public consultation on the proposals (**Annex D**); and the revised Regulatory Impact Assessment (RIA) (**Annex E**);
- (b) approve the draft Regulations (**Annex C**) for submission to the Minister of State; and
- (c) agree the text of the draft covering letter (**Annex A**) and of the synopsis on the draft Regulations (**Annex B**) for the Chair to send to the Minister of State.

Background

4. The proposed COSHH (Amendment) Regulations 2003 will amend the principal COSHH Regulations 2002 which came into force on 21 November 2002 to implement the Chemical Agents Directive (98/24/EC). Following the Commission's approval of the draft

Amendment Regulations (see paper **HSC/02/98**), they were the subject of a three months consultation exercise which ended on 10 January 2003.

5. There are two entirely separate aspects to the COSHH (Amendment) Regulations 2003.

Implementation of part of the 2nd Amendment to the Carcinogens Directive

6. COSHH aims to protect employees (and others who may be affected) from the dangerous health effects of hazardous substances. The Regulations do this by requiring employers to assess the risks from hazardous substances and to take steps to prevent or adequately control exposure in accordance with a hierarchy of risk control measures. Where the substances are carcinogenic (ie can cause cancer) COSHH imposes additional control requirements which implement the EC's 1990 Carcinogens Directive (90/394/EEC).

7. The 2nd Amendment to the 1990 Carcinogens Directive was adopted on 29 April 1999 and must be implemented by 29 April 2003. It introduced a number of changes but only one remains to be implemented in Great Britain: the extension of the scope of the Carcinogens Directive to include mutagens (ie substances which can cause heritable genetic defects). This change can be achieved by extending COSHH's additional control requirements for carcinogens to include mutagens.

8. The impact of the change described in the preceding paragraph will, in practice, be limited to the substance triglycidyl isocyanurate (TGIC) or preparations containing it, because TGIC is the only known mutagen that is not also carcinogenic. TGIC is used as a curing agent for polyester coating powders which provide the exterior finish for numerous manufactured products such as washing machines, refrigerators etc, as architectural finishes on buildings, and as a solder mask ink in the manufacture of printed circuit boards.

Inclusion of dioxins in Schedule 1 of COSHH

9. "Dioxins" are a group of unwanted by-products of industrial processes in which organic matter in the presence of chlorine is heated at high temperature, e.g. during the recycling of aluminium cans. Following a survey of occupational exposures to dioxins in certain industries, HSC's Advisory Committee on Toxic Substances (ACTS) recommended a package of measures intended to improve the control of occupational exposure to dioxins. These measures included explicitly identifying as carcinogenic within the meaning of COSHH the 17 key dioxins recognised by the World Health Organisation as those of particular concern. This will be achieved by adding them to Schedule 1 to the Regulations, "*Other substances and processes to which the definition of "carcinogen" relates*". Although the carcinogenicity of these substances is already implicit in COSHH, highlighting it in this way will remove any doubts among dutyholders and encourage better control of occupational exposure.

Argument

10. Twenty-four responses were received to the consultation document and these, together with HSE's comments on them, are summarised at **Annex D**.

11. In general, the proposals found acceptance among a majority of consultees. Only one respondent opposed aspects of the TGIC proposals, asserting that the proposed COSHH

(Amendment) Regulations and the current COSHH Regulations 2002 did not implement an important aspect of the 1990 Carcinogens Directive. The issue is addressed in **Annex D** together with some other matters where respondents expressed qualified agreement.

12. Only three respondents raised concerns about various aspects of the dioxin proposal, ie Millenium Chemicals, the Non-Ferrous Alliance (NFA) and Corus Plc. All three thought that the proposal did not take account of the wide variation in toxicity between the 17 dioxins concerned, and that there was insufficient justification for treating them all as equally hazardous. Corus and the NFA accepted that the dioxin 2,3,7,8-TCDD had been classified as a probable human carcinogen by the Committee on Carcinogenicity and WHO, but considered that there was little evidence to link other dioxins with cancer in humans. The NFA also raised other concerns and felt that additional work was needed on the proposal before introducing a potentially wide reaching measure which would be disruptive and for which benefits could not be quantified.

13. HSE wrote to the NFA to try to allay its concerns. In its letter, HSE:

- (a) reiterated that the proposal was a clarification of the status of the 17 dioxins rather than a new initiative;
- (b) stressed that although the strongest evidence for carcinogenicity potential in humans is for 2,3,7,8-TCDD, there is good circumstantial evidence to support the view that the other 16 dioxins of concern will have the same toxicological properties as 2,3,7,8-TCDD and differ only in respect of their potency;
- (c) reassured the NFA that it would not expect industry to carry out expensive air sampling for the presence of dioxins if they are added to Schedule 1 to COSHH; and
- (d) explained that it had prepared simple good practice guidance to complement and support the clarification of the status of the 17 dioxins to help ensure that employers were clear about their responsibilities.

The concerns raised by all three respondents are summarised on **Addex D** together with HSE's full response.

Consultation

14. Although copies of the consultative document were widely distributed to Government Departments and industry, the response to consultation has been very light. This suggests that the proposals for TGIC in particular as set out in the draft Regulations are generally supported and welcomed as modest measures that will help to improve yet further the protection given by COSHH to worker's exposed to TGIC. Alternatively, respondents may not have responded because the TGIC proposals are not seen as controversial and are driven by an EU Directive that has to be implemented.

Presentation

15. Subject to the Commission and the Minister approving the draft Regulations, HSE will issue a press release, and place a copy on its website, to announce the laying of the

Regulations before Parliament and the date when they will come into force. HSE will send copies of the press release to the trade association that represents the manufacturers of coating powders and to the three manufacturers of solder mask inks whose products contain TGIC, and also to the trade associations whose members are likely to be most affected by the dioxin's proposal. HSE will also arrange for manufacturers of products containing TGIC to be reminded of the need to revise any safety data sheet they supply under the CHIP Regulations, or other information they provide on the safe handling and use of their products, to reflect the classification of TGIC as a mutagen.

Costs and Benefits

16. The practical effect of the mutagen proposal is estimated to affect some 240 firms which include manufacturers of coating powders containing TGIC, coating powder applicators, and manufacturers and users of solder mask inks. Total quantified costs to these firms will be around £7.6 million over ten years, in present value terms, the largest element of which is likely to be improved cleaning services. Although these costs are modest, no significant health benefits are expected since there is already a MEL for TGIC. So costs are likely to exceed benefits.

17. The 10-year costs of adding the 17 specified dioxins to Schedule 1 of COSHH are very small, at about £1.5 million. The largest element of which will be improved cleaning services. This estimate is based on the assumption that only four sectors will be affected by the proposal: metal recycling, cement manufacture, municipal waste incineration and land fill, although the most significant impact will be on the metal recycling sector because it produces levels of dioxins posing the greatest risk to workers. In practice several other sectors will be affected by the proposal, but HSE judges that their costs are likely to be much lower or insignificant. The main requirement resulting from the proposed amendment to COSHH will, in practice, be to clean the workplace regularly and whenever necessary, and this is where the majority of costs will fall. The proposal should simply require more thorough cleaning by these firms, and a greater awareness of other measures to control and reduce exposure. Total benefits cannot be quantified because of a lack of firm data.

Financial/Resource Implications for HSE

18. The estimated cost to HSE is small and can be met within existing provision.

Environmental Implications

19. The inclusion of the 17 key dioxins in Schedule 1 to COSHH may reduce releases to the environment because of better containment, but this is unlikely to be significant.

Other Implications

20. **European:** Northern Ireland expects to have comparable regulations in force transposing the mutagens' requirements of Directive 1999/38/EC within three months of the GB Regulations coming into force.

21. **Devolution:** The new Regulations will apply across GB and there are no additional implications for Scotland and Wales.

Action

22. If the Commission agrees to the recommendations in paragraph 3, HSE will arrange for:

- (a) the Chair to submit the draft Regulations to the Minister of State for approval; and subject to that approval
- (b) the Regulations to be laid before Parliament in time for them to come into force by 29 April 2003 and for this to be announced in a press release.

Contacts

Bill Macdonald, HD C, Tel: 020-7717-6261; Fax: 020-7717-6190
E-mail: Bill.Macdonald@hse.gsi.gov.uk

Michael Ryan, HD C, Tel: 020-7717-6140; Fax: 020-7717-6190
E-mail: Michael.Ryan@hse.gsi.gov.uk