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# HEALTH AND SAFETY COMMISSION

# PROPOSED CHEMICAL (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) (AMENDMENT) REGULATIONS 2005 – REPORT ON CONSULTATION AND APPROVAL OF THE PROPOSED AMENDING REGULATIONS

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**Cleared by JONATHAN REES on 11 July 2005**

## Issue

1. To
   - Agree that the Chair should write to the Minister with proposals to make the Chemical (Hazard Information and Packaging for Supply) (Amendment) Regulations 2005 (Annexes A and B). The proposals will update and extend the list of harmonised classifications of chemicals, which provide the basis for the control of chemicals in work activities and by consumers, and for the single market in chemicals in which the UK chemicals industry is a significant player
   - Approve the new Approved Supply List (Annex D).
   - Note the feedback from formal consultation and agree the proposed minor changes to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP).
   - Note the proposed date to bring the Regulations into force (paragraph 20).

## Timing

2. Urgent. The regulations derive from an EC Directive which must be implemented by 31 October 2005. Agreement and approval is necessary at this meeting, to allow time for the Minister to sign the regulations and for the regulations to be laid before Parliament prior to entry into force.

## Recommendation

3. That HSC agrees the proposals and the Chair's letter to the Minister (Annexes A and B).

## Background

4. The Dangerous Substances Directive (67/548/EEC) sets out requirements to classify dangerous substances and, where they are supplied, to package and label them according to their hazards. Annex 1 of the Directive sets out the agreed classifications

and labelling requirements for approximately 5000 substances. The classifications are based on scientific evidence and trigger controls on storage (including major hazards sites) and use of these substances and products containing them. Classification also provides the basis for a single market in chemicals and determines the label and other information suppliers must provide about the hazards to human health, the environment or both. Adaptations to Technical Progress (ATPs) ensure that Annex 1 and other provisions of the Directive are kept up to date, in line with developing scientific knowledge and the development and commercialisation by industry of new and innovative substances. The proposals discussed in this paper constitute the 29th ATP to the Dangerous Substances Directive.

5. The Dangerous Substances Directive, including its Annex 1, is implemented in Great Britain by the CHIP regulations. Annex 1 of the Directive is transposed in GB through the HSC's Approved Supply List. The classifications and subsequent labelling requirements are binding on all MS. There are no exceptions. Amending regulations (to be know as CHIP 3.1) are required to implement Annex 1 changes.
6. The need for amending regulations also provides the opportunity to make some minor editorial changes to the existing regulations to clarify or correct minor aspects (Annex C). None of these changes affect the legal duties under CHIP.
7. The 29th ATP also introduces some new test methods to Annex 5 of the Directive. This is a portfolio of acceptable available test methods and does not impose regulatory requirements. No formal change to CHIP is needed to introduce the new test methods.

**Consultation and feedback [H6]**

8. Industry representatives are engaged in the substance-by-substance discussions in Europe, and ACTS and SCHIP (an ACTS sub-committee dealing specifically with classification and labelling) have been kept informed of progress on the 29th ATP.
9. After adoption of the 29th ATP, HSC published a Consultative Document (No 202) on 17 January 2005. This was sent to 218 stakeholders with an interest in the supply and use of chemicals, including 59 trade associations and companies, and 42 pesticide companies. Companies and organisations involved specifically in the use or manufacture of n-Propyl Bromide (nPB) and chromium trioxide were also consulted. We also consulted the TUC, local authority organisations, emergency services, other government departments and 33 health and safety specialists. Consultation closed on 8 April 2005.
10. There were 17 respondents to the CD, and the main issues raised are in Annex E.
11. ACTS considered a further paper at its meeting on 30 June 2005, including a draft of this HSC paper. No substantive points were raised.
12. Most respondents supported the classification changes introduced by the 29th ATP and the proposed minor changes to CHIP. However, the proposals to revise the classifications of two substances in particular have resulted in lobbying by industry: nPB, primarily used as a degreasing solvent in metal cleaning operations, and chromium trioxide, used in chrome plating.
13. The nPB industry has challenged vociferously the proposed classification for nPB as a Category 2 reproductive toxin with the risk phrase R60 (May Impair Fertility), claiming that the science on which it is based is incomplete. However, HSE believes the existing evidence is conclusive, and the classification of nPB was agreed unanimously by all Member States (MS). HSE also issued a Chemical Hazard Alert Notice (CHAN) on nPB, which set out the proposed classifications. Since the classification was agreed new information has been brought forward by the industry. HSE has agreed to help the

industry take this data forward for possible further consideration at EU level. If MS agree, the classification can be adjusted at a future ATP.

14. Concerns have also been raised, mainly by companies involved in aviation, about the basis for the classification of chromium trioxide and the effect this will have on the chrome plating industry. The revised classification will result in additional industrial sites falling within the scope of the Control of Major Accident Hazards Regulations (COMAH). COMAH uses CHIP classifications as one of the principal 'triggers' in applying its provisions.
15. A number of respondents, mainly from the pesticide industry, expressed concern at the limited time available for implementation and the practical difficulties that this will create (see Annex E paragraphs 22 to 35 for detail).
16. We will continue to keep ACTS and SCHIP informed. We also maintain close links with the Chemical Hazard Communication Society. In keeping with regulatory changes, HSE will announce the entry into force of the amending CHIP regulations via the HSE web site. We aim to bring the amending regulations into force on 31 October 2005 (see paragraph 20).

**Internal consultation**

17. HSE's Hazardous Installations Directorate was consulted on this paper's references to the COMAH regulations. The Field Operations Directorate's Industrial Chemicals Unit that provided the scientific involvement in the 29th ATP, was also consulted on this paper. HSE's Engineering Sector was consulted on implications for n-propyl bromide. This paper was also cleared with HSE's Legal Advisers and with DEFRA's Pesticide Safety Directorate. FOD inspectors will be informed of the changes made by the 29th ATP and reminded that existing operational and enforcement guidance remains valid and unchanged.
18. HSE's Planning, Efficiency and Finance Division has cleared the financial implications at paragraphs 22 and 23.

**Presentation**

19. The proposed regulations do not introduce new issues – they extend and amend the extensive database of the hazardous properties of chemicals agreed at EU level. Chemical suppliers are usually aware of the changes as they go through the EU process and before the adoption of the formal ATPs. The 29th ATP has also been the subject of formal HSC consultation.
20. The latest date by which the Directive has to be implemented is 31 October 2005. We have considered whether the new regulations should be brought into force on the 6 rather than the 31 October, in line with the recently introduced guidance on common commencement dates. We propose to advise the Minister that because we consulted on the basis that we would give industry the maximum time to make the necessary practical arrangements to comply, and as this is a single market measure intended to create a level playing field across Europe, that on balance we consider it would be more helpful for British industry to keep to the 31 October in this particular case.

**Costs and Benefits**

21. The final RIA (Annex F) has been revised following consultation. However, very little robust cost and benefit information was provided by respondents. The costs arise mainly from the need for suppliers to amend the labels on their products and to update safety data sheets, which provide further information for users about the hazardous

properties and appropriate precautionary measures. There are also cost implications for the application of COMAH, and the impact on specific chemical sectors (vapour degreasing, chrome plating and pesticides). The total annual cost to society, is estimated to be between £1.9m and £9m in the first year and between £11.4m and £18.5m in the following 10 years.

**Financial/Resource Implications for HSE**

22. Over the last two years, work by HSE staff on negotiation of the Directive and the preparation of the Consultative Document has cost approximately £46,000. The printing cost of the CD is estimated at £4580. Resource of HSE toxicologists and an HSE economist cost approximately £4150. HSE Solicitor's contribution costs are estimated at £3420. Costs to date have been met from within existing resources, future costs up to the time of the introduction of the regulations are included in these estimates.
23. Where, as a result of revised classification of chromium trioxide, three additional sites fall within the scope of COMAH, HSE's costs are recovered through a charging regime. These recovered costs are estimated to be between approximately £20,000 to £50,000 per site.

**Environmental Implications**

24. The European scheme for the classification of chemicals is holistic, and integrates environmental, and health and safety considerations. This approach is also followed in CHIP. There are no specific environmental implications in the 29$^{th}$ ATP.

**Other Implications**

25. Local authorities – it is estimated a total of three additional sites will become subject to the top tier requirements of COMAH, therefore needing off-site emergency planning.
26. Devolution – officials in Scotland and Wales have been consulted on the proposals but no issues were raised.
27. Small and medium-sized enterprises – the RIA notes that compliance costs may be disproportionately higher for SMEs (see paragraph 115 of Annex F).

**Next steps**

28. To approve a new edition of the Approved Supply List and to agree submission of the proposals to the Minister.