

Results of consultation and list of consultees and respondents

Overview

1. Consultation ran from 17 January to 8 April 2005. This was largely carried out over the Internet (4146 'hits'), with paper copies of the CD being provided on request. Additionally, HSE sent 218 copies to stakeholders with a specific interest in the supply and use of chemicals.
2. The consultative document (CD) asked nine questions, which included a standard question about whether the CD and partial RIA provided sufficient information for consultees to understand and comment on the proposals. Consultees were free to reply either via e-mail or through the post.
3. We received 17 responses. GB chemical industry has already implemented many ATPs through both amending and consolidating CHIP regulations and are used to dealing with the routine amendments. This may explain the small number of responses received, many of which focused on specific substances rather than the 29th ATP itself. Four respondents had no comment to make; three made general comments; two focused on a minor editorial change; one drew attention to typographical errors in the 29th ATP text; one raised an unrelated issue to do with safety data sheets; the remaining six focused on the impact of the revised classifications of the products they market and supply, or consequential inclusion under the COMAH regulations.
4. Overall, the proposals received support, as did HSE's implementation approach. Post-consultation work focused on three areas that were considered to be reflective of the main areas of impact: the proposed classifications of (i) n-propyl bromide (paragraphs 14 to 17) (ii) chromium trioxide (paragraphs 18 to 21) and (iii) pesticides (paragraphs 22 to 35).

Respondent groups

5. Respondents were not asked to provide information about themselves, however the CD encouraged respondents to provide sufficient detail to understand their interest, whether as a member of the public or as someone with a particular stake in the changes. There were particular questions aimed at: (a) chemical suppliers (on whom the CHIP duties fall); (b) recipients of chemicals and business users; (c) people who work with chemicals (as an employee or as a self-employed person); and (d) people who advise on the safe use of chemicals.
6. A number of key representative bodies responded including:
 - British Coatings Federation
 - Agricultural Industries Confederation
 - Crop Protection Association
 - Chief Fire Officers Association

- Chemical Hazard Communications Society

7. ACTS were consulted, via correspondence, both on the draft CD and as consultees. No comments were received.

8. A full list of respondents is at the end of this Annex. One reply was received from an individual who did not wish their name to appear in the public record. This has been respected.

9. In considering comments, HSE followed guidance on dealing with responses from individuals, groups and representative bodies designed to ensure that all responses are dealt with fairly.

Responses to the questions in the CD

10. The following summary follows the order of the questions in the CD.

Q1 The overall approach to implementing the 29th ATP

11. All respondents who commented on this question, supported HSE's approach to implementation.

Q2 Proposed minor changes to the CHIP regulations

12. All respondents, who commented on this question, supported the proposed changes. The Department for Transport requested an additional change to deal with the reference to RID in regulation 8A of CHIP and this has been implemented (see Annexes B and C of HSC/05/38). The Chemical Hazard Communication Society also raised regulation 8A seeking clarification on the text of transport labels. The Agricultural Industries Confederation noted that it understood the reasons for the deletion of regulation 13 on exemption certificates.

Q3 Impact on chemical suppliers

13. Understandably, this question resulted in the most comments as chemical suppliers carry the legal duties under the CHIP regulations. The comments focused mainly on the proposed classifications of particular chemicals.

n-Propyl bromide (nPB)

14. nPB was included in the 29th ATP as a Category 2 reproductive toxin. Responses from Enviro Tech Ltd and Amity UK Ltd objected to this proposed classification. nPB is not manufactured in the UK, but is marketed as the main constituent of metal cleaning solutions

15. The EU decision to classify nPB as a Category 2 reproductive toxicant is based on the results of animal studies which show that it can cause damage to reproduction both in terms of parental fertility and the development of offspring. This is consistent with advice from HSC's expert tripartite committee, WATCH, ACTS' Working Group on the Assessment of Toxic Chemicals. All Member States supported the classification for nPB.

16. The EU discussions on the substance were held over several meetings, and were attended by the International Brominated Solvent Association for the nPB industry. The discussions have been exceptionally prolonged and the chairs of the meetings have been particularly careful to facilitate industry's participation. The nPB industry expressed strong opposition to the proposed classification during the discussions, and continued to argue that it is not justified by the science and will mean nPB can no longer be marketed. The industry has also:

- Made a formal complaint against two HSE officials. The formal investigation by senior HSE managers concluded that the HSE officials has acted properly and appropriately, but recognised that complainant remained an aggrieved party;
- Twice taken its concerns to the European Courts of Justice. On the first occasion the ECJ dismissed the proposed action. The second is still pending at the time of writing.
- Threatened legal action against both the Committee of Member States National Experts on classification and labelling, and the HSE.

17. Dealings with the industry have, therefore, been difficult. HSE has, however, sought to maintain an open and helpful approach. The nPB industry has pointed to new scientific studies that have become available since the 29th ATP was agreed in Europe. Although HSE believes the Category 2 reprotoxicity is well founded, we are advising the industry on how best to take this forward for consideration in Europe. However, the agendas of the Classification and Labelling Working Group are set by the European Commission, and any revision of the classification will remain a matter for all Member States.

Chromium trioxide (CrO₃)

18. CrO₃ is already classified as a Toxic substance (among other hazards), but in the 29th ATP the classification is increased to Very Toxic. CrO₃ is used in various industrial processes but the revised classification to Very Toxic is seen by industry as of particular concern to those involved with chrome plating. Airbus UK and the British Coatings Federation (BCF) have registered their concern on this matter.

19. Although no formal response to the CD was received from Airbus, it has made its concerns known to HSE over many months, as well as being the subject of correspondence with both the Cabinet Office and the Department of Trade and Industry. Its concerns are centred around questions about the science on which the revised classification is based.

20. The re-classification to Very Toxic will have the effect of bringing certain chrome plating sites into the scope of the COMAH regulations if the quantity stored is 5 tonnes or more (lower tier) or 20 tonnes or more (upper tier). Where a site falls into the 'upper tier' a full safety report on the site has to be prepared, requiring the involvement of HSE and local fire and other emergency authorities. HSE can charge for assisting in this process. The Regulatory Impact Assessment sets out the range of costs involved based on the limited information provided by industry.

21. Airbus has submitted an additional scientific study on the inhalation effects of CrO₃ to HSE that, it believes, provides evidence that the classification to Very Toxic is incorrect. HSE are planning to meet with representatives from Airbus and advise on how to take forward their views to the European Classification and Labelling Working Group. However, HSE has sought to avoid building false expectations with the industry. Any revision of the classification will remain a collective matter for all Member States.

Pesticides

22. Comments were received both from the Agricultural Industries Confederation (AIC) and the Crop Protection Association (CPA). The AIC represents over 300 member supplier companies; the CPA represents pesticide approval holders. Both voiced concerns about the classification of certain pesticides and practical difficulties they may face given the implementation period available.

Background to pesticides and CHIP

23. Pesticides are already subject to tight regulation both in Europe and the UK. The Control of Pesticides Regulations (COPR) 1986 and the Plant Protection Products Regulations (PPPR) 2003 – the latter deriving from the PPP Directive – apply in England and Wales. The Plant Protection Products Regulations (Scotland) 2003 apply in Scotland. The Plant Protection Products Regulations (Northern Ireland) 2004, apply in Northern Ireland. The industry is used to this regulation and the detailed requirements that flow from them.

24. Under the PPP Directive a programme to review active substances is in progress. When all the available data on an active substance has been considered, Member States can agree to include the active on a positive list at EU level, and pesticides containing that active are authorised (approved) at national level. The Pesticides Safety Directorate, an Executive Agency of DEFRA, approves pesticides in GB.

25. The data set assembled by industry to support the active substance through review is also used to consider and amend as necessary the hazard classification and label of the active substance and products containing it.

26. The 2002 CHIP Regulations require pesticides to be subject to the same hazard classification and labelling scheme as other chemicals (previously they were exempt). Regulation 16 of CHIP provided a transitional period for pesticides, stating that all plant protection products subject to the PPPR (as well as biocidal products) would have to comply fully with CHIP classification and labelling requirements from 30 July 2004. CHIP is, therefore, relatively new for the pesticide industry.

Specific concerns

27. The 29th ATP introduces revised hazard classifications for 49 approved active substances. Both the AIC and the CPA express doubts about their members' ability to implement the 29th ATP on time. They have pointed to seasonal usage and weather as significant issues in decisions on the purchasing, use and longer-term storage of pesticidal products. This can result in products being held in the supply and distribution chain for longer periods of time. Products that were CHIP compliant when leaving the manufacturer or formulator become "non-complaint" if still held in the supply chain after the implementation date has passed.

28. These concerns have prompted both the AIC and the CPA to call for a "pragmatic" approach by the HSE on matters of enforcement of CHIP.

29. The AIC also raised concerns about the possible implications of triggering the COMAH regulations where revised classifications bring agricultural sites into the scope. For example, most pesticides (up to 80% of those approved for use in the UK) will have an environmental classification. Where threshold quantities are reached, classifications as, for example, toxic or very toxic to aquatic organisms, or may cause long-term adverse effects in the aquatic environment, will trigger application of COMAH.

30. Neither the AIC nor the CPA provided detailed costing of the impact of the 29th ATP on pesticides,

31. HSE takes the view that, in principle, the pesticides industry should not be treated any differently than any other specialist chemical supplier and user. However, it is expected that HSE inspectors will take a pragmatic view when it comes to enforcing changes in labelling legislation as it accepts that some products can take a considerable period of time to pass right through the supply chain from manufacturer to retailer, and on to the user.

32. Paragraphs 4 to 9 of HSE's Operational Circular 253/9, provided guidance for inspectors on a proportionate approach to enforcement when CHIP 3 was introduced in 2002. The OC remains valid.

33. In the first instance, where enforcement action was deemed appropriate, it is likely to be directed at the manufacturers and major distributors i.e. those at the start of the supply chain who may have the most influence on achieving compliance throughout the supply network and may be best placed and resourced to make the changes.

34. HSE will respond to the AIC and CPA, explaining how they can play a more active role in future pesticide classifications and their timely implementation. The industry will be aware of the review programme for pesticides. Review of an active can take up to 2 years. Inclusion of the active substance, or amendment of the existing entry in Annex 1 of the Dangerous Substances Directive will follow, and then implementation in CHIP. In practice, therefore, the pesticides industry will often have more notice of classification and labelling changes than other suppliers of speciality chemicals.

35. The AIC asked if a derogation was possible to delay the 29th ATP implementation date. As no derogation is provided for in the Directive, the HSE cannot offer one.

Q5 Impact on employees or the self-employed

36. There were no specific comments received.

Q6 Impact on chemical safety advisers

37. The Chief Fire Officers' association (CFOA) raised concerns about the resource implications for local fire authorities in assisting in the preparation of safety reports for new COMAH sites.

38. The CFOA had raised similar concerns in its response to the CD "Proposals for the Control of Major Accident Hazards (Amendment) Regulations to implement Directive 2003/105/EC on the control of major accident hazards involving dangerous substances. Regulation 13 of the COMAH Regulations allows the front-line emergency services to recover costs for their role in testing off-site emergency plans, albeit indirectly via the local authority (LA). However, it does not allow the fire service to recover costs for their contribution towards the preparation, review and revision of off-site emergency plans unless those fire authorities are emergency planning authorities in their own right.

39. The British Coatings Federation (BCF) highlighted the resource implications following the need to providing new or revised information on safety data sheets. No other comments were raised.

Q7 Benefits of the proposal

40. Overall there was little detail on potential benefits of the proposal. However, the following points have been reflected in the Regulatory Impact Assessment:

- The BCF could not identify any benefits for the coatings industry, but noted "the provision of information to those who handle or use re-classified chemicals will offer some health and environmental protection". BCF also noted that the reformulation "of products to remove newly-classified hazardous materials will also, eventually, result in a slightly safer workplace".

- Belzona recognised that ATPs affect market pressure and this had led to “benefits to the continued health of all employees throughout the supply chain”.
- The Agricultural Industries Confederation indicated the difficulties in quantifying benefits.
- HazmatLink saw the ATP as providing improved harmonisation within the EU community and affording help to some businesses - a reminder that one function of ATPs is to reduce the need for self-classification by suppliers.

Q8 Partial Regulatory Impact Assessment

41. A number of the respondents indicated that the partial regulatory impact assessment (RIA) did not adequately reflect the anticipated costs involved in implementing and complying with the 29th ATP. However, while some estimated costs were flagged, very little detail was provided to support assumptions made or enable HSE to refine the initial RIA.

42. From those responses that did mention costs, the replies indicated that cost concerns focused on the potential implications of the application of the COMAH regulations; the financial impact of the revised classification of n-propyl bromide (nPB); the practical costs of amending detailed pesticide labels; and the costs of updating labels and safety data sheets more generally. These have been incorporated in the revised RIA (Annex F of HSC/05/38) where possible.

List of respondents

Respondent No:	Name:	Organisation:
1	Tom Bell	Royal Environmental Health Institute for Scotland
2	Geraint Day	Institute of Directors
3	Neil Robinson	Belzona Polymeric Limited
4	Desmond Waight	Chemical Hazard Communication Society
5	Kevin Miller	HazmatLink
6	Bill Murray	Offshore Contractors Association
7	Kevin Stammers	United Kingdom Atomic Energy Authority
8	Wendy Gray	Crop Protection Association
9	Wayne Smith	British Coatings Federation
10	Sydney Treacher	EnviroTech Europe Ltd
11	Ram Singh	Amity UK Ltd
12	Individual	Requested confidentiality
13	Company	Requested confidentiality
14	Hazel Doonan	Agricultural Industries Confederation
15	Kieran Nolan	Chief Fire Officers' Association
16	Robin MacDonald	Department for Transport
17	Jim Hart	Individual