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ADVISORY COMMITTEE ON TOXIC SUBSTANCES

[REPORT ON THE OUTCOME OF THE EU VOTE ON THE 29TH ADAPTATION TO TECHNICAL PROGRESS OF THE EC'S DANGEROUS SUBSTANCES DIRECTIVE 67/548/EEC]

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Cleared by Michael Topping 14th June 2004

Issue

1. An information note summarising the outcome of the EU vote on the 29th Adaptation to Technical Progress (29th ATP) to the Dangerous Substances Directive (67/548/EEC) (DSD), held on 14 April 2004.

Timing

2. Routine.

Recommendation

3. Members are asked to note the contents of this paper and HSE's plans for the necessary amending regulations (to CHIP) in 2005.

Background

4. The 29th ATP contained European Commission (EC) proposals for changes to the annexes of the Dangerous Substances Directive. Details of the proposed amendments prior to the vote appear at Annex 1. ACTS paper 17/2004 provided the most recent update on the 29th ATP.
5. All MS, except Luxembourg, attended the Technical Progress Committee (TPC) meeting on 14 April 2004 that considered the draft proposals.
6. Prior to the meeting, a submission was made by the European Chemical Industry Council (CEFIC), in which a request was made for the modification of the proposal relating to creosote. In discussion among MS, it was agreed to modify the entries on creosote towards CEFIC's proposals. MS also agreed to modify the proposed entries

on chromium trioxide and chromates, and to add an entry for triclosan, which had been raised by stakeholders and the EC. Some minor editorial changes were also agreed.

7. MS unanimously adopted the proposed changes (including those above) and agreed an implementation date of 31 October 2005.

Member States' joint declaration

8. Prior to the TPC, MS were advised that the EC had omitted several substances from the 29th ATP, effectively ignoring the experts' recommendations. No reasons for these omissions were provided and the EC gave no details of its plans for dealing with the outstanding issues that some of these substances have raised. Disappointingly, as a result of this, all MS attending the meeting agreed to a joint declaration setting out concerns about the failure of the EC to offer an explanation for its refusal to bring forward proposals for these outstanding substances. A copy of the declaration is at Annex 2.
9. We were particularly concerned about the late addition of triclosan to the proposal. The EC failed to follow the agreed timetable and working procedure and prevented normal consultation. Our concern was expressed as a formal declaration which appears at Annex 3.

UK implementation - addressing errors in CHIP 3

10. In taking forward the necessary amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 to implement the 29th ATP, the latter provides an ideal opportunity to deal with the existing editorial errors in both the regulations and the supporting documentation and publications. HSE intends to publish a Consultation Document on the necessary amendments to CHIP 3 in October/November 2004. Implementation must be in place by 31 October 2005.

Consultation

11. Members will recall that the negotiations leading to the proposals have taken many years and during this time there has been close consultation with SCHIP, and with ACTS itself. SCHIP members had a chance to discuss the 29th ATP at their meeting on 23 April 2004.

Presentation

12. Effective control of chemicals requires high quality and reliable hazard information. The proposal will deliver this and will further develop the single market in chemicals. 

Costs and Benefits

13. When national regulations are made to implement the proposed changes, there will be costs to industry in terms of relabelling and the revision of safety data sheets. However, experience from previous adaptations shows that such costs diminish significantly with a suitable transition period, and in the case of labels (which are regularly revised for marketing reasons) become negligible. This is largely expected to be the case for the 29th ATP as MS have 18 months to implement national enabling legislation.

Financial/Resource Implications for HSE

14. Implementation costs will be taken from existing allocated resources.

Environmental implications

15. Where necessary, some of the new classifications will alert suppliers to those substances or preparations that pose a risk to the environment.

European implications

16. The 29th ATP is the latest in a series of agreed packages of amendments to the EC's Dangerous Substances Directive. All MS will be required to implement the latest amendments at a national level.

Devolution

17. None. Health and safety regulation, including that which follows agreed European Directives, is conducted on a Great Britain wide basis.

Other implications

18. None.

Action

19. That Members:

- a note the outcome of the 29th ATP negotiations and vote; and
- b note HSE's plans to implement the necessary amending Chemicals (Hazard Information and Packaging for Supply) Regulations, taking the opportunity to amend editorial errors in the CHIP 3 regulations and supporting documentation and publications.

Contact

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**Changes made to Annex 1 of the Dangerous Substances Directive (67/548/EEC) –
Provisional List of Existing and Newly Notified Substances of the 29th ATP**

1. Most of the proposed changes to Annex I either are editorial in nature, revisions of classification or correction of errors from previous ATPs, or to give effect to classifications agreed under the arrangements laid down in the Directive for notifying new substances.
2. The proposal consists of approximately 900 new or amended entries to Annex I of the Directive.
3. A full list of changes can be found at <http://ecb.jrc.it/classification-labelling/> and can be provided on request.

**Changes made to Annex V of the Dangerous Substances Directive (67/548/EC) –
Provisional list of new/revised test methods**

The test methods included on the 29th ATP are:

- 1 New test for liquid oxidisers
- 2 New test for skin sensitisation (LLNA)
- 3 Revised B4 skin irritation
- 4 Revised B5 for eye irritation
- 5 Revised B35 (2 generation)
- 6 Revised B31 (teratogenicity)
- 7 Revised B1bis fixed dose procedure
- 8 Revised B1tris acute toxic class method (probably)
- 9 New neurotoxicity as TG 424
- 10 New C21 and C22 N and C transformation tests for soil micro organisms
- 11 New C23 and C24 aerobic and anaerobic transformation either in soil or in sediments.

Joint Declaration

14 April 2004

Declaration: concerning lack of transparency about the decisions relating to the preparation of the draft 29th ATP and rejection of recommendations from Commission Working Groups.

We are concerned about the recently published proposals for the 29th ATP of Directive 67/548, which is the basis for the Regulatory Committee meeting on 14 April 2004. The proposal omitted several substances on which the Commission's working groups had made clear recommendations based on expert scientific analysis. This is the first time that such recommendations have been ignored. No reasons for the omissions were provided and the Commission gave no details of its plans for dealing with the outstanding issues.

Many Member States requested in writing an explanation from the Commission concerning this lack of explanation. The Commission's response (2 April 2004), however, did not provide a sufficient explanation.

We deeply regret the Commission's lack of transparency about the decisions relating to the preparation of the draft ATP. We think it is vital for the MS and Commission to work together and for there to be an open exchange of views. We believe that until there is a proper explanation of how the Commission reached its decision it will be very hard for MS to have confidence in the working arrangements.

If the Commission does not come with a follow-up of the recommendations from the Commission Working Groups, Member States may have to implement the classifications in their national laws, which will lead to disharmonisation.

We therefore ask the Commission to reflect on its position and to present to the forthcoming Competent Authority Meeting an action plan for dealing with the outstanding recommendations.

(Signed by all MS representatives present at the ATP meeting).

29th ATP to 67/548/EEC - DECLARATION FROM THE UNITED KINGDOM

The United Kingdom regrets the last minute decision of the Commission to Add a further substance (triclosan) to the list of substances in the 29th ATP. The timing of this addition does not conform to the agreed period of notice for proposals. Although late additions are possible under exceptional circumstances no convincing reasons have been given in this case.