

30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC on the classification, labelling of dangerous substances

1 Introduction

Council Directive 67/548/EEC (Dangerous Substances Directive) is concerned with the classification, labelling and packaging of dangerous substances. Classification involves the assessment of the hazard(s) of a substance, i.e. its inherent properties such as flammability, toxicological effects on human health or toxicity to aquatic organisms, and the subsequent placing of the substance in one or more defined classes of danger characterising the type and severity of these hazards. Substances are classified by comparing the available hazard information with the criteria set out in Annex VI of the Dangerous Substances Directive. Information on the dangers of the substance and the precautions to be taken are transmitted by means of standard warning labels. Professional users are also provided with a safety data sheet. Finally the Directive requires dangerous substances to be properly packaged.

The Directive places a general duty on the person placing the substance on the market to provisionally classify and label it until the classification and labelling has been harmonised at Community level. Substances with harmonised classification and labelling are included in Annex I to the Directive, which currently lists the harmonised classification of approximately 8000 substances. Any addition, modification or deletion of entries in Annex I, are made by an Adaptation to Technical Progress (ATP), as foreseen under Article 28 of the Directive, through a Comitology decision on a Commission proposal to modify the Annex. Priority is given to substances which have carcinogenic, mutagenic and reproductive toxicity effects. In addition, the classifications of new substances notified under the Directive are also included in this way. The Annex may also be revised if new scientific evidence shows that a classification in Annex I is no longer correct.

The determination of the classification of a substance requires specialised knowledge about the intrinsic properties. To provide a solid scientific basis for the preparation of Commission proposals for harmonised classification and labelling, DG Environment has set up a committee of Member State (MS) experts and industry observers, called the Technical Committee on Classification and Labelling (TC C&L). Meetings of this Technical Committee are organised by the European Chemicals Bureau (ECB) at the Joint Research Centre (JRC) at Ispra, Italy. All conclusions of the TC C&L have the status of recommendations for possible inclusion in an ATP of Directive 67/548/EEC. The Commission may also, when appropriate, consult experts designated by the Member States and having special qualifications with respect to carcinogenicity, mutagenicity or reproductive toxicity, called the Specialised Experts, for the purpose of obtaining advice when the interpretation of the scientific data is considered to be particularly difficult.

Several pieces of Community legislation refer to the classification criteria in Annex VI to the Directive or to the actual listings of harmonised classified substances in Annex I. This Community legislation relies on the Directive to provide information on the dangerous properties of substances. The Directive and these other pieces of Community legislation form a coherent system of policies, designed to protect human health and the environment.

On 27 June 2007, the European Commission adopted the 'Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No

1907/2006'¹ (the CLP Regulation), which is in line with the United Nations Globally Harmonised System for classification and labelling (GHS). The European Parliament and the Council reached agreement on a text in June 2008, however this must still be formally adopted by the two co-legislators. Final adoption and publication is expected by the end of 2008. The proposed Regulation will carry forward the existing Community agreements on harmonised classifications, and Annex VI of the draft CLP Regulation contains all harmonised classification up to the 29th ATP of the Dangerous Substances Directive. Additional harmonised classifications, including those of the 30th ATP, will be included in the Annex VI of the proposed Regulation via an ATP procedure.

2 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC

2.1 Introduction

On the basis of the TC C&L recommendations that had not been so far included in an ATP, DG Environment developed a draft proposal for a Commission Directive amending for the 30th time the Dangerous Substances Directive (30th ATP). The Member States (MS) gave a favourable opinion on the proposal by Qualified Majority in February 2007 and the Directive was adopted on 9 June 2008.

This measure, based on the recommendations of the TC C&L and in some cases the advice given by the Specialised Experts, makes the following changes to Annex I:

- the addition of 380 new entries, in many cases due to their carcinogenic, mutagenic or reproductive toxicity effects; and
- the revision of the classification and labelling of 516 substances and deletion of 3 substances currently in Annex I.

The Directive will enter into force on 5 October 2008.

2.2 Consultation

Extensive consultation on each of the substances that make up the 30th ATP occurred during the discussions of each substance at the TC C&L. Stakeholders, including the relevant industry representatives, Trade Unions and Non Governmental Organisations, were invited to take part in the deliberations with the MS and could present information that they thought the MS had not considered.

In addition, the relevant Commission Services also received a great deal of correspondence and participated in a number of meetings with concerned parties both before and after the proposal was elaborated.

The proposal was also notified to the World Trade Organisation (WTO) in May 2007 and was the subject of two rounds of discussions in the WTO's Technical Barriers to Trade Committee. The Commission provided a written response to the comments raised on both occasions.

¹ COM(2007) 355 final.

2.3 *Substances of high interest*

The changes to Directive 67/548/EEC agreed in the 30th ATP are a very important step forward in protection of human health and the environment as the 30th ATP contains a large number of substances classified for carcinogenicity, mutagenicity or reproductive toxicity. The classifications of nearly 250 existing entries have been revised to include these effects, including metals such as cobalt and lead, 96 coal-derived complex substances and 142 oil-derived complex substances. In addition 40 substances with these effects are included in the Annex for the first time along with another 139 new entries for substances that may cause either skin sensitisation, serious damage to health from prolonged exposure, or harm to breastfed babies. This information will allow manufacturers, importers and downstream users of the substances to apply, or recommend, risk reduction measures to protect workers, the general public and the environment from these effects.

During the elaboration of the proposal two substance-related issues were of particular interest and received significant attention.

2.3.1 *Nickel classification*

Denmark is rapporteur under the Existing Substances Regulation² for the risk assessment of five high production volume nickel substances: nickel metal, nickel sulphate, nickel dichloride, nickel dinitrate, and nickel carbonate. The hazard information, gathered as part of the risk assessment, was discussed in the TC C&L from November 2003 to September 2004 when agreement was reached on the harmonised classification and labelling of the 5 substances. The four nickel salts were classified as Carcinogenic Category 1; R49 (Carc. Cat. 1), as well as, for mutagenicity (Muta. Cat. 3) and reproductive toxicity (Repr. Cat. 2) and additional hazards.

Nickel metal remained classified as Carcinogenic Category 3. As a result the classification of nickel-containing alloys, and substances containing nickel as an impurity or a component, as carcinogens remains unchanged. In addition, the metal is classified for serious damage to health by prolonged exposure to inhalation. The 30th ATP also introduced a change in the way in which nickel alloys are classified as skin sensitisers. Instead of basing the classification on the nickel content, the classification is based on the rate of nickel release from the alloys as measured by a standardised test method. This change will lead to the declassification of some nickel-containing alloys (e.g. certain stainless steels) as skin sensitisers where the nickel release rate is below the cut-off set in the Directive.

At their meeting in April 2004, the Specialised Experts concluded that nickel sulphate and nickel chloride should be considered as human carcinogens (Carc. Cat. 1). The classification of the nickel salts were based on epidemiological results following inhalation exposure that demonstrating a causal association between human exposure to the substances and the development of lung cancer. There was also supporting evidence for their conclusion from more limited data on nasal cancer. There are also a variety of effects demonstrated in a large number of experimental studies with different nickel species. The Specialised Experts also agreed that nickel nitrate and nickel carbonate should be classified as Carc. Cat. 1. The Specialised Experts recognised that the water solubility of nickel nitrate was sufficiently similar to that of nickel sulphate and nickel chloride to justify the same classification. Since

² Regulation (EC) 793/93 on existing substances

both the water soluble nickel compounds considered at the meeting and the insoluble inorganic nickel compounds already classified in Annex I are considered as human carcinogens, nickel carbonate was also considered to be a human carcinogen.

2.3.2 Borates classification

The TC C&L has reviewed the evidence that certain borates should be classified as toxic to reproduction. The evidence included animal data, which was regarded as unequivocally positive, as well as a lack of confirmatory evidence from epidemiological studies. The Specialised Experts in the fields of Reprotoxicity were also consulted for advice on the classification of borates. The classification of borates agreed by the TC C&L and shown in the 30th ATP is based on their assessment and recommendations.

Before proposing the classifications in this Directive, the Commission has carefully considered all the available data on borates and the recommendation regarding borates made by the TC C&L. It has noted the consistency in the evaluation of the hazard of borates by the European Food Safety Authority (EFSA), the Scientific Committee on Cosmetic Products and Non Food Products (SCCNF) and the Technical Committee on Classification and Labelling.

The evidence from different animal species shows that boric acid and the borates have an adverse effect on fertility (rat, mouse, dog) and development (rat, mouse, rabbit), which is not a consequence of general systemic toxicity. Thus the criteria of Annex VI of the Dangerous Substances Directive for classifying borates based on the animal data as Toxic for Reproduction Category 2, regarding both effects on fertility and developmental toxicity, are fulfilled. The relevance for humans of the animal data is confirmed by toxicokinetic information and is not challenged by the available human data, toxicodynamic considerations, the doses administered or the route of administration. The latter is important, as the animal evidence is obtained from oral exposure to the substances but the main exposures in the workplace, for example, would be from inhalation. A comparison of the average repeated daily occupational exposure with the levels at which no adverse effects are seen leads to the conclusion that there is a need for limiting the risks and that additional risk management measures, beyond those already in place, are needed. Furthermore, the available evidence does not demonstrate that at the average inhalation exposure levels, humans would be prevented from taking up the substance due to vomiting. Thus the normal handling and use criteria in the Directive are fulfilled as the data used to classify are relevant for humans and for the way in which they would be exposed i.e. by inhalation and ingestion.

In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content.

3 Follow-up

As with any harmonised entries in Annex I, the classification and labelling of the substances listed in this Directive will be reviewed if new scientific knowledge becomes available. Further epidemiological studies are underway on the borates covered by this Directive including a current study in China, and particular attention will be paid to any implication of the results of these studies for the current classifications. In addition the outcome of the IARC

discussion of the classification of nickel substances or any new relevant scientific findings or interpretations given to the data used to establish the current classifications for the nickel compounds will be considered.

The Commission will also need to:

- include the harmonised classifications in the 30th ATP in the Annex VI of the CLP Regulation which should enter into force in June 2009.
- consider the substances classified as CMR Category 1 and 2 for inclusion in Annex XVII of REACH. Under Directive 76/769/EEC on the restrictions of certain dangerous substances and preparations, the Commission is, in principle, obliged (within six months of the publication of the classification) to propose a ban on their placing on the market and use by consumers as substances or in preparations (above specified concentrations). Exceptions may be made in cases where there are no unacceptable risks or where the socio-economic benefits outweigh the risks. In this regard, a study has been commissioned by DG Enterprise & Industry to advise on whether such exceptions could be justified for certain uses of the borates. With regard to nickel, nothing is foreseen for the substances on which classifications were agreed as they are not used in consumer products.