

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

General questions

1 What is Council Directive 67/548

Council Directive 67/548/EEC harmonises the rules on classification, labelling and packaging of dangerous substances in the EU Member States. Information on the dangers of the substance and the precautions to be taken are transmitted by means of warning labels containing standard symbols and phrases and also (for industrial users) by safety data sheets. Finally the directive requires dangerous substances to be properly packaged to prevent danger.

2 What is classification

Classification is 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 identification of one or more defined classes of danger characterising the type and severity of the hazards. Substances are classified by comparing the available information on it with the criteria set out in Annex VI of Council Directive 67/548/EEC.

The Directive places a general duty on the person placing the substance on the market to provisionally classify and label until the classification and labelling has been harmonised at Community level. Certain substances are given an EU harmonised classification that is included in Annex I of the Directive, which requires suppliers of the substances to use that classification. Priority is given to substances having concerns for carcinogenic, mutagenic and reproductive toxicity effects. Annex I currently lists the harmonised classification of approximately 8000 substances.

3 How are harmonised classifications decided

The determination of the classification of a substance requires specialised knowledge about the intrinsic properties of the substance. To provide a solid scientific basis for the preparation of Commission proposals for harmonised classification and labelling in Annex 1, 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). All conclusions of the TC C&L have the status of recommendations for possible inclusion in an ATP of Directive 67/548/EEC until legally adopted.

The Commission may also, when appropriate, consult experts, called Specialised Experts, designated by the Member States and having special qualifications with respect to carcinogenicity, mutagenicity or reproductive toxicity, for the purpose of obtaining specialised scientific advice on the interpretation of data on these effects.

The Annex may also be revised, following similar discussions, if new scientific evidence shows that entries in Annex I are no longer correct

4 What is an ATP?

The Directive contains a number of Annexes, included the harmonised list of dangerous substances, Annex I. Any modifications of these Annexes are made via an Adaptation to Technical Progress (ATP), as foreseen under Article 28 of the Directive, through a Comitology decision on a Commission proposal to adapt the Annexes. Modifications to Annex I normally consist of changes to existing entries, additions of new entries, and, in some cases, deletions of existing entries.

5 Will Directive 67/548/EEC be replaced?

Yes. 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). The CLP Regulation aligns the EU system of classification, labelling and packaging substances and mixtures to the United Nations Globally Harmonised System (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 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 classification, including those of the 30th ATP, will be included in the Annex VI of the proposed Regulation via an ATP procedure.

6 Why is the 30th ATP important?

The 30th ATP introduces and modifies the EU harmonised classification and labelling requirements for 896 substances and removes the requirements for 3 substances.

The ATP is a Commission Directive and will require all suppliers of the substances included in it to use harmonised descriptions of the hazards. It brings together the agreements on the results from expert discussions over a number of years. The practical form of the agreement is an updated list in Annex 1 of the Directive.

This measure is a very important step forward in protection of human health and the environment as it includes nearly 290 substances that have been identified as causing cancer, gene mutations, or effects on reproduction. In addition, there are 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, suitable control measures to protect both workers, the general public and the environment from these effects.

7 Why was it adopted under Directive 67/548/EEC and not the new Classification, Labelling and Packaging (CLP) Regulation?

The CLP Regulation has not yet been finalised and was still undergoing negotiation between the Council and the European Parliament at the time of agreement on the new classifications. Therefore Directive 67/548/EEC was updated and the CLP Regulation will be suitably adjusted later after final agreement.

8 Why did the 30th ATP take so long to be adopted?

The initial proposal for the 30th ATP was agreed in the Commission in March 2005, the Member States gave a favourable opinion on the proposal in February 2007 and the proposal was then adopted by the Commission on 9 June 2008. In addition, the proposal was notified to the World Trade Organisation on 4 May 2007 leading to 2 rounds of questions and comments that needed reply (see question 29). The reasons for this time span reflects the serious thought and debate given to the measure and time taken in assessment to ensure the entries are scientifically accurate. In addition it was necessary to consult with the social partners and other stakeholders and to allow further consultation with the EUs trading partners.

9 Could the entries in the 30th ATP be reviewed?

¹ COM(2007) 355 final.

Yes. As with any other entry in Annex I, the entries in the 30th ATP of Directive 67/548/EEC could be reviewed if new relevant scientific information/knowledge becomes available on the substances. For example, a further study of the carcinogenicity of metallic nickel in animals following inhalation, has been completed and will be reviewed by Denmark, the Rapporteur for the substance(s) under Regulation 793/93, and the conclusions discussed in the Risk Assessment Committee established under REACH. In addition, with regard to the borates, on conclusion of a current Chinese epidemiological study, the classification of borates may also be reconsidered.

10 What substances are included in the 30th ATP?

There are 380 new entries included in Annex I by the 30th ATP as well as 516 substances with revised classifications and labelling information and the deletion of 3 substances currently in Annex I. The revised entries include in particular the revision of large numbers of complex coal and oil substances to include additional classifications for flammability and mutagenicity. The new entries include a large number of new substances notified under the Directive.

Borates

11 What are borates?

Borates are a family of chemical compounds which are salts of boron bonded to three oxygen atoms. Borax is a natural mineral containing a sodium borate and water.

12 Which borates are included in the 30th ATP?

There are 7 new entries for inclusion in Annex I to Directive 67/548/EEC.

- boric acid, crude natural;
- diboron trioxide; boric oxide
- disodium tetraborate, anhydrous; boric acid, disodium salt; tetraboron disodium heptaoxide, hydrate; orthoboric acid, sodium salt
- disodium tetraborate decahydrate; borax decahydrate
- disodium tetraborate pentahydrate; borax pentahydrate
- 1-chloromethyl-4-fluoro-1,4-diazoniabicyclo[2.2.2]octane bis(tetrafluoroborate)
- tetrabutylammonium butyl tris-(4-trans-butylphenyl)borate

13 In what applications are borates used?

Various forms of borate are used as wood preservatives or fungicides. Boric acid, for example, is often used as an antiseptic, insecticide, flame retardant, and as a precursor of other chemical compounds. Sodium perborate, mono- and tetrahydrate, are used as oxidising and bleaching agents mainly in detergents for household and industrial uses, in cleaning agents (e.g. in dishwasher powder), and cosmetic preparations (denture cleansers).

14 How have borates been classified in the 30th ATP

The first 5 substances mentioned in question 12 are classified as substances toxic for reproduction Category 2 for both fertility and developmental effects (this is written as Repr.

Cat. 2; R60-61 for short). The other 2 entries are new notified substances which are not classified as substances toxic for reproduction.

15 What is the evidence that some borates are dangerous to toxic for reproduction?

The normal approach for evaluating danger for reproduction is for experts to examine existing data involving animals and see what conclusions may be drawn. The database has evidence from different animal species which shows that boric acid and the borates have an adverse effect on fertility (rat, mouse, dog) and development (rat, mouse, rabbit). In addition, there is evidence that humans can receive relevant doses of borates, and there are insufficient data to support an argument that the animal evidence should be regarded as not relevant to humans.

The Commission Specialised Experts in the field of Reprotoxicity were consulted for advice on the classification of borates. On the basis of their advice, the Technical Committee discussing Classification and Labelling concluded that borates should be classified as toxic for reproduction, with a majority of experts further considering the animal data to be unequivocally positive and therefore concluded that boric acid and borates fulfil the criteria for Toxic for Reproduction Category 2 R 60-61.

16 Can humans be exposed to a high enough dose to cause concern?

It has been argued that for the effects in animals to be seen in humans, the exposure of humans would have to be impossibly large and that humans would be incapable of tolerating such a dose without vomiting.

However, there is evidence of an average repeated daily occupational exposure of 5 mg/m³ to workers. If the standard risk assessment technique under Regulation (EEC) 1488/94 is employed, the conclusion is reached 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 suggests that, following inhalation exposure levels (e.g. around 5 mg/m³) humans would absorb the substance from the lung and would not be protected by the vomiting reflex.

17 Why have special concentration limits been given?

The Dangerous Preparations Directive (Directive 1999/45/EC) harmonises the regulations in the Member States regarding the classification and labelling of dangerous preparations. If a preparation contains a dangerous substance, then that preparation shall be classified according to the rules laid down in Directive 1999/45. Unless specific concentration limits are set in Annex I of Directive 67/548, then a preparation containing a substance classified as Toxic for Reproduction Category 2, shall be classified in the same way if the substance is contained in that preparation in a concentration above 0.1 percent.

The available evidence indicates that borates cause their effects only at higher dose levels, and this justifies the establishment of higher specific concentration limits for borates and a concentration limit of 5.5 percent for boric acid has been set, based on the level at which no adverse effects is seen for the substance. The other borate compounds have received a concentration limit based on the boric acid concentration.

18 Have there been any other assessments of borates and are they consistent with the 30th ATP?

Other evaluations of borates carried out within the framework of other Community legislation have concluded:

Cosmetics: Borates were prohibited from use in cosmetics products, on 29 February 2000 according to Directive 2000/6/EEC, in concentrations above 5 percent based on boric acid. This is based on an opinion of the Scientific Committee on Cosmetic Products and Non Food Products (SCCNF) after having considered a risk assessment.

Food Intake: The opinion of the European Food Safety Authority (EFSA) of 8 July 2004 is that the boron Upper intake Level for adults is 10 mg/person/day.

The evaluation of the hazards of borates and the setting of the concentration limits conducted by the Technical Committee on Classification and Labelling is consistent with the evaluations carried out by on borates in support of this other Community legislation.

Nickel

19 Which nickel substances have been classified under the 30th ATP?

There are 2 new entries in Annex I of Directive 67/548/EEC for nickel dichloride and nickel dinitrate, and 3 revised entries for nickel metal, nickel sulphate and nickel carbonate.

20 What uses do these substances have?

Nickel carbonate (more accurately, nickel hydroxycarbonate) is used in the manufacture of catalysts, certain nickel pigments and NiO by thermal decomposition, in Zn/Ni-electroplating, and as a neutralizing compound in nickel electroplating solution.

Nickel chloride is used for the production of nickel metal by electrolysis, catalysts and nickel containing chemicals, for electroplating, and other uses such as in electronic applications.

Nickel nitrate is used for the production of catalysts and nickel-cadmium batteries, and the chemical pre-treatment of metals prior to plating and in cold-forming.

Nickel sulphate is used for the production of nickel metal by electrolysis, catalysts, other nickel compound / salts, and nickel-containing batteries, and electroplating.

Nickel metal is used in the production of nickel-containing alloys (including stainless steel), in nickel plating, in the production of nickel-containing products (batteries, welding electrodes, etc.) and in the production of chemicals containing nickel.

21 What have they been classified as?

Nickel sulphate, nickel dichloride, nickel dinitrate, and nickel carbonate have all been classified as Carcinogenic Category 1 (Carc Cat 1: R49 for short), Mutagenic Category 3 (Muta. Cat. 3; R40 for short) and Toxic for Reproduction Category 2 (Repr. Cat. 2; R61 for short). Nickel sulphate and nickel carbonate were previously classified in Annex I as carcinogenic category 3 (Carc. Cat. 3: R68 for short). The classification of nickel metal as a category 3 carcinogen remains unchanged. Other hazards such as skin and eye irritation, acute oral toxicity, skin and respiratory sensitisation and hazards to the aquatic environment are also included where relevant.

The complete classifications are as follows:

Revised entries (new classifications added are in bold and underlined):

- Nickel: Carc. Cat. 3; R40 **T; R48/23** R43.²
- Nickel sulphate: **Carc. Cat. 1; R49 Muta. Cat. 3; R68 Repr. Cat. 2; R61 T; R48/23, Xn; R20/22 Xi; R38** R42/43 N; R50-53.
- Nickel carbonate³: **Carc. Cat. 1; R49 Muta. Cat. 3; R68 Repr. Cat. 2; R61 T; R48/23** Xn; **R20/22 Xi; R38 R42/43** N; R50-53.

New entries:

² The TC C&L has subsequently agreed a classification for environmental hazards applicable to fine metallic particles.

³ The entry includes a number of separate nickel carbonate compounds.

- Nickel dichloride: Carc. Cat. 1; R49 Muta. Cat. 3; R68 Repr. Cat. 2; R61 T; R23/25-48/23 Xi; R38 R42/43 N; R50-53.
- Nickel dinitrate: O; R8 Carc. Cat. 1; R49 Muta. Cat. 3; R68 Repr. Cat. 2; R61 T; R48/23 Xn; R20/22 Xi; R38-41 R42/43 N; R50-53.

22 What is the evidence that the 4 nickel salts are category 1 carcinogens?

All 5 substances mentioned in question 15 have been the subject of a risk assessment carried out by Denmark acting as Rapporteur under the Existing Substances Regulation⁴. The hazard information gathered as part of the risk assessment was submitted to the EU experts on classification for evaluation.

The Commission Working Group of Specialised Experts (SE) in the field of Carcinogenicity concluded that nickel sulphate and nickel chloride should be considered as human carcinogens, and thus category 1 carcinogens (Carc. Cat. 1), based on epidemiological evidence that established 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. 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 as Carc. Cat. 1. Since 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.

The TC C&L subsequently agreed that this classification should only apply to carcinogenicity following inhalation (Carc. Cat. 1; R49), rather than cancer following other routes of administration (e.g. when eaten).

23 Why nickel metal is not a category 1 carcinogen if some of its salts are?

The EU experts on classification have agreed that the available epidemiological evidence from inhalation of nickel metal does not establish a causal association between human exposure and cancer. Thus a carcinogenic category 1 classification cannot be justified. However, there is some evidence in animal studies which justifies a category 3 classification. The read-across approach used to classify the 4 nickel compounds was not applied to nickel metal for this effect as it is not clear how the nickel metal is related to the soluble nickel compounds. As more data on the issue will be forthcoming, the discussion in the TC C&L was postponed.

24 What is the basis of the read-across approach used to classify nickel compounds

There is considerable data available for the five nickel compounds considered in the 30th ATP. However, read-across was used to evaluate a number of endpoints for certain compounds.

The basis for the classification of the five compounds as carcinogens is shown above in questions 22 and 23. Inhalation of nickel metal, nickel subsulphide, nickel oxide, nickel sulphate and nickel chloride affects the lungs. Chronic lung inflammation and lung fibrosis are serious and potentially irreversible effects. Given that this effect is seen by a range of different nickel compounds, all five nickel compounds included in the 30th ATP are classified for this effect (T; R48/23).

For germ cell mutagenicity and reproductive toxicity which are effects that can occur when the nickel ion enters the body, the three water soluble salts (nickel sulphate, nickel chloride

⁴ Council Regulation (No) 793/93 on existing substances

and nickel nitrate) were classified in the same way. Nickel carbonate is also classified in the same way as there is evidence that this substance is also absorbed.

Irritation of the skin and eyes was based mainly on the results of experimental studies, but where positive effects seen in humans were given more weight than negative results in animal studies.

25 Although there is no data for acute inhalational toxicity for any of the five nickel compounds, classification for this effect (Xn; R20) has been included for the four salts as there is data that shows that the nickel ion can be absorbed and there is evidence from other studies that suggests this effect will occur. Are there any other recent assessments of nickel that are of relevance?

The human health hazard assessments in the five risk assessment reports have been reviewed by the relevant Commission Scientific Committee (SCHER)⁵, who supported the conclusions of the reports.

The health hazard properties of the five nickel compounds listed in the 30th ATP have been discussed by OECD experts in April 2007, who came to the same conclusion as the one proposed by EU in the 30th ATP.

Industry has submitted a report to the Commission prepared by the Natural History Museum in London on nickel sulphate, nickel hydroxide and nickel carbonate. The report contains no new information relevant to the hazard classification of the relevant substances.

Trade Issues

26 Has the 30th ATP been submitted to the World Trade Organisation (WTO)?

Yes the 30th ATP was transmitted to the WTO's Committee on Technical Barriers to Trade on 4 May 2007 (notification: G/TBT/N/EEC/151). Eleven countries commented on the draft measure between 26 June and 2 August 2007. The European Communities replied to the comments on the 7 and 9 September 2007, which elicited 6 further sets of country comments and which the EC sent further replies to on 12 March 2008.

Please see the European Commission website for more details: <http://ec.europa.eu/enterprise/tbt/>.

27 What have been the views of the international community?

The international community has been very interested in the outcome of the classification discussions as demonstrated by the 2 rounds of discussion in the WTO forum before the Commission adoption of the 30th ATP.

28 What were the main concerns raised by members

Some of the concerns of our trading partners have focussed on the inclusion of borates and nickel substances into Annex I of the Dangerous Substances Directive. The concerns raised included whether the classification included a risk assessment of the uses of borates, and have the rules in Directive 67/548/EEC been properly addressed. For nickel the concerns were also about the process followed and the use of read-across in coming to decisions about classification.

The EU answered these concerns in their replies mentioned above. On the issue of risk assessment of borates, the EC replied that the EU classification system is a hazard based approach similarly to the UN Global Harmonised System of Classification and labelling of Chemicals. Under this approach, a risk assessment is not required to establish the classification of a given substance, but instead a hazard assessment should be performed.

⁵ Scientific Committee on Health and Environmental Risks (SCHER) Opinion on Risk Assessment Report on Nickel. Human health part. Adopted by the SCHER during the 11th plenary of 4 May 2006. scher_o_034.pdf.

Other issues

29 How will the new CLP Regulation impact on the 30th ATP?

EU Member States can decide to implement the classifications in the 30th ATP in their national laws 20 days after the entry into force of the Directive. However, the Commission has informed EU Member States that the harmonised classification of the 30th ATP will be included in the Annex VI of the CLP Regulation which should enter into force in 2009. As an EU Regulation is directly applicable in all EU Member States and does not require transposition in national law, the EC does not expect any EU Member State to launch a transposition procedure of the 30th ATP.

30 Relationship to REACH Authorisation of the substances classified in the 30th ATP.

Under REACH, compounds classified as CMR category 1 or 2, as well as PBT and vPvB substances, will be potential candidates for authorisation. It is important to note that the process of identifying substances to be subject to authorisation consists of two steps (the establishment of the candidate status of the substance and then, the prioritisation of the substance for the actual authorisation procedure) which are subject to scientific evaluations following transparent scientific procedures. In addition, REACH provides for the possibility of exemptions to the obligation to obtain authorisations for certain uses or categories of uses. Authorisation will be given either on the basis of adequate control of the risks, or on the basis of a socio-economic analysis proving that the substance's use outweighs the risks it poses to human health or the environment and that there are no suitable alternative substances or technologies.