

Manual of European Environmental Policy

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Historical legislation: Restrictions on the marketing and use of certain dangerous substances and preparations

Formal references	
76/769/EEC (OJ L262 27.9.76)	Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations
Proposed 25.7.74 – COM(74)1189 and 29.4.75 – COM(75)186	
Amended by	Restricted substance
1st Amendment, Directive 79/663/EEC (OJ L197 3.8.79)	Ornamental objects etc.
2nd Amendment, Directive 82/806/EEC (OJ L339 1.12.82)	Benzene in toys
3rd Amendment, Directive 82/828/EEC (OJ L350 10.12.82)	PCTs
4th Amendment, Directive 83/264/EEC (OJ L147 6.6.83)	Fire retardants and novelties
5th Amendment, Directive 83/478/EEC (OJ L263 24.9.83)	Asbestos
6th Amendment, Directive 85/467/EEC (OJ L269 11.10.85)	PCBs and PCTs
7th Amendment, Directive 85/610/EEC (OJ L375 31.12.85)	Asbestos
8th Amendment, Directive 89/677/EEC (OJ L398 30.12.89)	Numerous additions including leaded paints and anti-fouling applications
9th Amendment, Directive 91/157/EEC (OJ L78 26.3.91)	Alkaline manganese batteries
10th Amendment, Directive 91/338/EEC (OJ L186 12.7.91)	Cadmium
11th Amendment, Directive 91/339/EEC (OJ L186 12.7.91)	Ugilec 21 and 141 and DBBT (PCB substitutes)
12th Amendment, Directive 94/27/EC [94/27/EC] (OJ L188 22.7.94)	Nickel in costume jewellery
13th Amendment, Directive 94/48/EC (OJ L331 21.12.94)	Flammable substances in aerosol generators for entertainment purposes
14th Amendment, Directive 94/60/EC (OJ L365 31.12.94)	Carcinogens, mutagens etc. (CMRs), creosote and chlorinated solvents
15th Amendment, Directive 97/16/EC (OJ L116 6.5.97)	Hexachloroethane (HCE) in non-ferrous in

	Non-ferrous metal industry
16th Amendment, Directive 97/56/EC (OJ L333 4.12.97)	Carcinogens, mutagens etc. (CMRs)
17th Amendment, Directive 1999/43/EC (OJ L166 1.7.99)	Carcinogens, mutagens etc. (CMRs)
19th Amendment, Directive 2002/61/EC (OJ L243 11.9.2002)	Azocolourants
20th Amendment, Directive 2002/45/EC (OJ L 177 6.7.2002)	Short-chain chlorinated paraffins (SCCPs)
21st Amendment, Directive 2001/41/EC (OJ L194 18.7.2001)	Carcinogens, mutagens etc. (CMRs)
22nd Amendment, Directive 2005/84/EC (OJ L344 27.12.2006)	Phthalates in toys and childcare articles
23rd Amendment, Directive 2003/34/EC (OJ L156 25.6.2003)	Carcinogens, mutagens etc. (CMRs)
24th Amendment, Directive 2003/11/EC (OJ L42 15.2.2003)	PentaBDE and octaBDE
25th Amendment, Directive 2003/36/EC (OJ L156 25.6.2003)	Carcinogens, mutagens etc. (CMRs)
26th Amendment, Directive 2003/53/EC (OJ L178 17.7.2003)	Nonylphenol, Nonylphenol ethoxylate and cement
29th Amendment, Directive 2004/73/EC (OJ L152 30.04.2004)	Various revisions; changes to animal testing
30th Amendment, Directive 2006/122/EC (OJ L372 27.12.2006)	Perfluorooctane sulphonates (PFOS)
Adapted by	Restricted substance
1st Adaptation, Directive 91/659/EEC (OJ L363 31.12.91)	Asbestos
2nd Adaptation, Directive 96/55/EC (OJ L231 12.9.96)	Chlorinated solvents
3rd Adaptation, Directive 97/10/EC (OJ L68 8.3.97)	Carcinogens, mutagens etc. (CMRs)
4th Adaptation, Directive 97/64/EC (OJ L315 19.11.97)	Ornamental objects etc.
5th Adaptation, Directive 1999/51/EC (OJ L142 5.6.99)	Organotin, PCP, cadmium
6th Adaptation, Directive 1999/77/EC (OJ L207 6.8.99)	Asbestos
7th Adaptation, Directive 2001/90/EC (OJ L283 27.10.2001)	Creosote
8th Adaptation, Directive 2001/91/EC (OJ L286 30.10.2001)	Hexachloroethane
9th Adaptation, Directive 2002/62/EC (OJ L183 12.7.2002)	Organotin compounds
10th Adaptation, Directive 2003/2/EC (OJ L 4/9 9.1.2003)	Arsenic

12th Adaptation, Directive 2003/3/EC (OJ L 4/12 9.1.2003)	‘Blue colourant’
13th Adaptation, Directive 2004/21/EC (OJ L 57/4 25.2.2004)	‘Azo colourants’
Legal base	Article 115 TFEU (originally Article 94 TEC)
Notification date	29 March 1977
Formal compliance	31 December 1978

Purpose of the Directives

The parent Directive 76/769/EEC creates a general framework for bans or restrictions on the marketing and use of dangerous substances. Restrictions are set out in an Annex and subsequent Directives have extended the Annex. This Directive has been repealed by the REACH Regulation (EC) No [1907/2006/EC](#). Annex XVII of REACH has replaced Annex 1 of Directive 76/769/EEC. Hence any future amendments to restrictions originally adopted under Directive 76/769/EEC will be incorporated in Annex XVII of the REACH Regulation (EC) No 1907/2006.

Summary of the Directives

Directive 76/769/EEC requires Member States to take all necessary measures to ensure that the dangerous substances and preparations listed in Annex I are only placed on the market or used subject to the conditions specified in the Annex. Directive 89/678/EEC provides for adaptation of the Annex to technical progress to be made by the Commission in consultation with the expert committee established by Directive 67/548/EEC. The restrictions do not apply to: marketing or use for the purposes of Research and Development or analysis. The Directive does not apply to

- the carriage of dangerous substances;
- substances exported to non-member countries; and
- substances in transit and subject to customs inspection.

The Annex lists polychlorinated biphenyls and terphenyls (PCBs, PCTs) as point 1 and monomer vinylchloride as point 2. PCBs and PCTs may only be used in closed system electrical equipment, large condensers and for certain other specified applications. Monomer vinyl chloride may not be used as an aerosol propellant.

Directive 79/663/EEC (1st amendment) adds to the Annex of Directive 76/769/EEC, establishing that trichloroethylene, tetrachloroethylene and carbon tetrachloride may not be used in ornamental objects intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays and that tris (2,3-dibromopropyl) phosphate, commonly known as Tris, and used as a fire retardant, is not to be used in textile articles intended to come into contact with the skin. Directive

97/64/EC modifies the restrictions for lamp oils.

Directive 82/806/EEC (2nd amendment) adds benzene to the Annex and bans its use in toys where the concentration of benzene is in excess of 5 mg/kg of the weight of the toy.

Directive 82/828/EEC (3rd amendment) relaxes the Annex by allowing PCTs to be used until 31 December 1984 in re-usable thermoplastic tooling compounds in the manufacture or maintenance of certain products, including gas turbines; nuclear reactors; ship and aircraft frames; semiconductor devices; and high-precision lenses.

Directive 83/264/EEC (4th amendment) adds to the Annex two substances used as fire retardants and several used in sneezing powders and in novelties, jokes and hoaxes.

Directive 83/478/EEC (5th amendment) adds asbestos to the Annex. Restrictions on use are defined by type of asbestos. The marketing and use of crocidolite (blue asbestos) fibres and products containing them is prohibited, but products manufactured before 1 January 1986 may be allowed to be marketed by Member States until 30 June 1988. Their use may also be exempt if manufactured, placed on the market or used before 1 January 1986. Member States may also exclude from the prohibition fibres and semifinished products essential to the manufacture of asbestos-cement pipes, various types of seals and gaskets, and torque convertors. All products containing asbestos, including crocidolite, may be marketed and used only if they bear a label in accordance with the provisions of Annex II of the Directive (the original Annex becomes Annex I).

Directive 85/467/EEC (6th amendment) bans all new applications of PCBs and PCTs and terminates with effect from 30 June 1986 the exemptions from a general ban on marketing and use of PCBs and PCTs permitted by Directive 76/769/EEC. Also banned from the same date is the marketing of second-hand equipment containing PCBs and PCTs and of fluids. Any material containing more than 0.01 per cent by weight of PCB or PCT (previously 0.1 per cent) is covered by the provisions. Discretionary clauses allow Member States to withdraw existing equipment and their labelling with maintenance, use and disposal instructions. Topping up liquid levels in existing equipment is also permitted where no substitute products exist. The use of PCBs and PCTs as primary and intermediate products is allowed to be continued indefinitely provided the Commission is informed and there are no deleterious effects.

Directive 85/610/EEC (7th amendment) revises the asbestos provisions by adding a further list of products which are not permitted if they contain asbestos fibres other than crocidolite. The list includes toys, items for smoking, catalytic filters and paints and varnishes. Directive 91/659/EEC bans all amphibole asbestos (crocidolite or 'blue' asbestos, amosite or 'brown' asbestos, anthrophyllite, actinolite, tremolite) allowing no exemptions. It further restricts the use of chrysotile (white) asbestos by prohibiting a number of chrysotile-containing building materials, consumer and industrial products. Directive 1999/77/EC bans the use of chrysotile (white asbestos) by 2005.

Directive 89/677 (8th amendment) Lead carbonates and lead sulphates are banned in paints, although their use may be authorized for the restoration or maintenance of works

of art and historic buildings. The use of arsenic and mercury compounds in anti-fouling, wood preservative and biocidal preparations is banned, as too are organostannic (organotin) compounds used on boats of less than 25 m in length. The maximum permitted concentration of PCBs/PCTs is cut from 100 to 50 ppm. The restrictions on organotin compounds have been extended by the 5th and 9th adaptations and by Regulation (EC) No 782/2003 (see below). Other substances are also restricted. 91/157 (in Article 3(2)) bans alkaline manganese batteries containing more than 0.025 per cent mercury by weight.

Directive 91/173/EEC (9th amendment) adds pentachlorophenol (PCP) as point 23. PCP and its salts and esters shall not be used in a concentration greater than 0.1 per cent by mass. Certain exceptions apply particularly as dry rot treatment for wood. Directive 1999/51/EC strengthens the requirements.

Directive 91/338/EEC (10th amendment) bans the use of cadmium to colour, stabilize or plate specified products and the marketing of such products with exemptions, for example, for safety reasons. Directive 1999/51/EC allows Austria and Sweden to maintain their more stringent restrictions until 31 December 2002.

Directive 91/339/EEC (11th amendment) bans the marketing and use of Ugilec 121 and 21 and DBBT and the use of Ugilec 141 in new equipment from 1994. These are substitutes for PCBs.

Directive 94/27/EC (12th amendment) bans nickel in costume jewellery if the rate of nickel release from the parts contacting skin exceeds $0.5 \mu\text{g}/\text{cm}^2/\text{week}$. A communication from the Commission (OJ L205 20.7.99) lists the European harmonized standards relating to nickel releases.

Directive 94/48/EC (13th amendment) bans certain flammable substances in aerosol generators intended for entertainment purposes, for example, artificial snow, 'silly string' aerosols.

Directive 94/60/EC (14th amendment) deals with three quite separate areas: (1) substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs) (2) creosote, and (3) certain chlorinated solvents. Substances are classified as CMRs under Directive [67/548/EEC](#) but only those listed in Directive 76/769/EEC are restricted for sale to the general public. The initial list of CMRs in Directive 94/60/EC included all those then classified as category 1 or 2 under Directive 67/548/EEC. Directive 97/10/EC adds to the list and the 16th amendment (see below) greatly extends it. Creosote which is carcinogenic and damaging to the environment may not be sold to the general public, nor may it be used by professionals if its level of benzo- alpha- pyrene (BAP) exceeds 50 ppm, nor may it be used for industrial pre-treatment if its BAP level exceeds 500 ppm. In October 1999 the Commission adopted decisions allowing the Netherlands, Sweden, Germany and Denmark to retain national laws restricting the marketing of creosote and another wood preservative PCP, which are stricter than the requirements of Directives 94/60/EC and 91/173/EEC. The Directive also bans the marketing to the general public of eight chlorinated solvents including chloroform, carbon tetrachloride and

pentachloroethane. Directive 96/55/EC extends the ban to use in diffuse industrial applications.

Directive 97/16/EC (15th amendment) restricts the use of hexachloroethane (HCE) in the manufacture or processing of non-ferrous metals. The Directive follows a Decision taken under the Paris Convention for the Prevention of Marine Pollution from land-based sources – PARCOM on the grounds that HCE is a possible precursor of certain persistent bioaccumulable organochlorine compounds. Since there is uncertainty that HCE is indeed a precursor the restriction is based on the precautionary principle. Two derogations in the Directive allow the use of HCE in non-integrated aluminium foundries producing specialized castings where consumption is less than 1.5 kg of HCE per day on average, and for grain refining in the production of certain magnesium alloys. These derogations will be reviewed.

Directive 97/56/EC (16th amendment) deals with CMRs – substances that are carcinogenic, mutagenic or toxic to reproduction, and greatly extends the list in the 14th amendment. The listed CMRs are not to be sold to the general public but the great majority are feedstock chemicals. Supply of articles incorporating the listed CMRs is not restricted.

Directive 1999/43/EC (17th amendment) extends the list of CMRs.

Directive 2002/61/EC (19th amendment) deals with Azocolourants, dyes used for colouring textiles and leather, now found to be carcinogenic. From 11 September 2003, marketing items using listed azocolourants will be prohibited.

Directive 2002/45/EC (20th amendment) relates to short-chain chlorinated paraffins (SCCPs). After 6.1.2004 SCCPs may not be placed on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 per cent in metalworking nor for fat liquoring of leather.

Directive 2001/41/EC (21st amendment) also extends the list of CMRs.

Directive 2005/84/EC (22nd amendment) prohibits the use of certain phthalates in concentration over 0.1 mass per cent in all toys and childcare articles. The Directive also prohibits the use of certain other phthalates in concentration over 0.1 mass per cent in those toys and childcare articles ‘which can be put in the mouth by children’. Member States shall transpose the Directive by 17 July 2006 and apply the measures from 16 January 2007.

Directive 2003/34/EC (23rd amendment) further extends the list of CMRs with national legislation needing to be in place by 15 July 2004 and applying by 15 January 2005.

Directive 2003/11/EC (24th amendment) extends marketing and use restrictions to diphenylether, pentabromo and octobromo derivatives.

Directive 2003/36/EC (25th amendment) again further extends the list of CMRs –

national legislation needs to be in place by 25 January 2004, and provisions in force by 25 December 2005.

Directive 2003/53/EC (26th amendment) extends the list to certain dangerous substances and preparations (nonylphenol (NP), nonylphenol ethoxylate (NPE) and cement). The placing on the market and the use of NP and NPE should be restricted for specific uses which result in discharges, emissions and losses to the environment. However, the restriction concerning co-formulants in pesticides and biocides will not override national authorizations of pesticides or biocidal products containing NPE, which have been granted before entry into force of the Directive. For cement, the CSTEE has confirmed the health effects of chromium VI in cement, and the Directive restricts the marketing and use of cement or cement preparations containing more than 2 ppm chromium VI – where there is a possibility of contact with skin. This measure has subsequently been amended by Communication [2005/C 23/03](#) on standards for the testing of cement.

Directive 2004/73/EC (29th amendment) republishes the list of dangerous substances, suitably updated to include further notified new substances and adapting some existing entries. For example 1,3-butadiene is reclassified as a mutagen. Furthermore, analysis methods as noted in Annex V of Directive 67/548/EEC are also amended to ensure that lesser use is made of animal testing.

Directive 2006/122/EC (30th amendment) restricts the use of perfluorooctane sulphonates (PFOS). These compounds may not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0.005 per cent by mass. In addition they may not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or higher than 0.1 per cent by mass or, for textiles or other coated materials, if the amount of PFOS is equal to or higher than 1 µg/m² of the coated material. This Directive also provides for some derogations (such as for photographic coatings and fire-fighting foams).

Regulation (EC) No [782/2003](#) of 14 April 2003 – on the prohibition of organotin compounds on ships – complements Directives 89/677/EEC and 2002/62/EC (9th adaption of technical progress) prohibiting the use, with effect from 1 January 2003, the marketing and use of organostannic compounds in anti-fouling systems for all ships, irrespective of their length. The Regulation requires that, as from 1 January 2008, ships bearing an active TBT (tributyltin) coating on their hulls will no longer be allowed in Community ports. The Regulation implements measures agreed at an International Convention on the control of harmful anti-fouling systems on ships (AFS-Convention), adopted on 5 October 2001, under the aegis of the IMP and with the attendance of Member States of the Community. The Regulation also calls for Member States to ratify the AFS-Convention, which contains the same deadlines. Entry into force follows ratification by 25 states representing 25 per cent of the world's merchant shipping tonnage.

Development of the legislation

Although the parent Directive 76/769/EEC sets out a general scheme for restrictions on marketing and use of products, its origin is to be found in a draft French law introduced to implement the decision by the OECD restricting PCBs. The Commission, however, saw the need for a general measure on the grounds that some Member States were already restricting some substances and that Community measures were needed to prevent barriers to trade. The Commission's explanatory memorandum, for example, quotes a British restriction on benzene in toys as the origin of Directive 82/806/EEC. The Commission had originally envisaged the Directive establishing a Committee empowered to add other substances by qualified majority vote but this was resisted by Britain, and doubtless other Member States, and in the event extra substances have to be added to the Annex by the Council in separate Directives.

There was some discussion whether the power to restrict marketing and use should form part of the Directives requiring notification and testing of substances before marketing but the power were kept separate although the two groups of Directives are clearly linked.

Directive 82/828/EEC which relaxes the restriction on PCTs for certain applications for a certain period seems to have arisen because it was found in Britain (and in other Member States though their authorities were unaware of the fact) that PCTs were in use despite the restrictions of Directive 76/769/EEC.

The Proposal on asbestos (Directive 83/478/EEC) took over three years to be agreed and discussions became linked with negotiations on the Directive on worker protection from asbestos exposure. Significant changes were made in the course of negotiations. The difficulties were to reconcile existing practices and differing views on the dangers from asbestos. In particular, some Member States made much use of asbestos-cement pipes manufactured from crocidolite. The result was a relaxation of the original proposal: though marketing and use of products containing crocidolite were prohibited after 30 June 1988, Member States could nevertheless exempt certain types of products (including asbestos-cement pipes) and the requirement to prevent harmful release of fibres was dropped. For other types of asbestos the proposed prohibition of use for thermal and acoustic insulation, air filtering and roadway surfacing and for decorative purposes was replaced by the simple requirement to label the product. The relaxations represent concessions to the powerful lobby of continental manufacturers.

Directive 85/610/EEC appears according to the preamble to have been a second bite at completing restrictions on asbestos to take account of differences in regulations in Member States. Although the Directive refers only to the original proposal from the Commission (COM(79)419), it does appear to incorporate products first listed in the amendments to that Proposal, which were not included in Directive 83/478/EEC. Those amendments appear to have been influenced by the European Parliament's recommendations and were put forward in September 1982 (COM(82)498). It is not clear why there should have been a three-year delay and a gap of over two years between the

fifth and seventh amendment. The Commission finally adopted Directive 1999/77/EC banning supply and use of white asbestos (chrysotile) by 2005, subject to some exceptions, and allowing earlier national bans. This was opposed by Canada, the largest supplier of white asbestos. In June 2000 a World Trade Organisation disputes settlement panel recommended rejection of Canada's complaints regarding restrictions on imports of white asbestos. It concluded that bans would be legitimate in order to protect health.

The 9th amendment (Directive 91/173/EC) was adopted under Article 100a and Germany was then allowed a derogation by the Commission to maintain its existing laws which are more stringent than the Directive in not allowing exemptions for the use of PCP in timber treatment. However, France challenged this in the Court of Justice on the grounds that the Commission had failed to assess Germany's argument that its stricter measures were justified. The Court (Case [C-41/93](#)) ordered the annulment of the derogation solely on procedural grounds and the Commission then issued a new derogation accompanied by a justification (Commission Decision [94/783/EC](#)). This was the first case before the Court on the use of Article 100a(4). In February 1996 the Commission allowed Denmark to maintain its ban on PCP (Commission Decision [96/211/EC](#)).

The 14th amendment (Directive 94/60/EC) in the form proposed by the Commission raised issues of principle because it would automatically have restricted sale to the public of substances whenever they were classified as category 1 or 2 carcinogens under Directive 67/548/EEC. This was opposed by the United Kingdom and also by the European Parliament but for different reasons, the Parliament objecting to the idea that substances classified in the future as carcinogenic, etc. could be restricted without its involvement. In the event, the Proposal was amended so that only those carcinogens listed are restricted. The Commission had also proposed the 14th amendment before the CMRs listed had been subject to a risk amendment. In contrast, the CMRs listed in the proposal for the 16th amendment had been subjected to assessment.