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Marketing and Use of Dangerous Substances

INTRODUCTION

On July 27, 1976, the Council of the European Communities (Council) enacted Directive 76/769 to harmonize member state laws regarding the marketing and use of certain dangerous substances in the European Community (EC or Community).¹ Since 1976, eight amendments to the directive have increased its overall effectiveness by tightening or defining standards and proscribing additional dangerous substances.² The amendments reflect both the Community's commitment to eliminate threats to health and environment posed by these chemicals, and to harmonize member state law in the pursuit of a uniform internal market by the end of 1992.³

Currently, three proposed amendments seek to subject several additional chemicals to the purview of Directive 76/769. The proposed ninth amendment, 1988 Commission proposal C117/

¹ Directive 76/769, Council Directive of July 27, 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L262/201 (1976). *See also* Proposal for a Council Directive on the approximation of the laws of the Member States restricting the marketing and use of certain dangerous substances and preparations, O.J. C126/33 (1974) [hereinafter Proposal]; Resolution embodying the Opinion of the European Parliament, O.J. C60/49 (1975) [hereinafter Resolution]; Opinion on the proposal for a Council Directive on the approximation of the laws of the Member States restricting the marketing and use of certain dangerous substances and preparations, O.J. C16/25 (1974) [hereinafter Opinion]. Directive 76/769 contains an annex that lists restricted substances and preparations, and standards for allowable uses thereof. The directive defines "substances" and "preparations" (dangerous substances) as natural and manufactured chemical elements, their compounds, and solutions or mixtures composed thereof. Directive 76/769, *supra*, at 202-03.

² *See infra* note 23 and accompanying text for a list and discussion of the amendments to Directive 76/769.

³ *See infra* notes 8 and 12 and accompanying text. *See also* Directive 76/769, *supra* note 1, at 201.

11, seeks to restrict the use of pentachlorophenol.⁴ The proposed tenth amendment, 1989 Commission proposal C8/06, seeks to proscribe certain applications and uses of cadmium.⁵ Finally, the proposed eleventh amendment, 1990 Commission proposal C24/15, would prohibit the use of two polychlorinated biphenyls (PCB) substitutes, and restrict and phase out a third.⁶

This Note discusses the three proposed amendments.⁷ Part I reviews the background and current status of Directive 76/769. Part II then outlines each of these three proposed amendments to the directive. Part III evaluates the potential impact of the amendments on industry, the environment, and the internal market. This Note concludes that each of the proposed amendments provides a strong framework in which the EC can further both

⁴ Proposal for a Council Directive amending for the ninth time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C117/14 (1988) [hereinafter Proposed Ninth Amendment]. *See also* Proposal for a Council Directive amending for the ninth time Directive 76/769, COM(88) 190 final—SYN 130 (explanatory memorandum) [hereinafter COM(88) 190 final]; Legislative Resolution, O.J. C291/58 (1989); Opinion on the proposal for a Council Directive amending for the ninth time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C208/55 (1988).

⁵ Proposal for a Council Directive amending for the tenth time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C8/8 (1990), O.J. C309/11 (1989) [hereinafter Proposed Tenth Amendment]. *See also* Proposal for a Council Directive amending for the tenth time Directive 76/769, COM(89) 548 final—SYN 224 (explanatory memorandum) [hereinafter COM(89) 548 final]; Opinion on the Proposal for a Council Directive amending for the tenth time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C112/1 (1990); Council Resolution on a Community Action Programme to combat environmental pollution by cadmium, COM(87) 165 final, O.J. C30/1 (1988) [hereinafter Cadmium Pollution Programme].

⁶ Proposal for a Council Directive amending for the eleventh time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C24/20 (1990) [hereinafter Proposed Eleventh Amendment]. *See also* Proposal for a Council Directive amending for the eleventh time Directive 76/769, COM(89) 665 final (explanatory memorandum) [hereinafter COM(89) 665 final]; Opinion on the proposal for a Council Directive amending for the eleventh time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C168/1 (1990).

⁷ This Note reflects developments through March 1, 1991 as reported in publicly available documents.

the harmonization of the internal market and the protection of health and environment.

I. DIRECTIVE 76/769

A. *Background and Purpose*

The Community enacted Directive 76/769 at a time of growing concern for the promotion of both trade and environmental protection.⁸ Relevant to both goals was the fact that in 1976, the Community as a whole was the largest producer of chemicals worldwide.⁹ To promote internal and external trade in these products, the Community had to harmonize the heterogeneous set of member state restrictions and standards.¹⁰ At the same time, awareness of environmental degradation led to efforts to protect health and environment from the dangers of these products and resulted in the Community's introduction or adoption of new and amended legislation.¹¹ A product of its time, Directive 76/769 thus has two primary objectives.

Directive 76/769 first aims at harmonizing heterogeneous member state regulations of the marketing and use of dangerous substances.¹² Uniform Community-wide regulation of dangerous chemicals would promote fair trade and assure true competition by erasing competitive advantages due to less restrictive member state laws.¹³ Not surprisingly, most amendments to Directive 76/769 refer to individual member state regulations that distorted competition in the Community.¹⁴

⁸ See generally R. BRICKMAN, S. JASANOFF & T. ILGEN, *CONTROLLING CHEMICALS: THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES* 274-93 (1985), for a discussion of the reaction of the Community and some member states to such issues as the 1976 enactment of the U.S. Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.* (1976), and several of the EC directives passed during this period.

⁹ Wyman, *Control of Toxic Substances: The Attempt to Harmonize the Notification Requirements of the U.S. Toxic Substances Control Act and the European Community Sixth Amendment*, 20 VA. J. INT'L L. 417, 421 (1980).

¹⁰ *Id.* at 418-20.

¹¹ See generally R. BRICKMAN, S. JASANOFF & T. ILGEN, *supra* note 8, at 250-93. See also Kelly, *International Regulation of Transfrontier Hazardous Waste Shipments: A New EEC Environmental Directive*, 21 TEXAS INT'L L.J. 85, 90-93 (1985).

¹² See Directive 76/769, *supra* note 1, at 201. See also Kelly, *supra* note 11, at 90-93. Unification of laws at the EC level will prevent economic disparities and distortions resulting from inconsistent member state regulations and will promote the internal market.

¹³ See Kelly, *supra* note 11, at 92.

¹⁴ See, e.g., Directive 79/663 supplementing the Annex to Council Directive 76/769 on

Second, the directive seeks to protect EC citizens and their environment from the harmful effects of chemical pollution¹⁵ by barring the use of certain substances in specific applications and products¹⁶ or by imposing labeling requirements on products containing dangerous substances.¹⁷ The legal basis for this second objective has been fortified over time. Originally, environmental protection was authorized indirectly under articles 100 and 235 of the Treaty of Rome (EEC Treaty).¹⁸ The 1986 enactment of the Single European Act (SEA), however, created a direct legislative mandate for Community protection of health and environment.¹⁹

the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L197/37 (1979) (first amendment); Directive 82/806 amending for the second time (benzene) Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L339/55 (1982); Directive 83/264 amending for the fourth time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L147/9 (1983); Directive 83/478 amending for the fifth time (asbestos) Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L263/33 (1983); Directive 85/610 amending for the seventh time (asbestos) Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L375/1 (1985); Directive 89/677 amending for the eighth time Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L398/19 (1989).

¹⁵ See recitals in Directive 76/769, *supra* note 1, at 201.

¹⁶ Directive 76/769, *supra* note 1, at 203; Directive 79/663, *supra* note 14, at 38 (barring use of several substances in ornamental or lighted objects and apparel); Directive 82/806, *supra* note 14, at 56 (restricting use of benzene in toys and toy parts); Directive 83/264, *supra* note 14, at 10 (barring use of several substances in "joke" or "hoax" products); Directive 85/610, *supra* note 14, at 2 (banning use of asbestos fibers in six product groups); Directive 89/677, *supra* note 14, at 20-23 (restricting use of several substances in a variety of product groups).

¹⁷ Directive 83/478, *supra* note 14, at 34-36 (providing for special labeling of products containing asbestos).

¹⁸ See Farquhar, *The Policies of the European Community Towards the Environment—The "Dangerous Substances" Directive*, J. PLAN. & ENVTL. L. 145, 145-52 (1983); Kelly, *supra* note 11, at 90-92. Protection of the environment and health in the EC was justified under a broad interpretation of articles 100 and 235 of the Treaty of Rome. Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter EEC Treaty].

¹⁹ See Single European Act, Feb. 17, 1986, O.J. L169/1 (1987) [hereinafter SEA]. See also Sands, *European Community Environmental Law: Legislation, the European Court of Justice and Common-Interest Groups*, 53 MOD. L. REV. 113, 115-17 (1990); Note, *The Control of*

B. *Subsequent Amendments*

Directive 76/769 was initially limited in scope, but provided for future amendment to adjust existing regulations and to include other dangerous substances as they became known.²⁰ The Community amended the directive eight times in its fourteen year history, adding new substances and changing the restrictions applicable to chemicals already included.²¹ The ability to change existing restrictions exemplifies the Community's desire to respond to new scientific discoveries regarding the environmental and health hazards of chemicals, and to remain sensitive to eco-

Nitrate Pollution in the EEC: Proposed Directive 88/708, 13 B.C. INT'L & COMP. L. REV. 415, 418-21 (1990). Article 25 of the SEA added Title VII to the EEC Treaty with the fundamental duties "to preserve, protect and improve the quality of the environment" and to protect human health. SEA, *supra*, at art. 130r(1).

²⁰ See Directive 76/769, *supra* note 1, at 201-03; Proposal, *supra* note 1, at 34. While the Commission proposal was only directed at PCB's, the final version of the directive restricted the use not only of PCB's but also polychlorinated terphenyls (PCT's) and chloro-ethylene (monomer vinyl chloride or MVC). PCB's and PCT's were originally prohibited for all but six conditional uses, two of which were to expire at the end of 1979, and MVC was barred completely as an aerosol propellant. Directive 76/769, *supra* note 1, at 203.

²¹ Directive 79/663, *supra* note 14, at 38 (amending Directive 76/769 to include tris phosphate and Annex I of Directive 67/548); Directive 82/806, *supra* note 14, at 56 (adding benzene); Directive 82/828 amending for the third time (PCT) Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L350/34, at 34-35 (1982) (allowing additional use of PCT's until 1984); Directive 83/264, *supra* note 14, at 9-10 (adding tris-aziridinyl-phosphin oxide; polybrominated biphenyls (PBB); soap bark powder (quillaja saponaria) and its derivatives containing saponines; powder of the roots of *Helleborus viridis*, *Helleborus niger*, *Veratrum album*, and *Veratrum nigrum*; benzidine and its derivatives; a-nitrobenzaldehyde; wood powder; ammonium sulphide, ammonium hydrogen sulphide and ammonium polysulphide; and volatile esters of bromoacetic acids: methyl bromoacetate, ethyl bromoacetate, propyl bromoacetate and butyl bromoacetate); Directive 83/478, *supra* note 14, at 33-36 (adding asbestos to Annex I and adding Annex II regarding the labeling of products containing asbestos); Directive 85/467 amending for the sixth time (PCB's/PCT's) Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L269/56, at 56-57 (1985) (further restricting the use of PCB's and PCT's); Directive 85/610, *supra* note 14, at 2 (supplementing asbestos requirements); Directive 89/677, *supra* note 14, at 20-23 (further amending PCB and PCT standards and adding 2-naphthylamine; bensidine; 4-nitrobiphenyl; 4-aminobiphenyl; lead carbons: neutral anhydrous, lead hydrocarbonate; lead sulphates; mercury compound; arsenic compounds; organostannic compounds and butylstanniohydroxyborane); Directive 89/678 amending Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. L398/24 (1989) (procedural changes).

conomic and industrial needs.²² This two-fold approach necessitated balancing the economic needs of industry against environmental concerns and led to some of the subsequent amendments to the directive.²³

Directive 76/769 originally aimed at barring PCB's and polychlorinated terphenyls (PCT's) from the market where viable substitutes existed, and restricting their use to certain "closed system" applications where no substitutes were available.²⁴ The directive also set phase-out time frames for other uses of PCB and PCT to promote the development of substitutes in moving gradually towards a complete ban of PCB's and PCT's. This gradual phase-out thus represented a compromise between industrial and economic interests on the one hand, and the threat to human health and the environment on the other.²⁵

Reflecting changed perceptions of industrial need and environmental harm, the Council subsequently shifted the original balance struck in Directive 76/769. The third amendment, Directive 82/829, temporarily authorized extended use of PCT for certain critical industries until December 31, 1984 because of the chemical's importance to industry.²⁶ The sixth amendment, Directive 85/467, also reassessed industrial need for PCB's and PCT's but did so in light of the fact that PCB and PCT pollution had not

²² See generally Directive 76/769, *supra* note 1, at 201-02. The recitals and legislative documents supporting the directive and subsequent amendments designate health, environmental, and economic factors as key elements in this balancing process.

²³ See generally Directive 76/769, *supra* note 1.

²⁴ Directive 76/769, *supra* note 1, at 201-03.

²⁵ See generally *id.*; Proposal, *supra* note 1; Resolution, *supra* note 1; Opinion, *supra* note 1. The recitals and legislative materials of the original directive reflect an overriding concern to protect Community health and environment from the ecotoxic effects of the regulated substances.

²⁶ See Directive 82/828, *supra* note 21, at 34-35; Proposal for a Council Directive amending for the fourth time Council Directive 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C31/9 (1980); Resolution embodying the opinion of the European Parliament, O.J. C175/88 (1980); Opinion on the proposal for a Council Directive amending, for the fourth time, Council Directive No 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, O.J. C182/11 (1980). In Directive 82/828, the Council recognized that PCT's "are of fundamental importance for the uses for which they were intended" in justifying their extended use because of critical industrial need, lack of viable substitutes, and the fact that these industries had a 95 percent PCT waste recovery rate. Directive 82/828, *supra* note 21, at 34.

lessened significantly since the 1976 directive.²⁷ The Council therefore decreased allowable PCB and PCT concentrations in closed system use and set June 30, 1986 as the phase-out date for new PCB and PCT uses in previously allowable systems.²⁸ This amendment acknowledged that a total ban on PCB's and PCT's was still not feasible in 1985. Nevertheless, it "constitute[d] an important step towards such a ban" and demonstrated the willingness of the Council to keep moving toward this goal.

In 1989, a procedural amendment facilitated the revision of standards applicable to already proscribed chemicals as warranted by technical progress and new scientific insights.²⁹ Rather than propose such revisions to the Council and the European Parliament (Parliament) under the full cooperation procedure,³⁰ the Commission of the European Communities (Commission), after consulting with an advisory committee, may now add new restrictions to the directive's annex or revise the standards for regulated substances.³¹

Currently, the directive prohibits or proscribes the marketing and use of more than twenty-two product groups of dangerous substances.³² Proposals to add new substances must still follow the full cooperation procedure.³³ Directive 76/769, however, does

²⁷ See Directive 85/467, *supra* note 21, at 56–58; Proposal for a Council Directive relating to restrictions to marketing and use of certain dangerous substances and preparations (second PCB/PCT Directive), COM(84) 513 final; Resolution of the European Parliament, O.J. C141/76 (1985); Opinion on the proposal by the Economic and Social Committee, O.J. C104/1 (1985).

²⁸ See Directive 85/467, *supra* note 21, at 56–58.

²⁹ Directive 89/678, *supra* note 21, at 24 (adopting procedure set forth in article 21 of Directive 67/548, O.J. No. 196/1 (1967)). This directive is currently under reexamination. See Re-examined proposal for a Council Directive, COM(89) 606 final—SYN 28, O.J. C30/89 (1990); Legislative Resolution, O.J. C262/84 (1988); Decision, O.J. C291/55 (1989); Opinion on the proposal by the Economic and Social Committee, O.J. C337/7 (1988); COM(83) 556 final; COM(86) 35 final; COM(87) 39 final.

³⁰ For a description of EC legislative process, see generally, J. BUHART & D. BURTON, LEGAL ASPECTS OF THE SINGLE EUROPEAN MARKET: A WORKING GUIDE TO 1992 4–7 (1989). The two methods of full procedure are standard procedure and cooperation procedure. Each requires participation by both the Council and the European Parliament but cooperation procedure provides a more significant role for the European Parliament.

³¹ See Directive 89/678, *supra* note 21, at 24. This amendment appears to offer a potential "bootstrap" procedure by allowing easy amendment by the Commission to restrictions of a substance once it is regulated by the directive. This amended procedure has yet to be used but should provide a streamlined process for revising restrictions on substances already covered by Directive 76/769.

³² See Directive 76/769, *supra* note 1.

³³ See *supra* note 30 and accompanying text.

not apply to the carriage of these substances, their export to non-member countries, their transit subject to customs, or their use in research and development or analysis.³⁴

II. THE PROPOSED NINTH, TENTH AND ELEVENTH AMENDMENTS

Each of the proposed amendments seeks to add new substances to Directive 76/769 and must therefore follow the full legislative process. This section will introduce each proposal individually.

A. *The Ninth Proposed Amendment*

The ninth proposed amendment would add pentachlorophenol and its compounds³⁵ to Directive 76/769, prohibiting their use in concentrations equal to or greater than 0.1 percent by mass in any marketed substance or product.³⁶ Pentachlorophenol poses many environmental and health hazards primarily because it is used as a pesticide and because it is insoluble in water.³⁷ Less dangerous substitutes for pentachlorophenol are available for many of its current applications.³⁸ In addition, individual member state restrictions relating to this substance directly affect the establishment and operation of the internal market.³⁹ Thus, justification for the inclusion and harmonization of pentachlorophenol regulations at the EC level is apparent. The Commission seeks to strictly regulate the general public's exposure to pentachlorophenol because its environmental hazards outweigh its benefits in all but certain industrial settings.⁴⁰ Nevertheless, three proposed exceptions permit the continued use of pentachlorophenol in industrial settings for the treatment of wood, the impregnation of heavy-duty textiles, and use as a synthesizing or processing agent. The Council would have to reexamine the fur-

³⁴ Directive 76/769, *supra* note 1, at 202.

³⁵ Pentachlorophenol is used as a pesticide, wood treatment, and as a processing and synthesizing agent both in consumer and industrial applications. See COM(88) 190 final, *supra* note 4, at 2-3; THE WORLD ALMANAC 157 (1987).

³⁶ Proposed Ninth Amendment, *supra* note 4, at 14-15.

³⁷ See N. SAX & R. LEWIS, DANGEROUS PROPERTIES OF INDUSTRIAL MATERIAL 2665-66 (7th ed. 1988). Pentachlorophenol is poisonous to humans and animals through ingestion and other methods of exposure. It is considered to be carcinogenic, mutagenic, and teratogenic, and chronic exposure can cause liver and kidney injury.

³⁸ COM(88) 190 final, *supra* note 4, at 2-3.

³⁹ Proposed Ninth Amendment, *supra* note 4, at 14-15; COM(88) 190 final, *supra* note 4, at 2.

⁴⁰ COM(88) 190 final, *supra* note 4, at 2-3.

ther need for these exceptions within five years of passing the amendment.

B. *The Tenth Proposed Amendment*

As part of the wider Community action program to combat environmental pollution from cadmium,⁴¹ the proposed tenth amendment seeks to reduce overall cadmium use by limiting its applications in three different settings. First, cadmium would be banned as a pigment or coloring agent where its content exceeds .01 percent by weight in certain finished products.⁴² Second, cadmium used as a stabilizer would be limited to .01 percent by weight of the finished product.⁴³ Finally, use of cadmium would be banned in plating or surface coating where the final products are designed to come into direct contact with humans or are used in food production and consumption.⁴⁴ These provisions are subject to certain time frames and exceptions.⁴⁵

The Commission has proposed the amendment on the environmental and economic grounds that have supported similar prior legislation.⁴⁶ The environmental and health hazards of cadmium and cadmium compounds are severe and well-documented.⁴⁷ Cadmium is poisonous, probably carcinogenic, and has

⁴¹ See ENCYCLOPEDIA OF MATERIALS SCIENCE AND ENGINEERING 408 (M. Bever ed. 1986). Cadmium and cadmium compounds are used in the plating and coating of parts used in transportation and defense equipment, architectural and precision hardware, electronics, home appliances, and industrial machinery. Cadmium is also used in the production of batteries, as a pigment, as a stabilizer for plastics and synthetics, and in nuclear engineering.

Recognizing the threat of cadmium pollution to human health, the Commission seeks to reduce the release of cadmium into the environment wherever possible. The seriousness with which cadmium pollution is regarded is reflected by the fact that as of 1987, there were 20 Council directives dealing with cadmium. See Cadmium Pollution Programme, *supra* note 5, at 7. The EC cadmium control strategy is to reduce cadmium emissions to the greatest extent possible, curtailing cadmium use overall and minimizing cadmium escapes where use is unavoidable. *Id.* at 7-12, 15, 17-19.

⁴² Proposed Tenth Amendment, *supra* note 5, at 9. See also Cadmium Pollution Programme, *supra* note 5, at 11-12, 15.

⁴³ Proposed Tenth Amendment, *supra* note 5, at 9.

⁴⁴ *Id.* at 10-11.

⁴⁵ *Id.* at 9-11.

⁴⁶ See *supra* notes 12-19, and accompanying text.

⁴⁷ N. SAX & R. LEWIS, *supra* note 37, at 664-67. Cadmium is poisonous; prolonged exposure causes severe kidney and liver injuries and serious bone disorders. It is believed to be carcinogenic, mutagenic, neoplastigenic, and teratogenic. For a compelling account of cadmium pollution and the effects of mass cadmium poisoning, see J. GRESSER, K. FUJIKURA & A. MORISHIMA, ENVIRONMENTAL LAW IN JAPAN 55-64 (1981) (discussing the

been linked to severe kidney, liver, and bone diseases. Furthermore, the need for Community harmonization arises in part from Denmark's enactment of regulations that ban and limit the use of cadmium in several industrial settings.⁴⁸ The proposed amendment and supporting legislative documentation thus emphasize the need for a uniform single market policy regarding cadmium pollution to promote both the internal market and the protection of the environment.⁴⁹

C. *The Eleventh Proposed Amendment*

The most recent proposed amendment would ban three PCB substitutes that industry developed in response to the initial PCB ban of Directive 76/769.⁵⁰ The proposed amendment completely bans the marketing and use of monomethyl dichloro diphenyl methane (tradename Ugilec 121 or Ugilec C21) and monomethyl dibromo diphenyl methane (DBBT).⁵¹ Also banned is the new use of monomethyl tetrachloro diphenyl methane (tradename Ugilec 141) starting three years after passage of the amendment and subject to a service-life exception for existing uses.⁵² Of the three substances, only Ugilec 141 is currently marketed.⁵³ Its current industrial use warrants the three-year phase-out and service-life exception. DBBT and Ugilec 121 are not currently on the market. Immediate prohibition is thus more appropriate.⁵⁴

The environmental justification for this amendment is clear because all three PCB substitutes possess many of the same hazardous attributes as the PCB's they were to replace. Furthermore, the need to harmonize member state law arose in part from the Dutch Government's 1988 notification of its intent to unilaterally

Itai-Itai case). See also Cadmium Pollution Programme, *supra* note 5, at 4 (alluding to Japanese causation research done in conjunction with that case).

⁴⁸ See Cadmium Pollution Programme, *supra* note 5, at 7.

⁴⁹ See Proposed Tenth Amendment, *supra* note 5, at 9. See also Cadmium Pollution Programme, *supra* note 5, at 11-16.

⁵⁰ Proposed Eleventh Amendment, *supra* note 6, at 20-21; COM(89) 665 final, *supra* note 6, at 1-8.

⁵¹ Proposed Eleventh Amendment, *supra* note 6, at 20-21.

⁵² *Id.* at 21. This service-life exception grants an exception for any quantity of Ugilec 141 in service at the time of, and three years following enactment of the proposed amendment.

⁵³ *Id.* at 20; COM(89) 665 final, *supra* note 6, at 1-8.

⁵⁴ See COM(89) 665 final, *supra* note 6, at 1-8.

restrict the marketing and use of these substances.⁵⁵ The objectives of the eleventh proposed amendment are thus consistent with Directive 76/769's goal to protect health and environment from the effects of dangerous chemicals, as well as to promote free movement of goods within the EC.⁵⁶

III. EVALUATION OF THE PROPOSED AMENDMENTS

The two goals underlying these proposed amendments to Directive 76/769 are the protection and improvement of human health and the environment, and the harmonization of member state laws to implement the unified internal market.⁵⁷ Achieving the two goals involves balancing the environmental and health risks posed by each substance against its value to industry and the market, the availability of substitutes, and the costs involved in implementing such regulations.⁵⁸ The balance of these factors determines the level of restrictions and the time frame in which to impose such restrictions.⁵⁹

The applications and availability of potential substitutes determine the economic need for the proscribed products.⁶⁰ For example, the Commission proposal recognizes the public availability of less hazardous substitutes for pentachlorophenol used in pesticides.⁶¹ Its industrial use, however, is apparently more important and less subject to substitutability, justifying the exceptions provided for in the proposal. Similarly, the proposed restrictions on the use of cadmium are more stringent where environmentally preferable substitutes are available to the industry or where potential human exposure is more likely.⁶²

Finally, each of the proposed amendments reflects the need to harmonize divergent member state regulations regarding the

⁵⁵ COM(89) 665 final, *supra* note 6, at 1. See also Proposed Eleventh Amendment, *supra* note 6, at 20.

⁵⁶ COM(89) 665 final, *supra* note 6, at 1-9.

⁵⁷ See Proposed Ninth Amendment, *supra* note 4, at 14; Proposed Tenth Amendment, *supra* note 5, at 8; Proposed Eleventh Amendment, *supra* note 6, at 20.

⁵⁸ For a discussion of this balancing process and examination of the hazards, substitutes, necessity, and time frames considered in formulating the standards of Directive 85/467 and the proposed tenth amendment respectively, see COM(84) 513 final, *supra* note 27, at 1-4; COM(89) 548 final, *supra* note 5, at 2-4, 13-17.

⁵⁹ See *supra* note 58.

⁶⁰ See *supra* notes 37-40, 41-45, 50-56, and accompanying text.

⁶¹ COM(88) 190 final, *supra* note 4, at 2.

⁶² See Cadmium Pollution Programme, *supra* note 5, at 11-12.

marketing and use of dangerous substances and preparations.⁶³ In each case, at least one member state has taken action within its domain to restrict these substances.⁶⁴ Other member states seeking to market such products or related products within the excluding nation must deal with these restrictions or forgo that nation's market.⁶⁵ Allowing one member state to maintain standards different from those of other member states will result in economic distortions and barriers to trade that are incompatible with the internal market.⁶⁶

CONCLUSION

The three proposed amendments to Directive 76/769 address the issues of environmental degradation and harmonization of member state laws. Each of the proposed amendments attempts to balance the environmental harm of certain substances against the associated costs of implementation. Furthermore, the anti-competitive effect of individual member state regulations in each of these three cases suggests the need for unifying EC legislation to resolve potential conflicts among member state laws. The Commission's proposals balance these factors and standardize restrictions throughout the EC. Each proposed amendment presents an appropriate level of protection in light of the specific economic necessities. It appears then, that the Commission has proposed a solid framework in which to regulate and restrict these substances on a Community-wide level.

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⁶³ See Proposed Ninth Amendment, *supra* note 4, at 14; Proposed Tenth Amendment, *supra* note 5, at 8; Proposed Eleventh Amendment, *supra* note 6, at 20.

⁶⁴ See *supra* notes 39, 48, 49, 55 and accompanying text.

⁶⁵ See *supra* notes 12-13 and accompanying text.

⁶⁶ See *supra* notes 12-14, 65 and accompanying text.