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Gathering Danger: The Urgent Need to Regulate Toxic Substances That Can Bioaccumulate

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INTRODUCTION

Dioxin. DDT. PCB's. PAH's.[1] Over the past two decades, fear that these chemical substances will harm human health or the environment has periodically swept through the public, the press, and Congress. These substances have three key qualities in common.[2] First, each class contains known toxic compounds.[3] Second, in contrast to many chemicals, they tend to persist in the environment, sometimes for decades. Third, each class contains constituents that are unusually capable of bioaccumulating, that is, of building up in living tissues. The release of significant quantities of substances having all three properties—high toxicity, persistence, and capacity to bioaccumulate—poses potentially severe risks for human health and the natural environment.[4] Of course, there might be little reason for concern over a chemical's toxicity or its bioaccumulation potential if it is not persistent (i.e., if it degrades prior to exposure).[5] Similarly, there is little reason to be concerned with sub-

1. These four classes of substances, their physical and chemical properties, and their toxicological effects are discussed throughout this article.

2. These classes are also "organic" chemicals, meaning that they contain carbon and, generally, that they are either naturally synthesized by living organisms or created artificially by human activity. They differ from metals and other "inorganic" chemicals, nearly all of which do not contain carbon.

3. Toxic substances are poisons, i.e., they cause death or other serious harm to an exposed organism. Because nearly all substances are poisonous to some organism in high enough doses, however, such a definition is not particularly useful. For the purposes of this article, toxic substances are those chemicals that, even in small doses, have the potential to damage the natural environment and/or adversely affect human health.

4. Numerous documents have recognized the three qualities of persistence, toxicity, and tendency to bioaccumulate as particularly important. For example, the new convention on the protection of the northeastern Atlantic contains the following statement: "For the purposes of this Annex, it shall, *inter alia,* be the duty of the Commission to draw up: (a) plans for the reduction and phasing out of substances that are toxic, persistent and liable to bioaccumulate arising form land-based courses . . . ." Convention for the Protection of the Marine Environment of the North-East Atlantic, Annex I, art. 3, 32 I.L.M. 1069 (done Sept. 22, 1992). Similarly, the recent Baltic Sea Convention declares: "The identification and evaluation of substances shall be based on the intrinsic properties of substances, namely: persistency; toxicity and other noxious properties; tendency to bio-accumulation." 1992 Convention on the Protection of the Marine Environment of the Baltic Sea Area (done Apr. 9, 1992), *reprinted in* Int'l Envtl. Rep. (BNA) 35:0401 (Mar. 1993); *see also* Richard L. Williamson, Jr., *Building the International Environmental Regime: A Status Report*, 21 U. MIAMI INTER-AM. L. REV. 679, 709 n.120 (1990) (discussing earlier international conventions).

5. A substance that degrades almost completely before an organism can be exposed is

stances bioaccumulating if they are not toxic.[6] These points are moot, however. As we will show, all organic chemical substances that are particularly likely to bioaccumulate are moderately to highly persistent in the environment;[7] all of them for which there are adequate test data are toxic.[8]

In this article we demonstrate that considerably greater regulation of substances with a propensity to bioaccumulate is necessary, is technically feasible, and can be accomplished in the near future at reasonable cost. We do not argue for more regulation generally. Rather, we urge a change in emphasis and approach. This change may allow a reduction in the regulatory burdens that would result from continued reliance on current approaches. In nearly all cases this change can be achieved without new statutory authority, if the responsible agencies have the political will to act.

Part I defines and outlines the general characteristics of bioaccumulation and bioaccumulating substances.[9] Part II discusses the capacity of high log P substances (i.e., those with a high propensity for bioaccumulation) to harm the natural environment and their potential to cause cancer and other adverse health effects in humans. In part III we explain how a method we call the "log P screening technique" can be used to test drinking water, contaminated ground water, treated wastewater, and even extracts from solid wastes to determine the presence of substances that are likely to bioaccumulate. Part IV explains how bioaccumulation fits into the current regulatory scheme. Since society's ultimate concern with bioaccumulation relates to toxicity, this part examines toxics regulation in general terms. We show that, under existing federal statutes and their

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far less likely to have toxic effects. Substances vary tremendously in terms of their persistence in the environment, ranging from those that degrade almost instantaneously to those that can last for decades. Substances also vary greatly as to the degree of their persistence in a particular medium. Phosgene, a deadly gas used as a chemical warfare agent in World War I, breaks down almost instantaneously in water. Brij B. Mathur & Gopal Krishna, *Toxicodynamics of Phosgene, in* CHEMICAL WARFARE AGENTS 237, 239 (Satu M. Somani ed., 1992). Several chlorinated solvents that have a half-life of only hours to days in air can persist for decades in water under anaerobic (no oxygen) conditions.

6. The authors are unaware of any chemical known to bioaccumulate to a high degree that has been conclusively shown to be benign. Moreover, experience has shown a need for caution before concluding that a substance causes no adverse effects. A number of substances that initially appeared to be relatively benign later turned out to cause severe toxic effects. High volume substances that have displayed this pattern include asbestos, vinyl chloride, benzene, trichloroethylene, and carbon tetrachloride, all of which are considered carcinogens, i.e., cancer-causing agents, by the U.S. Environmental Protection Agency (EPA).

7. *See infra* note 108.

8. We document this point in part II.B, *infra.*

9. By way of full disclosure, parts I, II, and III of this article establish the scientific basis for our proposal. While we have tried to make these parts as accessible as possible to a legal audience, they are inherently technical, and any further simplification would make them far less scientifically correct. For those readers without a technical background, we ask for your patience.

implementing regulations, the responsible agencies have given insufficient attention to the problem.[10]

Part V contains our regulatory proposal. We discuss the legal issues involved in using the log P screening technique to test and regulate actually or potentially contaminated samples for potential to bioaccumulate, advocate the use of other bioaccumulation control approaches, and recommend statutory and regulatory changes.

I
THE CHARACTERISTICS OF BIOACCUMULATING SUBSTANCES

The terms bioaccumulation, bioconcentration, and biomagnification all denote processes that concentrate a chemical substance in living tissues. Bioconcentration is the process by which a toxic substance enters an aquatic organism through the gills or epithelial tissues and is concentrated in the body. Bioaccumulation is the process by which a toxic substance is taken up by an organism not only from water, but also from food, and is the broader term. Frequently, "bioconcentration" and "bioaccumulation" are used as if they were synonyms. Biomagnification denotes the process by which a compound concentrates as it moves up the food chain. This article will use bioaccumulation in a broad sense to include the buildup of a substance in exposed organisms from all three processes.[11] We distinguish among the terms only when necessary to ensure scientific accuracy.

Most organic[12] chemicals are capable of bioaccumulating to some

10. This article deals only with those statutes that limit the release or require the treatment of toxic substances.

11. The definitions used in the text, while our own, are based on those originally proposed in W.A. Brungs and D.I. Mount, *Introduction to a Discussion of the Use of Aquatic Toxicity Tests for Evaluation of the Effects of Toxic Substances, in* ESTIMATING THE HAZARD OF CHEMICAL SUBSTANCES TO AQUATIC LIFE 15 (J. Cairns, Jr., et al. eds., ASTM STP 657, 1978).

12. Heavy metals such as lead, mercury, cadmium, selenium, copper, and zinc are also capable of concentrating in the tissues of exposed organisms, or in bones, shells, or other hard structures. This bioaccumulation of toxic heavy metals is a serious problem with consequences for human health and the well-being of the natural environment. We have chosen, however, not to deal with the bioaccumulation of metals for several reasons. First, the problem is generally well recognized and can be dealt with on a chemical-specific basis; we do not believe wholly new approaches are needed to deal with it. Second, the degree of bioaccumulation can be far more severe with organics than with metals. The reported bioconcentration factor for heavy metals in solution ranges from 16 for thallium to 1259 for copper, although a handful of organic compounds of metals (organo-metals) can concentrate to a considerably greater degree. For instance, the figure listed for methyl mercury is a 39,810-fold increase. OFFICE OF WATER, U.S. ENVTL. PROTECTION AGENCY & U.S. ARMY CORPS OF ENGINEERS, DEP'T OF THE ARMY, EPA-503/8-91/001, EVALUATION OF DREDGED MATERIAL PROPOSED FOR OCEAN DISPOSAL, at 9-20 (1991) [hereinafter EVALUATION OF DREDGED MATERIAL]. In contrast, some organic chemicals can bioconcentrate 100,000-fold or more. *See infra* note 16. Finally, the "log P screening technique" we advocate for determining whether there are bioaccumulating substances in water and other liquids does not work for metals or organo-metals.

degree;[13] they build up most in tissues with a high lipid (i.e., fatty) content.[14] This propensity varies enormously. Some organic substances do not bioaccumulate at all.[15] Others can bioaccumulate more than 100,000 times the level of exposure.[16] The vast majority of chemical substances have low to moderate bioaccumulating potential. This article deals with the substances with a "high" to "very high" capacity[17] to bioaccumulate, with a special emphasis on four classes of substances that have been the focus of public concern.[18]

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13. Bioaccumulation potential is usually expressed as the bioconcentration factor (BCF), the concentration of a substance in a test organism divided by the exposure concentration over some defined time period. For a more detailed explanation of BCF testing, see *infra* part III.A.

14. *See generally* I. Glenn Sipes & Jay Gandolfi, *Biotransformation of Toxicants, in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 88, 109-110 (Mary O. Amdur et al. eds., 4th ed. 1991) [hereinafter CASARETT & DOULL'S]; Curtis D. Klaassen & Karl Rozman, *Absorption, Distribution and Excretion of Toxicants, in* CASARETT & DOULL'S, *supra*, at 50. This phenomenon does not vary greatly from species to species. While animals differ considerably in the *amount* of lipid tissue they possess, in our experience the *concentration* that builds up in the lipid tissue is relatively constant for a given chemical over a fixed time.

15. Indeed, for some substances the concentrations in exposed organisms is lower than the exposure level.

16. Some polychlorinated biphenyls (PCB's), for example, can build up in fish to levels 100,000 times greater than the level found in the water. Sara E. Bysshe, *Bioconcentration Factor in Aquatic Organisms, in* HANDBOOK OF CHEMICAL PROPERTY ESTIMATION METHODS 5-1, 5-7, 5-18 (Warren J. Lyman et al. eds., 1982). Thus, a fish living in water that contained one part per billion (ppb) of a chemical substance with that strong a propensity to bioaccumulate could be expected over time to have that substance build up to 100 parts per million (ppm) or 1/100 of one percent of its weight.

17. For definitions of these terms, see *infra* notes 126, 127 and accompanying text.

18. Although they have received the most scientific and public attention, these four categories do not exhaust the list of highly bioaccumulative substances. Many of the other chemical groups with substances that are highly bioaccumulating are chemically similar to the groups discussed in text. For example, the polybromated biphenyls (PBB's), a class related to the PCB's, were used as a fumigant insecticide, and are still used as a fire retardant for clothing and other materials. Jack H. Dean & Michael J. Murray, *Toxic Responses of the Immune System, in* CASARETT & DOULL'S, *supra* note 14, at 282, 311. PBB's were responsible for one particularly serious contamination incident in 1973, ultimately leading to the destruction of nearly 20,000 contaminated cattle. *See* Richard A. Merrill & Michael Schewel, *FDA Regulation of Environmental Contaminants of Food,* 66 VA. L. REV. 1357, 1410-11 (1980). Another group are polybromated and mixed bromo-chloro dioxins and dibenzofurans, which have been found in fly ash and automobile exhaust, and related compounds such as polychlorinated biphenylenes and azobenzenes. H. Fiedler et al., *Dioxins: Sources of Environmental Load and Human Exposure,* 29 TOXICOLOGICAL & ENVTL. CHEMISTRY 157, 160, 163, 179 (1990). Another class are certain halogenated substances that are very similar to a pesticide but not used as such. Such substances are sometimes used as intermediates in chemical production or are produced as waste. Isomers of hexachlorocyclohexane other than the gamma isomer (Lindane) fall in that group. On the other hand, some individual high log P substances fall into other chemical groups. For example, some organophosphate pesticides, such as parathion and disulfoton, are also highly bioaccumulating, as are the brominated flame retardants such as pentabromodiphenyl ether. *See* 56 Fed. Reg. 29,140 (1991). Other highly bioaccumulating substances include the following: chlorinated benzidines such as 3,3'-dichlorobenzidine; some phthalates such as di-n-octyl phthalate; some halogenated anilines; and the flame-retardant Tris.

One class, the polycyclic aromatic hydrocarbons (PAH's),[19] are found in coal tar[20] or can occur as the result of incomplete combustion.[21] They are commonly found in the workplace in such industries as coke production, aluminum smelting, iron and steel production, coal gasification, asphalt production and use, and several other processes.[22] While processes producing PAH's are very important industrially, most of the PAH's have no practical uses.[23] Many substances in the class are considered carcinogens by EPA.[24]

Another common class of highly bioaccumulating substances, the polychlorinated biphenyls (PCB's), were once widely used throughout the United States, in transformers, capacitors, and other heat-transfer and manufacturing applications.[25] Due to concerns over both ecological effects and potential carcinogenicity, Congress decided to forbid their deliberate production, and EPA closely regulates their production as byproducts.[26]

A third class consists of chlorinated dioxins and dibenzofurans. Dioxins and dibenzofurans are usually created in trace quantities as unwanted byproducts from the chemical synthesis of complex chlorinated hydrocarbons, chlorine bleaching of paper pulp, and insufficiently controlled incineration of organic materials in the presence of chlorine compounds.[27] One dioxin isomer, 2,3,7,8-tetrachloro-dibenzo-p-dioxin (TCDD), is considered by EPA to be the most potent cancer-causing substance found to date in laboratory animal tests.[28] TCDD has been

19. PAH's are sometimes alternatively referred to as polynuclear aromatic hydrocarbons (PNA's).

20. ALF BJØRSETH & GEORG BECHER, PAH IN WORK ATMOSPHERES: OCCURRENCE AND DETERMINATION 35 (1986).

21. *Id.* at 15. The formation of PAH's is not dependent on what is burned, so that the combustion of coal, cellulose (as in wood or paper fires), and tobacco, as well as industrial chemicals, yields fairly similar PAH production. *Id.* at 16. As a result, almost any incomplete combustion, whether from smoking, open fires, internal combustion engines, or any other sources, will form some PAH's.

22. *Id.* at 35-56.

23. Anthracene, acenaphthene, fluorene, and phenanthrene are used as intermediates for the production of other chemicals such as dyes. Some of these have other minor uses. Most common PAH's, however, have no known uses. AGENCY FOR TOXIC SUBSTANCES AND DISEASE CONTROL, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, TOXICOLOGICAL PROFILE FOR POLYCYCLIC AROMATIC HYDROCARBONS 122 (1990) [hereinafter PAH PROFILE].

24. For a more thorough discussion of PAH toxicity to humans, see *infra* part II.B.

25. NATIONAL RESEARCH COUNCIL, POLYCHLORINATED BIPHENYLS 13-14 (1979); Wayland R. Swain, *An Overview of the Scientific Basis for Concern with Polychlorinated Biphenyls in the Great Lakes, in* PCB'S: HUMAN AND ENVIRONMENTAL HAZARDS 11, 13 (Frank D'Itri & Michael A. Kamvin eds., 1983).

26. Toxic Substances Control Act (TSCA) § 6, Pub. L. No. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. §§ 2605 (1988)). The detailed requirements for PCB's are contained at 40 C.F.R. § 761 (1992).

27. For a thorough discussion of dioxin and dibenzofuran sources, see Fiedler et al., *supra* note 18, at 166-204.

28. *Id.* at 159. EPA's potency index for TCDD is 5×10^7, which is over 25 times greater

implicated in the Times Beach, Missouri, evacuation, the Vietnam-era herbicide Agent Orange, and the explosion at Seveso, Italy.[29] It has no beneficial uses.

The fourth class consists of various halogenated (chlorinated or bromated) hydrocarbons used as pesticides. The most famous of these, dichlorodiphenyltrichloroethane (DDT), was widely used in the United States until it was banned.[30] Although DDT and its metabolites (biological breakdown products) are known to harm the environment, DDT is still used in some developing countries.[31] Other highly bioaccumulative chlorinated hydrocarbons used as pesticides include alpha-chlordane, hexachlorobenzene, hexachlorocyclohexane, pentachlorophenol, hexachlorophenol, kepone, and mirex. Not all chlorinated hydrocarbon pesticides, however, are capable of bioaccumulating to a high degree. There are dozens to thousands of individual chemical substances in each of these four classes.[32] Although the production of PCB's and chlorinated pesticides was substantial, these chemicals were not high volume substances when compared with many chemicals in common use.[33] Neither

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than the next most potent substance, hexachlorodibenzodioxin, which EPA declares to have a potency index of 2×10^6. See comparison data contained in OFFICE OF HEALTH & ENVTL. ASSESSMENT, U.S. ENVTL. PROTECTION AGENCY, EPA/600/8-82/006F, HEALTH ASSESSMENT DOCUMENT FOR TRICHLOROETHYLENE 8-133 to 8-136 (1985) [hereinafter TCE HAD].

29. TCDD-contaminated wastes from hexachlorophene production were mixed with used motor oils and then sprayed on dirt roads as a dust suppressant around the small, poor, rural town of Times Beach, Missouri. After a public outcry, the homes were purchased and demolished, and the townspeople relocated. Agent Orange was widely used as a herbicide in Vietnam to defoliate trees in order to deprive the Viet Cong of cover. It was later discovered that Agent Orange was contaminated with TCDD and related compounds. Levels of TCDD now found in former South Vietnam are far higher than in the North, presumably as a result. Numerous lawsuits and requests for congressional relief were made by veterans who believed they had been harmed by Agent Orange exposure, often with claims of cancers or reproductive dysfunctions. An explosion at a chemical plant in Seveso, Italy is the best known of several accidental releases at industrial plants making phenoxy herbicides. Several pounds of TCDD were released at Seveso, along with related compounds. For a general, mostly nontechnical discussion of these incidents, see AGENT ORANGE AND ITS ASSOCIATED DIOXIN: ASSESSMENT OF A CONTROVERSY (A.L Young & G. M. Reggiani eds., 1988). For a discussion of the known and debated health effects of TCDD, see *infra* notes 91-93 and accompanying text.

30. *See infra* notes 172, 175 and accompanying text.

31. For an interesting nontechnical discussion of current DDT impacts on African birds of prey, see Humphrey Crick, *Poisoned Prey in the Heart of Africa*, NEW SCIENTIST, Nov. 24, 1990, at 39.

32. For example, there are 683,101 possible PAH's with 12 rings alone. BJØRSETH & BECHER, *supra* note 20, at 21. Many of the substances in the class, however, have been discovered in nature only in trace quantities or created experimentally in the laboratory.

33. During the four and a half decades they were made in the United States, 570 million kg (roughly 1.25 billion pounds) of PCB's were produced. NATIONAL RESEARCH COUNCIL, *supra* note 25, at 12. That is hardly a small quantity, but it is tiny when compared with high volume commodity chemicals such as plastics, solvents, and the intermediates used to produce them. For example, about 42.5 billion pounds of ethylene are produced annually in the United States. Helga Tilton, *Bottomed Out,* Chemical Marketing Rep., Mar. 29, 1993, *available in* LEXIS, Nexis Library, MAGS File. Put differently, as much ethylene is produced every 11 days as the amount of PCB's ever produced in the United States. The production of chlorin-

dioxins and dibenzofurans nor PAH's have been synthesized as commercial products; they are generally found only as wastes.

II
THE IMPACTS OF BIOACCUMULATING SUBSTANCES

There are three principal reasons for being especially concerned about environmental releases of highly bioaccumulating substances.[34] First, many of these chemicals have been shown to cause death or other serious adverse consequences to aquatic organisms, birds, and wildlife in the natural environment. In some cases, the combination of toxicity and exposure levels threatened the extinction of species,[35] and caused epizootics[36] or other severe ecological effects.[37]

Second, all the highly bioaccumulative chemicals with adequate toxicity data have been shown in high dose tests on laboratory animals to be carcinogenic or teratogenic,[38] or to cause other severe consequences. In a few cases they have been demonstrated to cause these effects in exposed humans. Thus, their release under any conditions with a potential for direct human exposure, even at low exposure levels, may pose dangers to human health.[39]

Third, these same substances can also concentrate strongly in aquatic organisms and occasionally biomagnify up the food chain. The amount of exposure is a critical factor in determining whether a substance's toxicity poses a substantial human health risk. Bioaccumulation and biomagnification can vastly increase the chemical exposure of persons who eat the fish, shellfish, or birds concentrating these substances, thereby increasing the risks to their health.[40] Thus, we are concerned

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ated pesticides such as DDT and Kepone was significantly larger, but still very small when compared with dozens of industrial chemicals. DDT production reached a peak of 82 million kg in 1962, but declined to only 2 million kg in 1971, the year before it was banned in the United States. AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVICES, TOXICOLOGICAL PROFILE FOR DDT, DDE AND DDD 75 (1989) [hereinafter DDT PROFILE].

34. An environmental release occurs when chemical substances leave human control and can move freely in the environment. We are particularly concerned with releases that have a high probability of exposing humans or naturally occurring organisms. Such releases include the discharge of inadequately treated wastewater, the migration of contaminated ground water to wells or to surface waters, the application of pesticides or other air releases of chemicals, and the release of chemical substances already contained in contaminated sediments by dredging or by natural processes.

35. *See infra* notes 59-65 and accompanying text.

36. An epizootic is to animals what an epidemic is to humans. *See infra* notes 55-57 and accompanying text.

37. We document this concern in part II.A., *infra*.

38. *See infra* note 52 and accompanying text.

39. We document this fact and explain the terms used in the text in part II.B., *infra*. Direct exposure could occur through drinking water, contaminants in the air, or several lesser exposure paths.

40. Of course, large increases in potential human health risks from bioaccumulation are

both with the phenomenon of bioaccumulation of toxic substances and with the classes of substances that can bioaccumulate highly, even if the mode of release and subsequent exposure does not actually concentrate them.

A. Adverse Environmental Impacts

All variants of bioaccumulation occur in the environment. Bioconcentration has been widely documented in the laboratory.[41] Bioaccumulation of a number of compounds has occurred in the field.[42] Biomagnification, in contrast, is comparatively rare,[43] though DDT,

possible only if people somehow ingest sufficient quantities of organisms that have bioconcentrated the toxic substance. Current interests in health have increased the amount of finfish being consumed in the American diet. According to one report, per capita fish consumption in 1990 was 53% higher than in 1960. *Trends: Are We Really Eating Healthier?*, Food Marketing Briefs, Aug. 1991, *available in* LEXIS, Nexis Library, NWLTRS File. A fair portion of the population also eats shellfish or game birds. Severe problems may be faced by Inuits and others who live far from sources of initial contamination, but whose diet depends largely upon marine mammals, which sit atop the food chain and have biomagnified certain substances to exceptional levels. For a nontechnical discussion, see Karen Twitchell, *The Not-So-Pristine Arctic*, CANADIAN GEOGRAPHIC, Feb.-Mar. 1991, at 53. For additional details, see *infra* notes 524-26 and accompanying text.

41. While concentrations of substances greatly exceeding background levels have often been seen in aquatic organisms taken from the natural environment, it is impossible to know whether the exposure was from the water alone (bioconcentration) or from a combination of water and food (bioaccumulation). Proof of bioconcentration thus requires laboratory experiments. Proof of bioaccumulation in natural environments poses no such difficulty. *See infra* note 43. One researcher evaluated the relative importance of bioaccumulation to bioconcentration and concluded that food chain effects are not significant up to log P values of about 5.0. Above log P 5.0, substances bioaccumulated 10- to 100-fold above BCF values. Robert V. Thomann, *Bioaccumulation Model of Organic Chemical Distribution in Aquatic Food Chains*, 23 ENVTL. SCI. & TECH. 699, 699 (1989). Put more simply, the experimentally derived BCF is generally a good indication of the potential for concentration of a chemical in the whole food chain, but understates that potential for very high log P substances. *See* OFFICE OF WATER, U.S. ENVTL. PROTECTION AGENCY, EPA/505/2-90/001, TECHNICAL SUPPORT DOCUMENT FOR WATER QUALITY-BASED TOXICS CONTROL 38 (1991) [hereinafter TECHNICAL SUPPORT DOCUMENT].

42. In addition to the biomagnification of DDT and the bioaccumulation of PCB's and dioxins and dibenzofurans discussed extensively, *infra* note 43, bioaccumulation factors in excess of 100,000 have been measured in experiments on aquatic organisms. Examples include octachlorostyrene (log P=6.2), alpha-chlordane (log P=6.0) and mirex (log P=6.9). Barry G. Oliver & Arthur J. Niimi, *Bioconcentration Factors of Some Halogenated Organics for Rainbow Trout: Limitations in their Use for Prediction of Environmental Residues*, 19 ENVTL. SCI. & TECH. 842, 842-49 (1985).

43. The following are examples of biomagnification factors of two high log P substances for organisms taken from the field. (The data are expressed as BCF's, see *supra* notes 11, 13, in EPA's water quality criteria reports cited below, but are actually biomagnification factors.) Whole body DDT "BCF's" for kiyi (*Coregonus kiyi*), bloater (*Coregonus hoyi*), and lake herring (*Coregonus artedi*) have been reported to be 4,426,666, 2,870,000, and 2,236,666, respectively. U.S. ENVTL. PROTECTION AGENCY, EPA/440/5-80-038, AMBIENT WATER QUALITY CRITERIA FOR DDT, at B-37 (1980). Aroclor 1254 whole body "BCF's" for speckled trout (*Cynosclon nebulosus*) and blue crab (*Callinectes sapidus*) are $>670,000$ and $>230,000$, respectively, and the edible-portion "BCF" for Eastern oyster (*Crassostrea virginica*) is $>100,000$. U.S. ENVTL. PROTECTION AGENCY, EPA/440/5-80-068, AMBIENT WATER QUALITY CRITE-

PCB's, and several other substances have been shown to biomagnify in aquatic food chains.[44] In some cases, the levels found in organisms in the field as a result of biomagnification ranged from 100,000- to over 1,000,000-fold above the ambient level (i.e., the level in the aquatic environment.)[45]

Many studies have shown that high log P substances are toxic in various degrees to individual aquatic species. For example, TCDD has been shown to be toxic to aquatic life in short-term tests at very low levels.[46] Toxicity appears to be greatest among young fish and small species.[47] Commonly observed effects of TCDD on fish include epidermal hemorrhages and decreased food intake resulting in reduced growth. Except at near-lethal concentrations, TCDD apparently does not interfere

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RIA FOR POLYCHLORINATED BIPHENYLS (1980). Most organic chemicals do not biomagnify because the depuration (elimination) from the body occurs at a faster rate than assimilation from food.

44. *See generally* John P. Connolly & Chrissa J. Peterson, *A Thermodynamic-based Evaluation of Organic Chemical Accumulation in Aquatic Organisms*, 22 ENVTL. SCI. & TECH. 99 (1988) (thermodynamic approach to environmental modeling supports the results of past food chain models confirming bioaccumulation); J.B. Rasmussen et al., *Food Chain Structure in Ontario Lakes Determines PCB Levels in Lake Trout (*Salvelinus namaycush*) and Other Pelagic Fish*, 47 CAN. J. FISHERIES & AQUATIC SCI. 2030 (1990) (biomagnification can explain the occurrence of high levels of contaminants in biota from remote areas with longer food chains).

45. Occasionally, even higher increases over background levels in birds and marine mammals have been reported. For example, levels in herring gull eggs 10,000,000-fold or more above levels in ambient water were reported for hexachlorobenzene, PCB's, and DDE. R.J. Norstrom et al., *Coho Salmon* (Oncorhynchus kisutch) *and Herring Gulls* (Larus argentatus) *as Indicators of Organochlorine Contamination in Lake Ontario*, 35 J. FISHERIES RESOURCES BOARD CAN. 1401, 1407-08 (1978). Probably the highest biomagnification factors (BMF's) have been seen in arctic polar bears, with BMF's of up to 3.1 billion to 1 for PCB's and 2.6 billion to 1 for total chlordane-related compounds in fatty tissues (i.e., lipid/lipid basis). Calculated by Dennis T. Burton Based on a Telephone Conversation with Dr. Muir (Dec. 1993), and data in D.C.G. Muir et al., *Arctic Marine Ecosystem Contamination,* 122 SCI. TOTAL ENV'T 75, table 11 (1992).

46. The lowest observable-effect concentration (i.e., the lowest amount at which harm is demonstrated) for short-term exposures have ranged from 100 to 100,000 parts per quadrillion (ppq) (i.e., 0.0001 to 0.1 ppb), depending on the species, while the no-observable-effect concentrations (i.e., the highest levels at which no harm is seen) have ranged from 10 to 1,050 ppq. Theo Helder, *Effects of 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) on Early Life Stages of the Pike* (Esox lucius *L*), 14 SCI. TOTAL ENV'T 255 (1980); Theo Helder, *Effects of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) on Early Life Stages of Rainbow Trout* (Salmo gairdneri *Richardson*), 19 TOXICOLOGY 101 (1981); W. J. Adams et al., *Toxicity and Bioconcentration of 2,3,7,8-TCDD to Fathead Minnows* (Pimephales promelas), 15 CHEMOSPHERE 1503 (1986); Richard A. Miller et al., *Toxicity of 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD) in Aquatic Organisms*, 5 ENVTL. HEALTH PERSP. 177 (1973); Richard A. Miller et al., *The Response of Coho Salmon and Guppies to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) in Water*, 108 TRANSACTIONS AM. FISHERIES SOC'Y 401 (1979); Logan A. Norris & Richard A. Miller, *The Toxicity of 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) in Guppies* (Poecillia reticulatis *Peters*), 12 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 76 (1974).

47. Norris & Miller, *supra* note 46.

with immune responses.[48] Short-term TCDD exposures cause non-cancerous fish lesions.[49]

Several highly bioaccumulating substances have also been shown to be or implicated as mutagenic, teratogenic, and/or carcinogenic agents in aquatic systems.[50] PCB's, organochlorine insecticides, and PAH's have positive results on the Ames assay for mutagenicity.[51] PAH's, PCB's, and TCDD are teratogenic to embryo-larval fish.[52] Precancerous and cancerous liver lesions occurred in laboratory fish exposed to bioaccumulating substances including PCB's and DDT.[53] Cancerous diseases in fish and shellfish taken from the field have been attributed to a number of substances including PCB's, PAH's, and several chlorinated pesticides.[54] PCB's and dioxins have also been implicated in several mysterious massive die-offs of dolphins and seals.[55] Some researchers speculate that the

48. J.M. Spitsbergen et al., *Interactions of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) with Immune Responses of Rainbow Trout*, 12 VETERINARY IMMUNOLOGY & IMMUNOPATHOLOGY 263 (1986).

49. J.M. Spitsbergen et al., *Morphologic Lesions and Acute Toxicity in Rainbow Trout* (Salmo gairdneri) *Treated with 2,3,7,8-tetrachlorodibenzo-p-dioxin*, 23 J. TOXICOLOGY & ENVTL. HEALTH 333 (1988); Joseph D. Wisk & Keith R. Cooper, *The Stage Specific Toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin in Embryos of the Japanese Medaka* (Oryzias latipes), 9 ENVTL. TOXICOLOGY & CHEMISTRY 1159 (1990).

50. Mutagenic substances transform DNA, usually in detrimental ways. These changes correlate weakly but positively with carcinogens. Teratogenic substances cause defects in the young following post-conception exposure. Carcinogenic substances or carcinogens cause or promote the growth of cancer. For general overviews of mutagens, teratogens, and carcinogens, see respectively, George R. Hoffman, *Genetic Toxicology, in* CASARETT & DOULL'S, *supra* note 14, at 201; Jeanne M. Manson & L. David Wise, *Teratogens, in* CASARETT & DOULL'S, *supra* note 14, at 226; and Gary M. Williams & John H. Weisburger, *Chemical Carcinogenesis, in* CASARETT & DOULL'S, *supra* note 14, at 127.

51. *See* J. Fitchko, *Literature Review of the Effects of Persistent Toxic Substances on Great Lakes Biota* (Report to the Great Lakes Science Advisory Board, International Joint Commission, Great Lakes Regional Office, Windsor, Ont., 1986); S. DeFlora et al., *Genotoxicity, Biotransformations, and Interactions of Marine Pollutants as Related to Genetic and Carcinogenic Hazards, in* CARCINOGENIC, MUTAGENIC, AND TERATOGENIC MARINE POLLUTANTS: IMPACTS ON HUMAN HEALTH AND THE ENVIRONMENT 3-31 (1990); C.D. Metcalfe et al., *Carcinogenic and Genotoxic Activity of Extracts from Contaminated Sediments in Western Lake Ontario*, 94 SCI. TOTAL ENV'T 125 (1990).

52. *See* Judith S. Weis & Peddrick Weis, *Effects of Environmental Pollutants on Early Fish Development*, 1 REVIEWS IN AQUATIC SCI. 45, 48-53 (1989).

53. *See* W.E. Hawkins et al., *Small Fish Models for Identifying Carcinogens in the Aqueous Environment*, 24 WATER RESOURCES BULL. 941 (1988); W.E. Hawkins et al., *Carcinogenic Effects of Some Polycyclic Aromatic Hydrocarbons on the Japanese Medaka and Guppy in Waterborne Exposures*, 94 SCI. TOTAL ENV'T 155 (1990); J.D. Hendricks et al., *Histological Progression of Hepatic Neoplasia in Rainbow Trout* (Salmo gairdneri), 65 NAT'L CANCER INST. MONOGRAPH 321, 321-36 (1984).

54. *See, e.g.*, D.C. Mallins et al., *Chemical Pollutants in Sediments and Diseases of Bottom-dwelling Fish in Puget Sound, Washington*, 18 ENVTL. SCI. & TECH. 705 (1984); C.D. Metcalfe et al., *supra* note 51; Michael C. Mix, *Cancerous Diseases in Aquatic Animals and Their Association with Environmental Pollutants: A Critical Literature Review*, 20 MARINE ENVTL. RES. 1 (1986); U. Varanasi et al., *Chemical Carcinogenesis in Feral Fish: Uptake, Activation, and Detoxification of Organic Xenobiotics*, 71 ENVTL. HEALTH PERSP. 155 (1987).

55. Numerous press accounts attributed these epizootics to various high log P substances,

chemicals weaken these marine mammals' immune systems, making them more vulnerable to disease.[56] Unfortunately, most cases lack definitive data to determine which chemicals, groups of chemicals, or interactions among them are responsible for the observed diseases found in aquatic environments.[57]

These high log P substances have also adversely impacted entire animal populations.[58] For instance, DDT nearly wiped out several species of raptors.[59] Kepone, an organochlorine pesticide released in large

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usually PCB's, but in some cases also PBB's, dioxins and dibenzofurans, and organochlorine pesticides like DDT. *See, e.g.*, Michael Spector, *A Damage Report: The Oceans are Sending an S.O.S.*, N.Y. TIMES, May 3, 1992, § 4, at 5; Marlise Simons, *Dead Mediterranean Dolphins Give Nations Pause*, N.Y. TIMES, Feb. 2, 1992, § 1, at 12; Gary Witherspoon, *PCB's Suspected In Illness of Seals*, NEWSDAY, Jan. 21, 1992, § 1, at 22. Although the scientific literature is devoid of peer-reviewed studies causally linking epizootics among marine mammals to high log P substances, this does not mean that the press accounts are wrong.

56. Several of the press accounts quoted in the previous footnote speculate that the epizootics are due to the suppression of the immune system of the affected mammals, making them more vulnerable to bacterial and viral diseases that they otherwise could resist. This speculation rests on some known facts. Many high log P substances, including PCB's, PBB's, and TCDD, induce thymus atrophy in mammalian systems, and thus probably harm thymus-dependent immune functions. Similarly, many PAH's are potent immunotoxic compounds. Steve Wong et al., *Environmental Immunotoxicology, in* ANIMAL BIOMARKERS AS POLLUTION INDICATORS 167, 170-71, 179-83 (David Peakall ed., 1992). These associations do not add up to proof that the marine mammals were killed by bacteria or viruses because their immune systems were suppressed by high log P substances. It is, however, worrisome, and we hope research currently underway will resolve the issue.

57. It is not yet possible to evaluate potential cause-and-effect relationships by comparing lesion prevalence with concentrations of manmade organic chemicals in tissues of affected animals taken from the field. There is also concern that *mixtures* of high log P substances both in solution and in sediments can harm both individual species and broader populations. L.L. Marking, *Toxicity of Chemical Mixtures, in* FUNDAMENTALS OF AQUATIC TOXICOLOGY 164 (Gary M. Rand & Sam R. Petrocelli eds., 1985). Although high log P mixtures are suspected of causing such biota-specific and environmental effects, it is difficult to determine the combined effect of mixtures since the modes of toxicity may differ from one group of compounds to another. The problem may be made worse by the effects of other toxic substances (e.g., heavy metals, chlorine, low log P substances, etc.) and various environmental factors (e.g., low dissolved oxygen, nutrient enrichment, high temperatures, etc.). *See* Joan U. Clarke & Victor A. McFarland, *Assessing Bioaccumulation in Aquatic Organisms Exposed to Contaminated Sediments* (U.S. Army Corps of Engineers Vicksburg Experimental Station MBC. Paper No. D-91-2, 1991).

58. These adverse environmental effects seem to be limited to the animal kingdom. To the best of our knowledge, there have not been significant or widespread effects on plant species from exposure to high log P substances. Ron van der Oost et al., *Bioaccumulation of Organic Micropollutants in Different Aquatic Organisms, in* 14 AQUATIC TOXICOLOGY AND RISK ASSESSMENT 166 (M.A. Mayes & M.G. Barron eds., ASTM STP 1124, 1991).

59. *See infra* notes 172-73 and accompanying text. DDT and its analogs (primarily DDE) adversely affected the reproduction of mallards, black ducks, and screech owls. U.S. ENVTL. PROTECTION AGENCY, EPA/440/5-80-038, AMBIENT WATER QUALITY CRITERIA FOR DDT, at B-7 (1980). DDT and its analogs were also shown to have affected various aquatic populations. *Id.* DDT nearly caused the extinction of the brown pelican; the pelican substantially recovered following the ban on DDT in the United States. Charles Hillinger, *Brown Pelicans, Once Nearly Extinct, Are Flying High*, L.A. TIMES, June 19, 1989, at 3. Other high log P pesticides (e.g., endrin, dieldrin, and mirex) have also been shown to affect various aquatic groups and birds. *See* Fitchko, *supra* note 51.

quantities to the James River in Virginia in the late 1960's to mid 1970's, was linked to the decline of the blue crab fishery,[60] and harmed various other species as well.[61] PCB's reduce the reproductive success and harm other functional responses of various plant and animal groups, including phytoplankton,[62] zooplankton,[63] fish, birds, and mammals.[64] These environmental effects of high log P substances sometimes caused substantial economic harm as well.[65]

B. Potential Adverse Human Health Effects

All highly bioaccumulating substances with adequate toxicity data[66] are known or suspected to be harmful to human health. As we explain in part III.D., the propensity to bioaccumulate correlates strongly with the physical and chemical property of organic chemical substances known as "log P." A comparison of all available log P data[67] (for organic chemi-

60. Steven C. Schimmel et al., *Kepone: Toxicity to and Bioaccumulation by Blue Crabs*, 2 ESTUARIES 9 (1979).

61. *See* R.J. Klauda & M.E. Bender, *Contaminant Effects on Chesapeake Bay Finfishes, in* CONTAMINANT PROBLEMS AND MANAGEMENT OF LIVING CHESAPEAKE BAY RESOURCES 321 (Shyamal K. Majumdar et al. eds., 1987).

62. Phytoplankton are small, often one-celled aquatic plants such as algae, which are of great importance due to their role in converting carbon dioxide to oxygen.

63. Zooplankton are very small aquatic animals, which are often vital links in the food chain.

64. Richard J. Aulerich & Robert K. Ringer, *Current Status of PCB Toxicity to Mink, and Effect on their Reproduction*, 6 ARCHIVES ENVTL. CONTAMINATION & TOXICOLOGY 279 (1977); C. Kwei Lin & Milagros S. Simmons, *Effects of Pentachlorobiphenyl on Growth of Nutrient Enriched Phytoplankton from Lake Michigan*, 7 J. GREAT LAKES RES. 481 (1981); A.P. Gilman et al., *Effects of Injected Organochlorines on Naturally Incubated Herring Gull Eggs*, 42 J. WILDLIFE MGMT. 484 (1978); and Wayne A. Willford et al., *Introduction and Summary*, 105 U.S. FISH & WILDLIFE SERVICE TECHNICAL PAPERS 1 (1981).

65. High log P substances harmed commercial fisheries, sport fishing, and tourism. Kepone caused the James River fisheries to decline. Robert J. Huggett & Michael E. Bender, *Kepone in the James River*, 14 ENVTL. SCI. & TECH. 918 (1980). Economic losses to Virginia sport and commercial fishing were not only considerable from the contamination itself but also rendered much of the state's annual catch unmarketable. Merrill & Schewel, *supra* note 18, at 1359 n.8. Other economic losses were caused by PCB's in the Hudson River, R.J. Califano et al., *Polychlorinated Biphenyl Dynamics in Hudson River Striped Bass: Accumulation in Early Life History Stages*, 2 AQUATIC TOXICOLOGY 187, 187 (1982), and dioxins in Howe Sound, Prince Rupert, British Columbia. *See* M. Waldichuk, *Dioxin Pollution Near Papermills*, 21 MARINE POLLUTION BULL. 365 (1990).

66. As explained *supra* note 3, we are concerned in this article with those substances that are toxic in very low concentrations, roughly the range below 1 part per million. To say there is adequate toxicity data on such substances, in the absence of human epidemiological data, one would generally need at least one well-conducted chronic test on mammals for each of the following: carcinogenicity, reduction in reproductive success, teratogenicity, immune system disorders, and neurotoxicity. One would also want one acute test for lethal dose and one short-term chronic test for reproduction and growth on fish and crustacean test organisms. Of course in some cases, one or more of these might be pointless, while in other cases, additional tests would be needed, such as renal toxicity or hepatotoxicity in mammals, or phytotoxicity (harm to plants).

67. As part of our research, we used a number of government reports and peer-reviewed scientific literature which reported measured log P data, and compiled lists of high log P sub-

cals) with data on these substances' toxicity to humans revealed that all the high log P substances identified in our research fell into two categories: (1) those with potential human health risks (at least based on animal data); and (2) those that have been inadequately studied. Missing altogether are any high log P substances that have been shown to be relatively benign to humans.[68] Moreover, the high log P substances are clustered in a limited number of groups.[69] Table 1 summarizes the high

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stances, in order to be able to compare log P data on chemicals with known toxic effects. The sources consulted were: B.T. Bowman & W.W. Sans, *Determination of Octanol-water Partitioning Coefficients (K_{ow}) of 61 Organophosphorus and Carbamate Insecticides and Their Relationship to Respective Water Solubility (S) Values*, B18 J. ENVTL. SCI. HEALTH 667 (1983); J. Brodsky & K. Ballschmiter, *Reversed Phase Liquid Chromatography of PCB's as a Basis for the Calculation of Water Solubility and Log K_{ow} for Polychlorobiphenyls*, 331 FRESENIUS ZEITSCHRIFT FÜR ANALYTISCHE CHEMIE 295 (1988); Cary T. Chiou et al., *Partition Coefficient and Bioaccumulation of Selected Organic Chemicals*, 11 ENVTL. SCI. & TECH. 475 (1977); EVALUATION OF DREDGED MATERIAL, *supra* note 12; P.H. Howard, *Chlordecone*, 3 HANDBOOK OF ENVIRONMENTAL FATE AND EXPOSURE DATA FOR ORGANIC CHEMICALS 110-18 (1991); Colja Laane et al., *Rules for Optimization of Biocatalysis in Organic Solvents*, 30 BIOTECHNOLOGY & BIOENGINEERING 81 (1987); Albert Leo, *Parameter and Structure-activity Data Bases: Management for Maximum Utility*, 61 ENVTL. HEALTH PERSP. 275 (1985); Robert L. Lipnick et al., *Comparison of Fish Toxicity Screening Data for 55 Alcohols with the Qualitative Structure-activity Relationship Predictions of Minimum Toxicity for Nonreactive Nonelectrolyte Organic Compounds*, 4 ENVTL. TOXICOLOGY & CHEMISTRY 281 (1985); Donald Mackay, *Correlation of Bioconcentration Factors*, 16 ENVTL. SCI. & TECH. 274 (1982); D. Mackay et al., *Relationships Between Aqueous Solubility and Octanol-water Partition Coefficients*, 9 CHEMOSPHERE 701 (1980); W. Brock Neely et al., *Partition Coefficient to Measure Bioconcentration Potential of Organic Chemicals in Fish*, 8 ENVTL. SCI. & TECH. 1113 (1974); Robert A. Rapaport & Steven J. Eisenreich, *Chromatographic Determination of Octanol-water Partition Coefficients (K_{ow}'s) for 58 Polychlorinated Biphenyl Congeners*, 18 ENVTL. SCI. & TECH. 163 (1984); K.H. Reinert, *Aquatic Toxicity of Acrylates and Methacrylates: Quantitative Structure-activity Relationships Based on K_{ow} and LC_{50}*, 7 REG. TOXICOLOGY & PHARMACOLOGY 384 (1987); T. Wayne Schultz et al., *Structure-activity Relationships of Selected Pyridines*, 13 ECOTOXICOLOGY & ENVTL. SAFETY 76 (1987); T. Wayne Schultz, *Relative Toxicity of Para-substituted Phenols: Log k_{ow} and pKa-dependent Structure-activity Relationships*, 38 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 994 (1987); Rene P. Schwarzenbach & John Westall, *Transport of Nonpolar Organic Compounds from Surface Water to Groundwater*, 15 ENVTL. SCI. & TECH. 1360 (1981); Gilman D. Veith et al., *Structure-activity Relationships for Screening Organic Chemicals for Potential Ecotoxicity Effects*, 15 DRUG METABOLISM REVIEWS 1295 (1984-85); Gilman D. Veith & P. Kosian, *Estimating Bioconcentration Potential from Octanol/Water Partition Coefficients*, *in* PHYSICAL BEHAVIOR OF PCB'S IN THE GREAT LAKES 269 (D. Mackay et al. eds., 1983).

68. One might well ask whether any substances are known to be relatively benign. There are a few substances that have no toxic effects. For example, the polymer (plastic) of tetrafluoroetheylene (better known as Teflon) is so unreactive that it is commonly used in medical implants, and also as a non-stick surface on kitchenware (where some bits are certain to be consumed). Many other substances can be said to be relatively free of harm (i.e., to cause harm only in the ppm range or higher even when persons are exposed to such concentrations over a lifetime). Most simple hydrocarbons (one to five atoms of carbon arranged in a straight chain, with no other substance except hydrogen) fit that description. Many food additives have been tested and determined by the Food and Drug Administration (FDA) not to be carcinogens and to pose no other adverse human health risks in the quantities typically used. Several hundred other substances fall within FDA's classification of food additives "generally regarded as safe."

69. Our review revealed several large groups of substances including PAH's (i.e., naph-

log P substances we identified that have been judged to be carcinogens by the International Agency for Research on Cancer (IARC).

TABLE 1
LOG P VALUES OF IARC ORGANIC CARCINOGENS

Chemical Name	CAS #	Log P (1)	IARC Group (2)
Mirex	2385855	6.9	IIB
Dibenzo(*a,h*)anthracene	53703	6.8	IIA
2,3,7,8-Dibenzo-*p*-dioxin (TCDD)	1746016	6.7	IIB
1,2,7,8-Dibenzopyrene	189559	6.6	IIB
Indeno(1,2,3-*cd*)pyrene	193395	6.5	IIB
DDT	50293	6.2	IIB
Benzo(*a*)pyrene	50328	6.1	IIA
Benzo(*b*)fluoranthene	205992	6.1	IIB
Benzo(*k*)fluroanthene	207089	6.1	IIB
Polycholrinated biphenyls (PCB's)	1336363	6.0	IIA
Dibutyl phthalate	84742	5.6	IIB
Benz(*a*)anthracene	56553	5.6	IIA
Hexachlorobenzene	118741	5.2	IIB
Chlordecone (Kepone)	143500	4.5	IIB
Auramine	2465272	4.2	IIB(3)
Tris(2,3-dibromopropyl)phosphate	126727	4.1	IIA
alpha-Hexachlorocyclohexane (HCCH)	319846	3.9	IIB
Dimethylaminoazobenzene	60117	3.7	IIB
1,4-Dichlorobenzene	106467	3.6	IIB
1,2-Dichlorobenzene	95501	3.6	IIB
3,3'-Dichlorobenzidine	91941	3.5	IIB
Toxaphene (chlorinated camphenes)	8001352	3.3	IIB
3,3'-Dimethylbenzidine (*o*-Tolidine)	119937	2.9	IIB
4-Aminobiphenyl	92671	2.8	I
Carbon tetrachloride	56235	2.6	IIB
Tetrachloroethylene	127184	2.6	IIB
Dihydrosafrole	94586	2.6	IIB
Safrole	94597	2.5	IIB
1,2-Dibromo-3-chloropropane	96128	2.3	IIB
Benzene	71432	2.1	I
2-Naphtylamine	91598	2.1	I
1,3-Dichloropropene	542756	2.0	IIB
1,3-Butadiene	106990	2.0	IIB
Chlofoform	67663	2.0	IIB
1,1-Dichloroethane	75343	1.8	IIB
Ethylene dibromide	106934	1.8	IIA
1,2-Dichloroethane (EDC)	107062	1.5	IIB
Vinyl chloride	75014	1.4	I
Mustard gas	505602	1.4	I
Benzidine	92875	1.3	I
o-Toluidine	95534	1.3	IIB
Bis(chloromethyl)ether	542881	0.4	I

thalene, benz(a)pyrene, chrysene, anthracene, etc.), PCB's, chlorinated dioxins and dibenzofurans, and certain organochlorine pesticides (chlordane, DDT and its metabolites, heptachlor, dieldrin, etc.). As explained in note 18, *supra*, there are other high log P substances, but the ones which have received the most attention and which have the most human toxicity data fall into these four groups.

TABLE 1 (CONTINUED)

Chemical Name	CAS #	Log P (1)	IARC Group (2)
2,4-Diaminotoluene	95807	0.4	IIB
Acrylonitrile	107131	0.3	IIA
Ethyl methanesulfonate	62500	0.2	IIB
Epichlorohydrin	106898	0.2	IIA
1,4-Dioxane	123911	0.0	IIB
Formaldehyde	50000	0.0	IIA
Chloromethyl methyl ether	107302	0.0	I
Ethylene oxide	75218	−0.2	IIA
N-Nitrosopiperidine	100754	−0.5	IIB
Ethylenethiourea	96457	−0.7	IIA
N-Nitrosopyrrolidine	930552	−1.1	IIB
Uracil mustard	66751	−1.1	IIB
Gylcilaldehyde	765344	−1.6	IIB
1,2-Diethylhydrazine	1615801	−1.7	IIB
Amitrole	61825	−2.1	IIB
1,1-Dimethylhydrazine	57144	−2.4	IIB
Hydrazine	302011	−3.1	IIB
Methylnitrosourea	684935	−3.8	IIA

NOTES: (1) Source for Log P Data: *See supra* note 67.
(2) Source for IARC Data: *See supra* note 74.
(3) Auramine manufacture is listed as IARC Group I.

Listed are all IARC Group I, IIA, and IIB Carcinogens that are organic environmental contaminants (as opposed to pharmaceuticals) and that have log P data. Listing all substances mentioned in the scientific literature as human or animal carcinogens, and use of calculated log P data rather than measured log P would have increased greatly the number of substances listed. Doing so would probably have increased the percentage of high log P substances, since a large number of PAH's would have been included.

Except in relatively large doses, the majority of these chemicals do not cause severe *acute* human health effects.[70] As documented below, however, some of these chemicals are associated with serious *chronic* human health effects. Many more have positive (i.e., adverse) results in standard chronic toxicity tests on laboratory animals.

Assessing chronic human health effects (whether for cancer, birth defects, reproductive difficulties, or other effects) has frequently been a difficult and controversial process. Direct experimentation on human subjects is unethical and impractical. Controlled toxicological studies on animals have shown that many substances that are carcinogenic in animals are also carcinogenic in humans.[71] While extrapolating from high-dose experiments on rodents to very small-dose exposures in people has

70. The distinction between acute and chronic human health effects, though well established by medical usage, is not readily susceptible to precise definition. Generally speaking, acute health effects arise relatively rapidly from a single or short-term exposure of a person to a chemical substance. Typically, they involve death, permanent damage to an organ, or short-term effects. In contrast, chronic effects, such as cancer, gradually manifest themselves over time, usually from long-term exposure. *See* Curtis D. Klassen & David L. Eaton, *Principles of Toxicology, in* CASARETT & DOULL'S, *supra* note 14, at 12-49.

71. *Id.* at 31.

generated considerable controversy,[72] we assume for the purposes of this article that well-run positive animal tests are a basis for concern about potential human health effects. Even though such tests do not support our assumption conclusively, all alternative assumptions are even less satisfactory.[73]

Cancer is the most thoroughly studied and characterized of the chronic health effects associated with human-made organic chemicals. The majority of the high log P chemicals we surveyed are accepted animal carcinogens, and in most cases, known or suspected human carcinogens. Of the forty distinct chemical substances or processes accepted as human carcinogens in 1987, two had high log P values.[74] Of thirty-seven substances or processes listed as probable human carcinogens, five had high log P values.[75] Of seventy-three substances listed as possible human carcinogens, seventeen were listed with high log P values.[76] Thus, while a high log P is not necessary for a substance or process to be considered a carcinogen, high log P substances nonetheless are a substantial fraction of all carcinogens.[77] More significantly, of the chemicals in our survey that have high log P values, the majority are known or suspected human carcinogens.

PAH's are the group of high log P chemicals most widely accepted as being carcinogenic to humans.[78] Workers are exposed to these com-

72. *Id.*

73. Given the expense and often the impossibility of conducting human epidemiologic studies, in our view epidemiological evidence of chronic health effects cannot become the required standard for assessing and regulating all chemicals.

74. IARC has developed a hierarchical system of carcinogen evaluation. IARC's system has been adopted with various modifications by other standard-setting groups such as EPA and the American Conference of Governmental Industrial Hygienists (the ACGIH). In the IARC classification, epidemiologic data for particular agents in human populations are the key factor distinguishing accepted human carcinogens (Group I) from probable and possible carcinogens (Groups IIA & IIB). Group I differs from Groups IIA and IIB based on the sufficiency of human (rather than purely animal) evidence of the carcinogenic potential of an agent. Therefore, if a chemical has not been studied or cannot be studied easily in large human populations (as will usually be the case for low-volume chemicals), it will never be considered a confirmed human carcinogen, regardless of its carcinogenic potential. Groups IIA and IIB differ from each other based on the amount of positive animal evidence available; again, positive human data are rated more highly than animal data, and at least some information on human effects is needed for a IIA classification. INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS: OVERALL EVALUATIONS OF CARCINOGENICITY: AN UPDATING OF *IARC Monographs* vols. 1-42 (supp. 7, 1987) [hereinafter IARC MONOGRAPHS].

75. *Id.*

76. *Id.*

77. The IARC groups contain many substances, such as chemotherapy drugs and heavy metals, which do not concern the relationship between environmental organic contaminants with high log P values and chronic human health effects. Setting aside these substances yields a much higher percentage of known carcinogens that are high log P substances.

78. *See generally* IARC MONOGRAPHS, *supra* note 74. For a more thorough discussion of the extensive evidence of toxicity of individual PAH's and PAH mixtures to test animals and humans, see PAH PROFILE, *supra* note 23, at 58-67, 85-87.

pounds (generally as byproducts) in several industrial processes including coke oven combustion and petroleum refining, and in occupations involving contact with coal tars.[79] Thus, unlike most other substances, the carcinogenicity of PAH's collectively has been established in humans as well as animals. One large correlation survey of PAH toxicity data on laboratory animals showed a strong association between log P and carcinogenicity.[80]

A conclusive link between other high log P substances and human carcinogenicity has not been established, but many of these substances have had positive test results on laboratory animals, and some have supporting evidence from studies on humans. DDT and its metabolites DDD and DDE are known or suspected animal carcinogens.[81] Significant new evidence suggests an association between DDT exposure and breast cancer.[82] Based on animal data, EPA also considers PCB's, dioxins and dibenzofurans, and some organochlorine pesticides to be carcinogens that may pose risks to humans.[83]

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79. Increased rates of lung cancer and kidney cancer have been found among coke oven workers, especially among those working on top of the ovens where the PAH exposure is greatest. J. William Lloyd, *Long-term Mortality Study of Steelworkers: V. Respiratory Cancer in Coke Plant Workers*, 13 J. OCCUPATIONAL MED. 53, 53-60 (1971); Carol K. Redmond et al., *Cancer Experience Among Coke By-product Workers*, 271 ANNALS NEW YORK ACAD. SCI. 102, 104-5 (1976).

80. Litai Zhang et al., *The Structure-Activity Relationship of Skin Carcinogenicity of Aromatic Hydrocarbons and Heterocycles*, 81 CHEMICAL-BIOLOGICAL INTERACTIONS 149 (1992). Of course, such a study does not prove PAH's to be human carcinogens. But it is noteworthy for its scope, having surveyed 239 PAH's that cause skin cancer in mice, and for the strong association with log P.

81. *See* Table 1, *supra* p. 620.

82. A recent large study found statistically significant increases in levels of DDE (a very high log P substance) in the breast tissues of women who had breast cancer, when compared to women of similar age, socioeconomic status, and smoking habits who did not have breast cancer. Mary S. Wolff et al., *Blood Levels of Organochlorine Residues and Risk of Breast Cancer*, 85 J. NAT'L CANCER INST. 648 (1993). A statistically insignificant increase was also seen for PCB's. *Id.* Another study showed statistically significant increases in levels of PCB's, DDE, and DDT in women with breast cancer when compared to women with normal breast tissue. Frank Falck, Jr., et al., *Pesticides and Polychlorinated Biphenyl Residues in Human Breast Lipids and Their Relation to Breast Cancer*, 47 ARCHIVES ENVTL. HEALTH 143 (1992). A smaller study showed a statistically significant increase in levels of hexachlorocyclohexane. H. Mussalo-Rauhamaa et al., *Occurrence of Beta-Hexachlorocyclohexane in Breast Cancer Patients*, 66 CANCER 2124 (1990). Such a statistical association is often the first indication of a causal relationship, especially in well-designed studies that have adjusted for other possible causal factors. That association, however, is far from proof that the discovered substances caused the cancers that were seen.

83. EPA's conclusions for PCB's and TCDD are based on animal data. Whether these substances cause cancer in humans and if so, at what concentration, is controversial; the evidence as to each is equivocal. *See, e.g.*, NATIONAL INST. FOR OCCUPATIONAL SAFETY & HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVICES, CURRENT INTELLIGENCE BULLETIN NO. 40, 2,3,7,8-TETRACHLORODIBENZO-P-DIOXIN, at 8 (1984) (data are suggestive of but inconclusive as to TCDD carcinogenicity in humans). IARC considers PCB's to be Group IIA (probable human carcinogens), while it places TCDD in Group IIB (possible human carcinogens). IARC MONOGRAPHS, *supra* note 74, at 42, 46. The issue is a vital one for toxic waste

The IARC and EPA classification systems address only the strength of the evidence that a chemical is an animal or human carcinogen. A substance's carcinogenic potency is an entirely separate question.[84] The carcinogenic potency of chemicals, calculated by EPA from animal tests,[85] varies tremendously. Among suspected carcinogens, there is an apparent, positive correlation between log P values and EPA's calculations of carcinogenic potency.[86] Many of the very high log P substances have the highest EPA potency indexes.[87]

As with most chemicals, there is limited information concerning the association between high log P substances and human chronic disease other than cancer. Only in cases of extreme exposure of large populations (usually through ingestion), or very rare conditions in a small population, have these chemicals been associated definitively with chronic disease. For example, Yusho Disease in Japan involved over 1665 individuals who became ill from eating rice oil contaminated by PCB's; the disease included severe chloracne, liver disease, and a multitude of other symptoms.[88] In 1979, similar chronic disease patterns were seen in an-

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and toxic tort litigation. Although there is strong disagreement as to what prudent levels would be as a matter of regulatory policy, we rarely meet anyone who thinks it would be wise to allow the unrestricted release of PCB's and dioxins and dibenzofurans to the environment.

84. There is no reason why the strength of the evidence concerning a chemical's carcinogenicity should correlate with the chemical's toxic potency, and there are many examples where it does not. TCDD, for example, is the most potent animal carcinogen found to date, *see* Fiedler et al., *supra* note 18, but evidence that it is a human carcinogen is equivocal at best. *See* NATIONAL INST. FOR OCCUPATIONAL SAFETY & HEALTH, *supra* note 83, at 8; *see also infra* note 92. In contrast, the evidence is very strong that vinyl chloride is a human carcinogen, though it is not particularly potent. Williams & Weisburger, *supra* note 50, at 182.

85. EPA has listed potency values for only 54 synthetic organic chemicals. Though the estimation of potency is fraught with uncertainty and controversy, EPA believes that the potency value for the strongest carcinogen, TCDD, is one billion times greater than the weakest, methylene chloride (potency index for TCDD $=5 \times 10^{7}$; potency index for methylene chloride $=5 \times 10^{-2}$). If correct, these values mean that it would take a lifetime exposure to one billion times as much methylene chloride to cause one additional case of cancer in an exposed test animal as would be needed to do so with TCDD.

86. We performed a regression analysis of the potency values established by EPA for all 41 synthetic organic chemicals for which we could find log P data. The resultant moderate positive correlation ($R=0.297$) was statistically significant ($P=0.029$) (i.e., the possibility that this correlation resulted by chance is remote). Because of our doubts about the underlying potency data and methods, we did not rely on these results. We do believe, however, that these results merit further research. Furthermore, a strong relationship between carcinogenicity and log P has been shown, at least for PAH's causing skin cancer in mice. *See supra* note 80.

87. EPA's median potency value on its order-of-magnitude index was 2.5. High log P substances with potency values above that level include benzo(a)pyrene, chlordane, several hexachlorocyclohexane isomers, hexachlorodibenzodioxin, PCB's, TCDD, and toxaphene. As previously noted, TCDD has the highest index value. *See* TCE HAD, *supra* note 28, at 8-133 to 8-136.

88. Harakuni Urabe et al., *Present State of Yusho Patients*, 320 ANNALS NEW YORK ACAD. SCI. 273 (1979). It is possible that the adverse effects came from polychlorinated dibenzofurans contained as contaminants and/or created from heating the PCB's, not the PCB's themselves. *See, e.g.*, Takashi Kashimoto & Hideaki Miyata, *Differences Between Yusho and Other Kinds of Poisoning Involving Only PCB's*, *in* 3 PCB'S AND THE ENVIRON-

other PCB-contaminated rice oil epidemic, in Taiwan, known as Yu-Cheng disease.[89] During the 1950's, the chlorinated hydrocarbon hexachlorobenzene was used as a seed fungicide in Turkey. The seed was mistakenly ingested, causing over 3000 cases of porphyria cutanea tardea (a serious systemic chronic disease of the skin and liver). There was a ten percent mortality rate.[90] Lastly, several industrial accidents at plants producing chlorinated phenols led to the exposure of workers or the general public to high log P substances including TCDD.[91] The best known of these occurred in Seveso, Italy, in 1976 when an explosion at a chemical plant released significant quantities of TCDD.[92] This single acute exposure caused significant chronic disease: chloracne, polyneuropathy, and liver disease were all documented in persons living downwind of the plant.[93]

Excessive exposures to high log P substances also pose teratogenicity hazards, commonly known as birth defects. Proving human teratogenicity is even more difficult than proving carcinogenicity. Certainty would require epidemiological evidence, yet it is difficult if not impossible to find a large enough sample of exposed individuals with accurate data on the amount of their exposure.[94] Accordingly, data on possible human teratogenicity is based almost entirely on high dose animal tests.[95] Many

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MENT 2, 6-11 (John S. Waid ed., 1987).

89. Shu-Tao Hsu et al., *Discovery and Epidemiology of PCB Poisoning in Taiwan: A Four-Year Followup*, 59 ENVTL. HEALTH PERSP. 5, 5 (1985). Some of the less serious symptoms were widespread. For example, of 117 patients with PCB poisoning, 81% experienced significant discharges from their eyes, and 51% had discharges severe enough to cause transitory interference with vision. The discharges resisted treatment and only decreased over a period of years. Yao-An Fu, *Ocular Manifestation of Polychlorinated Biphenyl (PCB) Intoxication: Its Relationship to PCB Blood Concentration*, 101 ARCHIVES OPHTHALMOLOGY 379 (1983).

90. *See* Rudi Schmid, *Cutaneous Porphyria in Turkey*, 263 NEW ENG. J. MED. 397 (1960).

91. *See* G. Reggiani, *Dioxins, tetrachlorodibenzo-para*, ENCYCLOPEDIA OF OCCUPATIONAL HEALTH AND SAFETY 639 (Luigi Parmeggiani ed., 3rd ed. 1983) (listing these accidents).

92. So far, TCDD has not been shown to cause cancer in exposed humans. *See supra* note 83. Some observers, including two of the authors, believe that if dioxin were as potent a human carcinogen as EPA has declared based on animal studies, this potency should be reflected by the incidence of cancer in places such as Seveso, where the concentration was high and many persons were exposed. At this time, it is impossible to say whether the lack of a statistically significant increase in cancer at Seveso means that the substance is: (1) not a human carcinogen; (2) is a human carcinogen, but has a safe threshold, which was not exceeded at Seveso; or (3) is a human carcinogen, but has a lower potency in humans than in animals. By contrast, the noncarcinogenic effects at Seveso discussed in the text are well documented.

93. Francesco Pocchiari et al., *Human Health Effects from Accidental Release of Tetrachlorodibenzo-p-dioxin (TCDD) at Seveso, Italy*, 320 ANNALS NEW YORK ACAD. SCI. 311, 313-17 (1979).

94. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. DEP'T OF COMMERCE, REPRODUCTIVE HEALTH HAZARDS IN THE WORKPLACE 67 (1985).

95. *See id.* Indeed, the determination of human teratogenicity is in its infancy. As noted in the OTA report:

of the common very high log P substances are known animal teratogens and suspected human teratogens.[96]

In addition to teratogenicity, these compounds are also suspected to affect other aspects of reproduction and early childhood development.[97] For example, in three of the contamination incidents described above, infants and children were the most severely affected.[98] Moreover, due to their high lipophilic properties, many high log P substances have been found to concentrate in breast milk, leading to further contamination of infants whose mothers were exposed.[99]

> Of the thousands of chemicals used in the workplace, relatively few have been examined for their effects on reproductive function. A 1982 review of the reproductive hazards of industrial chemicals that explored the effects of 48 compounds . . . found significant gaps in information on reproductive toxicity in either experimental animals or humans for all but one of these chemicals. *These gaps in knowledge make estimation of human hazards difficult and prediction of human risk virtually impossible.*

Id. For these reasons, and given the high stakes, regulatory authorities will probably continue to accept positive animal evidence as indicative of possible human teratogenicity.

96. These include chlorinated hydrocarbons (DDT, chlordecone), the chlorinated herbicide 2,4,5 trichlorophenoxyacetic acid, the contaminant TCDD, and the polyhalogenated biphenyls PCB's and PBB's.

97. The evidence for adverse effects on reproduction and early development are stronger in animal tests than the epidemiological data for those effects in humans. TCDD is a teratogen in animals. PAH's, PCB's, chlorinated phenoxyacids, and benzene hexachlorides have been reported to affect both male and female reproduction in test animals. Based on animal data, EPA believes TCDD "displays an unusually high degree of reproductive toxicity," including teratogenicity, fetal toxicity, and reduced fertility. OFFICE OF HEALTH & ENVTL. ASSESSMENTS, U.S. ENVTL. PROTECTION AGENCY, EPA-600/8-84/014F, HEALTH ASSESSMENT DOCUMENT FOR POLYCHLORINATED-DIBENZO-P-DIOXINS, at D-1 (1985) [hereinafter DIOXIN HAD]. The effects of TCDD on human reproduction, however, are uncertain and based on equivocal Agent Orange studies. *See generally* Dan S. Sharp et al., *Delayed Health Hazards of Pesticide Exposure,* 7 AM. REV. PUB. HEALTH 441, 452-58 (discussing the reproductive hazards resulting from pesticides and the uncertainty of Agent Orange studies); D.R. Mattison et al., *Reproductive Effects of Pesticides, in* THE EFFECT OF PESTICIDES ON HUMAN HEALTH 297 (S.R. Baker & C.F. Wilkinson eds., 1990).

98. For a discussion on children, especially infants, see Pocchiari et al., *supra* note 93, at 314-16; Schmid, *supra* note 90; Urabe et al., *supra* note 88, at 274, 276. In those incidents, exposed smaller children were more likely to become ill than older ones, perhaps because their livers had yet to develop effective detoxifying abilities. In those cases where there was in utero exposure, the exposed fetuses tended to have more illness after birth than those not exposed.

99. For a discussion of human breast milk contamination, see *infra* notes 524-26 and accompanying text. The buildup of highly bioaccumulative substances in adult females can adversely affect their children, as they may be passed to the fetus through the placenta, and are known to pass into breast milk. Since the substances are lipophilic, they remain in the children and can build up, causing sources of exposure at very early ages when the nervous system and other body systems are going through critical development. One study found that blood levels of several high log P pesticides were higher among women who had preterm delivery than among those whose delivery was fullterm. M.C. Saxena et al., *Role of Chlorinated Hydrocarbon Pesticides in Abortions and Premature Labour,* 17 TOXICOLOGY 323 (1980).

III
DETERMINING BIOACCUMULATION POTENTIAL

A. Traditional BCF Analysis

In this article, we are concerned both with bioaccumulation as a phenomenon and with the class of substances which can bioaccumulate. The bioaccumulation factor (BCF) of a substance is a measure of the tendency of that substance to bioaccumulate. Several methods of measuring or estimating BCF are well accepted in the scientific community.[100] Indeed, a "standard practice" (i.e., a widely accepted test protocol) exists for conducting steady state bioconcentration tests.[101]

Nonetheless, the regulatory approach we propose[102] relies on a cal-

100. For determining BCF's in aquatic organisms, the steady state or plateau method is the most frequently used experimental method followed by pharmacokinetic (kinetic) methods.

The basic assumption underlying the plateau method is that compounds are taken directly from water. Under this procedure, organisms are exposed continuously to a constant concentration of test material in a flow-through bioassay system. Water and tissue samples are periodically collected for analysis of the compound. Exposure lasts some specified time period, usually at least 28 days. The BCF is defined as the equilibrium ratio of the concentration of the chemical in the organism to its concentration in the water. In addition, some estimate of the half-life for elimination or depuration is frequently determined. This information is often useful for estimating how long a fishery may have to be closed after an accidental spill or abatement action. The elimination phase of the test involves placing the organism in contaminant-free water for periods similar to those employed in the uptake phase and monitoring how long the chemical remains in the organism.

Pharmacokinetic methods of analysis are essentially the same as those used for the plateau analysis with the following exceptions. The test organisms and water are normally sampled for analysis more frequently during a brief exposure period, usually less than seven days. Following exposure, the test organisms are transferred to untreated water and sampled until the elimination rate is established. Reasonable agreement between BCF's determined by the kinetic and plateau procedures for several organic compounds has been shown to occur. The plateau method has an advantage because of its conceptual simplicity and the fact that the BCF established by this method is an observed factor based on measured equilibrium concentrations. For a general discussion of bioaccumulation measurement with an excellent explanation of rate kinetics, see A. Spacie & J.L. Hamelink, *Bioaccumulation*, *in* FUNDAMENTALS OF AQUATIC TOXICOLOGY, *supra* note 57, at 495.

101. AMERICAN SOCIETY FOR TESTING & MATERIALS, STANDARD PRACTICE FOR CONDUCTING BIOCONCENTRATION TESTS WITH FISHES AND SALTWATER BIVALVE MOLLUSCS (ASTM Designation E 1022-84, 1988). To defend against unreliable test results, the standard practices specify conditions that render the test unacceptable. As outlined in the ASTM standard practice, a test is unacceptable if (1) the test was initiated with organisms within 10 days after treatment for a disease or a disease occurs during a test; (2) the test organisms were not maintained in dilution water at the test temperature for at least 48 hours before they were placed in test chambers; (3) the uptake phase was terminated before either the apparent steady state occurred or 28 days was reached; (4) more than 10% of the organisms in any treatment died or showed signs of disease, stress, or other adverse effects; (5) the highest and lowest measured test temperatures differed by more than 6 °C during the test with fish or by more than 10 °C during a test with bivalve molluscs; (6) the time-weighted average for the dissolved oxygen concentration was less than 60% saturation in any test chamber; (7) the percentage of radioactivity associated with impurities was not determined when a radio-labeled test material was used. Several lesser factors that can influence reliability and render the test result unacceptable are also listed in the ASTM procedure. *Id.* at 664-65.

102. *See infra* part III.C.3.

culation of BCF from log P, rather than on any of the direct BCF tests, for several reasons. First, traditional steady-state BCF laboratory tests are expensive,[103] since the radioactive compounds used in most BCF tests require special care and equipment.[104] The cost of synthesizing those compounds varies considerably depending on the substance's chemical structure and the isotopes used. In some cases, detailed metabolism studies must be performed to determine whether or not the parent compound breaks down in the body of the test organism.[105] Second, many laboratory screening techniques routinely detect the presence of unidentifiable chemical substances.[106] An accurately estimated BCF for such "unknowns" would be useful for their regulation. Yet, as a practical matter, the traditional BCF testing can only be performed on previously identified substances. Third, a BCF test is typically conducted for one substance at a time.[107] The extrapolation technique we advocate suffers none of these defects, and is dramatically cheaper.

B. The Bioavailability Problem: Relationship to Persistence and Sorbtion

The ability of a substance to persist in the environment can be as important as its toxicity. A substance that degrades chemically, biologically, or physically before its ingestion by humans, wildlife, birds, or aquatic organisms is far less likely to pose health or environmental risks.[108] The persistence of organic chemical substances varies tremen-

103. We checked with two qualified commercial testing laboratories with a reputation for reasonable prices to determine the cost of a typical, simple 28-day plateau test for BCF, and were given quotes of approximately $20,000 in 1992 dollars. Occasionally, far greater costs (up to $100,000) are involved.

104. For a description of the materials, methods, and practices needed to use radioisotopes correctly in bioconcentration tests, see AMERICAN SOCIETY FOR TESTING & MATERIALS *supra* note 101, at 657, 664-66.

105. In our experience, other factors can also play a role in costs (e.g., the species and size of test organism which influence tank size, flow rate, amount of material needed for the test; test temperature; and water quality). Additional costs can be incurred if a depuration phase is included in the study. Likewise, if one is interested in determining whether the BCF and rate constants are dependent on the concentration of test material in water, additional treatments, utilizing different concentrations of test material during the uptake phase, must be used. The concentrations of high log P compounds in the tissues and water phase must be quantified frequently during the test, usually using gas chromatography (GC) or GC coupled with mass spectrometry (GC/MS). These are highly sensitive techniques for detecting and sometimes identifying and quantifying organic chemicals. Their use can be more expensive than some other types of chemical analyses.

106. *See infra* note 157 and accompanying text.

107. On rare occasions, mixtures of two or more substances are tested using conventional BCF techniques, though doing so adds greatly to the cost. However, it is virtually impossible with conventional BCF techniques to test a complex mixture of known and unknown substances and attempt to determine how many have bioaccumulated, and to what extent.

108. Substances that rapidly break down in the environment (e.g., by hydrolysis, oxidation, reduction, or photolysis), or which partition to another medium (e.g., volatilize to air) are less likely to reach an organism whereby they could bioaccumulate. Furthermore, rapidly

dously, ranging from virtually simultaneous decomposition in a new medium, to some plastics that may not degrade for centuries.[109] In practice, persistence can often be assumed,[110] partly because it correlates well with log P (i.e., the higher the log P, the greater the persistence).[111]

The ability of high log P substances to adhere or "sorb" readily to solids (such as sediments and soils) poses an analytical problem in assessing the substances' hazards. On the one hand, sorption of a high log P substance to a solid in water does not eliminate the associated toxicity risks since those substances may still reach living organisms and bioaccumulate.[112] On the other hand, a sorbed substance does not pose as great a risk as it would if completely mobile. The key issue is bioavailability—whether there are pathways by which living organisms can be exposed to the high log P substances.[113] Unless the contaminants are

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metabolizing substances may not build up in the target organism. Thus, generally, only fairly persistent substances are capable of bioaccumulating.

109. To complicate matters further, substances often break down far more quickly in one medium than in another. *See supra* note 5.

110. For example, adjusting for persistence is rarely necessary these days for discharges to surface waters. In both municipal sewage treatment plants and facilities in industries that produce or use organic chemicals, biological treatment is usually the treatment of choice. As a consequence, a great deal of degradation of substances will already have taken place prior to any testing of the effluent for toxicity or bioaccumulation. Those chemicals that remain after treatment are substances that have not rapidly biodegraded even under favorable conditions. In short, what remains to be discharged from many good wastewater treatment plants these days tends to be persistent. The same could be said for cleanup of past hazardous waste facilities; the toxic substances found have persisted in some cases for decades.

111. Many relatively low log P substances such as organophosphate residues (e.g., malathion, log P=2.4) degrade in water in a few hours to a few days. In contrast, organochlorine residues (e.g., DDT with a log P of 5.7, dieldrin with a log P of 5.5, and endrin with a log P of 4.7) may persist for years or even decades under the same conditions. *See* D.R. Nimmo, *Pesticides, in* FUNDAMENTALS OF AQUATIC TOXICOLOGY, *supra* note 57, at 335.

112. Organisms can be exposed to high log P substances as the substances enter the water column. Moreover, even if the substance does sorb to sediment, that does not necessarily eliminate the risks, as many organisms in the water column are exposed to toxicants released directly from the sediment into the overlying water column, or by consuming benthic (i.e., bottom-dwelling) organisms. In addition, benthic species and the eggs and larvae of fish and other organisms that spawn on sediments may receive exposure via (1) the ingestion of contaminated particles; (2) toxicants in the sediment pore water (interstitial water in the sediment); and (3) toxicants released from the sediment into the water column. For a more thorough discussion of exposure pathways for contaminated sediments, see William J. Adams, *Bioavailability of Neutral Lipophilic Organic Chemicals Contained on Sediments: A Review, in* FATE AND EFFECTS OF SEDIMENT-BOUND CHEMICALS IN AQUATIC SYSTEMS 219 (Kenneth L. Dickson et al. eds., 1987) [hereinafter FATE & EFFECTS]; John H. Rodgers et al., *Bioavailability of Sediment-bound Chemicals to Aquatic Organisms—Some Theory, Evidence and Research Needs, in* FATE & EFFECTS, *supra*, at 245; Peter F. Landrum & John A. Robbins, *Bioavailability of Sediment-Associated Contaminants to Benthic Invertebrates, in* SEDIMENTS: CHEMISTRY AND TOXICITY OF IN-PLACE POLLUTANTS 227 (Renato Baudo et al. eds., 1990).

113. Knowing the chemical composition of sediments does not allow one to predict the bioavailability of highly polar organics, charged organics, or heavy metals. These substances may be so tightly bound to other substances that only a portion of them will be available for bioaccumulation. In scientific terms, partitioning models do not adequately address sorption equilibria and cannot address sorption/desorption kinetics. *See* Adams, *supra* note 112; R.T.

bioavailable, they will not manifest toxic effects to the system in which they are found. Methods that measure total sorbed substances are irrelevant for regulatory purposes. Estimating the bioavailability of sorbed material, however, is difficult.[114]

C. *Testing for Log P*

Log P is widely used in environmental and medical science because it indicates the probability of a substance remaining in water or concentrating in fatty tissues. As a result, a highly accurate BCF can be calculated from a known log P value. There are several inexpensive methods of determining the log P of a specific chemical substance. One method, however, can also test complex mixtures of substances, including substances whose identities are unknown, and provide very accurate measures of the log P of each contained substance. We believe this method can be used to perform extensive screening of liquids and, with some modification, of liquid/solid mixtures to see if they contain high log P substances and thus possibly merit remedial action.

1. *Log P and Bioaccumulation*

Log P measures a substance's tendency to remain in an organic solvent rather than to remain in water when the two liquids are thoroughly mixed and then separated. The equilibrium ratio of the substance's amount in the organic solvent (n-octanol) to that in water is called the n-octanol/water partition coefficient.[115] Organic chemical substances vary enormously with respect to this ratio. Some partition primarily to water;[116] others concentrate in the n-octanol a million-fold, or more,

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Podoll & W.R. Mabey, *Factors to Consider in Conducting Laboratory Sorption/Desorption Tests*, *in* FATE & EFFECTS, *supra* note 112, at 99-108; Charles A. Staples et al., *A Model for Predicting the Influence of Suspended Sediments on the Bioavailability of Neutral Organic Chemicals in the Water Compartment*, *in* AQUATIC TOXICOLOGY AND HAZARD ASSESSMENT: SEVENTH SYMPOSIUM 417, 418 (R.D. Cardwell et al. eds, ASTM STP 854, 1985).

114. Factors that affect bioavailability include the chemical and physical characteristics of the toxicants, the structure and chemistry of the sediment and interstitial water, and the chemistry and habitat of the exposed aquatic life. *See, e.g.*, D. DiToro et al., *Synopsis of Discussion Section 2: Environmental Fate and Compartmentalization*, *in* FATE & EFFECTS, *supra* note 112, at 136-47; Ulrich Förstner, *Sediment-Associated Contaminants—An Overview of Scientific Bases for Developing Remedial Options*, 149 HYDROBIOLOGIA 221 (1987). *See generally* Wim Salomons, *Sediments and Water Quality*, 6 ENVTL. TECH. LETTERS 315 (1985) (discussing the role of sediments in water quality).

115. One of the first published papers suggesting a link between the n-octanol/water partition coefficient and the lipid content of aquatic organisms was Jerry L. Hamelink et al., *A Proposal: Exchange Equilibria Control the Degree Chlorinated Hydrocarbons are Biologically Magnified in Lentic Environments*, 100 TRANSACTIONS AM. FISH. SOC'Y 207 (1971). Hamelink et al. proposed that DDT accumulation in fish occurs because the material is exchanged (partitioned) between water and fat in fish. This study confirmed earlier observations that pesticide magnification in fish is roughly inverse to the water solubility of the compound.

116. These substances have a partition coefficient less than one and thus a negative log P.

than in water.[117] Because of this large range, scientists normally use the logarithm of the coefficient, commonly designated as log P.[118] Log P has become an important environmental partitioning indicator[119] and, consequently, many sources document log P values for compounds of environmental interest.[120] Several laboratory methods exist for measuring log P, including the "shake-flask" (centrifuge) method and high pressure liquid chromatography (HPLC).[121] Standard protocols exist for each of these methods.[122]

Dow researchers were among the first to publish the results of an investigation that determined an experimentally-derived relationship between log P values and the degree to which these constituents would partition into organic lipids and bioconcentrate.[123] They found a high correlation between log P and log BCF,[124] as determined by traditional tests on aquatic organisms.[125] Thus, the higher the log P, the higher the substance's concentration is likely to be in living tissue.

Like EPA, we are concerned with those chemicals with a log P of 3.5 or above.[126] For the purposes of this article we have designated these

117. Substances with n-octanol/water partition coefficients of 1 to 10 have log P values between 0 and 1.

118. Especially in older literature, the property is sometimes referred to as K_{ow} and, correspondingly, log K_{ow}.

119. Log P is used as a screening parameter to assess the significance of partitioning a chemical from the aqueous phase to a solid phase such as soil or sediment.

120. The sources for the survey are contained in *supra* note 67. Despite the wide use of log P, there are many chemical substances for which no measured log P value has been reported.

121. HPLC is a common laboratory technique that separates liquid mixtures of organic compounds by pushing them at high pressure through a specially designed column. When used in conjunction with standards and various detectors, it can sometimes provide identification and/or quantification of the compounds it has separated. HPLC is widely used in basic chemical and medical research. It is sometimes also used as an environmental testing method. For example, EPA's standard method 610 uses HPLC to test for certain PAH's, while method 605 is used for benzidine and dichlorobenzidine. 40 C.F.R. § 136.3 (1992). HPLC is sometimes alternatively referred to as high performance liquid chromatography.

122. EPA has promulgated test-method regulations under TSCA, 15 U.S.C. §§ 2601-2692 (1988 & Supp. IV 1992), for these two methods. 40 C.F.R. § 796.1550 (1992) (K_{ow} by shake flask method); 40 C.F.R. § 796.1570 (1992) (K_{ow} by HPLC). It has also promulgated regulations for the generator-column method, 40 C.F.R. § 796.1720 (1992), and a guidance document for Clean Water Act purposes. U.S. ENVTL. PROTECTION AGENCY, EPA/540/11-80-027, SUPPORT DOCUMENT TEST DATA DEVELOPMENT STANDARDS: PHYSICAL/CHEMICAL AND PERSISTENCE CHARACTERISTICS (1980).

123. *See* Neely et al., *supra* note 67.

124. For a discussion of BCF, see *supra* note 100.

125. These investigations featured determinations of the concentrations of organic compounds in trout muscle and their corresponding concentrations in the aqueous phase at equilibrium, examining log P within the range of 2 to 8 and log BCF within the range of 1 to 4. The corresponding regression line was Log BCF=0.542 Log P + 0.124. Neely et al., *supra* note 67, at 1115. Several similar regressions have been calculated. *See infra* notes 128, 139, and accompanying text.

126. EPA uses a log P of 3.5 as the point at which substances are considered highly bioaccumulative. See OFFICE OF WATER, U.S. ENVTL. PROTECTION AGENCY, ASSESSMENT AND CONTROL OF BIOCONCENTRATABLE CONTAMINANTS IN SURFACE WATERS, at III-13 (draft,

chemicals as "high log P substances." We are especially concerned with chemicals having a log P of 5.5 or more, which we designate as "very high" log P.[127]

One commonly used experimentally derived expression of the relationship between the BCF and Log P is log BCF=0.85 Log P - 0.70.[128] Using this formula, a BCF for a known organic compound can be estimated from the corresponding log P. The log P value can be obtained from tabulations of data obtained by one of the three previously mentioned measurement techniques. Where measured data are not available, the log P can be estimated based on its chemical structure[129] or by corre-

1991) [hereinafter BIOCONCENTRATION GUIDANCE DOCUMENT], for the latest in a long string of EPA documents using log P of 3.5 as the threshold of increased concern. Using the formula discussed in text accompanying note 128, *infra*, a log P of 3.5 corresponds to a log BCF of 2.77 or a BCF of 186 to 1. We are unable to determine exactly why EPA chose 3.5 (beyond the need for a bright line), but two possibilities suggest themselves from the record. First, research by EPA laboratories had suggested a positive relationship between log P values above 4 and acute aquatic toxicity. *See* Vieth et al., *supra* note 67, at 1297. Second, a log P of 4 equates closely to a BCF of about 500, using the same formula. While not a magic number, an actual increase of 500-fold suggests the possibility for greatly increased exposures. But if the actual line of concern is 4, given considerations of analytical variability, a measured log of less than 3.5 virtually assures that the true value is less than 4. For a more recent use of this line of reasoning supporting the use of 3.5 as the cutoff, see BIOCONCENTRATION GUIDANCE DOCUMENT, *supra,* at III-13. The recent data showing a carcinogenicity threshold at log P=4 for skin cancer in rodents exposed to PAH's also provides support for the use of 3.5 for screening and regulatory purposes. Zhang et al., *supra* note 80, at 169.

127. A log P of 5.5 corresponds to a log BCF of 3.97 or a BCF of just under 10,000 to 1, using the formula discussed in text accompanying note 128, *infra*. Unlike the log P of 3.5, this log is not a generally accepted benchmark. However, it does seem to suggest a good break point between those substances that strongly bioaccumulate and those that are unusually capable of doing so. Moreover, many substances receiving the greatest public and regulatory concern, including DDT, PCB's, and TCDD, have log P's above 5.5. *See* Table 1, *supra* p. 620.

128. OFFICE OF WATER, U.S. ENVTL. PROTECTION AGENCY, TECHNICAL SUPPORT DOCUMENT FOR WATER QUALITY-BASED TOXICS CONTROL 43 (original edition, 1984). Other mathematical expressions of the relationship between log P and BCF have been calculated with similar results *See infra* note 139.

129. Log P may be estimated using a substituent addition approach that is well founded in thermodynamics. Corwin Hansch & Toshito Fugita, *A Method for the Correlation of Biological Activity and Chemical Structure,* 86 J. AM. CHEMICAL SOC'Y 1616-26 (1964). For a discussion of the regulatory use of such structure-activity relationships to estimate log P, see *infra* notes 548-49 and accompanying text.

lations to known water solubilities,[130] provided the coefficients remain within the equation's parameter ranges.[131]

Investigations using HPLC have established such a mathematical relationship between the observed retention times for organic constituents in the HPLC column and their corresponding partition coefficients.[132] Both the ASTM standard test method for log P[133] and EPA's test regulations and guidance documents are based on this relationship.[134] HPLC used in this fashion allows researchers to measure the log P and thus calculate the log BCF for substances contained in a mixture of *unknown* organic constituents, something that cannot be done readily with other log P measurement techniques.

2. *Strength of Correlations*

By using these two correlations together—HPLC retention time with log P, and log P with log BCF—BCF can be accurately calculated solely from the HPLC retention time, even for a sample's unknown substances.[135] What makes this estimate especially useful for predictive and regulatory purposes is the exceptional strength of these two correla-

130. Research has demonstrated an inverse correlation between log P and log S, where S is the water solubility of the organic compound of interest. One reported correlation is as follows: Log P=5.00 − 0.670 Log S. In this investigation, the water solubilities ranged from 0.0095 ppm to 16,600 ppm with a corresponding range in log P's of 1.41 to 6.72. Chiou et al., *supra* note 67. Although solubility gives an estimate of log P, and thus allows an estimate of BCF, solubility alone is not a sufficient basis for estimating BCF, for two reasons. First, log P is a more direct measurement of partitioning behavior. D. Mackay et al., *Relationships Between Aqueous Solubility and Octanol-Water Partition Coefficients,* 9 CHEMOSPHERE 701, 705 (1980). As a consequence, EPA in its National Contingency Plan under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C.A. §§ 9601-9675 (West 1983 & Supp. 1993) [hereinafter CERCLA or Superfund], recommends that, for organic substances, actual BCF be used where known; where BCF is not known, log P be used; and, with one exception, only where log P is not known should log S be used as a means of estimating BCF. 40 C.F.R. § 300 app. A (1992). There is a second and substantially more serious defect in using log S for these purposes. Log S is only calculable for known substances. There is no practical way to put a complex sample into equipment that would indicate that there were, for example, 25 different substances contained therein with differing solubilities that can be measured and correlated to BCF.

131. The bioconcentration factor provides a good measure of bioaccumulation potential except for compounds with a very high log P, where the bioaccumulation factor may be greater than the bioconcentration factor. *See supra* note 41.

132. U.S. ENVTL. PROTECTION AGENCY, EPA/600/3-78-049, A RAPID METHOD FOR ESTIMATING LOG P FOR ORGANIC CHEMICALS (1978). One such regression line is as follows: Log P=5.106 Log RT − 1.258, where RT is the HPLC retention time. G.D. Vieth et al., *A Rapid Method for Estimating Log P For Organic Chemicals,* 13 WATER RES. 43, 46 (1979).

133. AMERICAN SOCIETY FOR TESTING & MATERIALS, ASTM No. E 1147-87, STANDARD TEST METHOD FOR PARTITION COEFFICIENT (N-OCTANOL/WATER) ESTIMATION BY LIQUID CHROMATOGRAPHY (1987) [hereinafter ASTM].

134. *See supra* note 122.

135. Of course, one could alternatively measure the BCF directly, but that demands a knowledge of the identity of the substance, and is far more time consuming and expensive. *See supra* note 100.

tions,[136] as confirmed in several studies. Dr. Vieth et al., in their pioneering work on the subject, calibrated HPLC retention times using compounds with known log P values in the range of 2.0 to 6.0. This yielded a virtually perfect correlation factor of $R=0.975$.[137] Similarly, Dr. Neely et al., who provided the first mathematical relationship between measured log P and the measured BCF, calculated a correlation coefficient for the same substances of $R=0.948$.[138] While many correlations between log P and log BCF have been calculated with R values both above and below that found by Neely, about half have R values of 0.95 and above.[139]

A perfect correlation between any two properties in the biological sciences is extremely rare.[140] Yet these two correlation coefficient values

136. If there were not a very strong relationship between the retention time of a substance in HPLC and its "true" log P value, some substances found in a sample would be identified as high log P substances when they are not (a "false positive" result), while some high log P substances would escape that designation (a "false negative"). Similarly, if the correlation between log P and log BCF was not very strong, and agencies acted on the incorrect BCF data, the results could be costly regulation of a substance where no regulation was warranted, or the failure to regulate a substance that might pose a significant threat to health or the environment.

137. Vieth et al., *supra* note 132, at 46.

138. Neely et al., *supra* note 67, at 1115.

139. One report summarized the 18 studies of the relationship reported in the scientific literature, for which 20 regressions were calculated. The range was from $R=0.63$ to $R=0.99$. Of them, half had R values of 0.95 or better; the arithmetic mean was 0.89. G. Schüürmann & W. Klein, *Advances in Bioconcentration Prediction,* 17 CHEMOSPHERE 1551, 1560 (1988). Several factors can affect the R value resulting from a particular regression, including the number and chemical properties of the compounds surveyed and the accuracy of the underlying data. The highest R values were obtained when measured log P values were used; lower values were associated with studies that used log P values calculated using structure-activity relationships. *Id.* at 1561-62. An additional factor may be that the precision of some BCF measurements used for the correlations is questionable, either because the study was not performed properly, or because it was not conducted long enough to reach equilibrium, which tends to understate the BCF of very high log P substances. For the purposes of this article, we have used the regression contained in the original *Technical Support Document, see* OFFICE OF WATER, *supra* note 128, because the study on which it relied, by Vieth et al., used HPLC-derived measurements. That has the practical effect of correlating HPLC retention time directly with log BCF, eliminating one possible source of uncertainty, namely, the interplay of the two correlations. EPA in its draft guidance document relies on a different study by Vieth, probably because it involved a correlation of the log P and log BCF values of 122 compounds, making it far larger than any other study. BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126, at II-4. It shows an R value of 0.93. The two studies yield virtually identical results. In explaining these correlations, we do not mean to suggest that log P is necessarily better than other predictors of BCF for all purposes. It may be, as Schüürmann & Klein have suggested, that for some classes of substances, solvent-accessible surface area and molar refraction will turn out to be as good as or even better predictors of BCF than *calculated* log P. Schüürmann & Klein, *supra*, at 1567-70. Their data do not support that supposition for measured log P. In any event, those approaches require a precise knowledge of the structure of the chemical. HPLC-measured log P, in contrast, requires no such knowledge, and does not even require a knowledge of the identity of a substance to provide a very good prediction of its likelihood to bioaccumulate.

140. In a brief and nonscientific survey of standard biostatistics texts, we were unable to

are very high, and vital decisions and even legal presumptions are often based on far weaker correlations.[141] Consequently, there is a strong and statistically defensible basis for the screening approach suggested below.[142] These two correlations are illustrated in figures one[143] and two.[144]

HPLC's greatest potential for regulatory uses rests in its capacity to test chemical mixtures for high log P substances without first identifying the chemicals.[145] Therefore it can be used to screen a complex sample containing dozens to hundreds of separate and potentially unknown chemical constituents, such as a treated wastewater or contaminated ground water.

3. *Our Proposal*

Relying solely on traditional HPLC to screen for log P can lead one to miss important data in some cases. The difficulty results from the inability of the ultraviolet (UV) detectors commonly used in HPLC to detect some substances.[146] Accordingly, the approach we have selected

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find any pair of measurements with an R value of 1.0.

141. The correlations cited in text are far stronger than other correlations that have been commonly used in the law. Consider, for example, the use of a blood-alcohol level to establish whether a person is intoxicated. The law needs a bright line for obvious reasons and establishes one, despite the fact that some people with blood-alcohol levels slightly above the specified level can function quite well and some people whose blood alcohol level is somewhat below the regulatory level cannot function at all. We are confident that the correlation between the degree of impairment and the blood alcohol level is positive, but that the R value is far below 0.9. The need for society's institutions to make rational decisions with less-than-perfect information often leads to the use of correlations that are far weaker than those supporting our proposal. One of particular interest to law students is the use of "index" scores, a weighted combination of the Law School Aptitude Test (LSAT) and undergraduate gradepoint average, in the admissions process for law school. The Law School Admission Services (LSAS) has correlated those index scores with first year grades at most American law schools, to substantiate that the index predicts law school success. The median R value was slightly under 0.5. At no school was it higher than 0.67, and at one it was only 0.25. (Use of the LSAT or gradepoint average alone yields even weaker correlations). Unpublished LSAS Report (Dec. 18, 1992) (on file with the *Ecology Law Quarterly*).

142. Of course, because the correlations are not perfect, there will be a small number of cases where the HPLC retention time does not predict log P, or where the log P does not predict BCF. In addition, as with all laboratory processes, there is the possibility of human-induced error. For those reasons, as we explain more thoroughly in part V, those responsible for generating or releasing the substance should have the right to challenge and rebut the results of the screening approach.

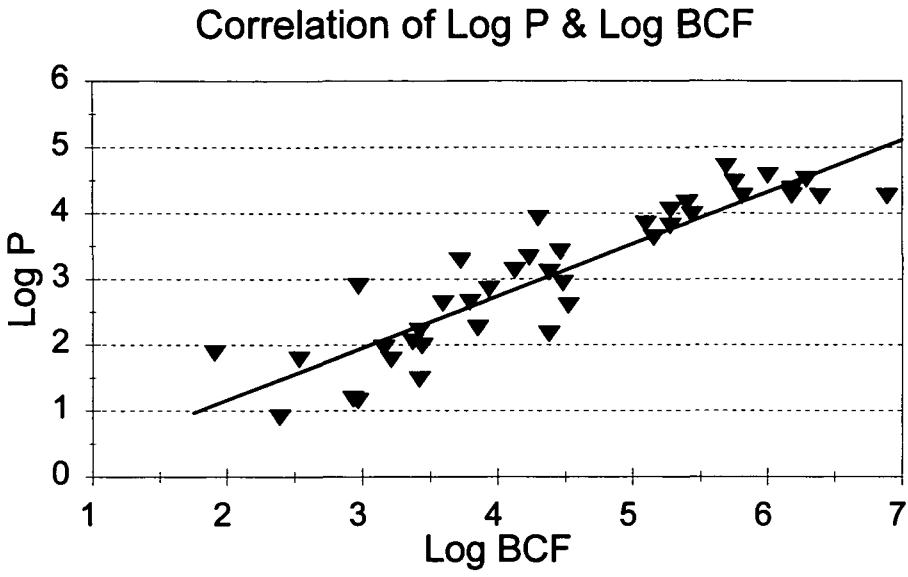
143. Prepared by the authors from data contained in Veith & Kosian, *supra note* 67 (discussing 40 individual compounds with 28- to 32-day BCF's on fathead minnows).

144. Prepared by the authors from data contained in Veith et al., *supra* note 132 (discussing 43 individual chemical compounds).

145. HPLC is not necessarily the best means of determining the log P of a known compound; it is generally more expensive than the shake-flask method.

146. The major reason for this false-negatives problem is that the HPLC UV detectors identify the existence of chromophores, most commonly from the existence of double bonds, such as those which occur between carbon atoms in many compounds. While a significant majority of high log P substances have such double bonds, there are high and very high log P

Figure 1



for detecting and, where possible, identifying and quantifying high log P substances relies primarily, but not exclusively, on standard HPLC. In appropriate cases, we supplement the routine HPLC procedure with additional detectors such as photodiode array, fluorescence, refractive index, and mass spectrometer.[147]

We label this enhanced HPLC procedure the "log P screening technique." We would not require additional detectors in every instance. In small-scale releases or releases whose composition is well known,[148] simple HPLC should provide sufficiently accurate data; in these cases, the additional detectors would be inefficient.[149]

With a few minor exceptions, our procedure follows well-established, standard protocols for HPLC-use to test a complex matrix.[150] The final detection phase is the primary difference. Briefly, the proce-

substances that do not have any chromophores. Telephone Interview (by Burton) with Dr. Michael A. Unger, Virginia Institute of Marine Science (Oct. 1993).

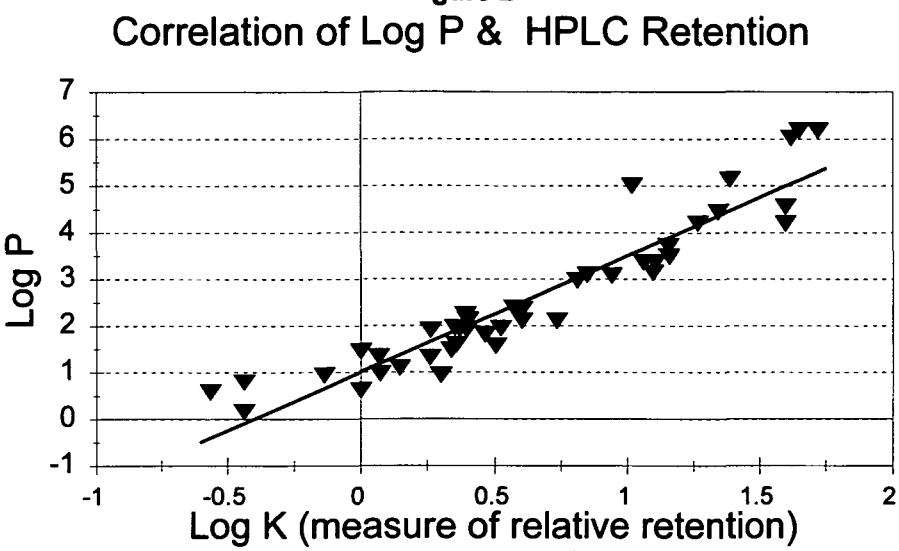
147. The additional detectors virtually eliminate the false-negative problem and improve the possibility that detected substances can be identified and quantified. The selection of the supplemental detectors should initially be left to the professional discretion of qualified independent laboratories based on the circumstances and properties of the sample. Over time, however, these would probably be specified by regulation.

148. For example, a permitholder with a complex release that had been frequently tested with the full, enhanced technique would often be able to show that HPLC with just the UV detector adequately characterizes the release. In that event, the permitholder should not be required to go on using the additional detectors.

149. While the simple HPLC is less precise than our proposal, its use would significantly improve environmental regulation. *See infra* part V.B.2.

150. *See, e.g.*, ASTM, *supra* note 133; BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126.

Figure 2



dure requires acquiring a sufficiently sized sample,[151] spiking it with three surrogate chemicals,[152] and then mixing, extracting, drying, and concentrating it.[153] Sample cleanup then removes biologically derived materials that may interfere with the analytical procedures.[154] After a final concentration step, the sample is then injected into the HPLC instrument.

The substances in the sample are separated as they pass through the instrument, with the lowest log P substances passing through first, followed by others with increasingly high log P's. The UV detector will show the presence of most high log P substances contained in the original sample. The detector charts these results on a graph; each "peak" represents one or more discrete chemical substance.[155] The separated sub-

151. For treated wastewater, EPA recommends beginning with ten liters, which are concentrated down to 10 milliliters (mL). We believe this is excessive and that, generally, one liter concentrated down to one mL should be sufficient. Greater amounts may be required for drinking water, while no concentration may be needed for liquid hazardous waste. Where large samples cannot be taken, as when testing human blood samples or the flesh of seafood, a clean sample of less than one mL will generally suffice. Nor does beginning with a small sample interfere with the validity of the results. Doing so may reduce the sensitivity, but that would rarely be an argument against the use of the technique, since the substances that are nevertheless detected are clearly present. The only difficulty would be that some high log P substances present at low concentrations might be missed.

152. The surrogate chemicals provide quality control information for the sample matrix and the analytical procedure.

153. Initial concentration is often needed because the contaminants are present only in very small amounts, though this will vary tremendously depending on what is being tested.

154. The sample cleanup also removes bioaccumulatable chemicals that are not stable in the acidic phase. These chemicals will not be detected.

155. When testing a single substance or a simple mixture, each peak represents a single substance. If the mixture is very complex, some peaks may overlap. The differing substances

stances are then diverted to other detectors, where the results are again recorded.[156]

The full log P screening technique described above provides several different kinds of useful data. First, it accurately indicates whether any high log P substances are present in a sample. Second, it provides an exceptionally accurate measure of the log P of any detected substances. Third, knowledge of the log P values permits an excellent estimate of their BCF. Fourth, the technique sometimes can identify the substance(s) present.[157] Fifth, where individual substances can be identified, they can usually be quantified.[158] Finally, even where identification of a substance is not possible, the technique frequently allows a rough estimate (accurate to about one order of magnitude) of the substance's concentration.

4. Technical Issues in the Use of the Technique

Screening approaches are often effective for regulatory purposes if the correlations used are reliable within half an order of magnitude or even a full order of magnitude; they do not require perfection to be useful and cost effective. All of the correlations discussed above easily meet this requirement. Indeed, given a careful selection of detectors, the log P screening technique can perform at or close to the sensitivity and precision of the most advanced state-of-the-art techniques, such as GC or GC/MS, for determining individual compounds.[159] Protocols for using HPLC have been promulgated by the American Society for Testing and

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making up that peak will have virtually the same log P.

156. For screening treated wastewaters under the CWA, EPA has proposed an approach that collects fractions coming off the HPLC, which correspond to various log P categories. These fractions can be individually analyzed with gas chromatography. This step permits the detection of additional compounds that are not detected by the HPLC UV detector. The GC with a flame ionization detector generally allows lower detection limits than the HPLC with only UV detectors. A final step of mass spectrometry further increases the chances of identifying and quantifying particular substances. BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126, at III-11 to III-17. The EPA approach is technically sound, and its widespread use would significantly reduce bioaccumulation problems. It is likely, however, to be more expensive and more prone to operator error, and possibly to have more false negatives than the approach we suggest.

157. First, the lab technician makes a guess based on the apparent log P and/or on known or anticipated substances in the sample. The technician then injects a "standard" of the suspected substance into the instrument to determine if the peak in the sample is the same as the peak for the standard. If so, the substances are probably identical. On the other hand, frequently the technician will have no reasonable basis for guessing what the substance might be, and/or no standard sample of that substance exists. In either case, identification is not possible by HPLC alone.

158. However, see the discussion of analytical variability in part V.B.4.c, *infra*.

159. *See supra* note 105. For example, EPA has had excellent results combining HPLC with mass spectrometry. One of our colleagues has seen three such arrangements on line at EPA's Cincinnati laboratory.

Materials[160] and by EPA under TSCA[161] and the CWA.[162] EPA also proposed, but did not adopt, such protocols for screening hazardous waste.[163] We would be remiss, however, if we did not point out that even with our suggested use of additional detectors, in a few situations false positives and false negatives could still be observed. Moreover, in some cases, sample-specific chemistry could complicate the evaluation.[164] With those exceptions, however, we do not foresee any technical problems with the use of the technique to screen samples of contaminated water.[165]

Although primarily intended for testing actually or potentially contaminated water, our proposed technique also can be used, in conjunction with additional procedures, to test solid or solid/liquid samples such as sediment, sludge, solid hazardous waste, or contaminated soil. Doing so, however, raises additional technical and policy issues.[166] The mere fact that a sediment, soil, solid waste, or sludge contains high log P substances in concentrations that would be grounds for concern in ground or surface water, however, does not necessarily mean that enough of the substances are bioavailable to pose an environmental or human health risk.[167] To have valid and useful results, the extraction or leaching technique must simulate the release of the substances with sufficient accuracy to mimic real conditions.[168] The most important current regulatory use

160. *See* ASTM, *supra* note 133.

161. *See supra* note 122.

162. *Id.*

163. *See infra* notes 415-16.

164. Environmental chemical factors that could impact the process include sorption, chemical precipitation, and other kinds of chemical reactions that would render the chemicals of interest less available for bioaccumulation than the kinds of screening analyses reported herein would indicate. In addition, as explained *supra*, note 12, the technique will not work on metals and organo-metals that are known to bioaccumulate. This is rarely a major problem in practice as there are precise and comparatively inexpensive tests for heavy metals.

165. Many university, government, industry, and commercial laboratories already have HPLC equipment, which is available from several manufacturers. Some testing laboratories might need to purchase additional equipment, but there would not be a serious shortage if the regulatory requirements were phased in. There are no special problems training experienced laboratory technicians to operate HPLC if they have already had experience with GC equipment. Of course, as with all modern detection and measurement techniques, the equipment must be run properly. Thus, we would allow an emitter to prove that the equipment in a particular case provided inaccurate measurements or predicted incorrect BCF values.

166. Extracting a portion of the contaminants for subsequent log P screening can accurately determine whether a mixture contains high log P substances. Problems can arise if the procedure extracts naturally occurring organic material from soil, sediment, or sludges, yielding false positives. Alternatively, the cleanup procedures for the sample may filter out anthropogenic chemicals that have been extracted, yielding false negatives.

167. *See supra* part III.B. (especially note 113) for a discussion of bioavailability as it relates to contaminated sediments.

168. The selection of the extractant is vital, since a given extractant may significantly overstate or understate the degree to which the substances in the mixture can be mobilized and become a matter of health or environmental concern. The possible regulatory use of the log P screening technique to assess sediments, sewage sludge, and soils, is discussed in part V.K.,

of an extractant to test solids or solid/liquid mixtures is the identification of wastes that are hazardous by virtue of toxicity under the Resource Conservation and Recovery Act[169] (the primary federal hazardous waste statute).[170]

5. *Cost Considerations*

The cost of a simple HPLC test can vary considerably depending on who conducts the test, the equipment used, the degree of sample cleanup required, and the intensity of competition among laboratories to supply testing services. Based on our own experience, a rough cost estimate in 1993 is $1250. The use of additional detectors in the log P screening technique will increase the cost by as much as 100%. However, we believe the increased likelihood of identifying and, sometimes, quantifying the individual high log P substances in the sample will usually justify this additional cost.[171]

IV
BIOACCUMULATION IN CURRENT TOXICS REGULATION

A. The Lack of Current Regulation

Public concern with bioaccumulation dates from the publication in 1962 of Rachel Carson's *Silent Spring*. Carson related nothing that was not already a subject of concern in the scientific community. She galvanized public opinion, however, with her graphic descriptions of the extraordinary degree to which DDT could biomagnify in the environment, leading ultimately to the inability of the bald eagle and other birds of prey to lay eggs with shells of sufficient strength to allow for successful reproduction.[172]

The publication of *Silent Spring* eventually led the federal govern-

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infra.

169. 42 U.S.C.A. §§ 6901-6992k (West 1983 & Supp. 1993). While titled the Solid Waste Disposal Act, this Act is usually referred to as the Resource Conservation and Recovery Act (RCRA), the title of its major amendment.

170. Under RCRA, an extractant is used that simulates the mild acids often found in a landfill, so as to predict whether a waste would leach excessive levels of hazardous constituents if placed in a typical landfill. See *infra* part V.E. for a description of this leaching procedure under RCRA, and our recommendation of how this procedure could be combined with the log P screening technique to determine whether wastes should be considered hazardous wastes.

171. In most circumstances, testing costs are already considerable. Use of either the HPLC or our enhanced technique will frequently add little to that burden. On the other hand, being able to reassure the public with higher confidence that a sample contains no high log P substances will often be well worth the modest additional cost. Specific testing costs will be addressed under the discussion of the various statutes in part V, *infra*.

172. A distinguished panel of writers, editors, columnists, and public figures, including former President Carter and Justice O'Connor, voted *Silent Spring* the most influential book of the past 50 years. Marilyn Goldstein, *A Literature of Warning*, NEWSDAY, July 27, 1992, at 8, 8.

ment to ban DDT's use in the United States.[173] Although concern with biomagnification had been a major factor awakening both the scientific community and the general public to the need for protection of the environment, relatively little was done to translate the concern with bioaccumulation into relevant regulatory controls. In the same year that DDT was finally banned, Congress adopted the first modern water pollution control statute[174] and significantly strengthened FIFRA, the federal pesticide statute.[175] Despite the experience with DDT, neither statute contained a single provision dealing directly with bioaccumulation.

Today, we know that high log P substances cause a disproportionately severe impact on the nonhuman environment and pose disproportionate risks of chronic human health effects.[176] High log P substances still receive virtually no attention in federal environmental statutes,[177]

173. In 1969, following growing public pressure for a total ban on DDT uses, the Department of Agriculture announced that it proposed to cancel certain uses of DDT. 34 Fed. Reg. 18,827 (1969). EPA, soon after acquiring jurisdiction from Agriculture, issued a cancellation notice for most remaining registered uses of DDT, and EPA Administrator Ruckelshaus affirmed this cancellation in 1972. 37 Fed. Reg. 13,369 (1972).

174. The Federal Water Pollution Control Act was first enacted on June 30, 1948, Pub. L. No. 80-845, 62 Stat. 1155 (1948). The original statute was nearly worthless, and the modern statute is thought to date from the 1972 amendments. Pub. L. No. 92-500, 86 Stat. 816 (1972). The statute is usually referred to by the title of its 1977 amendments, the Clean Water Act, currently codified at 33 U.S.C. §§ 1251-1387 (1988 & Supp. IV 1992).

175. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was first adopted as Pub. L. No. 80-104, 61 Stat. 163 (1947). It was substantially strengthened by Pub. L. No. 92-516, 86 Stat. 973 (1972). FIFRA is codified as amended at 7 U.S.C. §§ 136-136y (1988 & Supp. IV 1992).

176. We use the term disproportionate impact here in its literal sense. We do not suggest that high log P substances cause a high percentage of all environmental problems or that they are the most severe public health concern. That is clearly not the case. Even among chemical exposure problems, high log P substances do not rank with smoking or heavy metal toxicity (especially for lead), and probably are less serious than exposure to some common organic chemicals. But high log P substances almost certainly cause *disproportionately* severe impacts. For example, the adverse impact is certainly highly disproportionate if the number of log P substances is taken as a function of the total number of all substances. It is even more disproportionate if the weight of high log P substances produced per year is compared with the total weight of synthetic chemical substances. While the production levels of DDT and PCB's were hardly trivial, their total production before being banned was a small fraction of the annual production of dozens of substances. *See supra* note 33 and accompanying text.

177. According to a 1991 LEXIS search of the United States Code, of the several hundred potentially relevant sections in over a dozen environmental and public health statutes, the word bioaccumulation appears in only six current sections, though it is sometimes used several times in a section. Significantly, only one of these sections, 42 U.S.C. § 7412(a)(1) (1988 & Supp. III 1991), *requires* the regulation of substances because they bioaccumulate. The words biomagnification and bioconcentration (and other words having the same roots) do not appear in the United States Code.

however, and little attention in the implementing regulations.[178] State statutes give even less attention to the problem.[179]

This paucity of regulatory effort probably results from several factors. Because the lack of modern analytical methods hindered the detection and quantification of high log P substances in low concentrations,[180] the problem rarely came to regulators' attention. The time, cost, and technical difficulties inherent in performing accurate tests for bioaccumulation potential in the environment were considerable.[181] Competing demands on regulators' time and resources, and in the past decade, hostility to new regulation fortified inherent bureaucratic inertia.[182] Lastly, with respect to the CWA, some EPA officials believed that well-run wastewater treatment plants—which effectively remove other kinds of environmental contaminants—would consistently remove any high log P substances.[183]

B. A Separate Regulatory Effort for Bioaccumulation

Since we are concerned with bioaccumulative substances because they are toxic,[184] why not simply regulate all toxic substances? After all,

178. References to bioaccumulation or bioconcentration in federal regulations are too numerous to list. Most such references, however, are to research programs or to test methods. Of the remainder, nearly all list bioaccumulation as a factor to be considered in the regulatory program or in granting waivers, but do not set limits or regulatory standards. For example, the regulations requiring the Administrator of the National Oceanographic and Atmospheric Administration to consider the potential for bioaccumulation of pollutants discharged from deep seabed mining do not establish testing requirements or standards. 15 C.F.R. § 971.601 (1993).

179. A 1991 LEXIS search of all states statutory provisions showed only 19 references to bioconcentration or bioaccumulation (or related words), in the statutes of 14 states. Most of these references were in state hazardous waste statutes dealing with the factors to be used in one of the following: identification or listing of hazardous wastes (Alabama, Arizona, Florida, Indiana, Louisiana, and Minnesota); selection criteria for determining which hazardous substances would be banned from land disposal; conditions that must be met to obtain a variance from such a ban (California, Idaho, New York, and Tennessee); or making cleanup decisions (Kentucky and Oregon). Other statutory programs included various clean water issues (California and Wisconsin), and identification of air pollutants as toxic or hazardous (Louisiana and Maine). There is no electronic database which can be used to do a comparable search of state regulations.

180. Until the 1960's it was generally not possible to detect and quantify the concentration of a wide range of organic substances much below approximately one milligram per liter (i.e., one part per million). In contrast, particularly since the advent of gas chromatography several methods have been perfected that can detect substances in the low ppb range, and occasionally at much lower levels. For example, acceptable detection limits for measuring organic substances in drinking water are generally in the high parts-per-trillion range. 40 C.F.R. § 141.24(h)(18) (1992).

181. Factors affecting the accuracy and sensitivity of a BCF test for a single compound are discussed in part III.A. *supra*.

182. *See, e.g., infra* note 417.

183. In some cases this belief is unwarranted. *See infra* notes 280-82 and accompanying text.

184. There might be little incentive to regulate bioaccumulative substances that have no

if that regulatory effort is adequate, it should automatically address bioaccumulating substances. There are three main reasons why bioaccumulating substances require a separate regulatory effort. First, bioaccumulation seriously aggravates the toxicity problem because substances can build up to far higher levels than are found in the surrounding water or air, thereby increasing the potential for exposure. Focusing on bioaccumulating substances as a group, through the use of the log P screening technique, allows regulators to address this phenomenon most efficiently. Second, nearly all regulation of toxic substances begins by identifying and quantifying individual substances.[185] In contrast, the log P screening technique makes it possible to replace this chemical-by-chemical regulatory approach with controls over a whole class of substances, including that large portion whose identities cannot be readily established. Finally, even for identifiable substances, the database on toxicity, though better than that on BCF's, covers only a small fraction of known environmental contaminants.[186] A contaminant whose toxicity is unknown cannot be regulated under current approaches that require this information. In contrast, we may safely presume (subject to rebuttal) that any high log P substance is toxic.[187]

C. *How Toxic Substances Are Regulated Generally*

This section discusses five general characteristics of toxics regulation: (1) statutory authority is fragmented; (2) federal agencies assume the primary responsibility for regulation; (3) command-and-control approaches are used almost exclusively; (4) formal cost-benefit analyses are atypical; and (5) the emphasis on chemical-specific approaches helps cause the overregulation of a few substances and the failure to regulate all others.

1. *Fragmented Statutory Authority*

Interstate electricity rates, aircraft safety, broadcast regulation, and many other features of the modern regulatory state fall under a single statute. In contrast, the release of toxic substances is covered by six "environmental" statutes,[188] three "public health" statutes, and several

toxic effects on exposed persons or organisms, but the point is largely theoretical; we have been unable to identify any high log P substance that is not toxic.

185. *See infra* part IV.C.5.

186. For example, the 1985-86 edition of the *Registry of Toxic Effects of Chemical Substances* (*RTECS*) lists data for over 88,000 chemical substances. Of these, however, there are data on tumorigenesis for only 3640, on mutagenesis for only 8224, and on reproductive effects for only 4859. NATIONAL INST. FOR OCCUPATIONAL SAFETY & HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVICES, REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES (1988).

187. *See supra* part II.B.

188. Statutes requiring only the disclosure of information are not considered in this article.

other relevant statutes,[189] all with their own procedures for choosing which toxic substances to regulate, setting standards, and considering the proper role of cost, scientific uncertainty, and available control technologies.

The environmental statutes are of three basic types. One set, consisting of FIFRA and TSCA, focuses on particular substances.[190] These pollutant-oriented statutes are used primarily to determine whether, under what circumstances, or for what uses the substances may be released. A second set of media-oriented statutes, consisting primarily of the CWA, the CAA, and some provisions of RCRA, generally set upper limits on the concentration of a particular chemical substance that can be released into a particular medium (i.e., air, land, water, or ground water). A third set of remedial statutes, consisting primarily of CERCLA, but also including RCRA for active hazardous waste treatment and disposal sites, focuses on the cleanup of previously released hazardous substances that may currently endanger public health or the natural environment.

Public health statutes, particularly the Safe Drinking Water Act (the SDWA), the Federal Food, Drug and Cosmetic Act (the FFDCA), and the Occupational Safety and Health Act (the OSH Act),[191] are designed to protect the public from particular channels of exposure—such as drinking water, food, or the workplace—to toxic substances.

Most of our proposal below can be accomplished by federal agencies within this statutory framework. We do not recommend a new comprehensive statute on bioaccumulation, largely because a general and largely hortatory statute would likely be ineffective. The alternative of statutory micromanagement would create probable confusion and potential inconsistencies with the existing multi-layered statutory framework.[192]

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189. Numerous other statutes have been or could be used to minimize exposure to toxic substances, but are not as important as those discussed in text. For example, there are two statutes designed to protect consumers from various hazards, including chemicals, in consumer products: the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1277 (1988 & Supp. IV 1992); and the Consumer Product Safety Act, 15 U.S.C. §§ 2051-2083 (1988 & Supp. IV 1992); *see also infra* note 253. Both acts are administered by the Consumer Product Safety Commission. The Commission has done nothing to regulate potential exposure to high log P substances.

190. For a detailed discussion of the statutes discussed in this part, see *infra* part V.

191. The Occupational Safety and Health Act is sometimes abbreviated as OSHA. As that is also the common abbreviation of the Agency which administers the statute, we have used the term "OSH Act" throughout when referring to the law.

192. For example, suppose that Congress were to make it a crime to release any liquid to surface water if it contains a high log P substance in excess of 3.5, unless the concentration is below 10 ppb. Absent careful drafting, such a provision would raise a question as to whether the holders of National Pollutant Discharge Elimination System (NPDES) permits would need to comply immediately, or whether they could continue to rely on the provisions of the CWA, 33 U.S.C. § 1342(k) (1988), which declare that, with a few specified exceptions, compliance with permit conditions constitutes compliance with all regulatory requirements (until permit renewal). Similar problems could arise under other statutes.

2. *The Primary Responsibility Rests with Federal Administrative Agencies*

Generally, federal administrative agencies[193] determine which toxic substances are to be controlled and what concentrations are permissible, after following ordinary rulemaking procedures for public notice and comment.[194] The original authorizing statutes often provided little direction other than broad, sometimes vague, and occasionally contradictory goals.[195] Congress has provided the primary check on agencies, influencing them through devices such as oversight hearings, budgetary control, and the introduction of increasingly specific legislation.[196] Congressional efforts to condition agency behavior in this field have generally been to press for or require more vigorous action in regulating toxic substances.[197]

The courts have played a *comparatively* smaller role,[198] largely because they extend considerable deference to administrative agencies over matters of fact, expertise,[199] government policy, and even statutory inter-

193. Most of the relevant statutes are administered by EPA. However, the Occupational Safety and Health Administration (OSHA), in the Department of Labor, and the Food and Drug Administration (FDA), in the Department of Health and Human Services, each administer a key statute. *See infra* parts V.C. & V.G.

194. *See* Administrative Procedure Act (APA), 5 U.S.C. § 553 (1988). Individual states and/or published agency practice may accord procedural rights to interested persons beyond those guaranteed by the APA.

195. Consider, for example, the contradictory goals set by Congress in TSCA, 15 U.S.C. § 2601(b) & (c) (1988). However, in recent years, Congress has adopted increasingly specific legislative language, some of it seemingly more appropriate for regulations. *See, e.g.*, 42 U.S.C. § 6924(o)(5) (1988) (the maximum permeability for hazardous waste landfill liners set at 1×10^{-7} cm/sec.).

196. Congress sometimes enacts highly detailed regulatory provisions into legislation in response to its perception of agency neglect of statutory commands. For example, the 1984 amendments to RCRA contained "hammer" provisions that wholly banned classes of waste from land disposal unless EPA had adopted regulations governing such disposal by a specified date. *See, e.g.*, 42 U.S.C. § 6924(f)(3) (1988).

197. *See, e.g., infra* notes 512-16 and accompanying text (discussing the CAA Amendments of 1990).

198. In contrast to many areas of the law, the courts have only rarely been the primary decisionmaker on the control of toxic substances. Of course, the courts play a vital role in the indirect regulation of toxic substances through toxic torts litigation. They also significantly condition agency regulatory behavior because agencies seek to avoid having provisions overturned on judicial review. When a regulation comes before a court, it is highly unusual for a court to address the merits of a toxics regulation. *Cf.* E. Donald Elliott, *The Future of Toxic Torts: Of Chemophobia, Risk as a Compensable Injury and Hybrid Compensation Systems*, 25 HOUSTON L. REV. 781, 792 n.40 (1988) ("Most of us who teach environmental law sense that judicial review of the technical facts underlying administrative decisions has become a joke."). Perhaps the most prominent example of a court changing toxic substance regulation is the Flannery consent decree, NRDC v. Train, 8 Env't Rep. Cas. (BNA) 2120 (D.D.C. 1976), where the court carved out of whole cloth a new doctrine that under the CWA, the discharge of toxic substances should be controlled by industry-specific technology-based limitations. The court's approach was subsequently adopted by Congress. *See infra* notes 255-63 and accompanying text for a discussion of these effluent limitations guidelines.

199. The Supreme Court has recognized that an agency's scientific determinations are

pretation.[200] Certainly both industry and public interest organizations have been willing to sue when they object to a regulation's provisions. The agencies, however, have generally prevailed in court.[201]

In the unusual cases where Presidents have attempted to exert direct control over toxics regulation, they sometimes have been frustrated by differing statutory standards and bureaucratic realities.[202] The states are generally allowed to adopt laws that authorize their agencies to control toxic substances more stringently than do the federal laws and regulations, but not less stringently.[203] For the most part, the states have not been a major influence on the regulation of toxic substances,[204] except

among those within the agency's expertise and most entitled to deference. *E.g.*, Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983); *see also* NRDC v. EPA, 863 F.2d 1420, 1430 (9th Cir. 1988) ("In assessing difficult issues of scientific method and laboratory procedure, we must defer to a great extent to the expertise of the EPA.").

200. In Chevron U.S.A. v. NRDC, 467 U.S. 837 (1984), the Supreme Court articulated a two-step test for assessing an agency's interpretation of a term in a statute it administers. If Congress has directly spoken to the precise question at issue, the courts "must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. If Congress has not directly spoken to the precise issue, the courts must defer to the agency's reading of the statute as long as it is "permissible." *Id.* at 843. Courts have considered an agency's interpretation of a statute to be permissible "so long as it is reasonable and consistent with the statutory purpose." Ohio v. Dept. of the Interior, 880 F.2d 432, 441 (D.C. Cir. 1989). *Chevron* has spawned a vast literature. *See, e.g.*, Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L.R. 2071 (1990).

201. A study for the Administrative Conference of the United States found that agencies were wholly affirmed by the courts 76.6% of the time during 1984-85. Many of the remaining cases were remanded, and following remand no change favorable to the petitioners was made in the majority of cases (though in 40% of the amended cases there were "major changes"). "This means that petitioners succeeded in obtaining a major change in an agency's position in only 12% of the cases. . . ." Peter H. Schuck and E. Donald Elliott, *To the* Chevron *Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 985, 1060. The situation with respect to toxic substances may be even more favorable to the agencies than suggested by the statistics, as cases overturned or remanded often involved procedural defects or a disputed statutory interpretation, rather than a defect on the merits.

202. President Reagan required all agencies to assure that the benefits of proposed regulations exceeded the costs, to the extent that was allowed by law. Exec. Order No. 12,291, 3 C.F.R. 127, 128 (1982), *reprinted in* 5 U.S.C. § 601 (1988) Major regulations (those with an impact of greater than $100,000,000 on the economy) required preparation of a formal Regulatory Impact Analysis (RIA). *Id.* Most environmental and public health statutes do not provide for cost-benefit analysis. The agencies took the position that they were obliged to follow the standards in the statutes they administered, not those the President would have preferred. For example, in its 1983 proposal to strengthen the standards for ethylene dibromide in the workplace, OSHA made no attempt to weigh costs and benefits, though it discussed each, and only mentioned Executive Order 12291 to state that an RIA was not required. However, OSHA prominently mentioned that the Supreme Court in the *Cotton Dust* case, Industrial Union Dep't. v. American Petroleum Inst., 448 U.S. 607 (1981), had ruled that cost-benefit balancing was not required under the OSH Act. 48 Fed. Reg. 45,956 (1983).

203. *See, e.g.*, 33 U.S.C. § 1370 (1988) (the "savings clause" provision of the CWA). In other cases, contrary state rules are preempted. *See, e.g.*, 7 U.S.C. § 136v(b) (1988) (states may not impose different pesticide labels).

204. There are occasional exceptions, such as New Jersey's discharge to ground water requirements. N.J. ADMIN. CODE tit.7, §§ 7:14A-6.1 to 6.16 (1993). Generally, however, the states have a significant role in toxic control only to the extent they are carrying out federal

where they have been delegated standard-setting, permit issuance, or enforcement authority by the federal government under statutes such as the CWA and RCRA.[205]

3. *Regulation Is Almost Exclusively Command and Control*

To date government has almost exclusively relied on the command-and-control approach to regulate the release of toxic substances.[206] In our view, alternative market-based approaches could be useful in some cases involving individual high log P substances, where the substance can be identified and its toxicity is known.[207] However, we believe market approaches are impractical for the greater problems of unidentified high log P substances, identified substances whose toxicity is unknown, or regulation of groups of substances.[208]

4. *Formal Cost-Benefit Analyses Are Generally Not Required*

Congress has generally declined to require formal cost-benefit analyses as a prerequisite for regulation. TSCA and FIFRA are the two notable exceptions.[209] In place of formal cost-benefit analyses, agencies must consider costs or prepare feasibility standards that take costs into account.[210] As a practical matter, cost-benefit analysis is possible only for

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mandates.

205. CWA, 33 U.S.C. § 1342(b), (c) (1988 & Supp. IV 1992); RCRA, 42 U.S.C. § 6926 (1988).

206. Under the command-and-control approach, Congress and/or a government agency sets mandatory standards for toxic substances in various media, and sometimes specifies the technology to be applied.

207. There are isolated instances where market-based approaches have been successfully used to provide more cost-effective regulation of individual toxic substances. *See, e.g.*, 50 Fed. Reg. 13,116 (1985) (describing the "lead banking" concept) (subsequently codified at 40 C.F.R. § 80.20(e)).

208. Weighing the relative harm of toxic substances and allowing economic tradeoffs between different classes of toxic substances is highly problematic. EPA has proposed such a scheme for trading different toxic substances in the context of the program for early reductions of hazardous air pollutants. In addition to problems with how it selects and weighs different toxic pollutants—especially those belonging to different chemical groups—EPA's proposal makes no allowances for bioaccumulation, persistence, or any other factor affecting the environmental fate of the chemical following release. 56 Fed. Reg. 27,338, 27,353-56 (1991) (to be codified at 40 C.F.R. pt. 63) (proposed June 13, 1991). Given what we know about air transport and subsequent biomagnification, such a scheme seems not only crude, but highly imprudent.

209. TSCA § 6(b) gives EPA the authority to prohibit or limit a toxic substance if it presents "an *unreasonable* risk of injury to health or the environment." 15 U.S.C. § 2605(a) (1988) (emphasis added). Similarly, FIFRA § 3(a), 7 U.S.C. § 136a(a) (1988), requires the registration of a pesticide provided EPA finds its use "will not generally cause *unreasonable* adverse effects on the environment," as that term is defined in FIFRA § 2(bb), 7 U.S.C. § 136(bb) (1988) (emphasis added).

210. For example, when determining "best available technology" for effluent limitations guidelines purposes under the CWA, EPA must "take into account" numerous factors, one of which is "the cost of achieving such effluent reduction." 33 U.S.C. § 1314(b)(2)(B) (1988). For an illuminating analysis of the role of cost in environmental regulation generally, see Wil-

the minority of high log P substances that can be identified and for which adequate toxicity data exist. Furthermore, given the immense data requirements involved, if the burden of performing the analysis is placed on the government, the rulemaking process will slow to a glacial pace and few substances will be regulated. On the other hand, if cost-benefit analysis is required as a precondition for release, industry will be forced to endure a staggering burden of cost and delay, even assuming the releases are ultimately proven cost-effective.[211]

5. *The Chemical-Specific Approach and the Overregulation/Underregulation Pattern*

By far the most common approach to toxics regulation involves identifying individual substances, studying them, and eventually formulating chemical-specific release standards. This approach has been partially responsible for the imposition of highly stringent limitations[212] on a tiny fraction of all chemical substances—usually only those listed in statutes or regulations—leaving all other substances unregulated.[213] Professor Sunstein argues that overregulation of some chemicals actually results in underregulation of many others because agencies are concerned about effects on the economy, while industry is quick to oppose each new regulation because its effects are so draconian.[214]

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liam H. Rodgers, Jr., *Benefits, Costs and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191 (1980).

211. Once the government has made a threshold showing that a substance is toxic, the burden to show cost effectiveness could be placed on either the government or industry. In the toxics context, allocation of that burden will nearly always be outcome-determinative.

212. Where substances are subject to regulatory limits, these limits are sometimes very stringent. For example, under the Delaney Clause of the FFDCA, no amount of a carcinogen may be added to food, even if the risk to the public would be less than one chance in a billion of causing cancer in the most exposed individual. 21 U.S.C. § 348(c) (1988). This absolute prohibition was recently upheld in Les v. Reilly, 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 113 S.Ct. 1361 (1993). Very stringent limits are also possible under the CWA. Of 56 toxic organics controlled at chemical plants that utilize end-of-the-pipe biological treatment, 47 had monthly average limits in the 15-80 ppb range, 30 of which were required to be at or below 25 ppb. 40 C.F.R. §§ 414, 414.91 (1992). This does not mean that all regulated substances are overregulated. Some OSHA regulations reduce the cancer risk only to the one in 500 range. William S. Pease, *The Role of Cancer Risk in the Regulation of Industrial Pollution*, 12 RISK ANALYSIS 253, 260 (1992). OSHA personnel told one of the authors that they believe there are many workplaces where currently unregulated chemicals pose lifetime-of-work cancer risks of one in 100 or worse. Interview (by Williamson) with OSHA personnel in Washington, D.C. (June 26, 1990).

213. Of 232 industrial or energy-related substances, chlorination byproducts and/or environmental contaminants identified by the State of California as carcinogens, legally enforceable limits on releases have been imposed for no more than 10% under any major federal statute. Although 60% of them are listed as hazardous substances under CERCLA and 50% as hazardous waste under RCRA, no specific limits are placed on them. Pease, *supra* note 212, at 255. That study, because it deals only with known carcinogens, actually understates the problem of toxics generally.

214. Cass R. Sunstein, *Paradoxes of the Regulatory State*, 57 U. CHI. L. REV. 407, 416 (1990); *see also* JOHN M. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCE REGULATION:

D. *The Advantages of Whole Release Testing Over a Chemical-Specific Approach*

This section compares the chemical-specific approach to two alternatives: regulation of groups of substances, and regulation of the toxic properties of releases as a whole. We believe that whole-effluent testing techniques, such as the log P screening technique, will reduce the overregulation/underregulation pattern by allowing the expeditious regulation of a whole class of substances.

1. Evaluation of the Chemical-Specific Approach

With millions of known chemical substances,[215] and some seventy thousand of these in commercial use in the United States,[216] one might wonder whether regulatory regimes that rely almost exclusively on limited lists are at all prudent. Three principal justifications have been put forward for the use of such short lists. First, we expect that placing separate limits on every substance of potential concern in a discharge would be beyond the administrative capacity of the government, and of industry and municipalities, to comply. Second, many of the chemicals on the lists are high volume substances, while most of the substances which are not on the lists are not used in commerce at all or are low volume substances.[217] Accordingly, merely stating the percent of all substances regulated understates the percent of pounds produced that are subject to controls. Lastly, the number of possible treatment technologies is limited and any treatment technology which works on one substance will work on similar substances, at least to some extent.[218] Thus, regulatory authorities sometimes argue, it is not necessary to regulate every substance contained in a release, provided a permit regulates enough substances

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HOW OVERREGULATION CAUSES UNDERREGULATION AT OSHA (1988). For thoughtful critiques of the Sunstein/Mendeloff thesis, see Sidney A. Shapiro & Thomas O. McGarity, *Not so Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729 (1991); John P. Dwyer, *Overregulation*, 15 ECOLOGY L.Q. 719 (1988) (book review).

215. As of the end of 1991, there were 11,260,213 substances given identifying numbers in the *Chemical Abstract Service Index* published by the American Chemical Society. Telephone Interview (by Ms. Betty Blanco, research assistant to one of the authors) with Glen Davis, American Chemical Society.

216. The Administrator of EPA is required to maintain an inventory of substances in commercial use. 15 U.S.C. § 2607(b) (1988). *See* OFFICE OF TOXIC SUBSTANCES, U.S. ENVTL. PROTECTION AGENCY, EPA/560/7-85-002, TOXIC SUBSTANCES CONTROL ACT (TSCA) CHEMICAL SUBSTANCE INVENTORY, Vols. 1-5, 1985, and supplement (EPA/560/7-90-003, 1990). The 1985 edition and the 1990 Supplement contain 68,000 substances as of February 1, 1990. *Id.*, introductory page. Many more are added to the official inventory each year through the TSCA § 5 process. *See infra* part V.I.

217. *See, e.g., supra* note 33 and accompanying text.

218. For example, an air stripper of an appropriate size and design to remove benzene from wastewater could also be expected to remove all substances with higher Henry's Law constants, such as trichloroethylene and vinyl chloride. W. WESLEY ECKENFELDER, JR., INDUSTRIAL WATER POLLUTION CONTROL 136-39 (2d ed. 1989).

whose release level provides a general indicator of the effectiveness of the pollution control equipment.[219]

While these arguments sound plausible, none disproves the need for a separate regulatory effort for high log P substances. First, the impossibility of regulating every chemical to control its toxicity does not mean that the agencies should decline to do more, particularly if they are presented with more efficient approaches, such as our proposed log P screening technique, that allow control of whole classes of substances. Second, there is not a necessary relationship between the amount of substances used and their release, or between release and exposure. In particular, organic substances used in high volume are often valuable; there are strong incentives for industry not to waste them. On the other hand, many of the substances industry wants to dispose of are useless reaction products, which are not in commercial use. Some of them, because of their bioaccumulation potential, have greatly increased toxicity risks. Control of commercial substances will not address this problem. As for the third argument, it is only partially correct. Current treatment technologies do not capture or destroy many high log P substances. These substances are being released to the environment under existing statutory programs.[220]

2. *Regulation of a Group of Substances*

One alternative to chemical-specific regulation is to regulate a family of closely similar substances, rather than place separate limits on each substance in the class. PCB's are the most notable illustration of this approach. Maximum allowable amounts under the regulations implementing several statutes are set for total PCB's, rather than separate limits on each of the 209 PCB congeners.[221] Similarly, the regulations implementing the Safe Drinking Water Act limit the total quantity of trihalomethanes that may be contained in drinking water, not just the most common one, chloroform.[222]

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219. The New Jersey NPDES regulations, after specifying which toxic pollutants in a discharge must be regulated, state that in lieu of separate limits the requirement is met by "[l]imitations on other pollutants which . . . will provide treatment of the pollutants . . . to the levels required. . . ." N.J. ADMIN. CODE tit. 7, § 7:14A-3.13(a)(5)(ii)(2) (1993).

220. *See infra* part V. That current regulations do not prohibit releases from reaching the environment can also be inferred from the fact that high log P substances are ubiquitous; they are found in surface water, ground water, air, soil, sediment, and living organisms, including humans. For a brief description of EPA's National Human Monitoring Program and its National Human Adipose Tissue Survey, see NATIONAL RESEARCH COUNCIL, MONITORING HUMAN TISSUE FOR TOXIC SUBSTANCES 21-26 (1991).

221. For example, effluent standards and prohibitions have been established under the CWA for the class of PCB's taken as a whole. 40 C.F.R. § 129.105 (1992). Similarly, regulations under the SDWA limit the sum of all PCB's to 0.5 ppb. 40 C.F.R. § 141.61 (1992); *see also infra* note 540. No regulation under any statute places separate limits on any PCB congeners (the individual chemical substances making up the class of PCB's).

222. 40 C.F.R. § 141.12 (1992). A compilation of regulations where the agencies have

Regulating groups of substances has its problems, however. The wider use of this approach is constrained by the fact that setting limits on a group of substances usually requires a knowledge of how much of each individual substance is contained in a release, as there is often no test for the group as a whole. In addition, because it treats all chemicals in the group as if they had the same toxicity when they often do not, this approach also overregulates some substances while underregulating others. Furthermore, the approach is inappropriate where there is adequate toxicity data on each chemical in the group and ready laboratory methods for identifying and measuring them. Group regulation is most useful for controlling individual substances that lack sufficient toxicity data, provided there is adequate data on the group as a whole.

3. Regulation Based on the Toxic Properties of the Release as a Whole

A second alternative is to test a particular environmental release directly for toxicity.[223] A prototype for this approach involved carrying canaries into coal mines. The canary's death did not tell the workers which of several toxic gases or combinations of them caused the bird's demise, but it did tell them to get out quickly before they suffered the same fate.

The most important regulatory use of this approach for the control of toxic substances is whole-effluent[224] toxicity testing under the CWA.[225] These tests for toxicity of the discharge per se are generally carried out by placing small fish or crustaceans in a range of mixtures of effluent and pure water.[226] Whole-effluent toxicity testing has the goal of assuring

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controlled chemicals other than high log P substances as a group, rather than chemical-by-chemical, is beyond our purposes. It will be addressed in a future article.

223. This approach is far better developed for conventional pollutants than for toxics. For example, under the CWA, it is irrelevant which chemicals cause a discharge to have a particular level of biochemical oxygen demand or total suspended solids. The property itself is tested for, and if excessive, must be reduced to acceptable levels. *See* 40 C.F.R. §§ 400-471 (1992). Similarly, under the CAA, it is not important which chemicals are contained in the particulate matter: too much of any kind or combination could cause a violation of the National Ambient Air Quality Standard for particulates. 40 C.F.R. § 50.6 (1992).

224. Effluent is the term commonly applied to a wastewater outflow. If the water has been treated, it is properly called "treated effluent," but since, under the CWA, no untreated effluents are supposed to reach surface waters, the word "treated" is often assumed.

225. Whole-effluent toxicity is defined in EPA regulations as "the aggregate toxic effect of an effluent measured directly by a toxicity test." 40 C.F.R. § 122.2 (1992). EPA first announced a policy favoring the use of such whole-effluent tests in 1984, and asserted that there was legal authority to do so. *Development of Water Quality-Based Permit Limitations for Toxic Pollutants; National Policy*, 49 Fed. Reg. 9016 (1984). Thereafter, the use of whole-effluent testing has rapidly accelerated. Since 1989, the NPDES regulations, 40 C.F.R. § 122.44(d) (1992), in certain cases require permit limits based on whole-effluent toxicity tests. 54 Fed. Reg. 23,868, 23,875-96 (1989).

226. For an explanation of such aquatic bioassays and their use to measure whole-effluent toxicity, see Richard L. Williamson, Jr., & Dennis T. Burton, *Use of Aquatic Biological Testing under the NPDES Permit System to Reduce Toxic Pollution of the Chesapeake Bay*, *in* CON-

that no substance or combination of substances in a treated effluent will cause toxic effects in the aquatic environment. Our proposal can be thought of as whole-effluent bioaccumulation testing.

Whole-effluent toxicity testing has a number of important advantages. By testing the entire effluent directly on test organisms, the toxicity of the effluent taken as a whole can be measured. Furthermore, whole-effluent toxicity testing automatically takes into account the fact that the toxic effects of combinations of chemicals may be less than, greater than, or equal to the sum of their individual toxicities. In contrast, comprehensive regulation through chemical-specific controls would require identification of each substance—which is often impossible[227]—and its toxicity, as well as an understanding of each of the substances' toxicological interactions. Each of these steps would be extremely difficult for the hundreds of individual toxicants found in post-treatment discharges from organic chemical manufacturing plants, paper mills, and municipal sewage treatment facilities with high industrial waste inputs.

One weakness of whole-effluent toxicity is that there is no comparable whole-effluent test for toxic effects on human health.[228] Moreover, modest quantities of very high log P substances might not cause enough toxicity to be detected by current whole-effluent toxicity testing methods.[229] Yet subsequent bioaccumulation and biomagnification of the same substances could prove harmful to both humans and the environment. The whole-effluent bioaccumulation method that we advocate below would resolve those problems.

While, in our opinion, some aspects of the whole-effluent approach have been poorly designed and implemented by EPA and the states, it is

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TAMINANT PROBLEMS AND MANAGEMENT OF LIVING CHESAPEAKE BAY RESOURCES 518, 523-24 (Shyamal K. Majumdar et al. eds., 1987).

227. *See also infra* note 291.

228. The correlation between substances that are toxic to aquatic organisms and substances considered toxic to human health is positive but weak. This is not surprising since the modes of action for toxicants may be quite different for aquatic organisms and humans. For example, in low concentrations, chlorine in solution can be consumed by mammals with little consequence. Chlorine is highly toxic to aquatic organisms, however, because it causes the epithelium on the gills to separate from the secondary lamellae. This can be fatal to aquatic organisms since they can no longer exchange oxygen and carbon dioxide. In contrast, some substances believed by EPA to present serious cancer hazards to humans, such as trichloroethylene, are not particularly toxic to aquatic organisms.

229. An example concerning human health is TCDD, currently thought by both EPA and FDA to be carcinogenic. EPA considers an acceptable concentration in surface waters to be 0.013 parts per quadrillion (ppq), based on its extrapolation of human cancer risks from high exposure data on laboratory animals. *EPA Position on Toxicity [of Dioxin] to be Reassessed, Reilly Says*, 15 Chem. Reg. Rep. (BNA) 32 (Apr. 12, 1991). The substance is also acutely toxic to aquatic organisms, but short-term exposures would not present problems to aquatic organisms and thus not cause a discharge to fail a whole-effluent toxicity test if the concentration is held below about 10 ppq, nearly 1000-fold higher than EPA's figure for human exposure. For a more complete discussion and citations, see *supra* notes 46-49 and accompanying text.

a sensible concept. Considerable strides are being made in effluent quality as a result of its use. Ironically, as chemical-specific approaches to toxicity were becoming a deadend, EPA pressed hard to supplement them with a whole-effluent approach. Yet until very recently, the Agency has ignored the possibility of a whole-effluent approach to bioaccumulation.

V

A PROPOSAL FOR REGULATING HIGH LOG P SUBSTANCES

Given the adverse effects of bioaccumulating substances and their current lack of regulation, the regulatory agencies—and if necessary Congress—need to make changes to take bioaccumulation into account. This part provides a brief overview of how the log P screening technique can provide the basis for more effective regulatory control and examines the legal issues involved in expanding control of high log P substances under existing environmental and public health statutes.

A. Overview of the Proposal

Under existing federal statutes, regulators would use the log P screening technique primarily to assess and reduce the threat of highly bioaccumulating substances in surface and ground water. Regulators would also use variations of the technique to screen air releases, contaminated solids, commercial fish, and potentially exposed workers.[230] Where neither the log P screening technique nor its variants could be used, we propose improving existing chemical-specific regulatory techniques to reduce the threat of bioaccumulation.

Under each applicable statute, the relevant regulatory agency would pursue the following four steps: (1) testing; (2) presumption and rebuttal; (3) remediation; and (4) enforcement.[231]

1. Testing

Those responsible for any environmental release, cleanup of past environmental releases, or the direct exposure of the public by drinking

230. In some cases, using these variations would require additional research. Generally such research would involve establishing correlations of data between existing techniques or making minor improvements in existing equipment.

231. As we explain in the discussion of the various statutes, some variations in these steps will be necessary based on differing statutory requirements. Moreover, what we are proposing in the text will not apply where a substance is identified by our technique and the regulatory agency has adopted a release or exposure standard for that substance. In that case, the existing standard would apply. The steps discussed following "testing" are designed to cover the much larger number of cases where high log P substances are detected by the screening techniques and one of the following holds true: (1) they can be identified and their toxicity is known, but they have no current regulatory standards under the applicable statute; (2) they are identified but their toxicity is unknown; or (3) they cannot be identified.

water or seafood would be required to use the log P screening technique (or a variant) to determine if any high log P substances were present. For each detected substance, the test would also indicate a numerical log P value and, sometimes, identify individual substances and provide an estimated concentration. Testing frequency would vary, depending on the size of the release, the likely presence of highly bioaccumulating substances, and past tests results.

2. *Presumption and Possibility for Rebuttal*

If one or more high log P substances were detected, a presumption would arise that these substances constitute a hazard. The responsible party could accept the presumption and begin remediation or seek to rebut it. Rebuttal would involve proving one or more of the following: the test was in error; the substances found did not have as high a log P as the screening technique measured; the substances' BCF values were less than log P indicated; no humans or vulnerable species would be exposed; or the substances were not harmful. This presumption would shift the burden of persuasion from the government to the responsible party once the log P screening technique determines the presence of high log P substances.[232] In most cases, if a party successfully rebutted the presumption, no more action would be required.[233]

3. *Remediation*

Absent a successful rebuttal, the regulations would require the responsible parties to avoid releasing high log P substances or, in the case of past releases, to reduce the risk.[234] Although the applicable standards are statute-specific, remediation to prevent or minimize releases would fall under two broad headings: (1) pollution avoidance, and (2) treatment. Pollution avoidance may include changing raw materials, production processes, or the product itself, as well as recycling wastes back into

232. The law commonly uses such burden-shifting devices. Here, the shift in burden effectively determines who may need to do exposure, environmental fate, and/or toxicity testing if the necessary information is not available in the scientific literature. For an early discussion of burden-shifting in the environmental context, see Harold Leventhal, *Environmental Decisionmaking and the Role of the Courts,* 122 U. PA. L. REV. 509, 535-36 (1974).

233. In some cases, the log P test would permit detection, identification, and quantification of the substances that were already regulated under the relevant statute. The persons responsible for the release would be obliged in that event to meet whatever standards the statute required. Thus, if the standard for hexachlorobenzene in the air releases from a particular industry under regulations implementing CAA § 112 were four ppb, a release that contained two ppb would not trigger any remedial action, while one containing six ppb would need to come into compliance with the standard or face the possibility of government enforcement action.

234. At former hazardous waste sites, and in some other circumstances, the high log P substances have already been released into the environment. In that event, the challenge is to reduce the risks by cleanup and/or by blocking the exposure pathways.

the production process, to reduce or eliminate the amount of high log P substances used, produced, or created as waste that might be released.[235] Alternatively, or at the same time, several treatment technologies can remove or destroy high log P substances. In most cases these technologies will employ activated carbon, which is highly effective in removing high log P substances. In some cases, however, other treatment technologies, such as biological treatment or incineration, may be preferable.

4. Enforcement

While noncompliance with remediation requirements would warrant agency enforcement, we oppose routine imposition of a log P test result as a permit condition, which could result in civil or criminal penalties.[236] The correlations between HPLC retention times and log P and between high log P substances and risks of adverse human health or environmental damage are strong enough to compel further action to prevent their release, but are not strong enough to impose penalties without causing occasional injustice. Generally, once remediation has been successful, occasional monitoring would suffice to prevent recurring releases.[237]

While the regulatory steps described above would apply generally, the details will vary considerably, depending on the specific problem and statutory requirements. The remainder of this part explores these details. Periodic screening for log P substances testing would be imposed under the NPDES program of the CWA, followed, where necessary, by High Log P Reduction Evaluations or enhanced treatment. Large commercial catches of imported and domestic fish and other seafood would be screened and, where necessary, excluded from commerce under the FFDCA.[238] In cases involving CERCLA[239] cleanups of former hazardous waste disposal sites or corrective action under RCRA,[240] responsible parties would screen the contaminated ground water before cleanup activities—to assess the problem and suggest treatment alternatives—and again after cleanup—to validate the outcome. In addition, RCRA's defi-

235. There is considerable interest in pollution avoidance as an alternative to the treatment of wastes after they are generated. In response to a congressional request, EPA has announced a policy of encouraging pollution avoidance, citing "persistent, mobile and *bioaccumulating* toxics" as a new concern requiring a new response. 56 Fed. Reg. 7849 (1991) (emphasis added). For information on the subject as it relates to hazardous waste, see HAZARDOUS WASTE MINIMIZATION (Harry Freeman ed. 1990); THOMAS E. HIGGINS, HAZARDOUS WASTE MINIMIZATION HANDBOOK (1989).

236. Of course, in appropriate cases, permit requirements and enforcement actions may be necessary, consistent with the statutory standards. In that event, additional testing should be required to eliminate the possibility that the "violation" was a test artifact.

237. *See infra* notes 296-301 and accompanying text.

238. Although there was predecessor legislation from the Progressive Era, the modern FFDCA dates from the New Deal. It is currently codified at 21 U.S.C. §§ 301-695 (1988 & Supp. IV 1992).

239. 42 U.S.C.A. §§ 9601-9675 (West 1983 & Supp. 1993).

240. *See supra* note 169.

nition of the "characteristics of a hazardous waste" would be expanded to include bioaccumulation, and the log P screen would be used to test wastes currently screened for toxicity by the Toxicity Characteristic Leaching Procedure (the TCLP).[241] The SDWA[242] would require occasional screening of drinking water supplies for high log P substances and, where the contamination of the treated drinking water is detected and cannot be halted by ceasing the flow of high log P substances into the water supply, EPA would require treatment. The OSH Act,[243] the CAA,[244] TSCA[245] and FIFRA[246] also permit greater attention to risks posed by high log P substances, primarily through improved use of chemical-specific techniques. Finally, if testing and verification of suitable extractants provide representative results, a variant of the log P screening technique may also be useful in screening potentially contaminated soils, sludges, and sediments under several statutes. These statutes are discussed in detail below, in the decreasing order of their importance.

B. Discharges to Surface Waters Under the CWA

1. Current Regulation

The CWA[247] is the single most important statute for the control of high log P substances. The mode of exposure most likely to lead to damage of the natural environment from highly bioaccumulating substances is by release of those substances to surface water. Moreover, public concern over the risk to human health from high log P substances has largely focused on the possibility that persons would eat fish or shellfish that had highly bioaccumulated harmful substances from discharges to surface waters.[248] Accordingly, although adequate control of high log P substances requires changes to a number of other statutes,[249] this article puts the greatest emphasis on the CWA. Many of the same issues will be

241. For additional information on the TCLP, *see infra* notes 420-21 and accompanying text.

242. 42 U.S.C. §§ 300f-300j-26 (1988).

243. 29 U.S.C. §§ 651-678 (1988 & Supp. IV 1992); *see supra* note 191.

244. The modern CAA dates to 1977, Pub. L. No. 95-95, 91 Stat. 385, though its title and antecedents go back to 1955. The Act is codified as amended at 42 U.S.C. §§ 7401-7671q (1988 & Supp. III 1991).

245. 15 U.S.C. §§ 2601-2671 (1988 & Supp. IV 1992).

246. 7 U.S.C. §§ 136-136y (1988 & Supp. IV 1992); *see supra* note 175.

247. 33 U.S.C. §§ 1251-1387 (1988 & Supp. IV 1992).

248. *See, e.g.*, NATIONAL WILDLIFE FED. & CANADIAN INST. OF ENVTL. LAW & POLICY, A PRESCRIPTION FOR HEALTHY GREAT LAKES 37-41 (1991).

249. For example, we anticipate that the largest single risk to human health nationwide comes from dietary exposure, especially to fish and shellfish. But the CWA regulates neither the commercial distribution of fish, nor many of the waters, including foreign waters, from which seafood products reach American consumers. That regulation can only be done under the FFDCA. Similarly, hazardous wastes reaching surface waters from former waste disposal sites are regulated only under CERCLA and RCRA. Pollutants reaching surface waters by air transport of atmospheric pollutants are regulated through the CAA.

seen under other statutes, but are particularly well illustrated by the CWA.

The CWA sets the unachievable ultimate goal of halting the discharge of all pollutants into navigable water. The Act's more sensible intermediate objective is to make all waters of the United States fishable and swimmable.[250] It requires all "point sources"[251] to obtain an NPDES permit[252] prior to discharging any pollutant.[253] The Act subjects dischargers to the triple hurdle of technology-based limits, state water quality standards, and effluent standards and prohibitions.[254]

A discharger must comply with the Act's federally established technology-based limits. In most cases, these limits are found in "effluent limitations guidelines" promulgated by EPA for various industries.[255] In addition to other categories of pollutants,[256] these guidelines sometimes

250. 33 U.S.C. § 1251(a).

251. *Id.* §§ 1311(a), 1342(a), 1342(f). Point sources, such as industrial wastewater treatment plants and municipal sewage treatment plants, release pollutants to surface waters through a pipe or other discrete conveyance.

252. The ironically named National Pollutant Discharge Elimination System (NPDES) is an integral part of the CWA and its regulations. NPDES permits are the primary method by which the statute is implemented for point sources. *Id.* § 1342; 40 C.F.R. §§ 125.1-125.124 (1992).

253. The CWA and its implementing regulations also deal with spills from vessels. These regulations may reduce some bioaccumulation risks indirectly by specifying a long list of substances whose spill must be reported to the National Response Center. 33 U.S.C. § 1321(b); 40 C.F.R. § 116.4 (1992). The Hazardous Materials Transportation Act (HMTA), 49 U.S.C. § 1802-07 (1988 & Supp. III 1991), also indirectly deals with spills. Under that statute, the Department of Transportation's Research and Special Projects Administration (RSPA) sets standards for the safe carriage of several hundred substances considered hazardous by virtue of toxicity, including those on the CWA list. 49 C.F.R. §§ 171-180 (1992). The RSPA's regulations under the HMTA are not limited to risks of contamination of surface water, though that is likely to be one of their major practical impacts. The relevant lists contain several hundred toxic substances, including many of the highly bioaccumulating substances entering the stream of commerce. However, the HMTA list only covers substances in *commercial* use. Some of the substances of greatest concern are waste products and do not fall within the scope of the HMTA.

254. A discharger must meet the more stringent of these requirements.

255. 33 U.S.C. §§ 1311, 1314(b). Effluent limitations guidelines are not guidance documents but rather are binding regulations promulgated by EPA to implement the various technology-based standards contained in the CWA. I.E. du Pont de Nemours & Co. v. Train, 430 U.S. 112, 120 (1977) (rejecting industry claim that effluent limitations guidelines were for the assistance of permitwriters, but were not binding on them). To establish guidelines for an industry, EPA surveys well-run wastewater treatment facilities that it considers to have the requisite level of technology. It then uses statistical techniques to calculate discharge limits that those facilities have demonstrated to be technically and economically achievable within that industry. Where no effluent limitation has been promulgated, the permitwriter is expected to use "best professional judgment," 40 C.F.R. § 125.3 (a)(2) (1992), drawing on the case-by-case authority of CWA § 402(a)(1)(B). For an example, see 57 Fed. Reg. 32,475 (1992).

256. The guidelines often regulate "conventional pollutants" (e.g., biological oxygen demand, total suspended solids or pH) as defined in 33 U.S.C. § 1314(a)(4). "Non-conventional pollutants" (anything that is neither a toxic pollutant nor a conventional one) such as iron or ammonia are also sometimes regulated.

regulate "toxic" pollutants,[257] limited in practice to the 126 "priority pollutants."[258] Numerous industrial facilities discharge priority pollutants directly into surface waters. EPA, however, has only imposed stringent effluent limitations guidelines on the discharge of toxic organics by what it calls the "organic chemicals, plastics, and synthetic fibers" (OCPSF) industry.[259] The vast majority of industries have no controls on any organic chemicals, while most of the remaining industries must meet standards for four or fewer toxic organics;[260] these almost never include highly bioaccumulating substances.[261] Moreover, nothing in this

257. A concise explanation of the process EPA uses to generate technology-based limits can be found in American Meat Institute v. EPA, 526 F.2d 442 (7th Cir. 1975).

258. No organic chemicals are listed for control under any effluent limitations guideline except for those on the "priority pollutant" list. There is a good historical reason for this fact. In 1976, the U.S. District Court for the District of Columbia entered a consent decree (commonly called the Flannery Decree) requiring the EPA to measure and limit 65 compounds and classes of compounds in effluents discharged to receiving waters in the United States. NRDC v. Train, 8 Env't Rep. Cas. (BNA) 2120 (D.D.C. 1976). These classes of pollutants are listed at 40 C.F.R. § 401.15 (1992). The list of 65 was subsequently refined by EPA to a list of 129 specific analytes termed "priority pollutants" and codified as the § 307(a)(1) list of "toxic pollutants" in the 1977 CWA Amendments. It is only these toxic pollutants and those discussed under "standards and prohibitions" for which EPA must promulgate effluent limitations. 33 U.S.C. § 1311(b)(2)(C) & (D). EPA has authority to add or remove toxic pollutants from that list, 33 U.S.C. § 1311(g)(4) & (5), but has thus far only removed three chlorofluorocarbons. A list of the 126 priority pollutants may be found at 40 C.F.R. §§ 125, 423 (1992).

259. EPA's strong controls on the OCPSF industry make sense because it is one of the industries releasing large amounts of toxic organics, including high log P substances. It is hardly the only industry to do so, however. For example, EPA considers pharmaceutical production, although it involves the synthesis of organic chemicals, to be a separate industrial category for CWA purposes. Yet the effluent limitations guidelines for the pharmaceutical industry limit no toxic organics. 40 C.F.R. § 439 (1992). The situation was similar for pesticides until recently. *See infra* note 260.

260. One of the authors studied all of the effluent limitations guidelines contained in 40 C.F.R. §§ 405-471 (1990). R.L. Williamson, Jr., *U.S. Regulatory Approaches: A Critical Appraisal*, 25 WATER SCI. TECH. 13, 16-17 (1992). These spanned 1379 pages of fine print in the C.F.R. According to his tally, there were 923 different technology-based requirements in the regulations for new sources (which have the most stringent requirements) and existing sources. Each of these limits one to several dozen discharge parameters: direct discharges were prohibited in 123 cases (though there is no such limit for indirect discharge through a sewage treatment plant); 160 regulated only conventional pollutants; 560 regulated conventional pollutants and up to 10 inorganic substances (i.e., ammonia, cyanide, or toxic metals, but no toxic organics). Only 64, or 7%, regulated any toxic organics, and only 12, or 1.3%, regulated more than four of them. Because these categorizations unavoidably involved some subjectivity, the exact results would not be duplicated by another researcher. It is unlikely, however, that another researcher would see a significantly different pattern. In short, except for what EPA calls the OCPSF industry, toxic organics are virtually unregulated under the effluent limitations guidelines. Since that study, EPA has promulgated new effluent limitations guidelines for the pesticide manufacturing category. These regulate 260 pesticide active ingredient substances and categories, most of them toxic organics, as well as 23 of the priority pollutants regulated for the OCPSF category. 58 Fed. Reg. 50,638 (1993) (to be codified at 40 C.F.R. pt. 455). EPA is highly unlikely to promulgate any effluent limitations guidelines that would significantly increase the regulation of toxic organics in the near future. *See* EPA Semi-annual Regulatory Agenda, 58 Fed. Reg. 56,988, 57,027-33 (1993).

261. According to a 1993 LEXIS search, aside from the OCPSF industry, the only indus-

set of regulations requires dischargers to test for bioaccumulation.[262] The regulation of bioaccumulative substances is only slightly better for indirect dischargers who send their wastes to publicly owned treatment works (POTW's).[263]

The second hurdle requires that the discharge must not cause a violation of state water quality standards.[264] The 1987 amendments to the CWA require the states to adopt water quality standards for each of the 126 priority pollutants and to identify toxic hot spots.[265] In 1992, EPA promulgated federal standards to cover fourteen states that had still not complied.[266] In setting water quality standards, states must consider, but need not follow, the recommendations contained in EPA's water quality criteria documents.[267] Some of these criteria documents take bioaccumu-

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try groups for which EPA has regulated the direct discharge of high log P substances under effluent limitations guidelines are the coke-making subcategory of the iron- and steel-making category, 40 C.F.R. § 420.14 (1992), and the primary aluminum-smelting category, 40 C.F.R. § 421.24 (1992), both of which set limits for benzo(a)pyrene, a PAH, for some of their respective production processes. EPA has also regulated such discharges under the Pulp, Paper and Paperboard category, 40 C.F.R. § 430 (1992), and the Builders, Paper and Board Mill category, 40 C.F.R. § 431 (1992), several subcategories of which place limits on pentachlorophenol.

262. The essence of these "best technology" regulations is feasibility of control, not whether control of the substance at that level will do any good, or whether that concentration will be sufficient to protect the public. The resulting overregulation of some substances and underregulation of others has been criticized as inefficient. "On balance, the effect of the technology-based controls on point sources [under the CWA] is to require a significant level of expenditures with no beneficial environmental effect." William F. Pederson, Jr., *Turning the Tide on Water Quality*, 15 ECOLOGY L.Q. 69, 88 (1988). *See generally* Christopher H. Schroeder, *In the Regulation of Manmade Carcinogens, if Feasibility Analysis is the Answer, What is the Question?*, 88 MICH. L. REV. 1483 (1990). For a defense of technology-based restrictions, see Shapiro & McGarity, *supra* note 214.

263. For six industrial categories (all but one in the metal-working industries), EPA has established limits for "total toxic organics" (TTO) for those facilities that discharge indirectly. *See, e.g.*, 40 C.F.R. § 433 (1992) (limits for the metal-finishing category). While the substances making up the TTO list for each subcategory vary, often one or more PAH's and occasionally PCB's and/or chlorinated hydrocarbons are included. *Id.* With those exceptions, the situation for indirect dischargers is essentially the same as that noted for direct dischargers; only discharges from the OCPSF and pesticide manufacturing categories involve a substantial regulation of toxic organic chemicals. Final pretreatment standards for OCPSF indirect dischargers were recently promulgated. 58 Fed. Reg. 36,872 (1993) (to be codified at 40 C.F.R. pt. 414).

264. Responsibility for establishing water quality standards under the CWA rests in the first instance with the states. 33 U.S.C. § 1313(c)(1). Water quality standards consist of two parts: designated uses and water quality criteria. The states must also identify all water segments where the best practicable treatment cannot ensure compliance with water quality standards. *Id.* § 1313(d)(1)(A). For these segments, the states must establish maximum loads to implement the applicable water quality standards. *Id.* § 1313(d)(1)(C). The states must submit their proposed water quality standards and maximum loads to EPA. *Id.* § 1313(c)-(d). EPA can veto a state water quality standard, and where it deems necessary, can promulgate a federal standard for the state if the state fails to act.

265. *Id.* § 1313(c)(2)(B), (d).

266. 57 Fed. Reg. 60,848 (1992).

267. EPA's Ambient Water Quality Criteria documents contain the following statement:

lation considerations into account in establishing levels of substances that are presumptively safe.[268] Though these documents are not legally binding, many states rely on them when establishing state water quality standards, and EPA uses them when promulgating a federal standard for a state that fails to act.[269] Use of these criteria to set regulatory standards provides a modicum of control over the release of some high log P substances.[270] Until recently, however, state water quality standards were often only "narrative"; they set no numerical limits. Indeed, virtually none of the early state water quality standards had any explicit provision dealing with bioconcentration, bioaccumulation, or log P.[271] The situation had improved somewhat by 1988.[272] Just over half the jurisdictions

"Under the Act a criterion is a scientific entity, based solely on data and scientific judgment. It does not reflect considerations of economic or technological feasibility nor is it a water quality standard and in itself has no regulatory effect." U.S. ENVTL. PROTECTION AGENCY, EPA/440/5-80-040, AMBIENT WATER QUALITY CRITERIA FOR DICHLOROBENZIDINE, at i (1980).

268. *See, e.g.*, the criteria for dichlorobenzidine (DCB), *id.*, a high log P substance and animal carcinogen. Approximately half of the risk EPA calculated of DCB in water was from eating exposed aquatic organisms. *Id.* at vi.

269. 40 C.F.R. § 131 (1992). EPA also extensively used its water quality criteria in its proposed water quality guidance for the Great Lakes. 58 Fed. Reg. 20,802 (1993) (to be codified at 40 C.F.R. pts. 122, 123, 131, 132) (proposed Apr. 16, 1993).

270. Under water quality standards, controls of high log P substances are imposed on a discharger only if *all* of the following happen: (1) the high log P substance is listed as a priority pollutant; (2) EPA has promulgated for the substance a water quality criteria document that takes bioaccumulation into account (EPA has prepared criteria for over half the priority pollutants, and about two-thirds of these appear to have given some weight to bioaccumulation); (3) the state follows the EPA recommendation in its regulations or EPA imposes a federal standard; and (4) the state or the EPA (whichever conducts the permit-issuing process) actually imposes its water quality criterion in issuing its permits. In that long chain of requirements, a great deal of opportunity remains for substances not to be controlled. Only EPA would be able to survey all EPA and state-issued NPDES permits to see how many of them actually control any high log P substances. Doing so would be a substantial undertaking. Three of the authors have had substantial experience with NPDES permit issues, and we believe discharge permits that directly regulate high log P substances or otherwise deal with bioaccumulation in any way are rare. A few states do some screening.

271. For example, Maryland's standard required that the waters of the state shall at all times be free from: "D. High temperature, toxic, corrosive or other deleterious substances attributable to sewage, industrial waste or other waste in concentrations or combinations which interfere directly or indirectly with water uses, or which are harmful to human, animal, plant, or aquatic life." Maryland Regulation 08.05.04.02, effective date May 1, 1973, *reprinted in* U.S. ENVTL. PROTECTION AGENCY, A COMPILATION OF STATES WATER QUALITY STANDARDS FOR MARINE WATERS III-18 to III-19 (1978). Even states such as Mississippi, which had detailed provisions for the protection of shellfish beds (where bioaccumulation would be especially worrisome), did not mention the problem directly or indirectly. *Id.* at IV-89.

272. The lack of any mention of bioaccumulation or related concepts in early water quality standards did not necessarily mean the states were without legal authority to regulate high bioaccumulation substances in the unlikely event a problem were to be discovered. Nearly all substances with known high BCF's could have been considered "toxic" within the definitions then given to that term in many state water quality standards. By 1978, most state regulations gave the state the authority to deal with substances found in the waters of the state in concentrations toxic to aquatic organisms or to human health. Early Federal and State NPDES permits did not control substances, with the notable exception of a few pesticides such as

had adopted provisions establishing at least some explicit authority to deal with bioaccumulation.[273]

Third, a discharger must comply with any effluent standard or prohibition established by EPA.[274] The program to set such standards and prohibitions—the original toxicity control approach under the CWA—proved to be difficult to administer; standards or prohibitions have been established only for DDT and its metabolites DDD and DDE, aldrin/dieldrin, endrin, toxaphene, benzidine, and PCB's.[275] All but one of these substances have moderate to very high log P values.[276] No substances have had standards or prohibitions promulgated under this authority since 1977.

Although some individual bioaccumulative substances are regulated under one or more of the three programs discussed above, no federal regulations have been adopted requiring the screening of effluents for bioaccumulation potential prior to their discharge into surface water.[277] Some EPA officials have asserted privately that this lack of regulation is not a cause for worry because the treatment needed to meet the existing CWA regulatory requirements will automatically take care of high log P substances as well.[278] This assertion, as the following study proves, is sometimes incorrect.[279]

DDT, specifically because of their high bioaccumulation potential. In fairness, the technical basis to impose rigorous controls on high log P substances as a class had not yet been developed. *See supra* note 180.

273. Of the 57 jurisdictions for which standards were available, 30 had explicit references to bioconcentration, bioaccumulation, or words to that effect. In some cases, these references and standards grant the state broad authority to limit pollutants known to bioaccumulate to unacceptable levels. For example, Arizona water quality standards state that "pollutant specific techniques may be used where . . . bioaccumulation is suspected." In other cases, the grant of authority is far more limited (e.g., restricting the use of mixing zones where bioaccumulative substances will be present, but granting no explicit authority to limit the substances). The remaining 27 states and territories had no explicit provisions. This information is based on a 1991 survey by Michelle DeWald, research assistant to one of the authors, who located published water quality standards for 52 of the 58 states and federal territories. Summaries of water quality standards for five of the remaining six were found in U.S. ENVTL. PROTECTION AGENCY, EPA/440/5-88-031, STATE WATER QUALITY STANDARDS SUMMARIES (1988).

274. *See* 33 U.S.C. § 1317(a)(2).

275. 40 C.F.R. § 129.4 (1992).

276. Benzidine is not a high log P substance. Toxaphene is actually a blend of chlorinated camphenes for which the average log P is just below the 3.5 cutoff, but the log P of individual chemical substances in the mixture can be higher. All the remainder are high or very high log P substances.

277. At the federal level, the only arguable exception is the regulation implementing the CWA's Ocean Discharge Criteria, 33 U.S.C. § 1343, which requires consideration of the potential for bioaccumulation of a pollutant discharged by those few dischargers subject to the regulation. 40 C.F.R. § 125.120-.124 (1992). No testing for bioaccumulation potential is mandated.

278. Interview (by Williamson) with EPA program and legal staff, in Washington, D.C. (summer 1989).

279. The efforts of other EPA personnel to develop two substantial guidance documents

In a 1982 study of nineteen assorted industrial facilities and nine waste treatment plants,[280] researchers tested the treated effluents for conventional parameters, priority pollutants, and whole-effluent toxicity. The researchers also ran HPLC tests.

While neither HPLC testing nor the threat of bioaccumulation were the focus of the study, the data are illuminating. *Every* plant had at least two peaks indicating the presence of high log P substances (stated by the authors to be in measurable quantities) in their treated wastewater.[281] Thirteen of the nineteen industrial facilities had at least one high log P substance stated to be above ten ppb, as did six of the POTW's. Of even greater concern, three of the industrial facilities and four of the POTW's had at least one substance in their treated wastewater with both a very high log P and a concentration stated to be above 100 ppb. A few of these levels were quite severe (e.g., a log P of 6.81 and a reported concentration of greater than 360 ppb).[282] Most of the industrial facilities had otherwise well-run industrial wastewater treatment plants; their treated effluent contained low conventional parameters, low levels of priority pollutants, and low to moderate whole-effluent toxicity. Even the best performing facilities had anywhere from one to over a dozen peaks corre-

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focusing specifically on bioaccumulation also undermine this assertion. This disparity is not to suggest that EPA officials with whom we spoke were being disingenuous. EPA sometimes suffers from a lack of coordination and limited cross-fertilization among its offices. Thus, it is possible that EPA legal and program office personnel with whom we spoke in 1990 were unaware that EPA research personnel were already investigating the technical issues involved in establishing a regulatory regime for bioaccumulation under the CWA, an effort which subsequently led to the drafting of guidance documents.

280. Final Report: Toxic Point Source Assessment of Industrial Discharges to the Chesapeake Bay Basin (with accompanying individual reports), EPA Contract 68-02-3161 (Aug. 1982) (unpublished study available through FOIA). While this study is nearly ten years old, its data continue to be useful. In the time period since the report, large scale improvements in the efficacy of existing wastewater treatment works have taken place primarily in the chemical industry, which was lightly represented in the study, suggesting that the problems identified may still remain in many other industries. Moreover, any technical improvements in log P detection that may have occurred in the last decade would be expected to *increase* the number of log P substances that would be detected if the study were repeated using more modern equipment and detectors.

281. The report lists concentrations of these substances as varying from the low ppb range to levels *above* what the report declared quantifiable by its techniques (roughly 360 ppb). It is unclear how the concentrations were quantified; we assume GC/MS was used.

282. Consider a hypothetical discharge with an immediate dilution of 100:1. (Dilutions in small streams in low flow conditions can be 10:1 or less, while discharges to large rivers in high flow can be well over 1000:1.) A fish or clam continuously exposed to a discharge containing a substance with a log P of 6.81 at 360 ppb or greater would be expected to have the substance build up to over 440 ppm. (This figure is based on applying the equation discussed *supra* text accompanying note 128 to a log P of 6.81 and a concentration of 360 ppb, and dividing by 100 for dilution in the receiving water.) Worse yet, at least in theory, biomagnification through several trophic levels (i.e., a further concentration through several levels of the food chain) could increase the amount of the substance another 100-fold to as much as four percent of body weight. EPA believes a further biomagnification of up to 100-fold is possible where, as here, the log P is greater than 6.5. TECHNICAL SUPPORT DOCUMENT, *supra* note 41, at 38.

lating to a log P of 3.5 or above. The data display a similar pattern at the POTW's.

It is uncertain whether the plants in this study are representative of industrial facilities and POTW's nationwide.[283] Apparently no similar studies have been performed.[284] In any event, the results of this study negate the claim that otherwise adequate treatment of industrial wastewater will consistently prevent the release of high log P substances.[285]

2. *EPA's Proposal*

Recently, EPA has begun to show greater interest in bioaccumulation matters under the CWA. The Agency is in the process of completing a guidance document on bioaccumulation that urges EPA and state permitwriters to impose limited controls on bioaccumulation in NPDES permits.[286] While a significant improvement, EPA's proposed regulatory approach is nonetheless severely flawed. Using the log P screening technique would allow for better regulation at a lower cost.

EPA's proposed approach would require selected dischargers to conduct HPLC tests to determine if the treated effluent contains any high log P substances, followed by gas chromatography and mass spectrometry. If these tests identified a substance on a priority list of harmful substances,[287] the next renewal of the facility's NPDES permit would include numerical limits on that substance. For these purposes, a substance would be considered harmful based entirely on whether it posed a risk of human exposure to high concentrations of high BCF substances through fish or shellfish consumption. Discharges of that substance in

283. Without asserting that the study's results are representative, we note that the study did cover a range of wastewater treatment plants in a variety of industries—which are also found throughout the rest of the country—as well as several municipal sewage treatment plants.

284. Following the discovery of this study, one of the authors filed a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552 (1988), for all information and studies in EPA's possession dealing with bioaccumulation under the CWA. Little was obtained from the request apart from draft guidance documents elsewhere cited in this article, and a few preliminary investigations of bioaccumulating substances in sludges and sediments. No studies similar to the Chesapeake study were provided or indicated as being in EPA's possession.

285. High log P substances' tendency to sorb to suspended solids in the wastewater or to sludges formed in the wastewater treatment process did not prevent their presence in the treated effluents from these plants. Moreover, even if, following discharge, these substances were to sorb to sediment in the receiving waters, a portion of them may still be bioavailable. *See supra* notes 112-14 and accompanying text for a discussion of bioavailability as it relates to contaminants in sediment.

286. *See* BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126, at xvii.

287. EPA's list of 33 "Chemicals of Highest Concern" is contained in BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126, at II-9. This list has curious gaps. For example, no dioxins or dibenzofurans other than TCDD are listed, even though most are considered by EPA to be toxic and some, such as octachloro-dibenzo-p-dioxin, have much higher BCF's. If the substance can be identified, but the BCF of the substance is unknown, the permittee could be required to test it to determine its BCF value. *Id.* at II-5.

excess of the permit limit could then result in enforcement actions.[288] EPA does not intend to adopt this approach as a regulation, which would subject it to the notice and comment provisions of the Administrative Procedure Act (the APA), including the possibility for judicial review.[289] Rather, the Agency intends to press the states to adopt the plan under their water quality criteria.

EPA's proposed approach rests on a solid technical basis, but it is seriously deficient with respect to each of its essential regulatory features.[290] First, *nothing* happens unless a high log P substance is identified. It is not always possible to identify all the substances in a discharge. However, unidentified substances can still cause harm, and it is safe to assume that unidentified high log P substances—in high concentrations—will do so. Second, the EPA approach can be inefficient. Not only is identifying each substance expensive, but identification is not necessarily a prerequisite to removal from the discharge.[291] Third, the entire approach depends on the regulators knowing the toxic effects of the iden-

288. EPA's draft guidance document also suggests a second approach in which tissue samples would be taken from fish in a particular water body, and then, if high log P substances were detected, identified, and found to be persistent and toxic, steps would be taken to reduce the sources of the substance, whether from discharge points, farm run-off, etc. BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126, at I-1 to I-3, III-1 to III-10. We have no technical objection to this approach where needed for a specific body of water, though market-based approaches are more efficient. However, if our alternative were put into widespread use, this second "tissue" approach would be needed far less often than with EPA's "effluent" approach described in the text.

289. Proceeding by regulation would provide all interested parties, including public interest organizations and the regulated community, with notice and an opportunity to comment on them, and in a proper case, to challenge them. *See* 5 U.S.C. § 553 (1988) (outlining the notice and comment requirements of the APA).

290. For CWA purposes, our log P screening technique is preferable on technical grounds to the technique in EPA's guidance document, primarily in terms of cost and likelihood of human error. Nevertheless, we have no major objections to EPA's approach on technical grounds. In contrast, our difficulties with the regulatory uses EPA proposes for its screening technique are fundamental.

291. The following anecdotal evidence illustrates the economic waste that can result from attempting to identify all chemicals in a discharge prior to their removal. State regulators, under pressure from EPA, pressed a discharger to undertake a toxicity reduction evaluation (TRE). For a more detailed explanation of TRE's, see *infra* notes 309-12 and accompanying text. The initial investigation, which cost $15,000, revealed a number of unidentifiable substances which were apparently causing the toxicity observed in the effluent. The discharger and its consultants proposed to the state that they begin using activated carbon to remove the substances, as a pilot study revealed that doing so would be highly successful in their removal. The state declined, insisting that the discharger discover what the substances were. After spending another $225,000 on testing and analyses, the discharger identified some of the substances, but not others. At that point, the state decided that several of the substances must be removed from the discharge. The discharger then implemented the plan it had previously proposed. The expenditure of $225,000 was a total loss; it would have been almost enough to pay for the construction of the carbon treatment columns. We learned this story from a well-regarded environmental consultant with whom three of us have worked over a period of several years. The consultant, who does considerable work for EPA and the state regulators involved in this case, wishes to remain anonymous.

tified substances. Yet EPA has only limited knowledge of these effects.[292] Fourth, EPA may require a discharger to establish the BCF if unknown, even though doing so can cost roughly five to fifty times more than a log P screen.[293] Unless the discharger wants to attempt to prove that the log P value does not predict BCF, the money would be better spent on pollution prevention or treatment. Fifth, the EPA approach proceeds on the basis of permit conditions. There are several policy reasons to avoid imposing such permit conditions on a routine basis, however. Finally, and most seriously, the EPA approach directly reduces the risk *only* of adverse human health from eating exposed fish or shellfish that have bioaccumulated the substance. Such substances can also pose serious risks to aquatic species and communities, birds, and marine mammals; they may also pose risks to humans from drinking water. These additional risks, however, are dealt with, if at all, only as an incidental benefit of efforts to control human consumption of fish that have been exposed to one of a few listed chemicals. For these reasons, the EPA approach will do far less than would our proposal to reduce the risks to human health and the environment posed by high log P substances. EPA's approach would also be more expansive than necessary.[294]

3. *Our Proposal*

Under the CWA[295] each point source discharger must obtain an NPDES permit from the permit-issuing authority for that state.[296] These permits must be renewed periodically, usually every five years.[297] At the time of renewal, the discharger must provide the permit-issuing authority

292. EPA does not even have complete toxicity data on the 126 priority pollutants. *See, e.g.*, 58 Fed. Reg. 4133, 4134 (to be codified at 40 C.F.R. pt 372) (proposed Jan. 1, 1993) (no water quality criteria for di-n-octyl phthalate, a priority pollutant and high log P substance).

293. As explained *supra* note 103, a simple 28-day BCF test would cost $20,000, though a few short-term tests cost less. In some cases, a complex BCF analysis could cost over $100,000. In contrast, our log P screen would cost between $1250 and $2500 depending on the detectors.

294. In making this point, we recognize that an analysis of legal and policy alternatives is often bedeviled (and sometimes enriched) by a lack of commonly agreed standards for their evaluation. Such indeterminacy is not a problem here, as our proposal is superior to EPA's when assessed by the most likely standards, including effectiveness of environmental protection, protection of human health, administrability, fairness, cost to society, and cost to industry.

295. 33 U.S.C. §§ 1251-1387 (1988 & Supp. IV 1992).

296. The permit-issuing authority can be EPA or a state agency, if EPA has approved transfer of that authority to the state. 33 U.S.C. § 1342 (1988). The standards implemented are supposed to be the same irrespective of who the permitwriting agency is.

297. The CWA limits the term of state-administered NPDES permits to five years, 33 U.S.C. § 1342(b)(1)(B) (1988), while subsection (a)(3) of that section has the effect of imposing the same requirement on EPA-administered permits. EPA and the states already have difficulty meeting the five year renewal schedule, and lowering the average renewal period would greatly increase the workload of the regulatory agencies. For that reason, permits with terms shorter than five years are unusual.

with extensive data on the performance of the facility under its existing permit and on the types of chemicals used, produced, or otherwise expected to be in the wastewater.[298] Increasingly, permit applicants must also conduct whole-effluent toxicity tests of the treated effluent.[299]

We propose to require that selected dischargers also perform a log P screening test as part of the mandated CWA permit renewal process.[300] If the test reveals a substance in the treated effluent with a log P greater than 3.5, and that substance is identified as a priority pollutant under the CWA, the permittee would be required to comply with the standard for that substance.[301] The log P screening technique would improve the prospects for finding regulated substances, but the regulatory consequences would be no different than at present.

The screen could substantially alter the regulatory consequences, however, if it detects the presence of high log P substances that cannot readily be identified or of identifiable substances that are not on the current priority pollutant list. In such cases, we propose that the permittee must, as a condition of the renewed permit, select and carry out one of the following actions: (1) establish that the unregulated high log P substances in the discharge do not pose an unacceptable risk to the public health or the environment; (2) carry out a High Log P Reduction Evaluation (HLPRE); or (3) install additional or different wastewater treatment technologies.

a. Establishing No Unacceptable Risk

We have demonstrated in part III that, given the current state of scientific knowledge, both of the following propositions are true: (1) any high log P substance found in an effluent in measurable quantities poses a *potentially* serious risk; and (2) the correlations between high log P and adverse environmental and health effects are not enough, by themselves, to prove conclusively that a high log P substance released to the environment in small quantities poses an unreasonable risk. In light of these facts, the existence of any unknown or unregulated high log P substance in a discharge should create a rebuttable presumption of harm, with the discharger given the opportunity to show that the presumption is incor-

298. 40 C.F.R. § 122.21(f)-(g) (1992).

299. *Id.* § 122.44(d)(1)(iv); *id.* § 122.21(g)(11).

300. To minimize the administrative burden, to hold down total and relative costs, and to eliminate testing where there is little prospect of obtaining positive results, exceptions to a testing requirement need to be made for very small discharges, for small discharges where there is no reason to suspect high log P substances, and for other discharges where the nature of the discharge, supplemented by the results of a test for total organic carbon (TOC), indicates that only inorganic pollutants will be present.

301. If the discharger's NPDES permit did not limit that substance, a limit on it would be placed in the permit at its next renewal.

rect with respect to each high log P substance detected.[302] If successful in making this showing, the discharger need not take any further actions.

The discharger could overcome the presumption in one of two ways. First, it could prove that the correlations we have cited do not apply to the detected substance[303] for one or more of the following reasons: (1) the log P screening technique provided a false value for log P and the true value is less than 3.5; (2) the calculation of BCF from log P overstated the substance's true BCF; or (3) the substance degrades so rapidly in the environment that significant exposure of humans or aquatic organisms is highly improbable.[304]

The second, and more likely, possibility would be for the discharger to perform a risk assessment. Under this approach, the permittee would concede that the high log P substance or substances in question could be harmful in some concentrations, but not under the conditions of the discharge. For example, many regulatory authorities consider a risk of cancer to humans to be *de minimis* if the most exposed individual has a resulting increased lifetime risk of less than one in one million (a 10^{-6} risk) or, in some cases, one in ten thousand (a 10^{-4} risk) or one in one hundred thousand (a 10^{-5} risk).[305] A discharger might prove that the amount of the high log P substance, its subsequent environmental fate,[306] the instream concentration, and/or the pattern of human exposure would lead to no measurable cancer risk or a risk that is low enough to be considered acceptable.[307] Performance of a similar set of calculations

302. A question arises as to the appropriate burden of proof to be sustained in making such a showing. Erring on the side of protecting the environment and public health would suggest the standard should be clear and convincing evidence. But proving a substance is not harmful under a particular circumstance—like proving most negatives—is difficult even using the general civil standard of a preponderance of the evidence. To require more would make the presumption irrebuttable in practice. Declaring a presumption rebuttable while making rebuttal a practical impossibility is silly gamesmanship. Thus, these cases should use the preponderance of the evidence standard.

303. Such a showing will normally require the discharger to identify the substance, usually based on prior knowledge or by the log P screening technique. Some other cases, however, may require additional laboratory procedures such as GC or GC/MS.

304. The first two of these scenarios rarely occur. Another theoretically possible rebuttal would be that the substance is known conclusively to have no toxic effects on either humans or the natural environment. However, few manmade organic substances have such a clean bill of health, since virtually all substances are toxic in some concentration to some organism.

305. EPA considers acceptable risk ranges for cancer under CERCLA cleanups to be 10^{-4} to 10^{-6}, with 10^{-6} considered the "point of departure." 40 C.F.R. § 300.430(e) (1992). EPA similarly considers the acceptable cancer range for RCRA corrective action to be 10^{-4} to 10^{-6}. 55 Fed. Reg. 30,798, 30,804 (1990).

306. Nearly all organic chemicals will undergo some kind of chemical modifications over time, whether from exposure to light, water, or aerobic or anaerobic bacteria, though the rates of these chemical changes vary enormously. Similarly, some substances volatilize to air, while others remain in water, sorb to sediments or suspend in solids, among other fates. These processes are known collectively as the environmental fate of the chemical upon release.

307. *See infra* part V.B.3.d for a discussion of the concentration levels that might be considered to pose an acceptable level of risk. For a recent illustration of a similar methodology,

could demonstrate that no other unacceptable acute and chronic human health effects would result, and that no unacceptable damage to the aquatic environment would occur.[308]

b. *High Log P Reduction Evaluation*

Alternatively, dischargers could perform a High Log P Reduction Evaluation (HLPRE), closely patterned after the Toxicity Reduction Evaluation (TRE).[309] Where toxicity has been shown in an initial screening test for whole-effluent toxicity,[310] EPA and the states have had good results using TRE's to identify sources of toxicity and means of remediation. The content of each TRE differs and much depends on the application of professional judgment by the experts conducting the evaluation.[311] Generally, the first step in a TRE is a battery of tests to determine conclusively whether the effluent is toxic to aquatic organisms. Once toxicity is established, the experts evaluate the raw materials, plant production processes, and cleaning and maintenance procedures to identify any likely sources of toxicity that can be eliminated or reduced.[312] In some cases, such simple source controls will eliminate toxicity. In other cases, the effluent must undergo sophisticated "fractionation" techniques, which partition the treated effluent and separately test the various components for toxicity. This additional step sometimes identifies the source or suggests in-plant process or waste stream treatment changes to

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see 58 Fed. Reg. 4133 (1993), where EPA decided that di-n-octyl phthalate, a high log P substance, would not pose an unreasonable risk to aquatic organisms because EPA concluded it metabolizes rapidly enough that it is likely to disperse, rather than biomagnify. Di-n-octyl phthalate has a log P of 5.1, based on solubility data EPA provided and the equation in the text accompanying note 128, *supra*.

308. To take advantage of this approach, the discharger would need to know, among other things, the substance's identity, concentration in the discharge, subsequent fate in the environment, the amount to which people can reasonably be expected to be exposed, and the concentration that is harmful to people (for carcinogens, its potency, a matter not known for many chemicals). Risk assessments of this sort are common prior to CERCLA cleanups, and have also been used in numerous other environmental release situations. For a good overview and examples, see THE RISK ASSESSMENT OF ENVIRONMENTAL AND HUMAN HEALTH HAZARDS (D.J. Paustenbach ed., 1989); Alon Rosenthal et al., *Legislating Acceptable Cancer Risk From Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269 (1992). For a cautionary note, see Frank P. Grad, *Risk Assessment and the Tyranny of Numbers: A Brief Comment*, 1 J. ENVTL. L. & LIT. 1 (1986).

309. EPA first imposed a policy of using TRE's to reduce toxicity at POTW's in 55 Fed. Reg. 30,082, 30,110, 30,113 (1990).

310. Whole-effluent toxicity is explained in part IV.D.3.

311. We believe formulaic approaches to TRE's are futile. EPA, however, has made a concerted effort to develop them. *See* U.S. ENVTL. PROTECTION AGENCY, EPA/600-2-88/06, TOXICITY REDUCTION EVALUATION PROTOCOL FOR MUNICIPAL WASTEWATER TREATMENT PLANTS (1989); U.S. ENVTL. PROTECTION AGENCY, EPA/600-2-88/070, GENERALIZED METHODOLOGY FOR CONDUCTING INDUSTRIAL TOXICITY REDUCTION EVALUATIONS (TRE'S) (1989).

312. These measures could be thought of as a kind of pollution avoidance or pollution reduction. *See supra* note 235.

eliminate the toxicity. In other cases, source controls or in-plant process changes will not eliminate the toxicity, but the fractionation analysis may suggest changes in wastewater treatment technology that could sufficiently reduce the toxicity. Thereafter, the discharger installs internal process changes, in-plant treatment, or end-of-the-pipe treatment to reduce the toxicity. Modifications are then made to the discharger's permit to require periodic monitoring to assure that the problem does not recur, and to require further remediation if it does. In some cases, the agency imposes a numerical limit in the permit based on whole-effluent toxicity bioassays.[313]

An analogous HLPRE could identify sources of high log P substances and/or suggest ways of eliminating the substances from a plant's discharge. In some cases, performing such evaluations may require identifying the substances in question. In other cases, particularly when a wastewater treatment plant has many influent waste streams, it may suffice to identify the stream containing the high log P substances. The discharger would then be expected to use whatever means appropriate to eliminate or reduce the high log P substances in the discharge; the NPDES permit would be changed to require periodic monitoring using the log P screening technique and further remediation if the problem recurs.

c. *Treatment*

As the third alternative, dischargers could conduct different or additional treatment of the effluent, without first conducting an HLPRE. Several proven treatment technologies effectively remove high log P substances. Biological treatment systems can sometimes break down these chemicals into less harmful substances.[314] Activated carbon, whether added in powdered form directly into the biological treatment process or as

313. A permit might state that a plant's whole-effluent toxicity as measured on *mysidopsis bahia* (a small salt-water shrimp) cannot exceed an LC_{50} of 50% effluent, meaning roughly that a mixture of half water and half effluent will not be lethal to half of the test organisms.

314. For example, the Chemical Manufacturer's Association's study of the removal efficiency of aerobic biological treatment (the so-called "Five Plant Study") showed removal rates for high log P substances ranging from 36% for pentachlorophenol to 97% for anthracene. W. Wesley Eckenfelder, Jr., *Aerobic Biological Treatment, in* TOXICITY REDUCTION IN INDUSTRIAL EFFLUENTS 125, 126-27 (Perry W. Lankford & W. Wesley Eckenfelder, Jr., eds., 1990). EPA's data on biological degradation, while differing on individual substances, had somewhat similar overall results for high log P substances, with the range from 35% for anthracene to 100% for several substances. *Id.* Anaerobic biological treatment has been shown to bring about reductive dehalogenation in a number of highly chlorinated benzenes and phenols. *See* Richard E. Speece, *Anaerobic Biological Treatment, in* TOXICITY REDUCTION IN INDUSTRIAL EFFLUENTS, *supra*, at 146, 146-47. However, many chemical substances will not undergo substantial mineralization (destruction down to inorganic chemicals) by anaerobic treatment. *Id.* at 149-53.

a final treatment stage using a granular activated carbon column, removes high log P substances extremely effectively.[315]

Most dischargers will prefer the first or second options. In some cases, however, installing new wastewater treatment technologies and equipment without an initial HLPRE might be the preferable approach.[316] It would be pointless to force the discharger to incur the expense and considerable delay of a full-fledged HLPRE, which would probably require the treatment improvements anyway.[317]

d. Standards

Whether conducting a risk assessment, an HLPRE, or treatment, dischargers will need to know what levels of a high log P substance in a discharge will be acceptable. The answer will vary depending on what is known about the substance. As previously explained, if the substance is identifiable and if standards have already been promulgated for it under the CWA, the discharger would have to meet these standards. If the substance is known and adequate toxicity data exist, but no standard has been set, then a risk assessment could be performed to see if the risks posed fall below acceptable levels.[318]

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315. Two of the authors were involved in a case where HPLC was used to test the effluent of a plant that already utilized heavy doses of powdered activated carbon to control whole-effluent toxicity. Although the plant used and produced high log P substances, none could be detected in the treated effluent. Indeed, the analysis showed so little variation in the range equating to a log P above 3.5 that we thought it desirable to be able to defend against an accusation that the equipment was not functioning properly. We verified the equipment was working, recalibrated it, and reran the test, with the same result. In retrospect, these results should not have been particularly surprising. While a number of factors contribute to the removal efficiency of activated carbon, as a general proposition, absorbability in activated carbon increases with reductions in solubility. ECKENFELDER, *supra* note 218, at 264. High log P substances have unusually low solubility. *See supra* note 130 for the regression equation. We accordingly expect a high degree of removal of high log P substances will occur in nearly all cases where effluents receive high dosage activated carbon treatment. Reductions of TOC of 90% or better have been shown through the use of activated carbon in many industries. ECKENFELDER, *supra* note 218, at 284. Removal rates for high log P substances should be better than for TOC.

316. Such cases include plants whose effluent includes many high log P substances, and where neither pollution avoidance measures nor in-plant treatment are likely to resolve the problem. Another circumstance where changing treatment without going through the identification stage might be preferable is when a plant needs to upgrade its wastewater treatment works for other reasons (e.g., because it is not consistently meeting the permit standards for particular substances) or because there is excessive whole-effluent toxicity. A third case would be where the conduct of an HLPRE would unavoidably reveal trade secrets. Removing all high log P substances without identifying them could be a more attractive choice.

317. This suggestion is preferable to the EPA proposal, *supra* part V.B.2, because it can be time consuming and expensive to identify and quantify a "peak" detected, but not initially identified, by the log P screening technique. *See supra* note 291. Moreover, we are personally aware of cases where substances in a treated effluent could not be identified even by the Federal Government's best contract laboratories following extensive and expensive testing.

318. Risk assessments are discussed *supra* notes 305-08, and accompanying text. The discharger performs a risk assessment in this context to counter a presumption that a high log P

Frequently, however, the substance cannot be identified, or toxicity data are insufficient to allow the performance of a risk assessment. Doing nothing in that event—as happens now—is unacceptable, given what we know about the toxicity of high log P substances. Fortunately, in many cases it will be possible to finesse the question of the applicable standard, since other measures will deal with the problem to everyone's satisfaction.[319] In cases where the need for standards cannot be avoided, the regulatory authorities must determine an acceptable level. The known toxicity of substances in the class of high log P substances and their strong tendency to bioaccumulate argue for stringent limits. On the other hand, setting equally stringent standards for substances whose toxicity is unknown or not fully characterized as for a known harmful substance seems unreasonable and might contribute to overregulation.

Given these conflicting objectives, we believe the following two alternatives, based on existing CWA approaches, may be the best means for EPA to deal with unknown high log P substances in point-source discharges. First, EPA could use a simplified technology-based approach, similar to the effluent limitations guidelines, that places heavy emphasis on technical and economic feasibility. EPA could survey plants with well-run wastewater treatment facilities to see what concentrations of high log P substances can be found. EPA could then set limits on all plants in that industry based on the average achieved by well-run plants, modified as necessary to assure economic feasibility.[320] As with any technology-based standard under the CWA, the discharger would not be required to use that technology, so long as the concentration of high log

substance found in a discharge is harmful. For that purpose only, somewhat less stringent standards should apply than the government would use to set water quality standards, given the fact that the discharger would have the burden of persuasion. Thus, in our view, a discharger would have met its burden if it could show that the risk to the public from a known animal carcinogen was toward the low end of the range of acceptable risks (perhaps 10^{-4} to 10^{-5} additional lifetime risk), based on exposure conditions at that site. For other serious chronic human effects (teratogenicity, interference in reproductive success, and neurotoxicity) risk levels slightly less severe than those for cancer would be appropriate, that is, a 10^{-3} to 10^{-4} increased risk of harm based on typical exposure at that site. For other human effects, it would be sufficient to show that the discharge remained below the known no observable effect level with a modest extra margin for safety such as a factor of ten. In this context, we would not favor the extremely large safety margins (100-fold to 10,000-fold) that EPA has used for some substances. For toxicity to aquatic organisms, a discharge should be less toxic than the lethal concentration for acute toxicity and the lowest observable effect level for sublethal chronic effects. As at present, EPA could set more stringent standards of broader applicability by adding the substance to the priority pollutant list and preparing water quality criteria.

319. That circumstance is often the case now with TRE's, which sometimes result in such strong improvements that no whole-effluent toxicity can be detected, even in straight effluent. We believe the same would be the case for whole-effluent BCF in many instances involving improved treatment where large doses of activated carbon may eliminate detectable quantities of high log P substances. *See supra* note 315.

320. Plants with discharges fundamentally different from those surveyed should be allowed to qualify for a "fundamentally different factors" variance, as is now possible under effluent limitations guidelines. 33 U.S.C. § 1311(n) (1988).

P substances did not exceed the allowed concentration for that industry.[321]

The second alternative would be for EPA to develop health-based (or occasionally environmental harm-based) water quality standards for classes of unknown high log P substances and for known substances with unknown or incomplete toxicity data.[322] EPA would survey the data for substances in the class whose toxicity is known, and set limits based on those substances, using them, in effect, as a surrogate. There is precedent for doing so under CERCLA, though not under the CWA.[323] However, in setting limits based on surrogates, we believe a less stringent set of assumptions should be used, and somewhat greater risks considered acceptable than would be the case for substances with known toxicities.[324] The levels set should also be adjusted to reflect differences in bioaccumulation potential[325] and, where known, in persistence and other environmental fate considerations.

The resulting figures should be used as state water quality criteria for high log P substances, but would be considered only presumptively correct. Dischargers should have the opportunity to rebut the presumption. Over time, as more data became available, EPA would presumably

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321. The advantage of this approach is its apparent simplicity. Dischargers are required to reduce the pollutants to the lowest level feasible for that industry to achieve. The primary difficulties with this approach are the considerable time it has taken EPA to promulgate the existing effluent limitations guidelines, and the fact that there is no necessary relationship between the required levels and those needed to protect the public and the environment.

322. In our experience, it is often possible to determine the chemical class a substance belongs to, even where it is not possible to determine its precise chemical formula. *See infra* note 393. For those cases where a substance could not be put in a chemical class, the regulations might apply the least stringent standards adopted for any of the classes of high log P substances.

323. In EPA Region IV, site managers use benzo(a)pyrene as a surrogate for other PAH's. *See* EPA Region IV Interim Guidance (Feb. 11, 1992) (copy on file with the *Ecology Law Quarterly*) (establishing toxicity equivalency factors for other common PAH's).

324. Accordingly, less stringent limits should be set than those suggested *supra* note 318. Specifically, for carcinogens, the lowest end of the range of acceptable risks (perhaps 10^{-3} to 10^{-4} additional lifetime risk) should be used. Similarly, typical exposure conditions should be used instead of barely plausible ones. For other serious chronic human effects (teratogenicity, interference in reproductive success, and neurotoxicity) risk levels slightly less severe than those for cancer would be appropriate, that is, a 10^{-2} to 10^{-3} increased chance of the probability based on a lifetime of exposure. For all other human effects, it would be sufficient to show that the concentration remained below the known no observable effect level for other chemicals in the class.

325. Very high log P substances commonly have BCF's 500 times greater than the BCF's for substances with log P's of 3.5. (Measured BCF values for PCB's and some pesticides exceed 100,000, *see supra* notes 16, 43, while a log P of 3.5 equates to a BCF of just under 200. *See supra* note 126.) That range is far too great to ignore. Strictly by way of illustration, a simple mathematical formula that adjusted the allowable concentration downward roughly by the amount that the log P exceeded 3.5 might be $C=H/(n-3.5)^{10}$, where C is the allowable discharge concentration, H is the health-based concentration derived from the considerations discussed *supra* note 324, and n is the measured log P.

be able to refine the categories and promulgate water quality criteria for particular identified substances where necessary.

4. *Legal Authority for Our Proposal*

EPA and the states have adequate authority under the CWA to require dischargers to take the steps we have recommended. The regulatory agencies have clear authority to require NPDES permitholders, when renewing their existing permits, to determine whether high log P substances are in the discharge, and also to impose permit requirements for periodic (e.g., quarterly or annual) log P screening.[326] This authority derives from those express provisions of the CWA[327] requiring dischargers to provide discharge information to EPA and/or the states, and allowing permitwriting authorities to require testing methods, including non-pollutant-by-pollutant methods.[328] No court has addressed the precise question of whether EPA can impose HPLC testing as a means of screening for bioaccumulation potential, because EPA has never tried to impose this testing. Our research, however, indicates that no discharger has ever challenged EPA's imposition of any other kind of testing requirement in the permit-issuing process, or a permit requirement that the discharger conduct periodic monitoring tests. This lack of litigation is not surprising because the most expensive test routinely imposed is far cheaper than the least expensive lawsuit.[329]

In any event, we believe the courts would uphold a requirement to undertake log P screening for several reasons. In general, the courts are deferential to agencies on highly technical matters.[330] Moreover, while

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326. Indeed, the normal format of an NPDES permit has a monitoring requirements section, which frequently contains requirements to monitor for substances the permit does not actually control.

327. 33 U.S.C. § 1318(a) (1988) provides in pertinent part:

> (a) Whenever required to carry out the objective of this chapter, . . . (A) the Administrator shall require the owner or operator of any point source to (i) establish and maintain such records, (ii) make such reports, (iii) *install, use, and maintain such monitoring equipment or methods (including where appropriate, biological monitoring methods), (iv) sample such effluents* (in accordance with such methods, at such locations, at such intervals, and in such manner as the Administrator shall prescribe), and (v) *provide such other information as he may reasonably require* . . . . (emphasis added).

328. The Administrator can specify measurement techniques, including those for use in implementing state programs such as those establishing water quality standards. In determining methods for measuring water quality criteria for toxic pollutants, the Administrator may establish such measurements "on other bases than pollutant-by-pollutant criteria, including biological monitoring and assessment methods." *Id.* § 1314(a)(8). The log P screening technique, when used as we have proposed, is a nonpollutant-by-pollutant measurement technique.

329. Most biological and chemical tests of effluents range from a few hundred dollars to $1500.

330. "In particular, the choice of scientific data and statistical methodology to be used is best left to the sound discretion of the Administrator." National Ass'n of Metal Finishers v. EPA, 719 F.2d 624, 657 (3rd Cir. 1983). *Accord* Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983). *See also supra* note 200.

no court has ruled on testing requirements per se, the D.C. Circuit Court of Appeals has rejected a challenge to related regulations that required the discharger to provide information on all toxic substances in a discharge.[331] The matter was of particular importance to industry because in some cases a full inventory of the toxic substances in wastewater could reveal the substances used in a production process, potentially a vital trade secret. In upholding EPA's authority,[332] the court rejected an industry argument that the disclosure requirement was burdensome. The court relied on the regulatory provision which allowed for waiver in cases involving an undue burden. The court also rejected the claim that, because some of the toxic substances would not be discharged, the requirement was not reasonably necessary and thus violated the requirements of the statute.[333] The arguments for a CWA interpretation allowing EPA to impose the log P screening technique are far stronger than those for the provision upheld by the court of appeals: The technique's use is unlikely to result in the release of sensitive trade secrets; the same waiver provision would be available to avoid burdensome testing; and the substances detected would already have been discharged.

Dischargers might argue that while the federal CWA clearly authorizes and even requires EPA and the states to set standards for particular toxic pollutants,[334] the statute is virtually silent on high log P substances.[335] This point is untested, because EPA has never attempted to regulate on this basis. However, the courts have recognized that EPA and the states have the power to regulate on the basis of whole-effluent toxicity. Two of the circuits have agreed with EPA that "toxicity" is an attribute of pollutants subject to regulation under the CWA.[336] Regulating on the basis of whole-effluent bioaccumulation potential raises no legal issues not already settled in the whole-effluent toxicity litigation. Moreover, a court would be certain to conclude that substances detected by the log P screening technique are pollutants under the CWA.[337] The

331. NRDC v. EPA, 822 F.2d 104, 117-22 (D.C. Cir. 1987).

332. *Id.* at 120.

333. *Id.* at 119-20.

334. 33 U.S.C. § 1313(c)(1).

335. The list of factors the Administrator is supposed to consider in listing toxic pollutants and in establishing standards or prohibitions is extensive but does not mention bioaccumulation. *Id.* § 1317(a)(1) & (2). A concern for biomagnification is implied, however, in the definition of a toxic pollutant as one that, after discharge and upon exposure of an organism, "either directly from the environment or indirectly by ingestion through food chains" will cause one of a list of toxic effects. *Id.* § 1362.

336. NRDC v. EPA, 863 F.2d 1420, 1430 (9th Cir. 1988); NRDC v. EPA, 859 F.2d 156, 189 (D.C. Cir. 1988). Industry had argued that the statute authorized EPA to regulate specific toxic substances, but not a property like toxicity.

337. Virtually everything contained in water can be construed as a pollutant, given the broad definition of pollution under the Act. 33 U.S.C. § 1362(19) ("The term 'pollution' means the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water."). Individual high log P substances, whether or not they are

discharge of any pollutant by a point source is illegal unless it accords with the terms of an NPDES permit.[338] In addition, the courts recognize that Congress has strongly emphasized its desire that EPA and the states regulate toxicity under the CWA.[339] Finally, given the great deference shown to administrative agencies by the courts, especially on technical matters and questions of statutory interpretation,[340]it is likely that courts would uphold regulation of high log P substances as a class.[341]

The policy case for regulatory use of the log P screening technique is the weakest for the imposition of numerical limits on log P concentrations in NPDES permits, if violation of that permit condition would subject the permittee to civil or criminal penalties on the basis of a single log P test.[342] While imposing numerical limits on log P values in NPDES permits would probably pass legal muster, there are policy arguments against routinely imposing them.[343] First, doing so will often be unnecessary to achieve the objective of minimizing the risk from high log P substances. For instance, a permittee may have satisfactorily completed an HPLRE and/or installed additional treatment, thereby eliminating the problem. In such a case, the only worry is that the problem might resume. To guard against that, the NPDES permit could be modified to

designated "toxic," are clearly pollutants.

338. *Id.* § 1311.

339. NRDC v. EPA, 822 F.2d 104, 118 (D.C. Cir. 1987) ("The indications are abundant that EPA was intended to possess broad latitude in identifying and regulating suspected toxics.").

340. *See supra* note 200.

341. In theory, a question could arise as to the authority of EPA to order high log P reduction evaluations. The analogous issue of compelling an unwilling discharger to carry out a TRE is untested. It is possible that a discharger could convince a court that it is prepared to reduce toxicity to any level that EPA has the legal authority to compel, but that it already knows how to do so, and should not be compelled to waste money on a formal TRE. The point is moot as it relates to our proposal for HPLRE's. EPA clearly has the authority to regulate on the basis of high log P substances as a group. Yet, in contrast to current practice on TRE's, we offer the discharger the possibility of carrying out HPLRE's as an alternative to direct regulation. It would be impossible for a discharger to argue that it was improper for EPA or a state to give the discharger the choice between doing something the regulatory authority has the power to order, and doing something else that the regulators may not otherwise have the power to require.

342. There could also be legal difficulties if EPA attempted to put such limits in permits in the absence of authorizing regulations. When reviewing enforcement actions in which criminal penalties or quasi-criminal sanctions such as civil penalties could be imposed, the courts tend to construe ambiguities against the government, on the grounds that it is unjust to penalize someone for engaging in conduct that was not clearly contrary to law. For a discussion of this "void for vagueness" doctrine, see 1 WAYNE R. LAFAVE & AUSTIN W. SCOTT, JR., SUBSTANTIVE CRIMINAL LAW § 2.3(a)-(d) (1986). EPA and the states could easily overcome this notice difficulty by promulgating regulations that explicitly authorize NPDES permit conditions forbidding the discharger from having high log P substances in concentrations above the level specified in a permit. Those wishing to challenge such a regulation would have the opportunity to do so before their conduct subjected them to enforcement action.

343. Even if enforcement personnel recognize these potential difficulties and act accordingly, however, no comparable protection exists from citizen suits.

require periodic monitoring, performance of a new HLPRE, and additional remediation if high log P substances reappear in the treated effluent.[344] Only if the problem persists does it make sense to limit the concentration of log P substances in the discharge. In the ordinary case, however, periodic monitoring—with a right to reopen the permit if high log P substances again are found—amply protects the public.

Second, while the correlations between HPLC retention time and measured log P, and between measured log P and laboratory-measured BCF, are both exceptionally good, their overall predictive capability is less than a certainty.[345] It would be unjust to impose civil penalties on a discharger if, for example, one chance in twelve exists that a spurious correlation is the *sole* basis for doing so. The problem of false correlations will be compounded by our proposed use of the log P screening technique to screen for and regulate *unidentified* high log P substances. Knowledge that all the high log P substances with adequate toxicity data are harmful to some organisms in low doses[346] would support an agency's decision to pursue the remedial steps we have recommended. Without a stronger toxicity data base, however, this knowledge does not support subjecting the discharger to civil penalties based on the results of a single log P test.[347]

Analytical variability presents a third problem.[348] No detection method allows quantification of the concentration of a substance unless its identity is known or at least suspected. Although rough estimates are

344. Routinely imposing a numerical limit on high log P substances (as opposed to a requirement that an HLPRE be undertaken) has a further, potentially severe problem: a company could eliminate all the high log P substances in its discharge only to have a completely different, unknown substance show up at some later date, because of the difficulty or even the impossibility of forecasting what kinds of reaction products may be formed. If the permit required periodic monitoring, and high log P substances began to show up, the state or EPA would impose further remedial requirements. Companies would have an ample incentive to avoid this outcome, as an HPLRE, like a TRE, could be expensive. However, imposing new HLPRE's rather than numerical log P limits would avoid the harsh consequence of having that very first test, which showed high log P substances in a discharge, constitute a permit violation that could subject the discharger to, at a minimum, civil penalties.

345. The first of these correlations has an R value of 0.975, while the second has a median R value of 0.95. *See supra* notes 137-38 and accompanying text. If these values were entirely independent correlations, the predicted R value of the HPLC retention time for BCF would be 0.93 (i.e., 0.975 x 0.95). The two are probably not completely independent, in which case the combined R value would be higher, but could not exceed the lower of the two individual values. Thus, we can infer that the range of possible values of R for HPLC as a predictor of BCF is between 0.93 to 0.95. Those values are exceptionally high, but below a certainty.

346. *See supra* note 67 and accompanying text.

347. This problem does not arise where the high log P substance can be identified and accurately quantified and its toxicity is known. In those cases, substance-specific standards could be set. Thereafter material violations could lead to civil penalties and, for knowing violations, to criminal sanctions.

348. Several kinds of variation in test results are possible. Analytical variability occurs where tests of the same sample by multiple laboratories or in the same laboratory at different times will not yield identical results, even if the test protocols are carefully followed.

often possible for substances whose identity is unknown, the results are uncertain and subject to substantial variation from test to test. In the context of permit conditions, this analytical variability could lead to unjust results. Suppose, for example, that a particular NPDES permit requires that no substance with a log P of 3.5 or greater be contained in an effluent in a quantity greater than five ppb. Suppose further that the screening technique detects but cannot identify a high log P substance. It can, however, estimate the substance's concentration to be 500 ppb. In that case it is highly probable that the 5 ppb permit limit has actually been violated (i.e., that the difference exceeds the expected variability of the test) and the result is therefore not an artifact of the testing method's precision limits. Penalizing the discharger for violating the permit would be just. On the other hand, suppose the estimate of the substance from the test is six ppb. In that case, the chance that the five ppb standard had been violated is virtually identical to the chance that no violation had occurred.[349] If, contrary to our recommendations, regulatory authorities decide to use log P screening results as permit conditions, analytical variability can be minimized, but only at the cost of added expense for the discharger and additional administrative burdens for permitwriting and enforcement.[350] Finally, certain very technical issues, such as how to report results, become far more important once the discharger faces the possibility of penalties and citizen suits.[351]

349. As explained in part III *supra*, in some cases it is possible to identify a substance found through the log P screening technique. In that event, the concentration can be separately measured with far greater precision. This circumstance will often narrow—but will not eliminate—the fairness problem associated with analytical variability, as an analogous but smaller problem exists for *all* current detection and measuring techniques when trying to quantify values for known substances close to the limits of detection. Thus, an actual measurement at six ppb might still be a test artifact, rather than a true permit violation, even for a known substance.

350. Correctly imposed numerical permit limits for whole-effluent toxicity (and thus by analogy for whole-effluent bioaccumulation) can cope with the analytical variability problem discussed above. The variability for any one test can be very high. Yet, the variability associated with the average results from a suite of five to ten tests will be dramatically lower. Accordingly, one can envision the following scheme: if the toxicity of a plant or municipality's discharge exceeds a standard set in the permit for whole-effluent toxicity, and the amount by which it does so is greater than the known analytical variability of the test, immediate compliance actions can be brought. But if the exceedance is less than that amount, it triggers a requirement for an immediate and intensive set of additional tests to determine an average toxicity. If that average exceeds the state standard, the discharger has violated the permit. If the average does not, but the tests suggest the existence of toxicity, a new TRE is triggered to see what can reduce toxicity at the plant generally. Something analogous could be done for whole-effluent log P, thereby significantly reducing the analytical variability problem.

351. For example, there are several options for reporting the results of high log P screening, including: (1) the detection of any compounds correlating to a log P above 3.5, irrespective of concentration; (2) the detection of any compounds correlating to a log P above 3.5, but only for peak heights above some minimum; and (3) a summation of the concentrations of all compounds correlating to a log P above 3.5, as a representation of the entire sample's bioaccumulation potential. While we would favor the second option in those cases where concentration can be measured or estimated, all three options are reasonable for screenings and HLPRE's; in

5. *Costs*

Although we cannot precisely predict the costs of our proposal, we believe they will be modest compared to the current costs of CWA compliance.[352] We expect the annual national costs of running the log P screening technique to be less than $30 million.[353] Since much depends on the details of the program's administration, and on the number of high log P substances discharged in quantities requiring removal, we can only offer some general observations about testing and compliance costs.

First, it is possible to estimate the additional costs for both capital and operating expenses for the large number of plants already using biological treatment,[354] which will need to supplement their existing treatment with activated carbon. According to one study, the one-time capital requirements for utilizing powder activated carbon treatment (PACT) averaged ten percent of the cost of biological treatment alone,[355] while the average for granular activated carbon columns (GAC) was twenty-seven percent.[356] Annual average increases in operating costs above the cost of biological treatment alone were thirty-one percent for GAC and thirty-nine percent for PACT, assuming no on-site regeneration of the carbon.[357] While these percentages are large, they are based

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those contexts the choice is an interesting but minor technical issue. However, if the discharger is subject to civil penalties, the choice becomes critical because the first and third options (since they are subject to greater analytical variability) could lead to unjust results.

352. The 1987 cost was $32.1 billion. COUNCIL ON ENVIRONMENTAL QUALITY, EXECUTIVE OFFICE OF THE PRESIDENT, ENVIRONMENTAL QUALITY: 20TH ANNUAL REPORT 431 (1990). Inflation and some new requirements have likely pushed the total above $35 billion.

353. Of the approximately 50,000 individual NPDES permits nationwide, we expect less than half would require any testing. Most of the remainder would require testing only at permit renewal. A smaller number would require annual testing, but only the largest chemical plants, paper mills, and other dischargers shown to have significant amounts of high log P substances would require quarterly testing. Assume that 15,000 permitholders were tested every five years, another 4000 every year, and 1000 more on a quarterly basis. That means that 11,000 tests would be conducted annually. Even at $2500 per test, the annual cost would be only $27,500,000. We believe the numbers in each of those categories would actually be lower. If half of the permitholders could use HPLC without the additional detectors, the cost would drop to $20,655,000. We also expect that the average price per sample tested will fall below $2500 (in 1992 dollars) as more laboratories obtain the equipment and train the personnel to perform the log P screening technique.

354. Many industrial plants that have organic chemicals in their waste use biological treatment because of its cost advantages over other approaches. Municipal sewage treatment facilities must use secondary (i.e., biological) treatment unless they obtain a waiver. 33 U.S.C. § 1311(b)(1)(B), (h) (1988). We are not in a position to estimate the costs of requiring high log P reduction for plants that currently employ wastewater treatment technologies other than biological treatment.

355. PACT is a registered trademark of Zimpro, the licensee of du Pont.

356. Kevin D. Torrens, *Economics of Toxicity Reduction, in* TOXICITY REDUCTION IN INDUSTRIAL ELEMENTS, *supra* note 314, at 235, 235-36. The percent figures quoted are the additional amount required above and beyond a base system of activated sludge (biological) treatment. Capital costs for GAC ranged from 22% to 37% depending on the daily flow of wastewater to be treated, and for PACT from 7% to 13%.

357. Operating costs for GAC ranged from 9% to 12% above the biological treatment

on actual costs for toxicity reduction. We expect the costs for reducing high log P substances to be lower.[358] Secondly, and more importantly, these figures only apply in those cases requiring end-of-the-pipe treatment. We believe most dischargers who have high log P substances will meet these new regulatory requirements through pollution avoidance techniques and/or in-plant treatment of selected waste streams, rather than the generally more expensive end-of-the-pipe treatment.[359]

C. *Screening Seafood Under the FFDCA*

Human exposure to high log P substances could also be significantly reduced by screening food, especially seafood,[360] under the Federal Food, Drug and Cosmetic Act.[361] The purpose of the FFDCA is to protect

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base case for the operation of the columns, and from 12% to 31% for carbon regeneration. Operating costs for PACT ranged from 35% to 43% if there was no carbon regeneration. Regenerating the carbon on site can lower the costs dramatically, to an average 9% increase in operating costs and an additional 19% for the carbon regeneration over the base case. Doing so, however, requires considerable additional capital investment, running an average of 44% of the basic biological treatment system cost, and is accordingly only feasible for the relatively larger wastewater treatment systems. *Id.*

358. First, we anticipate that less carbon will be needed for high log P reduction than for toxicity reduction. Second, these are average rates; the percentage rates are lower for the larger facilities, however, and we expect that larger facilities will provide a disproportionate fraction of the number requiring high log P reduction efforts. Third, many existing facilities will need to add some form of carbon treatment for whole-effluent toxicity reduction, or to meet new chemical-specific limits being imposed by EPA. Where these expenses must be undertaken for some other purpose, the additional costs of carbon treatment for high log P reduction will be a tiny fraction of the total increase. High log P substances have low solubilities, and will be preferentially removed when compared to many other chemical substances. *See supra* note 112 and accompanying text. Accordingly, removal of the high log P substances would virtually never be the factor dominating carbon use rates whenever other substances are required to be removed as well.

359. In addition to potential added costs, there might occasionally be adverse impacts from our proposals, namely, the creation of solid waste out of substances that had been in water (or, under other statutes discussed below, in air). We believe these residues present less risk than the physical form that the same substances were in before treatment. Before, they were contained in air, surface water, or ground water, where they were readily bioavailable or where they could directly expose humans. After treatment, they are in a less bioavailable form. Nevertheless, the exact public health and environmental consequences depend largely on what is done with those residues. In our view, biological sludges, which can be used for agricultural purposes, should be tested with a variation of the log P screening technique to assure that they will not release unacceptable levels of high log P substances. Those that fail the test should be incinerated. Once spent, activated carbon used for treatment can either be regenerated or incinerated, in the process destroying, respectively, most or virtually all of the high log P substances.

360. None of the authors has had substantial experience in assessing the existence of high log P residues in or on foods other than fish and shellfish. In any event, one would expect the problem to be particularly severe with seafood, as the bioaccumulation and biomagnification of one or more harmful chemical substances may already have occurred. Moreover, with few exceptions, there is no regulatory structure currently in place specifically designed to deal with high log P substances in seafood.

361. 21 U.S.C. §§ 301-392 (1988 & Supp. IV 1992).

consumers of food, drugs, and other items of commerce regulated by the Act, from deceptive practices and harmful substances.

Using the log P screening technique to test seafood for high log P substances raises no special technical problems.[362] The technique requires homogenizing the sample, and then using an organic solvent, such as methylene chloride, to extract synthetic chemicals from the tissues of fish or shellfish. The sample is then run through the log P screen described in part III.C.3. This screen indicates the presence of any high log P substances, specifies their log P, and sometimes identifies and quantifies them.

As a practical matter, however, FDA's severe resource limitations[363] preclude it from adopting a comprehensive regulatory program for log P substances. Moreover, the burden on the fishing and shellfish industries of routine log P tests could be very high relative to the benefits.[364] Accordingly, we propose testing only large shipments of imported and domestic seafood. Large lot shipments could be required to have a representative sample tested by private U.S. laboratories licensed for that purpose by FDA.[365] FDA would thus be saved the costs and administrative burdens of routine testing; it could concentrate on auditing and compliance actions and spot-checking smaller catches.[366] The burden on

362. Well-established methods for testing fish and shellfish tissues for chemical contaminants already exist. EPA has proposed procedures in its draft guidance document. BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126. EPA, FDA, and the Corps of Engineers have extensive experience with the methods for obtaining an extract from fish or shellfish for testing by GC, GC/MS, or HPLC.

363. One of the authors toured FDA laboratories, and heard extensive complaints about the difficulties of doing good analytical work with obsolete equipment. He was later told by a senior FDA official that the average equipment age was now about 15 years. In the authors' experience, university laboratories dealing with environmental fate and toxicology would be considered obsolete once the average equipment age was five years. Many commercial and industry labs have average equipment ages less than three years. Resource limitations also restrict the number of inspections FDA can carry out. For example, although FDA rejects 27% of all seafood inspected, only two to four percent of the total catch is inspected. Herbert Burkholz, *A Shot in the Arm for the F.D.A.*, N.Y. TIMES, June 30, 1991, at 15.

364. Assessing log P substances in fish and shellfish would be economically feasible only where the quantities are fairly large, such that the costs of testing a representative sample would be a small percentage of the total cost of doing business.

365. Foreign fish are nearly always frozen fish, as are some large-scale domestic landings. There should accordingly be no difficulty requiring a log P screen before the seafood is distributed in commerce, as the turn-around time for the results would not be great. On the other hand, fresh fish may need to begin being distributed before the results are available. This should be no problem if the importers are bonded and the fish is subject to recall. Moreover, since we are concerned predominantly with chronic exposures, if a single shipment got through and then the results for significant quantities of high log P substances turned out to be positive, the consequences would not be worrisome so long as the authorities could assure that it would not happen again.

366. We advocate less rigorous testing of small catches, as an efficient use of limited regulatory resources, to minimize the burden on small fishing boat owners. We do not believe fish or shellfish from small catches are less likely than those from larger catches to contain high log P substances.

distributors and FDA could be further reduced if FDA granted exceptions to the screening requirement when the log P screening technique had shown that the fish or shellfish taken from particular waters are safe.[367]

As with our other recommendations, if high log P substances were found, the seafood could not be sold if it exceeded FDA tolerances; the seafood would be subject to enforcement if it contained levels of identified high log P substances above FDA action levels. For other identified substances, for high log P substances for which no such standard had been established, and for unidentified high log P substances, sale would be prohibited unless the supplier could establish that the substances in question were not harmful or only involved acceptable levels of risk. To minimize the burden on fisheries and the cost to the consuming public, however, no action would be necessary if the concentration of unidentified high log P substances in the fish tissue were less than one ppb. If the concentration were between one ppb and ten ppm, the burden would be on FDA to show that the fish were harmful. Only if the concentration were above ten ppm would a rebuttable presumption arise that the unknown high log P substance rendered the fish tissues "adulterated" and thus unsuited for sale. We base this recommendation on the data EPA has developed, which show that the "safe" concentration for identified high log P substances in fish and shellfish tissues is above one ppb in virtually all cases, and that for the vast majority of high log P substances, the safe cutoff is above ten ppm.[368]

There is no question that FDA itself has the authority to use the high log P testing procedure to test seafood.[369] FDA then could use a positive test result to justify seizing seafood containing substances that can be identified, that have adequate toxicity data, and that are in quanti-

367. Because of atmospheric transport, *see infra* notes 517-26 and accompanying text, some high log P substances can be found virtually everywhere. Nonetheless, the bioaccumulation of synthetic organic chemicals in commercial fish products is likely to be most severe where the environmental controls dealing with the environmental releases are the least stringent.

368. BIOCONCENTRATION GUIDANCE DOCUMENT, *supra* note 126, at III-20. EPA calculated "Reference Tissue Concentrations" (RTC's), which it defines as the "concentration of a chemical in edible fish or shellfish tissue which will not cause adverse impacts to human health when ingested." *Id.* at xi. EPA calculated such RTC values for all the substances in its IRIS database that had high log P values above 3.5 and for which there was adequate toxicity data. Its methodology was conservative, so that a concentration in fish or shellfish below the RTC will cause either no harm or no "appreciable risk of deleterious effect." On the other hand, virtually all high log P substances had RTC's under one part per thousand. *Id.* at III-20.

369. FDA has asserted the right to determine the test methods it uses to detect substances. 42 Fed. Reg. 52,814, 52,816 (1977). That assertion has not been challenged in reported cases. One successful challenge of FDA's method for detecting DDT in fish, which predated the 1977 policy statement, was overturned by a higher court. United States v. Ewig Bros. Co., 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975).

ties FDA considers potentially injurious to health.[370] However, for FDA to attempt to regulate "unknowns" and substances that do not have toxicity data may be stretching the limits of its statutory authority.[371] More seriously, under current statutory authority, we see little prospect that the courts would uphold our recommended shift of the testing burden onto the distributors of seafood.[372] Congressional action to strengthen

370. The statute gives FDA the authority to ban the sale of "adulterated" food. Food is considered adulterated "[if] it bears or contains any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. § 342(a)(1) (1988). That definition clearly covers identified toxic substances, though pesticide residues may be separately covered under the FFDCA, 21 U.S.C. § 348 (1988 & Supp. IV 1992), a provision administered by EPA. The legal standard for determining whether a substance is adulterated depends on whether the substance is considered an "added substance." For added substances, no proof of actual harm is necessary; that requirement was eliminated by the 1938 amendments to the Act. 1 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 9.04, at 9-4 n.19 (1979). For those which are not "added substances," the FFDCA specifies that food will not be considered adulterated "if the quantity of such substance in such food does not ordinarily render it injurious to health." 21 U.S.C. § 342(a) (1988). This language seems to require affirmative findings on the part of the FDA as to what constitutes harmful concentrations to humans. In practice, this provision does not significantly limit FDA's authority to regulate high log P substances, as the courts have upheld FDA's expansive definition of "added substances" contained in 21 C.F.R. § 109.3(c) & (d) (1993), to include those that occur in nature but whose concentration has been increased by human activity. *See* United States v. An Article of Food Consisting of Cartons of Swordfish, 395 F.Supp. 1184, 1186 (S.D.N.Y. 1975) (mercury found in swordfish was an added substance even though it has been found in fish for centuries); United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980) (if a toxin is present in seafood because it was introduced to the environment by man, all of it will be considered an "added substance"). We expect that any high log P substance would meet that definition of an added substance since most occur only as a result of human activity, and the amount of the few which do occur naturally (i.e., the PAH's) has been greatly increased by human activity. Assuming high log P substances found in seafood were determined to be an added substance, FDA would have to decide how much of a particular substance rendered the food injurious to health. It could do so by a tolerance rulemaking under FFDCA § 406, 21 U.S.C. § 346 (1988 & Supp. IV 1992), though with respect to anthropogenic toxic organics, it has chosen that route only for PCB's. 21 C.F.R. § 109.15 (1993). Alternatively, FDA can set an action level at the concentration that it believes renders food injurious. Such action levels are not themselves binding regulations, but FDA uses them when it brings compliance actions against those who do not comply. For an excellent discussion of action levels, their relationship to tolerances, and the broader health and economic issues FDA faces in controlling toxic substances in food, see Merrill & Schewel, *supra* note 18.

371. No express language in the FFDCA authorizes FDA to regulate food solely on the grounds that it contains unknown substances. Even if the courts would agree that unknowns are "added substances," in the sense discussed in the previous footnote, FDA might not be able to establish to a court's satisfaction that any unknown detected in seafood meets the test of a substance that may be injurious to health. Of course, the term "may" seems to provide substantial latitude to FDA in this context, as the Supreme Court recognized in dicta in an early case. United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914) (an added substance violates the "may injure" standard if the food containing it may possibly injure vulnerable segments of the population). Moreover, regulation of unknowns would be consistent with the prophylactic purposes of the statute. Finally, the courts have been quite deferential to FDA's expertise on the source and nature of chemical contaminants in food. O'REILLY, *supra* note 370, at § 9.03. Nevertheless, the willingness of the courts to uphold regulation of unknowns and known substances with unknown toxicity is far from certain.

372. While requirements that responsible parties test their effluents, potentially contami-

and clarify FDA's authority is thus desirable, and possibly essential, if FDA wishes to regulate on the basis we have proposed.[373] Prospects for legislative action seem fairly good, as there is considerable public and congressional concern over the safety of seafood.[374]

If FDA and Congress do not act, we face an unsettling and somewhat ironic prospect: the states may ultimately promulgate the very stringent and expensive measures EPA currently is advocating, under the CWA, to reduce the risk of eating recreationally-caught fish that may have bioaccumulated harmful chemical substances. Those measures and others being taken under other statutes, however, will do little to reduce risks from nonpoint sources, and nothing to reduce exposure of fish contaminated from foreign sources. Accordingly, the significantly larger exposure of the public to high log P substances in commercially processed seafood will remain virtually unregulated.

D. Cleaning Up Contaminated Ground Water Under CERCLA and RCRA

The Superfund program established under CERCLA[375] was designed to provide a rapid and thorough means of eliminating the health and environmental problems caused by the past improper disposal of hazardous waste.[376] Past releases of hazardous substances can reach,

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nated ground water, pesticides proposed for regulation, etc., are common under other statutes, there is no express authority for such requirements under the relevant sections of the FFDCA. Doing so would be out of keeping with over a half-century of FDA practice. Of course, FDA could avoid that problem by doing the testing itself, but it would need a significant increase in resources to do so. While it would be sensible to pass those costs on to the distributors of seafood, that might be more controversial than requiring them to perform the testing themselves in the first place, and would itself presumably require congressional authorization.

373. Congress could clarify that FDA can make determinations that food is "adulterated" if it contains substantial quantities of unknown substances or substances which have inadequate toxicity data, if they belong to classes of chemical substances that contain harmful constituents, or if they have properties—such as high log P values—commonly associated with toxicity. At the same time, any such determination by FDA should be subject to rebuttal by a preponderance of the evidence, as is the case under present law. O'REILLY, *supra* note 370, § 9.01 at 9-7 n.39.

374. The Coalition for Consumer Health & Safety has made mandatory testing of seafood for toxic substances and bacteria one of its major priorities and has received the support of key congressional leaders including Senator Chafee and Congressman Waxman. *Consumer Safety Coalition Report Lists Priorities for Congress*, Daily Rep. for Executives (BNA) A-3 (Apr. 10, 1991). According to one report, 2.9 billion pounds of seafood are imported annually, one half the total U.S. consumption. Very little of it is ever tested. Ellen Haas, *Tighten Rules on Seafood Safety*, N.Y. TIMES, Feb. 27, 1992, at A-25. The FDA Commissioner, David Kessler, says he has made seafood toxicity a subject of regulatory focus. Michael Unger, *FDA's New Chief Is Carrying a Big Stick*, NEWSDAY, June 9, 1991, at C-10. Nevertheless, only 800 seafood samples were planned for testing in 1992 for industrial chemicals and pesticides, a doubling from 1991, but still a trivial percentage. Daniel P. Puzo, *FDA Inspection Finds 20% of Seafood Tainted*, L.A. TIMES, Feb. 27, 1992, at A-1.

375. 42 U.S.C.A. §§ 9601-9675 (West 1983 & Supp. 1993).

376. As CERCLA contains no statement of purpose or objectives, and the bill which was

and possibly harm, people by the venting of toxic gases, airborne dust, contact with contaminated soils, and several other pathways. In our experience, however, the primary concern of site managers assessing and carrying out cleanups has been with surface and ground water contamination.[377] Ground water constitutes by far the vast majority of available fresh water.[378] Contamination of ground water can pose risks to humans either because it provides drinking water from wells down gradient from the source[379] or because it recharges to surface waters. The contaminated surface water can then enter drinking water supplies. Exposed aquatic organisms could also bioaccumulate harmful substances contained in the water.

The National Contingency Plan required by CERCLA[380] specifies that when selecting a cleanup plan for former disposal sites[381] on the National Priorities List (NPL)[382]—in theory the worst cases—EPA (or the state if it is the lead agency) must address all hazards found at a site,[383] not just those hazards caused by listed substances.[384] Officials making cleanup decisions for contaminated ground water reduce bioaccumulation risks in two circumstances. First, listed high log P substances found in the ground water will be controlled for toxicity. Second, if the ground water is known to recharge to surface waters, site managers are required to assess the risk of human exposure from eating fish that

passed has virtually no legislative history, CERCLA's legislative purposes have to be inferred from its provisions and from the legislative history of earlier proposed bills.

377. The emphasis on surface and ground water contamination can be seen in the provisions of CERCLA requiring special health assessments of water contamination risks, 42 U.S.C.A. § 9605(c)(2), and placing high priority on sites that have contaminated drinking water supplies. 42 U.S.C.A. § 9618.

378. R. ALLAN FREEZE & JOHN A. CHERRY, GROUNDWATER 5 (1979); DAVID A. MILLER, WATER AT THE SURFACE OF THE EARTH 395 (1977).

379. Downgradient is the underground equivalent of downstream for surface waters (i.e., the direction toward which the water flows).

380. 42 U.S.C.A. § 9605; 40 C.F.R. § 300 (1992).

381. CERCLA imposes liability for response costs whenever there has been a "release" of a "hazardous substance." 42 U.S.C.A. § 9607(a)(4).

382. The new Hazard Ranking System used to decide whether to place a site on the NPL substantially takes bioaccumulation into account, at least for chemical substances that can be identified. *See* 40 C.F.R. § 300 app. A (1992), especially §§ 4.1.4.2.1.4, 4.1.4.2.3, 4.2.3.2.1.5, 4.2.4.2.1.4, & 4.2.4.2.1.5, and Tables 4-15, 4-21, 4-28, & 4-30. These provisions increase the score for a site if chemicals found there have a known high BCF or a high log K_{ow} (i.e., a high log P).

383. 40 C.F.R. § 300.430 (1992) requires that the assessment of cleanup alternatives must consider whether they adequately protect human health and the environment from "hazardous substances, pollutants or contaminants" present at the site, not just from the "hazardous substances" on the CERCLA list.

384. The CERCLA list contains the substances listed under the spill provisions of the CWA plus RCRA hazardous wastes and several other categories. 40 C.F.R. § 302.4 (1992). Nearly all these substances are listed because of concerns for toxicity.

may have bioaccumulated substances known to be in the ground water.[385]

The misleadingly titled Resource Conservation and Recovery Act[386] is the second important federal statute dealing with past disposal of hazardous waste. Specifically, RCRA mandates "corrective action" (cleanup) for all releases of hazardous waste from any facility involved in such wastes' treatment, storage, or disposal.[387] EPA requires the owners or operators to clean up all the hazardous constituents and decomposition products at the site to acceptable levels, not just to remove the RCRA designated hazardous wastes.[388] As with CERCLA, in our experience, EPA's primary concern in RCRA corrective actions has been the potential contamination of ground water.

Ground water cleanup actions under either statute raise common questions: What substances are located in the ground water and what hazards do they pose? Is ground water cleanup per se required?[389] If so, to what standard? At present, under either statute, if a substance is found at the site in measurable quantities, the first step is to see if it is subject to an applicable legal standard. If so, subject to certain feasibility limitations, that standard must be used.[390] If there is no such legal standard for that substance, a risk assessment is performed;[391] for carcinogens, acceptable risks to the most exposed individual are usually set by EPA or the state in the 10^{-4} to 10^{-6} range.

The log P screening technique should be run on ground water sam-

385. OFFICE OF EMERGENCY AND REMEDIAL RESPONSE, U.S. ENVTL. PROTECTION AGENCY, EPA/540/1-89/002, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I: HUMAN HEALTH EVALUATION MANUAL (PT. A) 6-6, 6-7 (1989).

386. 42 U.S.C.A. §§ 6901-6922k (West 1983 & Supp. 1993).

387. *Id.* § 6924(u). Frequently actual cleanup takes place at "closure," when the facility is no longer undertaking hazardous waste activities. RCRA is better known for its role in regulating current hazardous waste generation, treatment, and disposal. *See infra* part V.E.

388. 40 C.F.R. § 265.111(b) (1992).

389. At about one-quarter of the Superfund sites, the contamination has been addressed solely by containment (i.e., by preventing the percolation of water through the contaminated zone by using relatively impervious caps and slurry walls). U.S. ENVTL. PROTECTION AGENCY, A COMPARATIVE ANALYSIS OF REMEDIES SELECTED IN THE SUPERFUND PROGRAM DURING FY87, FY88, AND FY89, at 2-19 (1990). About two-thirds of the time some from of treatment is required. *Id.* Often, that involves "pump-and-treat" approaches—sometimes in conjunction with containment—where wells are sunk, and the contaminated ground water is pumped out and treated with biological, chemical, and/or physical techniques. The process can take years, decades, or even longer; as a result it is becoming increasingly controversial. *See, e.g.*, Randy M. Mott, *Aquifer Restoration Under CERCLA: New Realities and Old Myths*, 23 Env't Rep. (BNA) 1301 (Aug. 28, 1992).

390. EPA must follow any "applicable" or "relevant and appropriate" standards (ARAR's in CERCLA-speak) in implementing a cleanup, provided it is feasible to do so. 42 U.S.C.A. § 9621(d)(2)(A).

391. CERCLA requires, inter alia, that remedies selected by EPA be protective of human health and the environment. 42 U.S.C.A. § 9621(b)(1). To determine whether substances found at the site or in surface or ground water coming from the site could harm actually or potentially exposed persons, risk assessments are performed. *See supra* note 308.

ples from CERCLA and RCRA corrective action sites to determine if high log P substances are present in the ground water. No special technical issues are involved.[392] Nor would screening all ground water contamination sites add greatly to the administrative burden.

Where high log P substances can be identified and quantified, and where adequate toxicity data exist, EPA (or state) decisionmakers would do nothing different from what they currently do: they would apply any applicable standards. Where there are no such standards, a risk assessment would be performed, using current guidelines for deciding "how clean is clean." In short, the log P screening technique would make a modest contribution by providing additional data, but would require no new regulatory techniques.

To deal with cases where an unidentifiable or inadequately studied high or very high log P substance is found, we propose that EPA develop maximum concentration levels for high log P substances contained in the ground water. Where higher levels are found, treatment should be required to remove the substances down to the maximum concentration level, provided it is feasible to do so. These levels should vary depending on the log P value and the toxicity data for substances in the same chemical class.[393] The RCRA permittee or the CERCLA "potentially responsible parties" must be allowed to prove that the stringent treatment levels suggested by these rules of thumb are not necessary for their particular sites.[394] Similarly, EPA, the states, and the affected public should be allowed to prove that even more stringent standards are required.[395] Under CERCLA, the party proposing a standard for unknowns that differs from EPA's concentration limits should petition the decisionmaker, usually the EPA Regional Administrator, in time for consideration in the record of decision (ROD).[396] Doing so would prevent log P screening from further delaying a program already widely criticized for its slow pace.

The log P screening would also assist EPA decisionmakers in selecting a treatment technology. At present, we have noticed, site managers with ground water remediation problems generally choose among biolog-

392. The log P screening technique for testing potentially contaminated ground water would be no different than for testing treated effluents under the CWA.

393. When substances are found in very low concentrations, it is often far easier to establish the family of chemical substances to which they belong than to provide a precise identification. In our experience, this is particularly true for GC/MS, or for HPLC coupled with a mass spectrometer.

394. Less stringent standards might be appropriate at a given site, for example, where the only affected aquifer is so salty as to preclude its use as a drinking water source.

395. More stringent standards might be needed if an aquifer is a common drinking water source, or the ground water recharges in locations that contain sensitive natural environments, such as breeding areas for endangered, threatened, or commercially important species.

396. The ROD records EPA's decision on the nature of cleanup actions to be carried out at a contaminated site.

ical treatment, air stripping, activated carbon, a combination of these, or occasionally one of several newer technologies. A determination that the ground water contains any high log P substances requiring treatment would affect the selection of a treatment technology since in most cases activated carbon, either alone or in conjunction with other treatment, would then become the technology of choice. Finally, subsequent log P screening would help to verify whether the treatment, containment, and other measures undertaken at the site actually reduced or eliminated the contamination.

There should be few legal difficulties implementing these suggestions. EPA has broad authority to carry out investigations and could easily add a log P screen to the test methods currently required.[397] EPA also has express statutory authority to clean up unlisted pollutants.[398] In at least one way, our proposal potentially makes the situation easier for the responsible parties, by allowing them to prove a different standard is more appropriate than the one EPA proposes.[399]

Total nationwide testing costs for all CERCLA and RCRA sites under this proposal will not be insignificant, but for any given site, will be a small fraction of the total testing costs and a trivial fraction of the total costs to remedy site conditions.[400] At a typical site, dozens of ground water samples are taken, and subjected to GC, GC/MS, and other analyses. Selecting a portion of these samples, compositing them,[401] and doing a log P screen procedure on the composite sample should add roughly $2500 to the total cost of the remedial investigation of the site. In our experience, the total remedial investigation frequently costs hundreds of thousands of dollars.

Estimating cleanup costs is more difficult. We expect there will rarely, if ever, be a site that will require cleanup solely by virtue of substances discovered by the log P screening technique.[402] Consequently,

397. *See, e.g.*, 40 C.F.R. § 264.97 (1992), for an illustration of EPA's broad authority under current regulations to order testing of ground water.

398. *See supra* notes 383-84 and accompanying text.

399. EPA would, of course, need to comply with all the substantive and procedural requirements of CERCLA and the NCP, or of RCRA and its implementing regulations.

400. Indeed, by having a method of assessing and dealing with the single most dangerous class of unknowns, EPA will be in a better position to show the public that its health is being adequately protected. In the end, this may allow for somewhat *less* expensive cleanups.

401. Often at a CERCLA or RCRA site, it is important to know which aquifers are contaminated, the exact dimensions of the contaminant plume, the direction of the plume's movement, and other information. That requires a chemical analysis of each sampling well. For our purposes, however, all we really need to know is whether there are high log P substances present in the site's ground water. For that purpose, the various well samples can be combined, and this composited sample can be tested. This process greatly reduces testing costs.

402. At a typical site, many different kinds of hazardous waste were disposed of, often from many different waste generators. Such sites often have dozens or even hundreds of hazardous waste constituents. In a few cases, sites are on the NPL or equivalent state lists primarily because of high log P substances, usually PCB's or coal tar. We would not rule out the

the appropriate cost consideration in nearly all cases will be the incremental expense, if any, of removing these high log P substances from the ground water. The treatment technology selected to remove the high log P substances from the ground water will sometimes cost more and sometimes cost less than air stripping, the other technology commonly used to clean up contaminated ground water.[403] Even if carbon treatment is more expensive than air stripping or some other alternative, it will be a very small percentage of total remediation costs at the site.[404]

E. Waste Management Under RCRA

RCRA[405] has the goals of reducing or eliminating the generation of hazardous waste, and of assuring that waste which is generated is stored, treated, and disposed of in a manner that minimizes environmental and health risks.[406] RCRA imposes on those who generate and handle hazardous waste a "cradle-to-grave" system of records,[407] and elaborate controls on the facilities which treat, store or dispose of hazardous waste.[408] The statute defines a hazardous waste in part as "a solid waste, or combination of solid wastes, which because of its quantity, concentration or physical, chemical, or infectious characteristics may . . . (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, transported, or disposed of, or otherwise managed."[409] By itself, this definition is probably broad enough to include all high log P substances that could be extracted from a waste in measurable

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hypothetical possibility that EPA or a state would think a site was contaminated, and begin the remedial investigation stage, only to discover that no hazardous substances were being released except for high log P substances found by the high log P screening technique. However, that seems highly improbable. It is more likely that the log P screen would detect additional substances at an already identified site and that, in some of these cases, the kind of treatment technology to be used will be changed as a result.

403. Generally speaking, carbon treatment will be somewhat more expensive than air stripping if the air stream containing the stripped organics can be freely released to the air. However, if the air stream itself requires carbon or thermal treatment to prevent excessive quantities of the same toxic organics being released to the air, then the use of carbon to treat the water in the first place can be cheaper.

404. Protecting the ground water at a site usually requires some kind of containment structures (e.g., caps and slurry walls) to keep rain water from entering the contaminated zone. Anywhere from a handful to scores of wells are needed to intercept, collect, and transport the contaminated ground water plume to the surface for treatment. The costs of these measures often dwarf the cost of treating the ground water.

405. 42 U.S.C.A. §§ 6901-6922k (West 1983 & Supp. 1993).

406. *Id.* § 6902(b).

407. *Id.* §§ 6922, 6923.

408. *Id.* §§ 6924, 6925.

409. *Id.* § 6903(5) (emphasis added). The requirement that to be a hazardous waste, the waste must first be a *solid* waste, does not significantly limit the class, as the term solid waste is defined to include "solid, liquid, semisolid, or contained gaseous material" from nearly all industrial, commercial, mining, or agricultural operations. *Id.* § 6903(27).

quantities; any high log P substance *may* pose a *potential* hazard to either human health or the natural environment.

For most purposes relevant to toxicity, a waste becomes a hazardous waste, thus triggering the other features of RCRA, in one of two ways. First, a waste type may be placed on a list of hazardous wastes promulgated by EPA (a "listed waste").[410] Alternatively, a waste may be tested (usually by the waste generator) and found to possess one of the four designated characteristics of a hazardous waste (a "characteristic waste").[411]

Under RCRA, EPA must consider "potential for accumulation in tissue" when deciding whether to add a particular kind of waste to the listed waste category.[412] In its initial 1978 proposal for listed wastes, EPA identified nine different classes of wastes that could be listed, including wastes containing substances that could bioaccumulate. However, EPA did not adopt the rule in that form, and current RCRA regulations do not expressly list any waste on that basis.[413] It is unclear to what extent, if any, EPA is living up to this congressional mandate to consider bioaccumulation potential when it makes individual listing decisions.

Characteristic wastes are arguably more important than listed ones as a means of identifying the hazardous wastes; even if a waste is not listed, it is hazardous if it displays one of the four characteristics.[414] Bioaccumulation is *not* one of the four characteristics currently designated by EPA, although in 1978 the Agency announced that it was planning to add bioaccumulation as a characteristic, and proposed a test method.[415] In 1980, however, EPA reversed itself, announcing that it would not add bioaccumulation or any of several other characteristics. EPA's stated reasons for this reversal were, in our opinion, conclusory and undocumented.[416] The real reasons may have been political.[417] We

410. 40 C.F.R. §§ 261.30-.35 (1992).

411. For our purposes, toxicity is the only relevant characteristic. *Id.* § 261.24. *See* the description of the TCLP test *infra* notes 419-22. The three other existing characteristics are ignitability (ability to catch fire unusually easily), reactivity (ability to explode), and corrosivity. 40 C.F.R. §§ 261.21-.23.

412. 42 U.S.C.A. § 6921(a).

413. *Compare* 40 C.F.R. §§ 250.14-.15 as initially proposed in 43 Fed. Reg. 58,946, 58,957-60 (1978) *with* the current regulation at 40 C.F.R. §§ 261.30-.33 (1992).

414. There are probably tens of thousands of unique industrial waste streams and only a few hundred of these are currently listed as RCRA hazardous wastes through the listing processes. As a consequence, EPA relies heavily on the characteristic wastes to determine which of the remainder really pose hazards.

415. *See* 43 Fed. Reg. 59,022, 59,022-27 (1978).

416. At the time, EPA justified its decision not to add organic toxicity, mutagenicity, teratogenicity, phytotoxicity, and bioaccumulation to the set of characteristics of a hazardous waste on the ground that "the properties defining the characteristic [must] be measurable by standardized and available testing protocols." 45 Fed. Reg. 33,084, 33,105 (1980). It said, without further explanation and without providing any supporting data, that it "considered

believe it would have been possible to promulgate technically sound test methods in 1980 that allowed the use of bioaccumulation as a hazardous waste characteristic. In any event, in the 1984 amendments to RCRA, Congress ordered EPA to add additional hazardous waste characteristics.[418] To date, EPA has not done so.

If EPA adds potential to bioaccumulate as a characteristic, a variation on the log P screening technique could serve as the test method.[419] EPA's Toxicity Characteristic Leaching Procedure (TCLP) provides a ready mechanism to obtain an extract of any waste.[420] The TCLP requires subsequent analyses of that extract for certain organics and met-

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the available test protocols for measuring these characteristics to be either insufficiently developed or too complex and too highly dependent on the use of skilled personnel and special equipment." *Id.* Finally, EPA "did not feel that it could define with any confidence the numerical threshold level at which wastes exhibiting these characteristics would present a substantial hazard." *Id.*

417. One environmental advocate has argued that the real reason why additional characteristics, including bioaccumulation, were not added after they were originally proposed was the strong mood of deregulation in the White House in the waning years of the Carter administration. Sidney M. Wolf, *Hazardous Waste Trials and Tribulations*, 13 ENVTL. L. 367, 369-75 (1983). We are not in a position to evaluate that assertion as a historical evaluation of agency motives, except to note that in 1980, the technical merits of EPA's argument opposing the adoption of additional characteristics were substantially stronger for some proposed characteristics (teratogenicity, for example) than for bioaccumulation. In any event, analogous arguments would not stand close scrutiny now when the science is far stronger, particularly since EPA is urging the states to impose permit conditions using similar test methods in the CWA context.

418. 42 U.S.C.A. § 6921(h).

419. To list an additional hazardous waste characteristic, EPA need not demonstrate that the characteristic is as important as the existing characteristics. In any case, in implementing RCRA, EPA appears to be primarily concerned about toxicity. EPA's various lists of hazardous waste, found in 40 C.F.R. §§ 261.30-.33 (1992), rarely include a waste unless it involves toxicity. For example, of the approximately 90 "K" wastes, three are regulated for reactivity, nine for toxicity and some other characteristic, and the rest for toxicity alone. *Id.* Toxicity is also the basis of our concern about bioaccumulating substances. It does not follow that we should attempt to deal with bioaccumulation by dealing with toxicity. In testing to decide whether something violates the characteristic of toxicity, and thereby becomes a "characteristic" waste, EPA uses the TCLP procedure, *see infra* notes 420-21, to determine if an extract of the waste contains one of a short list of a toxic substances in concentrations above allowed amounts. The *vast* majority of toxic substances on the RCRA hazardous constituents list would not cause a waste to be considered toxic under the TCLP procedure irrespective of its concentration. A far larger number of toxic substances are not on the list. As a class, highly bioaccumulative substances are probably as important as this one narrow subset of the whole toxicity problem that EPA currently uses. Even if they were not, it is more efficient to consider the class of bioaccumulating substances collectively, than to deal with them individually under the general heading of toxicity.

420. The technical features of the TCLP procedure are detailed in 40 C.F.R. § 261 app. II (1992).

als.[421] Performing the log P screen on a portion of that extract would not present any technical difficulties.[422]

EPA has ample statutory authority to regulate on the basis of bioaccumulation potential, though the situation differs between listed wastes and characteristic wastes. The statute already requires the Agency to consider bioaccumulation in deciding whether to list a waste as hazardous,[423] and no new regulations are needed for it to do so. As for characteristic wastes, RCRA gives the Agency the authority to add potential to bioaccumulate, or similar language, to the existing four characteristics. Moreover, Congress has ordered EPA to consider adding other characteristics.[424] Adding bioaccumulation as a characteristic of a hazardous waste is important enough that if EPA fails to act promptly, Congress should remedy the problem by legislation. Once potential to bioaccumulate becomes a characteristic of hazardous wastes, EPA should adopt a regulation requiring log P screening in the manner we have recommended.[425]

Determining the threshold concentration of high log P substances that would trigger their regulation as hazardous wastes would be rela-

421. Under the TCLP, a waste is hazardous by virtue of toxicity if an extract from the waste contains more than the stipulated concentrations of any of eight metals, eight pesticides or 23 non-pesticide organic toxic substances, a few of which are high log P substances. *Id.* § 261.24. The TCLP replaced an older extraction procedure (EP toxicity) that did not test for any non-pesticide organics.

422. The TCLP generally requires two liters of extracting fluid. *See id.* § 261 app. II. In our experience, nearly all the extracting fluid is recovered and available for use in laboratory analysis. That should provide more than enough sample to run the log P screening technique, assuming that the screen only requires one liter. *See supra* note 151. Even if our conclusion is incorrect, having only one liter available rather than 10 would only slightly reduce the sensitivity of the procedure; it could not detract from its validity, though there would be more false negatives. It should be noted that in any event, no such problem arises if the waste is a liquid, since a full 10 liter sample could be tested.

423. 42 U.S.C.A. § 6921(a). EPA was also required to assess "propensity to bioaccumulate" when making decisions on land disposal prohibitions for the so-called "California list" wastes. *Id.* § 6924(d)(1).

424. *Id.* § 6921(h).

425. The RCRA regulations do not literally require testing of each waste to prove it is not a "characteristic" hazardous waste. A generator may rely instead on its knowledge of the waste's characteristics. However, the penalty, cleanup, and liability costs to the generator of being wrong could exceed the gross national product of many nations. Disposing of a hazardous waste as if it were nonhazardous would be a violation of RCRA, and could subject the violator to civil penalties of up to $25,000 per day. If a facility improperly disposed of hazardous waste every day for a year, it could, at least in theory, face a fine of as much as $9,125,000. *Id.* § 6928(g). Moreover, a knowing violation could result in criminal penalties of $50,000 per day, as well as jail time. *Id.* § 6928(d). Failure to obtain information could, under the terms of the statute, constitute circumstantial evidence of knowledge for the purposes of determining if the violation met the state-of-mind test. *Id.* § 6928(f). In addition, the place of improper disposal would be subject to the statute's corrective action requirements, including those beyond the facility boundary, *id.* § 6924(u)&(v), which can involve cleanups as expensive as CERCLA remedial action. Finally, if the waste caused harm to other persons or property, an attorney for the plaintiffs bringing a toxic tort action would likely be delighted to learn that the disposer had failed to perform the RCRA test for the toxicity characteristic.

tively easy for known substances that have adequate toxicity information.[426] EPA could use the same method it used to set levels for the toxicity characteristic.[427] For unknown substances, we propose that EPA use the same maximum contaminant levels that we proposed for treated ground water from CERCLA sites.[428] These levels could then be utilized in EPA's computer model to extrapolate presumptively unsafe threshold levels. Any wastes containing unknown high log P substances over the threshold level would be considered a hazardous waste subject to RCRA handling and disposal requirements. The waste generator should have the right, however, to rebut the presumption that the waste is hazardous by showing that it is not harmful, or that it does not pose unacceptable risks.[429]

426. A question would arise as to how the toxicity and bioaccumulation characteristics would relate. This is less a problem than it might first appear, as the situation can arise now with the existing characteristics. Thus, a waste containing large amounts of lead in an acid solution could be hazardous by virtue of both the corrosivity and toxicity characteristics. The general rule under RCRA is that a substance which is a hazardous waste because it meets the terms of one of these characteristics remains a hazardous waste as long as it has either characteristic. Thus, if the acid/lead mixture has lime added to it as a form of treatment to neutralize the acid, it would no longer be a corrosive waste, but it might still be hazardous because of the toxicity characteristic. If bioaccumulation were added as a characteristic, the result would not be different. A waste that failed the TCLP test because it contained an identified high log P substance in quantities above the cutoff might be hazardous because of toxicity, and then if it met the definition of bioaccumulation, be hazardous for that reason as well. In that case, no additional requirements would need to be met. On the other hand, it is possible that a waste that passed the TCLP would not pass the new bioaccumulation test. In that event it would have to be handled, treated, and disposed of as a hazardous waste.

427. In establishing the existing regulations for the toxicity characteristic, EPA first determined the level of a substance that would cause adverse health effects to the most exposed individual. A 100-fold attenuation (dilution) factor was then used to extrapolate levels of these substances that would not be safe if contained in a waste and improperly disposed of in a nonhazardous waste landfill. *See* 45 Fed. Reg. 33,084, 33,110-12 (1980). At best this dilution factor was a crude guess, and beginning in 1985, EPA shifted to a computer model to do some of these extrapolations. The HVS computer model for calculating the horizontal and vertical spread of a pollutant in ground water is explained at 50 Fed. Reg. 7882, 7896-7900 (1985). Examples of its use in generating compliance-point levels are detailed at 50 Fed. Reg. 48,886 (1985). EPA has since proposed a newer computer model, the EPACML. 56 Fed. Reg. 32,993 (1991). There would be no difficulty utilizing the same computer model to establish the concentration that would render a waste hazardous by virtue of a new bioaccumulation characteristic for those high log P substances whose identity could be established and whose toxicity is well characterized. Indeed, EPA has already taken an analogous step for delisting RCRA wastes for CERCLA purposes, setting maximum allowable concentrations for approximately 185 hazardous constituents. These were "back-calculated" from health-based values using the HVS model. U.S. ENVTL. PROTECTION AGENCY, A GUIDE TO DELISTING OF RCRA WASTES FOR SUPERFUND REMEDIAL RESPONSES, *reprinted in* ALFRED R. LIGHT, CERCLA LAW AND PROCEDURE COMPENDIUM (BNA) II-419, II-421 to II-422 (1992). Several high log P substances were included.

428. *See supra* notes 324-25. These levels would reflect both the log P of the substance and the toxicity of other substances in the same chemical class.

429. In the vast majority of cases, doing so would require the generator to identify the high log P constituent(s) and test to determine their toxicity. Given the difficulties of proving a negative, the burden of establishing that the waste is safe (posing no risk or an acceptable risk) should be the preponderance of the evidence standard. *See supra* note 302.

Conducting the high log P screening test would not add significantly to the testing costs already incurred by hazardous waste generators.[430] The additional handling, treatment, and disposal costs resulting from the screen's identification of some additional substances as hazardous waste, while impossible to specify, would be considerable.[431]

F. Safe Drinking Water Act

The Safe Drinking Water Act[432] is designed primarily to protect users of public water systems from contaminants that may adversely affect human health.[433] Such contaminants are not limited to toxic substances; indeed, much of the effort under the statute has been to control waterborne bacteria and other pathogens.[434] To regulate toxic substances under the SDWA, EPA first establishes a nonbinding health-based objective, the maximum contaminant level goal (the MCLG).[435] MCLG's are often very stringent, and for carcinogens and lead have arbitrarily been set at zero. EPA then sets the maximum contaminant level (the MCL) for that substance as close to the MCLG as is feasible,[436] generally using best technology.[437]

The SDWA and its regulations do not take bioaccumulation into account. The SDWA itself makes no reference to bioaccumulation or to log P. However, the legislative history of the original act made clear that EPA was expected to regulate both individual substances and chemical groups; the history specified PAH's, which generally have high to very

430. Using the log P screening technique in this manner should not be more expensive than under the CWA.

431. Wastes that become defined as hazardous wastes by virtue of this proposal would normally be disposed of in RCRA-permitted hazardous waste landfills. (Most high log P substances, if mixed with carbonaceous material to reduce their mobility, will receive adequate protection in hazardous waste landfills that meet RCRA's fairly stringent conditions.) In that case, the additional disposal cost would be considerable. If, on the other hand, EPA decides to declare any of the substances to be listed wastes subject to a land ban, treatment would be required prior to land disposal. 42 U.S.C.A. § 6924(d)-(m). A common method of treatment would be incineration, which for most hazardous wastes requires 99.99% destruction efficiency. 40 C.F.R. § 264.343(a)(1) (1992). EPA might go further and require "six nines" incineration (99.9999% destruction), as it does for certain waste streams that often contain dioxins, *id.* § 264.343(a)(2) (1992), but curiously not for pure liquid PCB's under TSCA regulations, which only require 99.9% destruction efficiency. 40 C.F.R. § 761.70 (a)(2) (1992). Six nines incineration would considerably increase disposal costs and, in our view, could be justified only in highly unusual cases.

432. 42 U.S.C. §§ 300f-300j-26 (1988).

433. The Act was designed to assure that persons served by public water supplies would be provided high quality water; it set national drinking water standards on substances that could harm human health.

434. Reflecting that concern, the SDWA implementing regulations set MCLG's for *Giardia, Legionella,* viruses, and total coliforms at zero. 40 C.F.R. § 141.52 (1992).

435. 42 U.S.C. § 300g-1(b)(3).

436. *Id.* § 300g-1(b)(4).

437. *Id.* § 300g-1(b)(5) (defining feasible as the use of best technology, treatment techniques, and other available means, taking cost into consideration).

high log P values, as an example of chemicals which should be regulated as a group.[438] Despite this congressional concern, EPA has done little to regulate high log P substances under the SDWA. EPA's inaction reflects a larger failure to deal decisively with toxic organics. As late as 1992, EPA had only established MCL's for total trihalomethanes and five specified organics, including some pesticides.[439] That year, under pressure from Congress,[440] EPA added eight organics—none of which were high log P substances—to the list of substances for which it had published MCL's.[441] At present, there are thirty-six organic contaminants for which EPA has set MCL's.[442] EPA plans to add MCL's for additional toxic organics, but its pace has been glacial.[443]

In our view, this is a woefully inadequate regulatory effort. Because there has never been comprehensive testing for non-pesticide organics, let alone for high log P substances,[444] we have no way of knowing whether drinking water contains high log P substances and, as a result, poses significant human health risks. We do know, however, that all the drinking water governed by the SDWA[445] comes either from surface water or

438. H.R. REP. NO. 1185, 93d Cong., 2d Sess. (1974), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6463-64.

439. 40 C.F.R. § 141.12 (1989).

440. *See infra* notes 443, 460.

441. 40 C.F.R. § 141.62 (1990).

442. 40 C.F.R. § 141.61 (1992).

443. The 1986 SDWA amendments required EPA to promulgate national primary drinking water standards for a list of additional inorganic and organic contaminants. 42 U.S.C. § 300g-1(b). EPA then proposed to set MCL's and MCLG's for 18 additional organics, mostly volatile industrial chemicals, including several high log P substances. 55 Fed. Reg. 30,370, 30,371 (list of organics), 30,384-30,409 (MCLG's), 30,412-14 (MCL's) (proposed July 25, 1990). Although EPA was under a statutory deadline of January 1, 1991, and a judicial deadline of June 30, 1993, to complete the program, the Agency has not even scheduled final action of the last phase until December 1996. EPA Semi-annual Regulatory Agenda, 58 Fed. Reg. 56,998, 57,036 (1993).

444. No systematic testing has been done to determine the extent to which there is a problem with high log P substances in drinking water, though a 1984 report by the Office of Technology Assessment found ground water nationwide polluted by over 200 contaminants. *OTA Calls for National Groundwater Program with "Sustained" Federal Funding for States*, 15 Env't Rep. (BNA) 1053, 1053 (1984) [hereinafter *OTA Calls for National Groundwater Program*]. EPA has only recently completed the first systematic national sampling of drinking water wells checking for significant concentrations of pesticides. The results were mixed. A total of 564 community wells and 783 rural domestic wells were sampled. Ten percent of the former and four percent of the latter showed detectable levels of at least one pesticide, but only one percent of the wells exceeded levels EPA considers protective of human health. 14 Chem. Reg. Rep. (BNA) 1245, 1245 (Nov. 16, 1990). No comparable research effort has been undertaken with respect to non-pesticide organics in wells, or for organics in surface waters used as drinking water sources. Thus, neither we nor the regulatory authorities are in a position to declare whether there is a problem, and if so, how widespread and severe. We would predict that extremely low levels of high log P substances in drinking water are common. As for more significant concentrations, we expect the problem is not widespread, but that there are some drinking water systems delivering high log P substances in excess of 10 ppb.

445. By its terms, the SDWA regulates "public" drinking water systems. 42 U.S.C. § 300f(1), (4). It does not regulate drinking water wells used by individuals.

ground water.[446] Both of these sources are potentially—and often actually—contaminated.

A regulatory scheme to control high log P substances under the SDWA would be fairly simple. The Agency could initially require the public water suppliers serving the most customers to perform a log P screening test on their water, with additional tests performed every five years for large systems and annual tests for the largest.[447] Where high log P substances are found above a *de minimis* cutoff,[448] the public water supplier would be required to remove them with granular activated carbon,[449] to the feasible level.[450] If the water supplier could prove that the substance in fact does not pose an unacceptable level of risk, however, it would not be required to remove that substance.

There are no technical obstacles to the log P screening of drinking water.[451] Moreover, test sensitivity should be at least as high for drinking water as for wastewater and contaminated ground water.[452]

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446. About half of the public receives its drinking water from ground water. *OTA Calls for National Groundwater Program*, *supra* note 444, at 1053.

447. Entities serving as few as 15 customers or 25 individuals can qualify under the SDWA as public water suppliers and be subject to terms of the SDWA. 42 U.S.C. § 300f(4). For such small entities, a $2500 screening cost could be prohibitive. Accordingly, a blanket exception to the log P screening requirement should be made for suppliers serving fewer than 500 customers. Relatively small suppliers (e.g., those serving fewer than 5000 customers) should also be exempt unless EPA or the states suspect high log P substances might be present. In that case perhaps the regulatory authorities should pay for the initial test.

448. EPA should establish such a *de minimis* level based on the log P screening technique's sensitivity limitation, and the feasibility of removal; because the MCLG's are set artificially low, feasibility becomes the dominant consideration under the statute. Such a *de minimis* level would not be an MCL, but rather a limit on test-result reporting. The level might vary with the log P. Strictly by way of illustration, EPA might set the *de minimis* level at < 10 ppb for substances with log P values between 3.5 and 5.5, and < 1 ppb for substances with log P values at or above 5.5. The *de minimis* limits might alternately be set on peak height, rather than concentration per se.

449. EPA lists GAC or packed tower aeration (PTA) as the "best technology" for all organic contaminants, except vinyl chloride, for which MCL's have been established. 40 C.F.R. § 141.61(b) (1992). Activated carbon is especially useful in contexts like the SDWA where the water is already fairly pure (at least compared with treated effluents or contaminated ground water). With a dirtier matrix, the carbon removes substances one may not care about, greatly increasing carbon utilization rates. ECKENFELDER, *supra* note 218, at 270-71 (exhaustion of carbon occurs sooner with increased initial solute concentration).

450. There is no legal authority to regulate contaminants under the SDWA at levels below the feasibility level, even if that level is not protective of human health. *See infra* note 471.

451. As explained *supra* notes 151-54 and accompanying text, samples of treated wastewater need to go through several preparatory steps before they can be inserted into the HPLC equipment; otherwise the equipment could foul. This is because even well-treated wastewater can have suspended solids, tiny particles of waste matter, silt, fragments of dead treatment bacteria, etc. Drinking water is comparatively free of such materials, and while no step can be omitted, the technician may have less work to do to prepare the sample.

452. There are no difficulties with sample size with drinking water; a full 10 liters can be used to begin the concentration phase. Moreover, the detectors are best able to differentiate substances when the matrix is clean, as here, in contrast to highly contaminated samples, as might be found at some former hazardous waste sites.

The legal situation is somewhat less certain. The SDWA authorizes the EPA Administrator to set an MCLG and issue a national primary drinking water regulation for each "contaminant," which "in the judgment of the Administrator, may have any adverse effect on the health of persons and which is known or anticipated to occur in public drinking water systems."[453]

The statute defines contaminant[454] as "any physical, chemical, biological or radiological substance or matter in water."[455] It is hard to imagine what that definition does not cover. Clearly, any identified substance in drinking water, irrespective of its log P value, is a contaminant. It might be argued that a mere high log P value itself is not a "substance," and therefore not a "contaminant." No court has addressed this point, but the argument is analogous to the theory rejected by the courts, that "toxic substances" are pollutants under the CWA, but "toxicity" is not.[456] The argument is even weaker in the SDWA context. High log P substances clearly are contaminants under the SDWA, because each peak detected by the log P screening technique represents one or more individual chemical substances in the water. That fact does not depend on whether the substances are identifiable.

To regulate such contaminants, the EPA Administrator must first determine that they "*may* have *any* adverse effect on the health of persons."[457] As we documented in part II, all high log P substances for which there are adequate toxicity data pose potential risks to human health at low concentrations, at least to the extent that an adverse effect from a high concentration dose in laboratory animals predicts an increased risk of human health effects at low doses. Given that fact, it would not be unreasonable for the Administrator to find that any high

453. 42 U.S.C. § 300g-1(b)(3)(A).

454. The Act's legislative history suggests that the use of the singular "contaminant" in the statute should not preclude the regulation of high log P substances as a group and that the regulation of unknowns and substances with inadequate toxicity data is important: "[T]he Committee anticipates that the Administrator will establish primary drinking water regulations for some groups of contaminants, such as organics and asbestos. The establishment of such group-wide regulations should help to assure that the public health will be protected from currently undiscovered, unidentified or underresearched subgroups or specific contaminants within the group." H.R. REP. NO. 1185, 93d Cong., 2d Sess. (1974), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6463.

455. 42 U.S.C. § 300f(6).

456. *See supra* note 336 and accompanying text.

457. 42 U.S.C. § 300g-1(b)(3)(A) (emphasis added). Since virtually every substance is toxic in some concentration, taking the terms "may" and "any" in the statute too literally would allow regulation of virtually all chemical substances. It is doubtful that is what Congress intended. On the other hand, Congress did not expect too much proof of harm as a condition of regulation: "[T]he Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the Administrator make a reasoned and plausible judgment that a contaminant *may* have such an effect." H.R. REP. NO. 1185, *supra* note 454, at 6463.

log P substance *may* have some adverse effect on human health, particularly if that determination were expressed in the form of a rebuttable presumption.

A third issue is somewhat more troublesome. Congress required the Administrator to promulgate primary drinking water regulations for those contaminants "known or anticipated to occur in public drinking water systems."[458] The exact purpose of this provision was not stated. The courts would likely uphold regulations based on log P screening for several reasons. First, the regulations would only impose treatment requirements on those public water systems actually containing high log P substances. A court might have little patience with a party pleading for relief from measures reasonably necessary to protect the public health, because a substance that is in fact in its water was not previously "known" or "anticipated." Second, as under the CWA and other environmental and public health statutes, courts generally defer to administrative agencies.[459] Third, only the most rigidly textualist jurists are likely to see the provision as a limitation on the Agency since its purpose was to spur more action. As the legislative history makes clear, Congress was irritated by EPA's lack of progress in setting primary drinking water standards, and wanted more aggressive regulation of substances already known to be in drinking water.[460] Finally, and perhaps most importantly, we believe EPA could put together a good case that high log P substances as a class meet the "known or anticipated" test. We doubt that EPA could prove they were "known" to be in drinking water, but the case for them being "anticipated" seems strong. Despite the current controls under the CWA, high log P substances are being discharged into surface waters.[461] Some of those discharges are above the intakes for drinking water. Floods can scour streambed sediments containing high log P substances, causing some of the material to be resuspended. High

458. 42 U.S.C. § 300g-l(b)(3)(A). The legislative history is silent on the specific point. However, *see infra* note 460 and accompanying text.

459. There has been very little litigation on the SDWA and none on point. In the one key SDWA case that addressed the evidence needed to determine whether a substance was a carcinogen meriting a "zero" MCLG, the court was at least as deferential to EPA's determination on technical matters as courts have been under other EPA-administered statutes. NRDC v. EPA, 824 F.2d 1211 (D.C. Cir. 1987) (court accords virtually total deference to EPA decision to treat trichloroethylene, and not vinylidene chloride, as a carcinogen, though the scientific evidence as to each was equivocal.). Similarly great deference was shown to the Agency's scientific determinations on carcinogenicity and on the technology to be used in detecting and measuring PCB's in International Fabricare Inst. v. EPA, 972 F.2d 384, 400 (D.C. Cir. 1992) ("As we are not scientists and must defer to the Agency's judgments on matters within its technical competence, our task is to assure that they be reasoned, not that they be right.").

460. "The greatest problem with implementation of the program established by the Safe Drinking Water Act is the failure of EPA to issue standards for most contaminants known or anticipated to be found in drinking water." S. REP. NO. 56, 99th Cong., 2d Sess. 5-6 (1985), *reprinted in* 1986 U.S.C.C.A.N. 1566, 1570-71.

461. *See supra* notes 280-85 and accompanying text.

log P substances can reach surface waters used as drinking water supplies via air transport.[462] Many of the tens of thousands of present and former hazardous waste disposal sites in the United States[463] release high log P substances.[464] The underlying ground water in many of these areas is upgradient of drinking water wells, or recharges to surface waters used for drinking. Thus, EPA can certainly anticipate that high log P substances are in drinking water.[465]

A final potential legal problem is that the Act generally requires the Administrator to establish an MCLG for a substance based on a knowledge of adverse health effects with an ample margin of safety. As previously explained, the legally binding MCL for that substance must then be set as close to the MCLG as is technically and economically feasible, using best technology.[466] The Administrator probably could not do so in many cases, without knowing the substance's identity. Where it is impossible to ascertain the level of the contaminant, however, another provision gives the Administrator the authority to specify a required treatment technology instead of an MCL.[467] Congress determined that granular activated carbon is a feasible best technology for removing synthetic organic chemicals.[468] That technology should effectively remove high log P substances, many of which are synthetic organics,[469] from drinking water.[470]

If EPA is unable or unwilling to take these steps, Congress could adopt new legislation requiring the Agency to regulate all high log P substances detected in a sample of drinking water, regardless of whether they can be identified or whether EPA knew or anticipated the substances would be in drinking water generally. The legislation should allow EPA to specify treatment technologies in lieu of setting MCL's for categories of substances it considers generally harmful, even when spe-

462. *See infra* notes 517-23 and accompanying text.

463. An OTA study that was widely cited during the 1985 CERCLA reauthorization, stated that there may be 10,000 potential superfund sites. *See, e.g.*, Patrick Crow, *Congress Eyes "Superfund" Extension,* OIL & GAS J., Sept. 2, 1985, *available in* LEXIS, Nexis Library, OMNI file. Many observers now consider that number to be low. The National Research Council tallied over 200,000 potential sources of ground water contamination, not counting several million more associated with petroleum extraction, refining and distribution. NATIONAL RESEARCH COUNCIL, GROUND WATER MODELS Table 1.1 (1990).

464. *See supra* notes 376-84 and accompanying text.

465. Of course, because high log P substances have low solubilities, we would not usually anticipate high concentrations in solution. The high log P substances are more likely to be attached to fine particles suspended in the water.

466. 42 U.S.C. § 300g-1(b)(4), (5).

467. *Id.* § 300g-1(b)(7)(A).

468. *Id.* § 300g-1(b)(5).

469. If carbon is required to remove those high log P substances that are synthetic organics, it would also remove those occurring naturally.

470. If a drinking water supplier uses carbon technology, it has done all that the statute requires. Routinely requiring the use of carbon would be unnecessarily expensive.

cific substances cannot be identified. Congress should also authorize EPA to establish *de minimis* levels for which no action would be necessary.[471] However, obtaining congressional authorization for such changes is problematic, at least in the short run.[472]

EPA could alternatively begin a nationwide screening of public drinking water systems for high log P substances similar to its recent screening of wells for pesticides.[473] Based on the results, EPA could declare whether high log P substances are in fact known or anticipated to be in drinking water, and proceed to regulate. We find this alternative overly cautious as a matter of regulatory policy and potentially risky in terms of the protection of human health, but preferable to the existing situation.

Costs under our proposal would consist primarily of testing costs if, as we anticipate, systems with log P values above a *de minimis* level are uncommon.[474] For large drinking water suppliers, serving hundreds of thousands or millions of customers, an annual expenditure of $2500 for each source—to assure that it does not contain high log P substances—is a modest cost indeed. Surely a per capita cost of one cent per year or less[475] is trivial. We suspect that few people, if any, would object even if the annual testing cost were as high as one dollar per capita.

Significant costs to drinking water suppliers arise under our proposal only if high log P substances are found. Gauging those costs for a typical case is not possible because there are so many variables, including the system's size and water quality, the volume of the high log P substance,[476] and the presence of other kinds of organic chemicals.[477] If

471. Since pollutants in drinking water supplies are usually not the fault of the water supply company, Congress may wish to consider strengthening the rights of water suppliers against those who intentionally contaminate their supplies. In an analogous situation under CERCLA, Congress created a federal right of contribution far stronger than was available under most state laws. *See* 42 U.S.C. § 9613(f)(1) (1988). It should create a federal cause of action on behalf of public water suppliers against any source of pollution that requires removal under the SDWA, whether or not as a result of new controls on high log P substances, even if the release of the pollutants to the environment is otherwise lawful.

472. Congress made major changes in the SDWA in 1986, Pub. L. No. 99-339, 100 Stat. 642, largely because it thought that EPA had not been vigorous enough in promulgating standards. *See supra* note 460. There seems to be little congressional interest in making further changes in the statute.

473. *See supra* note 444.

474. We would exempt the smallest public water suppliers because the testing costs are likely to exceed the benefits. The likelihood of a problem with high log P substances does not increase for larger water supply systems. Rather, the testing cost as a function of total revenues drops precipitously. Also, the number of people who might be exposed if high log P substances come into the large systems is much greater than for smaller systems.

475. This would be the cost, for example, of testing four sources annually for a system serving one million customers, or one source every five years for a system serving 50,000 people.

476. Average removal rates for a given substance will be a function of carbon usage. Thus, to determine carbon usage, it will be necessary to know, inter alia, how much of the substance

other organic chemicals must be removed, the incremental cost of removing the high log P substances may be small.[478]

G. Occupational Health and Safety Act

The greatest human exposure to toxic chemicals occurs in the workplace.[479] Congress adopted the OSH Act,[480] "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions."[481] While concerned primarily with the physical safety of workers at a job site, the Act focuses substantial attention on protection from toxic materials.[482] Specifically, the Secretary of Labor is required to promulgate standards for toxic materials to assure that no employee suffers material health impairment, so long as meeting these standards is "feasible" for the employer.[483]

The Occupational Safety and Health Administration (OSHA) establishes regulatory controls on toxic substances or categories of substances of concern. OSHA has set full-fledged standards under the Act for two dozen organic chemicals.[484] These standards not only specify exposure limits, but also mandate a program of exposure monitoring and medical surveillance.[485] Maximum exposure limits have been set for several hundred additional airborne contaminants, but these have no exposure and monitoring requirements.[486] In setting these standards, OSHA has

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is included and the level down to which it must be removed.

477. Water supply systems vary considerably as to the amount of relatively benign solids (e.g., tiny particles of leaves) contained in the drinking water. These could greatly affect carbon use rates, making it hard to estimate costs for a system of a particular size.

478. Typically high log P substances have been released along with other toxic organics. If any other organic chemicals, especially volatile compounds, require control, the amounts of carbon needed to remove them will probably remove all the high log P substances.

479. There are, of course, occasions such as chemical spills, when a portion of the general public can be exposed to much higher levels of chemical substances than are found in the workplace. But the workplace remains the location where most adults receive their greatest exposure to synthetic toxic organics. Allowable exposure levels under the OSH Act are generally in the ppm range, while EPA often limits environmental releases of the same substance to the ppb range. We do not know whether that is the case for high log P substances generally. We speculate that nationwide, the mode and location of greatest exposure to PAH's is the workplace, but that for most other high log P substances, the single source of greatest exposure is food, especially fish and seafood. Even for those substances, exposure in the workplace may be greater than dietary exposure for those involved in manufacturing or handling the chemicals or their byproducts. *See* PAH PROFILE, *supra* note 23, at 24 (discussing various sources of exposure to PAH's).

480. 29 U.S.C. §§ 651-678 (1988 & Supp. IV 1992).

481. *Id.* § 651(b).

482. *Id.* § 655(b)(5).

483. *Id.*

484. 29 C.F.R. §§ 1910.1003-.1048 (1993).

485. These provisions can be very detailed. *See, e.g.*, Requirements For Semen Analysis of Employees [the regulation does not specify gender] Exposed to the Nematode-Control Pesticide 1,2-dibromo-3-chloropropane. 29 C.F.R. § 1910.1044(m) & app. C, pt. IV (1993).

486. *Id.* § 1910.1000.

shown no particular interest in highly bioaccumulative chemicals.[487] As we have shown, there are severe limits to the capacity of a list-oriented, chemical-specific regulatory regime to identify and control all high log P substances. Nevertheless, OSHA could place greater weight on substances known to have a high log P when deciding whether standards should be issued for particular chemicals. Rebuttable presumptions could be helpful in that regard; for instance, OSHA could establish a presumption that substances with a log P above 5.5 pose a special risk and merit extra regulatory attention.

Unfortunately, no efficient methods are presently available to monitor either the workplace or the workers for all high log P exposures, though the prospects are improving that a technique could be developed for monitoring workplace air for high log P substances.[488] Chances appear slightly better for monitoring the exposed workers. Those workers who have been exposed to significant quantities of high log P substances ought to show a buildup of those substances in their fatty tissues, since high log P substances, upon entering the body by any route,[489] will partition to fatty substances rather than to water.[490] In theory, testing body

487. In a typical workplace situation, there is no chance for bioaccumulation of toxic organics to have taken place, and accordingly no reason to focus on the bioaccumulation phenomenon as meriting special regulatory attention. We anticipate that OSHA's small staff of toxicologists has not focused on the fact that all high log P substances for which adequate data exist are toxic, since EPA's far larger staff has not done so either.

488. The development of semipermeable membrane devices, which should allow far more efficient monitoring of surface waters for high log P substances, *see infra* note 536, may also be useable to monitor workplace air. Initial results from experimental monitoring for PCB's are encouraging. Jimmie D. Petty et al., *Application of Semipermeable Membrane Devices (SPMDs) as Passive Air Samplers*, 27 CHEMOSPHERE 1609 (1993); Telephone Interview (by Burton) with Dr. James Petty (Dec. 13, 1993). We anticipate these devices, when used in conjunction with the log P screening technique, will be very effective in detecting high log P substances in the vapor phase in workplace air. (Allowable daily average limits for air contaminants are generally in the ppm range. *See* 29 C.F.R. § 1910.1000 (1993)). We urge OSHA and NIOSH to begin investigating this possibility on a priority basis. Such research should not be expensive. On the other hand, the devices are much less likely to be successful in detecting those log P substances attached to fine particulate matter suspended in workplace air, and could not detect the non-air exposures discussed in the next footnote. The blood monitoring approach discussed in the text would thus still be necessary, and the two approaches would complement each other in an integrated monitoring strategy.

489. OSHA personnel believe, as do many industrial hygienists, that for nearly all substances, workplace exposures are from air. However, other exposures are possible, including substances that can be absorbed through the skin. Workers may touch the substance directly, as a part of their duties, may come in contact with dust containing the substance, or may inadvertently ingest small amounts in dust.

490. Sipes & Gandolfi, *supra* note 14, at 109-10. Most high and very high log P substances do not readily metabolize in the body (or they metabolize to other high log P substances) and are not readily excreted, so they build up in body fat. *See generally* 5 WAYLAND J. HAYES, JR. & EDWARD R. LAWS, JR., HANDBOOK OF PESTICIDE TOXICOLOGY (1991); Wayland J. Hayes et al., *Storage of DDT and DDE in People with Different Degrees of Exposure to DDT*, 18 AM. MED. ASS'N ARCHIVES INDUS. HEALTH 398, 400 (1958); D.G. Patterson et al., *Levels of Polychlorinated Dibenzo-P-Dioxins and Dibenzofurans in Workers Exposed to 2,3,7,8-Tetrachlorodibenzo-P-Dioxin*, 16 AM. J. INDUS. MED. 135, 136 (1989).

fat would provide a basis for identifying workplaces that may have exposed workers to excessive levels of high log P substances and then requiring the employers to remedy the situation.[491] It is technically feasible to take a sample of body fat and, following the use of a suitable extractant, run the liquid mixture through the log P screening technique. But for practical reasons, it is not currently possible to make regulatory use of this technique. Lipid tissues can be removed for analysis only by a fat biopsy, an invasive technique, or during surgical procedures being done for other purposes.[492] Doing so routinely for monitoring purposes would require a substantial number of volunteers willing to go through a procedure that involves much more discomfort than a blood test. It is doubtful that enough volunteers could be found to provide statistically meaningful results.[493]

We believe blood sampling, which is less invasive, may provide results for high log P substances that could correlate with levels in lipid tissues, especially in the case of continuously exposed workers. This correlation has been demonstrated for DDT and its metabolites in both environmentally and occupationally exposed populations.[494] If strong statistical correlations can be shown between blood levels of high log P substances and their levels in lipid tissues, these correlations would provide a basis for monitoring and controlling high log P substances in the workplace.[495] We recommend that OSHA conduct research to determine the correlations between levels of high log P substances in blood and fat.[496] If a high correlation is established, further invasive fat biopsy monitoring would not be necessary.

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491. If workers show a statistically significant increase in a substance over levels found in the general public, that increase is probably due to workplace exposure, given that workplace exposures are so much higher than environmental exposures.

492. *See* Robert Levine, *Recognized and Possible Effects of Pesticides in Humans, in* 1 HANDBOOK OF PESTICIDE TOXICOLOGY, *supra* note 490, at 275, 301.

493. This is particularly true given the need to have repetitive sampling in an individual worker beginning with the onset of employment, and also given the lack of data on background levels in the general population.

494. *See* Levine, *supra* note 492, at 301-03.

495. Existing OSHA regulations require medical surveillance, usually consisting only of a free annual medical examination with no details specified, but presumably including blood analysis. *See, e.g.*, 29 C.F.R. § 1910.1013(g) (1993) (medical surveillance for beta-Propiolactone). However, occasionally more detailed blood test requirements are imposed. *See, e.g.*, *id.* § 1910.1028, app. C, para. V. Taking blood samples prior to employment, whether as part of a routine physical examination, for drug screening, or to detect prior exposure to harmful substances such as lead, has become commonplace in manufacturing jobs.

496. OSHA or Congress could delegate this research project to the NIOSH. The research could be performed on worker populations prior to exposure, and on those presently exposed to high log P substances to establish the following: (1) the correlation between blood and adipose (fat) levels in humans with chronic exposure to high log P substance(s); and (2) the validity of using a protocol similar to the log P screening technique on human fat biopsies and blood. If the worker could have exposures to multiple high log P substances, then the preliminary analysis would be for the presence of high log P substances as a group. If such substances are present, further analyses could be performed to identify, where possible, the individual

With this evidentiary basis in place, OSHA could proceed to regulate. Employers could be required to establish a program to monitor willing workers, by taking blood samples and performing analyses for high log P substances.[497] Testing a representative sample of volunteers from a particular workforce should suffice for this purpose.[498] Where that testing shows the presence of high log P substances above some *de minimis* level,[499] and the increase over the levels found in the general public is statistically significant, the employer would then have to choose one of the following options, with respect to each such substance: (1) to prove that there was no exposure to that substance in the workplace;[500] (2) to demonstrate through a risk assessment[501] that the substance poses an acceptable level of risk to the most exposed worker;[502] or (3) to reduce exposure below the acceptable level, to the extent feasible, using compliance programs designed by the employer and reviewed by OSHA.[503] If

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substances and their concentrations. For this research to be successful, it would not be necessary to establish the blood and adipose relationship for every individual high log P substance, only that the correlation exists when there is chronic ongoing exposure. While generally less accurate than fat sample testing, substantial progress has been made in developing blood tests for PCB's, TCDD, and other individual toxic substances to which workers may be exposed. Our interest here, in contrast, is to develop a test that can determine whether *any* high log P substances are present in workers' tissues, whether or not these substances can be identified. Our proposal is consistent with the recommendations of the National Research Council that blood monitoring become the primary method of measuring toxic substances in human tissues. *See* NATIONAL RESEARCH COUNCIL, *supra* note 220, at 98.

497. Existing OSHA standards routinely compel employers to have medical monitoring programs, but make participation by the workers voluntary, thereby avoiding Fourth Amendment problems. *See, e.g.*, 29 C.F.R. § 1910.1029(j) (1993) (employers must give employees exposed to coke oven emissions opportunity for free medical examinations, and must inform any employee who refuses of the possible health consequences). In any case, we would oppose compelling worker participation on privacy and self-autonomy grounds, even if there were no constitutional considerations. Workers generally favor such monitoring, provided the medical procedures are not too painful, degrading, invasive, or time-consuming. Indeed, most of the political pressure for more medical monitoring comes from the unions.

498. Once a sample is large enough to have statistical power, additional monitoring is pointless. On the other hand, the costs of monitoring are roughly proportional to the number of workers monitored.

499. As we suggested for the SDWA, such a *de minimis* level would not be a regulatory level per se, but rather a limit on reporting test results. All people have very small levels of log P substances in their bodies.

500. There is always some possibility that employees at a particular workplace could have a statistically significant increase in their body burdens of a particular chemical substance over the level found in the public generally, but that the exposure is from some other place. Presumably, to show there was no workplace exposure, the employer would have to show that the substance was not used or produced as a product or waste at the location, and that monitoring showed it not to be present, at least not above ambient levels.

501. The employer would not need to do a full risk assessment if it could show through citations to the scientific literature that the substance was known to pose no harm to the worker. We doubt that would frequently be the case.

502. The level considered acceptable for increased cancer or other health risks for workers under the OSH Act is far higher than the health risk considered acceptable for the general public under other statutes.

503. The courts have already upheld regulations allowing the employer to design the com-

the substances cannot be identified, safe levels of the substance are not known, or the "safe" level cannot be reached, the employer would be required to reduce exposure to the lowest level that is technically and economically feasible.[504]

This technique has several advantages. It avoids the need to identify substances and quantify their toxicity before remedial steps could be ordered. It also places the scientific burden largely on the employer, rather than on OSHA, whose small staff of scientists and other experts is not in a position to investigate the levels of exposure and toxicity of the over 70,000 chemicals in commercial use.

Does OSHA have sufficient legal authority to regulate on this basis, assuming an adequate scientific foundation could be established? The question is a close one; it would certainly be preferable for Congress to provide the Agency with explicit legal authority to do so. Because the OSH Act uses the plural, when specifying the "standards" requirement for toxic materials,[505] the plain wording of the statute seems to allow OSHA to regulate a class of substances as a whole, rather than substance by substance. OSHA apparently interprets the statute in this way and has imposed limits on classes of substances.[506] On the other hand, the Secretary of Labor must utilize "the best available evidence," and the standards "shall be based on research, demonstrations, experiments, and such other information as may be appropriate."[507] It is not clear whether the qualitative relationship we have demonstrated between high log P values and adverse human health effects would be sufficient to meet this burden. The two key Supreme Court cases on OSHA standards do little to clarify the meaning of the statutory language and provide no guidance on how much data is required to support a proposed standard.[508] In any case, the courts have never been presented with our approach, which would rely on considerable data about the health effects of the category of high log P substances. Moreover, the primary consequence of the regulation would be to shift the burden to the employer to

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pliance program, subject to OSHA review. *See* Asarco v. Occupational Safety and Health Admin., 746 F.2d 483 (9th Cir. 1984).

504. The statute requires employers to meet standards that assure no health impairment, but only to the extent feasible. *See supra* notes 482-83 and accompanying text.

505. 29 U.S.C. § 655(b)(5).

506. For example, the air contaminants regulation, 29 C.F.R. § 1910.1000 (1993), sets maximum exposure levels for, inter alia, carbon black, coal tar pitch volatiles, hexane isomers, xylenes, and particulates not otherwise regulated. All these are mixtures or groups of chemicals rather than individual chemical substances.

507. 29 U.S.C. § 655(b)(5).

508. *Compare* Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607, 614-15 (1980) (OSHA must show that a toxic substance poses a significant health risk and that a proposed standard is reasonably necessary to provide healthful employment) *with* American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 506-22 (1981) (cost-benefit analysis not required when Secretary sets standards dealing with toxic materials).

demonstrate a lack of harm. Certainly our proposed approach is consistent with the purpose of the statute, and would obviate the need for OSHA to make a substance-by-substance showing of harm.[509]

H. Clean Air Act

The Clean Air Act[510] is intended to protect the quality of the nation's air, "so as to promote the public health and welfare and the productive capacity of its population."[511] The Act establishes a framework for the regulation of many kinds of air pollution problems. Toxic pollutants, which the Act calls "hazardous air pollutants," are only a part of that effort. Congress passed a major revision to the CAA in 1990.[512] One of the most important changes was the adoption of a new Title III dealing with hazardous air pollutants.[513]

Hazardous air pollution regulation focuses primarily on protecting individuals downwind of toxic releases from direct exposure (i.e., from inhaling potentially harmful amounts of toxic pollutants). With respect to high log P substances, public concern over direct exposures has concentrated on the risk of dioxins and dibenzofurans created in and released by incinerators.[514] The CAA amendments address direct exposure largely on a chemical-specific basis, based on a congressionally established list of 189 substances and categories, including many, but not all, of the most commonly discussed high log P substances.[515] EPA must

509. This conclusion assumes that a court would agree that the case for a particular class of high log P substances being harmful was strong. As previously noted, the temptation to rubber-stamp agencies' decisions on technical matters is strong. Nevertheless, congressional action giving OSHA a clear mandate to regulate on this basis would be preferable.

510. 42 U.S.C. §§ 7401-7671q (1988 & Supp. III 1991).

511. *Id.* § 7401(b).

512. Under the version of the CAA in effect until 1990, little was done to regulate any hazardous air pollutants, whether or not they might bioaccumulate, except as an indirect benefit of reducing the "categorical pollutants" such as particulate matter, for which National Ambient Air Quality Standards were established under 42 U.S.C. § 7409(a). Despite the explicit authority to regulate under § 112 of the Act, only eight substances were subject to regulation under that authority. Don G. Scroggin & William J. Hamel, *Mopping Up After the Clean Air Act: For Industry, No Breathing Easy About Toxic Pollutants*, LEGAL TIMES, Feb. 11, 1991, at 39. None of these was an organic chemical known to bioaccumulate. However, one of the eight—coke oven emissions—nearly always contains substantial quantities of PAH's, along with other toxic substances. PAH's have log P values ranging from moderate to very high.

513. Pub. L. No. 101-549, §§ 301-306, 104 Stat. 2531 (codified at 42 U.S.C. § 7412).

514. In response to those concerns, EPA has imposed a de facto moratorium on new hazardous waste incinerators and tightened restrictions on existing ones. *EPA Targets Hazwaste Incinerators, Orders Risk Data, Lower Emissions*, AIR & WATER POLLUTION REP., May 24, 1993, *available in* LEXIS, Nexis Library, NWLTRS File.

515. 42 U.S.C. § 7412(b)(1). The list includes categories of high log P substances, such as PCB's, as well as "polycyclic organic matter." The latter is broadly defined to include any substance with more than one benzene ring and a boiling point above 100°C, a definition that should cover nearly all PAH's and several other high log P substances. A number of individual high log P substances are also listed, including 2,4,5-trichlorophenol, hexachlorobenzene, pentachlorophenol, and Lindane. There are important omissions, however, including the fol-

regulate releases of all listed substances for each category of major sources or area sources.[516]

Direct exposure to an airborne emission is not the only basis for concern with toxic pollutants released to the air. In the past decade, scientists have recognized that substances released to the air can wind up in meaningful quantities in the aquatic environment, sometimes at considerable distances from the source.[517] Because of the bioaccumulation and biomagnification phenomena, high log P substances reaching surface waters from air transport can sometimes pose risks to exposed organisms and humans consuming them. For example, polychlorinated dioxins and dibenzofurans are emitted into the atmosphere from various combustion sources, including stationary systems (e.g., waste incinerators, fossil fuel power plants, and sewage sludge incinerators), diffuse sources (e.g., automobile exhaust, home heating, and cigarette smoking), and accidents (e.g., PCB fires, combustion of polyvinyl chloride, and wood and forest fires), and can be transported from the source to aquatic environments.[518]

After deposition in aquatic systems, high log P substances tend to settle to the bottom sediments.[519] Resulting concentrations of high log P substances may be much higher than in the contaminated air. For example, concentrations of dioxins and furans may range from 1 to 750 femtograms[520] per cubic meter in ambient air; concentrations in rain

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lowing: hexachlorocyclohexane isomers other than Lindane; PBB's; and the pesticide mirex. DDE is on the list, but curiously, both its parent compound DDT and the other common metabolite, DDD, are not. TCDD is the only dioxin or dibenzofuran on the list. A separate provision does govern TCDD and "2,3,7,8-tetrachlorodibenzofurans." *Id.* § 7412(c)(6).

516. *Id.* § 7412(d)(1).

517. We know that the air transport phenomenon can take place because medium to high log P substances like PCB's, dioxins and dibenzofurans, and toxaphene have been found in Lake Siskiwit, a small lake on Isle Royale. Isle Royale is an island in a wilderness area of Lake Superior. It is physically impossible for these substances to have reached the small lake by waterflows. The only possible explanation, and one which is generally accepted, is that there has been air transport. *See* Fiedler et al., *supra* note 18, at 207; Michael Weisskopf, *'Toxic Clouds' Can Carry Pollutants Far and Wide: Poisoned Fish of Remote, Pristine Island Were Key Clue*, WASH. POST, Mar. 16, 1988, at A3.

518. Dioxins and furans are generally carried on particulates. The distance traveled is largely a function of the size of the particle: larger particles settle closer to the source while smaller particles may have sufficient residence times in the atmosphere to be transported to remote locations. *See* Paul E. des Rosiers, *National Dioxin Study, in* SOLVING HAZARDOUS WASTE PROBLEMS: LEARNING FROM DIOXIN 34 (Jurgen H. Exner ed., 1987); *see also* Fiedler et al., *supra* note 18. PCDD's can also be present in both particulate-bound and dissolved phases of precipitation. B.D. Eitzer & R.A. Hites, *Atmospheric Transport and Deposition of Polychlorinated Dibenzo-p-dioxins and Dibenzofurans*, 23 ENVTL. SCI. & TECH. 1396, 1396 (1989). PAH's are also usually transported on particulates. Chlorinated pesticides may be in gaseous form or contained in fine mists.

519. Jean M. Czuczwa & Ronald A. Hites, *Environmental Fate of Combustion-Generated Polychlorinated Dioxins and Furans*, 18 ENVTL. SCI. & TECH. 444, 445 (1984).

520. A femtogram is one quadrillionth of a gram.

samples are in the picogram[521] per liter range.[522] However, dioxin concentrations, primarily the result of atmospheric transport, range from less than 0.1 to approximately 40 ppb in sediment taken from the Saginaw River and Bay in Michigan.[523]

When this atmospheric transport mechanism is combined with biomagnification, high dietary exposures to high log P substances are possible, even in extremely remote locations. According to press accounts, some of the highest concentrations of PCB's, DDT, and other very high log P substances have been found in Inuits (Eskimos) living in the Arctic, in some cases hundreds of miles from any direct source of industrial contamination.[524] Because of foodchain biomagnification, very low levels in the air and water have resulted in very high concentrations in the tissues of animals key to the Inuit diet.[525] The elevated levels of high log P substances found in the breast milk of Inuit women raise concerns about possible developmental effects on nursing children and also about the mothers' health.[526]

Environmental protection and human health are enhanced and the regulatory burden on industry is reduced when agencies break away from the rigidities and limitations inherent in substance-by-substance regulation, and find a means of detecting and regulating high log P substances as a class. Unfortunately, neither the high log P screening technique nor its variations can screen an air sample to determine the presence of any high log P substances. We believe that such a technique can be developed, however, and we urge that its development become a priority for

521. A picogram is one trillionth of a gram.

522. Brian D. Eitzer & Ronald A. Hites, *Concentrations of Dioxins and Dibenzofurans in the Atmosphere*, 27 INT'L J. ENVTL. & ANALYTICAL CHEMISTRY 215, 215 (1986).

523. *See* Czuczwa & Hites, *supra* note 519. It is not clear whether the units quoted in the study are in dry- or wet-weight sediment. High dioxin concentrations in sediment are common in industrialized countries. Concentrations of 334 to 656 pg/g wet-weight sediment have been reported in the Passaic River, New Jersey, and concentrations up to 1,500 pg/g dry-sediment (i.e., roughly 1.5 ppb) have been found in the AuBeren Veringkanal in the harbor of Hamburg, Germany. N.I. Rubinstein et al., *Bioavailability of 2,3,7,8- TCDD, 2,3,7,8-TCDF and PCB's to Marine Benthos from Passaic River Sediments*, 20 CHEMOSPHERE 1097, 1099 (1990); Fiedler et al., *supra* note 18, at 209.

524. For an interesting nontechnical account, see Mary W. Walsh, *In Arctic, a Toxic Surprise*, L.A. TIMES, June 18, 1991, at A1. Proof of adverse human health effects in the exposed Inuit peoples has not yet been reported in peer-reviewed scientific literature. For related materials, see Eric Dewailly et al., *Coplanar PCB's in Human Milk in the Province of Quebec, Canada: Are They More Toxic Than Dioxin for Breast Fed Infants?*, 47 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 491 (1991); Eric Dewailly et al., *High Levels of PCB's in Breast Milk of Inuit Women from Arctic Quebec*, 43 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 641 (1989).

525. Walsh, *supra* note 524. The Inuit are particularly vulnerable because much of their diet consists of fat from whales, seals, polar bears, and other predators high on the food chain.

526. Statistically significant increases in levels of several high log P substances have recently been found in the breast tissue of women with breast cancer, when compared to women with normal breast tissue. *See supra* note 82.

further research. For example, as with many existing sampling methods for industrial substances or classes, a portion of an air emission from a stack or vent could be diverted by a probe and bubbled through a small sieve tray or packed column containing a mixture of water and a suitable organic solvent.[527] The resulting mixture could then be tested by the log P screening technique and high log P substances, both identified and unknown, could be regulated in a manner similar to our recommendations under other statutes.

In the meantime, we believe that under the CAA's existing chemical-specific approach, the risks posed by high log P substances could be reduced consistent with statutory requirements. First, the Act required EPA to phase in emission standards for the sources most responsible for emitting the 189 substances and groups of substances on the list of hazardous air pollutants established by Congress.[528] In regards to bioaccumulating substances, EPA's response to date under this authority has been disappointing.[529] Nevertheless, over the next several years, EPA

527. An analogous approach is already used under the CAA for monitoring categorical pollutants such as sulfur dioxide at some power plants; developing our recommended approach would thus be an extrapolation from existing techniques. The California Air Resources Board (CARB) has developed techniques whereby a small probe is inserted into a stack and a small portion of the gases are routed through an organic solvent, allowing a subsequent analysis of the contents. CARB has methods for a wide variety of hazardous air pollutants, including PAH's (method # 429) and PCB's and dioxins/furans (method # 428). David F. Todd & William V. Loscutoff, *An Overview of CARB-Adopted Source Test Methods for Toxic Compounds and Results of Testing Natural Gas-Fired Utility Boilers, in* ELECTRIC POWER RESEARCH INSTITUTE PUB. NO. TR-101890, MANAGING HAZARDOUS AIR POLLUTANTS: STATE OF THE ART (Winston Chow & Katherine K. Connor eds., 1993). CARB's methods are well regarded and used in some locations outside California. Telephone Interview (by Burton) with David Bailey, Potomac Electric Power Company (Oct. 1993). As noted in the text, we believe that combining those proven methods for stack sampling with the log P screening technique would not be difficult. Nevertheless, it would be unwise to recommend an untried method. At a minimum, validation testing would be needed. If successful, however, use of such a method would allow one to determine whether there were any high log P substances in a stack emission, what their log P values would be, and thus the likelihood that the substances would bioaccumulate if they reached surface waters.

528. 42 U.S.C. § 7412(c), (d). The requirement for a scheduled phase-in for those standards, *see id.* § 7412(e)(3), specified that some standards must be in place by November 15, 1992, and others at intervals 3, 5, and 8 years thereafter. Few such standards have been published. Section 7412(e) also required EPA to publish the dates on which each source category will be regulated. EPA published the list on December 3, 1993. 58 Fed. Reg. 63,941 (1993).

529. In setting its priorities, EPA apparently considered highly bioaccumulative substances only as an indirect consequence of its analysis of their adverse effects. Specifically, when calculating "SCRS" rating scores for particular source categories, EPA looked only at the statutory requirements of 42 U.S.C. § 7412(e)(2). 58 Fed. Reg. 64,491 (1993). While acknowledging that this was not entirely satisfactory, EPA made clear that it would not re-rank sources later based on better information. *Id.* We consider EPA's method to be unfortunate, even though it complies with the minimum statutory requirements, as it does not take environmental fate into account. Information on persistence and bioaccumulation is generally available for substances on the list and gaps could easily have been filled in the two years EPA had to make these decisions. EPA's approach will accelerate the regulation of sources that emit substances that degrade in air relative to sources of substance that are both highly persistent

will be promulgating emission limits for hazardous air pollutants from particular sources, and it could give greater weight to bioaccumulation as part of that process. Second, for several categories and substances, EPA must list sources, accounting for at least ninety percent of the emissions of each category or substance, to apply emission standards to. These categories must be listed by November 15, 1995, and EPA must promulgate emissions standards for the categories within five years thereafter.[530] Included in this short congressionally established list are high or very high log P substances, including PCB's, hexachlorobenzene, "polycyclic organic matter," and certain chlorinated dibenzofurans and dioxins.[531] As many of these as possible should be subjected to standards in the first two groups EPA regulates, thereby assuring that these substances will be regulated as quickly as possible.

In the 1990 revisions, Congress authorized the Administrator to add substances to the list of hazardous air pollutants based, among other things, on bioaccumulation.[532] A good portion of the air transport problem will be resolved if, in setting internal priorities for listing additional pollutants, EPA gives considerable weight to bioaccumulation.[533] In the same vein, the CAA requires EPA to study the atmospheric deposition of hazardous air pollutants as a source of pollution in the Great Lakes, Lake Champlain, the Chesapeake Bay, and coastal waters.[534] That study must assess the degree to which these depositions may be causing adverse health and environmental effects from bioaccumulation; by November 15, 1995, the Administrator must adopt any additional emission standards necessary to prevent such effects from indirect pathways including bioaccumulation.[535] We believe the log P screening technique could help determine the extent to which high log P substances are found in those bodies of water.[536]

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and highly bioaccumulative.

530. 42 U.S.C. § 7412(c)(6).

531. *Id.*

532. *Id.* § 7412(b)(2). Indeed, there are seven separate references to bioaccumulation in the revised version of § 112 of the CAA, significantly more than the total for any other federal environmental statute. By contrast, there is no authority under the CWA to regulate substances reaching surface waters from air.

533. The new statute also authorizes any person to petition EPA to have substances added to the list based on any of several listed factors, including bioaccumulation. *Id.* § 7412(b)(3)(B). Whether this petition procedure is any more effective than the many such petition provisions in other environmental statutes remains to be seen. Generally, the courts have subjected agency decisions not to undertake action pursuant to such petitions to a cursory review. *See* KENNETH C. DAVIS, ADMINISTRATIVE LAW OF THE EIGHTIES, § 6:28, at 210 (1989).

534. 42 U.S.C. § 7412(m).

535. *Id.* § 7412(m)(6).

536. No systematic testing of surface waters for organic chemical substances takes place in the United States. See generally 58 Fed. Reg. 20,802 (1993) for the various sources EPA and the states try to use to determine the extent of toxic pollution in the Great Lakes region. Accordingly, it is not possible to determine conclusively whether high log P substances are a

I. Toxic Substances Control Act

Congress enacted the Toxic Substances Control Act[537] in 1976, intending it to become a comprehensive statutory vehicle for protecting the public health and the environment from the effects of toxic substances.[538] Political impetus for the statute arose in good part because of the experience with PCB's, a class of high log P substances.[539] Scientists did not discover that mixtures of PCB's posed a serious threat to the aquatic environment and were generally, though not necessarily, carcinogenic[540] until after significant quantities of these substances had been disposed in the environment.[541] The PCB experience helped shape Congress' approach to toxic substance regulation. Determined never again to allow substances to enter commerce without some prior review of their risks, Congress required all producers of "new" chemicals[542] to give EPA ninety days notice before manufacturing or importing the substance for

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widespread problem in the surface waters. The recent development of semipermeable membrane devices, *see supra* note 488, may allow far better monitoring of surface waters for high log P substances. The devices consist of a special polyethylene membrane filled with triolein, a neutral triglyceride. If the devices are suspended in surface waters, any high log P substances preferentially exchange through the membrane and concentrate in the triolein. James N. Huckins et al., *Semipermeable Membrane Devices Containing Model Lipid: A New Approach to Monitoring the Bioavailability of Lipophilic Contaminants and Estimating their Bioconcentration Potential,* 20 CHEMOSPHERE 533 (1990); J.A. Lebo et al., *Use of Semipermeable Membrane Devices for the In Situ Monitoring of Polycyclic Aromatic Hydrocarbons in Aquatic Environments,* 25 CHEMOSPHERE 697 (1992). The U.S. Fish and Wildlife Service's Columbia, Missouri, laboratory has been having excellent results with the devices in field tests, concentrating PAH's 50,000-fold. Telephone Interview with Dr. Petty, *supra* note 488. By first greatly concentrating the high log P substances, the log P screening technique could detect them, and thus provide a measure of their log P and BCF values in far lower concentrations.

537. 15 U.S.C. §§ 2601-2671 (1988 & Supp. IV 1992).

538. "After 15 days of hearings and extensive analysis over the last five years, the Toxic Substances Control Act has evolved into a comprehensive measure to protect the public and the environment from exposure to hazardous chemicals." S. REP. NO. 698, 94th Cong., 2d Sess. 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4493.

539. PCB's are fire-resistant chemicals with excellent electrical insulation and heat-transfer properties. PCB's were very useful and hundreds of millions of pounds were produced. *See supra* note 33.

540. Possible human health effects from exposure to PCB's are discussed *supra* part II.B. We still do not know which of the 209 PCB congeners actually cause the increase in tumors in exposed laboratory animals. Dr. Steven Safe and others have proposed toxicity equivalency factors for PCB's based on structure-activity relationships (SAR's), according the highest toxic potency to those congeners that are co-planar (i.e., structurally the most like dioxins). *See generally* U.S. ENVTL. PROTECTION AGENCY, EPA/625/3-91/020, WORKSHOP REPORT ON TOXICITY EQUIVALENCY FACTORS FOR POLYCHLORINATED BIPHENYL CONGENERS (1991). However, such postulated differences have not yet been proven in tests on laboratory animals.

541. EPA estimated that by 1975, 400 million pounds of PCB's had entered the environment, over 25% of which was considered "free" (i.e., a direct source of contamination), with the rest in landfills. Environmental Defense Fund v. EPA, 636 F.2d 1267, 1270 (D.C. Cir. 1980).

542. New chemicals are those not on a subsequently developed EPA list of substances declared by their producers to be in commercial use.

commercial purposes.[543] TSCA thus draws a sharp distinction between new and "old" chemicals, subjecting all of the former to EPA's premanufacture notice (PMN) review, while placing far less emphasis on the latter.

EPA's PMN review period provides a good opportunity to assess and deal with any bioaccumulation risks of new chemicals. The Agency has not fully exploited this opportunity, however, even though its early TSCA guidance documents expressed concern for bioaccumulation,[544] and it had promulgated BCF[545] and log P[546] test methods for use under TSCA.[547]

Part of TSCA's weakness in dealing with potential bioaccumulation risks in new chemicals derives from EPA's decision not to require mandatory testing of all new chemicals for toxicity. In many respects, we support this decision, but EPA does not even require the submitters of PMN's to supply data on a substance's physical and chemical properties.[548] The Agency does try to predict bioaccumulation potential through its analysis of a chemical's structure during the PMN review. There is little evidence, however, that it gives much weight to the resulting information if the analysis shows moderate toxicity but high bioaccumulation potential.[549]

While EPA's efforts to regulate new chemicals have received a

543. 15 U.S.C. § 2604(a)(1).

544. *See Notification of Substantial Risk Under TSCA § 8(e)*, 21 Envtl. L. Rep. (Envtl. L. Inst.) 35,377 (Feb. 24, 1978). This guidance document, which places more emphasis on bioaccumulation than does any other aspect of TSCA, is not a binding regulation. However, it is taken seriously by industry because many EPA officials consider reporting evidence of substantial risk of injury under TSCA § 8(e) to be the statute's most important obligation. *See, e.g.*, Office of Pesticides and Toxic Substances, U.S. Envtl. Protection Agency, Recordkeeping and Reporting Rules, TSCA Sections 8, 12 and 13: Enforcement Response Policy, at 11 (July 30, 1984) (unpublished policy statement, available through FOIA).

545. 40 C.F.R. § 797.1520 (1992) (fish bioconcentration); *id.* § 797.1830 (oyster bioconcentration).

546. *Id.* § 796.1550 (K_{ow} (i.e., log P) by shake flask method); *id.* § 796.1570(K_{ow} by HPLC); *id.* § 796.1720 (K_{ow} by generator column method).

547. The most important exception is a May 31, 1979, EPA regulation implementing the PCB production and use prohibitions mandated by TSCA § 6(e). 44 Fed. Reg. 31,514 (1979).

548. Although specific testing is not required before filing a PMN notice, the manufacturer or importer must provide all known toxicity information. EPA can require additional data if its review indicates a possible problem based on its analysis of SAR's, which predict potential difficulties based on the toxicological properties of similar chemicals. If the tests required by EPA seem excessive relative to the likely benefits of the substance, the submitter can withdraw the notice and cancel plans to produce the substance. EPA does occasionally reject a new chemical, but it far prefers to have the submitter "voluntarily" withdraw the substance from consideration.

549. Interviews with EPA personnel and with those who deal with EPA frequently on TSCA § 5 matters suggest that EPA cares primarily about the possibility that a new chemical substance may be a carcinogen or teratogen, and secondarily that it may be acutely or chronically toxic to aquatic life. We agree that the former is a high priority concerns. It does not follow that so little weight should be given to a new chemical's bioaccumulation potential.

mixed reception,[550] it is hard to find any support for the Agency's regulation of existing chemicals under TSCA.[551] For the roughly 70,000 chemicals in commercial use, EPA has adopted final test rules for only twenty-nine substances or categories under TSCA section four.[552] In practice, test rules are a necessary first step to regulation. Only three of these test rules required any form of bioaccumulation testing.[553] EPA has chosen to ban or control only five existing toxic chemical substances or classes of substances under TSCA sections six and seven.[554] Except for regulation of PCB's, and certain dioxins and dibenzofurans, none of these were promulgated by concern for bioaccumulation. This level of effort is inadequate to assess and control the many existing chemical substances with potential to bioaccumulate.[555]

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550. *See, e.g.*, CONSERVATION FOUNDATION, TOXIC CHEMICAL PROGRAM NEEDS REINFORCEMENT, *reprinted in* ROGER W. FINDLEY & DANIEL A. FARBER, CASES AND MATERIALS ON ENVIRONMENTAL LAW 483-86 (3rd ed. 1991).

551. EPA's existing chemicals program under TSCA is one of the Agency's weakest programmatic efforts, a fact the Agency itself noted in a report to the President. *EPA Reports Weakness in Chemical Testing Hurting Regulatory Efforts*, 12 INSIDE EPA, Feb. 1, 1991, at 17. EPA conceded that it has promulgated only a few test rules, and that "only a limited number of the many thousands of chemicals that could or should be tested have undergone the testing necessary" to make regulatory decisions. *Id.* This echoes a June 1990, GAO report, *EPA's Chemical Testing Program has Made Little Progress. Unreleased GAO Report Chastises EPA for Mismanaging TSCA Chemical Testing*, 11 INSIDE EPA, June 15, 1990, at 11. Agency personnel and budget resources for these tasks have actually been declining. 14 Chem. Reg. Rep. (BNA) 1498 (Jan. 14, 1991). Nevertheless, EPA recently has attempted to strengthen its existing chemicals program under TSCA. One proposed change would target four groups of chemicals of special interest, which EPA calls "screening clusters," such as chemicals already under consent orders under TSCA § 5(e) or significant new use rules under TSCA § 5(a). One cluster is persistent and bioaccumulative substances. *EPA Toxics Substance Office Develops New Process to Speed Chemical Reviews*, 11 INSIDE EPA, Dec. 14, 1990, at 2. Possibly reflecting this new emphasis, EPA has proposed a test rule under TSCA § 4(a)(1)(A) for bromated flame retardants, most of which are very high log P substances. 56 Fed. Reg. 29,140 (1991).

552. 40 C.F.R. §§ 799.500-.4440 (1992). EPA also entered into consent orders with chemical producers for the testing of some 30 additional substances or mixtures. *Id.* §§ 799.5000-.5025 (1992).

553. *Id.* § 799.500 (anthraquinone), § 799.925 (biphenyl), § 799.4000 (tetrabromobisphenol A).

554. These were certain metalworking fluids, hexavalent chromium when used as a water-treatment chemical in cooling systems, chlorofluorocarbons, asbestos, and certain dioxins and dibenzofurans. 40 C.F.R. §§ 747, 749, 762, 763, & 766 (1992). Congress separately mandated the regulation of PCB's. *See supra* note 547.

555. A full evaluation of the reasons for the weaknesses of the U.S. approach to regulating existing toxic substances under TSCA is beyond the purposes of this article. EPA, however, is not solely to blame. Congress imposed cumbersome testing requirements. For example, to trigger TSCA § 4 test rules, EPA must (1) already possess some information suggesting a substance may pose an unreasonable risk, or (2) the substance must be one produced in "substantial quantities." EPA has proposed to define a substantial quantity as a production of over one million pounds, even though it believes that only 11% of all chemicals are produced in that amount. 56 Fed. Reg. 32,294 (1991). Congress and the OMB have also provided EPA with woefully inadequate funding to have an effective program on existing chemicals. Total estimated 1993 program costs for toxic substances (not just for testing and regulating existing chemicals) were only $53.5 million. EXECUTIVE OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, app. 974 (1993). Moreover, as a practical matter, EPA's

The log P screen is not necessarily the most cost-effective technique to measure the log P of an identified individual substance. For this reason, the screening technique we have advocated will have little applicability to substance-specific statutes such as TSCA and FIFRA.

EPA could nevertheless give greater attention to high and very high log P substances under TSCA by revising its testing and reporting rules for new and existing chemicals. Neither TSCA nor its implementing regulations require log P testing of new chemicals. While EPA can obtain a reasonable estimate of log P through SAR,[556] the difference between an SAR-based estimate of log P and measured log P can vary on occasion by more than one order of magnitude.[557] Such a large difference could be enough to change the Agency's perception of relative risks, and thus vary the restrictions it might place on the substance.

It would accordingly be helpful to change the regulations to require a manufacturer or importer submitting a PMN for a new chemical to submit data on log P and other key physical and chemical properties of the substance.[558] Such a requirement would not be costly and would not raise some of the problems associated with routinely requiring toxicity testing.[559] EPA should also require the provision of log P data, if not already known, when promulgating test rules for toxicity testing under section four.[560]

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authority to order testing of high log P substances under either § 4 or § 5 is limited to commercial products. (Under TSCA, 15 U.S.C. § 2603 (a)(1), (b)(3)(B), the Administrator can order testing of substances the manufacture, distribution, or disposal of which "may present an unreasonable risk of injury to health or the environment." However, she can only order such testing to be done by persons who manufacture or process the substances.) The resultant lack of toxicity data for the vast majority of known noncommercial chemicals is a fundamental flaw in TSCA, but one for which there are no easy "fixes."

556. *See supra* note 548. Quantified variations for these methods are sometimes called QSAR's. Confusingly, QSAR is also the name of EPA's computer model for generating data on chemicals based on their structures.

557. A study of 49 compounds for which there were both measured log P and calculated log P showed that the average absolute difference between them was 0.84 (nearly a factor of seven-fold), and that 37 of them differed by an order of magnitude or more. Schüürmann & Klein, *supra* note 139, at 1559, 1562. EPA, in apparent recognition of the limits of precision of QSAR estimates for log P, recommends against their use for CWA permitwriting in the absence of confirmatory information. OFFICE OF WATER, U.S. ENVTL. PROTECTION AGENCY, EPA/440/4-87-006, PERMIT WRITER'S GUIDE TO WATER QUALITY-BASED PERMITTING FOR TOXIC POLLUTANTS, at C-5 (1987).

558. These regulations should require the submission of, at a minimum, a chemical's molecular weight, Henry's law constant (which measures the propensity of a substance to partition from water to air), and log P.

559. EPA already requires a log P test under FIFRA's regulations for all pesticide active ingredients that are non-polar organics. 40 C.F.R. § 158.190(a) (1992). Doing so for TSCA as well should not be difficult.

560. 15 U.S.C. § 2603(a)(1). An additional step EPA should consider under TSCA would be a voluntary call-in of toxicity data for all substances known by their manufacturers to have a log P over 3.5. Correlating measured log P data with existing toxicity data would facilitate rapid improvement in the state of the science at very low cost. Standard reference works on the toxic effects of chemicals, such as the RTECS, rarely have log P data available. RTECS

In making decisions on new chemicals, EPA should also give greater priority to high and very high log P substances. Here, as with other statutes, rebuttable presumptions may be helpful. EPA could require that any new chemical with a log P greater than 3.5 but less than 5.5 would be subject to a significant new use rule (SNUR), thereby assuring that EPA would have the chance to approve each new use.[561] Companies could prove by a preponderance of the evidence that the SNUR is unnecessary. New chemicals with a log P greater than 5.5 would be presumptively banned, subject to the same opportunity to overcome the presumption. Congress could reinforce these measures by forbidding the export of any chemical with a log P greater than 5.5.[562]

We do not expect there to be significant cost or other economic effects from our TSCA proposals for new chemicals. The tests necessary to supply data on the log P and other physical properties of new chemicals are inexpensive relative to toxicity testing and should add well under $1000 to the cost of PMN review. Since the vast majority of new chemicals do not pose severe bioaccumulation risks, more closely regulating those that do would not significantly impede commerce in new chemical substances generally. The cost impact of more closely regulating existing chemical substances cannot be predicted until EPA determines which chemicals to regulate and what controls to impose. But given current statutory requirements, we would not expect many new controls to be adopted on existing chemicals. Moreover, because TSCA is a cost-benefit statute,[563] the benefits of the controls must exceed the costs.

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summarizes the results of toxicity studies of chemicals, particularly those relevant to human health. *See* NATIONAL INST. FOR OCCUPATIONAL SAFETY & HEALTH, *supra* note 186.

561. Regulation of significant new uses is detailed under 15 U.S.C. § 2604(a), (b)(4)(B); 40 C.F.R. §§ 721.1-.185 (1992).

562. Chemical substances that are intended exclusively for export may be lawfully exported even though they have not gone through TSCA § 5 PMN review. 15 U.S.C. § 2611. Whatever the merits of exporting other chemicals without PMN review, export is imprudent for very high log P substances, which can pose serious problems for the global commons and even return to be an environmental and public health problem for the United States. EPA could resolve this problem by regulation because it has express authority under TSCA to prevent chemical exports that could pose an unreasonable risk of injury to health or the environment of the United States. *Id.* If EPA will not act, Congress should ban the export of very high log P substances. An international treaty imposing that obligation on all exporting nations would further protect the global commons. Exceptions might be allowed where EPA can establish that there are no feasible alternatives to the use of the high log P substance, and that there is no credible risk of harm to the United States or the global commons from the export. We can think of no substance with a log P >5.5 that meets both of these criteria.

563. To be regulated, a substance must pose an *unreasonable* risk, and the Administrator must impose the least burdensome requirements for control. 15 U.S.C. § 2605(a), (c)(1). The Administrator cannot promulgate a TSCA § 6 rule if the matter would be adequately handled under another statute. 15 U.S.C. § 2605(c)(1).

J. Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act [564] is the primary pesticide statute.[565] Despite its title, the statute applies to all types of pesticides.[566] Although the political support for the adoption of the 1972 modernization of the statute resulted largely from concern over DDT,[567] relatively little has been done under the statute about bioaccumulation. EPA has promulgated regulations (sometimes requiring tests for log P) for the registration of new pesticides and the re-registration of existing ones.[568] We cannot establish what weight, if any, EPA attaches to bioaccumulation potential when considering pesticides for registration. Numerous pesticides never went through the modern FIFRA registration procedures, however, and the re-registration program mandated by Congress is now far behind schedule.[569]

Our recommendations for FIFRA parallel those for TSCA. EPA should give greater weight to the bioaccumulation potential of pesticides in the registration and re-registration process, in part through the use of presumptions: any pesticide with a log P greater than 3.5 but less than 5.5 would be presumed to be classified for pesticide use, meaning generally that it could only be applied by certified applicators.[570] Pesticides with a log P greater than 5.5 would be presumed to pose an unacceptable risk. Either of these presumptions could be overcome by the applicant, who would bear the burden of proof. Pesticides with log P values of 5.5 should also be banned from export.[571]

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564. 7 U.S.C. §§ 136-136y (1988 & Supp. IV 1992). *See supra* note 175.

565. Residues of pesticides on food are regulated by EPA under the FFDCA. *See* 21 U.S.C. § 346a. EPA often sets standards for residues ("tolerances") based on toxicity. These standards incidentally restrict the use of some bioaccumulating pesticides, but the FFDCA does not require that all pesticides be tested for bioaccumulation potential as a condition of granting a tolerance.

566. Particularly since the 1972 amendments, the Act reflects a requirement for balancing sometimes conflicting interests, including the interests of farmers and ranchers in inexpensive, effective pesticides, the safety of exposed persons, and the need to avoid damage to the environment.

567. *See supra* notes 173-75 and accompanying text.

568. Under the FIFRA regulations, environmental fate data for bioaccumulation is required for fish and aquatic "non-target" organisms only "if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms." 40 C.F.R. § 158.290 (1992). Testing of wildlife and aquatic organisms for bioaccumulation is subject to the identical limitation. *Id.* § 158.490. Due to the weakness of these provisions, many pesticides are not required to be tested for BCF prior to registration or re-registration. On the other hand, this is not particularly important because uniquely among the regulations implementing federal environmental statutes, the FIFRA regulations require a test for log P for all pesticide active ingredients that are non-polar organics. *Id.* § 158.190(a).

569. 14 Chem. Reg. Rep. (BNA) 1395 (Jan. 4, 1991) (program is at least six months behind schedule).

570. 7 U.S.C. § 136a(d)(1)(C).

571. Under current law, pesticides that are intended exclusively for export may be lawfully exported even though they are not registered under FIFRA for use in the United States. 7

K. Screening of Contaminated Soils, Sludges, and Sediments

High log P substances can be found in contaminated soils at CERCLA and RCRA sites, in sludges generated at wastewater facilities governed by the CWA, in other sludges regulated under RCRA, and in particulate matter remaining in treated wastewater which will form sediments. Any of these have the potential to become bioavailable and cause harm to health or the environment. The statutory authorities for dealing with these problems have already been discussed. In addition, existing sediments may need to be moved, usually to deepen shipping channels. The ocean dumping of such spoils is governed by special open dumping regulations under the CWA.[572] Before authorizing the dumping of dredge spoils or other materials at sea, EPA and the U.S. Army Corps of Engineers generally investigate whether the proposed wastes contain substances known to bioaccumulate to such a degree as to cause adverse effects in marine organisms.[573]

The log P screening technique could be invaluable in determining whether log P substances are present in these soils, sludges, and sediments. However, there is a threshold issue of how much of the material will be bioavailable.[574] It is essential that extractants be selected that will mimic the mobilization potential in the environment.[575] Until this is

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U.S.C. § 136o. Allowing pesticides to be exported that are not registered in the United States has been highly controversial. On the one hand, the export of such pesticides can subject users in other countries to excessive risks. Moreover, some of the exported pesticides can do harm to the global commons, or even return to the United States in the form of residues on imported food. The latter concern has been labeled the "circle of poison." On the other hand, benefits and risks may be weighed quite differently in a foreign country; it might be reasonable to ban a pesticide in the United States while its use could be justified elsewhere. Williamson, *supra* note 4, at 720-22. Our suggestion differs from categorical bans on pesticides not registered for use in the United States, in that we would restrict and in some cases bar the export of high log P substances irrespective of the registration status of the pesticide.

572. The statutory provisions mandating these regulations do not mention bioaccumulation, but the implementing regulations do. 40 C.F.R. § 227.18(g) (1993). In assessing the impact of proposed dumping, the presence of chemical constituents that may bioaccumulate and adversely affect humans must be considered. *Id.*

573. *See* 40 C.F.R. § 230 (1993); *see also* the Marine Sanctuaries Act, 16 U.S.C. §§ 1431-1445 (1988 & Supp. IV 1992). International treaties relevant to ocean dumping include the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 26 U.S.T. 2403, 2415 (entered into force Aug. 30, 1975), and the Convention on the Law of the Sea, 21 I.L.M. 1261 (done Dec. 10, 1982).

574. *See supra* notes 167-70 and accompanying text.

575. The issue is whether the results obtained from screening such solids for high log P substances have any predictive value. EPA already does something similar under RCRA to determine whether a waste is a hazardous waste by virtue of EP toxicity. *See supra* part V.E. In that case, because EPA chose poor extractants, there was widespread criticism within the environmental community. Congress decided that the test understated the risks and ordered EPA to come up with a better one. 42 U.S.C. § 6921(g) (1988). An extractant that understates the risks provides one with inadequate environmental protection; one that extracts too much overstates the risks, and can yield dramatically increased treatment costs with no corresponding environmental payoff.

done, we strongly urge that no regulatory use be made of our technique for soils, sludges, or sediments.

CONCLUSION

For the past thirty years, the primary approach of EPA and other regulatory authorities for controlling the toxic effects of environmental releases has been the imposition of highly stringent limitations on a tiny fraction of all chemical substances, usually only those listed in statutes or regulations, leaving all other substances unregulated. While much has been accomplished with this chemical-specific approach, some regulatory programs have reached the point of diminishing returns, with progressively smaller benefits to the public and rapidly increasing costs to the economy and the taxpayers.

For environmental toxicity under the CWA, EPA recognized the limitations of chemical-specific regulation, and has increasingly turned to a whole-effluent toxicity approach. In retrospect, it was a brilliant shift in perspective, allowing regulation of all released chemical substances based on their harmful properties, rather than their identity. This approach is already bringing about better environmental protection at lower cost. The agencies administering the public health and environmental statutes should undertake the same shift in perspective for environmental releases that may contain high log P substances.

As we have shown, our proposal will be significantly less expensive, both in testing requirements and compliance costs, than the chemical-specific approaches usually favored by regulatory agencies. It places the burden of information gathering and testing on those responsible for releasing high log P substances. At the same time, the proposal makes it relatively easy for the parties to meet that burden (at least when compared with a requirement for cost-benefit analysis), and grants parties the flexibility to achieve the objective in one of several ways. In short, our proposal constitutes a reasonable middle course that adequately accounts for cost and feasibility.

Compared to other regulated substances, high log P substances pose a greatly disproportionate risk to human health and to the natural environment. Yet remarkably little has been done to regulate this risk. A far greater focus on them would yield substantial benefits for the public. There are few legal difficulties preventing the regulatory agencies from more aggressively regulating these substances. Those few statutes which would involve legal difficulties should be addressed quickly by Congress. The real impediments are politics and inertia. If the agencies do not act, Congress should impose non-discretionary duties on them to do so.

Writing in 1974, W. Brock Neely put the problem quite well:

> The ability of some chemicals to move through the food chain resulting

> in higher and higher concentrations at each trophic level has been termed biomagnification or bioconcentration. . . . From an environmental point of view this phenomenon becomes important when the acute toxicity of the agent is low and the physiological effects go unnoticed until the chronic effects become evident. Due to the insidious nature of the bioconcentration effect, by the time chronic effects are noted, corrective action such as terminating the addition of the chemical to the ecosystem, may not take hold soon enough to alleviate the situation before irreparable damage has been done.[576]

Nearly two decades have past since Dr. Neely identified the central issue. It is time to act.

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576. Neely et al., *supra* note 67, at 1113 (footnotes omitted).

GLOSSARY[577]

activated carbon: carbon, as from coal or petroleum, that has been specially treated to increase the probability of sorption. *See sorption.*

bioaccumulation: the process by which a toxic substance is taken up by an organism, not only from water, but also from food. For the purposes of this article, we use bioaccumulation unless a reference to bioconcentration or biomagnification is necessary to ensure scientific accuracy.

bioavailable: the portion of a chemical substance found in the environment that can readily be ingested or otherwise absorbed by living organisms.

bioconcentration: the process by which a toxic substance enters an aquatic organism through the gills or epithelial tissues and is concentrated in the body.

biomagnification: the process by which a compound concentrates as it moves up the food chain.

bioconcentration factor (BCF): an experimentally-derived expression of the bioaccumulation potential of a chemical substance; the concentration of a substance in a test organism divided by the exposure concentration over some defined time period.

chlorinated dioxins and dibenzofurans: a class of highly bioaccumulating substances. Dioxins and dibenzofurans are usually created in trace quantities as unwanted byproducts from the chemical synthesis of complex chlorinated hydrocarbons, chlorine bleaching of paper pulp, or the insufficiently controlled incineration of organic materials in the presence of chlorine compounds.

DDT: dichlorodiphenyltrichloroethane, a chlorinated hydrocarbon pesticide once widely used in the United States. Although banned since 1972, DDT and its metabolites DDE and DDD are still commonly found in the United States in environmental samples and human lipid tissues.

high log P reduction evaluation (HLPRE): a proposed EPA program in which experts would evaluate a discharge containing high log P substances in order to determine these substances' sources and identify possible remedial measures. *See also toxicity reduction evaluation.*

high log P substances: those substances with a log P value at or above 3.5. EPA considers these substances to have a high propensity for bioaccumulation.

high pressure liquid chromatography (HPLC): a separation technique whereby chemical constituents of liquid mixtures are separated according to their differing solubilities when the mixture is passed over a coated column. HPLC can be used for both quantitative and qualitative chemi-

577. Note on sources: These definitions are our own, and are intended as a reading aid for a legal audience. Most of them are less technical versions of definitions found in standard reference works.

cal analysis and provides a way of identifying the presence of high log P compounds in an aqueous sample.

K_{ow}: the n-octanol/water partition coefficient. *Log K_{ow}* is a synonym for *log P.*

log P: the logarithm of the n-octanol/water partition coefficient. Log P is a measure of a substance's tendency to remain in an organic solvent (octanol) rather than to remain in water when the two liquids are thoroughly mixed and then separated. Sometimes referred to as log K_{ow}.

n-octanol/water partition coefficient: *see log P.*

persistent substance: those chemical compounds that are very stable in ecological systems. The rate of degradation of persistent compounds in a particular medium is often expressed as its halflife. Some organochlorine pesticides can persist in aquatic systems for decades.

polycentric aromatic hydrocarbons (PAH's): a common class of highly bioaccumulating substances, sometimes occurring naturally, but usually the consequence of human-caused incomplete combustion of carbon-containing substances. Sometimes referred to as polynuclear aromatic hydrocarbons (PNA's).

polychlorinated biphenyls (PCB's): a common class of highly bioaccumulating substances, once widely used throughout the United States, in transformers, capacitors, and other heat-transfer and manufacturing applications.

sorption: the binding of one substance by another, such as by absorbing.

structure activity relationship: the quantitative relationship between the chemical structure of a substance and its toxicity.

TCDD: a dioxin isomer, 2,3,7,8-tetrachloro-dibenzo-*p*-dioxin, possibly the most potent cancer-causing substance found to date in laboratory animal tests.

toxicity reduction evaluation (TRE): An assessment of the various alternatives that can be used to reduce the toxicity of an effluent.

very highly bioaccumulative: for the purposes of this article, chemicals having a log P of 5.5 or more. Sometimes designated as "very high log P."