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October 12, 1982

MEMORANDUM ON LEGISLATIVE CONCERNS ARISING FROM THE "GRAD REPORT"

An area of potential legislative concern to companies that manufacture or use hazardous substances arises from the recent report of the "Superfund §301(e) Study Group" on the improvement of legal remedies for injuries and damages from hazardous wastes. The Group was established under Section 301(e) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (the "Superfund legislation") to study the adequacy of existing common law and statutory remedies in "providing legal redress for harm to man and the environment caused by the release of hazardous substances into the environment". The report of the Study Group (commonly referred to as "the Grad Report", after the reporter, Professor Frank P. Grad of Columbia Law School) finds that current statutory and legal remedies pose significant impediments to recovery for injuries arising from hazardous wastes and proposes a series of federal and state statutory reforms which would significantly alter existing law. These proposals have at least two significant implications. First, if legislation were adopted along the lines of the Grad Report recommendations, it would impose very significant burdens on companies involved in generating, transporting, and disposing of hazardous wastes. Second, the ideas proposed by the Study Group may well have an impact on the development of the law in areas not directly covered by the Report such as product liability and workmen's compensation.

In very broad terms, the Report proposes the establishment of a two-tier system of compensation for harm occasioned by exposure to hazardous wastes. The first tier would be a system of no-fault administrative compensation, similar to workmen's compensation. It would be financed out of a hazardous waste compensation fund, established by taxes on the production of hazardous or toxic chemicals and crude oil and by a tax on the disposal of hazardous wastes. For claims arising from exposure that occurred after adoption of the proposed legislation, the compensation fund would be entitled to assert a claim for contribution or subrogation against the party responsible for the exposure. Thus companies involved in the chemical and petroleum industries and all companies that generate hazardous wastes would bear the cost of maintaining the compensation fund at whatever level was deemed appropriate. In addition, individual companies (including waste transporters and disposers) could face substantial claims for compensation in individual cases.

The second tier which would be established under the Grad Report proposal would be the continuation of existing tort law causes of action in state courts, but with significant substantive and procedural modifications which would make it generally easier for plaintiffs to recover. Thus the proposal differs significantly from the traditional workmen's compensation systems on which the Tier One remedy is based. Under workmen's compensation laws, the no-fault liability that compensates victims of occupational injury or disease is accompanied by a bar against tort law recovery from the employer. The Study Group proposal would prevent cumulation of Tier One and Tier Two awards and contains provisions intended to discourage claimants from frivolously pursuing tort law claims under Tier Two. It seems likely, however, that adoption of the proposal would lead to increased exposure to liability on the part of companies involved in hazardous wastes.

For purposes of the Tier One administrative remedy, the Grad Report recommends the adoption of rebuttable presumptions for the purpose of establishing

causation and other factors. These presumptions would not be applicable to Tier Two tort actions. Their acceptance, however, in federal legislation could affect the development of case law and state legislation in a variety of contexts, including product liability.

The foregoing briefly summarizes a lengthy and complex set of proposals, which should be considered in detail in making an assessment of their potential impact. Such an examination should be included by companies interested in hazardous substances in any consideration of possible legislative activity with reference to federal product liability or workmen's compensation law. Although the Grad Report does not purport directly to affect either of these areas, it is likely to play a role in congressional deliberation on these related areas insofar as hazardous substances are concerned.

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November 18, 1982

MEMORANDUM FOR AIHC BOARD OF DIRECTORS

Re: Legislative Issues in 1983

The attached tabulation describes in brief form the principal legislative provisions concerning chronic health hazard science issues, agency listing and science panels that are contained in legislation expected to be reconsidered during the 98th Congress. An Executive Summary of these provisions is also provided.

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MAJOR RELEVANT LEGISLATION TO BE RECONSIDERED IN THE 98TH CONGRESS

Executive Summary

1) Environmental Research, Development and Demonstration Authorization Act, 42 U.S.C. § 4365	Sets up Science Advisory Board and requires EPA to use it for determinations under specified statutes.
2) Clean Air Act, 42 U.S.C. § 7401 et seq.	a) Ambient Air Quality Standards -- EPA sets standards necessary to protect the public health.
	b) Hazardous Air Pollutants -- EPA controls air pollutants which may be expected to cause an increase in mortality or illness.
	c) Halocarbons -- EPA controls substances which may be expected to affect the stratosphere.
	d) Motor Vehicles -- EPA sets standards for pollutants that may be anticipated to endanger health or welfare.
3) Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq.	a) Toxic Effluents -- EPA lists toxic pollutants and subjects them to effluent limitations based on best available technology.
	b) Toxic Discharges -- Discharges of substances presenting "an imminent and substantial danger" to health or welfare are prohibited.
4) Resource Conservation & Recovery Act, 42 U.S.C. § 6901 et seq.	EPA establishes criteria for hazardous waste and sets standards for its generation, transport, and disposal.
5) Safe Drinking Water Act, 42 U.S.C. § 300f et seq.	a) Drinking Water Standards -- Standards for contaminants which "may have any adverse effect" on health are to be set at levels at which no adverse effects on health occur.

	b) Imminent hazards -- EPA may act to protect people from contaminants which present an "imminent and substantial" danger to health.
6) Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 et seq.	EPA may control use of or ban pesticides that create "any unreasonable risk to man or the environment."
7) Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.	a) Toxic Substances -- EPA may test and regulate substances presenting "unreasonable risk of injury" to health or environment. Priority is given to substances presenting "a significant risk of serious or widespread harm to human beings."
	b) Manufacturing and Processing Notices -- EPA may temporarily prohibit or limit manufacture of new chemicals until evidence on their health and environmental effects is available.
8) Ocean Dumping Act, 33 U.S.C. § 1401 et seq.	EPA may issue permits for ocean dumping if it will not "unreasonably degrade or endanger" health, welfare, or the ocean environment.
9) Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.	Commission may control or ban products that present an "unreasonable risk" of injury.
10) Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq.	a) Adulterated Food -- Food is considered adulterated if it contains any substance that is injurious to health or unsafe.
	b) Food Additives -- An additive is deemed to be unsafe if, after appropriate tests, it is found to induce cancer in man or animals.
	c) Color Additives -- An additive will be considered unsafe if, after appropriate tests, it is found to induce cancer in man or animals.

MAJOR RELEVANT LEGISLATION TO BE RECONSIDERED IN THE 98TH CONGRESS

Statutes	Scientific Criteria for Regulation	Regulatory Lists	Science Panels
Environmental Research, Development and Demonstration Authorization Act -- Science Advisory Board, 42 U.S.C. § 4365			Requires Administrator of EPA to establish Science Advisory Board (SAB) and to refer to it any document, standard, limitation or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource Conservation and Recovery Act of 1976, the Noise Control Act, the Toxic Substances Control Act, the Safe Drinking Water Act and any other authority of EPA. SAB must prepare advice and comments on the adequacy of the scientific and technical bases of the proposed criteria, document, standard, limitation or regulation.
Clean Air Act, 42 U.S.C. § 7401 et seq.	§§ 7408, 7409 (National ambient air *quality standards*) -- *Administrator* shall prescribe national primary air quality standards for air pollutants, the attainment and maintenance of which, based on air quality criteria reflecting the latest scientific knowledge of identifiable health effects and allowing an adequate margin of safety, are requisite to protect the public health. Pollutants to be considered are those which are	§ 7408 -- Administrator shall publish and revise a list of air pollutants which are emitted by numerous mobile or stationary sources, which may reasonably be anticipated to endanger public health or welfare, and for which air quality criteria have not been issued. Criteria must be issued within 12 months	§ 7409(d) -- Administrator shall appoint a seven member independent scientific review committee which, on January 1, 1980 and at five year intervals thereafter, shall complete a thorough review of the criteria established under §7408 and the ambient air quality standards. The committee

emitted from numerous mobile or stationary sources and cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.

§ 7411 (Standards of performance) -- The Administrator shall establish standards of performance for new stationary sources of air pollutants. The standards "shall reflect the degree of emission limitation and the percentage reduction achievable through application of the best technological system of continuous emission reduction."

§ 7412 (National emission standards for hazardous air pollutants) -- Administrator shall establish emission standards for air pollutants not covered by ambient air quality standards which cause, or contribute to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness. The emission standards shall provide "an ample margin of safety to protect the public health;" if an emission standard is not feasible, a design, work practice, or operational standard which is "adequate to protect the public health . . . with an ample margin of safety" must be promulgated.

§ 7457 (Halocarbons) -- Administrator shall propose regulations for the control of a after the pollutant is placed on the list.

§ 7412 -- Administrator shall publish and revise a list including each hazardous pollutant for which he intends to establish an emission standard.

§ 7422 -- Radioactive pollutants, cadmium, arsenic, and polycyclic organic matter shall be included on the list established by §7408 if the Administrator finds that they cause or contribute to air pollution which may reasonably be anticipated to endanger public health.

shall make such recommendations to the Administrator as are appropriate.

§ 7417 (Advisory committees) -- Administrator shall, from time to time, establish advisory committees to provide assistance in the development and implementation of the purposes of the Clean Air Act including air quality criteria, recommended control techniques, and to encourage continued efforts on the part of industry to improve air quality. Committee members must include persons who are "knowledgeable concerning air quality from the standpoint of health, welfare, economics, or technology."

substance, process, practice, or activity which may reasonably be expected to affect the stratosphere (especially ozone) if such effect may reasonably be expected to *endanger public health* or welfare. The regulations must "take into account the feasibility and the costs of achieving such control."

§ 7521 (Emission standards for new motor vehicles) -- Administrator shall set emission standards for air pollutants emitted from any class of new motor vehicles or engines which cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare. Such standards must take effect after such period as is necessary to permit *development and application of* the requisite technology, giving appropriate consideration to the cost of compliance. Standards for particulate matter emissions in 1981 and later must reflect the greatest degree of emission reduction achievable through the application of technology that will be available, giving appropriate consideration to the cost of applying such technology within the necessary period of time. Emission control devices which will cause or contribute to an unreasonable risk to public health, considering increases in unregulated pollutants and the availability of alternative devices, may not be used to comply with such standards.

§ 7545 (Regulation of fuel and fuel additives) -- Administrator may control or prohibit manufacture or sale of fuel or fuel additives an emission product of which "causes or contributes to air pollution which may reasonably be anticipated to endanger the public health or welfare." The Administrator must consider all relevant medical and scientific evidence available to him and must consider technologically or enomically feasible means of achieving emissions standards *under* §7521. Control or prohibition of a fuel or fuel additive may not cause the use of any other fuel or fuel additive which will produce emissions that endanger public health to the same or greater degree.

§ 7571 (Aircraft emission standards) -- Administrator shall set emission standards for air pollutants emitted by any class or classes of aircraft engines which cause or contribute to air pollution reasonably anticipated to endanger public health or welfare. The standards shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance.

Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq.

§ 1317 (Toxic effluent standards) -- Administrator shall publish list of toxic pollutants listed in NRDC Consent Decree and any others which

§ 1316 (National standards of performance) -- Administrator will publish and revise a list

	"cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in *reproduction) or physical deformations*, in such organisms or their offspring." Administrator may add or remove pollutants from the list taking into account toxicity, persistence, degradability, presence and importance of affected organisms, and nature and extent of effects. Listed toxic pollutants must be subjected to effluent limitations based on best available technology. Administrator may impose more stringent effluent standards on toxic pollutants, taking into account same factors, and in addition the extent to which effective control is being or may be achieved under other regulatory authority. Any such effluent standard shall provide "an ample margin of safety." § 1321 (Hazardous substance liability) -- *Discharge* of hazardous substances into navigable waters in "reportable quantities," as determined by the Administrator, is prohibited. Hazardous substances are those compounds which, when discharged in any quantity into navigable waters "present an imminent and substantial danger to the public health or welfare."	of categories of pollution sources, including, at a minimum, those stated in the statute. After a category is included in the list, the Administrator shall establish standards of performance for new sources within such category. The standards must reflect the cost of achieving the required effluent reduction. § 1317 -- see discussion in Column II.
Resource Conversation & Recovery Act (RCRA) 42 U.S.C. § 6901 et seq.	§§ 6921 - 6924 (Standards for hazardous waste and waste generators, transporters and treatment, storage and disposal facilities) -- Administrator shall develop	§ 6921 (Listing hazardous waste) -- Administrator shall list hazardous wastes that are subject to regulation. Wastes

criteria for identifying hazardous waste and list particular hazardous wastes subject to regulation. "Hazardous waste" is defined as: "Solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical or infectious characteristics may (A) cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness, or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." Criteria for identifying characteristics of hazardous wastes must take into account "toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Regulations identifying the characteristics of hazardous wastes and listing particular hazardous wastes must be based on the criteria. Standards for generators and transporters of hazardous waste treatment, storage, and disposal facilities shall be established "as may be necessary to protect human health and the environment."

may be added to the list upon petition by the Governor of any state.

Safe Drinking Water Act, 42 U.S.C. § 300f et seq.

§ 300g-1(a), (b) (National primary drinking water standards) -- Administrator shall, within 180 days of the Act's passage, issue national interim primary drinking

§ 300j-5 (National drinking water advisory council) -- A fifteen member council, with five members from appropriate

water standards governing contaminants in drinking water which "may have any adverse effect on the health of persons." The standards were to "protect health to the extent feasible" using generally available technology, treatment techniques and other means which EPA found to be generally available (considering costs). Based on an NAS report, EPA is to establish recommended maximum contaminant levels at which "no known or anticipated adverse effects" on the health of persons occur and which allows an adequate margin of safety. The national primary drinking water regulations are to set actual maximum contaminant levels as close to the recommended maximum as is "feasible" with the use of the best generally available technology, treatment techniques and other means which EPA finds are generally available (considering costs). These regulations are to be revised whenever changes in technology, treatment techniques and other means permit greater protection of the health of persons.

§ 3001 (Emergency powers) -- If state and local authorities have not acted, the Administrator may take such actions as he deems necessary to protect the health of affected persons from any contaminant which is present in or likely to enter a public water system and "which may present an imminent and substantial engenderment to the health of persons."

state and local agencies, five members from the general public, and five members from private organizations demonstrating an active interest in the field of water hygiene and public water supply. The council shall advise, consult with, and make recommendations to the Administrator on matters under this subchapter.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 et seq.	§ 136a(c) (Registration), § 136d(b) (Cancellation) -- Registration shall be denied or cancelled if the pesticide poses "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits." § 136a(d), § 136d(b) (Classification) -- A registrable pesticide will be classified for restricted use if, absent regulatory restrictions in addition to instructions on use, it may generally cause unreasonable risks to the environment. § 135d(c) (Suspension) -- A pesticide whose use poses an "imminent hazard" may be suspended if continued use "would be likely to result in unreasonable adverse effects on the environment" pending cancellation proceedings.		§ 136w(d)-- Administrator must submit to Scientific Advisory Panel notices of intent to cancel, actions to suspend and proposed and final regulations.
Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq.	§ 2603(a)(Testing) -- The Administrator may require testing of a substance which "may present an unreasonable risk of injury to health or the environment" (or to which human or environment exposure may be "significant" or "substantial") if the data to be provided by the tests are necessary to assess whether there is an unreasonable risk. § 2603(f) (Priority regulation) -- Whenever information demonstrates "that there may be a reasonable basis" to conclude that a substance presents "a significiant risk of	§ 2603(e) (Priority list) -- A committee of eight members from various federal agencies shall develop a list of chemical substances, based on several factors focusing on the quantity manufactured and the threat and extent of exposure, in the order that EPA should take action under §2603(a) with respect to the substances. In making up the list, the committee should give priority to those	

serious or widespread harm to human beings from cancer, gene mutations, or birth defects," EPA must, within 180 days, publish a finding of no *unreasonable risk* or commence a proceeding to regulate the substance so as to prevent such risk or reduce it to a sufficient extent.

§ 2604 (Manufacturing and processing notices) -- If EPA lacks sufficient information to permit a reasonable evaluation of the health *and environmental effects regarding* a new chemical or significant new use, which "may present an unreasonable risk of injury" or to which there is likely to be "substantial" or "significant" human or environmental exposure, EPA may issue a proposed order (enforceable only by court order if properly objected to) or may seek a court order to *temporarily prohibit or* limit manufacture or processing until sufficient evidence becomes available. If EPA has a "reasonable basis" to conclude that the substance presents or will present an unreasonable risk of injury to health or the environment before a rule can be promulgated under section 2605, EPA may (1) issue a proposed, *immediately effective* rule under section 2605(a) or (2) issue a proposed order (or seek a court order) prohibiting or limiting manufacture or processing.

§ 2605(a) (Regulation) -- If there is a "reasonable basis" to conclude that a chemical "presents or will

substances and mixtures that "*are known to cause* or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects."

§ 2604 -- By rule, EPA may compile and update a list of substances with respect to which EPA finds that the manufacture, processing, distribution in commerce, use, or disposal "presents or may present an unreasonable risk of injury to health or the environment."

present an unreasonable risk of injury to health or the environment," after consideration of: (1) effects on health and the magnitude of human exposure; (2) effects on the environment and the magnitude of environmental exposure; (3) the benefits of the substance and the availability of substitutes; and (4) the reasonably ascertainable economic consequences, considering the effects on the national economy, small business, technological innovation, the environment and public health, EPA shall regulate the substance "to protect adequately against such risk using the least burdensome requirements."

§ 2606 (Imminent hazards) - EPA may start a civil action against the manufacturer or processor for seizure of chemicals that are "imminently hazardous" or for other relief. A court may grant any relief necessary to protect health or the environment from an unreasonable risk.

§ 2607(e) (Substantial risk notifications) -- Any manufacturer, processor or distributor of a chemical who obtains information which "reasonably supports" the conclusion that that chemical presents a "substantial risk of injury to health or the environment" must immediately inform EPA of such information.

Ocean Dumping Act, 33 U.S.C. § 1401 et seq.

§ 1412-13 (Permits) -- Administrator may issue permits for dumping if it will not

	"unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities."		
Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.	§ 2056 (Consumer product safety standards) -- Commission may promulgate standards containing requirements expressed in terms of performance requirements or requirements relating to clear and adequate warnings and instruction. Any requirement shall be "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." § 2057 (Banned hazardous products) -- Commission may ban a consumer product that presents an "unreasonable risk" of injury and for which no feasible consumer product safety standard would adequately protect the public from the risk. § 2061 (Imminent hazards) -- Commission may file a court action for seizure of an "imminently hazardous consumer product" (defined as a product which "presents imminent and unreasonable risk of death, serious illness, or severe personal injury").		§ 2077 (Chronic hazard advisory panels) -- Commission shall appoint a seven member panel made up of independent scientists to advise the Commission on issues relating to the chronic hazards of cancer, birth defects, and gene mutations associated with consumer products. The Commission may not issue proposed regulations relating to cancer, birth defects, or gene mutation until it has received the report of an advisory panel.
Food, Drug & Cosmetic Act 21 U.S.C. § 301 et seq.	§ 342 (Adulterated food) -- Food is considered to be adulterated, if inter alia, (1) it contains any poisonous or deleterious substance which may render it injurious to health (or, in the case of an intrinsic substance, the quantity	§ 376 (Color additives) -- Secretary is to create separate lists of color additives certified for use in or on food, for use in or on drugs, and for use in and on	§ 346 (Tolerances) -- Upon request of a petitioner or if the Administrator deems it necessary, the Administrator shall submit data to an advisory

of such substance ordinarily renders it injurious to health); (2) if it bears any added poisonous or deleterious substance which is unsafe (other than certain otherwise regulated substances); and (3) if it consists in whole or in part of any filthy, putrid or decomposed substance, or is otherwise unfit for food.

§ 346 (Tolerances) -- Tolerances may be set for poisonous or deleterious substances added to food, if substances cannot reasonably be avoided in the production of the food, at the level necessary for the protection of public health.

§ 348 (Food additives) -- The Secretary may issue a regulation prescribing the conditions under which a food additive may be used, if the food additive has been adequately shown through scientific procedures to be safe under the conditions of its intended use. An additive will not be considered safe "if it is found to induce cancer when ingested by man or animal, or it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

§ 376 (Listing and certification of color additives) -- A regulation allowing the use of a color additive may be put into effect if the color additive is safe under proposed conditions of use. A color additive shall be considered unsafe "for any use which will or may cosmetics, based on whether they are safe and suitable for such uses.

committee to perform an independent study of the data. The advisory committee is to consist of competent experts selected by the NAS and must contain one or more representatives from land-grant colleges. The report and recommendations of the committee are to be considered by the Administrator in the decision as to an appropriate tolerance level.

§ 376 (Color additives) -- Upon request or at the Secretary's initiative, scientific questions regarding color additives are to be referred to the advisory committee of qualified experts, to be selected by the NAS.

The Sub-Cabinet Working Group has proposed that a Food Science Advisory Committee be created to advise the Secretary on cancer and other food safety issues. If further data evaluation is needed, a Science Evaluation Committee is to be formed. Where a food additive is thought to induce cancer, the Secretary must submit the data to the Food Science

result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal" and shall be considered unsafe "for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for such use, or after relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal."

The Sub-Cabinet Working Group's latest proposals for an administrative position include: (1) definition of "safe" as "a reasonable certainty of no significant risk, based on adequate scientific data, under the intended conditions of use of a substance;" (2) codification of judicial de minimis rule for food contact substances; (3) clarification of Delaney Clause as applying (a) to additive as a whole, (b) only where qualified experts find risk of cancer to man and (c) only where risks outweigh health benefits from additive use; and (4) allowance of use of risk assessment procedure to determine safety.

Advisory Committee or to a Science Evaluation Advisory Committee.

Humane Care and Development of Substitutes for Animals In Research Act, H.R. 6928 and S. 2948 (Proposed Legislation)	The legislation strengthens existing federal laws concerning the proper treatment of laboratory animals. The bills would require laboratories receiving federal funds to set up animal care committees to monitor the experimental use of animals; set standards for the animals' care and treatment, and provide awards to researchers who develop alternatives to animal experimentation. The House bill also would require accreditation of laboratories.