Appendix B

Federal Regulation of and Research on Neurotoxic Exposure

Legislation on toxic agents of many kinds provides the framework for Federal regulation of many industrial and environmental agents. Those activities relevant to regulation and research on substances toxic to the nervous system are reviewed in this appendix, Agents toxic to other organs and organ systems are regulated in a similar manner in many cases, but regulation of agents toxic to other organs is not summarized here.

Federal regulation of toxic substances, including neurotoxins

The Environmental Protection Agency [EPA) is responsible for enforcement of several laws that regulate toxic substances. The Toxic Substances Control Act (TSCA), the Clean Water Act, the Clean Air Act, the Resource Recovery and Conservation Act (RRCA) amendment to the Solid Waste Act, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), with its sister legislation, the Federal Environmental Pesticide Control Act (FEPCA), all provide authority to regulate exposure to toxic substances. The Food and Drug Administration (FDA) regulates drugs, food, and cosmetics under the Food, Drug, and Cosmetic Act; and the Occupational Safety and Health Administration (OSHA) of the Department of Labor administers the Occupational Safety and Health Act. The major laws, agencies, and regulated entities are summarized in table B-1.

The FDA, OSHA, and EPA have enabling legislation to include setting standards for neurotoxicity in regulation of drugs and cosmetics, occupational exposures, and environmental exposures, respectively. Some of OSHA'S regulatory standards have been based partially on neurotoxic effects, and neurological side effects of drugs are monitored by FDA. However, none of these agencies has published standards for testing of neurotoxic effects. One reason for the absence of guidelines is the unsettled state of the science of measuring neurotoxicity. No consensus on standard methods for determining guidelines regarding neurotoxic exposure has been established, although there has been much recent progress. To explore the possibilities of standardizing neurotoxicity tests, the FDA has undertaken a long-term project that is examining batteries of neurotoxic tests with the goal of establishing a reliable, cheap, and effective means of testing for neurotoxic effects.

Pesticide regulation

One aspect of Federal involvement in regulation of neurotoxic chemicals that deserves special mention is the registration of pesticides. Pesticides are regulated by the EPA Office of Pesticide Programs. Proposed pesticides and pesticide ingredients are subject to EPA approval. Such approval requires testing for toxicity. However, approval for some uses can be obtained by application for emergency exemptions or provisions for "special local needs."

Table B-l. -Selected Federal Agencies and Laws Regulating Neurotoxic Exposure

Agency	Law	Application
Environmental Protection Agency	Toxic Substance Control Act	Chemical substances
	Federal Insecticide, Fungicide and Rodenticide Act	Pesticides and other antibiotic agents
	Solid Waste Act	Solid wastes (including ground water contamination)
	Clean Air Act	Airborne pollutants (including lead and gases)
	Clean Water Act	Water pollutants
Occupational Safety and Health Administration	Occupational Safety and Health Act	Occupational exposures
Food and Drug Administration	Food, Drug, and Cosmetics Act	Food, food additives, drugs, and cosmetics

SOURCE: Office of Technology Assessment.

Congressional hearings on pesticide regulation and related topics were held by the Subcommittee on Department Operations Research and Foreign Agriculture of the House Committee on Agriculture on February 22-23, 1983. Documents submitted as testimony identified concerns regarding operation of the Office of Pesticide Programs at EPA. Concern was expressed about the adequacy of EPA resources to meet projected needs, methods of approval that avoid formal registration, and the scientific basis for approval of pesticides at EPA. EPA has since issued a more than 400 page set of guidelines for pesticide testing.

Federal research on toxicology, including neurotoxicology

Several Federal agencies are involved in research on neurotoxicity. All those mentioned in this paragraph and in figure B-1 are parts of the Public Health Service of the Department of Health and Human Services. The National Institute of Environmental Health Sciences (NIEHS) and the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), both institutes of the National Institutes of Health, conduct studies on neurotoxicity. The National Institute of Mental Health has a laboratory devoted to research on Developmental and Behavioral Neurotoxicity. The FDA has a Nationa] Center for Toxicological Research (NCTR), which is charged with developing and validating test procedures. The Centers for Disease Control include the National Institute for Occupational Safety and Health (NIOSH), which does research and provides exposure guideline recommendations to OSHA. The National Toxicology Program, headed by NIEHS, coordinates the activities of NIEHS, NCTR, and NIOSH in toxicology. The institutional arrangement of some of the major agencies doing research on neurotoxicology is shown in figure B-1.

Research on pesticides is carried out in industrial laboratories, by university scientists, and at several land-grant universities supported in part by the U.S. Department of Agriculture. Information based on research into efficacy, specificity, and health effects, including neurotoxicity, is submitted to EPA as part of the pesticide registration process.

Figure B-l.—Selected Agencies Doing Federal Research on Neurotoxicity