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ENVIRONMENTAL HEALTH LEGISLATION
(An interim report - 92nd Congress, 1st Session)

CONGRESSIONAL RESEARCH SERVICE

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ENVIRONMENTAL HEALTH LEGISLATION

I. Introduction

The subject of environmental health -- broad and frequently ambiguous in scope -- has been defined as "that aspect of public health that is concerned with those forms of life, substances, forces, and conditions in the surrounding of man that may exert an influence on man's health and well being. This definition includes other people as part of man's surroundings that contribute to the status of environmental health." 1/

Of particular interest in the 92nd Congress thus far have been such environmental health issues as: urban health (lead-based paint poisoning); chemicals which affect human health (hazardous and toxic substances in food, air, cosmetics, etc.); radiation health; and health in the occupational environment. The point of departure for purposes of this report in considering the legislative aspects of environmental health are the:

Lead-based Paint Poisoning Prevention Act
Radiation Safety and Health Act
Poisoning Prevention Packaging Act
Federal Food, Drug, and Cosmetic Act
Federal Hazardous Substances Act
Occupational Health and Safety Act

In the total field of environmental science, there is a great deal of legislation which will have an indirect effect on health. Some of this legislation is so comprehensive as to require more specific

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1/ Purdom, P. Walton, Environmental Health, Academic Press, New York 1971, p. 2.

reporting than will be provided within this report. Examples of environmentally related problems which are not included within the scope of this report are the issues of environmental control, planning, and management efforts for improvement of air and water quality and solid waste disposal. Other Congressional Research Service publications will provide summaries of current legislation on these latter topics.

A. General Reports of Interest

1. Compilation of Selected Public Health Laws. Volume I and Volume II. Prepared for the Use of the House Committee on Interstate and Foreign Commerce and Senate Committee on Labor and Public Welfare. 92nd Congress, 1st Session, March, 1971. Joint Committee Print.

These reports were prepared in order to have in readily available form an up-to-date compilation of selected and basic public health laws. Included in these volumes are the Public Health Service Act, the Developmental Disabilities Services and Facilities Construction Act, the Community Mental Health Centers Act; the Clean Air Act; the Solid Waste Disposal Act; the Narcotic Addict Rehabilitation Act of 1966; the Controlled Substances Act; the Federal Food, Drug, and Cosmetic Act; the Federal Hazardous Substances Act; the Fair Packaging and Labeling Act; and several other laws pertaining to Indian health, to mental retardation, and to the health and safety of the consumer.

2. Consumer Product Safety Act of 1971. Hearings Before the Committee on Commerce, United States Senate, 92nd Congress, 1st Session On S. 983, S. 1685, and S. 1797. July 19, 21, 22, 23, and 26, 1971.

These hearings are considered significant because they provide an introduction to an attempt to "establish a comprehensive safety program

with full authority to move to head off any unreasonable product safety hazard, no matter what product, no matter what hazard - immediately by banning if necessary - deliberately, but without needless delay, to set a minimum safety performance standard, where appropriate." The hearings consider the overlap of regulatory responsibilities within such legislation as toy safety, flammable fabrics, poison prevention packaging, hazardous substances, electronic product radiation and refrigerator safety.

3. Federal Environmental Pesticide Control Act. Hearings Before the Subcommittee on Agricultural Research and General Legislation of the Committee On Agriculture and Forestry, United States Senate, 92nd Congress, 1st Session, S. 232, S. 272, S. 660, and S. 745, March 23, 24, 25, and 26, 1971. Hearings Before the Committee on Agriculture, House of Representatives, 92nd Congress, 1st Session, on H.R. 26, H.R. 1077, H.R. 1722, H.R. 4152, H.R. 4596, H.R. 5182, H.R. 6576, and H.R. 6761. February 22, 23, 23; March 1, 2, 3, 8, 9, 10, 15, 16, 17, 18, 22, 23, 24, 25, 1971.

These hearings are of particular interest as they provide a comprehensive review of the Federal Insecticide, Fungicide, and Rodenticide Act and changes being proposed to that Act which will have an impact on the use of these toxic materials. Environmental health implications of pesticide use are discussed by a variety of witnesses, in addition to a very complete review of the ecological effects of pesticides.

4. Environmental Quality. The Second Annual Report of the Council on Environmental Quality. August 1971.

In addition to a review of programs directed toward pollution control, water quality, land use, and worldwide developments of interest

in environmental quality, this report provides a summary of accomplishments and recommendations in the environmental health field including radiation health, control of toxic substances, and urban health programs.

II. Urban Health: Lead-based Paint Poisoning

As pointed out by the Secretary of the Department of Health, Education and Welfare during the appropriations hearings (H.R. 10061), July 19, 1971:

> Leaded paint, like the communicable disease, is a preventable health hazard that strikes hardest against children, and especially poor children. About 400,000 children suffer from lead poisoning each year because they eat leaded paint that peels from the walls and furnishings of their homes. Over 3,000 children a year suffer moderate to severe brain damage as a result of lead poisoning, and 200 die. Like many environmental health problems, this one is not entirely medical; solving it will require removing the source of the problem as well as treating its victims. We have asked for an additional $2 million in an amendment to the 1972 budget to make a significant start toward eliminating lead paint poisoning once and for all.

A. Legislation

The Lead-Based Paint Poisoning Prevention Act (Public Law 91-695), 91st Congress, H.R. 19172, January 13, 1971 is "An Act to provide Federal financial assistance to help cities and communities to develop and carry out intensive local programs to eliminate the causes of lead-based paint poisoning and local programs to detect and treat incidents of such poisoning, to establish a Federal demonstration and research program to study the extent of the lead-based paint poisoning problem and the methods available for lead-based paint removal, and to prohibit future use of lead-based paint in Federal or federally assisted construction or rehabilitation." The Act provides authorizations for appropriations for Title I (Grants for the detection and

treatment of lead-based paint poisoning): $3,330,000 for FY 71 and $6,660,000 for FY 72; for Title II (Grants for the elimination of lead-based paint poisoning): $5,000,000 for FY 71 and $10,000,000 for FY 72; Title III (Federal demonstration and research programs): $1,670,000 for FY 71 and $3,340,000 for FY 72.

B. Legislative Proposals

Most of the bills introduced during the first session were for the purpose of securing appropriations for funding the Act. Fiscal year 1972 appropriations are $7.5 million (P.L. 92-80). Two bills were introduced to secure an amendment of P.L. 91-695 so as to permit the awarding of grants to States. In a few instances, local departments of health have merged into statewide health departments and the terminology of the Act prevents States from securing grants for which local communities with separate health departments would be eligible. The following table lists the bills introduced thus far:

Lead-Based Paint Poisoning Prevention Bills

Bill No.	Member	Date	Committee
1. To provide for appropriations for P.L. 91-695 for FY 71			
H.R. 1748	Mr. Ryan	Jan. 22	Appropriations
H.R. 1749	Mr. Halpern	Jan. 22	Appropriations
H.R. 1750	Mr. Ryan	Jan. 22	Appropriations
H.R. 2626	Mr. Ryan	Jan. 29	Appropriations
2. To provide for appropriations for P.L. 91-695 for FY 71 and FY 72			
H.R. 1751	Mr. Ryan	Jan. 22	Appropriations
H.R. 2627	Mr. Ryan	Jan. 29	Appropriations
H.R. 8876	Mr. Roe	June 2	Appropriations
H.R. 9047	Mrs. Hicks	June 10	Appropriations

Bill No.	Member	Date	Committee
3. To provide supplemental appropriations for P.L. 91-695 for FY 72			
H.R. 10570	Mr. Ryan	Sept. 9	Appropriations
H.R. 10871	Mr. Rangel	Sept. 23	Appropriations
H.R. 10933	Mr. Rangel	Sept. 28	Appropriations
H.R. 10934	Mr. Rangel	Sept. 28	Appropriations
H.R. 11252	Mr. Rangel	Oct. 14	Appropriations
4. To amend P.L. 91-695 to permit grants to states			
H.R. 11456	Mr. Tierman	Oct. 27	Bank and Currency
S. 1874 (amendment 666)	Mr. Pell	Nov. 12	Labor and Public Welfare

C. Recent Reports of Interest

1. National Academy of Sciences - National Research Council, Airborne Lead in Perspective (Preliminary draft - final version expected in early 1972), September 7, 1971.

This report reviews the literature available and other knowledge concerning the effects of lead on human health and welfare. A major objective of the report is to assess the danger to man, animals, or plants of harmful effects of lead in the environment in the near future. Of particular interest are the comments concerning the effects of lead in air in cities since this is considered to be the major focus of any danger which might develop. The study points out the need for more information on the lead in air contributing to the effects of lead from other sources, such as lead-paint. Air-borne lead is considered to have the potential of providing a significant additive effect under certain circumstances.

2. U.S. Environmental Protection Agency, Environmental Lead and Public Health, March, 1971 (Air Pollution Control Office, Research Triangle, North Carolina).

"The purpose of this document is to briefly summarize the major public health problems associated with lead in the environment and the role that the Department of Health, Education, and Welfare and EPA fulfill with respect to these problems. Following a basic discussion of lead metabolism and toxicology, the sections on diet and consumer goods and on ambient air deal primarily with general population exposures. Because industrial workers and children constitute two distinct exposure groups, they are discussed in separate sections."

3. Seven-City Study of Air and Population Lead Levels. An Interim Report. L.B. Tepper. A study released by the Environmental Protection Agency, June 4, 1971.

"Lead levels in the air have increased significantly over the past seven years at several individual locations in Cincinnati, Los Angeles, and Philadelphia, according to a preliminary summary of test data released today by the Environmental Protection Agency. . . It has not yet been determined whether there is a true relationship between the ambient air lead levels and the blood lead levels measured in the four communities. EPA officials stressed that further statistical analysis of the data is needed before firm conclusions can be drawn." This is one of the studies which added to the controversy concerning the recommendations provided within the NAS-NRC study on lead. Further, as pointed out in the NAS study, when referring to blood concentrations as considered to be near the range requiring further evaluation: "These high blood lead concentrations cannot be ascribed specifically to the inhalation of lead, although that is a possibility." There is a

requirement for more study of the possible effects of prolonged low-level exposure to lead.

D. Recent Events of Interest

1. Lead in Paints.

The Food and Drug Administration proposed rules designed to implement the Lead-Based Paint Poisoning Prevention Act which would result in a requirement that the amount of lead permitted in paints used in areas accessible to children would be limited to a maximum of 0.5 percent. These regulations, when effective, would be applicable for all paints used for such purposes as painting pencils, toys, interiors of dwellings, and such exterior surfaces as stairs and windowsills which children can easily reach. This new regulation, if approved, would become effective in early 1972. The FDA proposal for the change in lead content of paint was published in the Federal Register for November 2, 1971.

2. Lead Poisoning in New York City. Transactions New York Academy of Sciences, May 1971, pp. 539-545.

New York has been one of the leaders in the fight to eliminate lead-based paint poisoning in children. A report of the results of a recent survey indicated that more effort is required to screen and identify and treat children with lead poisoning and to correct the housing problems associated with lead poisoning.

3. Surgeon General's Guidelines on Lead Poisoning.

Guidelines for the detection and treatment of lead poisoning in children were approved by the Surgeon General. The Public Health Service

statement indicates that children with blood lead values of 80 micrograms per 100 milliliters (ml) blood or higher, regardless of the presence or absence of lead poisoning symptoms, should be considered an active case of lead poisoning requiring immediate hospitalization and treatment. Blood lead levels of 50 to 79 micrograms per 100 ml blood should be considered as evidence of possible lead poisoning and children should be evaluated further by physicians. Wherever possible, children with blood lead levels between 40 and 49 microgrms per 100 ml blood should also be evaluated further by a physician. (Using these standards, New York City classifies all children with blood levels of 60 micrograms lead per 100 ml of blood or more as a "case". Other cities use 50 micrograms as a level. The definition of standards to classify "cases" must be identified in any comparison of incidence of lead poisoning among various reporting cities).

4. Symposium on Science and the Environment

The Washington Academy of Sciences initiated the first of a number of planned symposia on science and the environment in January 1971 by examining the problem of lead in the environment. Although primary emphasis was placed upon the use of lead in gasoline, the total biological effect of lead was considered in evaluating the hazard of air borne lead. In terms of the hazard to children, and particularly from ingestion, G.J. Stopps said: "I believe that lead poisoning in children constitutes a definable problem of considerable seriousness about which something useful can be done. Since our resources are

finite, I would put this item far ahead of the threat to health from other sources of lead in the environment."

III. Health Implications of Chemicals Affecting Man

There has been increasing concern about the impact on human health of trace chemicals encountered accidentally or added deliberately to foods as additives or accumulated as contaminants in foods. This concern has been extended from earlier fears about acutely toxic substances to the more subtle and difficult to evaluate effects on long term health as might be induced by carcinogenic, teratogenic, or mutagenic substances. In addition, the increasing use of complex chemicals in cosmetics and for household purposes has extended the interest of the American consumer beyond price to include increasingly sophisticated questions about health effects. From a legislative standpoint, these consumer fears have led to the introduction of bills requiring actions which range from reorganization of the regulatory agencies to the strengthening of regulations controlling the approval for safety levels of chemicals in food, cosmetics, and other chemical substances encountered in the life of modern man.

A. Legislation

The Federal Food, Drug, and Cosmetic Act (Public Law 75-717), 75th Congress, S. 5, June 25, 1938 is an "Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, and cosmetics."

The Federal Hazardous Substances Labeling Act (Public Law 86-613), 86th Congress, S. 1283, was signed on July 12, 1960 to

"regulate the interstate distribution and sale of packages of hazardous substances intended or suitable for household use." This Act was amended by the Child Protection Act, (Public Law 89-756), 89th Congress, S. 3298, on November 3, 1966. This is an Act to "ban hazardous toys and articles for children and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles for household use."

On December 30, 1970, the Poison Prevention Packaging Act was approved. This Act, (Public Law 91-601), 91st Congress, S. 2162, is an "Act to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances."

B. Legislative Proposals

During the first session of the 92nd Congress there were numerous bills introduced which were concerned with the problem of the regulation and/or distribution of hazardous chemicals, both directly and indirectly.

Several bills were introduced to amend the Federal Food, Drug, and Cosmetic Act to require that cosmetics which contain mercury or any of its compounds bear labeling stating that fact. Also proposed to amend this Act were two bills requiring the premarket clearance of all additives to food, and two bills banning the use of diethylstilbestrol (DES) in animal food. One bill was introduced during the first session for the establishment

of a national drug testing center. There were three bills introduced to prohibit the introduction into commerce of polychlorinated biphenyls (PCB's). One bill was introduced for a comprehensive revision of all aspects of the Food, Drug, and Cosmetic Act including new requirements for pretesting of cosmetics and medical devices.

The Toxic Substances Control Act of 1971 was introduced through several bills during the first session. This proposed legislation amends the Federal Hazardous Substances Act, as amended, to provide for the regulation of the distribution and use of toxic chemicals. There were also three bills introduced to amend the Federal Hazardous Substances Act to authorize the Secretary of HEW to ban glue and paint products containing toxic solvents. One bill was introduced to provide for a special study of household detergents and to provide for the labeling of those household detergents found to be hazardous. Also, one bill provides for more effective protection against hazards caused by economic poisons.

No legislation was proposed during the first session to amend the Poison Prevention Packaging Act of 1970.

The following table shows the legislation proposed thus far in the general area of chemicals affecting man:

(Table starts on following page)

TABLES NOT
AVAILABLE

These hearings were announced as a "beginning of an inquiry into the effects on man of chemicals in his environment -- chemicals in the food we eat, the drugs we take, the air we breathe, and water we drink." The hearings were broad in scope and included testimony from five experts who discussed reasearch and problems concerned with the hazards to human health from chemicals in the environment; benefit/risk assessments; and Federal Government actions required to assure safety.

2. Regulation of Food Additives and Medicated Animal Feeds. Hearings Before A Subcommittee of the Committee on Government Operations, House of Representatives, 92nd Congress, 1st Session, March 16, 17,18, 29, and 30, 1971.

As pointed out in the opening remarks of the hearings, the purpose of the hearing was to examine the administration of the food additives amendment in the light of various developments concerning several food additives. Witnesses discussed current knowledge about the hazards to health posed by nitrites and nitrates in nature, antibiotics and diethylstilbestrol (DES) in animal feeds, the on-going review of food additives; and the danger from botulism outbreaks.

3. U.S. FDA Ad Hoc Science Advisory Committee. Report to the Commissioner of Food and Drugs from the FDA Ad Hoc Science Advisory Committee. 1971.

"The committee's task was to review and evaluate the total scientific effort of the Food and Drug Administration, and to advise the Commissioner on aspects of FDA's science activities that, in its judgment warrent improvement."

4. Advice to Consumers on Laundry Detergents. A Report to the Senate Committee on Commerce, prepared by Honorable William B. Spong, Jr., December 31, 1971.

The purpose of this report is to provide "useful information to American consumers regarding the various products available for laundry use." Dealt with in the report are the environmental effects of currently marketed products and the general safety and effectiveness of products for laundry use.

D. Recent Events of Interest

1. Studies of Food Additives.

The Food and Drug Administration is evaluating all food additives on the GRAS list. A final regulation prescribing criteria for determining whether a food additive is GRAS (generally recognized as safe) or is a regulated food additive was published in the Federal Register on June 25, 1971. FDA is awarding contracts to assemble into monographs on each substance all available data being collected by the National Academy of Sciences and other agencies. These monographs will then be used for the evaluation of the safety of the various GRAS substances. In addition to these studies, the Massachusetts Institute of Technology is beginning a series of studies to determine the chronic effect of nonnutritive food additives which may be consumed over a long period.

2. Diethylstilbestrol in Animal Feed.

The compound diethylstilbestrol (DES) has been used to increase the weight of livestock. The discovery that DES causes cancer in laboratory animals and that residues of DES were being detected in samples of meat produced a demand for the withdrawal of the use of this compound in animal feeds. The regulations concerning the use

of this compound have been changed to require a 7-day withdrawal period and mandatory certification that the compound has been withdrawn as required or was not used. Statements made during the House Intergovernmental Relations Subcommittee hearings on December 13, 1971, indicate that if industry does not comply with these new regulations, approval for use of the compound will be withdrawn.

3. Botulism.

An outbreak of botulism involving one death occurred during 1971. The incident was traced to a canning process failure at the plants of BonVivant. Only one product, vischyssoise, was implicated and FDA personnel participated in the investigation and recall of BonVivant products.

4. Polychlorinated Biphenyls.

These toxic compounds, usually referred to as PCB's, were reported by the FDA as being detected in a number of market basket surveys. The source of the contaminants was variable, in some instances as a result of leaching from packaging materials, in others as a result of machinery leaks into animal feeds. Several isolated instances involving contaminated feed led to the destruction of a large number of chickens, turkeys, and eggs. The President's Council on Environmental Quality and the Office of Science and Technology established an interdepartmental task force to coordinate studies of the PCB problem. Other agencies represented on the task force are the Environmental Protection Agency, Food and Drug Administration, the National Institutes of Environmental Health Sciences (NIEHS) and the U.S. Department of Agriculture. An international conference,

sponsored by NIEHS, was held in December, 1971 to discuss the effect of PCB's on human beings.

5. Hexachlorophene.

The Food and Drug Administration proposed a program to insure consumer safety in the use of drugs and cosmetics containing bacteria-fighting chemicals. This action was taken on the basis of studies questioning the safety of hexachlorophene. The initial effect will be to prohibit the use of all skin cleansing products containing hexachlorophene at more than 0.75% content except for prescription products. Details of the action were published in the Federal Register of January 7, 1972.

6. Aerosols in Cosmetics.

A "Government - Industry Conference on Aerosols" was held on June 21, 1971. The purpose of this conference, attended by Congressmen, adminstrators of the FDA, FTC and aerosol industry marketers and suppliers was to discuss toxicity and labeling problems. Concern about adverse reactions being encountered by consumers from the use of various forms of cosmetics in aerosol form stimulated the need for the conference. A major concern of legislators was the rising incidence of fatalities due to inhalation of aerosolized products (primarily by teenagers). The need for stricter labeling and consideration of the use of alternate, less toxic materials were discussed without specific recommendations being developed for a change of either the Federal Hazardous Substances Labeling Act or the Food, Drug, and Cosmetic Act.

7. Report of the Center for Responsive Law (Ralph Nader). Sowing the Wind by Harrison Wellford. 1971. A report of an investigation into the interaction of business and government in the general area of meat, pesticides, and poultry regulations.

Particular emphasis is placed upon the Department of Agriculture policies and actions. The threat from additives in animal feed, heavy metals, pesticides residues, and microbiological contamination of food is reviewed.

IV. Radiation Health and Safety (Other than radiation sources regulated under the Atomic Energy Act)

There has been much concern in the public mind about the unknown hazards of radiation. This concern is caused in part by the fact that the frequent discussion of radiation as a public health hazard is a relatively new phenomenon. There is much confusion in the way that the term radiation is used and a significant part of this confusion is caused by a failure to understand the difference in the sources of and the hazards imposed by different kinds of electromagnetic energy as well as particulate radiation. Ionizing radiation (such as x-rays) produced by the reactions associated with certain medical equipment should be considered quite separately from ultraviolet radiation or microwave radiation, two other types of electromagnetic energy which are discussed frequently in the press and popular journals.

The Radiation Control for Health and Safety Act of 1968 (Public Law 90-602) assigned broad responsibilities to the Secretary of Health, Education and Welfare to set and enforce performance standards for electronic products to protect the public health. It should be noted, however, that this legislation did not authorize the Federal Government to regulate the safe use of such devices. Congressional interest in radiation health and safety was evident in 1967 and 1968 in the hearings that culminated in P.L.90-602. The event that triggered the hearings was the discovery that certain color television receivers were emitting x-rays in intensities exceeding those of professionally and industrially recognized safe standards. These same hearings gave special attention to microwave generators and lasers as other sources of radiation for which safety standards should be established (there was particular concern about the need for standards

for the new microwave ovens). This concern about radiation health safety continues in the 92nd Congress.

A. Legislation

The Radiation Control for Health and Safety Act of 1968, (Public Law 90-602), 90th Congress, H.R. 10790, October 18, 1968, amends the Public Health Service Act "to provide for the protection of the public health from radiation emissions from electronic products."

B. Legislative Proposals

On January 28, 1971, Senator Randolph proposed the Radiation Health and Safety Act of 1971. This bill, introduced as S. 426, is "to amend the Public Health Service Act to provide for the protection of the public health from unnecessary medical exposure to ionizing radiation." The main purpose of this legislation is to assure proper and adequate training and licensing of radiologic technologists. The bill was referred to the Committee on Labor and Public Welfare.

C. Recent Reports of Interest

1. Annual Report On the Administration of the Radiation Control For Health and Safety Act of 1968. Message From the President of the United States Transmitting the Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602) Covering 1970. May 20, 1971. House Document No. 92-113, 92nd Congress, 1st Session.

In addition to summarizing the actions taken as required by P.L. 90-602, the report provides information on an appraisal of biological inquiry and effects; Federal electronic product radiation control standards; a summary of outstanding problems; an analysis and evaluation of research activities and progress for safety; a list of judicial actions;

extent of information dissemination; and the extent of cooperation between Government and industry.

2. Basic Radiation Production Criteria. National Council on Radiation Protection and Measurements, NCRP Report No. 39, January 15, 1971.

The basic radiation protection criteria provided in the report are intended for three areas of application:

(a) To provide a contemporary and more or less uniform framework for more detailed recommendations of the various NCRP Scientific Committee that deal with specific aspects of protection.

(b) In conjunction with reports of other NCRP Scientific Committees to provide guidance in radiation protection to all concerned legislative bodies, governmental agencies, practitioners of the healing arts and their technical associates, all branches of the nuclear industry, and laboratories, universities, and their staff and students.

(c) To contribute to the public understanding of the prudent use of radiation as a beneficial agent even though some slight risk may be associated with it. Because the criteria involve value judgments on matters that potentially affect the welfare of future generations as well as of living individuals, ultimate acceptability for the criteria also rests with society as a whole, rather than with any member or group.

3. State and Federal Control Hazards from Radioactive Materials Other than Materials Regulated Under the Atomic Energy Act of 1954. U.S. Department of Health, Education and Welfare Public Health Service, Bureau of Radiological Health, June, 1971. BRH/DMRE Report No. 71-4.

This is a report prepared in accordance with the requirements of P.L. 90-602 for the study of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954. The study includes a review of health hazards, a determination of use, and an evaluation of problems with control of such materials. The study indicates that radium still has extensive use in industry, in

medicine, and in consumer products. The use of radium is not regulated uniformly. There is no Federal authority to establish uniform and compatible use or product safety standards.

D. Recent Events of Interest

1. Whole Body Radiation Research.

It was disclosed during October, 1971, that whole body radiation treatment was being investigated on advanced cancer patients at the University of Cincinnati. The report indicated that the research was partially financed by the Department of Defense which hoped to obtain some information of possible relevance to the effects of radiation from nuclear blasts. An investigation was conducted by the American College of Radiology at the request of Senator Mike Gravel. The investigation by the College of Radiology study group indicated that the experiments were valid and were carried out in accordance with good medical practice. The investigating committee noted that the DOD concurrent studies in no way detracted from the fundamental experiment. Some reports indicate that the Senate Health Subcommittee will hold hearings to investigate this particular medical research.

2. Microwave Ovens.

The Bureau of Radiological Health, Food and Drug Administration developed and issued a Federal Standard which requires that microwave ovens manufactured after October, 1971 must not emit radiation in excess of one milliwatt per square centimeter prior to sale and five milliwatts per square centimeter throughout the useful life of the oven. The U.S. National Committee of the International Electrotechnical

Commission has recommended adoption of all requirements of the Federal standard for use as an international oven standard.

3. Diagnostic X-ray Examination.

Members of the American College of Radiology Commission on Radiologic Units, Standards and Protection, produced a booklet entitled "X-ray Examinations ... A guide to Good Practice". This booklet was published by the Bureau of Radiological Health, Food and Drug Administration and distributed to about 300,000 physicians. Other individuals involved in the use of diagnostic X-ray equipment also received the booklet. The booklet is designed to improve professional judgment in requiring the use of diagnostic X-rays and to increase patient and user protection. In this regard, the Food and Drug Administration also proposed, by announcement in the Federal Register, new performance standards for both medical and dental diagnostic X-ray equipment. The standard was developed in accordance with the responsibilities established under P.L. 90-602.

4. Television Receiver X-ray Radiation.

The Food and Drug Administration announced in September, 1971 that government-industry efforts to reduce X-ray emissions from home television receivers have made it possible to rescind previous warnings to television viewers. The FDA now advises that there should be no significant health hazard in watching a properly serviced and operated home TV at a distance at which image quality is satisfactory to the viewer. A Federal standard is now in effect which requires manufacturers to produce sets that will not emit X-rays in excess of 0.5 milliroentgen

per hour. Information on these developments is available in a pamphlet produced by the FDA, "What's Being Done About X-rays From Home TV Sets", available from the Superintendent of Documents.

V. Medical Devices

Recently there has been increasing concern on the subject of the safety and efficacy of medical devices. In the Appropriations hearings held in April, 1971, the Food and Drug Administration pointed out that:

> In the past decade, medical devices have emerged as a fundamental element of health care to the point where they now represent an industry with sales exceeding two billion dollars a year, growing at the rate of 10-15 percent annually. The increasing application of electronics and new materials to medical care has resulted in thousands of lives being saved through such techniques and products as intensive-care monitoring, internal pacemakers, and artificial heart valves. Accompanying these major advances has been the potential for increased hazards. While complete and reliable data is not available, instances of injuries and death are all too common.

The potential hazards of medical devices have led to the introduction of several bills proposing new programs for the testing and monitoring of all medical devices.

A. Legislation

The Federal Food, Drug, and Cosmetic Act (Public Law 75-717), 75th Congress, S. 5, June 25, 1938 is an "Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, and cosmetics." This Act also provides the basis for the regulation of medical devices.

B. Legislative Proposals

During the first session of the 92nd Congress, there were four bills introduced which proposed a Medical Device Safety Act to amend

the Federal Food, Drug, and Cosmetic Act to assure the safety, reliability, and effectiveness of medical devices. One bill was introduced as the National Medical Devices Standards Commission Act to create a commission to study performance standards and quality controls of medical devices. Three bills were introduced to establish the Federal Medical Evaluations Board to carry out the functions, powers, and duties of the Secretary of HEW relating to the regulation of biological products, medical devices, and drugs.

The following table lists the bills introduced thus far relating to medical devices:

Bill No.	Member	Date	Committee
1. Medical Device Safety Act - to assure safety of medical devices			
H.R. 1545	Mr. Rogers	Jan. 22	Interstate and Foreign Commerce
H.R. 7474	Mr. Green	April 19	Interstate and Foreign Commerce
*H.R. 12316	Mr. Staggers	Dec. 14	Interstate and Foreign Commerce
S. 1824	Mr. Nelson	May 11	Labor and Public Welfare
2. National Medical Devices Standards Commission Act			
H.R. 3122	Mr. Fuqua	Feb. 1	Interstate and Foreign Commerce
3. To establish a Federal Medical Evaluations Board			
H.R. 925	Mr. Minshall	Jan. 22	Interstate and Foreign Commerce
H.R. 2567	Mr. Wyatt	Jan. 29	Interstate and Foreign Commerce
H.R. 11983	Mr. McDade	Dec. 1	Interstate and Foreign Commerce

*-Administration bill

Bill No.	Member	Date	Committee
4. Amend Food, Drug and Cosmetic Act to require approval for medical devices			
H.R. 1235	Mr. Sullivan	Jan. 22	Interstate and Foreign Commerce

C. Reports of Interest

1. Medical Devices: A legislative Plan. ("Cooper Report"). Study Group on Medical Devices, Department of Health, Education and Welfare, September, 1970.

The final recommendation of the study group included the observation that there are sufficient differences between drugs and devices to require new regulations designed specifically for medical devices. It was believed that a plan which provides for several general aims should be followed in the regulation of devices. These aims include the concept that devices should be classified in three categories -- (a) those that can be exempt from standards of pre-clearance; (b) those which meet existing criteria and can be certified easily; and (c) those devices which should be made subject to performance review prior to clinical application and marketing. Suggestions are provided for determining each of these categories of devices.

2. Electric Hazards in Hospitals. Proceedings of a Workshop. National Academy of Sciences, 1970.

"The participants in this workshop discussed several types of electric shock but focused on the special hazard attendant on instrumentation of the heart and great vessels." A number of technical recommendations are provided for the improvement of the safe use of biomedical devices.

3. An Assessment of Industrial Activity in the Field of Bio-Medical Engineering. Committee on the Interplay of Engineering with

Biology and Medicine, Task Group on Industrial Activity, National Academy of Engineering, 1971.

This report is the result of an assessment by the National Academy of Engineering of current attitudes and committments of industry in the area of biomedical engineering. As a result of the assessment, the Task Group of the Acacemy developed three objectives which may be considered as recommendations of the group. These are the need for: National guidelines to develop industrial biomedical engineering efforts; formation of a national overview body in biomedical engineering; and expansion and delineation of the roles of the National Institutes of Health and other Government agencies in biomedical engineering activities.

D. Events of Interest

1. Product Testing.

The Emergency Care Research Institute of Philadelphia initiated a new endeavor in the field of medical devices by sponsoring a service called Health Devices Evaluation Service. Their publication, "Health Devices," patterned after other reports on consumer products, has the objective of reporting test results of biomedical devices and providing hospital administrators with ratings to include safety and effectiveness.

VI. Occupational Health

According to the survey conducted by the Department of Labor in 1970, there are around 55 - 60 million employees and over 4 million employers in this country. Many of these people work in unsafe and unhealthful working conditions. The Department of Labor survey found "a full 13 percent of the workers interviewed reported that they had actually experienced a work-related injury or illness in the last three years." In the hearings before the Appropriations Committee in May, 1971, the DOL pointed out that, "injury frequency rates have been slowly rising in manufacturing and are unacceptably high in construction and many other industries. Major program increases are necessary to reduce this drain on the nation's human and economic resources." These concerns reflect the need for the establishment and enforcement of job safety and health standards.

A. Legislation

The Occupational Safety and Health Act of 1970 (Public Law 91-596), 91st Congress, S. 2193, December 29, 1970, is an "Act to assure safe and healthful working conditions for working men and women: by authorizing enforcement of the standards developed under the Act; by assisting and encouraging the States in their efforts to assure safe and healthful working conditions; by providing for research, information, education, and training in the field of occupational safety and health."

B. Legislative Proposals

During the first session of the 92nd Congress, eight bills were introduced to amend the Occupational Safety and Health Act of 1970. Two of these bills propose to require the adoption of standards which will provide protection to workers against excessive noise. Three bills were introduced to exempt small farmers from the requirements of the Act, two bills to exempt small farmers from the requirements of the Act, two bills to exempt lumber dealers, and one bill to exempt small nonmanufacturing business.

The following table lists the bills introduced thus far concerning the Occupational Safety and Health Act of 1970:

Bill No.	Member	Date	Committee
1. To adopt standards for noise			
H.R. 6990	Mr. Ryan	March 30	Education and Labor
H.R. 6991	Mr. Ryan	March 30	Education and Labor
2. To exempt small farmers from the regulations of P.L. 91-596			
H.R. 10876	Mr. Sebelius	Sept. 23	Education and Labor
H.R. 10913	Mr. Brinkley	Sept. 28	Education and Labor
H.R. 11409	Mr. Shriver	Oct. 21	Education and Labor
3. To exempt lumber dealers from the regulations of P.L. 91-596			
H.R. 11512	Mr. Fisher	Nov. 1	Education and Labor
H.R. 11756	Mr. Fisher	Nov. 15	Education and Labor
4. To exempt nonmanufacturing business from the regulations of P.L. 91-596			
H.R. 12185	Mr. Collier	Dec. 10	Education and Labor

C. Recent Reports of Interest

1. Annual List of Toxic Substances. U.S. Department of Health, Education, and Welfare, Health Services and Mental Health Administration, National Institute for Occupational Safety and Health, 1971.

This is the first list published in response to the requirements of the Occupational Safety and Health Act of 1970. The listing provides a reference for potentially hazardous materials and serves as a guide for research needed in setting new occupational health standards. The list provides the chemical name of the toxic substance, data on toxic dose and effects for man and/or animal, and the literature references.

2. Legislative History of the Occupational Safety and Health Act of 1970. Prepared by the Subcommittee on Labor of the Committee on Labor and Public Welfare, United States Senate, June 1971.

3. Implementation of the Williams-Steiger Act: A 6 Month Status Report. U.S. Department of Labor, December 1971.

The report is a summary of the progress that has been made under the new Occupational Safety and Health Act of 1970. Data are provided in the form of inspections and investigations completed through October, 1971; violation information through October, 1971; OSHA rules and regulations, OSHA standards and OSHA notices published in the Federal Register; and other related material.