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Ag Chemicals Industry Voices Approval of Miller Bill

Agreement on principles, disagreements on procedures highlight testimony on Miller pesticides-residue bill

WASHINGTON.—Approval of all major provisions of the "Pesticides-Residue Amendment to the Federal Food, Drug, and Cosmetic Act" was voiced by representatives of trade associations, agricultural experiment stations, farm organizations, and several congressmen at recent hearings before a House subcommittee. Opposed to certain portions of the proposed measure were representatives of the Food and Drug Administration and the judiciary.

Lea S. Hitchner, executive secretary of National Agricultural Chemicals Association, testified on behalf of the Miller bill

Chief proponent of the new measure, which was introduced by Congressman A. L. Miller (R. -Neb.), was Lea S. Hitchner, executive secretary of the National Agricultural Chemicals Association. Mr. Hitchner said that the proposed new legislation recognizes that the problems involved in pesticides are quite different from those of adding chemicals to foods.

More effective pesticide control would result from enactment of this bill, he said, by improving the procedures for setting residue tolerances. This is done by eliminating time-consuming and costly hearings, eliminating the need for formal proof of necessity for using pesticides in favor of a certification by the Secretary of Agriculture that the pesticide is useful, and by requiring the prompt establishment of pesticide tolerances by the Secretary of Health, Education, and Welfare.

The bill also makes provision for advisory committees of qualified experts to be consulted in the setting of tolerances. One other advantage of the bill, he added, is that it makes provision for appeal to the courts in case an interested party feels that the tolerances are unjust.

Without legislation which recognizes the need for use and which permits prompt and flexible action, essential continued research and development of new products will be hampered, he added.

Existing legislation, Mr. Hitchner said, provides adequate protection to the public if properly administered and enforced. The present act, for example, calls for the establishment of tolerances for poisonous or deleterious substances required in food production. Mr. Hitchner noted that while this law has been in effect 15 years, only one tolerance has been established. In 1950, nine months of hearings were held to obtain data on which tolerances could be established for pesticides used in the production of fresh fruits and vegetables. To date no tolerances have been issued, and none are in sight for probably another year.

The proposed legislation, Mr. Hitchner says, is designed to correct this situation by establishing a more realistic and workable procedure for establishing tolerances.

Under the Miller bill, a person desiring to market a new pesticide would apply to the Secretary of Agriculture and to the Secretary of the Department of Health, Education, and Welfare (HEW). His application to USDA would set forth information to show his product is useful.

USDA is granted 30 days to certify that the pesticide is useful. The Secretary of the Department of Health, Education, and Welfare would then have 90 days to establish a tolerance for the chemical. The question may be referred by HEW or the applicant to an advisory committee for its recommendation. The committee would be composed of disinterested experts selected by the applicant, the Secretary of Health, Education, and Welfare Department, and the Food Protection Committee of the National Research Council. The committee would have 60 days in which to act.

Charles W. Crawford, FDA Commissioner, raised questions about the procedural aspects of the Miller bill

HEW would then establish a tentative tolerance. Interested parties may file objections to this tolerance within 90 days. If the final ruling is still questioned by the affected party, he may request the U. S. District Court for the District of Columbia to review the case. The court will then consider the entire matter, including the taking of new evidence (*de novo* proceeding). The court's decision is subject to appeal to the U. S. Circuit Court of Appeals for the District of Columbia. The decision of this court is final.

HEW may establish, repeal, or modify tolerances when it is felt that such action is required in the public interest.

The judicial review provisions, Mr. Hitchner believes, removes the "power of life and death over the development of new products by one government agency."

Many Supporting Witnesses

Other witnesses whose testimony was similar to that of Mr. Hitchner included Willard M. Fifield, University of Florida Agricultural Experiment Station. Dr. Fifield stated that his view was supported by 30 to 40 groups representing all phases of Florida's agricultural interests.

George C. Decker, Illinois Agricultural Experiment Station, and H. H. Schwardt, Cornell University Agricultural Experiment Station, also voiced similar sentiments. State and federal records reflect that very few deaths from pesticides have resulted, and these have been due to carelessness of the applicator in handling, Dr. Decker said.

Samuel Fraser, International Apple Association, while supporting the objectives of the bill, raised some questions. He said that the Food and Drug Administration should not be a combined fact-finding agency, promulgator of regulations, and source of information to the prosecutor. He advocated placing the fact-finding and determination of tolerances with the U. S. Public Health Service and the administration of the law with the Food and Drug Administration. He also voiced objections to the lack of definitions of such terms as "insects, rodents, fungi, weeds, and viruses" and pointed out the need for standard methods of analysis of residues.

Opposition to Certain Provisions

Judge Harold M. Stephens, U. S. Circuit Court of Appeals, and Judge James J. Morris, U. S. District Court, both of the District of Columbia, testified in opposition to the legal appeal provisions of the law. In nonlegal terms, they said, the *de novo* (new trial) procedure called for in the proposed law would in effect give the courts administrative and regulation-making responsibility which should be vested in the legislative and executive branches.

Legal appeals are possible under existing law. However, if Congress desires to include some additional legal appeal, they suggested that the *de novo* requirement be eliminated from the bill and that legal appeals not be limited to courts of the District of Columbia. Instead, they believe a petitioner should be allowed to seek court action in the district in which he resides or has his business.

Spokesmen for the Food and Drug Administration, Charles W. Crawford, Commissioner, and William W. Goodrich, legal counsel, voiced objections to

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Effects of Radiation on Biological Systems of Increasing Interest

Radiations may act on living cells both directly and through the action of radiolytic products

IOWA CITY.—A desire to know more about the action of radiation on living cells brought together more than 300 chemists, physicists, biologists, and medical scientists at the first annual meeting of the Radiation Research Society here June 22 to 24.

The society is a new one and was organized to foster a closer relationship among the rather heterogeneous group of scientists working in this field.

An ionizing radiation may kill microorganisms by two different methods. It may directly damage some vital component of the cell or it may bring about the formation of toxic substances by decomposing water. In the latter case the toxic substances diffuse and kill the cell.

The fact that radiation can act in these two ways was the basis for an explanation of how temperature affects irradiation of yeast cells.

Thomas H. Wood, Institute of Radiobiology and Biophysics, University of Chicago, studied suspensions of *Saccharomyces cerevisiae* irradiated at temperatures between −30° to 40° C. He found that the radiosensitivity above the freezing point and in supercooled liquids cold as −10° C. was practically independent of the temperature. From −30° to −10° C. there was also little temperature effect, but in this case the radiosensitivity was only about half that found in the liquid suspensions. In frozen suspension between −10° and −0.5° C. (the freezing point of the suspension) the radiosensitivity increased with the temperature.

Dr. Wood was of the opinion that when liquid suspensions are irradiated both types of inactivation occur. In frozen suspensions, however, there is little or no diffusion, so only direct action comes into play. Between −10° and −0.5° C. the quantity of free water varies with the temperature, thereby allowing diffusion to take place accordingly.

Temperature Influence. It is generally thought that bacterial inactivation with x-rays is independent of temperature. Evidence to the contrary was introduced by G. E. Stapleton, Biology Division, Oak Ridge National Laboratory. He described experiments in which he exposed buffered suspensions of *Escherichia coli* to x-ray irradiation at various temperatures from 78° to 313° K. From these data he was able to plot a family of exponential survival curves. The slopes of these curves decreased with decreasing temperatures. Below 240° K. there was no change in slope; between 240° to 313° K., however, there was an eight to tenfold difference.

The change in slope of the survival curves of oxygen saturated suspensions was discontinuous at the freezing point. This effect was not observed in oxygen free suspensions. Dr. Stapleton said that his experiments indicated the importance of diffusion in x-ray inactivation of bacteria.

Radiolysis of Water. The changes which take place when aqueous solutions are irradiated are but little understood. It is known that hydrogen atoms, molecular hydrogen, free hydroxyl radicals, and hydrogen peroxide are formed. The diffusion of these and possible other entities may have a profound effect on biological systems. J. L. Magee, University of Notre Dame, said that there is much disagreement among investigators in this field.

He called for the establishment of a standard experiment in which all conditions could be carefully controlled. Once established, such an experiment would enable workers in different laboratories to compare their work on the same basis, he said.

Seeds X-Rayed. In exposing dormant barley seeds to x-rays and thermal neutron radiation, R. S. Caldecott, Brookhaven National Laboratory, found that in both cases frequency of interchange and mutation was directly proportional to dosage.

X-radiation was applied in dosages varying from 5000 to 25,000 R. Thermal neutron radiation was varied between 2.3×10^{12} and 30.1×10^{12} per square centimeter. Frequencies of interchanges and mutations were about 1.5 to 2 times as great in the case of the highest thermal neutron dosages as with the highest x-ray exposures.

The water content of barley seeds affects their susceptibility to x-ray damage. C. F. Konzak, also of Brookhaven National Laboratory, exposed both wet and dry barley seeds to x-radiation up to a level of 1000 R. The reduction in growth of the exposed seedlings was used as a measure of the radiation effect. Similar experiments with thermal neutrons showed no difference between wet and dry seeds.