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UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

APR 20 1970

NOTICE TO MANUFACTURERS, FORMULATORS, DISTRIBUTORS
AND REGISTRANTS OF ECONOMIC POISONS

Attention: Person Responsible for Federal Registration of
Economic Poisons

Suspension of 2,4,5-T Products Bearing Certain Directions for Use

Recent studies by the National Environmental Health Service of the Department of Health, Education, and Welfare have shown that the subcutaneous administration of high concentrations of the purest samples of 2,4,5-T that are practical to manufacture at the present time produce a significant number of fetal abnormalities in mice.

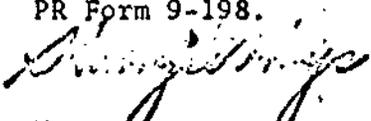
In accordance with the Interdepartmental Agreement for Protection of the Public Health and the Quality of the Environment in Relation to Pesticides, the Secretary of Health, Education, and Welfare has advised the Secretary of Agriculture that exposure to this herbicide may present an imminent health hazard to women of child-bearing age and has recommended suspension of certain registered uses of 2,4,5-T.

On the basis of the above and in accordance with Section 4.c. of the statute, it is hereby found that in order to prevent an imminent hazard to the public it is necessary to suspend the registration for products containing 2,4,5-T and bearing directions for use as follows:

- I. All uses in lakes, ponds or on ditch banks.
- II. Liquid formulations for use around the home, recreation areas, and similar sites.

Therefore, such registrations are hereby suspended and such products may not be lawfully distributed in interstate commerce.

Labeling for products containing 2,4,5-T that can be modified by deleting the above claims may be amended. Revocation of these suspension orders will be considered if 5 copies of acceptable labeling are submitted with PR Form 9-198.


Harry W. Hays
Director

UNITED STATES DEPARTMENT OF THE INTERIOR
UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Washington, April 15, 1970

Home Use of 2, 4, 5-T Suspended:

Secretary of Agriculture Clifford M. Hardin, Secretary of the Interior Walter J. Hickel, and Secretary of Health, Education, and Welfare Robert H. Finch today announced the immediate suspension by the Department of Agriculture of the registrations of liquid formulations of the weed killer 2,4,5-T, for uses around the home and on lakes, ponds, and ditch banks.

These actions are being taken pursuant to the "Interagency Agreement for Protection of the Public Health and the Quality of the Environment in Relation to Pesticides" among the three Departments.

The three Secretaries also announced that the Department of Agriculture intends to cancel registered uses of non-liquid formulations of 2,4,5-T around the home and on all food crops intended for human consumption (apples, blueberries, barley, corn, oats, rice, rye and sugar cane).

The suspension actions were based on the opinion of the Department of Health, Education, and Welfare that contamination resulting from uses of 2,4,5-T around the home and in water areas could constitute a hazard to human health.

New information reported to DHEW on Monday, April 13, 1970, indicates that 2,4,5-T, as well as its contaminant, dioxins, may produce abnormal development in unborn animals. Nearly pure 2,4,5-T was reported to cause birth defects when injected at high doses into experimental pregnant mice but not in rats. No data on humans are available.

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These actions do not eliminate registered use of 2,4,5-T for control of weeds and brush on range, pasture, and forests or on rights of way and other non-agricultural land. Users are cautioned that 2,4,5-T should not be used near homes or recreation areas. Registered uses are being reviewed by the three Departments to make certain that they include adequate precautions against grazing treated areas long enough after treatment by 2,4,5-T so that no contaminated meat or milk results from animals grazing the treated area.

While residues of 2,4,5-T in meat and milk are very rare, such residues are illegal and render contaminated products subject to seizure. There is no tolerance for 2,4,5-T on meat, milk or any other feed or food.

USDA will issue guidelines for disposal of household products containing 2,4,5-T. The chemical is biologically decomposed in a moist environment.

Background Information

Secretary Finch's Commission on Pesticides, which reported its findings in November and December 1969, expressed concern that research conducted at Bionetics Research Laboratories, under the Direction of the National Cancer Institute, indicated that 2,4,5-T had produced a number of birth defects when fed or injected into certain strains of mice and rats. Because the test material contained substantial concentrations of chemical impurities (dioxins), the birth abnormalities could not be attributed with certainty either to 2,4,5-T, or to the impurities known to be present. Representatives of the chemical industry pointed to evidence of extreme potency of the impurities as toxic agents. They demonstrated that 2,4,5-T now being marketed is of a greater purity than that which had been tested in the Bionetics experiments and urged that further testing be undertaken to clarify the questions raised.

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Responding to this suggestion and utilizing materials supplied by one of the major producers of 2,4,5-T, scientists at the National Institute of Environmental Health Sciences promptly initiated studies to determine whether 2,4,5-T itself, its impurities or a combination of both, had caused the earlier findings, and whether the 2,4,5-T now being marketed produces birth abnormalities in mice and rats. The experiments were completed last week and the statistical analyses performed over the weekend. On Monday and Tuesday of this week the analyses of the data were presented to the regulatory agencies of the Federal Government and to the members of the Cabinet.

The dioxin impurities and the 2,4,5-T as it is now manufactured, separately produced birth abnormalities in the experimental mice. Because absolutely pure 2,4,5-T was not available for testing, it is possible only to infer from certain of the observations that the pure 2,4,5-T probably would be found to be teratogenic if it were tested. But, since pure 2,4,5-T is not marketed and could not be produced in commercial quantities, this is not a practical issue for consideration.

Believing that prudence must dictate action in these circumstances, the regulatory agencies of the Federal government are moving to minimize human exposure to 2,4,5-T and its impurities. The measures being taken are designed to provide maximum protection to women in the childbearing years by eliminating formulation of 2,4,5-T from use in household, aquatic, and recreational areas. Its use on food crops will be cancelled, and use on range and pastureland will be controlled. Maximum surveillance of water

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supplies and marketed foods will be maintained as a measure of the effectiveness of these controls. These measures will be announced more specifically in the Federal Register shortly.

While the restriction to be imposed upon the use of this herbicide may cause some economic hardship, the Secretaries urged full cooperation to protect human health from potential hazards of 2,4,5-T, other pesticides and the dioxins.

The three Secretaries commended the chemical industry for its prompt and willing cooperation with the NIEHS in the studies to clarify questions raised by the initial studies of this herbicide and for working closely with the FDA in the other studies still underway. They urged the full support of industry, agriculture and the home gardner in insuring the safe use of 2,4,5-T and other pesticides which contribute in important ways to the welfare of the Nation.

USDA 1176-70