THE RPAR AND 2,4,5-T[1]

by Harvey Warnick

Abstract. Pesticide usage in the United States is regulated by the Environmental Protection Agency (EPA). The instrument of authority is the Federal Insecticide, Fungicide and Rodenticide Act, as amended. One of the many provisions of FIFRA regulations is the establishing of certain "risk criteria" for possible adverse effects of chemical pesticides. Any chemical which meets or exceeds one or more of these "risk criteria" is presumed to present an unreasonable risk to humans or the environment. A notice of such presumption [called a Rebuttable Presumption Against Registration (RPAR) notice] is published in the Federal Register. The EPA, after a comprehensive review of all available scientific data on the chemical herbicide 2,4,5-T, concluded that pesticide products containing 2,4,5-T presented an unreasonable risk to humans because the "risk criteria" for oncogenicity and teratogenicity/fetotoxicity were exceeded. EPA published its RPAR notice in the Federal Register on April 21, 1978. Interested parties were given until August 4, 1978 (105 days from the date of the RPAR Notice) to submit evidence in rebuttal or in support of the presumption. That evidence is currently being evaluated by EPA.

The United States Environmental Protection Agency's authority to regulate pesticide usage is the Federal Insecticide, Fungicide and Rodenticide Act (or FIFRA). Under FIFRA, the Agency's Office of Pesticide Programs is responsible for the registration of new pesticides, for the reregistration and classification of pesticides that are already registered, and for the cancellation or restriction of pesticides that are most dangerous.

In addition, the Agency enforces the proper use of pesticides through adherence to label directions for use in order to ensure protection of nontarget animals, plants, and humans. FIFRA provides for criminal and civil penalties for use of a pesticide in a manner inconsistent with its labeling. These provisions apply to all users, private and public, including other United States government agencies.

EPA's present regulatory mandates did not evolve overnight. The regulation of pesticides in the United States dates back to the original Pesticides Act of 1910, which provides that adulterated or misbranded products could not be manufactured or distributed.

That was the extent of pesticide regulation until Congress enacted legislation in 1938 prohibiting the movement of foods in interstate commerce that were adulterated or misbranded. The United States Food and Drug Administration was charged with keeping illegal pesticide residues out of food. This began the effort in the United States to establish tolerances for residues of pesticides in food and feed.

Regulation of pesticides was carried out under this legislation until 1947 when Congress passed the original FIFRA, which provided for premarket registration of pesticide products to be shipped in interstate commerce. In 1972, Congress amended the 1947 FIFRA; this amended law forms the basis for the regulation of pesticides in the United States today. Under the amended FIFRA, all pesticides must be federally registered, based on firm scientific data. Several new EPA programs have grown out of this law.

One of these is the Rebuttable Presumption Against Registration Process, or RPAR. In July 1975 regulations governing the RPAR process were published in the Federal Register under Section 3 of FIFRA. These regulations establish certain "risk criteria" for possible adverse effects of chemical pesticides. These criteria are (1) acute toxicity, (2) chronic toxicity, and (3) lack of emergency treatment.

Acute toxicity means high toxicity to humans and domestic animals or fish and wildlife after brief exposure. Chronic toxicity means toxic effects that take much longer, decades in some cases, to manifest themselves. Chronic effects covered by the criteria include:

Oncogenicity—the potential to cause caner;
Mutagenicity—damage to the chromosomes which may cause inherited defects;

Other delayed toxic effects, such as

Fetotoxicity—poisoning of the fetus;

[1]Presented at the annual conference of the International Society of Arboriculture in Toronto, Ontario in August 1978.

Teratogenicity—birth defects;
Reductions in population of nontarget plants or animals, particularly endangered species.

Any chemical which meets or exceeds one or more of these risk criteria is presumed to present an unreasonable risk to humans or the environment. If the Agency finds that a chemical presents unreasonable risks, notice of such a presumption (called an RPAR notice) is published in the Federal Register.

After an RPAR notice has been issued, registrants, user groups, environmental groups, and any other interested persons have forty-five (45) days to send the Agency data which either support or refute our presumption of risk. (Agency regulations provide for an extension of sixty (60) days to this comment period for good cause.) If the presumption of risk has been rebutted, the chemical may be registered or reregistered. If the presumption of risk has not been rebutted, the Agency begins an examination of the pesticide's benefits versus its risks.

This risk/benefit analysis considers the value of crops on which the pesticide is used, the availability of alternatives to the pesticide, pest management techniques, exposure to humans and the environment, and any history of adverse episodes. In developing this analysis, EPA involves registrants, user groups, environmental groups, and other federal agencies in the RPAR process. For instance, the U.S. Department of Agriculture has set up a group especially to provide benefits data for EPA's RPAR reviews. As a matter of policy and practicality EPA relies heavily on USDA to provide data on alternatives chemicals, and their costs, in assessing RPAR chemicals. In addition, EPA's proposed regulatory decision is reviewed by the Science Advisory Panel, a group of non-government scientists established by Congress to advise EPA.

After the risk/benefit analysis has been completed, the Agency proposes possible actions to regulate the pesticide; these proposed regulatory actions are reviewed by USDA and a Scientific Advisory Panel. The final regulatory decision, which may incorporate changes suggested by USDA or the Scientific Advisory Panel, is then published in the Federal Register. Examples of the types of decisions which might be made include:

—restriction of certain uses;
—improved labeling;
—cancellation of some uses;
—cancellation of all uses;
—other regulatory action which would reduce risk;
—suspension;
—registration;
—changes in application method;
—use limitations;
—protective clothing, etc.

The herbicide 2,4,5-T is currently being reviewed by EPA in the RPAR process. EPA is also investigating possible adverse effects of a chemical contaminant of 2,4,5-T known as TCDD (a kind of dioxin).

Although 2,4,5-T was registered as a pesticide in the United States in March 1948, the first evidence that 2,4,5-T was fetotoxic and teratogenic resulted from a teratogenic study of 2,4,5-T conducted at Bionetic Laboratories in 1969. The dioxin content of the 2,4,5-T used in this study was approximately 30 ppm (2,4,5-T currently being manufactured contains less than 0.1 ppm TCDD.). This study caused concern for the safety of people, especially women of childbearing age, who used or are exposed to 2,4,5-T.

On March 10, 1970, USDA identified 2,4,5-T as one of several compounds requiring further study because of teratogenic effects. On April 20, 1970, USDA suspended the registrations of all 2,4,5-T products for use in lakes and ponds or on ditch banks, and of liquid 2,4,5-T formulations for use around the home, recreational areas, and similar sites. On May 1, 1970, USDA cancelled registrations for all granular 2,4,5-T formulations for use around the home, recreational areas, and similar sites, and for all 2,4,5-T uses on food crops intended for human consumption. All registrants were advised of these actions. Two registrants, Dow Chemical and Hercules Incorporated, exercised their right under Section 4(e) of the FIFRA to petition for referral of the cancellations (rice use only) to an Advisory Committee.

The nine-member Advisory Committee of scientists submitted their report to the Administrator of the Environmental Protection Agency on May 7,

1971. The Committee recommended that the use of 2,4,5-T be permitted in forestry, rangeland, and rights-of-way provided: that TCDD contamination be limited to 0.1 ppm for all future production of 2,4,5-T; that 2,4,5-T be applied no more than once a year at any one site; and that 2,4,5-T be applied so as to avoid contaminating areas where it may come into contact with humans.

In July 1972, Dow Chemical obtained an injunction against EPA, enjoining further administrative action against 2,4,5-T. The United States Court of Appeals for the Eighth Circuit overturned the injunction of 1973, and administrative proceedings were allowed to go forward.

On July 20, 1973, a notice of intent to hold public hearings on *all* uses of 2,4,5-T was filed with the EPA Hearing Clerk. All federally approved uses of 2,4,5-T were to be explored in a public hearing scheduled for April 1974, after completion of an intensive monitoring program to detect dioxin in the parts per trillion range.

On June 24, 1974, EPA discontinued these information gathering proceedings initiated against 2,4,5-T because of its inability to monitor food for TCDD residues with the necessary analytical precision. Although the 2,4,5-T notice of hearing was withdrawn, EPA stated that it would continue its TCDD residue monitoring program and would take other action as it deemed appropriate once results of the monitoring project were available.

On July 25-26, 1974, EPA held a Dioxin Planning Conference in Washington, D.C., primarily for those parties having an interest in the withdrawn 2,4,5-T/dioxin hearings, to address data anlysis and retrieval (in the areas of analytical methodology, toxicology, and monitoring) with emphasis on analytical methodology for TCDD at the ppt level. As a result EPA established a Dioxin Implementation Plan intended to identify a reliable analytical methodology to monitor human and environmental samples for TCDD.

On-going TCDD studies under this plan include: an analytical method validation study to produce statistically defensible data; monitoring for residues in human milk in the Pacific northwest; beef fat residue studies; technical pesticide residue studies; and an environmental monitoring program for TCDD residues in soil, water, and biota.

Because there was still concern over possible adverse effects from 2,4,5-T and its contaminant, TCDD, EPA began an RPAR review of the chemical. A comprehensive computer search of the published literature on 2,4,5-T and TCDD was initiated. This search turned up over 1,200 citations to published studies. Additional citations for recent studies were found by manually searching various abstract files.

As a result of this comprehensive search of the literature, a number of teratogenic/fetotoxic studies and an oncogenic study were found.

EPA's 2,4,5-T Working Group reviewed these studies and wrote an Agency Position Document. This document was published in the Federal Register on Friday, April 21, 1978 (43 FR 17116-17157, April 21, 1978, Part II). The Agency concluded that 2,4,5-T products presented unreasonable risks because of:

1) Oncogenic effects — studies indicate that 2,4,5-T containing less than 0.05 ppm TCDD or TCDD alone have oncogenic effects in two mouse strains and one rat strain. 2,4,5-T, as currently formulated, contains TCDD at a maximum of 0.099 ppm;

2) Teratogenic and/or fetotoxic effects — studies show that 2,4,5-T containing 0.5 ppm TCDD (or less) produces teratogenic and/or fetotoxic effects in mice at 30 mg/kg; in rats at 100 mg/kg; in hamsters at 40 mg/kg; and in birds at 1 mg/kg. Other studies show that pesticide-free TCDD is fetotoxic and/or teratogenic at doses as low as 0.125 ug TCDD/kg in rats and 0.1 ug TCDD/kg in mice. Specifically, these studies show that exposure to TCDD and/or 2,4,5-T containing TCDD during pregnancy is associated with statistically significant increases in the incidence of cleft palate, kidney anomalies, skeletal and intestinal tract anomalies, and embryonic resorption. The Agency concluded from these studies that 2,4,5-T containing TCDD, 2,4,5-T without detectable TCDD, and TCDD alone produce fetotoxic and teratogenic effects in mammals. The Agency also concluded that an ample margin of safety does not exist for the population at risk (women of child-bearing age) for dermal and inhalation exposure and for cumulative oral, dermal,

and inhalation exposure to both 2,4,5-T and/or TCDD.

Registrants and other interested parties were given forty-five (45) days from the date of the RPAR notice to submit evidence in rebuttal of the presumption. However, the regulations governing rebuttable presumption provide that, for good cause shown, an additional sixty (60) days may be granted.

A major producer of 2,4,5-T requested this additional 60 days in which to present evidence to the Agency. The requester specified a need for additional time to respond to the risk presumptions and to address the additional potential adverse effects identified in the notice, and to assess the environmental fate and benefits of 2,4,5-T.

The Agency agreed that additional time would be beneficial for the submission of complete and accurate responses to the notice of presumption. All registrants, applicants for registration, and other interested persons were given until August 4, 1978, to submit rebuttal evidence and other comments or information.

The formal rebuttal period was concluded on August 4, 1978. Comments and information received by the Agency on or before that date are currently being reviewed and their validity evaluated to determine whether the Agency's presumptions of risk have been rebutted.

If the evidence submitted does not rebut the presumption, the regulations require the Agency to issue a notice to this effect within 180 days from the date of this notice. It should be noted, however, that this 180 days does not allow for a 30 day USDA/SAP review. However, because of the volume of information to be reviewed and resource constraints the Agency has not thus far been able to meet the 180 day schedule with previous RPAR chemicals.

Comments and information regarding the RPAR, received after August 4, 1978, will be considered to the extent feasible in arriving at a final decision within a reasonable time frame. The Agency originally considered a reasonable time frame for completing the RPAR process as being within a year of the RPAR notice. However, actual practice has shown the RPAR decision-making process to run about two (2) years per chemical.

The Agency is dependent upon support from many outside sources for information to be used in arriving at its final decision. In order to meet a proposed time schedule for such a decision, it is imperative that these outside sources commit the resources necessary to carry out their part of the decision making process.

If the 2,4,5-T RPAR stays on the original schedule of a year for completion, the final decision should be issued about March 1979. However, a more realistic final decision date would be late 1979. In the meantime, 2,4,5-T may continue to be manufactured, sold, and used in the United States for all of its currently registered uses.

Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C.

ABSTRACT

Cannon, W.J., Jr., H.J. Barger, and D.P. Worley. 1977. **Dutch elm disease control: Intensive sanitation and survey economics.** USDA Forest Service Research Paper NE-387. 10 p.

Sanitation, the removal and disposal of diseased elms and any elm wood that can be colonized by bark beetles, has long been the mainstay of successful Dutch elm disease control programs. Prompt removal of diseased elms has been a recommended sanitation practice for many years. Many communities have Dutch elm disease control plans that call for such a sanitation program, but have found it difficult to carry out. Frequent surveys are the key to intensified sanitation. In this paper we present evidence of the cost of detection and its relation to the effectiveness of intensive sanitation. We have used a strictly financial approach to assess the impact of survey and tree-removal costs on the municipal budget.