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Environmental News

FOR IMMEDIATE RELEASE
TUESDAY, APRIL 29, 1980 O'Neill (202) 755-0344

EPA ASKS FOR MORE INFORMATION ON HERBICIDE 2,4-D

Barbara Blum, Deputy Administrator of the U.S. Environmental Protection Agency, announced today that the Agency is requesting additional information from manufacturers to determine whether 2,4-D, a widely used herbicide, is safe for humans and the environment.

"We have made this decision following a review of health effects studies of 2,4-D," Blum said. "The review showed that significant information gaps exist on the effects of 2,4-D, preventing a definite conclusion on the safety of the herbicide.

"We will ask the manufacturers of the weed killer to commence the studies to provide the missing evidence."

Blum said that if the manufacturers fail to notify EPA within 90 days that they will provide the necessary information, EPA will use a stringent new provision of the pesticides law, Section 3(c)(2)(B), which allows the agency to stop all uses of the pesticide.

If the manufacturers comply, Blum said, EPA will allow 2,4-D to continue to be used while studies are underway. However, should any of the new studies demonstrate a major health or environmental problem, she said EPA would then take appropriate regulatory action without waiting for completion of all the studies.

The name 2,4-D refers to the phenoxy herbicide 2,4-dichlorophenoxyacetic acid and related salt and ester forms. There are approximately 1500 2,4-D products which are used to kill undesirable plants in home lawns, forests, right-of-way, drainage ditch banks, rangeland, pastures, aquatic areas, cereal crops, sugar cane and commercial turf.

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(more)

Basic manufacturers of 2,4-D include Dow Chemical Co., Midland, Michigan; Monsanto Chemical Co., St. Louis; Diamond Shamrock Corp., Dallas; PBI Gordon Corp., Kansas City, Kansas; Thompson-Hayward Chemical Co., Kansas City, Kansas; AmChem Products, Inc., Ambler, Pa.

"EPA conducted its review of health-effects studies on 2,4-D because of increasing citizen concern about the high level of exposure to 2,4-D around the country and because of its chemical similarity to the dioxin-contaminated herbicides, 2,4,5-T and Silvex." Blum said.

There also has been concern because 2,4-D was a component--along with 2,4,5-T--in Agent Orange, the defoliant used by the military in Vietnam. Although never approved by EPA for civilian use in the United States, its use in Vietnam has resulted in numerous claims of adverse health effects to American military personnel. These claims are now under investigation by the Veterans Administration.

EPA, about a year ago, imposed an emergency ban on many major uses of 2,4,5-T and Silvex. More recently, the agency opened hearings to determine whether all uses of these chemicals should be banned on grounds that they can cause cancer, birth defects and miscarriages.

EPA's review, of 2,4-D studies showed that the evidence of adverse health effects weighs far more heavily against 2,4,5-T than against 2,4-D.

"For one thing," said Blum, "there is no evidence at this time that 2,4-D contains any form of dioxin; the contaminant in 2,4,5-T associated with cancerous tumors and birth defects."

Blum stated that "toxicity studies of 2,4-D have either showed that significant adverse effects were unlikely at expected human exposure levels, or they were inconclusive, or they were not conducted in a manner acceptable by today's scientific standards."

At this point, she said, the agency, while taking no action restricting use of the chemical, will require the manufacturers of 2,4-D to provide additional information in the areas of oncogenicity (tumor-inducing), reproductive effects (particularly effects to the fetus), and metabolism in animals. She said EPA also plans to conduct certain reproductive studies on 2,4-D in its own laboratories, while awaiting the industry results.

In addition, EPA will consult with its Scientific Advisory Panel during its May 28-30 meeting to determine if there are additional studies necessary to determine the safety of 2,4-D. Following the findings of the Scientific Advisory Panel, the agency will formally specify to the manufacturers what studies are needed.

Details of the agency's review of the health effects information on 2,4-D are in the attached fact sheet.

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# # #

FACT SHEET

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 1980

2,4-D is one of the most widely used herbicides in the United States. There are approximately 1,500 products containing 2,4-D registered with EPA, and more than 70 million pounds of the active ingredient are distributed annually. The term "2,4-D" refers to the phenoxy herbicide 2,4-dichlorophenoxy acetic acid and its 35 derivative salt and ester forms. 2,4-D is used to control broadleaf weeds in a variety of places including home lawns, cereal and grain crops, commercial areas, commercial turf, rights-of-way, and forests.

Public concern about the potential adverse health effects of 2,4-D has intensified since the emergency suspension of 2,4,5-T and Silvex in March 1979. This concern stems primarily from 1) the chemical similarity of 2,4-D and 2,4,5-T as phenoxy herbicides, and 2) the question of 2,4-D dioxin-contamination, especially contamination with tetrachlorodioxin, a manufacturing contaminant in 2,4,5-T, which causes cancer and miscarriages. Due to the chemical similarity of 2,4-D and 2,4,5-T, the public has expressed concern about the potential for cancer and miscarriages from the use of 2,4-D. There is also concern because the controversial military defoliant Agent Orange, used in Viet Nam, was composed of 2,4,5-T and 2,4-D. Agent Orange was never registered by EPA for civilian use in the United States. Its use in Viet Nam by the U.S. military has resulted in claims of adverse health effects to American military personnel. The Veterans Administration is studying these claims.

Prompted by these concerns and EPA's need to resolve the questions surrounding the use of 2,4-D, the Agency initiated a review of the available information on the potential health effects of 2,4-D. This review was conducted in part to determine if the herbicide should be reviewed under the RPAR process (Rebuttable Presumption Against Registration) or if another regulatory action was appropriate.

II. Agency Review and Conclusions

Based on the results of this review, EPA has concluded that a) the presently available information on the potential adverse health effects of 2,4-D does not support a regulatory action to remove 2,4-D products from the market; b) information from scientifically valid studies does not indicate that the continued use of 2,4-D poses an imminent hazard or unreasonable adverse effect when used according to label precautions and direction for use; and c) the Agency should act quickly and vigorously to obtain better toxicological information on 2,4-D.

These conclusions are based on these following considerations:

1. There is no evidence available at this time that indicates 2,4-D contains any form of dioxin. This includes the tetrachloro-dioxin (TCDD), which is a manufacturing contaminant of 2,4,5-T and causes cancer and miscarriages.

TCDD is not theoretically expected to be found in 2,4-D. The manufacturing processes and starting chemicals from which 2,4-D and 2,4,5-T are made are not the same. Although other much less toxic dioxins are theoretically possible in 2,4-D, they have not been found despite thorough chemical analyses.

2. Because products containing 2,4-D have been registered for use since the 1940's, most of the scientific data submitted to support the product registrations now on the market were developed many years ago. While some of these studies are scientifically valid, many others do not meet today's standards for scientific testing. As a result, there are significant information gaps in several areas including cancer-potential, reproductive effects, neurotoxicity, and metabolism in animals.

3. The studies most pertinent to the question of tumor-causing potential (oncogenicity) of 2,4-D were considered inadequate and inconclusive. No valid conclusions could be drawn one way or another from the data.

4. Almost all animal tests conducted on the potential reproductive effects of 2,4-D show that, unlike 2,4,5-T with its contaminant TCDD, there is a no-effect level for injury to the fetus (fetotoxiciy) from 2,4-D. A no-effect level in animal studies is the dose level below the lowest dosage that produces observable adverse effects. At comparable dose levels, 2,4-D induces less serious fetotoxic effects than 2,4,5-T contaminated with TCDD.

In tests with rats, 2,4,5-T with its TCDD contamination caused resorptions of the fetus (dissolution of the unborn animal) at very low levels. This effect was virtually non-existent in rats fed 2,4-D at the same dose levels. Because of the significance of fetotoxic effects and because several of the reproductive tests on 2,4-D were found to be scientifically deficient, new tests will be needed before sound conclusion can be made.

5. The scientific evidence available at this time does not indicate the potential human exposure is sufficient to result in human health effects.

6. The most vigorous authority available to EPA under the pesticide law to fill information needs is a new section of FIFRA (Federal Insecticide Fungicide Rodenticide Act) passed in 1978. This provision, known as 3(c)(2)(B), allows EPA to request any additional data from pesticide registrants that is considered necessary to maintain the registration of existing products. The Agency can immediately require the manufacturers to develop the data where gaps exist. The registrants have 90 days to show that they are complying. Their product registrations may be summarily suspended if they fail to meet the Agency's conditions. No other action could obtain this information any faster. EPA is putting the data requirements into final form and they will be issued to the registrants after review by our Scientific Advisory Panel. These scientific experts will review and comment on the data requirements to assure that they will provide the information EPA needs to more definitively answer the questions on potential health effects of 2,4-D.

7. Based on a review of the toxicology data (see section IV below), and a review of the risks of other pesticide chemicals now undergoing regulatory action, the Agency believes that the risks of several other pesticides are higher and better documented than those associated with 2,4-D. To put the review of these other higher priority chemicals aside in order to devote EPA resources to taking action against 2,4-D would not, in the Agency's opinion, best serve the public interest.

III. Additional Actions

In addition to requiring several important studies of the manufacturers on 2,4-D, EPA will also:

1. Conduct several tests on reproductive effects (through our Office of Research and Development) of several derivatives of 2,4-D in order to quickly get new information and have a good basis for comparison with the company-produced data.

2. Continue its ongoing review of forest pest control practices. This review will evaluate all chemical and non-chemical controls to identify the most environmentally protective ways to control forest pests. The Agency believes that a piecemeal approach to forest chemical regulation only leads to confusion, both to the industry and to the public. Unless we review the whole range of possible controls, examining one chemical at a time only gives rise to questions about the chemicals which would be used to replace those examined and prohibited from use.

3. Review all new data as it comes in to determine if a change in our regulatory posture is warranted. This includes evaluating the results of new animal tests as well as looking into reported incidents involving human exposure to the chemical.

4. Continue to support field tests to measure exposure to 2,4-D during the present growing season.

5. EPA is informing the Inter-Agency Work Group, established by the White House to study the possible long-term effects of Agent Orange, of the actions being taken. EPA will also share its scientific findings with this committee.

IV. Toxicology Background

The potential hazard of a chemical is usually measured in laboratory animal tests. Animals are given doses of a chemical over a specific time period. Scientists attempt to derive from most of these tests a "no observable effect level" (NOEL) -- the dose level below the dosage where effects are first observed. From the animal tests and NOEL's, the potential effects on humans and other animals can be estimated. A set of brief definitions is provided below to permit better understanding of the subsequent discussion of toxicological findings.

A. General terms

1. Acute oral toxicity (LD50) - this test determines the dose level which produces death in half the test animals after a single oral dose (short-term test). Used to predict the near-term toxicity of the chemical immediately upon contact with people or other non-target animals.

2. Chronic feeding tests - animals are fed for most their life span (usually greater than 18 months in rodents) in order to determine the dose level which shows no toxic effect in test animals. This is the test from which the NOEL is (usually) derived.

3. Oncogenicity testing - animals fed relatively large doses of the test chemical for their life span (usually 18 months to 2 years in rodents) to try to induce tumors. These tests are used to predict whether the chemical may pose a cancer hazard.

4. Reproductive testing - these tests evaluate the effects of the chemical on the fertility of both the male and female parents by exposing the animals for a period of time before breeding. The tests also measure the possible effects of the chemical on the pregnant female and the fetuses through several generations. (The test with rodents through 3 generations runs approximately 14 months.)

5. Teratology testing - these tests evaluate the effects of the chemical on fetuses by exposing pregnant females during the short period of time that the fetus is most susceptible to congenital malformation. Teratogenic effects include cleft palate, central nervous system deformities, eye and limb deformities, and internal organ malfunction. These are considered to be life-threatening effects that put the animal at a disadvantage for surviving in its environment.

6. Fetotoxicity - fetotoxic effects can be seen in either the reproduction or teratology tests. Toxicity may be seen in the extreme form as fetal death or as less severe problems, such as delayed formation of bones, reduced body weights at birth, or edema (abnormal fluid accumulation in the tissue). Most fetotoxic effects appear to be reversible once exposure to the test chemical is curtailed. Therefore most fetotoxic effects are considered to be less serious than teratogenic effects, with the exception of fetal death.

B. Summary of Toxicology Review

Most of the data in EPA files on the potential health effects of 2,4-D are centered on the acid form, even though there are many derivatives, such as salts and esters. This is because the many forms of 2,4-D metabolize to the acid form in the environment and in the body. The discussion of animal data below, therefore, concerns the acid form of 2,4-D unless otherwise noted.

1. Acute toxicity - low to moderate. The potential for immediate poisonings from contact with the chemical is unlikely.

2. Neurotoxicity - There is little definitive information on the possible neurological effects of 2,4-D. In several reported cases of impaired nerve function, it was not known if the individuals were peculiarly sensitive to that type of effect or were exposed to other toxic materials.

3. Reproductive effects (effects on the unborn) - Tests have been conducted on rats, mice and hamsters to evaluate the possible reproductive effects of 2,4-D. In almost all tests, no observable effect level has been established. 2,4-D causes some of the less serious fetotoxic effects, such as edema (swelling of tissues) at the lower dose levels tested, and causes life-threatening birth defects (skeletal malformations) and cleft palates only at the very high levels tested.

Based on the no observable effect levels in the animal studies, EPA estimates that the level of exposure in a "worst case" situation (eg. a person standing directly under a spray plane) would be 500 to 1000 times less than the dose level that might cause an effect.

Much of the data available to judge these effects was generated by old study protocols, has deficiencies in the test methods, and needs clarification by further study.

EPA also reviewed summaries of tests conducted in the Soviet Union which state that some derivatives of 2,4-D produced adverse effects on unborn animal fetuses at much lower levels than indicated by the data in EPA's files. These summaries could not be used in the Agency's review because the identity of the test material, and its impurities, was unclear, and because there were no numerical data to back up the summary conclusions. In some cases tests need to be done on specific derivatives of 2,4-D.

4. Oncogenicity (potential for causing tumors) - Several rodent studies have been conducted to date. The tests were conducted a decade ago and are considered to be inadequate and inconclusive by today's scientific standards. New studies on rodents are needed.

5. Mutagenicity (inheritable effects) - The vast majority of the mutagenicity studies conducted on 2,4-D are negative. However, there are three positive studies. Taken as a group, the results of the studies can be described as inconsistent and inconclusive. A new series of tests being conducted by the Department of Health, Education, and Welfare will be reviewed by EPA when they are completed.

6. Epidemiology - No epidemiological studies of human health effects from 2,4-D exposure have been completed. However, EPA is currently investigating reports about alleged adverse effects from potential chemical exposure in several parts of the country. EPA will be looking at the results of those studies and will decide in the near future about additional field work.

V. Exposure to 2,4-D

There are at least three ways that the average citizens might come into contact with 2,4-D - through the diet, during home use, and drift of the herbicide from nearby use.

a) Diet

The EPA has set tolerances for residues of 2,4-D in various food crops. The Food and Drug Administration (FDA) routinely samples a variety of foods (the Market Basket Survey) which FDA considers to be representative of the average American diet. Samples are analyzed for pesticide residues. During the period of 1974 to 1977, no 2,4-D residues were found in any of the products surveyed. However, during the 1965 to 1977 period, a variety of other food products were analyzed, of which about 1.1% were positive for 2,4-D in very minute quantities that were well below EPA's tolerance (allowable residue) levels.

b) Home use

There are currently a number of registered home-use products which contain 2,4-D in a variety of formulations. Exposure to the herbicide in home-use situations will depend to some extent on the specific formulation used. If care is exercised by the homeowner in adhering to the directions for use and precautionary statement on the label, exposure to 2,4-D should be low.

c) Drift

"Drift", the airborne transport of pesticide materials to a non-target area, is a common source of exposure. Sometimes, a pesticide will drift during application, depending on climatic conditions (temperature, wind speed), type of formulation used, terrain (forests, mountains), and type of application method used (aerial, ground spray). Several States have imposed restrictions on 2,4-D use in order to cut down on drift potential.

Once on the ground or target crop, the herbicide may become airborne again by the process of vaporization. This particular type of drift has been the subject of intensive research by the producers of 2,4-D. Since the introduction of less volatile forms of the herbicide over the last few years, this kind of drift has become much less extensive.

VI. Environmental Persistence

2,4-D is not a persistent pesticide. Breakdown of the herbicide begins almost immediately after application at a rate dependent on several environmental factors such as temperature, humidity and medium (air, soil, crop, water). The rate of loss (commonly referred to as the half-life) is a measure of the time required for half of the substance to be degraded or lost.

On sprayed vegetables, the half-life varies from 1-3 weeks depending on geographic location, climatic conditions, vegetation type, application technique and formulation used.

In soil, the half-life varies from several days to 2 weeks, depending on acidity, soil type and amount of rain.

In water, the half-life varies from a few days to several months depending on factors such as oxygen concentration, acidity, light intesity, water temperature and formulation used.