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EMERGENCY ACTION TO STOP SPRAYING OF THE HERBICIDES 2,4,5-T AND SILVEX

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#### PRESS CONFERENCE STATEMENT

#### BY EPA DEPUTY ADMINISTRATOR BARBARA BLUM

THURSDAY, MARCH 1, 1979 WASHINGTON, D.C.

Good afternoon. We are taking emergency action today to halt the spring spraying of the herbicide 2,4,5-T on the basis of new information indicating its potential link to human miscarriages.

As many of you know, 2,4,5-T has been under intensive review by EPA for over a year due primarily to adverse health effects shown in test animals because of a contaminant known as TCDD or tetra-dioxin. This dioxin, even at very low levels, causes severe reproductive effects -- miscarriages and birth defects -- and tumors in laboratory animals.

We have just received the results of a study which shows a high probability that the herbicide is linked to actual human miscarriages in an area where 2,4,5-T is used regularly.

New studies in the Alsea basin area of Oregon, show a high miscarriage rate shortly after the spraying of 2,4,5-T in the forests. This alarming correlation comes at a time when 7 million pounds of 2,4,5-T are about to be used across the Nation to control weeds on power line rights-of-way, to manage forest lands, and to control weeds in pastures. The emergency suspension action we are taking today will protect the nearly 4 million people who may be unknowingly and involuntarily exposed as a result of those uses. The potential for significant human exposure, the warning signals from the Alsea study, the preponderance of strong animal test data, and the low short-term economic impact, compel this unusual emergency action.

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The new study was initiated by EPA because of complaints from women in Alsea reporting that they had experienced miscarriages right after the forest area in which they lived was sprayed with 2,4,5-T. The study was completed by scientists from the Environmental Health Institute of Colorado State University and the University of Miami Medical School, Department of Public Health and Epidemiology. It compared the miscarriages in the Alsea basin area of western Oregon with those of women in a control area in eastern These findings, spanning a six year period, were Oregon. then correlated with the spraying of 2,4,5-T in the State. The Alsea basin is in a national forest area of Oregon which is sprayed each spring with 2,4,5-T. The control group was from a similar rural area in the eastern part of the state which is not sprayed with the herbicide.

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Let me show you what we found.

- First, you see the numbers of pounds of 2,4,5-T used in the area. As you can see, almost all of the herbicide is used in the months of March and April;
- -- Second (first overlay) here is a line representing the miscarriages occurring in the study area. Comparing the line with the 2,4,5-T bar graphs, you see that the miscarriage rate appears to be correlated to the amount of 2,4,5-T sprayed. Notice this dramatic peak in June which follows the heaviest use of the herbicide by only 2 months. This peak occurred consistently in each year examined.
- -- And third, (second overlay) the June peak is not present for the control group. Indeed, the control group data shows a generally lower rate of miscarriages altogether.

Obviously, we are very concerned about the health implications of these findings not only for the residents of Oregon but to all citizens who may be exposed to the herbicide. We estimate that over 4 million people across the Nation may be at risk through the use of the herbicide in forestry, rights-of-way clearance, and pasture uses.

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I want to reemphasize four points about today's action:

 a preponderance of animal test results in several species show adverse reproductive
 effects at low levels of exposure;

o there is a remarkably high miscarriage rate in June in the Alsea study not seen in

Do: Drivthe June peak follows by 2-3 months the Disspraying of 2,4,5-T in the Alsea area; and Out: Dancestimated 4 million people are at risk Pressure the spray season about to begin.

Taken together, these facts sound an alarm. They compel EPA to act to stop use until we have a fuller understanding of this phenomenon and its implication for human health: power reference

We are also taking emergency suspension action against related uses of Silvex, another herbicide contaminated by TCDD, to preclude similar exposure. Silvex is used primarily for weed control on suburban lawns and other turf uses, and it could be used as a substitute for 2,4,5-T on forests, rights-of-way, and pastures.

This emergency suspension action is analogous to a temporary restraining order issued by a court. We are not saying that the health effects in humans are positively proven, or that 2,4,5-T should never be used again. What

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we are saying is that there is sufficient evidence to stop further exposure to the chemical until the issues can be resolved.

The manufacturers of 2,4,5-T have 5 days to appeal the Agency's emergency suspension order. If appealed, EPA will convene a hearing panel to examine all information bearing on the question of whether an emergency exists. The panel will, by law, be required to reach findings and make a recommendation on the emergency suspension issue to the Administrator within 10 days after evidence has been heard. The Administrator would then have 7 days to issue a final order on whether the suspension should continue through the cancellation process.

After the suspension issue is decided, the cancellation hearing process will begin to consider the larger issue of the risks and benefits of the herbicide to society.

The law requires EPA to balance the benefits of the use of a pesticide against its risks. And, from the information we have already gathered from the Department of Agriculture, the timber industry, power companies, and others, it is clear that the economic benefits of 2,4,5-T. are important to several segments of society. However,

-5-

the short-term economic impact of this action--i.e., suspension of uses over the period of the expedited hearing and the cancellation proceedings--should not be serious. This is so because alternatives are available for pasture and rights-of-way uses, and because only a tiny fraction of commercial forest acres are treated in any given year. Moreover, in many cases treatment of forests, rights-of-way, and pastures can be deferred until these proceedings are completed. The long-term economic impacts will be fully evaluated--along with the long-term health risks--in the cancellation proceedings.

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Thank you. I will be happy to answer your questions.

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# 2,4,5-T Spraying and Miscarriages in Alsea, OR Study





Passers by (equal to 10% of rural residents); and occupational (applicators, etc.) - Approximate values. Excludes rangeland





Note: No. of persons include rural residents within 1/2 mile of applications; Passers by (equal to 10% of rural residents); and occupational (applicators, etc.) --Approximate values.





Note: No. of persons include rural residents within 1/2 mile of applications; Passers by (equal to 10% of rural residents); and occupational (applicators, etc.) – Approximate values.

#### FORESTRY - SITE PREPARATION

1. Chemical

Amitrole-T	3-amino-1,2,4-triazole and ammonium thiocyanate
2,4-D	2,4-dichlorophenoxyacetic acid
Fosamine	2,4-dinitro-6-methylphenol
Glyphosate	N-phosphonomethylglycine
Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

Manual

Mechanical

Fire

## FORESTRY - CONIFER RELEASE

1. Chemical

Amitrole-T	3-amino-1,2,4-triazole and ammonium thiocyanate
2,4-D	2,4-dichlorophenoxyacetic acid
Dicamba	3-methoxy-3,6-dichlorobenzoic acid
Fosamine	2,4-dinitro-6-methylphenol
Glyphosate	N-phosphonomethylglycine
MSMA	monosodium methanearsonate
Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

Manual

One cannot assume that these alternatives are complete substitutes for 2,4,5T in respect to herbicidal effectiveness, means of application, geographic suitability, or economic considerations.

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FORESTRY - PCT and TSI

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# 1. Chemical

2,4-D	2,4-dichlorophenoxyacetic acid
MSMA	monosodium methanearsonate
Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

Manual

Mechanical

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PCT - Pre-Commercial Thinning

TSI - Timber Stand Improvement

# PASTURES

1.	Chemical	
	2,4-D	2,4-dichlorophenoxyacetic acid
	Dicamba	3-methoxy-3,6-dichlorobenzoic acid
	Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

Manual

Mechanical

One cannot assume that these alternatives are complete substitutes for 2,4,5T in respect to herbicidal effectiveness, means of application, geographic suitability, or economic considerations.

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# RIGHTS-OF-WAY

1. Chemical

Amítrole-T	3-amino-1,2,4-triazole and ammonium thiocyanate
AMS	ammonium sulfamate
2,4-D	2,4-dichlorophenoxyacetic acid
Dicamba	3-methoxy-3,6-dichlorobenzoic acid
2,4-DP	2,4-dichlorophenoxypropionic acid
Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

Manual

Mechanical

# ALTERNATIVES FOR SILVEX

# FORESTRY - SITE PREPARATION

1. Chemical

Amitrole-T	3-amino-1,2,4-triazole and ammonium thiocyanate
2,4-D	2,4-dichlorophenoxyacetic acid
Fosamine	2,4-dinitro-6-methylphenol
Glyphosate	N-phosphonomethylglycine
Picloram	4-amino-3,5,6-trichloropicolinic acid

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#### 2. Non-chemical

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Manual	!	
Mechanical		
Fire		

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# FORESTRY - CONIFER RELEASE

# 1. Chemical

Amítrole-T	3-amino-1,2,4-triazole and ammonium thiocyanate
2,4-D	2,4-dichlorophenoxyacetic acid
Dicamba	3-methoxy-3,6-dichlorobenzoic acid
Fosamine	2,4-dinitro-6-methylphenol
Glyphosate	N-phosphonomethylglycine
MSMA	monosodium methanearsonate
Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

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Manual

# FORESTRY - PCT and TSI

# 1. Chemical

2,4-D	2,4-dichlorophenoxyacetic acid	
MSMA	monosodium methanearsonate	
Picloram	4-amino-3,5,6-trichloropicolinic acid	

2. Non-chemical

Manual

Mechanical

PCT - Pre-Commercial Thinning

TSI - Timber Stand Improvement

#### HOME LAWNS AND COMMERCIAL TURF

1. Chemical

2,4-D<sup>1</sup>/ 2,4-dichlorophenoxyacetic acid MCPP (Mecoprop)<sup>1</sup>/ 2-methoxy-4-chlorophenoxypropionic acid Dicamba<sup>1</sup>/ 2-methoxy-3,6-dichlorobenzoic acid

2. Non-chemical

Hand weeding

Mechanical mowing

Cultural practices (optimize fertility, pH and tilth for grass growth)

1/ Many formulations contain mixtures of 2 or 3 of the above.

# PASTURES

1.	Chemical		
	2,4~D	2,4-dichlorophenoxyacetic acid	
	Dicamba	3-methoxy-3,6-dichlorobenzoic acid	
	Picloram	4-amino-3,5,6-trichloropicolinic acid	
2.	Non-chemical		

Manual 🐳

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Mechanical

One cannot assume that these alternatives are complete substitutes for silvex in respect to herbicidal effectiveness, means of application, geographic suitability, or economic considerations.

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# ALTERNATIVES FOR SILVEX

RIGHTS-OF-WAY

1. Chemical

Amitrole-T	3-amino-1,2,4-triazole and ammonium thiocyanate
AMS	ammonium sulfamate
2,4-D	2,4-dichlorophenoxyacetic acid
Dicamba	3-methoxy-3,6-dichlorobenzoic acid
2,4-DP	2,4-dichlorophenoxypropionic acid
Picloram	4-amino-3,5,6-trichloropicolinic acid

2. Non-chemical

Manual

Mechanical

# AQUATIC SITES

# 1. Chemical

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Alligatorweed control

2,4-D 2,4-dichlorophenoxyacetic acid

Emersed weeds

2,4-D	
Diquat	9,10-dihydro-8a,10a-diazoniaphenanthrene-2A
Endothall	3,6-endoxohexahydrophthalic acid
MCPA	2-methyl-4-chlorophenoxyacetic acid

Submersed weeds

2,4-D	
Dichlobenil	2,6-dichlorobenzonitrile
Diquat	
Endothall	

2. Non-chemical

Mechanical

**Biological** 



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

FACT SHEET

OFFICE OF TOXIC SUBSTANCES

# WHAT DOES SUSPENSION MEAN?

Under the Federal Pesticide Law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pesticides may be registered by EPA when evidence presented by the manufacturer shows that they may be used without posing "unreasonable adverse effects" to humans or the environment. In order to apply the "unreasonable adverse effects" standard the EPA Administrator must balance the risks posed by a pesticide against its economic and social benefits. Registration is granted if the benefits outweigh the risks. The law places the burden for showing that the pesticide does not pose unreasonable risks on the proponents of use, who typically submit experimental information they develop to the government as a basis for evaluating any risks the pesticide may pose.

There are times when, because of advances in science or when new information becomes available, questions arise about whether a registration should remain in effect. There are several procedures EPA can follow in such situations:

# 1) Rebuttable Presumption Against Registration ("RPAR")

The RPAR process begins with a notice summarizing evidence of potential unreasonable adverse effects and inviting public comment on the risks and benefits of the pesticide in question. The RPAR process is characterized by its informal (i.e., non-adjudicatory) nature. Its purpose is to gather information and stimulate broad public debate about whether the seriousness of problems with a pesticide indicated by "validated tests or other significant evidence" warrants regulatory action. Manufacture and use may continue during the process. RPAR leads to a decision to take no action, restrict some or all uses of the pesticide, or initiate cancellation.

#### 2) Cancellation Proceedings

Cancellations begin with a statement of findings by the Administrator of his reasons for believing that the risks of a pesticide outweigh its benefits, and that its uses should be "cancelled" (i.e., permanently banned). The notice receives review by the Secretary of Agriculture and independent scientific review by a special Panel created by the law.

Producers and interested parties have 30 days to request a hearing. If a hearing is requested the hearing will fully explore risks and benefits. This is a formal courtroom-like process before an Administrative Law Judge; expert witnesses are sworn in and cross examined. Within 25 days after the hearing is over, the Judge reports his findings and makes a recommendation to the Administrator. The Administrator has 90 days after the close of the hearing to issue a final order. The Final Order may provide for continuation of some or all uses of the pesticide. restrictions on its use, or termination of registration, whichever the Administrator may conclude is supported by the record. Any party adversely affected by the final order may seek review in the Court of Appeals. This may include persons opposed to use of the pesticide, if the order continues registration, as well as proponents of use if cancellation is ordered.

Cancellation hearings have typically taken 2 years or more to complete. The pesticide in question may continue to be marketed until and under the terms of the final order issued by the Administrator.

#### 3) Suspension Proceedings

Suspension proceedings begin with a finding by the Administrator that an "imminent hazard" is posed by a pesticide. An imminent hazard is a situation where the risks from use of a pesticide during the time required to complete cancellation proceedings outweigh the benefits that may be be derived from such use. The suspension is not effective immediately. Instead, the law affords registrants an opportunity to request an expedited hearing within 5 days of receiving notice from the Administrator that he intends to suspend. If an expedited hearing is not requested, the Administrator may implement the suspension by issuing an order. However, before issuing the order, the Administrator must begin cancellation proceedings if he has not already done so. (This is because suspension is an <u>interim</u> remedy and can be effective only for the duration of cancellation proceedings.)

If an expedited hearing is requested, the statute requires that it begin promptly. The sole issue at this hearing is whether an imminent hazard exists.

The presiding officer, or hearing panel, has 10 days after completion of the hearing to submit findings and a recommendation to the Administrator. The Administrator has 7 days to decide whether to affirm the imminent hazard determination; if he does, a final suspension order is issued. The final suspension order is reviewable in the Court of Appeals.

The pesticide(s) in question may be marketed during the time it takes to complete the expedited hearing.

#### 4) Emergency Suspension Proceedings

This proceeding begins with a finding that an imminent hazard exists and that an <u>emergency</u> exists -that the situation is so critical that the Administrator does not have time to hold a hearing before suspending. (In other words, the Administrator finds that unreasonable risks would be posed by continued use of the pesticide during a suspension hearing.)

An emergency suspension order is issued without prior notice to registrants and takes effect immediately. The Order must be accompanied by a notice beginning cancellation proceedings, unless they are already in progress. Although they do not receive advance notice, registrants may still request an expedited hearing within five days to determine whether the suspension order should remain in place for the duration of the cancellation proceeding. In other words, the emergency order only applies during the expedited suspension hearing, if one is requested. The Administrator may lift the emergency order, modify it, or keep it in place for the duration of the cancellation hearing.

Unlike "regular" suspension, <u>only</u> the registrant and the Agency may participate in the expedited hearing; others may present briefs. The presiding officer or hearing panel has 10 days from the conclusion of the hearing to submit findings and recommendations to the Administrator. The Administrator then has 7 days to issue a final order on the issue of suspension. A final order on suspension after a hearing before the Agency; may be reviewed in the Court of Appeals.

Producers may appeal an emergency suspension order to a Federal District Court which reviews only whether the emergency finding is supported. The District Court order may be appealed to the Appellate Court by either the Agency or the registrant.

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Suspension, it should be remembered, involves a preliminary assessment of evidence and probabilities, not an ultimate resolution of the larger question of the risks and benefits of the pesticide to society over the long run. That larger question is addressed in the cancellation proceedings. The Courts have found in the past that for a suspension action, "It is enough if there is a <u>substantial</u> <u>likelihood</u> [emphasis in original] that serious harm will be experienced during the year or two required in any realistic projection of the administrative (cancellation) process" [Environmental Defense Fund, Inc. vs. Environmental Protection Agency, 465 F2d 540 (D.C. Cir 1972)].

To: Col Maban X-2001

United States Environmental Protection Agency Office of Public Awareness (A-107) Washington DC 20460



Environmental News

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FOR IMMEDIATE RELEASE, THURSDAY MARCH 1, 1979

EPA TAKES EMERGENCY ACTION TO HALT HERBICIDE SPRAYING Acting on significant new evidence linking the herbicide 2,4,5-T with miscarriages in women in Oregon, the Environmental Protection Agency today halted major uses of the herbicide until a full review of its impact on human health and its benefits is completed.

The Agency's "emergency suspension" action -- the most drastic measure EPA can take under the law -- was needed because the spring spray season is only a matter of weeks away.

"Studies completed only days ago show a high miscarriage rate immediately following the spraying of 2,4,5-T in the forests around Alsea, Oregon," said EPA Deputy Administrator Barbara Blum. "This alarming correlation comes at a time when 7 million pounds of 2,4,5-T are about to be used to control weeds on power line rights-of-way and in pastures, and to manage forest lands across the Nation."

Those uses will be halted immediately by EPA's order. The remaining legal uses of 2,4,5-T on rangeland and rice may continue until the final decision because they appear at this time not to involve human exposure comparable to the suspended uses. "The emergency suspension action we are taking will protect the nearly 4 million people who may be unknowingly and involuntarily exposed as a result of the forestry, rights-of-way, and pasture uses," Blum said. "The potential for significant human exposure, the warning signals from the Alsea study, the strong animal test data, and the low short term economic benefits compel this unusual action."

The new study was initiated by EPA because of complaints from women in Alsea reporting that they had experienced miscarriages right after the forest area was sprayed with 2,4,5-T. The study was performed by scientists from the Environmental Health Institute of Colorado State University and the University of Miami Medical School, Department of Public Health and Epidemiology. It compared miscarriages over a 6 year period in the Alsea basin area of western Oregon with a control area in the eastern part of the State. The conclusions were:

- The miscarriage rate in the Alsea area was significantly higher than that in a control area in eastern Oregon where no 2,4,5-T is typically sprayed;
- -- The number of miscarriages peak dramatically for the 6 years, and particularly for the last 3 years, in the Alsea area for the month of June. Forest spraying occurs annually in March and April;
- -- there is a statistically significant relationship between the spray season and the high miscarriage peak which follows application of 2,4,5-T by 2-3 months.

"It's a remarkable correlation," said Blum. "While it is not proof of a cause and effect relationship, it is highly suggestive, particularly in light of animal data, and gives great cause for concern." Numerous laboratory tests in several animal species reveal similar reproductive problems with 2,4,5-T. "There are considerable data on the health effects of 2,4,5-T in animal tests which are predictive of the same human health effects we are seeing in Alsea," said Blum. 2,4,5-T is contaminated with 2,3,7,8-tetrachlorodibenzo-pdioxin (TCDD), which even at very low levels, produce birth defects, miscarriages, and tumors in laboratory animals.

"Taken together, all these facts sound an alarm. Prudence dictates EPA to stop use until we have a fuller understanding of this phenomenon and its implication for human health," said Blum.

2,4,5-T was first registered in 1948 as a herbicide for control of broadleaf weeds. Acting in 1970 on the basis of the animal tests, the Federal Government halted those uses to which there was a high probability of pregnant women being exposed: home and garden, recreational area, and aquatic sites. All food uses, except for rice which was appealed by the manufacturer, were halted as well.

Since that time, the herbicide has been used against unwanted vegetation primarily in forest management (2.6 million pounds used annually on 1.16 million acres), rights-of-way clearance (3.8 million pounds used annually on 683,000 acres), pastureland (500 thousand pounds on 1 million acres), rangeland (2 million pounds on 1.7 million acres), and rice (300 thousand pounds on 300,000 acres). Forresters regard the herbicide as a valuable tool in reforestation and in encouraging conifer growth (by eliminating hardwoods which compete for light and nutrients), and in allowing maintenance access to power lines.

There have been years of debate about the safety of these uses of 2,4,5-T. In April 1978 EPA issued a rebuttable presumption against registration (RPAR) on 2,4,5-T, which solicited public input on the risks and benefits of the herbicide. That review of rice and rangeland uses will continue during the suspension proceedings. "This emergency action only suspends use until the risks and benefits can be more fully evaluated," said Blum. "We have considerable data on the long term economic benefits of 2,4,5-T. The extensive analysis and data from the manufacturers and users and the USDA/State/EPA benefits assessment team in the RPAR procedure will be very valuable as we continue these deliberations. The groundwork laid in the public commant period will be instrumental in reaching as rapid and fair a final conclusion of this difficult question as possible."

"The short-term economic impact of this action -- i.e., suspension of uses over the period the expedited hearing and the cancellation proceedings -- should not be serious. This is so because alternatives are available for pasture and rights-of-way uses, and because only a tiny fraction of commercial forest acres are treated in any given year. Moreover, in many cases treatment can be deferred until these proceedings are completed. The long-term economic impacts will be fully evaluated -- along with the long-term health risks -- in the cancellation proceedings.

In a corollary action, EPA is also suspending related uses of silvex, another herbicide contaminated by TCDD, to preclude similar exposure, especially since silvex could be used as an alternative to the suspended 2,4,5-T uses. Silvex is used primarily for weed control on suburban lawns and other turf. Several alternatives are available for this use.

Any sale, distribution, or use of a suspended pesticide during the period of its suspension is illegal and may be punished by substantial penalties. The Agency will be issuing Stop Sale, Use, or Removal Orders to all registrants and distributor registrants of 2,4,5-T and silvex, as well as to all establishments which produce 2,4,5-T or silvex. EPA is requesting the cooperation of States in assuring that the Suspension Order is followed. Persons who hold quantities of these products must stop any further distribution or use. Stocks should be stored in an out of the way area and in accordance with storage instructions on the products' labeling until EPA issues a final order after the cancellation proceedings. Manufacturers of the herbicides, including Dow Chemical Co., Rhodia, Inc., Thompson Hayward Chemical Co. and Vertac, Inc., have 5 days to appeal EPA's emergency suspension order. If it is appealed, a special expedited hearing will be convened to consider the Administrator's finding that an imminent hazard exists. The hearings will be run by a special panel, which must reach findings and make a recommendation to the Administrator within 10 days after evidence has been heard. The Administrator would then have 7 days to issue a final order on whether the suspension should continue through the cancellation process.

After the suspension issue is decided, the cancellation hearing process will begin to consider the larger issue of the risks and benefits of the herbicide to society over the long run. Cancellation proceedings usually take between one to two years to complete.

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