NURSERY SAFETY

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Several changes that will affect both the use patterns and availability of pesticides used in nurseries have been proposed.

In April 1987, the U.S. Environmental Protection Agency announced new policies designed to reduce the potential risk to public health or the environment from the use of toxic inert ingredients in pesticide products.

Inerts are chemical products added to pesticides to serve as solvents, surfactants, and diluents (extenders such *as* water, corn cob, etc.). Each pesticide product may have one or more inert ingredients, the identities of which are generally claimed as confidential business information by the manufacturer or registrant.

"In developing a policy for inerts our basic goals are to reduce the uncertainties about the toxic effects of these products and to minimize the risks to public health and the environment that may result through exposure to these ingredients," said Dr. Jack Moore, EPA's Assistant Administrator for Pesticides and Toxic Substances. "As part of our new policy, we are encouraging registrants to use the least toxic inert ingredients available."

The agency has identified approximately 1,200 inert ingredients in the 45,000 registered pesticide formulations used in this country.

Most of the inert chemicals have been tested only for acute toxicity and not for adverse chronic or long-term effects. Chronic data on some inerts are available because they are also used as active ingredients in some pesticide products or these data are available through other government programs.

ERA has identified about 50 of the 1,200 inerts as being of significant toxicological concern. The criteria for determining toxicity include demonstrated significant adverse effects, such as carcinogenicity, birth defects, and neurotoxicity in laboratory animals as well as documented ecological effects such as fish toxicity. In assembling this list, no consideration was given to exposure.

EPA has further identified about 50 inert ingredients which the agency believes are potentially toxic and should be assessed for effects of concern (list 2). Many of these inerts are structurally similar to chemicals known to be toxic; some have data suggesting a basis for concern about the toxicity of the chemical, and most have been designated for testing by other regulatory or government bodies.

Inert ingredients were put in another group if they were generally regarded as minimally hazardous to either humans or the environment. These include inert ingredients such as a cookie crumbs, corn cobs, and substances generally recognized as safe by the Food and Drug Administration. There are approximately 300 ingredients in this category.

Inerts in the final group number about 800 and include those for which there was no basis for listing in any of the other three categories.

EPA intends to focus its initial regulatory efforts on the inerts of toxicological concern, new inert ingredients, and new food uses with existing inerts. As resources permit, the agency will extend its activities to the other inert ingredients.

The agency will take a number of actions to encourage registrants with list 1 inert ingredients to use the least toxic inert ingredients available and to obtain the data necessary to determine the conditions under which their products can be used without posing unreasonable risks to the public or the environment:

Registrants of existing products will be encouraged to substitute inerts not included in lists 1 or 2.

Registrants not substituting safer inerts will be directed to add the statement "This product contains the toxic inert ingredient (name of inert ingredient)" on product labels as an immediate step to inform users and the general public of the presence of inerts of toxicological concern.

Registrants who retain inerts of toxicological concern in their product(s) will be required to provide the agency with a battery of data similar to the data required for an active chemical. The data requirements will take into consideration the chemical's existing data base and the product's use.

For certain inerts on list 1, the agency intends to hold a hearing under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act to gather and present information on the risks and benefits of these inert ingredients. On the basis of the information, EPA will determine whether the inert in list 1 should be cancelled, subject to additional restrictions or allowed to continue to be used under current registrations.

EPA intends to reclassify as active ingredients the inert ingredients that prevent damage by pests. These include formaldehyde, paraformaldehyde, hexachlorophene, 2, 2-dichloro vinyl dimethyl phosphate, and the pyrethrins/pyrethroids. The agency issued a notice of intent to reclassify formaldehyde and paraformaldehyde on Jan. 5, 1987.

If the agency determines that an inert on list 1 is no longer used in any food-use pesticide product, or if sufficient data are gathered to establish a finite tolerance, the existing exemptions from tolerance will be revoked.

No new product with list 1 inert ingredients will be registered unless the product is identical or substantially similar to an existing registered product. The label will be required to indicate the presence of inert ingredients and the product will be registered conditionally subject to data requirements that the agency imposes on registrants of similar products.

New products containing inert ingredients on list 2 that are not identical or substantially similar to existing products will be reviewed on a case-by-case basis.

Registrants containing inert ingredients not included in the current list of 1,200 and new food uses of existing inerts will be required to provide at least a minimum set of data to enable the agency to assess dietary, groundwater, or applicator exposure as appropriate. These data are a subset of those data now required for active ingredients. If these studies indicate potential human health concerns or environmental problems, further testing may be required.

A second source of potential change in the pesticides that may be used in nurseries may come from the implementation of the label improvement program designed to protect threatened and endangered plant and animal species.

The U.S. Environmental Protection Agency (EPA) was advised by an independent consulting firm (Center for Environmental Education) on September 2, 1986, that they were in noncompliance with the Endangered Species Act. As a result, EPA embarked upon an intensive Endangered Species Protection Program identifying clusters of similar-use pesticides that could affect endangered species. In cooperation with EPA, the U.S. Fish and Wildlife Service (FWS) identified Federally listed endangered species potentially at risk. Pesticide prohibitions and restrictions were then established by EPA under authority of FIFRA, as amended.

Initial action was concentrated on four clusters: forest, range - and pastureland, mosquito larvicides, and cropland. Bulletins and range maps were not prepared for the forest and mosquito larvicide clusters. In this case, users were to check the label to determine if FWS personnel need to be consulted. A FWS information phone number was to be provided on the pesticide products label. The four additional pesticide clusters scheduled for later implementation were for rice, aquatics, non-crop, and alfalfa.

Recent interagency discussion with EPA and concern expressed by public groups prompted EPA to delay their program until at least February, 1989. Prior to EPA's announcement, Congress enjoined EPA, in the December 1987 Appropriation Act, to work with the States and not seek to enforce the Endangered Species Protection Program before September 15, 1988. On March 9, 1988 EPA published in the Federal Register a notice of their proposed program.

Meanwhile, EPA has provided the States an opportunity to develop their own state plan to implement all or portions of the program.

Issues needing resolution before the Endangered Species Protection Program can be effectively implemented include:

- The need to provide all maps and related pesticide information to each State to allow for a proper response to EPA's proposals.
- Revision of maps and development of alternatives for mobile species with seasonal locations. The original maps were a source of serious concern to many managers.
- The need to address adverse economic impacts to user groups.

The need to prepare definitive and comprehensive documents which discuss the potential toxicology of those pesticides adversely affecting endangered species.

Review of jeopardy opinions to ensure that data, information, and conclusions are current and complete regarding effects of a specific pesticide given species.

In the original program, seed orchards and nurseries were going to be exempt from the application restrictions since they are special use areas discreet from the forest environment; however, since the new program will includes a complete review of the policies and procedures of the original one, no one is able to predict accurately what the impact of this program on nurseries may be.

The proposed farmworkers protection rule, if implemented, will have an impact on nursery pest management. The rule is currently being circulated for comment amoung the State lead agencies, members of the negotiated rulemaking group which worked on it, and others. The proposed rule as drafted will impose extensive and intensive training, warning, medical monitoring, and labeling requirements on a wide range of pesticide users.

The proposal has been published in the Federal Register with a 90-day comment period following review by the USDA, the FIFRA Scientific Advisory Panel, and key congressional committees. The proposed rule will cover workers in pesticide-treated fields, forests, nurseries, and greenhouses. States may establish more restrictive standards than the minimum Federal standards; however, amoung the standards expected to be proposed are:

Scope--Owners, leasees, and operators of nurseries, forests, greenhouses, their contractors, and workers will be subject to the rule. The coverage of forest workers includes commercial forest but excludes "trees and vegetation used solely for parks, recreation, or wilderness preservation."

Training--Handlers (mixers, loaders, applicators, flaggers, disposers), must be trained by certified applicators.

Notification--The proposed guidelines take a four-tiered approach, including oral warnings, treated area posting, central notice board, and information on request. Oral warnings must be given to workers about all pesticide applications to be made and areas under reentry restrictions. Central notification must contain emergency medical information and a training placard. Treated area posting will be with specific signs indicating reentry intervals greater than 48 hours. Protective clothing and special equipment are specified for early reentry workers and handlers based on the toxicity of the pesticide, route of potential exposure, and duties to be performed.

Reentry--Reentry intervals will be based on active ingredient toxicity. For all pesticides entering Special Review, reentry intervals will be continuously re-evaluated.

Decontamination--Potable water must be available for removal of pesticides during emergencies and for removing residues from hands and face before eating, drinking, toileting, and/or using tobacco.

Cholinesterase Monitoring--Detection of excessive blood cholinesterase inhibition will be required for commercial pesticide handlers who are exposed to Toxicity category 1 or 2 organophosphate pesticides.

Emergency Duties--Workers must be provided the name, address, and telephone number of the nearest emergency medical facility.

Nursery Worker Risk Assessment

The Forest Service has published a document that examines the health risks to workers who use pesticides in all Forest Service nurseries. The information was published in October, 1987, as FS-412.

The executive summary of the risk assessment explains the basic concept of the document as follows:

> The USDA Forest Service operates 11 bareroot tree seedling nurseries in eight States. About half of the total area of the 11 nurseries (1,179 of 2,351 acres) is treated annually with pesticides. Twenty-eight different pesticides, including herbicides, fungicides, fumigants, and insecticides, are applied as needed to control the growth of weeds, diseases, and insects. Nursery managers use only those pesticides amoung the 28 that they have determined will be most effective in their particular nursery.
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> The analysis of human health risks from the use of the 28 pesticides was accomplished using the methodology of risk assessment widely accepted by the scientific community. In essence, the nursery pesticide risk assessment compares pesticide doses that people may get with doses shown likely to be safe to humans in long-term studies on laboratory test animals. Doses were estimated for people who may be exposed in applying the pesticides, in working in the seedbeds or with the tree seedlings, or by being near an appliance site.
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> For the pesticides that could possibly cause cancer, the risk of a person developing cancer in his or her lifetime was based on animal studies that related the chances of developing tumors to increasing pesticide doses. The risk assessment also examined whether any of the nursery pesticides was likely to cause herbitable mutations, synergistic or cumulative effects, or effects on sensitive individuals. Because none of the nurseries uses all 28 pesticides, the risk assessment was done on all the pesticides in a "generic" nursery and the results were then applied to assess the risks of the pesticides used in each individual nursery.
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> The following 28 pesticides were examined in the risk assessment:

Herbicides

Atrazine	Dicamba	Oxyfluorfen
Bifenox	Diphenamid	Sethoxydim
2, 4-D	Glyphosate	Simazine
DCPA	Napropamide	

Fungicides

Benomyl	DCNA	Thiram
Captan	Metalaxyl	Triadimefon
Chlorothalonil	Maneb	

Insecticides

Carbaryl	Diazinon	Fenvalerate
Chlorpyrifos	Dimethoate	

Fumigants

Dazomet	Methyl bromide + chloropicrin
1,3-Dichloropropene	Vorlex

The risk assessment used a conservative approach that tended to exaggerate the estimated risks to human health. Assumptions about the nursery pesticide applications, about the work with the seedbeds and seedlings, and about pesticide movement and degradation tended to overestimate the doses workers and the public would be likely to receive. Toxicity levels used to judge risks were the dose levels where no systemic or reproductive effects were seen in the most sensitive laboratory test animals. Cancer potencies were derived from data on the species and sex with the highest tumor rate. In addition, the model that used the potencies to quantify cancer risk is the most conservative now in use. This conservatism, both in estimating exposures and in setting and extrapolating from toxicity levels, led to an exxageration of the real risks of the nursery pesticide application program to ensure that it erred on the side of protecting human health.

Risk Assessment Structure and Methods

The risk assessment consisted of three steps: a hazard analysis, an exposure analysis, and a risk analysis.

In the hazard analysis, toxicity studies in the open literature and publicly available summaries of proprietary data were reviewed to determine the toxic properties of each pesticide. Each review included acute (single dose), subchronic (short-term dosing), and chronic (long-term or lifetime dosing) laboratory toxicity studies that showed effects caused by dermal, inhalation, and ingestion exposures. Threshold toxicity values that included acute oral LD_{50}'s and systemic and reproductive no-observed-effect levels (NOEL's) were determined for each pesticide. The hazard analysis also reviewed available results of mutagenicity assays and cancer studies and developed cancer potency values for 13 of the 28 pesticides (atrazine, 2, 4-D, glyphosate, oxyfluorfen, benomyl, captan, chlorothalonil, maneb, carbaryl, dazomet, 1,3-dichloropropene, methyl bromide, and Vorlex) that had positive cancer tests.

extreme unlikely. "Routine-realistic" scenarios were used to estimate the doses that workers and the public may reasonably be expected to receive as a result of routine pesticide applications. "Routine-extreme" scenarios were used to give higher dose estimates that are not likely to be exceeded except in the case of an accident.

Accident scenarios were used to estimate doses to workers that may result from direct exposure to the spray mix or concentrate or from premature reentry into treated beds, and to workers who may be downwind of an accidental spill of a fumigant. The risks to the public from accidents were considered minimal because the nurseries are fenced, access to the public is limited, and no aerial applications are done. Therefore, the public was assumed to be exposed only to accidental spill of a fumigant.

Estimates of worker exposures and doses were based on field studies of agricultural workers. Exposures and doses to the public were either extrapolated from the field worker data or calculated from pesticide drift rates, dermal exposure and absorption rates, and food intake rates using realistic and extreme assumptions concerning pesticide residue levels.

Routine worker exposures were estimated for:

Mixer/loader/applicators	Fumigators
Weeders, irrigators	Tarp lifters
Inventory personnel	Seed treaters
Lifters, sorters, packers, and tree planters	Root treaters

Routine public exposures were estimated for exposure to residues by:

Eating a garden vegetable	Drinking water with runoff residues
Eating beef from grazing cattle	Absorption through the skin from direct exposure
Drinking water with drift residues	

For each of the public exposure routes, residue levels were estimated at two distances from the nursery: 100 feet (routine-realistic) and 25 feet (routine-extreme).

The risk analysis was conducted after the worker and public exposures were estimated by comparing the scenario-based dose estimates with the toxicity levels found in the hazard analysis. For threshold effects, the doses were compared to systematic and reproductive NOEL's determined in the most sensitive test animal species. A margin of safety (MOS), the animal NOEL divided by the smaller estimated human dose, was computed to relate the doses and effects seen in animals to estimated doses and possible effects in humans. For example, an animal NOEL of 20 mg/kg divided by an estimated

human dose of .02 mg/kg gives an MOS of 100. A margin of safety of 100 is comparable to the 100-fold safety factor that is the generally recognized value for setting safe doses for humans. The larger the margin of safety (the smaller the estimated human dose compared to the animal NOEL), the lower the risk to human health.

A cancer risk analysis was conducted when a pesticide (or a contaminant or breakdown product) tested positive in a cancer study on laboratory animals. The cancer analysis was done using estimates of lifetime doses to workers or the public and estimates of cancer potency derived in the hazard analysis. The risk of any of the 28 pesticides causing heritable mutations was judged on a qualitative rather than a quantitative basis, with a statement of the probable risk based on the available evidence of mutagenicity and carcinogenicity.

RISK ASSESSMENT CONCLUSIONS

Public Risk of Threshold Effects

The risks to the public of health effects from the use of all herbicides and fungicides and for the use of the insecticides carbaryl, dimethoate, and fenvalerate are negligible. Public margins of safety for the "routine-realistic" exposures based on systematic and reproductive NOEL's were greater than 100 for all of the nursery herbicides, for all of the fungicides, and for the insecticides carbaryl, dimethoate, and fenvalerate. Routine applications of these nursery pesticides could take , place every day and the public still would not suffer any ill effects from exposure.

The insecticides chlorpyrifos and diazinon present some risk of systemic effects from cholinesterase inhibition, although these effects are likely to be minor and transitory. Chlorpyrifos doses also present some minor risk of effects on pregnant women.

The public is at slight risk from routine-extreme exposures of captan, chlorpyrifos, dimethoate, and diphenamid. There is a slightly higher risk of oxyfluoren systemic effects and for cholinesterase inhibition from diazinon, although the risk of severe effects from either pesticide is negligible. Highest public risks are from eating vegetables 25 feet offsite.

All MOS's for routine-realistic and routine-extreme public exposure to fumigants are lower than 100, so it is likely that individuals exposed in these situations will experience some low-level effects, such as eye and lung irritation, should they be immediately downwind of a fumigation operation. As in the case of insecticide exposure, the toxic symptoms should be transitory with no long-term consequences to health.

There is an increased risk of toxic effects to the public from fumigant spill accidents. Accidental releases of methyl bromide and chloropicrin pose a greater risk because the exposures exceed the NOEL's. However, the extremely irritative properties of these chemicals should reduce any exposure time and any toxic effects should be transitory.

Public Risk of Nonthreshold Effects

Cancer risks for the pesticides are low. Available laboratory evidence indicates that bifenox, DCPA, dicamba, diphenamid, napropamide, sethoxydim, simazine, DCNA, metalaxyl, thiram, triadimefon, chlorpyrifos, diazinon, and fenvalerate do not cause cancer.

Only in the cases of 30 lifetime exposures to maneb and atrazine are the risks of cancer greater than 1 in 1 million (1.0×10^{-6}). In no instance does the public cancer risk exceed 1 in 100,000 (1.0×10^{-5}). Cancer risk resulting from accidental fumigant exposure does not exceed 1 in 1 million. However, multiple public fumigant exposures under routine conditions may result in higher risks. After 10 years of exposure, cancer risk from methyl bromide fumigation may be 2 in 100,000; for 1, 3-dichloropropene, 6 in 1 million.

Mutagenic risks appear to be low for most of the nursery pesticides. Glyphosate, fenvalerate, metalaxyl, diphenamid, sethoxydim, triadimefon, 1, 3-dichloropropene, methyl bromide + chloropicrin mixtures, and Vorlex tested negative for mutagenicity in all assays conducted, and thus can be considered to pose no mutagenic risk. Bifenox and DCPA also tested negative in all mutagenicity tests. Chlorpyrifos is considered by EPA to be nonmutagenic. EPA has also concluded that chlorothalonil is not mutagenic in mammals. Dicamba, simazine, and napropamide were nonmutagenic in most of the essays performed, so their mutagenic risk should be extremely limited.

EPA-validated data are insufficient to determine whether DCNA, diazinon, or dazomet are mutagenic, but it appears that their probability of causing heritable mutations is low because they have not been shown to cause cancer in any long-term studies. Although carbaryl may be weakly mutagenic, EPA has concluded that present information does not indicate that it is a mutagenic hazard to humans.

Fifteen of 17 studies found in the open literature were positive for thiram. Because dimethoate tested positive in a number of test systems, it can be considered a potential human mutagen. Atrazine tested positive for mutagenicity in 15 of 33 assays. Technical oxyfluoren and its contaminant PCE have in some instances tested positive for mutagenicity. EPA considers maneb to be mutagenic to mammals. Benomyl has tested positive for mutagenicity in some assays and negative in others. 2,4-D has questionable mutagenic potential. The worst-case risk of heritable mutations from atrazine, 2,4-D, oxyfluoren, benomyl, maneb, 1,3-dichloropropene, methyl bromide + Chloropicrin, dazomet (because of its soil breakdown product formaldehyde), and Vorlex should be at worst comparable to the risk calculated for cancer.

Worker Risk of Threshold Effects

Risks to workers are higher than those for the public both in routine operations and as a result of accidents. Workers have a much higher chance of being exposed than do members of the public and are likely to get higher doses than the public when they are exposed. As was the case for the

public, workers are assumed to be at some level of risk if their exposures resulted in a margin of safety less than 100 for a particular pesticide.

Lifters are not at risk from any of the pesticides in routine-realistic exposures. The herbicides present a low to negligible risk to the other categories of workers for systemic and reproductive effects. Oxyfluoren presents a low risk only to weeders and applicators. Atrazine and 2,4-D present risks only to applicators. Risks from the other fungicides, particularly chlorothalnil and maneb, present a higher (but still moderate) risk to weeders. Applicators are at negligible risk from the fungicides.

The insecticides present the highest risk to workers, especially weeders, in routine applications. Diazinon and chloropyrifos exposures, in particular, approach or exceed the systemic NOEL's. Cholinesterase inhibition symptoms are likely to occur, but there should be no severe irreversible effects. The risk from dimethoate is significantly less, and risks from carbaryl and fenvalerate are negligible.

Routine fumigant exposures to workers also present a risk. Methyl bromide exposures approach the systemic NOEL. Chloropicrin exposures exceed the NOEL and may cause some transitory toxic symptoms. However, the irritative properties of the chemical should prevent prolonged exposures.

In routine-extreme exposures, lifters are at risk only from the fungicides benomyl, chlorothalonil, and maneb. All of the fungicides present a moderate risk to the other worker categories, but the risk is generally less for applicators than for weeders or inventory personnel. Of the herbicides, oxyfluoren presents the highest risks (the minimum MOS is 1) to the other worker categories, followed by diphenamid (the minimum MOS is 4). Amoung the insecticides, risks to applicators, weeders, and inventory personnel are low for carbaryl and insignificant for fenvalerate. Risks are greater (MOS of 6 or less) for the other insecticides.

Concentrate spill accidents present the greatest risk to workers. Worker exposure to dicamba, 2,4-D, metalaxyl, fenvalerate, and carbaryl approach the LD_{50}. For these pesticides, there is a clear risk of severe effects or fatality if the chemicals are allowed to remain on the worker's skin. Washing immediately should greatly reduce the risk. Accidental exposure from methyl bromide presents a similar risk for inhalation. The warning effect of chloropicrin in the fumigant mixture should reduce the risk.

Worker Risk of Nonthreshold Effects

Cancer risk to workers exposed for 5 years do not exceed 8 in 100,000 except for weeders exposed to maneb, who could have a risk of 8 in 10,000. Cancer risk from longer exposures would be proportionately greater. After 30 years of exposure, the risk from maneb exposure would be a maximum of 5 in 1,000. The maximum risk from exposure to the other chemicals would be 8 in 100,000.

The risk to workers of heritable mutations should be greater than those for the public, because workers are likely to be exposed more ofter and for longer periods of time. However, none of the pesticides have been proven

to be more than weakly mutagenic, so the risk to workers should still be relatively low. The risks of heritable mutations should be at worst comparable to the cancer risks discussed above.