

## PESTICIDE ISSUES FOR 1992

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### Renewal of the Delaney Clause:

Section 409 of the Federal Food, Drug and Cosmetic Act is up for renewal this year. This clause of the Act sets a zero risk standard for carcinogenic pesticides on food. Since nursery uses are a minor registration on any pesticide label compared to the food crop uses, any pesticide registered for food crops which is determined to have carcinogenic properties will likely be de-registered for all uses. Three bills currently pending before Congress could change the Delaney Clause or modify the Environmental Protection Agency's (EPA's) risk standard.

### Congress:

Congress will address four issues that could affect the availability of pesticides: (1) The cancellation process may be streamlined so it will move faster, resulting in less time for registrants to develop complete responses to the concerns that initiated the cancellation process. (2) Enforcement actions may be increased by adding additional personnel, or by pursuing suspected violations more vigorously. (3) A potentially positive issue is that Congress may provide some exemptions for minor use pesticides in the registration process. (4) The development of a "fast track" registration process for pesticides EPA decides are "safer" may help us obtain registration in a more timely manner for some pesticides prepared for use in nurseries. Currently, 8 to 10 years is required for a new pesticide to get in the marketplace. There is concern, however, that this policy may result in the loss of some currently registered pesticides EPA believes are "bad," but which are very useful in nursery pest management programs.

### Continuation of the Re-registration Program:

The EPA was mandated by Congress in 1988 to review the data used to grant registration to all pesticides registered before November 1, 1984. This process was to have been completed by 1997. EPA has recently acknowledged that unless their budget for this process is increased by 40 million dollars, they will only be able to achieve 48 percent completion of the draft document by 1997, with final documents available in 2002. Priorities for re-registraion review are set by several factors:

- A. Congress
- B. Public concerns over some properties of a particular pesticide or formulation.

Recent examples of public concern are: alar, malathion, carbofuran, granular insecticides in general, and the dioxin contaminants in agent orange, which was largely responsible for the cancellation of 2,4,5-T in this country.

- C. Pesticides whose registration data packages have identifiable data gaps under present day registration criteria.

A major area of concern here is that a few contract labs have been accused of providing fraudulent data to registrants which cast significant doubt over the whole aspect of data gathering for pesticide registration. As a result of these problems, EPA has instituted a formal procedure for evaluating the methods, personnel, and facilities engaged in gathering data used for pesticide registration. The process is called the Good Laboratory Practices (GLP) procedure, and while it was originally designed for laboratory work it is being modified for application to field studies. The very rigorous protocols that must be followed when gathering data under this procedure will probably result in an increased cost for pesticides. The estimated increased cost of studies conducted under GLP guidelines varies from 10 to 20 percent. GLP protocols are not required for efficacy studies; only for those studies required to register a pesticide.

- D. Pesticides which contain one or more of the "inerts of concern" as identified by EPA

In April 1987, EPA published the results of an intensive review of the 1200 ingredients listed on various pesticide labels as "inert." This information was presented in the following four listings:

List 1. Inerts of toxicological concern. This list contains about 50 inert ingredients EPA identified as being of significant toxicological concern.

List 2. Potentially toxic inerts/high priority for testing. This list contains about 60 inert ingredients that are structurally similar to chemicals known to be toxic; some have data suggesting a basis for concern about the toxicity of the chemical.

List 3. Inerts of unknown toxicity. This list contains approximately 800 inert ingredients that EPA has no basis for including on other lists.

List 4. Inerts of minimal concern. This list contains approximately 300 inert ingredients that EPA regards as innocuous. Examples are: Cookie crumbs, corn cobs, and substances generally recognized as safe by the Food and Drug Administration (FDA).

In many cases it is difficult to learn much about the inert ingredients in a specific product since many companies consider the inerts in a particular product to be confidential business information. The Forest Service has been able--by working with EPA and the pesticide manufacturers--to develop a list of pesticide products, by active ingredient, which corresponds to EPA list of inerts. List A contains pesticides

which do not contain inert ingredients on EPA lists 1 or 2. List B is documentation of forestry-use products which do contain inert ingredients on EPA's list 1 or list 2. List C names pesticide products that do contain confidential inert ingredients on EPA list 1 or list 2.

Intpretation and Application of the Provisions of the Endangered Species Act of 1973, as Amended:

Congress passed the Endangered Species Act of 1973, as amended, to provide protection for animal and plant species that are threatened or endanged of becoming extinct and to conserve the ecosystems upon which they depend. The ESA institutes certain prohibitions against the "taking" of listed species of plants and animals.

Section 7 of the ESA (15 U.S.C. 1536) requires all federal agencies to insure that any action authorized, funded or carried out by the agency will not be likely to jeopardize the continued existence of listed species or to result in the destruction or adverse modification of the critical habitat of a listed species. This duty extends to licensing activities, such as the registration of pesticides by EPA. In other words, EPA, in registering pesticides, must ensure that its actions do not harm listed species.

The FWS is the federal agency responsible for administering the ESA for most species. However, the National Marine Fisheries Service (NMFS) of the Department of Commerce also administers the ESA and is responsible for protecting listed marine species. USDA's Animal, Plant and Health Inspection Service has some enforcement responsibility for the import/export of terrestrial plants under ESA and under the convention on International Trade in Endangered Species of Wild Fauna and Flora.

In 1988, both FIFRA and ESA were amended. The amendments to FIFRA do not contain any explicit references to EPA's Endangered Species Protection program. However, the ESA amendments directly address EPA and its activities affecting pesticides. The ESA amendments require that EPA work jointly with USDA and the U. S. Department of Interior to identify appropriate alternatives for implementing a labeling program to protect listed species from pesticides, while allowing agricultural food and fiber commodity production to continue. The ESA amendments require EPA to investigate the best available methods to develop maps, alternatives to mapping, and to identify alternatives to prohibitions on pesticide use. The ESA Amendments also require EPA to inform and educate fully those engaged in agricultural production of the elements of any proposed pesticide labeling program and to provide an opportunity to comment on the elements of such a program.

Briefly, the consultation process under ESA begins when a federal agency makes a determination that its authorized or funded action, in EPA's case registration and re-registration of pesticides, may affect a listed species or its critical habitat ("may affect" determintion) and requests a biological opinion from FWS. To comply with EPA's responsibilities under seciton 7 of ESA, EPA conducts an assessment of the potential effects of pesticides on listed species. If EPA determines that a particular pesticide use "may affect" a listed species, EPA initiates a formal consultation under seciton 7 of ESA. Generally, these consultations have been with FWS

because most pesticide uses do not affect listed species under NMFS jurisdiction, such as whales, seals, and other marine animals.

In response to any agency's "may affect" determination, FWS develops a biological opinion on that action. A biological opinion regarding a pesticide indicates whether the use of the pesticide in question is likely to jeopardize the continued existence of a listed species or destroy or adversely impact a listed species critical habitat. The biological opinion may contain reasonable and prudent alternatives and measures. Reasonable and prudent alternatives are actions which (1) the consulting agency is capable of implementing under its authority and jurisdiction; (2) are economically and technologically feasible; and (3) could avoid the likelihood of jeopardy to listed species or avoid the destruction or adverse modification of critical habitat.

In addition, the FWS may include reasonable and prudent measures if an incidental take statement is provided in the biological opinion. (Incidental take is the inadvertent killing, harming, or removal of federally listed species that results from carrying out an otherwise lawful activity, such as the use of a pesticide in accordance with label directions). If incidental take is specified, reasonable and prudent measures will be provided to reduce the likelihood of incidental take. Incidental take and the associated reasonable and prudent measures may be specified for species regardless of whether or not FWS has declared jeopardy for the species.

If the federal agency cannot comply with the biological opinion, it may apply for an exemption under ESA to be considered by the Endangered Species Committee which is composed of the Secretaries of Agriculture, Army and the Interior, Administrators of EPA and the National Oceanic and Atmospheric Council of Economic Advisors; and representatives from each affected state who are appointed by the President of the United States, as appropriate. Regulations governing section 7 consultation procedures are described in 50 C.F.R. Part 402. Unit VI. A., provides a summary of the procedures for complying with section 7 consultation requirements.

The EPA began developing the Endangered Species Protection Program in 1982 because the approach the EPA has been using to comply with the ESA had been criticized as inadequate. The EPA's consultations were conducted only on individual registration actions that were submitted to EPA, which resulted in a case-by-case approach. This approach was slow and generally did not consider older and often more toxic pesticides. Since newer pesticides were being reviewed routinely as part of the registration process, newer pesticides were more likely to be referred to FWS than older pesticides. This resulted in inadequate protection for listed species. Also, the case-by-case approach resulted in market inequity among registrants of different pesticides for the same uses.

Consequently, EPA in cooperation with FWS developed the "cluster" approach to requesting consultations, in which all pesticides registered for the same use pattern were addressed at the same time. Each pesticide in a cluster was evaluated independently for its toxicity and expected exposure to listed species. The individual evaluations were grouped together and referred to FWS for consultation as a cluster. The purpose of this approach was to accelerate the review of a larger number of pesticides that could affect listed species. To treat

new and old pesticides consistently, and to eliminate market inequities by reviewing pesticides with similar uses as one group.

After EPA received biological opinions for certain pesticides included in the initial cluster consultations, EPA intended to implement the reasonable and prudent alternatives identified by FWS for these pesticides by using pesticide product labeling and county specific Pesticide Use Bulletins for Protection of Endangered Species (Bulletins). The Bulletins would contain habitat maps and would describe pesticide use limitations within the habitat of listed species. However, EPA encountered difficulties in acquiring accurate maps and map information and also received many comments from other federal agencies, states, and users regarding the overall approach. Criticism about the lack of public involvement also was raised. The EPA concluded that more time was required to develop the Endangered Species Protection Program and that public comment on the proposed program was needed. The EPA issued a FR Notice on March 9, 1988 (53 FR 7716) which described EPA's proposed program and request comment. The EPA also held public meetings across the country to obtain additional comments.

On March 9, 1988 EPA issued a FR Notice (53 FR 7716) requesting public comment on the Endangered Species Protection Program described in that Notice, as well as on alternative approaches that would protect listed species from jeopardy resulting from the use of pesticides. The proposed Endangered Species Protection Program described in the March 9, 1988, FR Notice, which is superseded by the revised proposed endangered Species Protection Program set forth in this Notice is discussed in the Units I.D. 1 through 6.

1. Cluster Approach. The EPA originally proposed an Endangered Species Protection Program based on the cluster approach to consultations, as opposed to case-by-case approach that had been previously used. The EPA proposed to evaluate all pesticides registered for a particular use and to refer to one time to FWS for a biological opinion those for which a "may affect" determination was made.

The EPA had completed reviews and received Biological Opinions for clusters encompassing pesticides used on selected crops (corn, soybeans, cotton, sorghum, oats, barley, wheat and rye); in forests; as mosquito larvicides; and on rangeland or pasture land. Under this approach, additional use patterns would have evaluated until all pesticide/listed species combinations were addressed.

2. Exemptions: The proposed program would have exempted home and garden uses and certain forestry uses. The FR Notice also indicated that under ESA, pests identified by the Department of Interior to present an overriding risk to man would not be eligible for listing under the ESA.
3. Labeling/Bulletins. The EPA's proposed Program relied on the labeling of affected pesticides to instruct users that they must comply with the limitations on use, as identified in the Bulletins. In May 1987, EPA issued Pesticide Registration (PR) Notices 87-4 and 87-5, which indicated that in order to remain in compliance with FIFRA, all registrants of pesticide products identified in the clusters as causing jeopardy to listed species must modify their product labeling to provide users with

the information necessary to protect listed species. Specifically, labels would list the counties in which use limitations applied and would refer users to the Bulletin for the county in which the product was to be used, or labels to user with FWS telephone number to obtain further information. The Bulletins also would contain a map of the county identifying the area in which there was pesticide use limitation to protect listed species.

4. State-initiated Plans: In October 1987, EPA invited states to develop alternative plans to protect listed species, these plans could include changes in pesticide application rates, timing, methods, or any other measures that would protect listed species and would be subject to the approval of both EPA and FWS. These state-initiated plans would provide EPA with recommendations to achieve compliance with the ESA in the state and would reduce the potential adverse impact on the user community within the state.
5. Program Deferral. When PR Notices 87-4 and 87-5 were issued, EPA intended that the labeling approach would take effect in the 1988 growing season. However, it became clear that implementation of the Endangered Species Protection Program would be far more complex and time-consuming than originally anticipated. Public response to the draft maps and program in general indicated a number of significant concerns, such as map inaccuracies, the need for more public review and comment on the program, the necessity for additional education and training programs, and others. Also, the development of state-initiated plans would require coordination among several groups, announced on January 7, 1988, which rescinded PR Notices 87-4 and 87-5. Deferral of the Program was in keeping with Congressional action. In passing the 1988 Continuing Appropriations Bill, Congress blocked expenditures prior to September 15, 1988, of EPA funds to implement or to enforce the Endangered Species Protection Program.
6. Request for Public Comment. In the FR Notice (53 FR 7718) EPA invited public comment on any aspect of the program and invited participation in public meetings to be held across the country. The FR Notice identified several major areas on which comments were of particular interest. These areas included identifying alternatives to use prohibition to preclude jeopardy to listed species; evaluating the appropriateness of an approach based on clusters, maps, and product labels assuring consistency between pesticide-specific and use-cluster biological opinions that declared jeopardy; maintaining consistency with other federal programs involved with pesticide use; providing assistance to non-traditional user groups; and providing guidelines or minimum requirements for state-initiated plans recommending alternative measures.

Since deferral of the Endangered Species Protection Program the Office of Pesticide Programs (OPP) within EPA has continued work to identify listed species that may be harmed by pesticide use and to develop the program. To ensure that the maps describing the habitat of listed species are accurate and reflect currently occupied habitat, EPA has been working closely with other federal agencies and the states in