



PESTICIDE REGISTRATION (PR) NOTICE 2005 -1

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Labeling Statements on Products Used for Adult Mosquito Control

This Notice presents the Agency's guidance on appropriate label language for pesticide products intended for wide-area application to control adult mosquitoes. EPA undertakes initiatives such as this in order to improve and clarify pesticide product labeling. The specific label statements and label organization principles recommended in this Notice are intended to improve existing labels by clarifying language conveying environmental hazards posed by these products, as well as specific use directions and instructions to the applicators. The Agency believes that adoption of these recommendations will help both pesticide users and pesticide enforcement officials to improve effective mosquito control and protection of public health, while ensuring that use of these products will not pose unreasonable risks to the environment. The Agency believes the incremental cost of label modifications is outweighed by the benefits to public health protection by having appropriate label statements that help ensure the proper and effective use of these products for mosquito control.

I. BACKGROUND

In recent years state pesticide regulators and vector control agencies have raised a variety of concerns about the labeling of pesticides used for adult mosquito control. For example, in 1999 the State FIFRA Issues Research and Evaluation Group (SFIREG) submitted an issue paper to the Agency raising two specific concerns about such labeling. (SFIREG is a committee of the Association of American Pesticide Control Officials, and its public meetings serve as a forum for state regulators to discuss issues concerning the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) with Agency officials and other interested parties). The SFIREG paper noted that the statement "do not apply directly to water" which appears on many outdoor use pesticide products, if broadly interpreted, would severely restrict the application of mosquito adulticides, especially in floodwater situations, such as those encountered in the aftermath of hurricane Floyd

in September 1999. SFIREG also noted that the standard label language intended to protect bees, which prohibits pesticide applications “...to blooming crops or weeds if bees are visiting the treatment area”, could be seen as making virtually any daylight application of mosquito adulticides a violation of the label, even during an urgent threat to public health. Since state agencies enforce pesticide use regulations under cooperative agreements with EPA, and since FIFRA section 12(a)(2)(G) makes it an unlawful act “to use any registered pesticide in a manner inconsistent with its labeling”, the interpretation of label requirements is a critical issue for EPA headquarters and regional offices, state pesticide regulatory agencies, and users.

In February 2001, the increasing impact of West Nile Virus on vector control and regulatory agencies led EPA’s Region II office to sponsor an Inter-Regional Mosquito Control Conference for EPA and state agency representatives. Although labeling was one of many subjects discussed at the conference, participants felt this was an area that should be addressed. It was agreed that a group representing EPA’s Office of Pesticide Programs (OPP), Office of Enforcement and Compliance Assurance (OECA), EPA Regional offices and state lead agency volunteers would develop initial, informal proposals for improving mosquito control product labels, with the focus on adulticides only. The EPA-State workgroup developed a paper which included seven recommendations. It also raised the question of overriding bee protection use directions in a public health emergency, but did not make a recommendation on that issue.

In April 2003, the initial recommendations were discussed at a public meeting of the Pesticide Program Dialogue Committee (PPDC). The PPDC is chartered under the Federal Advisory Committee Act to advise EPA on pesticide issues. Its members represent a broad spectrum of interests, including the pesticide industry, grower groups, public health agencies, academic researchers, public interest and advocacy organizations. In general, PPDC agreed that improved labeling for this class of products should be pursued, and that the initial set of recommendations were generally appropriate, but needed further development. PPDC recommended that EPA develop the initial recommendations into more formal Agency positions.

This notice is the result of Agency deliberations and public input, and represents the Agency’s formal recommendations. The recommendations consist of some specific statements that should generally appear on labels for this class of products, some model statements that registrants may adapt to the specific characteristics of their products, and some principles on organizing elements of the label.

II. PRODUCTS POTENTIALLY AFFECTED BY THIS NOTICE

Since current labels for adult mosquito control products show a great deal of variation, the relevance of the recommendations in this Notice will vary from product to product. Registrants are encouraged to review and, as appropriate, apply to amend their product labels for insecticides registered for wide-area adult mosquito control to include the additional or revised use directions and other statements, and take related actions as described in this Notice. These recommendations

apply to products labeled for wide-area application by ground or aerial equipment, as Ultra Low Volume (ULV) sprays or fogs, and not to home and garden use products which may list mosquitoes on the label, or to coarse non-ULV sprays intended for residual treatment of vegetation or other surfaces. Control of mosquito larvae is a wholly different use pattern from adult mosquito control, and thus, products registered as mosquito larvicides are not included in the scope of this Notice.

III. DISCUSSION OF ISSUES AND RECOMMENDATIONS

This section presents seven labeling issues the Agency wishes to address, followed by a statement of a specific improvement that the Agency believes appropriate to deal with each issue. The label improvements recommended in this Notice are not identical to the seven initial recommendations presented to the PPDC in April 2003. In some cases, the initial recommendation was stated as a general principle, which has now been developed into specific language. The Agency's own assessment led to merging some of the initial recommendations and adding new ones.

The general purpose of these recommendations is to improve consistency in the labeling of this group of products. Differences in use directions and hazard statements are appropriate for different active ingredients, formulations or application methods. However, since products were registered and labels approved individually over many years, variations have occurred in the level of detail for use directions and approaches to precautionary language, especially those related to hazards to aquatic organisms. The Agency has identified seven aspects of labeling discussed below for which consistency rather than differences among labels for this class of product would generally better serve the needs of users, regulators and the public.

Most publicly supported mosquito or vector control programs use an Integrated Pest Management (IPM) approach to mosquito control which includes public education, control of mosquito larvae through habitat modification and the use of registered larvicides, breeding site elimination and bite-prevention advice for the public, as well as wide-area spraying or fogging when necessary to control adult populations. EPA supports IPM approaches in its public outreach materials and believes that the use of mosquito adulticides should be consistent with IPM principles, including the use of mosquito population surveillance data in determining treatment schedules. Similarly, mosquito control program guidance developed by the federal Centers for Disease Control and Prevention (CDC) and interim recommendations developed by the Association of State and Territorial Health Officials (ASTHO) also advocate the use of an array of control strategies with adulticide applications as one available component.

Wide-area adult mosquito control employs different techniques from those used to control most other insect pests. Mosquito adulticides are typically applied as Ultra-Low Volume (ULV) sprays or fogs in which small amounts of pesticide, typically a few ounces per acre, are dispersed over a relatively wide area in the form of extremely fine droplets. Optimum control is achieved by

the dispersion of the ULV spray over a wide area in order to make direct contact with mosquitoes in flight. In other words, the primary area being treated by a ULV spray is the air where flying mosquitoes are present, rather than a specific, defined area of infestation on the ground. Since mosquitoes are often found in close proximity to and over bodies of water, effective targeting of ULV sprays may require application of the pesticide over or near a body of water in order to disperse the pesticide to a downwind area where mosquitoes are present. Given the tendency of a ULV spray to stay airborne and be carried by wind, deposition of pesticide droplets to a body of water may occur on some occasions, even though this is incidental to the intended application. A body of water is never the intended target site of application for a mosquito adulticide. These pesticides are applied over, as opposed to directly to, water.

All currently registered pesticides for adult mosquito control pose some degree of risk to aquatic organisms, and the synthetic pyrethroids, such as permethrin, sumithrin and resmethrin, are considered very toxic to aquatic organisms. All of the commonly used adulticides carry label precautions to warn of potential adverse effects to aquatic life. To avoid such adverse effects, an applicator treating areas near water must calculate many factors in order to avoid depositing spray material into a body of water. Weather conditions including wind speed and direction are important, but other factors that determine how far a spray will carry include the size of the spray droplets, the height above ground at which spray is applied, nozzle orientation, the flow rate, and the speed of the delivery vehicle. Some of these factors are addressed by label directions, but as noted above, with varying degrees of specificity among different products. The recommendations given below are intended to improve the clarity of certain use directions and precautions, and bring about more consistency among labels for this group of products. The Agency believes that adopting these recommendations will assist users in making effective mosquito control applications with minimal risks to the environment. Clear and consistent labels also assist regulators and the public in recognizing appropriate application practices.

Issue 1. Adult mosquito control applications should be limited to trained personnel.

Adult mosquito control often includes treatment of residential areas and publically controlled lands, and typically involves special ground or aerial equipment for applying Ultra Low Volume (ULV) sprays or fogs. Correct use of the equipment and application techniques require adequate training. The state and local agencies responsible for vector control programs are also accountable to the public for ensuring safe and effective applications. Given the complex application methods and the potential of the adulticide chemicals to cause adverse effects to the aquatic environment if misapplied, there is broad agreement among interested parties that proper training and supervision of applicators are essential to avoid adverse effects and ensure a safe and effective mosquito abatement program. However, there is not complete agreement on how best to accomplish this goal. For example, state laws can limit the use of pesticides for wide-area mosquito control to persons trained in a specified manner, and some states do have such requirements. However, not all states limit use in this manner. Since pesticide use regulation is geared to enforcing label provisions, there is a strong interest among regulators in using the label

to help ensure use by appropriately trained and supervised applicators.

One way to ensure use or supervision by trained applicators is to classify a product for restricted use. Products classified by EPA for restricted use under section 3(d) of FIFRA are labeled as such, and may only be applied by or under the direct supervision of a certified applicator. Each state has an EPA-approved certification and training (C & T) program for the purpose of allowing trained applicators to use restricted pesticides. Resmethrin, sumithrin, permethrin, malathion and naled are among the pesticides most often used for adult mosquito control programs. Products using the active ingredient resmethrin are classified by the Agency as restricted use products (RUPs), and some states restrict other mosquito control products through state regulations. However, at this time, most of the pesticides used in adult mosquito control are not classified for restricted use. As noted above, some states do require health or vector control agency personnel or their contractors to be certified even though RUP products are not used. However, other states require a lower level of training or none at all for mosquito control applicators, unless RUPs are being applied.

Independent of EPA's authority to classify a product for restricted use pursuant to FIFRA section 3(d), it is also possible to limit use to appropriate personnel through enforceable use instructions, provided that the label language identifies a clearly defined group of potential applicators. It would not be effective, however, to use a phrase that is ambiguous or subject to broad interpretation, such as "pest control professionals". Since there is considerable variation among state programs for both the regulation of vector control applicators and the certification categories that cover training for mosquito control, the Agency has not been able to identify a universally appropriate training requirement to include on product labels. However, the Agency believes that limiting the use of mosquito adulticides to appropriately trained and supervised persons should be part of the label of any such product which is not already classified for restricted use. In the recommendation below the term "direct supervision" is similar in meaning to the FIFRA definition of "under the direct supervision of a certified applicator" (FIFRA section 2 (e)(4)), that is, the applicator must act under the instruction and control of an appropriately authorized person, but such person does not have to be physically present at the time and place the pesticide is applied. It is the Agency's position that the following statement should appear on the label of non-restricted use products labeled for wide-area adult mosquito control:

Recommendation 1. "For use only by federal, state, tribal, or local government officials responsible for public health or vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision."

Issue 2. Some products combine adult mosquito control and other uses on the same label, generating uncertainty about which directions and precautions are applicable to which uses.

The Agency believes that adult mosquito control products should be labeled solely for adult mosquito control, or for mosquitoes and other pests such as blackflies or midges which are treated in essentially the same manner. Different uses involve different use directions and precautionary statements, which can be confusing when they appear on a single label. For example, among products currently labeled for agricultural uses in addition to mosquito control, the “Environmental Hazards” section of the label usually includes this statement: “For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.” In this context, EPA employs “terrestrial uses” as a collective term for conventional agricultural and non-agricultural outdoor uses, but the term is not meant to include certain other general use patterns including adult mosquito control, direct aquatic applications (e.g., mosquito larvicides, aquatic weed control, etc.), greenhouse applications, indoor uses, or aerial forestry applications. The statement has become virtually standard on outdoor use pesticides. Thus, on some labels, the qualifying phrase “For terrestrial uses” introduces an environmental hazard section of the label that is intended to distinguish these other uses from mosquito adulticide treatments. However, the overall effect is that when the language quoted above appears on a label of a product intended for multiple uses, it may not be clear to users that it does not apply to adult mosquito control. To avoid confusion over what language is meant to apply to adult mosquito control, products should be labeled solely for that use. If a label does include non-mosquito control use directions, it is essential to distinguish portions of the label applicable to different uses.

Recommendation 2. Products labeled for wide-area adult mosquito control should not bear container labeling for uses unrelated to adult mosquito control. The standard terrestrial use water hazard statement should not appear on product containers labeled solely for mosquito control. If a container label includes non-mosquito control use directions, those directions and associated precautions should be clearly distinguished from those applicable to mosquito control. The terrestrial use statements on a mixed-use label should be followed by the statement “See separate directions and precautions for mosquito control applications.”

Issue 3. Label statements intended to protect bodies of water and aquatic life should be harmonized, as well as improved to assist effective mosquito control applications.

The precautionary label language intended to manage risks to aquatic life varies considerably from product to product. For example, some permethrin based mosquito control products direct the user not to apply the product within 100 feet of lakes or streams. This restriction or “buffer zone” was put on many permethrin labels out of concern for aquatic toxicity that might result due to runoff from agricultural sites, not as a result of an assessment of risks associated with the significantly lower concentrations of the active ingredient involved in ULV mosquito control applications. Resmethrin product labels state “Avoid direct application **over** lakes, ponds and streams” (emphasis added), but the same labels state that vegetation “around stagnant pools, marshy areas, ponds and shorelines may be treated” and there is no buffer zone

requirement. Products based on other active ingredients, including malathion and sumithrin, have label warnings about hazards to aquatic organisms, but neither buffer zones nor the prohibition of “over water” applications appear on these labels. Naled labels explicitly do allow application over water in order to treat adult mosquitoes, blackflies or houseflies.

For different active ingredients, differing environmental hazard statements may be warranted, based on the level of risks posed. Generally, however, the Agency believes that a consistent approach to the environmental hazard label statements for this class of products is a practical benefit to both users and enforcement agencies and should be achieved where permissible under FIFRA. The language recommended in this notice will help to resolve inconsistencies among labels, although departures from this language may prove necessary on a case-by-case basis. For example, the Agency may not approve an application for an amended label based on these recommendations, if analysis indicates that the amended label would lead to increased risks to aquatic organisms compared to the previous label for that product.

The recommended language will also help to achieve the objective of effective mosquito control. From a vector control point of view, applications sometimes do need to be made over or near bodies of water in order to reach areas where mosquitoes are present, and limitations such as buffer zones or “over water” prohibitions can impede effective control. For example, an “over water” prohibition may sometimes interfere unnecessarily with the timely treatment of infested areas adjacent to water if an area happens to be downwind of a water body. In such cases, the pesticide needs to be applied over the water in order to target mosquitoes in the air above and adjacent to the water. Similarly, a 100-foot buffer zone may require leaving potentially infested areas untreated if they happen to be within 100 feet of a water body. In mosquito control, ULV sprays or fogs are intended to remain in the air for an extended time, unlike typical agricultural applications where the droplets are intended to fall immediately. Thus, mitigating risks to water bodies during mosquito control applications is best accomplished by controlling for such factors as droplet size, wind direction and speed, application rate and the height and speed of release, rather than an absolute prohibition on application over water or a buffer zone requirement. Under the language in today’s recommendation, mosquito adulticides can be applied over water bodies when such application is necessary to target mosquitoes in the air above and near water, and where the weather conditions will facilitate movement of the pesticide away from the water body to the target area, such that any incidental deposition into the water body is minimized. Factors such as droplet size, application rate, and height and speed of release will be addressed in other provisions of the label.

The Agency believes that the purpose of environmental hazard statements for these pesticides, in general terms, is to enable the user to recognize and minimize risks in the context of carrying out an effective public health pest control program, consistent with the risks posed by the product’s use. Protecting public health from mosquito-borne diseases with the pesticides now available often involves some degree of ecological risk. The Agency concludes, however, that the public interest would generally be better served in terms of health protection if ULV mosquito

control pesticides can be applied in a manner consistent with commonly accepted vector control practices, rather than under widely varying limits that now appear on some products. It also follows that environmental hazard statements need to be as clear as possible in order to identify the potential risks that applicators are expected to avoid. When necessary, according to our regulations and based on the results of studies conducted by the applicant/registrant, the Agency will retain the general statement that these products are toxic to aquatic organisms, but believes that it is also useful to add less abstract language, such as “toxic to fish, crustaceans, and oysters,” if the Agency has information showing that to be the case. These are intended to be general statements about types of organisms and not refer to specific species, such as rainbow trout or bluegill, which may have been tested under laboratory conditions in order to determine toxicity levels. Proper application, including mitigation measures for mosquitocides and similar applications noted above, i.e., droplet size, wind direction and speed, application rate and height and speed of release, can reduce and/or avoid potential toxic effects. Warnings about types of organisms should be consistent for products based on a particular active ingredient, and the Agency will identify the appropriate general types of organisms for registrants to include at the time labels are amended.

Based on all of these considerations, the Agency recommends the model environmental hazard statement embodied in recommendation #3 for mosquito adulticides. (Note that the parts of this statement concerning bee protection and consultation with state agencies are the subject of additional recommendations in this Notice, and are represented here with a placeholder in brackets).

Recommendation 3. “ This pesticide is [toxic/extremely toxic] to aquatic organisms, including [insert general types of organisms]. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to [insert general types of organisms]. [If appropriate, insert any additional wildlife hazard statements]. [Bee precaution can be inserted here or as a third paragraph of this section of the label]. [Insert consultation with state/tribal agency statement].

Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters .”

Issue 4. Users should consult with the State or Tribal lead agency for pesticide regulation to determine if permits or other regulatory requirements exist.

State and Tribal agencies often have specific information about sensitive areas in terms of species habitats, drinking water sources and other factors, and may require specific protective

measures through permits or other regulations. Obligations imposed on applicators by a State or Tribal regulation do not depend on whether there is any notice of them on a pesticide label, nor can a pesticide label create a new role for a state (or federal) agency if they do not already have one under existing laws and regulations. The Agency does not believe it is appropriate for the label to create an obligation for applicators to consult state/tribal pesticide agencies, but it is reasonable that applicators be advised of the possibility of additional requirements, since this promotes compliance with measures to protect the environment.

Current labels are inconsistent in referring the user to state authorities. Some labels are silent on the matter, others mention “applicable state and federal regulations”, and others instruct the user to consult the State’s Fish and Wildlife Agency. Some labels do instruct users to consult the State or Tribal agency responsible for pesticide regulation, which the Agency believes is the better approach. States differ widely in terms of agency roles in protecting environmental and wildlife resources, so no single term like “Fish and Wildlife Agency” is universally appropriate. The Agency concludes that the most reliable source of information on whether there are additional requirements for mosquito control is the lead agency for pesticide regulation. Although the pesticide agency is often not the permitting authority, they will generally know if such regulations exist in their state or tribe, and who administers them. The Agency concludes that the following statement is appropriate for all wide-area mosquito control product labels.

Recommendation 4. “Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.”

Issue 5. Labels need to specify the appropriate spectrum of ULV spray/fog droplet sizes, and indicate that droplet size must be determined according to directions from the equipment manufacturer or vendor, pesticide registrant or a facility using laser-based measurement methods.

Effective use of mosquito adulticides depends on proper application rates delivered in the appropriate droplet spectrum. Current labels vary greatly in the level of detail instructing the user on what droplet size spectrum to use and how to achieve a particular droplet size spectrum. While some labels simply specify a droplet size spectrum, others appear to make the user responsible for selecting the appropriate droplet size. Because droplet size is a critical parameter in defining efficacy and risk to non-target organisms, the Agency believes that droplet size affording good efficacy and low risk should be specified on product labels and applicators should regularly evaluate the performance of their equipment. The appropriate range of droplet sizes may vary somewhat from one formulation to another, so registrants should propose the acceptable droplet size range for their individual products. Many methods are available for evaluating equipment performance, including methods described in state sponsored training sessions, published by mosquito control organizations, and in a few cases, by pesticide registrants as part of labeling. The Agency believes that equipment used for mosquito control must be evaluated at least once a year

using sound methods supported by states, professional organizations or registrants. Also, since ground-based and aerial application equipment and conditions are different, the Agency believes application directions would be more clear if requirements for ground and aerial applications were identified in separate paragraphs with appropriate headers.

The Agency believes the most reliable approach for calibrating application equipment to produce specified size spectra is for the applicator to follow equipment manufacturer directions for droplet size or to rely on directions from a facility using laser-based measurement methods (*i.e.* laser diffraction, phase doppler or imaging). The Agency acknowledges that many applicators prefer to have flexibility in choosing droplet size spectra appropriate for their specific treatment areas. The recommended language below provides an upper bound requirement for droplet size, allowing applicators to use finer sprays when necessary. Identifying an allowable range of droplet spectra also allows the Agency to estimate downwind airborne concentrations and deposition levels of adulticide sprays for risk assessment purposes. The following language is recommended as a model for droplet size calibration instructions on adulticide labels.

Recommendation 5. “Ground-based application:

Spray equipment must be adjusted so that the volume median diameter is less than [X = value to be provided by registrant] microns ($D_v 0.5 < X \text{ um}$) and that 90% of the spray is contained in droplets smaller than [Y = value to be provided by registrant] microns ($D_v 0.9 < Y \text{ um}$). Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.

“Aerial Application:

Spray equipment must be adjusted so that the volume median diameter produced is less than [A = value to be provided by registrant] microns ($D_v 0.5 < A \text{ um}$) and that 90% of the spray is contained in droplets smaller than [B = value to be provided by registrant] microns ($D_v 0.9 < B \text{ um}$). The effects of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.”

Issue 6. Precautionary language to protect bees should have a provision to allow mosquito control applications that might otherwise be prohibited in order to respond to immediate threats to public health.

Applications for adult mosquito control are generally made in the evenings, at night, or in the early hours of the morning – the periods when most mosquito species are active. These are the

periods of the day when bees are not active, so mosquito control applications usually do not pose a serious threat to bees, nor do they conflict with bee precautionary language which prohibits applications "...to blooming crops or weeds if bees are visiting the treatment area." In some circumstances, however, public health protection may require daylight treatments which could include areas being visited by bees. For example, the widespread flooding caused by Hurricane Floyd in 1999 caused a mosquito and fly population explosion that threatened public health and required extremely large area applications by military aircraft. These applications were made in daylight for safety reasons. There are also some mosquito species that do feed during the day and can be vectors for West Nile Virus and other diseases. If those species are numerous at a time when human or animal disease cases have occurred in the region, daylight applications may be appropriate in spite of increased risk to bees.

The Agency believes that provision should be made to allow public health considerations to override a strict interpretation of bee precaution label language, and that the determination to make this unusual type of application needs to be linked to specific evidence of a health threat. The Agency recognizes, however, that it is not possible or appropriate to try to define a specific threat level on a pesticide label. In its guidance for West Nile Virus programs, CDC points out that many local variables affect the seriousness of a health threat, and no specific, quantified thresholds for number or types of cases or similar factors would be appropriate for all situations. The Agency also does not believe the label should try to limit the authority to evaluate threats to a particular state or local agency, since these have widely variable technical capabilities and legal authorities across the country. Linking any extraordinary applications to specific evidence of a disease threat helps to assure pesticide regulators and the public that the applications are warranted. The following language should be added to the last sentence of the bee precaution statement on the labels of mosquito adulticide products.

Recommendation 6. "... [do not apply to blooming crops or weeds when bees are visiting the treatment area], except when applications are made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort."

Issue 7. Mosquito adulticide labels should include specific statements on timing and frequency of applications.

The Agency's labeling regulations at 40 CFR 156.10 (i)(2)(vii) state that directions for use shall include "[T]he frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment." With very few exceptions, however, mosquito adulticide labels direct the user to "repeat as necessary" and do not specify an interval between treatments, or any limitation on the number of treatments to the same site, and this poses several problems. "Repeat as needed" clearly does not meet the intent of the regulation

by indicating to users or enforcement agencies what is an acceptable, efficacious, and safe application frequency, and it may lead to overuse and increased risks. It also impedes the Agency's ability to conduct risk assessments for the pesticides involved, since there is no clear starting point for estimating use and exposure. For risk assessment purposes the Agency would ideally like to know the maximum number of applications in a year, since some endpoints of concern may have cumulative or chronic effects. A specific limit on applications provides a baseline for assessment, rather than relying on assumptions about what may be "typical" and "worst case" use scenarios.

The Agency recognizes that many vector control agencies utilize Integrated Pest Management (IPM) principles and mosquito population surveillance data in determining treatment schedules. The Agency also recognizes that there may be limited health effects data available to support specific interval and frequency limitations for some products, since comprehensive reassessments of some of the mosquito control pesticides have yet to be completed. Nevertheless, registrants have data on the toxicity, environmental fate and efficacy of their products, and should be able to propose reasonable interval and frequency limits appropriate to their individual products.

Although interval and frequency limits are appropriate for the adulticide labels, mosquito control is primarily a public health concern, and the Agency does not believe that the label should prevent applications needed for effective control unless there is specific evidence that finite limitations are appropriate for a particular product or active ingredient. For that reason, the Agency is recommending a model for timing and frequency statements that includes the same provisions for additional treatments to address threats to public health as contained in recommendation #6 for the bee precaution. Thus, the following language should be included in the directions for use section of the label.

Recommendation 7. "Do not re-treat a site more than once in [X hours/days]; no more than [Y] applications should be made to a site in any [Z weeks/months] or [one year]. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort."

IV. IMPLEMENTATION

A. Application for New Registration

EPA expects that beginning on the effective date of this Notice each applicant for registration of new products labeled for adult mosquito control will adopt the recommended labeling statements and principles in this Notice, to the extent appropriate for the product.

B. Application for Amendment

EPA requests that registrants of existing products covered by this Notice submit an application for amended registration. An acceptable application for amendment includes the following items:

- a completed EPA application form 8570-1;
- three copies of the draft label (highlighting the changes made on one label);
- a description on the application, such as, "Amended consistent with the guidance set out in PR Notice 2005-1."

All such submissions must pertain only to this PR Notice. Additional unrelated amendments and/or changes to the product must be submitted as a separate action or the submission will be considered unacceptable and will not be reviewed. The Agency will attempt to process correctly submitted applications in a timely manner.

The Pesticide Registration Improvement Act of 2003 (PRIA) established a new registration service fee system for applications for registration, amended registration, and associated tolerance actions. Under this system, registration service fees are charged for covered applications received by the Agency on or after March 23, 2004. However, applications for EPA-initiated amendments are not subject to a fee. Therefore, an application to amend a registration submitted solely in response to this Notice will be classified as an "EPA-initiated amendment" and will not be subject to a registration service fee provided that the only changes being proposed to the labeling for the registered product are those described in this Notice.

Registrants should send applications for amendment to the following addresses:

U.S. Postal Service Deliveries:

The following official mailing address should be used for all correspondence or data submissions sent to OPP by mail:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Hand-Carried/Courier Deliveries:

The following address should be used for all correspondence or data submissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, Virginia 22202

V. SCOPE OF POLICY

This Notice describes certain requirements set forth by FIFRA and its regulations and provides general guidance to EPA and affected parties. While the requirements in FIFRA and its regulations are binding on EPA and other affected parties, this Notice is intended to provide guidance to EPA, applicants, registrants and the public. As guidance, this policy is not binding on either EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice. Registrants and applicants may propose alternatives to the recommendations in this Notice, and the EPA will assess them on a case-by-case basis. If a product does not meet the requirements of FIFRA section 2(q) or the regulations at 40 C.F.R. Part 156, the Agency may find the product to be misbranded and may take appropriate enforcement and/or regulatory action.

VI. EFFECTIVE DATES

For all products covered by this PR Notice:

- The effective date of this Notice is April 15, 2005. As of that date, EPA will review all applications for new pesticide product registrations, amendments to registered products and reregistration of registered products consistent with the guidance contained herein.
- As of October 1, 2005, EPA will begin to evaluate products released for shipment by registrants and distributors to ensure consistency with the guidance contained herein. Registrants are reminded that they are responsible for informing their distributors when they change their labeling, and for monitoring the labeling of their distributors to assure that they make the necessary changes.

Various states' requirements should be taken into consideration when deciding on the timing of your amendment submission to EPA. Some states may require a review of the modified label by EPA prior to submission to the state for state approval purposes.

VII. FOR FURTHER INFORMATION

For information on this Notice contact Jim Roelofs (Telephone 703-308-2964; e-mail roelofs.jim@epa.gov).

Jim Jones, Director
Office of Pesticide Programs