

Label Language for Malathion - Rice and Watercress

Jim,

Here are our suggestions for label language for malathion products to be applied to watercress (aquatic/non-terrestrial):

1. Directions for Use

“Allow water to drain from the area to be treated prior to application to watercress. Flow-through water may be re-introduced 24 hours after the application. OR Prior to application, stop water flow out of the field to be treated. Apply this malathion product at the specified rate. Hold/impound the field flood-water--or release field flood water into a holding area--for a minimum of 24 hours after application before releasing into a natural body of water or a ditch connecting to a natural body of water.” (A)

2. Environmental Hazards

Currently, most of the malathion products licensed in Hawai‘i for which there are directions for use on watercress say, “Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.”

Therefore, after consulting with state regulators, to accommodate application to a flooded watercress paddy, the language of the “Environmental Hazards” section would also have to be amended. Otherwise, application to a flooded field would be regarded as illegal.

Suggested language for this section: "For terrestrial uses: do not apply directly to water. . . " (B) and, "On aquatic sites: . . . Do not apply directly to water except as specified on this label." (C)

References:

- A. The closest relevant label language we could find as a “standard” for directions for holding/impounding flood-field water was from the label for Deadline M-PS (EPA Reg. No. 5481-507). The language presented here is adapted from the Deadline M-PS directions for application to taro (wetland). (See note #3 for “taro (wetland)” on the attached label.)
- B. This language was taken from chapter 8 (p. 8-3) of EPA’s “Label Review Manual” (<http://www2.epa.gov/sites/production/files/2015-03/documents/chap-08-sep-2012.pdf>).
- C. This language was taken from the Environmental Hazards section of the label for Malathion 5 EC (Arysta, EPA Reg. No. 66330-220, attached).

Background: Typically, Hawai‘i’s watercress growers cannot stop the water flow because it naturally percolates up through the caprock into the paddy. (Caprock water is created by leakage from the basal aquifer into permeable aquifers within the caprock which is a thick sequence of sediments forming a coastal plain. The result is an exceptional location of naturally occurring spring water.) Growers at such sites would not be able to dam, impound, hold or contain the spring water. There may be sites of watercress production, where (similar to some sites for wetland taro production), growers have more control of the water flow. The language for the directions suggested here is considered to be potentially the most workable for some watercress growers in Hawai‘i.

If you have any questions, please contact me.

Best,
Cathy

- > On Mon, Jun 22, 2015 at 3:18 PM, Chin, Teung
- > <Teung.Chin@ars.usda.gov> wrote: Hello Jim and Danesha:
- >
- > Can we get feedback for FMC regarding label language for a 24 hour
- > holding time on the flood water after malathion is applied on rice
- > and watercress?
- >
- > Jim: Cathy Tarutani, HI weighed in on watercress during
- > reregistration in 2003 or so.
- >
- > Danesha: I think watercress is grown in Florida as well.
- >
- > Can we provide the information to EPA in two weeks?
- >
- > Thanks in advance!
- >
- > Teung
- >
- > Thank you
- > Teung
- >
- > Teung F. Chin, Ph.D.
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Label Review Manual

Chapter 8: Environmental Hazards



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I. Introduction

The Environmental Hazards statement provides the precautionary language informing users of the potential hazards to the environment from transport, use, storage, or spill of the product. These hazards may be to water, soil, air, beneficial insects, plants, and/or wildlife as identified in risk assessments performed by the Environmental Fate and Effects Division. Generally, the information contained in this section is based upon the results of eight basic acute toxicity studies performed on the technical grade of the active ingredient(s) in the formulation. These eight studies are: (1) avian oral LD₅₀ (with mallard *or* bobwhite quail), (2) avian dietary LC₅₀ (mallards), (3) avian dietary LC₅₀ (bobwhite quail), (4) freshwater fish LC₅₀ (rainbow trout), (5) freshwater fish LC₅₀ (bluegill sunfish), (6) acute LC₅₀ freshwater invertebrates (*Daphnia magna* or water flea), (7) honeybee contact LD₅₀, and (8) mammalian acute oral LD₅₀. For specific data requirements: [40 CFR Part 158](#).

In addition, data concerning a product's potential to be transported to groundwater, surface water, aquatic sediment, to drift, to adversely affect non-target plants and bees provide important information. Data include, but are not limited to, results from hydrolysis, batch equilibrium, aerobic soil metabolism, field dissipation, and prospective groundwater studies.

The data generated from all of these studies support the language used for the Environmental Hazards statements. Review of the data is performed by the Environmental Fate and Effects Division (EFED) or other science reviewers who may also evaluate any label text proposed by the registrant to determine what statements are required.

The label reviewer should consult with the product manager/team leader and EFED or science reviewer for chemical specific statements, such as groundwater/surface water, spray drift/runoff, or endangered species statements that will be added to the label as they are identified.

II. Reviewing the statements

A. When Required

The label reviewer must first determine whether the use patterns on the label require any Environmental Hazards statement. The use pattern of a pesticide helps determine the need for and the specific text of the Environmental Hazards section. The label reviewer may assume that any pesticide product used outdoors must include the Environmental Hazards statement on the label. However, the reviewer should also look at the proposed statement with a critical eye towards its applicability. Does it make sense for the product? For example, a granular herbicide would not generally need a statement warning of potential spray drift problems since granular formulations are not “sprayed” and are seldom associated with any “drift”.

- 1. Exclusively Indoor Products.** Products which are intended for use exclusively *indoors* may omit the Environmental Hazards statement. Products applied to domestic animals, such as flea collars or ear tags may in most cases omit the statement. However, the statement may be required for a domestic-use product such as a dog dip due to the potential for contamination of water by the use of such a product. Thus it is important for reviewers to carefully evaluate the use pattern of the product to determine whether potential risk from the transport, use, storage or disposal of the product should be mitigated by the Environmental Hazards statement.
- 2. Manufacturing Use Products (MPs).** Although used indoors to formulate other products, MPs may require some Environmental Hazard statements text because MPs may be highly concentrated and could pose a serious hazard if a spill occurred. A discharge statement may also be required; see section VII. A. below for recommended language.
- 3. Outdoor Use Products.** The Agency has typically required products labeled for use outdoors to have Environmental Hazards statements on their labels. 40 CFR 156.80 – 156.85. If the reviewer determines that the use pattern triggers the need for Environmental Hazards labeling, the proposed draft labeling must be reviewed according to the requirements outlined in the regulations.

B. Statement Location

The Environmental Hazards section of the label should be located under the general heading “Precautionary Statements”. It *must* have the heading “Environmental Hazards” (not “Environmental Precautions”, “Environmental Protections”, or anything similar). ([40 CFR Part 156.80\(b\)](#)).

C. Support for Statements

The text of the proposed Environmental Hazards statements is then reviewed according to the type of product. If the action represents a submission accompanied by data, the environmental science reviewer will evaluate the environmental hazards statements and recommend any necessary label changes as part of the data review. The label reviewer must specify all requested changes in the response to the registrant, and assure that the changes are in accordance with mandatory/advisory guidance. ([Chapter 3](#) and [PR Notice 2000-5](#))

- 1. Technical/End-Use Products.** The environmental reviewer is responsible for reviewing data on all technical products and may also review data associated with end-use formulations. Data requirements are governed by FIFRA and the implementing regulation set out in [40 CFR Part 158](#). Generally, data are required when an end-use formulation is likely harmful to non-target organisms (for example, micro-encapsulated insecticides which are used on crops are potentially harmful to pollinators). If a Reregistration Eligibility Decision (RED) Document has been issued, it may contain appropriate Environmental Hazards statements, but the reviewer should evaluate

whether the decision document specifically addresses the use at issue and then make appropriate changes to the label statement.

2. **Identical or Substantially Similar Products.** If the label reviewer is working on an application for registration for an identical or substantially similar product, the Environmental Hazards statements of the similar formulation should be compared with those in the RED. If the similar registered product label language is consistent with the RED, the identical or substantially similar product Environment Hazard language should be the same as the currently registered product. If there are no similar products, route the application to EFED or the science reviewers. Additionally, if a registrant wishes to amend the Environmental Hazards statements, environmental reviewers may need to see the amendment application.

Since the cited label may have some statements that are outdated and/or missing (required or recommended since the label was accepted), it is important to check the regulations and the statements outlined in the rest of this chapter to make sure that both the cited label and the draft label reflect current Agency requirements and policy.

If an error is discovered in the Environmental Hazards section of the cited identical or substantially similar product label, the reviewer should send a letter informing the registrant of the cited identical or substantially similar product label of the error(s) and request an application for amendment be submitted within a reasonable time, such as 30 days.

III. General statements

A. Outdoor, Terrestrial Uses

Generally, all products with directions for outdoor, *terrestrial* uses should have the following statements in the Environmental Hazards section:

“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. Do not contaminate water when disposing of equipment washwater or rinsate”.

These statements are preceded by “**For terrestrial uses**”, to make it clear that the statements **do not** apply to the other general use patterns—e.g., aquatic uses such as mosquito larvicides, aquatic herbicides, piscicides, etc., or greenhouse and indoor uses.

Aerial Forestry Application Statement. If a pesticide product is aerially applied to forests, the above statements should be preceded with the phrase:

“For terrestrial uses, except when applying aerially over the forest canopy:”

There are many creeks and streams under forest canopies. The statement as written allows spraying the forest canopy, but requires spray valves to be shut off when passing over ponds, streams, etc. that are not under the forest canopy.

B. *Bacillus thuringiensis* (Bt)

For Bt products that are intended for forestry treatments or aquatic uses (e.g. mosquito control with *Bt israelensis*), variations of the above Environmental Hazards statements may be required.

1. Forestry Uses. For forestry uses, the statement should read:

“Do not contaminate water when disposing of equipment washwaters or rinsate”.

2. Aquatic Uses. For aquatic uses, the statement should read:

“Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption”.

C. Outdoor, Residential Consumer Products

For outdoor residential consumer products (except for lawn care products applied by a Pest Control Operator which use the same statement as outdoor terrestrial uses), the statements preferred by the Agency to meet risk/benefit concerns are as follows (See [PR-Notice 2008-1](#)).

Table 1. Outdoor Residential Consumer Product Statements

Formulation type	Preferred Language
Liquid Concentrate	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.
Broadcast Granular	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.
Dust	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

Formulation type	Preferred Language
Liquid Ready-to-Use (RTU)	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

These statements provide the basic use instructions for avoiding water and other environmental contamination; they are used in addition to other required environmental statements, such as wildlife hazard statements determined by the toxicology data (e.g., specific precautionary statements concerning bees, fish or aquatic organisms).

The reviewer must also keep in mind the use pattern of the product undergoing a label review. If the product is actually intended for application to water to control algal growth, for example the above statements may be inappropriate as written.

D. Outdoor, Terrestrial Products Requiring Fish or Aquatic Invertebrate Statements

Products with directions for outdoor terrestrial uses requiring a fish or aquatic invertebrate toxicity statement usually contain a statement warning of hazard from drift and/or runoff. The word *drift* should be omitted if the product is a “granular” or if it is applied “in furrows” or injected into the soil. The Agency has historically required that the following statement appear in the Environmental Hazards section:

“Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas”.

E. Groundwater Label Advisories

There are two groundwater label advisory options available. The need for a groundwater label advisory is based on the environmental fate properties of the chemical and/or detections of the chemical in groundwater. One option is for chemicals with little or no monitoring data that have environmental fate properties similar to pesticides that have been found in groundwater. The other option is for chemicals that have actually been found in groundwater.

1. Based on Laboratory/Field Data. If no detections are reported in groundwater (for example, a new chemical) but the chemical (or a major degradate) has a combination of environmental fate properties similar to other pesticides found in groundwater as a result of normal label uses:

- ▶ mobility characteristics (e.g. K_d less than 5, or field dissipation results that indicate the chemical leaches)
- ▶ persistence characteristics (e.g., hydrolysis half-life greater than 30 days at any pH or aerobic soil metabolism half-life greater than 2 weeks)

then the Agency has generally required the following label language:

“Groundwater Advisory

This chemical has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow”.

- 2. Based on Groundwater Monitoring.** If detections are reported in groundwater in a prospective groundwater study or other monitoring study conducted for registration, or other reliable monitoring data in the publicly available literature, then the Agency has generally required the following label language:

“Groundwater Advisory

[Name of chemical] [A degradate of (name of chemical)] is known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow”.

F. Surface Water Label Advisories

When appropriate, after the environmental assessment, the Agency requires the following statement to be added to outdoor household/residential, agricultural, and other outdoor labels modified for the specific pesticide characteristics and targeted audience.

“This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water.

This product is classified as having [insert phrase 1.a., 1.b., or 1.c., according to the pesticide’s “mean” soil partition coefficient (K_d)] for [insert phrase 2.a., 2.b., or 2.c. according to the pesticide’s aerobic soil metabolism half-life]. [insert phrase 3.a or 3.b depending on whether the product is intended for the household user or farmer]”.

1. Soil Partition Coefficient Phrases

- (a) K_d less than 15 – *“high potential for reaching surface water via runoff”*
- (b) K_d between 15-300 – *“a medium potential for reaching both surface water and aquatic sediment via runoff”*
- (c) K_d greater than 300 – *“high potential for reaching aquatic sediment via runoff”*

2. Aerobic Soil Metabolism Half-Life Phrases

- (a) $t_{1/2}$ less than 8 days – “*several days after application*”
- (b) $t_{1/2}$ between 8 and 30 days – “*several weeks after application*”
- (c) $t_{1/2}$ greater than 30 days – “*several months or more after application*”

3. Targeted User Community

- (a) Household/Residential Label

See Table 1 on page 8-4.

- (b) Agricultural Label

“A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of [Name of chemical] [A degradate of (name of chemical)] from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours.. [For pesticides with a soil partition coefficient greater than 300 add the following, “Sound erosion control practices will reduce this product’s potential to reach aquatic sediment via runoff”.]

IV. Non-target organism statements

A general requirement for products to bear environmental hazard statements, including hazards to non-target organisms, is stated at 40 CFR Part 156.80. In Part 156.85, examples are given of statements the Agency typically requires when data indicate certain acute toxicity levels for mammals, birds, fish, etc., or there is other information such as accident history indicating significant risks to non-target wildlife. Other statements than those listed may be required if more appropriate to the formulation or use.

A. Hazard Statements for Birds, Mammals, Fish, Aquatic Invertebrates and Estuarine Organisms

This information will be found in submitted data, the RED document, or the Registration Standard. It may not necessarily be available to the label reviewer, but helps you to understand the origin of the statements

- 1. Bird and Mammal Hazard Statement.** The following statement has typically been required when a pesticide intended for outdoor use contains an active ingredient which has a mammalian acute oral $LD_{50} \leq 100$ mg/kg, an avian acute oral $LD_{50} \leq 100$ mg/kg, or a subacute dietary $LC_{50} \leq 500$ ppm:

“This pesticide is toxic to [birds] [mammals] or [birds and mammals]”.

- 2. Fish/Aquatic Invertebrate Statement.** The following statement has typically been required when a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ or aquatic invertebrate (including estuarine species such as oyster and mysid shrimp) EC₅₀ ≤ 1 ppm:

“This pesticide is toxic to [fish] [fish and aquatic invertebrates] [oysters/shrimp] or [fish, aquatic invertebrates, oysters and shrimp]”.

- 3. Incident Data Statement.** If field studies or accident history, such as the FIFRA 6(a)(2) reports, indicate that use of the pesticide may result in fatality to birds, fish or mammals, the following statement has typically been required:

“This pesticide is extremely toxic to [birds], [mammals], [fish], or [birds and mammals and fish]”.

B. Pollinating Insect Hazard Statements

If a pesticide is used outdoors as a foliar application, and is toxic to pollinating insects, a “Bee Hazard” warning has generally been required to be included in the Environmental Hazards. See [40 CFR § 156.85\(a\)](#). The following table sets out the toxicity groupings and examples of label statements for honey bees and other pollinating insects. Crop-specific use instructions would optimize bee and other pollinating insect safety. There may be other options for mitigating risk that may be considered (i.e. applications at night for continuously blooming crops). These instructions could be placed in the Directions for Use.

Table 2. Pollinating Insect Acute Toxicity Groups and Precautionary Statement Examples

Toxicity Group	Precautionary Statement if Extended Residual Toxicity is Displayed	Precautionary Statement if Extended Residual Toxicity is not Displayed
I Product contains any active ingredient with acute LD ₅₀ of 2 micrograms/bee or less	<i>This product is highly toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees or other pollinating insects are visiting the treatment area.</i>	<i>This product is highly toxic to bees and other pollinating insects exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees or other pollinating insects are actively visiting the treatment area.</i>

Toxicity Group	Precautionary Statement if Extended Residual Toxicity is Displayed	Precautionary Statement if Extended Residual Toxicity is not Displayed
<p>II</p> <p>Product contains any active ingredient(s) with acute LD₅₀ of greater than 2 micrograms/bee but less than 11 micrograms/bee.</p>	<p><i>This product is moderately toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees or other pollinating insects are visiting the treatment area.</i></p>	<p><i>This product is toxic to bees and other pollinating insects exposed to direct treatment. Do not apply this product while bees or other pollinating insects are actively visiting the treatment area.</i></p>
<p>III</p> <p>All others.</p>	<p>No bee or pollinating insect caution required.</p>	<p>No bee or pollinating insect caution required.</p>

Potential chronic hazards to honey bees, and other pollinating insects, and the resulting label language will be dealt with on a case-by-case basis. The Agency is in the process of developing chronic toxicity label statements for pollinator protection. When the proposed language has been thoroughly vetted, the appropriate conditions and statement will be included.

C. Aquatic Weed Control Label Statement

If a pesticide product is used to control aquatic weeds, the Environmental Hazards section generally is required to contain the following statement:

“Treatment of aquatic weeds can result in oxygen loss from decomposition of dead weeds. This loss can cause fish suffocation. Therefore, to minimize this hazard, treat 1/3 to 1/2 of the water area in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outwards in bands to allow fish to move into untreated areas. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed”.

D. Irrigation Water Label Statement

If a pesticide product is applied to irrigation water and contains an ingredient requiring an aquatic organism toxicity statement, the Environmental Hazards section generally must contain the following statement:

“Irrigation water treated with this product may be hazardous to aquatic organisms. Treated water must either be held on the irrigated field until sorbed by the soil or not released for (number) days after application”.

V. Mosquito control label statements

Pesticide products that include directions for mosquito control may require one of the following statements in the Environmental Hazards section, although the aquatic toxicity of the specific product may lead to more or less stringent statements. For example, certain bacterial larvicides, such as some Bt products, are considered non-toxic to aquatic organisms and would not require any statement. Some pyrethroids registered as mosquito adulticides are highly toxic to aquatic organisms and may require stronger precautions than those listed below, tailored to the specific products, in order to prevent adverse effects to water quality. Products with aquatic toxicity concerns between these extremes should have the following recommended statement, as appropriate:

A. Larvicides

“Aquatic organisms may be killed in waters where this pesticide is used. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed”.

B. Adulticides

PR Notice 2005-1 lays out seven specific adult mosquito control label recommendations and details Agency rationale for these statements. Pesticide manufacturers are being requested to incorporate these statements in the labeling of any new products seeking registration for adult mosquito control use, or to request amendments of existing labels with this use pattern.

These recommendations apply only to products labeled for wide-area application as Ultra Low Volume (ULV) sprays or fogs, and not to home and garden use products which list mosquitoes on the label, or to coarse non-ULV sprays intended for residual treatment of vegetation or other surfaces. Control of mosquito larvae in water is a completely different use pattern from adult mosquito control, and is not included in the scope of *PR Notice 2005-1*.

1. Adult mosquito control applications should be limited to trained personnel. It is the Agency’s position that the following statement should appear on the label of non-restricted use products for wide-area adult mosquito control:

“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”.

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”.

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 Agency recommends the following statement to appear on mosquito adulticide labels:

“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”.

4. Users should consult with the State or Tribal agency for pesticide regulation to determine if permits or other regulatory requirements exist. The Agency concludes that the following statement is appropriate for all wide-area mosquito control product labels:

“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”.

5. Labels should specify a spectrum of spray/fog droplet sizes, and indicate that droplet size should be determined according to directions from equipment manufacturers or other appropriate sources. The following language is recommended as a model for droplet size calibration instructions on adulticide labels:

“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 ($D_v 0.5 < X \mu\text{m}$) and that 90% of the spray is contained in droplets smaller than [Y = value to be provided by registrant] microns ($D_v 0.9 < Y \mu\text{m}$). 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 (Dv 0.5 < A μm) and that 90% of the spray is contained in droplets smaller than [B = value to be provided by registrant] microns (Dv 0.9 < B μm). 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”.

6. Precautionary language to protect bees should have a provision to allow mosquito control applications in order to respond to threats to public health which are identified by health or vector control agencies on the basis of evidence of disease organisms or disease cases in animals or humans. The following language should be added to the last sentence of the bee precaution statement on the labels of mosquito adulticide products:

“... (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”.

7. Mosquito adulticide labels should include limits on timing and number of applications to the same location. Exceptions to these limits may be allowed in order to respond to threats to public health which are identified by health or vector control agencies on the basis of evidence of disease organisms or diseases cases in animals or humans. The following language should be included in the directions for use section of the label:

“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”.

In addition to the label language recommended in *PR Notice 2005-1*, the following information is recommended to add to the labels for adult mosquito control products, based on label requirements issued in REDs for these products:

- ▶ Maximum amount of active ingredient per acre/year
- ▶ Wind speeds
- ▶ Flight altitude- minimum and maximum

VI. Endangered species protection requirements

To protect endangered species, some products require Endangered Species Protection Bulletins that will contain geographically specific use limitations. Users will be directed to these Bulletins through a standard label statement. This statement may only be placed on a label after the completion of a risk assessment and determination that it is necessary. For complete endangered species labeling information, refer to *Chapter 11, Section IV, subsection J*.

VII. Miscellaneous statements

A. Point Source Discharge

For certain registered end-use products, technical grade products and other manufacturing use products, a “point source discharge” is a possibility because effluent from the manufacturing plant may contain pesticides. This does not include those products used to control roaches or other pests in the facilities, but applies to those chemicals used in the formulation processes.

The Agency recommends that the following National Pollutant Discharge Elimination System (NPDES) statement (as outlined in *PR Notice 93-10*) should appear on such products, in addition to any other required statements.

“Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA”.

PR Notice 95-1 exempts certain end-use products (i.e., products in containers of less than 5 gallons (liquid), less than 50 pounds (solid, dry weight) and in aerosol containers of any size) from bearing effluent discharge statements specified by *PR Notice 93-10*. This policy applies to any pesticide product that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems. Such products include but are not limited to: (a) technical grade and manufacturing use products; (b) end-use products registered for industrial preservative, water treatment, or other industrial processing use such as in cooling tower water systems, pulp and paper mill water systems, secondary oil recovery injection water systems, food processing operations, leather tanning, and wood protection and textile treatment; and (c) large scale commercial and institutional end use (such as hospitals).

The exemption of certain containers from the labeling requirements of *PR Notice 95-1* does not relieve a producer or user of such products from the requirements of the Clean Water Act or state or local requirements, if applicable.

B. Seed Treatment or Granule/Pellet/Treated Bait Products

If a pesticide product contains directions for use in treating seed or is formulated as a granule, pellet, or treated bait, the Agency has historically required the following Environmental Hazards statements when appropriate:

“Treated _____[seed], [granules], [pellets], [baits] exposed on soil surface may be hazardous to _____[birds], [wildlife], [fish and aquatic invertebrates] or [birds, other wildlife, and fish]. Cover or collect _____[seeds], [granules], [pellets], [baits] spilled during loading”.