# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY BEFORE THE ADMINISTATOR

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In the Matter of:

FMC Corporation,

Respondent.

Docket No.: FIFRA-03-2015-0248

COMPLAINANT'S FIRST SUPPLEMENT TO PREHEARING EXCHANGE

# COMPLAINANT'S FIRST SUPPLEMENT TO PREHEARING EXCHANGE

Pursuant to 40 C.F.R. § 22.19(f) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* ("Consolidated Rules of Practice"), and to Administrative Law Judge Christine Donelian Coughlin's May 6, 2016 Prehearing Order, Complainant hereby supplements its prehearing exchanges filed heretofore<sup>1</sup> in the above-captioned matter as follows:

# I. <u>SUPPLEMENT TO WITNESS TESTIMONY (EXISTING WITNESSES)</u>

On March 13, 2017, Respondent, through counsel, requested Complainant to voluntarily provide additional information about certain specified areas of expected testimony of Complainant's expert witnesses, specifically requesting the bases for their opinions, and the documents or information upon which the witnesses will rely. Complainant is hereby supplementing its prior prehearing exchanges to provide the additional information requested by Respondent.

1. <u>Dana Friedman</u>, Environmental Protection Specialist, Pesticide Re-evaluation Division, was identified in Complainant's Initial Prehearing Exchange as an individual who may be called to testify as a FACT WITNESS and/or as an EXPERT WITNESS. EPA PHE at 1-2. Any expert opinion testimony provided by Ms. Friedman regarding the history and current status of EPA's risk assessments for chlorpyrifos/organophosphates and cypermethrin; EPA's determinations of risk to human health and to the environment associated with chlorpyrifos/organophosphates and with cypermethrin; EPA's indicated label language for pesticide products containing chlorpyrifos and cypermethrin to address risks to human health and to the environment; or the bases for EPA's restricted use pesticide ("RUP") classification of products containing chlorpyrifos or cypermethrin will be based on information in the following documents:

- a. Reregistration Eligibility for Cypermethrin (revised 01/14/08), Cx2, EPA 0003 EPA 0115;
- b. Reregistration Eligibility for Chlorpyrifos (07/31/06), Cx3, EPA 0116 EPA 0375;

<sup>&</sup>lt;sup>1</sup> Complainant filed an Initial Prehearing Exchange on June 15, 2016, and a Rebuttal Prehearing Exchange on July 22, 2016.

- c. Chlorpyrifos, Evaluation of Potential Risks from Spray Drift and Impact of Potential Risk Reductions Measures (07/13/12), Cx4, EPA 0376 EPA 0436; and
- Implementation of Updated Spray Drift Language for Pyrethroid Agricultural Use Products and Cypermethrin RED Mitigation on Cypermethrin Agricultural Use Products (2/21/08) with FMC delivery confirmation; Cx55, EPA 1762 – EPA 1777.

2. <u>Linda Arrington</u>, Environmental Protection Specialist, Pesticide Re-evaluation Division, was identified in Complainant's Initial Prehearing Exchange as an individual who may be called to testify as a FACT WITNESS and/or as an EXPERT WITNESS. EPA PHE at 2-3. Any expert opinion testimony provided by Ms. Arrington regarding the circumstances surrounding EPA's development of PR Notice 98-10, or the provisions of PR Notice 98-10 relevant to adding brand names and bases for such provisions will be based on her experiences working in EPA OPP's Registration Division up to and including her previous position as Ombudsman and Notification Team Leader, including and in addition to information included in the following documents:

- a. Curriculum vitae Linda Arrington, Cx6, EPA 0468 EPA 0469;
- b. Pesticide Registration (PR) Notice 98-10: Notifications, Non-Notifications and Minor Formulation Amendments (10/22/98); Cx7; EPA 0470 EPA 0492; and
- c. Pesticide Registration (PR) Notice 95-2: Notifications, Non-Notifications and Minor Formulation Amendments (5/31/95); Cx56; EPA 1778 EPA 1789.

3. Julie Chao, former Lead Environmental Protection Specialist/Product Manager, Antimicrobials Division, was identified in Complainant's Initial Prehearing Exchange as an individual who may be called to testify as a FACT WITNESS and/or as an EXPERT WITNESS. EPA PHE at 3. Any expert opinion testimony provided by Ms. Chao regarding the bases for EPA's classification of FMC's F9047-2 EC Insecticide, EPA Reg. No. 279-9545 as a RUP, or EPA's determination that the brand name "Stallion Insecticide" is false and misleading and the bases for such determination will be based on information in the following documents:

- a. Reregistration Eligibility for Cypermethrin (revised 01/14/08), Cx2, EPA 0003 EPA 0115;
- b. Reregistration Eligibility for Chlorpyrifos (07/31/06), Cx3, EPA 0116 EPA 0375;
- Notice of Pesticide Registration F9047-2 EC Insecticide (01/21/11), Cx9, EPA 0495 EPA 0521;
- d. Letter to Thomas Harris (EPA) from Jill Holihan (FMC) re: F9047-2 EC Insecticide (01/24/11) (attachments), Cx10, EPA 0522 EPA 0550;
- e. Email to Jill Holihan (FMC) from Thomas Harris (EPA) re: Three actions for 279-9545 (04/26/11) (w/ attachment No. 2), Cx11, EPA 0551 EPA 0581;
- f. Letter to Jill Holihan (FMC) from Thomas Harris (EPA) re: F9047-EC Insecticide, EPA Reg. # 279-9545 (04/28/11), Cx12, EPA 0582;
- g. Email chain between Thomas Harris (EPA) and Jill Holihan (FMC) re: F9047-2 EC Insecticide Question (09/26/11) (no attachments), Cx13, EPA 0583;

- Letter to John Cummings (FMC) from Meredith Laws (EPA) re: Amended Labeling, Proposed Alternate Brand Name "Stallion Insecticide (Not for use on horses) (04/02/12), Cx17, EPA 0591 – EPA 0592;
- i. Pesticide Registration (PR) Notice 2002-X Draft: False or Misleading Pesticide Product Brand Name (03/14/02), Cx21, EPA 0626 EPA 0634;
- j. Pesticide Regulation (PR) Notice 93-6 False or Misleading Statements Related to Efficacy; Revision of PR Notice 91-7 (03/31/93), Cx22, EPA 0635 EPA 0637; and
- k. Summary Report of Products Coded with "Horse" as a Use Site (06/05/16), Cx23, EPA 0638 EPA 0676.

# II. <u>POTENTIAL ALTERNATIVE WITNESS</u>

Complainant learned that one of the witnesses named in its Initial Prehearing Exchange, i.e., Julie Chao<sup>2</sup>, no longer works for the United States Environmental Protection Agency. At this early stage of the proceedings where the date(s) and location of the hearing are not yet known, no determination can be made as to whether Ms. Chao will be available to testify as initially expected. Should Ms. Chao be unavailable and/or no alternative arrangement for the provision of her testimony be found acceptable, Complainant names the following individual as an alternate witness, whose testimony is expected to include, but may not be limited to, the matters described generally below.

Venus Eagle (7505P) Invertebrate & Vertebrate Branch 3 (IVB3) Registration Division U.S. EPA Ariel Rios Building 1200 Pennsylvania Ave., N.W. Washington, DC 20460

Ms. Eagle is Acting Branch Chief of Invertebrate & Vertebrate Branch 3 in the Registration Division of EPA's Office of Pesticide Programs. Beginning in March 2007, she worked as a Lead Biologist/Product Manager in the Insecticide Rodenticide Branch/Invertebrate-Vertebrate Branch 3 in OPP's Registration Division where she managed a diverse portfolio of pesticide products to ensure safety to human health and the environment, and served as the former Product Manager for *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545.

In connection with her position serving as a Product Manager, Ms. Eagle may be called to testify as a FACT WITNESS and/or as an EXPERT WITNESS with respect to: a) her relevant education, training, and experiences; b) her roles and duties working in EPA OPP's Registration Division; c) communications between EPA's Registration Division and Respondent concerning the registration of and alternate brands names to FMC's *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545; d) the bases for EPA's classification of FMC's *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545 as a RUP; and e) EPA's determination that the brand name "Stallion Insecticide"

<sup>&</sup>lt;sup>2</sup> See EPA PHE at 3.

is false and misleading and the bases for such determination. (Any expert opinion testimony provided by Ms. Eagle regarding the bases for EPA's classification of FMC's F9047-2 EC Insecticide, EPA Reg. No. 279-9545 as a RUP, or EPA's determination that the brand name "Stallion Insecticide" is false and misleading and the bases for such determination will be based on information in the documents identified above for Julie Chao.)

A copy of Ms. Eagle's curriculum vitae is included as an exhibit in accordance with the Prehearing Order. Ms. Eagle may also be called to testify as a rebuttal witness to provide testimony in rebuttal to that provided by Respondent's witnesses.

# III. EXHBITS

Complainant intends to introduce the following additional exhibits at hearing, copies of which are attached hereto:

| 55. | Implementation of Updated Spray Drift Language for<br>Pyrethroid Agricultural Use Products and Cypermethrin RED<br>Mitigation on Cypermethrin Agricultural Use Products<br>(2/21/08) with FMC delivery confirmation  | EPA 1762 – EPA 1777 |
|-----|--|---------------------|
| 56. | Pesticide Registration (PR) Notice 95-2: Notifications, Non-<br>Notifications and Minor Formulation Amendments (5/31/95)   | EPA 1778 – EPA 1789 |
| 57. | Curriculum Vitae – Venus Eagle   | EPA 1790 – EPA 1791 |
| 58. | Examples of FMC print advertisements. (These examples were<br>included as "Attachment 1" to "Complainant's Reply to<br>Respondent FMC Corporation's Opposition to Complainant's<br>Motion for Partial Accelerated Decision as to Liability for<br>Violations 1-12,273 of the Complaint" filed on September 16,<br>2016.) | EPA 1792 – EPA 1799 |
| 59. | Examples of Website screen captures from Pesticide<br>Distributors showing multiple retail locations and individual<br>contacts for each location.   | EPA 1800 -EPA 1808  |

Respectfully Submitted,

APR 2 6 2017

Jennifer M. Abramson Janet E. Sharke U.S. EPA, Region III <u>Abramson.Jennifer@epa.gov</u> <u>Sharke.Janet@epa.gov</u>



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 21, 2008

Re: Implementation of Updated Spray Drift Language for Pyrethroid Agricultural Use Products and Cypermethrin RED Mitigation on Cypermethrin Agricultural Use Products

Dear Cypermethrin Registrant:

## Background

You are receiving this letter because your company holds registrations for cypermethrin products used on agricultural crops (Attachment 1). In the Reregistration process for pyrethroids registered prior to 1984, EPA determined that the existing spray drift language needed to be updated in order to be in compliance with FIFRA. Because of similarities in use patterns, and concern for exposure to aquatic resources, EPA believes that this updated language is necessary for all pyrethroid products with use on agricultural crops. Please see Attachment 2 for a Label Table with the necessary buffer zone and spray drift language.

# What You Need to Do

The Cypermethrin Reregistration Eligibility Decision (RED), signed June 14, 2006, stated that you are eligible for reregistration provided you make several label changes for products used on agricultural crops in addition to the inclusion of spray drift language.

Since that time, we have amended the original RED, Label Table, appendices, and spray drift language.

The Agency believes that in the absence of this revised spray drift language, as well as the other risk mitigation identified in the Amended Cypermethrin RED Label Table (Attachment 2, pages 5-14), cypermethrin agricultural use products will not have sufficient directions for use and/or precautionary statements to adequately protect human health and the environment and could therefore be considered "misbranded" under section 2(q) of FIFRA. To ensure that your products remain in compliance, you must submit amended labels for the products listed in Attachment 1, no later than May 30, 2008. Please note that your response to this letter does not constitute reregistration of your product. In the near future the Agency intends to issue Data-Call Notices (DCI) requiring label amendments, product specific data, and additional generic (technical grade) data.

If the list included as Attachment 1 does not represent all of your agricultural crop products affected by this letter please identify missing products with your response. If you have any questions regarding this letter, or believe that this letter does not apply to your product, please contact George LaRocca at (703) 305-6100.

Sincerely,

George LaRocca

Product Manager, Registration Division

**Attachments** 

Attachment 1: Registered Cypermethrin Agricultural Labels

Attachment 2: Amended Cypermethrin RED Label Table (Abbreviated Table: Includes Manufacturing Use and Agricultural Label Sections Only)

| Reg. No.  | Name  | Date<br>Registered | Company                    |
|-----------|---|--------------------|----------------------------|
| 279-3027  | Ammo 2.5 EC Insecticide                         | 12-Jun-1984        | FMC Corp.                  |
| 279-3044  | Ammo 2.5 Oil Insecticide<br>(cotton, only)      | 6-Aug-1984         | FMC Corp.                  |
| 279-3046  | Ammo 2.5 Miscible<br>Insecticide (cotton, only) | 28-Aug-1984        | FMC Corp.                  |
| 279-3084  | Ammo WSB Insecticide                            | 15-Jun-1989        | FMC Corp.                  |
| 1381-188  | Battery 2.5 EC                                  | 30-Jan-2003        | Winfield Solutions,<br>LLC |
| 34704-875 | Cypermethrin 2.5 EC                             | 5-Apr-2005         | Loveland Products,<br>Inc. |
| 53883-137 | Cyper Ag II                                     | 18-Nov-2004        | Control Solutions,<br>Inc. |
| 70506-20  | Up-Cyde 2.5 EC Agricultural<br>Insecticide      | 11-Feb-2003        | United Phosphorus,<br>Inc. |
| 83222-7   | Cyper G-Ag 2.5 EC                               | 13-Jan-2006        | J. Oliver Products,<br>LLC |

# Attachment 1: Registered Cypermethrin Agricultural Labels

# Attachment 2

| Amended Cypermethrin RED Label Table<br>(Abbreviated Table: Includes Manufacturing Use and Agricultural Label Sections Only) |  |                    |  |
|--|--|--------------------|--|
| Description  | Amended Labeling Language  | Placement on Label |  |
| For all<br>Manufacturing Use<br>Products   | <ul> <li>"Only for formulation into an <i>insecticide</i> for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."</li> <li>"This product must not be formulated into end-use products that contain directions for use on sod farms, agricultural uncultivated areas, fencerows, hedgerows, or rights-of-way. These use sites must be removed from all end-use product labels and any special need registration must be canceled."</li> <li>"This product must not be formulated into wettable powder end use formulations unless they are packaged in water soluble bags."</li> <li>"This product must not be formulated into end-use products that contain directions for use on both agricultural crops and for other uses, such as in and around residential, commercial and industrial</li> </ul> | Directions for Use |  |
|  | sites or on farm animals. This product may only be formulated into<br>end-use products that with directions for use for agricultural crop<br>(WPS) uses only, or end-use products with directions for use for<br>non-agricultural-crop (Non-WPS) uses only."   |                    |  |
| One of these<br>statements may be<br>added to a label to   | "This product may be used to formulate products for specific use(s)<br>not listed on the MP label if the formulator, user group, or grower<br>has complied with U.S. EPA submission requirements regarding   | Directions for Use |  |

| allow reformulation<br>of the product for a<br>specific use or all<br>additional uses<br>supported by a<br>formulator or user<br>group | support of such use(s)."<br>"This product may be used to formulate products for any additional<br>use(s) not listed on the MP label if the formulator, user group, or<br>grower has complied with U.S. EPA submission requirements<br>regarding support of such use(s)."  |                                    |
|--|---|------------------------------------|
| Environmental<br>Hazards Statements<br>Required by the RED<br>and Agency Label<br>Policies   | "This pesticide is toxic to fish and aquatic invertebrates. Do not<br>discharge effluent containing this product into lakes, streams,<br>ponds, estuaries, oceans, or other waters unless in accordance with<br>the requirements of a National Pollutant Discharge Elimination<br>System (NPDES) permit and the permitting authority has been<br>notified in writing prior to discharge. Do not discharge effluent<br>containing this product to sewer systems without previously<br>notifying the local sewage treatment plant authority. For guidance,<br>contact your State Water Board or Regional Office of the EPA. | Precautionary Statement            |
| End Use Products for V   | WPS (agricultural) use ONLY   |                                    |
| Restricted Use   | "RESTRICTED USE PESTICIDE Due to Toxicity to fish and   | Front Panel and Directions for Use |
| Pesticide required for all products.   | aquatic invertebrates or retail sale to and use only by certified<br>applicators or persons under the direct supervision and only for<br>those uses covered by the certified applicator's certification."   | Front Faner and Directions for Use |

| Note: Wettable<br>powder formulations<br>must be packaged in<br>Water Soluble Bags<br>to be eligible for<br>Reregistration. As an<br>alternative, a dry<br>flowable formulation<br>may be developed. | "Mixers, loaders, applicators, and other handlers must wear:<br>> Long-sleeve shirt and long pants,<br>> Shoes plus socks, and<br>>In addition to the above, handlers using hand-held equipment<br>must also wear chemical-resistant gloves."<br>"See engineering controls for additional requirements."  |   |
|--|---|---|
| Handler PPE<br>Requirements<br>Established by the<br>RED <sup>1</sup> for Liquid<br>Concentrate and Dry<br>Flowable<br>formulations.   | "Personal Protective Equipment (PPE)"<br>"Some materials that are chemical-resistant to this product are<br>( <i>registrant inserts correct chemical-resistant material</i> ). If you want<br>more options, follow the instructions for category [ <i>registrant</i><br><i>inserts A,B,C,D,E,F,G,or H</i> ] on an EPA chemical-resistance<br>category selection chart." | Precautionary Statement under Hazards to<br>Humans and Domestic Animals |
|  | <ul> <li>"Mixers, loaders, applicators, and other handlers must wear the following:</li> <li>&gt; Long-sleeve shirt and long pants,</li> <li>&gt; Shoes and socks and</li> <li>&gt; In addition to the above, handlers using hand-held equipment must also wear chemical-resistant gloves."</li> </ul>  |   |
|  | "See engineering controls for additional requirements."   |   |

| User Safety<br>Requirements  | <ul> <li>"Follow manufacturer's instructions for cleaning/maintaining PPE.<br/>If no such instructions for washables exist, use detergent and hot<br/>water. Keep and wash PPE separately from other laundry."</li> <li>"If the product is a concentrate and pesticide handlers are required<br/>to wear coveralls, use the following statement in addition to the<br/>statement above."</li> <li>"Discard clothing and other absorbent materials that have been<br/>drenched or heavily contaminated with this product's concentrate.<br/>Do not reuse them."</li> </ul>  | Precautionary Statements under: Hazards to<br>Humans and Domestic Animals immediately<br>following PPE Requirements            |
|--|--|--|
| Engineering controls<br>for Wettable Powder<br>Formulations,<br>formulated into water<br>soluble bags.<br>Note: Wettable<br>powder formulations<br>must be packaged in<br>Water Soluble Bags<br>to be eligible for<br>Reregistration. As an<br>alternative, a dry<br>flowable formulation<br>may be developed. | <ul> <li>"Engineering controls"</li> <li>"Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</li> <li>-wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, and</li> <li>-be provided, must have immediately available for use, and must wear in an emergency, such as a broken package, spill, or equipment breakdown a NIOSH-approved respirator with:</li> <li> a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or</li> <li> any N, R, P, or HE filter."</li> </ul> Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil. "Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural | Precautionary Statements under Hazards to<br>Humans and Domestic Animals Immediately<br>following the User Safety Requirements |

|  | pesticides [40 CFR 170.240(d)(6)]."<br>"Human flagging is prohibited. Flagging to support aerial<br>application is limited to use of the Global Positioning System<br>(GPS) or mechanical flaggers."   |   |
|--|--|---|
| Engineering controls<br>for Liquids and Dry<br>Flowables | <ul> <li>"Engineering controls"</li> <li>"Pilots must use an enclosed cockpit that meet the requirements<br/>listed in the Worker Protection Standard (WPS) for agricultural<br/>pesticides [40 CFR 170.240(d)(6)].</li> <li>"Human flagging is prohibited. Flagging to support aerial<br/>application is limited to use of the Global Positioning System<br/>(GPS) or mechanical flaggers."</li> </ul>  | Precautionary Statements: Hazards to<br>Humans and Domestic Animals Immediately<br>following the User Safety Requirements |
| User Safety<br>Recommendations                           | "USER SAFETY RECOMMENDATIONS"<br>"Users should wash hands with plenty of soap and water before<br>eating, drinking, chewing gum, using tobacco, or using the toilet"<br>"Users should remove clothing/PPE immediately if pesticide gets<br>inside. Then wash thoroughly and put on clean clothing."<br>"Users should remove PPE immediately after handling this<br>product. Wash the outside of gloves before removing. As soon as<br>possible, wash thoroughly and change into clean clothing." | Immediately following Engineering Controls<br>(Must be placed in a box.)  |
| Environmental<br>Hazards                                 | "This pesticide is toxic to fish, aquatic invertebrates, oysters and<br>shrimp. Do not apply directly to water, or to areas where surface<br>water is present or to intertidal areas below the mean water mark.<br>Do not apply when weather conditions favor drift from treated<br>areas. Drift and runoff from treated areas may be hazardous to<br>aquatic organisms in neighboring areas. Do not contaminate water<br>when disposing of equipment wash waters."                              | Precautionary Statements immediately<br>following the User Safety Recommendations   |

|  | "This pesticide is highly toxic to bees exposed to direct treatment<br>on blooming crops or weeds. Do not apply this product or allow it<br>to drift to blooming crops or weeds while bees are actively visiting<br>the treatment area."  |   |
|--|---|---|
| Restricted-Entry<br>Interval for products<br>with directions for<br>use within scope of<br>the Worker<br>Protection Standard<br>for Agricultural<br>Pesticides (WPS) | "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."   | Place in the Direction for Use, In<br>Agricultural Use Requirements Box                                   |
| Early Entry Personal<br>Protective Equipment<br>for products with<br>directions for use<br>within the scope of<br>the WPS  | "PPE required for early entry to treated areas that is permitted<br>under the Worker Protection Standard and that involves contact<br>with anything that has been treated, such as plants, soil, or water,<br>is:<br>* coveralls,<br>* shoes plus socks<br>* chemical-resistant gloves made of any waterproof material" | Place in the Directions for Use In<br>Agricultural Use Requirements box,<br>immediately following the REI |
| General Application<br>Restrictions  | "Do not apply this product in a way that will contact workers or<br>other persons, either directly or through drift. Only protected<br>handlers may be in the area during application."   | Place in the Directions for Use directly above the Agricultural Use Box.                                  |
| Buffer Zone<br>Requirements  | <ul> <li>"BUFFER ZONES"</li> <li>"Vegetative Buffer Strip<br/>Construct and maintain a minimum 10-foot-wide vegetative filter<br/>strip of grass or other permanent vegetation between the field edge<br/>and down gradient aquatic habitat (such as, but not limited to,</li> </ul>                                    | Place in Directions for Use under the heading "BUFFER ZONES"  |

|             | <ul> <li>lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds)."</li> <li>"Only apply products containing (<i>name of pyrethroid</i>) onto fields where a maintained vegetative buffer strip of at least 10 feet exists between the field and down gradient aquatic habitat."</li> <li>"For guidance, refer to the following publication for information on constructing and maintaining effective buffers: <i>Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services.</i> USDA, NRCS. 2000. Fort Worth, Texas. 21 pp. http://www.in.csusda/v/technical/agronom/newconbuf.pdf"</li> <li>"Buffer Zone for Ground Application (groundboom, overhead chemigation, or airblast)</li> <li>Do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."</li> <li>"Buffer Zone for ULV Aerial Application</li> <li>Do not apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."</li> <li>"Buffer Zone for Non-ULV Aerial Application</li> <li>Do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."</li> </ul> |  |
|-------------|--|--|
|             | Do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."   |  |
| Spray Drift | "Spray Drift Requirements" "Wind Direction and Speed"  | Directions for Use under Spray Drift<br>Requirements |

| "Only apply this product if the wind direction favors on-target deposition."  |
|---|
| "Do not apply when the wind velocity exceeds 15 mph."   |
| "Temperature Inversion"   |
| "Do not make aerial or ground applications into temperature inversions."  |
| "Inversions are characterized by stable air and increasing<br>temperatures with height above the ground. Mist or fog may<br>indicate the presence of an inversion in humid areas. The<br>applicator may detect the presence of an inversion by producing<br>smoke and observing a smoke layer near the ground surface." |
| Droplet Size  |
| "Use only Medium or coarser spray nozzles (for ground and non-<br>ULV aerial application) according to ASAE (S572) definition for<br>standard nozzles. In conditions of low humidity and high<br>temperatures, applicators should use a coarser droplet size".  |
| Additional Requirements for Ground Applications   |
| "Wind speed must be measured adjacent to the application site on<br>the upwind side, immediately prior to application."   |
| "For ground boom applications, apply using a nozzle height of no<br>more than 4 feet above the ground or crop canopy."  |
| "For airblast applications, turn off outward pointing nozzles at row  |

|   | ends and when spraying the outer two rows. To minimize spray<br>loss over the top in orchard applications, spray must be directed<br>into the canopy."   |                                 |
|---|--|---------------------------------|
|   | Additional Requirements for Aerial Applications  |                                 |
|   | "The spray boom should be mounted on the aircraft as to minimize<br>drift caused by wingtip or rotor vortices. The minimum practical<br>boom length should be used and must not exceed 75% of the wing<br>span or 80% rotor diameter."         |                                 |
|   | "Flight speed and nozzle orientation must be considered in determining droplet size."  |                                 |
|   | "Spray must be released at the lowest height consistent with pest<br>control and flight safety. Do not release spray at a height greater<br>than 10 feet above the crop canopy unless a greater height is<br>required for aircraft safety."    |                                 |
|   | "When applications are made with a cross-wind, the swath will be<br>displaced downwind. The applicator must compensate for this<br>displacement at the downwind edge of the application area by<br>adjusting the path of the aircraft upwind." |                                 |
| Other Application<br>Restrictions (Risk<br>Mitigation)  | Any directions for use on sod farms, agricultural uncultivated<br>areas, fencerows, hedgerows, and rights-of-way must be removed<br>from all product labels. Special Local Need registrations with these<br>uses must be cancelled.            | Place in the Directions for Use |
| (Note: The maximum<br>application rate and<br>maximum seasonal<br>rates specified in this<br>table must be listed<br>as pounds or gallons | Products must be amended to reflect the following maximum<br>application rates (a.i./A), minimum re-treatment intervals and<br>maximum annual application rates  |                                 |

| of formulated         | Cotton:   |  |
|-----------------------|---|--|
| product per acre, not | Maximum single application rate of 0.1 lbs a.i./A                 |  |
| just as pounds active | Minimum re-treatment interval of 5 days                           |  |
| ingredient)           | Maximum annual application rate of 0.4 lbs a.i./A/year            |  |
|                       |   |  |
|                       | "Do not make more than 10 synthetic pyrethroid applications (of   |  |
|                       | one product or combinations of products) to cotton in one growing |  |
|                       | season."  |  |
|                       |   |  |
|                       | Pecans:   |  |
|                       | Maximum single application rate of 0.1 lbs a.i./A                 |  |
|                       | Minimum re-treatment interval of 7 days                           |  |
|                       | Maximum annual application rate of 0.5 lbs a.i./A/year            |  |
|                       |   |  |
|                       | Head and Stem Brassica and Head Lettuce:                          |  |
|                       | Maximum application rate of 0.1 lbs a.i./A                        |  |
|                       | Minimum re-treatment interval of 7 days                           |  |
|                       | Maximum seasonal application rate of 0.6 lbs a.i./A               |  |
|                       | Leafy Brassica:   |  |
|                       | Maximum application rate of 0.1 lbs a.i./A                        |  |
|                       | Minimum re-treatment interval of 7 days                           |  |
|                       | Maximum seasonal application rate of 0.4 lbs a.i./A               |  |
|                       |   |  |
|                       | Bulb Vegetables:  |  |
|                       | Maximum application rate of 0.1 lbs a.i./A                        |  |
|                       | Minimum re-treatment interval of 7 days                           |  |
|                       | Maximum seasonal application rate of 0.5 lbs a.i./A               |  |

<sup>1</sup> PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

| SENDER: COMPLETE THIS SECTION  | COMPLETE THIS SECTION ON DELIVERY         A. Signature         X       Agent         B. Received by (Printed Name)       Contact of Defiver         D. Is delivery address different from item 1?       Yes         If YES, enter delivery address below:       No |  |  |
|--|--|--|--|
| <ul> <li>Complete items 1, 2, and 3. Also complete<br/>item 4 if Restricted Delivery is desired.</li> <li>Print your name and address on the reverse<br/>so that we can return the card to you.</li> <li>Attach this card to the back of the mailpiece,<br/>or on the front if space permits.</li> <li>Article Addressed to:         <ul> <li>Linda Froelich</li> <li>FMC Corp. Agricultural</li> <li>Products firsup</li> <li>FI35 Market Street</li> <li>Philadelphia, PA 19103</li> </ul> </li> </ul> |  |  |  |
|  | 3. Service Type<br>Certified Mail Express Mail<br>Registered Return Receipt for Merchandise<br>Insured Mail C.O.D.   |  |  |
|  | 4. Restricted Delivery? (Extra Fee)  |  |  |

UNITED STATES POSTAL SERVICE IA PA 191 US DAR NH. SPELBostage & B ees Paid John Adam 26 FEB 2008 PM 8 PerfoNo. G-10 Sender: Please print your name, address, and ZIP+4 in this box • Dana L. Fricoman US EPA Giffice of Pesticide Programs (7508P) 1200 Pernsylvania Ave. Washington, DC 20460 haldhardeddalladhardhardhardhardadd 0000

# Pesticide Registration (PR) Notice 95-2:Notifications, Non-Notifications and Minor Formulation Amendments

NOTE: THIS DOCUMENT MAY VARY IN APPEARANCE FROM THE PRINTED NOTICE. IT HAS BEEN REFORMATTED TO FIT WITHIN THIS SCREEN.

#### 5/31/95

PR NOTICE 95-2

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

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

SUBJECT: Notifications, Non-Notifications and Minor Formulation Amendments

This Notice describes new policies and procedures effective immediately which will help streamline and accelerate many registration amendments. Highlights of this notice include:

expanding the types of labeling and product chemistry amendments which may be accomplished by notification,

accelerating the review of minor formulation amendments, and

a new certification statement which affirms compliance with this PR Notice and applicable regulations, and which describes the consequences of non-compliance.

This PR Notice supersedes PR Notice 88-6 (August 12, 1988) and the second edition of General Information On Applying For Registration of Pesticides In The United States (The Blue Book, Chapter 4. C. and D). This PR Notice also modifies parts of PR Notices 83-3 and 84-1 (Storage and Disposal Statements), and PR Notice 91-1 (Use Deletions). Table A lists the registration amendments which may be accomplished by notification, non-notification or accelerated minor formulation changes as described in this notice.

#### I. BACKGROUND

On August 12, 1988, the Agency issued PR Notice 88-6 to implement 40 CFR 152.46, Modifications To Registration Not Requiring Amended Applications. Section 152.46(a) allows certain registration amendments to be accomplished by notifying the Agency of those changes before the product is distributed or sold. Section 152.46(b) allows other minor changes in labeling or packaging to be made without notification to the Agency. PR Notice 88-6 described the Agency's policies and procedures at that time for notifications and nonnotifications under Section 152.46.

Section 152.44(b), Application for Amended Registration, requires any modification in the composition, labeling or packaging of a registered product to be submitted with an application for amended registration, with the exception of notifications and nonnotifications under Section 152.46. Section 152.44(b) provides that the Agency may waive the requirement for an amendment or permit a registrant to certify compliance with an Agency requirement instead of submitting an amendment.

EPA is issuing this notice to allow minor, low risk registration amendments to be accomplished through notification, nonnotification or as accelerated amendments. EPA believes these streamlining changes will speed up the process, reduce the waiting time for registrants and maintain protection to the public health and the environment.

**US EPA ARCHIVE DOCUMENT** 

CX 56 EPA 1778

#### II. NOTIFICATIONS

The following registration amendments may be accomplished by notification.

#### A. Labeling

1. Adding Alternate Brand Names

A registrant may sell a product under one or more alternate brand names provided he/she notifies the Agency of those names. Each name must differ from the name of any other of the registrant's products so as to permit clear identification. Brand names may not be false or misleading. The addition of alternate brand names for use by the registrant is not the same as supplemental distribution by a different company or individual under agreement with the registrant (see 40 CFR 152.132). Changing the primary brand name of a product must be done by submitting an application for amendment.

2. Adding or Deleting Pests

A pest that does not pose a threat to public health, except termites, may be added to the label provided that:

(a) the registrant maintains efficacy data for each pest added;

(b) the pest occurs on one or more sites on the approved label;

(c) the pest matches the type of product registered (e.g., a fungus may not be added to an insecticidal product); and

(d) the dosage, frequency, concentration or method of application do not change.

To add public health pests or termites to a label, the registrant must submit an Application for Amended Registration (EPA Form 8570-1). Public health pests include, but are not limited to, mosquitoes, rodents, viruses and bacteria (other than odor-causing). Microbial pests and claims which are related to public health are described in OPP's Antimicrobial Program Branch DSS/TSS Sheet #16. Questions on whether other pests are considered public health related may be referred to the appropriate branch or PM team. Questions on termiticide products may be referred to the Insecticide-Rodenticide Branch.

A pest may be deleted from the label by notification at any

time.

3. Adding Indoor, Nonfood Sites for Antimicrobial

Products

Indoor, nonfood sites, subsites or substrates may be added to antimicrobial products provided that:

(a) no additional data (such as efficacy data for public health pests or termites, groundwater data, ecological effects data, etc.) are required for the added nonfood sites;

(b) these sites are within an already registered use pattern category for the product (as specified in 40 CFR Part 158);

(c) exposure is not increased (examples of increased exposure include adding use in paints to a product registered for caulking, or adding broadcast treatment to a product registered for spot treatment);

(d) an agency decision or directive does not explicitly prohibit addition of nonfood sites to particular products;

(e) the labeling of the technical product from which the end

Statements

use product is formulated does not prohibit the proposed site; and

(f) the dosage, concentration, frequency or method of application do not change.

4. Adding, Revising or Deleting Advisory Statements

Advisory statements (such as those related to use precautions, efficacy, crop damage and product incompatibility) may be added or revised provided that the statements:

(a) are not mandatory phrases such as: "do not," "must not" and "shall not;"

(b) do not negate or detract from the required precautionary statements or other label statements;

(c) do not trigger efficacy, human health or environmental concerns;

(d) do not change the dosage, frequency, concentration or method of application;

(e) are not false or misleading; and

(f) do not negate or conflict with statements made on any other product label which refers to use of the subject product or chemical.

Examples of advisory statements include: "This product is not recommended for use on natural marble surfaces" and "This product should not be used with products containing X due to risk of explosive reaction."

Advisory statements may be deleted by notification at any time.

5. Changes in Packaging and Related Labeling

Changes in the shape, color or composition of packaging and in related labeling statements may be done by notification only if all of the following criteria are met:

(a) the dosage, concentration, frequency or method of application do not change;

(b) exposure is not likely increased (examples that might increase exposure include: adding non-water soluble packaging to a product which is only registered for water-soluble packaging; protective clothing or equipment required because of the proposed package change; and new data requirements triggered for increased exposure);

(c) the product is not subject to child resistant packaging (CRP), either before or after the proposed change;

(d) the product is not a rodenticide;

(e) no Worker Protection Standard labeling statements are changed;

(f) the package size is not reduced to the point that the net contents of the package is smaller than the dosage required by directions for use;

(g) the package size or other characteristics is not changed in a way which violates EPA-mandated restrictions imposed on a product (e.g., size limitations may be imposed on a product to limit its use to homeowners only); and

(h) no changes are made to "bait stations," "control

stations," "attractant stations" or other packaging that houses the pesticide during its use.

#### 6. Use Deletions Related to Data Call-In's

Section 6(f) of FIFRA requires EPA to publish a notice of receipt of a voluntary cancellation of a product or one or more of its uses in the Federal Register for public comment. If a registrant of the source(s) of an active ingredient (manufacturing use product--MP) decides to voluntarily cancel one or more uses in response to a data call-in, EPA will publish a Federal Register notice announcing the proposed voluntary cancellation of those uses on the MP and indicate that such uses will be deleted from all products containing the active ingredient unless someone responds within the comment period that they wish to support the continued registration of those uses. After the comment period closes and no one has requested to support the use(s) proposed for deletion, end use registrants will be given three options: support the deleted use(s), request deletion of the use(s) by notification or voluntarily cancel the product. If deletion of the use(s) is chosen as a response to a data call-in, the end use registrant should submit a notification for each product rather than an amendment as described in PR Notice 91-1. Use deletions for MP products, or for end use not responding to a data call-in, may only be submitted as amendments as described in PR Notice 91-1.

#### 7. Storage and Disposal Statements

PR Notices 83-3 and 84-1 permitted registrants to adopt storage and disposal labeling statements as specified in those notices without amendment. Registrants may continue to adopt labeling statements verbatim from those notices by notification. However, a request for variation in the wording of those statements should be submitted as an amendment.

#### 8. Bilingual Labeling

The Agency may require bilingual labeling to protect public health and the environment [40 CFR 156.10(a)(3)]. When bilingual labeling is not required by the Agency, registrants may submit by notification a copy of the foreign language labeling. The foreign text must be a true and accurate translation of the English text. Note: Both language versions of the labeling should appear on a container in their entirety.

#### 9. Use of Symbols and Graphics

Symbols and graphics may be used in conjunction with and in close proximity to explanatory label text, provided that they do not substitute for or conflict with label text, and are not false or misleading (as described in 40 CFR 156.10(a)(5)). Examples include:

arrow diagrams demonstrating how to open product containers.

graphics displaying application patterns such as aerial application.

pictograms displaying various exposure routes.

pictures of where the product can be used. pictures of persons wearing appropriate protective clothing.

10. Redundant Labeling Statements

Statements may be combined to remove redundancy anywhere on the label, provided that statements required by the Agency are not removed or changed. The revised statements must be consistent with 40 CFR 156.10 and Agency policy.

#### 11. Changes in Warranty Statement

Warranty statements may be revised provided they do not disclaim the performance or safety of the product when used in

accordance with label directions, and are otherwise consistent with 40 CFR Part 156.

12. Other Revisions

Minor label changes not described in Section II.A.1.-11. and Section III. which are related to FIFRA may be made by notification, provided they:

(a) are consistent with 40 CFR Part 156; and

(b) involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use; and/or

(c) are permitted or required by a PR Notice.

B. Product Chemistry

1. Active Ingredients

A registrant may change the source of an active ingredient by notification, provided that the alternate source:

(a) is registered for at least the same uses for which the formulated product is registered; and

(b) is similar to the current source, i.e., meets the criteria given in 40 CFR 152.43(b)(1) and (2).

A registrant should submit a Formulator's Exemption (EPA Form 8570-27) along with the notification of source change if the new source is registered for the same uses as the existing source [40 CFR 152.85(c)].

A registrant may not make the following active ingredient related changes by notification, but must submit an application for amendment:

A change in the source of an active ingredient which would result in a change in the amount of any inert ingredient such that it would fall outside its certified limits. This would be considered an alternate formulation. Such a change may result in significant changes in the toxicological or chemical properties of the product.

A change to an unregistered source of an active ingredient.

Addition, deletion, or substitution of an active ingredient or increase or decrease in the amounts of existing active ingredient would constitute a new formulation, which requires a separate registration.

A change in the stated nominal concentration of any active ingredient or change of certified limits that are not shown on the previously submitted Confidential Statement of Formula (CSF), EPA Form 8570-4.

If the new source is not registered for the same uses as the existing source, an amendment for registration must be submitted to delete unsupported uses from the formulated product, or to support the additional uses with data.

2. Inert Ingredients

#### a. Change in Source

If the Agency has required that a registrant identify the source of an individual inert ingredient, the identity of which is known to the registrant, the registrant may change the source of that inert ingredient by notification. However, if the Agency has not required identification of the source of an inert ingredient, the registrant may change a source without notification to the Agency.

b. Change in Nominal Concentration

A registrant may change the stated nominal concentration of any inert ingredient by notification, provided that:

(1) the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and

(2) the composition of the ingredient is known to the registrant.

c. Change in Certified Limits

A registrant may change the certified limits of any inert ingredient(s) in a formulation by notification, provided that they fall within the standard certified limits in 40 CFR 158.175(b)(2). Certified limits may not be changed via notification for products for which:

(1) the Agency has previously determined that alternative certified limits will apply; or

(2) the registrant has already changed the nominal concentration per Section II.B.2.b. above.

Notification

d. Inert Changes Not Permitted by

Changes in proprietary ingredients such as specific solvents or common commodity diluents, which generally are composed of a mixture of ingredients and whose composition is not disclosed to the registrant, require the Agency to determine their acceptability based upon information on their composition supplied by the producer.

Changes of inerts for: (1) antifoulant paints (because such changes may affect the release rate of these products) or (2) products used for the control of vertebrate animals (because odor, taste and dye are usually crucial to product effectiveness).

Minor formulation changes covered in Section IV. below.

Products

3. Starting Materials for Integrated Systems

A registrant who produces a product by an integrated system [40 CFR 158.153(g)] which uses an unregistered source of active ingredient is required to supply the Agency with the sources of the starting materials for each ingredient (40 CFR 158.153). A registrant may change the source of his starting materials to other sources if the change will not result in:

(a) an increase in the upper certified limit of any existing impurity;

(b) the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient; or

(c) the formation of other impurities of toxicological concern (e.g., dioxins, furans, nitrosamines, arsenicals) above levels previously permitted by the Agency.

4. Change in Formulation Process

A registrant may modify a formulation process of a product made by a non-integrated system (a blending or dilution of product components involving no chemical reaction--distinguished from a reaction process), provided:

(a) the certified limits of the active and inert ingredients

(b) the physical/chemical/biological characteristics and/or the effectiveness (efficacy) of the product will not change.

#### III. NON-NOTIFICATIONS

In accordance with 40 CFR 152.46(b), a registrant may accomplish the following types of actions without notification to the Agency:

A. Correcting typographical and printing errors in labeling as well as changes in grammar and/or phrasing that do not change how the product will be used (e.g., adding and/or changing prepositions) provided that the use directions, signal words or requirement for child-resistant packaging does not change and that the format is consistent with Agency labeling requirements. Any corrections which result in changes in use directions, use precautions or the ingredient statement must be submitted as a notification or an amendment as described in this PR Notice.

B. Changes in package size and the net contents, except for:

(1) products subject to child-resistant packaging requirements under 40 CFR Part 157 (either before or after the package size change);

(2) product subject to other special Agency-mandated sizerelated requirements; and

(3) rodenticidal products.

C. Revision, addition or deletion of non-FIFRA related label elements, such as the following:

Symbols and graphics required by other government agencies such as the Department of Transportation.

State-required analysis of a fertilizer product.

Lot or batch codes, barcodes or other production identifiers.

Date of manufacture or label approval.

Use of metric units in addition to standard U.S. units for net contents, dosages and other numeric expressions.

D. Changes in the name or address of the registrant on the label, except for a change resulting from transfer of ownership, which requires Agency approval in accordance with 40 CFR 152.135. 40 CFR Section 152.122 requires, however, that a registrant notify EPA of a change in its company name, address or designated agent.

E. Redesign of label format that does not modify approved label text and is consistent with the format requirements of 40 CFR 156.10 and Agency policy. These may include, among other things, changes in color, type size or style, use of space, configuration or placement of label elements.

#### IV. ACCELERATED REVIEW OF MINOR FORMULATION CHANGES

Although a formulation change may only be accomplished through submission of an application for amended registration, the Agency has developed an accelerated review for certain minor formulation amendments. The criteria are listed below, followed by a description of the review process.

A. Minor Formulation Amendments

Amendments involving the following types of formulation changes will be considered eligible for accelerated review subject to these limitations: 1. Addition, deletion or substitution of one or more colorants in a formulation:

(a) the total percentage of changed colorant does not exceed 1% by weight of the formulation;

(b) the component(s) of the colorant are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;

(c) if the product is registered for food use, the colorant has the appropriate exemption from the requirement of a tolerance under 40 CFR 180.1001; and

(d) the product is not intended for use on seed.

2. Addition, deletion or substitution of one or more fragrances in a formulation:

(a) the total percentage of changed, added or deleted fragrance does not exceed 1% by weight of the formulation;

(b) information on the composition of the fragrance has been provided to the Agency by the fragrance manufacturer or registrant;

(c) the fragrance has been determined to be acceptable for such use by the Agency at the proposed concentration or the component(s) of the fragrance are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4; and

(d) if the product is registered for food use, the fragrance components are exempt from the requirement of a tolerance under 40 CFR 180.1001.

(e) the product is not intended for use in baits or repellents.

3. Addition, deletion or substitution of one or more inert ingredients (other than fragrances or dyes) in a formulation:

(a) the nominal concentration of active ingredient does not change;

(b) the change does not invalidate any product-specific data submitted in support of the initial registration which causes additional data to be required;

(c) the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;

(d) if the product is registered for food use, the inert ingredient is considered to be exempt from the requirement of a tolerance under 40 CFR 180.1001;

(e) any change is for inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and

(f) the product is not intended for use in public health antimicrobial products, baits or repellents.

Applications for accelerated review of the above kinds of amendments should not be submitted if the proposed reformulation will:

(1) change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or

(2) affect the product's efficacy so that supporting data

are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact sanitizing solutions subject to regulation under 21 CFR 178.1010, and liquid or aerosol insecticides intended for household use).

#### B. Review Process

If a registrant believes that an amendment meets the criteria above, he/she should identify it as such on the application for amended registration with a statement such as "Minor Formulation Amendment per PR Notice 95-2 ." The submission should be addressed to the Product Manager and contain:

1. an application (EPA Form 8570-1),

2. one (1) copy of the CSF for the existing

formulation,

3. two (2) copies of the CSF of the proposed formulation, and

4. any supporting information such as MSDS sheets on the added inert ingredient(s).

The PM will make every effort to prepare an appropriate response to the registrant either accepting or rejecting the amendment within 45 days of receipt of application.

V. PROCEDURES FOR NOTIFICATIONS

A. Notifications

1. Notification Submission

For each product a notification should be submitted with a completed Application for Registration (EPA Form 8570-1). A photocopy of the EPA application form is acceptable; an original form is not needed. The application should bear the following statements:

"Notification of (insert type of change, such as 'Alternate Brand Name') per PR Notice (insert number)."

"This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

2. Labeling

For each notification involving labeling changes, one (1) copy of the labeling must be submitted with the changes clearly marked so that they can be photocopied.

3. Confidential Statement of Formula (CSF)

Two (2) original and signed CSFs must be submitted for either a notification or an amendment involving a CSF change. In addition, a Formulator's Exemption form (EPA Form 8570-27) should be submitted for any change in the identity or source of active ingredients.

4. Signature

Each notification should be signed by the registrant or authorized agent and include that person's current address and telephone number.

5. EPA Mailing Address

All correspondence concerning notification actions should be addressed and mailed to: Document Processing Desk (NOTIF) or (AMEND) (as applicable) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency 401 M Street S.W. Washington, D.C. 20460-0001

6. EPA Delivery Address

The official delivery address used for notification actions hand-carried or courier delivered Monday through Friday, 8:00 AM to 4:30 PM, excluding Federal holidays is:

> Document Processing Desk (NOTIF) or (AMEND) (as applicable) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

> > 7. EPA Processing of Notifications

EPA will screen all notifications to determine whether they meet the criteria in this PR Notice or other notices. If a notification is determined not to qualify for notification, EPA will inform the registrant via letter that the submission does not qualify and is being sent to the RD PM team for processing as an application for amended registration. EPA will attempt to screen each notification within 30 days of receipt.

B. Pending Applications

If a registrant has an application for amended registration pending with the Agency which qualifies for notification pursuant to this Notice, the registrant should: (1) send a letter to the PM requesting that the application for amended registration be withdrawn and (2) submit a notification to one of the addresses above. The Agency will then process the notification in lieu of the application for amended registration.

C. Distribution and Sale

When amendment of a registration is permissible by notification, the notification must be received by the Agency before the registrant may distribute or sell the product. Final printed labeling must be also be submitted to the Agency before a product, as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a)(6)]. For notifications, one (1) copy of the final printed labeling is required per product, either with or separate from the notification. For all other amendments, two (2) copies of the final printed labeling are required. A product distributed or sold before a notification and final printed labeling are received is in violation of FIFRA.

#### VII. COMPLIANCE

Notifications and non-notifications should comply with Agency regulations and policy. Notifications and non-notifications which are not in compliance may be subject to enforcement action under FIFRA sections 12 and 14. The Agency will audit notifications to assure that the process is working properly and that such submissions are in compliance.

#### VIII. ADDITIONAL INFORMATION

If you have questions about this notice, call Ms. Sherada Hobgood (703-308-8352).

/signed by Stephen L. Johnson/ Stephen L. Johnson, Director Registration Division

| TABLE A. Re                                | egistration Chan<br>Applicable secti                          | ges Described in t<br>on of this notice | his PR Notice<br>is in parenth | esis).                                    |
|--|---|---|--------------------------------|---|
| TYPE OF<br>CHANGE                          | NOTIFICATION  | NON-NOTIFICATION                        | ACCELERATED<br>REVIEW          | AMENDMENT                                 |
| LABEL OR<br>PACKAGE                        |   |   |                                |   |
| Brand<br>Name                              | Alternate<br>brand name<br>(II.A.1.)                          |   |                                | Primary<br>brand name                     |
| Add/Delete<br>Pests                        | (II.A.2.)<br>Non-Public<br>Health<br>Pests Except<br>Termites |   |                                | Public<br>Health<br>Pests and<br>Termites |
| Add Indoor,<br>Non-Food<br>Use Sites       | (II.A.3.)<br>Antimicrobials<br>only                           |   |                                |   |
| Advisory<br>Statements                     | (II.A.4.)   |   |                                |   |
| Packaging<br>& Related<br>Labeling         | (II.A.5.)   |   |                                |   |
| Use<br>Deletions                           | (II.A.6.)   |   |                                |   |
| Storage and<br>Disposal<br>Statements      | (II.A.7)  |   |                                |   |
| Non-<br>Mandatory<br>Bilingual<br>Labeling | Non-English<br>(II.A.8.)                                      |   |                                | English                                   |
| Symbols or<br>Graphics                     | (II.A.9)  |   |                                |   |
| Redundant<br>Statements                    | (II.A.10.)  |   |                                |   |
| Warranty<br>Statements                     | (II.A.11.)  |   |                                |   |
| Туроѕ                                      |   | (III.A.)                                |                                |   |
| Package Size<br>and Net Conte              | ents  | (III.B.)                                |                                |   |
| Non-FIFRA<br>Related Eleme                 | ents  | (III.C)                                 |                                |   |
| Name and<br>Address                        |   | (III.D.)                                |                                |   |
| Format                                     |   | (III.E.)                                |                                |   |
| PRODUCT CHEMISTRY                          |   |   |                                |   |
| Source of C<br>Active                      | Criteria are met<br>(II.B.1)                                  |   |                                | Criteria<br>not met.                      |

# TABLE A. Registration Changes Described in this PR Notice

(II.B.1)

Source of EPA has EPA has asked for asked for source (II.B.2.a) source (II.B.2.a) Inert Nominal Concentration (II.B.2.b) ofInert Certified Limits of (II.B.2.c) Inert Proprietary (II.B.2.d.) Inerts Minor Reformulation (IV.)

**EPA 1789** 

# Venus Eagle

(703)308-8045 eagle.venus@epa.gov

## EDUCATION

| University of Maryland, College Park, College of Public Affairs, Master of Public Policy | 1996 |
|--|------|
| University of Maryland, College Park, Bachelor of Science, Horticulture                  | 1987 |

#### PROFESSIONAL EXPERIENCE

U.S. Environmental Protection Agency, Office of Pesticide Programs, Registration Division (RD)

#### Lead Biologist/Product Manager/Invertebrate and Vertebrate Branch 3 2007-present

- Set direction and priorities for team regulatory work and projects including applications for new
  active ingredients, new uses, new products, amendments, registrations for special local needs, and
  notifications; product reregistrations; registration review; procedural guidance; and maintenance of
  regulatory records.
- Provide guidance, training and support to team on procedures for new active ingredients and uses, tolerance petitions, and OPP's public process consistent with requirements to the Pesticide Registration Improvement Act, FIFRA, FFDCA, and FQPA.
- Apply knowledge of scientific assessment and risk management to develop mitigation and make regulatory decisions for new registrations and uses of insecticides and rodenticides.
- Review and comment on external communications to states, Congress, White House and oversight agencies
- Communicate within and outside of EPA to explain applicable federal laws, regulations, processes and guidelines.
- Decide regulatory actions based on data evaluation records and risk assessments.
- Former Product Manager for F9047-2 EC Insecticide (EPA Reg. No 279-9545) and others
- Served on: e-Confidential Statement of Product Specification Project Workgroup, OPP Personal Protective Equipment (PPE) Workgroup, SFIREG Supplemental Labeling Workgroup Label Review Manual Subcommittee, RD Product Manager Workgroup (Chair 2015 and Co-Chair 2014)
- RD respiratory labeling expert and PRIA screening expert.

#### Acting Chief, Invertebrate and Vertebrate Branch 3, Registration Division Dec 2016-April 2017

• Temporary detail. Supervised 7 staff who reviewed and processed risk management decisions for new active ingredients, new uses, new products; reviewed amendments, registrations for special local needs, and notifications; product reregistrations; and registration review.

#### Acting Chief, Risk Integration, Minor Use and Emergency Response Branch July-November 2011

• Temporary detail. Supervised 11 staff who reviewed and processed risk management decisions for emergency exemptions and special local needs, food use tolerance petitions.

#### Lead Biologist/Acting Product Manager, Insecticide-Rodenticide Branch July 2006-March 2007

- Provided technical and administrative oversight of applications for: pesticide registration, reregistration and amendments; experimental use permits; and special local needs as well as petitions for pesticide residue tolerances.
- Reviewed and edited internal and external correspondence.
- Reviewed and analyzed team work load including other division reviews in OPP
- Responded to inquiries from registrants.

#### U.S. EPA, Office of Pesticide Programs, Special Review and Reregistration Division (SRRD) Biologist/Senior Product Reregistration Chemical Review Manager April 1997-July 2006

- Managed all aspects of pesticide product reregistration process including communicating with product registrants, creating product-specific data call-ins, reviewing applicant submissions, and coordinating with other SRRD branches.
- Recommended regulatory actions based on scientific review and prepared decision packages.
- Served as lead product reregistration CRM for teams responsible for review of more than 900 CX 57

pesticide products, including Rodenticide cluster, Diazion and Chloropyrifos.

• Served as SRRD representative to the National Pesticide Incident Center.

### Biologist, Product Reregistration Chemical Review Manager

- Coordinated and reviewed active ingredients registered prior to 1984 for re-registration by creating data call-ins, assembling appropriate data, assessing risks and benefits associated with pesticide use, developing risk mitigation strategies, and identifying appropriate regulatory requirements.
- Lead six-person RRD team and other multi-disciplinary teams for reregistration eligibility decisions for OBPA, Nabam, Picloram (with 3 derivatives) and Paraquat Dichloride.

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PROGRESSIVE FORAGE GROWER

February 1, 2013 | VOL. 14 ISSUE 2

# Yield and profit potential

Effective alfalfa management practices are vital. **PG. 5** 

### Plus

### **Dollars to density**

Substantial monetary gains are possible when silage packing densities are improved. **PG. 24** 

### Graze among the trees

Silvopasture requires a successful integration and knowledge of both pastures and woods. **PG. 30** 

Find your free copy of this 6-page, pull-out forage stats poster in the center of this issue.

### **2012 U.S. forage statistics inside!**

|    | State ranking-<br>all forage production<br>All forage production<br>(in thousands of tons) | 0klaho<br>5,073 |           | 38.7% | Percentage<br>increase/decrease<br>in forage production<br>2011-2012 |
|----|--|-----------------|-----------|-------|--|
|    | State ranking-<br>alfalfa yield  |                 |           |       | State ranking-<br>other hay yield                                    |
| 1  | Alfalfa yield (in thousands of tons)   | 475             | 4         | 3,900 | Other hay yield<br>(in thousands of tons)                            |
|    | State ranking-<br>alfalfa acres  |                 |           |       | State ranking-<br>other hay acres                                    |
| ť  | Alfalfa acres (in thousands of acres)  | 190             | 3         | 3,000 | Other hay acres (in thousands of acres)                              |
|    | Percentage<br>increase/decrease of<br>alfalfa new plantings                                | <sup>%</sup> 20 | 30        | 698   | State ranking-<br>silage yield                                       |
| ć, | Alfalfa new plantings<br>(in thousands of acres)   | 20              |           | 030   | Silage yield<br>(in thousands of tons)                               |
| 1  | 2011 hay receipts as a percentage of state's 8%  | \$74,717        | 26        | 45    | State ranking-<br>silage acres                                       |
| 2  | 2011 hay receipts  | /               |           |       | Silage acres<br>(in thousands of acres)                              |
| 5- | annual total   | Cattle/calves,  | Hogs, Bro | ilers | Top 3 ag commodities   |

### Aim for the moon, cont'd from page 9

night and left the hay tinder-box dry. One of the growers who understood alfalfa hay arrived on the scene early one morning to find that his custom harvesting crew had baled all night in too-dry conditions. He fired them on the spot. "But we have to bale every night to keep up," was the excuse. The grower countered that they had just turned early-cut, high-test dairy alfalfa into junk feeder hay.

There are times custom operators are available who will do a quality harvesting job, and there are times they are not. This is a consideration to make when looking at the purchase

of haying machinery. This is a heartbreaker for someone just getting into the hay-growing business. If custom operators are not willing to take the time to make your hay topquality, there is another option. That is to sell it either standing or in the windrow. This option usually is less lucrative than having a whole stack of super-premium hay to sell, but you do not take the risk of too-dry baling conditions or of a rainstorm reducing the quality of your hay. In most areas, this option is available either with or without a "rain" clause. Rain insurance is also available, at least in central

Washington State. This cuts down on the sales of Tums and Rolaids during the hay-making time of the year.

In "aiming for the moon" as to hay quality, it helps to understand what the markets are for premium hay of the kind you grow. This can be a moving target, and it can be a case of "in the eye of the beholder." If the top-dollar hay in your area goes to a dairy, a feed store, an exporter or to a feedlot, ask those people what they want. It may surprise you to learn that with corn and soybean prices going up, feedlot operators will gladly pay more for hay higher in protein than



hay that is just a roughage filler. To hit a target, you need to know where the target is and its distance from you.

Every person I have ever known who is involved in any way with buying hay will take the time to answer one question from any hay grower. That question is, "What do I need to do to make my hay worth more money?" Then listen to the answers, don't make excuses, don't get mad and try not to argue too much.

My answers to the above question over the years have been some of these:

• "Your hay needs to be more uniform. In the same stack, you have premium and feeder hay and everything in between."

• "When you think your hay is ready to bale, go fishing for a day or two instead. You are baling it with too much stem moisture."

• "You need to cut it by the maturity of the plant and not by the number of days since the last cutting. If the weather is 105 degrees and windy, the alfalfa will mature faster than in cool weather."

• "You need to watch the dew moisture closer at baling so you get the leaves inside the bale – and even better, all still attached to the stem. If the stems are dry, you can bale at a higher total moisture than if you are trying to bale with stem moisture."

• "You need to improve your stack yards or hay barns. Elevate the base of the stack area and cover it with coarse drain rock. That will keep most of the bottom bales dry most of the time. Hay trucks need to be able to get in and out of your hay storage area most of the year."

I fully realize that neither you nor I can control the weather. I fully realize there are times when you must bale too wet or too dry. I hope you don't ever need to bale too wet and too dry at the same time; if you do, fire insurance would be a better buy than rain insurance. There is a reason why the "5 percent" hay is only that small a percentage of all production. I have a gut feeling that if more growers understood what it took to make the "5 percent" hay, there could easily be more of it. **FG** 

> **C** I have a gut feeling that if more growers understood what it took to make the '5 percent' hay, there could easily be more of it. **?**

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Issue 2 • February 1, 2013

FALL 2013

A PUBLICATION OF THE AMERICAN SOYBEAN ASSOCIATION

Vol.1, No.2

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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY BEFORE THE ADMINISTATOR

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In the Matter of:

FMC Corporation,

Respondent.

Docket No : FIFRA-03-2015-0248

### CERTIFICATE OF SERVICE

I hereby certify that, on the date below, copies of COMPLAINANT'S FIRST SUPPLEMENT TO PREHEARING EXCHANGE were served upon the persons listed in the manner indicated.

Original and one copy of Complainant's First Supplement to Prehearing Exchange via the OALJ E-filing System

Sybil Anderson, Headquarters Hearing Clerk

### One copy of Complainant's First Supplement to Prehearing Exchange via the OALJ Efiling System

Christine Coughlin, Administrative Law Judge

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APR 0 5 2017

Jennifer M. Abramson (3RC50) Senior Assistant Regional Counsel U.S. EPA, Region III

Date