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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN - 7 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Pesticide Regulation (PR) NOTICE 95-3

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF AGRICULTURAL PESTICIDES

Attention: **Persons Responsible for Registration of Pesticide Products**

Subject: **REDUCTION OF WORKER PROTECTION STANDARD (WPS) INTERIM RESTRICTED ENTRY INTERVALS (REIs) FOR CERTAIN LOW RISK PESTICIDES**

On January 11, 1995, EPA published a draft policy statement on "Reduced Restricted Entry Intervals for Certain Pesticides," in the Federal Register. The final policy was published in the Federal Register on May 3, 1995. This PR Notice contains the final policy that was published in the Federal Register Notice.

EPA will permit registrants to reduce the Worker Protection Standard (WPS) interim restricted entry intervals (REIs) from 12 to 4 hours for certain low risk pesticides. A list of active ingredients that are eligible for reduced interim WPS REIs is included in this notice. End-use products (EP) containing active ingredients that appear on the list are to be evaluated using the criteria described within the notice to determine if the current REI may be reduced to 4 hours. This PR Notice is effective immediately.

I. Summary of the PR Notice

EPA will permit registrants to reduce the current WPS interim REIs from 12 to 4 hours for pesticides that contain specific active ingredients that meet certain additional criteria. Using the criteria described in Unit III, the Agency screened a total of 495 active ingredients and determined that over 100 active ingredients met the low toxicity criteria. As a result, end use products containing these active ingredients may be eligible for a reduced REI. Unit IV lists the active ingredients that the Agency has determined to meet the low toxicity criteria.

Registrants of end use products which are subject to WPS and which contain only these active ingredients may apply the criteria in Unit VI of this notice to determine whether their end use product qualifies for the reduced REI. The Agency will allow registrants to revise labeling to reflect the reduced REI, through a notification process, until December 31, 1995. After that date, registrants must submit an application for an amended registration. Such applications would be evaluated and approved on the basis of the criteria in this notice.

If the Agency becomes aware of information and determines at any time that the reduced REI is not appropriate, EPA will inform and, after opportunity for discussion, may direct the registrant to revise the REI on the label.

If any person believes that an active ingredient, not listed as a candidate for a reduced REI in Unit IV, meets the low toxicity criteria of this notice, and that products containing that active ingredient should be eligible for a reduced REI, the registrant should contact Judy Smith at 703-305-5621. By mail: U.S. Environmental Protection Agency, Field Operations Division 7506C, 401 M Street S.W., Washington DC 20460.

II. Background

The 1992 WPS established an interim minimum REI of 12 hours for all end use pesticide products for agricultural uses. Longer interim REIs were established for more toxic products. Many commentors, during the promulgation of the rule, stated that it was difficult to determine when the sprays have dried or dusts have settled; thus, judgment was required to assess when such REIs had expired. Other commentors requested that the Agency establish minimum REIs to protect workers against possible unknown chronic or delayed health effects since a product-specific health effect evaluation would take the Agency a long time to conduct. Therefore, the 12-hour minimum REI was established for two reasons: (1) to replace previous REIs that had the statement "when sprays have dried and dusts have settled"; and (2) to incorporate a margin of safety for unknown chronic or delayed health effects.

Since 1992, numerous registrants and pesticide users have asked EPA to consider reducing the minimum 12 hour REI for lower toxicity products that they believe do not need a 12 hour REI to protect workers. In response to these concerns, on January 11, 1995, the Agency published a proposal (60 FR, p. 2848-2852) for public comment. The January proposal contained 75 active ingredients that were eligible for 4 hour REIs. Many commentors stated that all Toxicity Category III's and IV's should be included on the list. The Agency conducted a thorough evaluation of the toxicological data of 495 WPS in-scope active ingredients, and has added 39 more active ingredients to the list.

III. Policy and Rationale for Low Toxicity Criteria

The 1992 WPS revised a 1974 regulation that expressed REIs in terms of the statement "when sprays have dried and dusts have settled." This phrasing was sufficiently vague to cause both enforcement problems and concerns about necessary margins of safety for chronic or delayed health effects. The 1992 revision addresses these problems and concerns by establishing an interim minimum REI of 12 hours for all end use pesticide products for agricultural uses. The 12 hour figure was applied because data indicated that many of the residue concerns were not present after 12 hours.

The 12 hour default covers a very large number of active ingredients, with only active ingredients in Toxicity Categories I and II (more toxic) having longer REIs under the WPS. Some of the active ingredients subject to the 12 hour REI, however, have such low levels of toxicity as to pose minimal risk to workers, even if a fair degree of exposure occurred. These active ingredients are classified as: microbial pesticides (living organisms, including protozoa, fungi, bacteria, and viruses); biochemical pesticides (materials that occur in nature and possess a nontoxic mode of action to the target pest(s)); and certain conventional agricultural chemicals.

Therefore, EPA developed screening criteria to identify those active ingredients with low toxicities from the universe of all Toxicity Categories III and IV active ingredients covered by the WPS. The Agency was concerned that the active ingredient should not be acutely toxic and have no other associated developmental, reproductive, neurotoxic, or carcinogenic effects. Additionally, the active ingredient should not be a cholinesterase inhibitor (N-methyl carbamate and organophosphate) since those chemicals are known to cause a large number of pesticide poisonings and have the potential for serious neurological effects. Finally, no adverse incident data must be present for those active ingredients.

For the few active ingredients where limited data were available on the specific active ingredient, the Agency evaluated data on chemically similar active ingredients (analogs which EPA beleives are predictive of the toxicity of active ingredients) and used that data as a surrogate. Examples of such active ingredients are 2,4-D Isopropyl, and 2,4-D, Isooctyl(2-octyl).

The Agency believes that reducing the REIs for pesticides which meet the criteria below would still provide adequate protection to workers. Reducing the REI would provide agricultural producers with greater flexibility and may promote the use of these inherently less toxic products over those with greater risks and longer REIs. The Agency concludes that the modification of the REIs will not result in unreasonable risk to workers.

Accordingly, the Agency established the following criteria to select the active ingredients with low toxicity, which would be eligible for shorter REIs.

(1) The active ingredient is in Toxicity category III or IV based upon data for acute dermal toxicity, acute inhalation toxicity, primary skin irritation, and primary eye irritation. Acute oral toxicity data were used if no acute dermal data were available. If EPA lacked data on primary skin irritation, acute inhalation, or primary eye irritation of the active ingredient, the Agency reviewed data on that end-point for similar active ingredients (analogs), and excluded such active ingredients from consideration for the reduced REI, if the analog is in Toxicity Category I or II for that endpoint.

(2) The active ingredient is not a dermal sensitizer (or in the case of biochemical and microbial active ingredients, no known reports of hypersensitivity exist).

(3) The active ingredient is not a cholinesterase inhibitor (N-Methyl carbamate and Organophosphate) as these chemicals are known to cause large numbers of pesticide poisonings and have the potential for serious neurological effects.

(4) No known reproductive, developmental, carcinogenic, or neurotoxic effects have been associated with the active ingredient. If active ingredients did not have data available for these chronic health effects, EPA considered data on appropriate chemical and biological analogs. Active ingredients that have been classified as carcinogenic in Category B (probable human carcinogen) or Category C with a potency factor, Q* (possible human carcinogen, for which quantification of potential risk is considered appropriate), or are scheduled for the Health Effects Division's Cancer Peer Review process, were omitted from consideration.

(5) EPA does not possess incident information (illness or injury reports) that are ``definitely'' or ``probably'' related to post-application exposures to the active ingredient.

(6) Some active ingredients are not included in Unit IV because they have been the subject of a reregistration eligibility decision document (RED) which concluded that a 12 hour or longer REI was necessary to protect workers. Active ingredients with REIs established during the recent reregistration activities are NOT eligible for reduced REIs through the notification process. Although a RED has been completed on Glyphosate, the REI for Glyphosate was set utilizing end use product data, and hence, the Agency will add it to the active ingredient list. However, the registrant for those end use products must meet criteria listed in Unit VI to be eligible for a 4 hour REI reduction.

It should also be noted that WPS does not apply to pheromones used in insect traps.

IV. Active Ingredients Meeting Low Toxicity Criteria

The following is a list of 114 active ingredients currently subject to the WPS requirements that meet the lower toxicity criteria.

Acetylchitin
Agrobacterium radiobacter
Ampelomyces quisqualis isolate M-10
Azadirachtin (Neem extract)
B. t. subsp. aizawai
B. t. subsp. aizawai strain GC-91
B. t. subsp. israelensis
B. t. subsp. kurstaki
B. t. subsp. kurstaki HD-263
B. t. subsp. kurstaki strain EG2348
B. t. subsp. kurstaki strain EG2371
B. t. subsp. kurstaki strain EG2424
B. t. subsp. san diego
B. t. subsp. tenebrionis
Bacillus popilliae and B. lentimorbus
Bacillus sphaericus
Bacillus subtilis GB03
Bacillus subtilis MBI 600
BNOA (b-naphthoxy acetic acid)
Borax
Calcium hypochlorite
Calcium oxytetracycline
Calcium thiosulfate
Candida oleophila
Capsicum oleoresin
"Checkmate" peach twig borer pheromone
Chitosan
Chlorsulfuron
Colletotrichum gloeosporioides
Copper as ammonia complex
Copper salts of fatty acids
Cytokinin
2,4-DP, isooctyl
Diatomaceous earth
Disodium octaborate tetrahydrate

Disparlure
Ethoxyquin
Ethylene
Farnesol
Fatty acids, C8-12, Methyl esters
Fenridazone-potassium
Fluazifop-butyl
Fluazifop-r-butyl
Gibberellic acid
Gibberellins A4 and A7
Gliocladium virens G-21
Glyphosate, ammonium
Glyphosate, isopropylamine
Glyphosate, sodium
Gossyplure: Hexadecadien-1-ol acetate
Gypsy moth NPV
Heavy aromatic naphtha
Imazethapyr
Imazethapyr, ammonium salt
Indole-3-butyric acid
Kinoprene
Lagendidium giganteum, mycelium
Mefluidide, diethanolamine
Mefluidide, potassium salt
Methoprene
Methyl nonyl ketone
Metsulfuron-methyl
Milky spore
Mineral oil
Muscalure, component of (E)-9-Tricosene
Muscalure, component of (Z)-9-Tricosene
N-6-Benzyladenine
NAA, Ethyl ester
Nerolidol
Nicosulfuron
Nosema locustae
Octyl bicycloheptenedicarboxamide
Oxytetracycline hydrochloride
Paradichlorobenzene
Paraffin oils
Periplanone B
Phytophthora citrophthora
Poly. inc. bodies of Autographa californica
Poly. incl. bodies of Heliothis NPV or Helicoverpa zea NPV

Poly.incl. bodies of beet armyworm NPV
Poly.incl. bodies of Neodiprion sertifer NPV
Potassium gibberellate
Promalin
Pseudomonas cepacia type Wisconsin
Pseudomonas fluorescens
Pseudomonas fluorescens A506
Pseudomonas fluorescens EG-1053
Pseudomonas fluorescens strain NCIB 12089
Pseudomonas syringae 742RS
Puccinia canaliculata (Schweinitz)
Rimsulfuron DPX-E9636
Ryania speciosa
Ryanodine
Sesame plant, ground
Siduron
Silica gel
Silicon dioxide
Sodium carboxymethylcellulose
Sodium metaborate
Soybean oil
Streptomyces griseoviridis
Streptomycin
Streptomycin sesquisulfate
Sulfometuron-methyl
Thifensulfuron-methyl
Thiobencarb
Tomato pinworm (E)-4-Tridecen-1-yl acetate
Tomato pinworm (E)-11-Tetradecenyl acetate
Triasulfuron
1-Triacontanol
Trichoderma harzianum var. Rifai (KRL-AG2)
Trichoderma harzianum (ATCC 20476)
Trichoderma polysporum (ATCC 20475)
Tussock moth NPV (Douglas Fir)

V. Procedure for Adding Active Ingredients To List

If a registrant believes an active ingredient not on the list meets the criteria set forth in Unit III of this notice, and that products containing that active ingredient should be eligible for a reduced REI, the registrant should contact Judy Smith at EPA, Field Operations Division, at 703-305-5621, before December 31, 1995.

To be considered for a reduced REI, the active ingredient must meet the criteria outlined in this policy, based upon studies determined by the Agency to be acceptable. The registrant is required to submit the studies or cite their MRID numbers and provide copies of Agency reviews that confirm that the criteria are met.

If a registrant believes a new active ingredient may meet the criteria set forth in Unit III of this policy statement, the registrant should request that EPA apply the screening criteria for the reduced REI and reference this policy in the application for registration. Registrants having pending applications may also request the reduced 4 hour REI by amending their application for registration. The registrant must also cite this policy and indicate that a reduced REI of 4 hours is being sought. Such pending applications will be considered against the criteria of this notice, and, if acceptable, will be permitted the reduced REI. The screening criterion for incident data would not apply to new active ingredients.

If a registrant wishes to add a new WPS use to an existing WPS product, and the active ingredient and product would qualify for a 4 hr REI, the registrant must use the standard label amendment process.

After December 31, 1995, registrants should use the existing label amendment process to request a reduction in a REI. In the future, the Agency will continue to apply the lower toxicity criteria to identify active ingredients which may be eligible for the 4 hour REI during both registration and reregistration process. The Agency will update the list of the candidate active ingredients periodically.

VI. Procedures for Determining Eligibility of End-Use Products

If the registrant wishes to qualify for REI reduction of an end use product(s) that contains any active ingredient(s) included on the list in Unit IV or any subsequent update, the registrant is responsible for determining if that end use product(s) qualifies for REI reduction. To qualify, the following criteria must be met:

(1) The end-use product is in Toxicity Category III or IV for all of the following acute toxicity studies: acute dermal toxicity, acute inhalation toxicity, primary skin irritation, and primary eye irritation.

(2) Based on the required sensitization or hypersensitivity studies, the end use product is not a sensitizer and there have been no reports of hypersensitivity.

(3) The registrant has no data indicating, and is not aware of, adverse health effects associated with the end use product, e.g., carcinogenicity, developmental effects, or reproductive effects.

(4) The registrant is not aware and has not been informed of incident information (illness or injury reports) that are ``definitely'' or ``probably'' (as defined by the California Incident Reporting System) related to post-application exposures to the product.

VII. Procedure for Notification/Certification

A. Notification

If a registrant determines that an end use product qualifies for a reduced REI, the registrant may notify EPA using the following procedures. The registrant would submit, for each product, to the Agency, Office of Pesticide Programs, Registration Division:

1. An Application for Registration (EPA Form 8570-1), identified as a notification under this policy.
2. Two copies of the proposed labeling with changes highlighted in a way that can be photocopied.
3. The information required to demonstrate that the product is eligible for the reduced REI.
4. The following certification statement:

"I certify that this notification is in complete accordance with the provisions of EPA's Reduced REI policy and that no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that if this notification does not comply with the terms of EPA's Reduced REI policy, 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. I understand that the Agency may direct a change in the REI of a product subject to this notice if the Agency determines that a change is appropriate, and that products may be subject to regulatory and enforcement action if the appropriate changes are not made."

Notifications should be sent to:

U.S. Postal Service Deliveries

Document Processing Desk (WPS Reduced REI)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460-0001

Personal/Courier Service Deliveries
(Mon.-Fri., 8:00 a.m. to 4:30 p.m., except Federal holidays)

Document Processing Desk (WPS Reduced REI)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. Final Printed Labeling

For each product, final printed labeling must be submitted either as part of the notification or separately in accordance with PR Notice 82-2, before the product may be distributed or sold.

VIII. Sale and Distribution of Pesticide Products Qualifying for a Reduced REI

After the registrant has submitted the information and certification specified in Unit IX, the registrant may sell or distribute products bearing the registrant-certified revised labeling that was submitted to the Agency.

Such registrants may revise labeling of products already in channels of trade through stickering or full relabeling. Stickering, or full relabeling, may occur at sites where the product is not under direct registrant control (such as distribution or retail sites), by any person the registrant designates, and without registration of the site as a pesticide producing establishment. The registrant, however, retains full responsibility for ensuring that such labeling modifications are carried out correctly.

IX. Agency Determination to Revise the REI

FIFRA sec. 6(a)(2) requires that registrants submit to the Agency "additional factual information regarding unreasonable adverse effects on the environment of the pesticide." Registrants may become aware of information or data concerning adverse effects, illnesses or injury associated with exposure of an agricultural worker to a pesticide product or its use, including those resulting from post-application exposures. The Agency generally regards this information as relevant to the Agency's on-going assessment of the risks associated with pesticide products.

If, on the basis of information received from a registrant or other sources, the Agency determines that the 4-hour REI should be increased, the Agency will inform the

registrant of that determination and of the new REI to replace the existing REI. The Agency will also inform the registrant at that time of actions, if any, that must be taken with respect to existing stocks of a product labeled with a 4-hour REI.

Reregistration decisions or decisions resulting from other Agency review processes may supersede this notice. Please note that REIs established by this policy are considered to be interim REIs. Once an active ingredient has gone through the reregistration process, it may result in an active ingredient either being removed or added to the candidate list, and a subsequent change in the length of the REI.

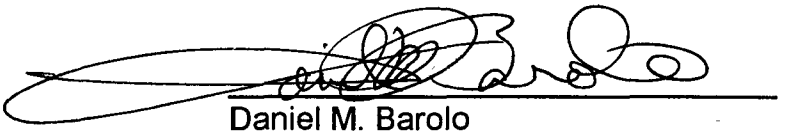
X. Compliance

Registrants are responsible for the content and accuracy of labeling and for compliance with labeling requirements. The Agency will monitor selected submission to verify compliance with the required criteria in this policy. Registrants that submit notifications which do not comply with this policy or EPA's requirements may be subject to enforcement action under FIFRA sections 12 and 14.

Registrants electing to sell or distribute products bearing registrant-verified revised labeling are responsible for correcting any errors on the proposed labels. In most cases, incorrectly reducing the REI from 12 hours to 4 hours would be considered a serious error possibly requiring stop-sale orders, recalls, or civil penalties. A serious error is one which may create a potential for harm to workers, handlers, or other persons, or the environment, or when the errors prevent achievement of the basic goals of the WPS or FIFRA.

XI. Further Information

Questions regarding this notice may be addressed to Dr. Judy Smith (703-305-5621).



Daniel M. Barolo
Director, Office of Pesticide Programs