

August 4, 1998

PESTICIDE REGISTRATION NOTICE 98-4

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

ATTENTION: Persons Responsible for Federal Registration of Pesticides

SUBJECT: Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for
Pesticide Product Registrants

I. BACKGROUND

On September 19, 1997, EPA published in the Federal Register the final rule codifying EPA's interpretation and enforcement policy regarding section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which requires pesticide registrants to report information concerning unreasonable adverse effects of their products to EPA (62 FR 49370). The purpose of the rule is to clarify what information to submit, how and when to submit it, as well as which failures to report information, or delays in reporting, will be regarded by EPA as violations of FIFRA section 6(a)(2), actionable under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N). This rule became effective June 16, 1998, and superseded all previous policy statements pertaining to section 6(a)(2).

EPA has been working with registrants to prepare them for effective implementation of the new FIFRA 6(a)(2) regulations. As a result of those efforts, the Agency has taken several actions. On April 3, 1998, the Agency issued Pesticide Registration Notice 98-3 which provided registrants guidance on implementing the new regulations. It addressed questions and issues raised by registrants and other parties subsequent to the publication of the final rule. On June 19, 1998, the Agency published a Final Rule and Technical Corrections to amend and correct the final regulations (63 FR 33580). The action changed the definition of a registrant to make it consistent with the statutory definition and thus clarified the scope of the registrant's responsibilities and liabilities under section 6(a)(2). The corrections included omitted, yet implied, reporting time frames and required reportable information, missing conjunctions, and minor editorial changes. On August 3, 1998, the Agency published a notice in the Federal Register which deferred the compliance date of the regulations from June 16, 1998 to August 17, 1998 (63 FR 41192). This was done because the Final Rule and Technical Corrections were not published until after the original effective date of the regulations. Finally, through a series of registrant-sponsored workshops and other discussions, additional issues were raised which the Agency has decided to address in this PR notice. In addition to providing guidance on the details of the June 19, 1998 Final Rule and Technical Corrections and other matters, this PR notice notifies registrants of the elimination of a reporting requirement for at least one year.

II. PURPOSE

The purpose of this PR notice is to announce the availability of the attached document which will provide registrants guidance on the June 19, 1998 Final Rule and Technical Corrections; the August 3, 1998 Federal Register notice that deferred the compliance date of the regulations; address additional issues raised by registrants since publication of PRN 98-3; and notify registrants of the elimination of a specific reporting requirement for a period of at least one year. The guidance in this document has been organized alphabetically by subject area, and a table of contents has been provided for ease of reference.

III. FOR FURTHER INFORMATION

Registrants may contact Kathryn Bouvé for information or questions concerning this PR notice and attached guidance document at: Office of Pesticide Programs (7502C), U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Crystal Mall #2, Rm. 224, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-5032, e-mail: Bouve.Kate@epa.gov.

Marcia E. Mulkey, Director
Office of Pesticide Programs
Environmental Protection Agency

Attachment to PR Notice 98-4

**Additional Guidance on Final FIFRA 6(a)(2) Regulations
for Pesticide Product Registrants**

August 4, 1998



**Environmental Protection Agency
Office of Pesticide Programs**

Additional Guidance on Final FIFRA 6(a)(2) Regulations

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I. INTRODUCTION

On September 19, 1997, EPA published in the Federal Register the final rule codifying EPA's interpretation and enforcement policy regarding section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which requires pesticide registrants to report information concerning unreasonable adverse effects of their products to EPA. The purpose of the rule is to clarify what information to submit, how and when to submit it, as well as which failures to report information, or delays in reporting, will be regarded by EPA as violations of FIFRA section 6(a)(2), actionable under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N). In comparison to previous EPA policy statements, some reporting requirements have been expanded, and others reflect increased flexibility or exemptions for reporting specific types of information. This rule became effective June 16, 1998, and superseded all previous policy statements pertaining to section 6(a)(2).

EPA has been working with registrants to prepare them for effective implementation of the new FIFRA 6(a)(2) regulations. As a result of those efforts, the Agency has taken several actions.

On April 3, 1998, the Agency issued Pesticide Registration Notice 98-3 which provided registrants guidance on implementing the new regulations. It addressed questions and issues raised by registrants and other parties subsequent to the publication of the final rule.

On June 19, 1998, the Agency published a Final Rule and Technical Corrections to amend and correct the final regulations (63 FR 33580). The action changed the definition of a registrant to make it consistent with the statutory definition and thus clarified the scope of the registrant's responsibilities and liabilities under section 6(a)(2). The corrections included omitted, yet implied, reporting time frames and required reportable information, missing conjunctions, and minor editorial changes.

On August 3, 1998, the Agency published a notice in the Federal Register which deferred the compliance date of the regulations from June 16, 1998 to August 17, 1998 (63 FR 41192). This was done in response to a petition from seven trade associations asking for deferral of the compliance date of the regulations. The Agency agreed to the request because the Final Rule and Technical Corrections were not published until after the original effective date of the regulations. The Agency acknowledged that the deferral will give registrants sufficient time to implement compliance programs.

Finally, through a series of registrant-sponsored workshops and discussions, additional issues were raised which the Agency has decided to address in this PR notice. This includes elimination, for a period of at least one year, of the requirement to report incidents in which adverse effects have not occurred, but exposed individuals may suffer adverse effects in the future.

For further information, contact Kathryn S. Bouvé, Office of Pesticide Programs (7502C), U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Crystal Mall #2, Rm. 224, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-5032, e-mail: Bouve.Kate@epa.gov.

II. DEFERRAL OF COMPLIANCE DATE

In the August 3, 1998 Federal Register notice, the Agency announced that the compliance date of the 6(a)(2) regulations is deferred until August 17, 1998. EPA is aware that some registrants may wish to comply with the new regulations immediately rather than continue to comply with the pre-existing requirements for another two months. Any registrant that wishes to comply with the new regulations immediately may do so provided that the registrant first informs the Agency in writing of its desire to be bound by the new regulations effective June 16, 1998. Such notice should be submitted to Kathryn Bouvé, the Agency contact person, at the address given above.

Please see VI. and VII. below for additional guidance related to the deferral of the compliance date of the regulations.

III. DEFINITION OF REGISTRANT

In the June 19, 1998 FR Final Rule and Technical Corrections, the Agency changed the definition of registrant to make it consistent with the definition of registrant in FIFRA. Registrant is now defined as “..any person who holds, or ever held, a registration for a pesticide product issued under FIFRA section 3 or 24(c).” The language about employees and agents has been removed from 159.153(b) and is incorporated into 159.155(b). The effect of this change is to make clear that only registrants are obligated to submit adverse effects information to the Agency. Employees and agents, with the exception of supplemental distributors, have no independent obligation to submit adverse effects information to the Agency. Registrants are, however, responsible for information possessed by their employees and agents.

Regarding supplemental distributors, guidance provided in PRN 98-3 is still in effect. Supplemental distributors are defined in 40 CFR section 152.132 as agents of the registrant and both the supplemental distributor and underlying section 3 registrant are liable for violations pertaining to the distributor product. Nevertheless, regarding the submission of adverse effects information under 6(a)(2), the Agency prefers that supplemental distributors deliver reportable information to the underlying registrant (in sufficient time for registrant to report) and not directly to EPA.

IV. ELIMINATION OF REPORTING REQUIREMENT - 'MAY SUFFER' INCIDENTS

Section 159.155(a) states that: "EPA may, in its discretion,eliminate reporting requirements entirely." This is accomplished by providing registrants with written notification of the change in reporting requirements. As the Preamble to the regulations explains, EPA may eliminate a reporting provision if the Agency believes the provision will not provide useful information. By this PR Notice, beginning on the effective date of the regulations of August 17, 1998, the Agency eliminates for all registrants the requirement to report incidents in which a registrant has been informed that a person or non-target organism may suffer a delayed or chronic adverse effect in the future. This requirement is found in section 159.184(a)(2). The elimination of this requirement will remain in effect for at least one year and for any further period until the Agency provides written notice to registrants that the requirement has been reinstated.

To summarize, with this change, the general conditions for reporting toxic or adverse incidents reports are as follows:

- (1) The registrant is aware, or has been informed that a person or non-target organism may have been exposed to a pesticide.
- (2) The registrant is aware, or has been informed that the person or non-target organism suffered a toxic or adverse effect.
- (3) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

The elimination of the requirement to report incidents in which a person or non-target organism may suffer a delayed or chronic adverse effect in the future results in a slight change in the definition of incident exposure type/severity category H-E found in 159.184(c)(5)(i)(E). Included in that category were incidents in which future or delayed effects are reported. With this change, incidents in that category are limited to those in which symptoms are unknown or unspecified.

The Agency has eliminated this requirement for at least a one year period in response to information provided by registrants and other parties during the implementation workshops and meetings held since the final regulations were published in September 1997. Registrants pointed out that many individuals contact them to inquire if adverse effects may occur as a result of exposure or possible exposure to their pesticide. Under the final regulations, such incidents appear to be reportable. After consultation with Agency scientists in OPP's Health Effects Division and staff at a major poison control center, it was agreed that the very small number of potentially useful incidents reports could be buried in the much larger number of reports that were

essentially inquiries about possible effects. In order for registrants and the Agency to remain focused on a manageable volume of useful adverse effects information, the Agency has eliminated the requirement for at least one year. On the other hand, incidents of very significant or unexpectedly high exposure to pesticides whose primary toxic properties are chronic or delayed should be reported. The same is true for reports of unexpectedly high exposure to very toxic pesticides regulated to ensure very low exposure although no adverse effects occurred. Such information would be reportable under 159.195 of the regulations because such information could have impact on continued registration of the product or on terms and conditions of registration. During the first year the 6(a)(2) regulations are effective, the Agency will monitor to evaluate reporting pursuant to 159.195 in an effort to determine whether these kinds of incidents appear to be properly reported through that provision.

V. INFORMATION ABOUT MCL's AND HAL's FOR CHEMICALS

Sections 159.178(b) and 159.184(c)(5)(vi) describe the requirements for reporting contamination of water by pesticides. Section 159.153(b) includes definitions of the water reference levels that trigger reporting.

For human health concern, the regulations refer to the maximum contaminant levels (MCL) and the health advisory levels (HAL) which are the drinking water regulations and health advisories developed by EPA's Office of Water. The standards are set for many chemicals some of which are pesticides. If an MCL has been established for the pesticide detected, 10% or more of the MCL is the reporting trigger. If an MCL has not been established, but an HAL has been established for the detected pesticide, 10% or more of the HAL is the reporting trigger. HAL's are set for different exposure durations and weights of exposed individuals. When relying on an HAL as a trigger for reporting a pesticide in water, the lifetime adult level - the most conservative level - should be used.

Registrants have asked how to find the MCL's and HAL's for chemicals. Copies of the Drinking Water Regulations and Health Advisories may be ordered free of charge from the:

SAFE DRINKING WATER HOTLINE
1-800-426-4791
Monday thru Friday, 9:00A.M. to 5:30 P.M. EST

They are also available on the Internet at the following URL:

www.epa.gov/OST/Tools/dwstds.html

VI. MODIFICATION OF REPORTING TIMEFRAME - AUGUST 17 - 31, 1998

As noted above, with publication of the August 3, 1998 Federal Register notice, the 6(a)(2) regulations become effective on August 17, 1998. Consequently, August 17, 1998 marks the transition from the old reporting requirements - the 1979 Enforcement Policy - to the new regulations. Part of the transition is the shift from the 1979 Enforcement Policy's 30-day reporting timeframe for all information to the new regulations' variable reporting timeframes for different categories of information.

For some categories of information, information may be accumulated for one month and may be submitted by the end of the month following the accumulation period. For other categories of information, information may be accumulated for three months and may be submitted by the end of the second month following the accumulation period. In the interest of simplicity, the Agency would like registrants to use the last day of a month as the deadline for reporting adverse effects information as applicable to the Agency.

Registrants have raised the question of how to handle submission of adverse effects information that comes into a registrant's possession during the period August 17 - 31, 1998. To address that concern, by this PR Notice, the Agency is permitting registrants to include reportable information that arises during the period of August 17 - 31, 1998 in the following way:

For categories of information that may be accumulated for one month and submitted by the end of the month following the accumulation period, information arising between August 17 and 31, 1998 may be accumulated with information arising during the month of September 1998. Such reports will be due to the Agency by the end of October, 1998.

For categories of information that may be accumulated for three months and submitted by the end of the second month following the accumulation period, information arising between August 17 and 31, 1998 may be accumulated with information arising during the months of September, October, and November, 1998. Such reports will be due to the Agency by the end of January, 1999.

This is a one-time modification of reporting timeframes and applies to the period August 17 - 31, 1998 only. This modification of reporting timeframes is done per section 159.155(a) which provides EPA the discretion to notify registrants in writing of a different reporting period for specific information.

VII. REPORTING OF INFORMATION OBTAINED BEFORE PROMULGATION

Section 159.159 of the regulations specifies the requirements regarding information obtained before June 16, 1998 which is reportable under the regulations but was not reportable

under the 1979 Enforcement Policy. The September 19, 1997 regulations required that information of this type be submitted to the Agency by June 16, 1999. This has been referred to as the 'look back' provision. Notwithstanding the deferral of the compliance date of the regulations, reportable information under 159.159 is still required to be submitted by June 16, 1999. Registrants have been aware of the requirement since September 1997 which has given them 21 months to review records and prepare the summary report specified in the regulations.

VIII. TECHNICAL CORRECTIONS - REPORTABLE INFORMATION

Among the technical corrections in the June 19, 1998 FR notice, the Agency specified the information items to be provided with reports of adverse effects information. The technical corrections linked requirements to report to the lists of data elements in section 159.184. What follows is a summary of those requirements:

For detection of pesticides in food or feed - 159.178(a)

Administrative, Pesticide, and Circumstance information in 159.184(c)(1), (2), and (3)

Incident Specific Information in 159.184(c)(4)(iv)

- (E) Sample type (grab, composite)
- (F) Sampling times/frequency
- (G) Pesticides and degradates analyzed for, the detection limits, and the amount detected.
- (H) Method of analysis

For detection of pesticides in water - 159.178(b)

Administrative, Pesticide, and Circumstance information in 159.184(c)(1), (2), and (3)

For detections in surface water - Incident Specific Information in 159.184(c)(4)(iv)

- (A) If raw water samples, water bodies sampled and approximate locations in each water body.
- (B) If raw water samples, proximity of sampling locations to drinking water supply intakes and identities of systems supplied.
- (C) If finished water samples, water supply systems sampled.
- (D) If finished water samples, percent surface water source by specific surface water sources to water supply system(s).
- (E) Sample type (grab, composite).
- (F) Sampling times/frequency.

(G) Pesticides and degradates analyzed for, the detection limits, and amount detected.

(H) Method of analysis.

For detections in groundwater - Incident Specific Information in 159.184(c)(4)(v)

(A) Pesticide and degradates analyzed for, the analytical method used, the detection limits, and amount detected.

(B) Sample date.

(C) Amount pesticide applied (lbs-ai/acre).

(D) Date of last application.

(E) Depth to water.

(F) Latitude/longitude.

(G) Soil series and texture(sand/silt/clay).

(H) Frequency of applications per year.

(I) Aquifer description (confined/unconfined).

(J) Method of application.

(K) Years pesticide used.

(L) Well use and well identifier.

(M) Screened interval.

(N) Annual cumulative rainfall (inches).

(O) Maximum rainfall and date.

(P) Cumulative irrigation (inches).

(Q) Hydrologic group.

(R) Hydraulic conductivity.

(S) pH.

(T) Organic matter or organic carbon (percent).

Also (5)(vi) - Severity Category

IX. TECHNICAL CORRECTIONS - REPORTING TIMEFRAMES

Among the technical corrections in the June 19, 1998 FR Notice, the Agency specified the reporting timeframes for all categories of reportable adverse effects information. What follows is a summary of those requirements:

ASAP - No later than 15 calendar days Allegation of human death - H-A

No later than 30 calendar days	Scientific studies - section 159.165 Information about discontinued studies - section 159.167 Human epidemiological and exposure studies - section 159.170 Detection of pesticide in or on food or feed - section 159.178(a) Detection of metabolites, degradates, contaminants, impurities - section 159.179 Failure of performance studies - section 159.188(a)(2), (b)(2), and (c) Other information - 159.195
Accumulate for one month/submit by end of next month	Major human incident - H-B Moderate human incident - H-C Major wildlife incident - W-A Major plant damage incident - P-A Major water incident - G-A Efficacy failure incident - section 159.188(a)(1) and (b)(1)
Accumulate for three months/submit by end of second month after accumulation period	Minor human incident - H-D Human incident - symptoms unknown or not specified - H-E Domestic animal death - D-A Major domestic animal incident - D-B Moderate domestic animal incident - D-C Minor domestic animal incident - D-D Domestic animal incident - symptoms unknown or not specified - D-E Minor wildlife incident - W-B Minor plant damage incident - P-B Incidents involving all other non-target organisms - ONT Moderate water incident - G-B Minor water incident - G-C

X. VOLUNTARY INCIDENT REPORTING FORMS

A work group comprising representatives of registrant companies and trade associations, with input from OPP staff, designed forms for capturing and submitting individual and aggregate incident reports. The individual incident form is designed to capture the basic information about the incident in order to determine if it is reportable (exposure, adverse effect, contact person, pesticide identification, and where it occurred). In addition, it will foster the process by which registrants categorize each incident by exposure type and severity category and determine how much information is to be reported and when to submit the reports. An aggregate report format is also being designed. Detailed instructions accompany both forms. This will support aggregate reporting of appropriate categories of exposure types and severity as specified in the regulations. Use of these forms is voluntary and information submitted using the forms will be accepted by the

Agency. Other formats that meet the requirements of the regulations will be acceptable to the Agency as well. The forms and instructions are available to any interested party from the participating trade associations that follow:

American Crop Protection Association

1156 15th Street, N.W. Suite 400
Washington, DC 20005
Staff contact - Ray McAllister
Phone - 202-296-1585
Fax - 202-463-0474
Web site - www.acpa.org

Chemical Manufacturers Association

1300 Wilson Blvd.
Arlington, VA 22209
Staff contact - Has Shah
Phone - 703-741-5000
Fax - 703-741-6091
Web site - www.cmahq.com

Chemical Producers and Distributors Association

1430 Duke Street
Alexandria, VA 22314
Staff contact - Warren Stickle
Phone - 703-548-7700
Fax - 703-548-3149
Web site - www.cpda.com

Chemical Specialties Manufacturers Association

1913 Eye Street, N.W.
Washington, DC 22206
Staff contact - Steve Kellner
Phone - 202-872-8110
Fax - 202-872-8114
Web site - www.csma.org

International Sanitary Supply Association

7373 North Lincoln Ave.
Lincolnwood, IL 60646
Staff contact - Bill Balek
Phone - 847-982-0800
Fax - 847-982-1922
Web site - www.issa.com