

a pesticide product, unless EPA has established or proposed a maximum contaminant level (MCL) or health advisory level (HAL) for that substance, or has estimated a health advisory level based on an established reference dose (RfD) for that substance, and notified registrants of that level.

(5) Information to be submitted is the same as that required in § 159.184(c)(1), (2), (3), (4)(iv) and (v), and (5)(vi).

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.179 Metabolites, degradates, contaminants, and impurities.

(a) *Metabolites and degradates.* Information which shows the existence of any metabolite or degradate of a pesticide product must be submitted if either of the following conditions is met:

(1) The metabolite or degradate may occur or be present under conditions of use of the pesticide product, and the existence of the metabolite or degradate or the association of the metabolite or degradate with the pesticide product has not been previously reported to EPA.

(2) The metabolite or degradate has been previously reported, but it is detected at levels higher than any previously reported; and either of the following conditions is met:

(i) Any person described in § 159.158(a) has concluded that the metabolite or degradate may pose a toxicological or ecological risk based on any one or more of the following:

(A) The physical or chemical properties of the metabolite or degradate.

(B) Data regarding structurally analogous chemicals.

(C) Data regarding chemical reactivity of the metabolite or degradate and structurally analogous substances.

(D) Data on the metabolite or degradate.

(ii) The registrant has concluded, or has been advised by any person described in § 159.158(a) that the metabolite or degradate, or analogous chemicals, may have any experimentally determined half-life greater than 3 weeks as shown from laboratory aerobic soil metabolism studies or field dissipation studies, or may have any experimentally determined resistance to hydrolytic degradation, or photolytic

degradation on soil or in water, under any conditions, resulting in degradation of less than 10 percent in a 30-day period.

(b) *Contaminants and impurities.* The presence in any pesticide product of a contaminant or impurity not previously identified by the registrant as part of the pesticide product's approved composition must be reported pursuant to this part if the contaminant or impurity is present in the product in any of the following quantities:

(1) Quantities greater than 0.1 percent by weight (1,000 parts per million).

(2) Quantities that EPA considers, and so informs registrants, to be of toxicological significance.

(3) Quantities that the registrant considers to be of toxicological significance.

(4) Quantities above a level for which the registrant has information indicating that the presence of the contaminant or impurity may pose a risk to health or the environment.

(5) Quantities that a person described in § 159.158(a) has informed the registrant is likely to be of toxicological significance.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.184 Toxic or adverse effect incident reports.

(a) *General.* Information about incidents affecting humans or other non-target organisms must be submitted if the following three conditions are met:

(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, or may suffer a delayed or chronic adverse effect in the future.

(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.

(b) *Exceptions.* Information regarding an incident need not be submitted if any of the following conditions are met:

(1) The registrant is aware of facts which clearly establish that the reported toxic effect, or reported exposure, did not or will not occur.

(2) The registrant has been notified in writing by the Agency that the reporting requirement has been waived for this incident or category of incidents, and the registrant has not been notified in writing by the Agency that the waiver is rescinded.

(3) It concerns a toxic effect to non-target plants, which were at the use site at the time the pesticide was applied, if the label provides adequate notice of such a risk.

(4) It concerns non-lethal phytotoxicity to the treated crop if the label provides an adequate notice of such a risk.

(5) It concerns a toxic effect to pests not specified on the label, provided that such pests are similar to pests specified on the label.

(6) It concerns minor skin or eye irritation effects warned of on the label of a product which is registered for use in residential use sites, and the effects occurred as a result of use in a residential site.

(c) *Required information on individual incidents.* To the extent that the registrant has any of the information listed in paragraphs (c)(1) through (c)(4) of this section, the registrant must supply the information on each pesticide incident that meets the requirements outlined in paragraph (a) of this section. If the registrant acquires additional information concerning an incident previously reported to the Agency under this part, such information shall be reported if it meets the criteria set forth in paragraph (f) of this section. In the future, the Agency may by notice specify a format for such submissions. The Administrative, Pesticide, Circumstance and Exposure Type(s) of information must be reported for individual incidents, except where the provisions of paragraph (e) of this section allow for aggregated summary forms of reporting, or if EPA in the future grants permission in writing for alternative reporting formats. The registrant must also provide one or more Exposure Type and Severity categories and their designations for each incident as set forth in paragraph (c)(5) of

this section, depending on the applicability of the criteria listed below. The criteria listed should be used in assigning a category. For example, an incident which allegedly caused serious but non-fatal effects to human beings and domestic animals might be designated "H-B: D-B." When a single incident involves multiple pesticides, the registrant need only report on their specific product. However, if a single incident involves more than one type of non-target organism—for example, both humans and domestic animals are involved—all appropriate available information dealing with each of the victims must also be reported. The informational items below are grouped by sections for ease in reporting pesticide incidents.

(1) *Administrative.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

- (i) Name of reporter, address, and telephone number.
- (ii) Name, address, and telephone number of contact person (if different than reporter).
- (iii) Incident report status (e.g., new or update); if update, include the date of original submission.
- (iv) Date registrant became aware of the incident.
- (v) Date of incident (if appropriate, list start and end dates).
- (vi) Location of incident (city, county and state).
- (vii) Is incident part of a larger study.
- (viii) Source if different from reporting registrant.

(2) *Pesticide.* Pesticide incident reports must be submitted for each pesticide that may have contributed to the incident, if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

- (i) Product name.
- (ii) Active ingredient(s).
- (iii) EPA Registration Number.
- (iv) Diluted for use, or concentrate.
- (v) Formulation, if known.

(3) *Circumstance.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Evidence the label directions were not followed (e.g., yes, no, unknown).

(ii) How exposed (e.g., spill, drift, equipment failure, container failure, mislabeling, runoff, etc.).

(iii) Situation (e.g., household use, mixing/loading, application, reentry, disposal, transportation, other (describe)).

(iv) Use site (e.g., home, yard, commercial turf, agricultural (specify crop), industrial, building/office, school, nursery, greenhouse, pond/lake/stream, well, forest/woods, other).

(v) Applicator certified (yes, no, unknown).

(vi) A brief description of the circumstances of the incident.

(4) *Other incident specific information.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) If the incident involves humans:

(A) Route of exposure (skin, eye, respiratory, oral).

(B) List signs/symptoms/adverse effects.

(C) If laboratory tests were performed, list name of test(s) and results.

(D) If available, submit laboratory report(s).

(E) Time between exposure and onset of symptoms.

(F) Was adverse effect the result of suicide/homicide or attempted suicide/homicide.

(G) Type of medical care sought, (e.g., none, Poison Control Center, hospital emergency department, hospital inpatient, private physician, clinic, other).

(H) Demographics (sex, age, occupation).

(I) If female, pregnant?

(J) Exposure data: amount of pesticide; duration of exposure; weight of victim.

(K) Was exposure occupational; days lost due to illness.

(L) Was protective clothing worn (specify).

(ii) If domestic animal:

(A) Type of animal (e.g., livestock, poultry, bird, fish, household pet e.g., dog/cat etc.).

(B) List signs/symptoms/adverse effects.

(C) Breed/species (name and number affected, per adverse effect).

(D) Route of exposure (e.g., skin, eye, respiratory, oral).

(E) Time between exposure and onset of symptoms.

(F) If laboratory test(s) performed, list name of tests and results.

(G) If available, submit laboratory report(s).

(iii) If fish, wildlife, plants or other non-target organisms:

(A) List species affected, and number of individuals per species.

(B) List symptoms or adverse effects.

(C) Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).

(D) Pesticide application rate, intended use site (e.g., corn, turf), and method of application.

(E) Description of the habitat and the circumstances under which the incident occurred.

(F) If plant, type of plant life (i.e., crop, forest, orchard, home garden, ornamental, forage).

(G) Formulation of pesticide if not indicated by brand name (granular, flowable).

(H) Distance from treatment site.

(I) If laboratory test(s) performed, list name of test(s) and results.

(J) If available, submit laboratory report(s).

(iv) If surface water:

(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.

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

(H) Method of analysis.

(v) If ground water:

(A) Pesticides and degradates analyzed for, the analytical method used, the detection limits, and the 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).

(vi) If property damage.

(A) Provide description.

(B) [Reserved]

(5) *Exposure types and severity category designations*—(i) *Humans*. If an effect involves a human, provide the appropriate 2-letter exposure types and severity categories and their designations, based upon the following categories:

(A) H-A: If the person died.

(B) H-B: If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability.

(C) H-C: If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment of the person would have been indicated. Symptoms were not life threatening and the person has returned to his/her pre-expo-

sure state of health with no additional residual disability.

(D) H-D: If the person alleged or exhibited some symptoms, but they were minimally traumatic. The symptoms resolved rapidly and usually involve skin, eye or respiratory irritation.

(E) H-E: If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future.

(ii) *Domestic animals*. If an effect involves a domestic animal, provide the appropriate 2-letter notation based upon the following categories:

(A) D-A: If the domestic animal died or was euthanized.

(B) D-B: If the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability.

(C) D-C: If the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment would have been indicated to treat the animal. Symptoms were not life threatening and the animal has returned to its pre-exposure state of health with no additional residual disability.

(D) D-D: If the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involve skin, eye or respirator irritation.

(E) D-E: If symptoms are unknown or not specified.

(iii) *Fish or wildlife*. If an alleged effect involves fish or wildlife, label the incident W-A if any of the following criteria are met, or W-B if none of the criteria are met:

(A) Involves any incident caused by a pesticide currently in Formal Review forecological concerns.

(B) Fish: Affected 1,000 or more individuals of a schooling species or 50 or more individuals of a non-schooling species.

(C) Birds: Affected 200 or more individuals of a flocking species, or 50 or more individuals of a songbird species, or 5 or more individuals of a predatory species.

(D) Mammals, reptiles, amphibians: Affected 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species.

(E) Involves adverse effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic).

(F) Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide.

(G) Involves adverse effects caused by a pesticide, to federally listed endangered or threatened species.

(iv) *Plants*. If an alleged effect involves damage to plants, label the incident P-A if the following criterion is met, or P-B if the criterion is not met:

(A) The effect is alleged to have occurred on more than 45 percent of the acreage exposed to the pesticide.

(B) [Reserved]

(v) *Other non-target organisms*. If an alleged effect involves damage to non-target organisms other than fish, wildlife or plants (for example, beneficial insects), label the incident ONT.

(vi) *Water contamination*. If a pesticide is alleged to have been detected in groundwater, surface water or finished drinking water, label the incident in accordance with the following criteria:

(A) G-A: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory level (HAL) or an applicable criterion for ambient water quality.

(B) G-B: If the pesticide was detected at levels greater than 10 percent of the MCL, HAL or a criterion for ambient water quality but does not exceed the MCL or other applicable level.

(C) G-C: If the pesticide was detected at levels less than 10 percent of the MCL, HAL, or other applicable level, or there is no established level of concern.

(vii) *Property damage*. If an incident involves alleged property damage the applicable term(s) shall be included along with any other applicable effect category label; for example, "H-B: property damage." Label the incident in accordance with the following criteria:

(A) PD-A: The product is alleged to have caused damage in a manner that

could have caused direct human injury, such as fire or explosion.

(B) PD-B: The product is alleged to have caused damage in excess of \$5,000.

(C) PD-C: Any allegation of property damage that does not meet the criteria of paragraphs (c)(5)(vii)(A) or (B) of this section, including cases in which the level of damages is not specified.

(d) *Time requirements for submitting incident information*. Information concerning incidents reportable under this section must be submitted within the time frames listed for different exposure and severity categories, as follows:

(1) For allegations involving human fatality (H-A), registrants must submit the required information, to the extent it is available, no later than 15 days after learning of an allegation.

(2) Information concerning incidents which meet the criteria for the following exposure and severity category labels described in paragraph (c)(5) of this section, reports of detections of pesticides in water, and efficacy failure incidents may be described in §159.188(a)(1) and (b)(1), may be accumulated for a 30-day period, and submitted to the Agency within 30 days after the end of each 30-day accumulation period for: Humans, H-B, and H-C; Wildlife, W-A; Plants, P-A; Water, G-A; Property Damage, PD-A.

(3) Incidents or reports of detections of pesticides in water meeting all other exposure and severity label categories, information may be accumulated by registrants for 90 days and submitted within 60 days after the end of each 90-day accumulation period.

(e) *Aggregated reports*. For incidents that are reportable under the schedule requirements of paragraph (d)(3) of this section, in lieu of individual reports containing the information listed in paragraphs (c)(1) through (c)(4) of this section, registrants must provide an aggregated report listing:

(1) The time period covered by the report.

(2) For each exposure and severity label category, a count of the number of incidents, listed by product registration number (if known) or active ingredient.

(3) A count of domestic animal incidents in categories, other than D-A or

D-B, which can be added together and reported as a single number.

(f) *Reporting additional information.* If, after the submission of an incident report to the Agency, a registrant acquires additional information concerning that incident, the information should be submitted within the same time frame as applied to the original incident report, if any of the following conditions apply:

(1) The information concerns an alleged human fatality (H-A), and the information consists of any of the elements listed in paragraphs (c)(1) through (c)(4) of this section.

(2) The information concerns an incident originally reported as alleging a major human illness or injury (H-B), or fatality to a domestic animal (D-A), or wildlife (W-A), and the additional information consists of pesticide or circumstance information listed in paragraphs (c)(2) or (c)(3) of this section, or is a laboratory report concerning persons or animals involved in the incident.

(3) The information concerns any incident not originally reported with one of the exposure and severity labels H-A, or H-B for human incidents, or at the "A" level of severity for any other exposure or incident type, and the new information would result in labeling the incident H-A or H-B for a human incident, or at the "A" level of severity for any other exposure or incident type listed in paragraph (c)(5) of this section.

[62 FR 49388, Sept. 19, 1997; 63 FR 33583, June 19, 1998]

§ 159.188 Failure of performance information.

(a) *Microorganisms that pose a risk to human health.* Information must be submitted which concerns either incidents described in paragraph (a)(1) of this section or a study described in paragraph (a)(2) of this section:

(1) Information which concerns an incident which meets all of the following conditions:

(i) The registrant has been informed that a pesticide product may not have performed as claimed against target microorganisms.

(ii) The possible failures of the pesticide to perform as claimed involved

the use against microorganisms which may pose a risk to human health.

(iii) The pesticide product's use site is other than residential.

(iv) 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.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims made by the registrant regarding uses intended for control of microorganisms that may pose a risk to human health, including any of the public health antimicrobials identified in part 158 of this chapter.

(b) *Animals that pose a risk to human health.* For the purposes of this section, any animal (including insects) poses a risk to human health if it may cause disease in humans, either directly or as a disease vector; produce toxins that are harmful to humans; or cause direct physical harm to humans. Information must be submitted which concerns either incidents described in paragraph (b)(1) of this section or a study described in paragraph (b)(2) of this section.

(1) Information which concerns an incident which meets all of the following conditions:

(i) The registrant has been informed by municipal, State, or Federal public health officials that a pesticide product may not have performed as claimed against target animals.

(ii) The possible failures of the pesticide to perform as claimed involved the use against animals that pose a risk to human health.

(iii) 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.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims by the registrant regarding uses intended for control of animals that pose a risk to human health, including any of the public health pesticides identified in part 158 of this chapter.