

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.

(c) *Development of pesticide resistance.* Information must be submitted concerning substantiation of any incident of a pest having developed resistance to any pesticide (both public health and non-public health) that occurred under conditions of use, application rates and

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methods specified on the label if either of the following conditions is met:

(1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions.

(2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

§ 159.195 Reporting of other information.

(a) The registrant shall submit to the Administrator information other than that described in §§159.165 through 159.188 if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product. Examples of the types of information which must be provided if not already reportable under some other provision of this Part include but are not limited to information showing:

(1) Previously unknown or unexpected bioaccumulation of a pesticide by various life forms.

(2) Greater than anticipated drift of pesticides to non-target areas.

(3) Use of a pesticide may pose any greater risk than previously believed or reported to the Agency.

(4) Use of a pesticide promotes or creates secondary pest infestations.

(5) Any information which might tend to invalidate a study submitted to the Agency to support a pesticide registration.

(b) A registrant is not obligated under paragraph (a) of this section to provide information to the Administrator if the registrant is aware of facts which establish that otherwise reportable information is not correct.

(c) The registrant shall submit to the Administrator information other than that described in §§159.165 through 159.188 if the registrant has been informed by EPA that such additional information has the potential to raise

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questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

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