



US Environmental Protection Agency Office of Pesticide Programs

Amendment to RED for Metaldehyde

Combined PDF document consists of the following:

- June 22, 2007 Memorandum - Amendment to Metaldehyde RED
- Revised Metaldehyde Label Table
- Protocol for Incident Data Collection



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 22, 2007

CERTIFIED MAIL

Dear Registrant:

SUBJECT: AMENDMENT TO METALDEHYDE RED

The Reregistration Eligibility Decision (RED) document for metaldehyde was signed on July 27, 2006. A public comment period for the RED and supporting documents was conducted from August 9 to October 10, 2006. The RED documents and public comments can be found on the Federal docket system, available at www.regulations.gov (docket # EPA-HQ-OPP-2005-0231). The Agency has reviewed the public comments and has prepared a response to comments document which addresses the substantive comments. The response document is available for viewing at www.regulations.gov under the same docket number. This amendment to the metaldehyde RED makes changes to the original decision document based on the Agency's evaluation of the public comments and other information that became available during the comment period. This amendment includes changes to the RED label tables for metaldehyde products (attached).

In the discussion below, the portions of the RED that prompted the original comment (or related comments) are cited, the comment(s) summarized, and the appropriate revision(s) explained.

AMENDMENTS TO REQUIRED LABEL LANGUAGE

1. Precautionary language and storage restrictions for end-use product labels

RED text (labels of products intended for agricultural use):

Domestic Animal Precautionary Statement: "This product can be fatal to children and dogs (and other domestic animals) when ingested. Children and dogs may be attracted to the product. Application of this product is prohibited unless children and domestic animals can be excluded from the treated area from the start of the application until applied material is no longer visible."

Storage Restrictions: “This product can be fatal to children and dogs (and other domestic animals) if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets. Do not store in any location where children and domestic animals can access the packaging or the product.”

RED text (labels of products intended for residential and similar uses):

Precautionary Statements: “Keep out of reach of children and domestic animals. This pesticide may be fatal to children and dogs (and other domestic animals) when ingested. Exclude children and pets from treated areas until the applied product is no longer visible. For additional precautionary measures, see “Directions for Use” and “Storage and Disposal.”

“IMPORTANT: This product may be fatal to children and dogs (and other domestic animals) if ingested. Keep out of reach of children and domestic animals. Children and dogs may be attracted to metaldehyde products and their packaging. Keep children and dogs (and other domestic animals) out of treated areas from the start of application until the applied product is no longer visible.”

Storage Restrictions: “This product can be fatal to children and dogs (and other domestic animals) if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets. Do not store in any location where children or domestic animals can access the packaging or the product.”

Comments: These statements are excessive in length and the contents are redundant. Metaldehyde has not been associated with lethal poisonings in children.

Amendment: The Agency has revised the precautionary statements and storage restrictions labeling to be more concise. The precautionary statements are revised to indicate that ingestion by children may be harmful, rather than lethal.

2. The graphic representation for residential product labels

RED text: “The label of any end-use product with directions for use on residential sites...must contain a graphic that depicts the prohibition on allowing children and domestic animals access to treated areas. For example, the symbol may be a red circle with the words “Children” and “Pets” within the circle and with a red bar running diagonally through it.” This statement is to appear on the front panel of the packaging, and the RED specifically solicited comment on what type of graphic representation would be best

Comments: Comments on this subject were divided between supporters of the graphic and those who opposed it. The primary concerns of those in opposition were: the graphic could be

misinterpreted as prohibiting use by people with children or dogs; the graphic is confusing; no standards exist on pesticide labels for warning of this type. Commenters in support of the graphic thought it would help alert dog owners, and noted that graphic warnings have been used successfully to communicate hazards to consumers. The suggestion was made that educational outreach efforts could further the objective of protecting the public. The specific graphic suggested in the original RED (red circle with a red slash running diagonally across the circle from upper left to lower right; the words “Children” and “Pets” printed within the circle) is a universally recognized symbol connoting prohibited or undesirable behaviors and situations; this type of graphic is most effective if accompanied by warning statements in text.

No comments were made on alternate graphic representations.

Amendment: The Agency continues to believe that the graphic can act as a readily visible warning on keeping children and pets out of treated areas. Since no alternatives were suggested, the Agency is requiring the red circle and slash symbol as the only acceptable graphic at this time. The Agency agrees to discuss educational outreach to consumers and conveying pertinent information via websites with the registrants.

3. Poisoning hotline label statements

RED text (for labels of all metaldehyde end-use products): “Seek medical care as soon as possible after exposure. Have the product container or label with you when you call a poison control center or doctor or when going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.”

RED text (for labels of residential use products only): “For incidents involving animals, seek veterinary care as soon as possible after exposure. Have the product container or label with you when you call a poison control center or veterinarian or when taking an exposed animal for treatment. For treatment advice and other information about exposures of animals to this pesticide, call [*registrant enters name of reporting service*] at [*registrant enters appropriate toll-free telephone number*].”

Comments: Requiring two different reporting numbers (human and domestic animal) is confusing to the user. Directing incident calls to NPIC should not be mandated.

Amendment: The Agency’s concern for the poisoning hotline text and toll-free number required to be placed on all metaldehyde end-use product labels is three-fold: 1) callers should have quick access via the hotline number to practical poisoning information (which in many cases will be referral as follows); 2) depending on the potential seriousness of a poisoning incident, callers should be referred rapidly to their human or animal health care providers, or if a provider is not available, to an entity qualified to provide emergency care information (such as a local poison control center or the Animal Poison Control Center); and 3) information on exposure and poisoning incidents must be collected and reported to the Agency in a uniform

manner so that statistics on poisonings are comparable between hotline service providers. When these criteria can be satisfied, the Agency feels no need to mandate that the registrant use a particular hotline service. Therefore, the Agency is allowing the registrants to use the hotline services they select, but they will be required to collect and report incident information and provide advice to callers reporting a poisoning incident using a protocol substantially similar to the one employed by NPIC and the certified poison control centers. Data collected and reported in this way should allow the Agency to compare incident types and numbers between registrants.

The required protocol for incident data collection and referral is detailed in an attachment to this amendment.

The Agency is requiring one statement that will cover both human and domestic animal incidents. The label table of the RED is amended so that the hotline statements for human and animal incidents are combined.

In addition, in researching how metaldehyde poisoning incidents should be handled, the Agency determined that many metaldehyde end-use product labels do not include a “Note to Physician” and a “Note to Veterinarian” to provide key advice to health and veterinary care professionals treating metaldehyde exposures. Among those product labels that do, the statements vary and some do not provide information that will aid professionals to the extent the Agency feels is needed. Therefore, the Agency is requiring specific language that can be used by physicians and veterinarians to respond quickly to patients in their care. The specific language is found in the label table attached to this amendment. To address a concern expressed by several experts in the field during development of this language, the statements will warn that individuals other than human and animal health professionals should refrain from utilizing this information, because only these professionals will be able to make judgments about specific therapies, and improperly applied treatments may worsen the condition of the exposed person or animal.

The notes to the veterinarian and doctor must appear directly below the first aid box on the product label. The first aid box will cover actions that non-professional responders may undertake after an accidental exposure, such as directions to remove the exposed individual from the treatment area, rinse eyes and skin, and contact a medical or veterinary health care provider as soon as possible.

4. Environmental hazard statements for end-use products

RED text (labels of products intended for agricultural use): “This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark except as noted on appropriate labels. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate. This pesticide is toxic to birds and mammals. Granules on soil surface may be hazardous to terrestrial wildlife. Cover or collect any such materials spilled during loading.”

RED text (labels of products intended for residential and similar uses): “This product is toxic to fish and aquatic invertebrates. Do not apply product near water or storm drains. Do not apply if heavy rain is expected. Apply this product only around gardens and ornamental plants.” For granular or pelletized product, add: “This pesticide is toxic to birds and mammals. Sweep up or collect and remove any product that lands on the driveway, sidewalk, or other hard surface on which it is spilled.”

Comments: Metaldehyde applied as a spot treatment is not likely to be present on impervious surfaces after residential applications, so the labeling, “[s]weep up or collect and remove any product that lands on the driveway, sidewalk, or other hard surface on which it is spilled” is not needed. Metaldehyde does not meet the LC₅₀ threshold for aquatic hazard statement.

Amendment: In the interest of reducing the volume of label text, the Agency will require abbreviated text for the hazard statement on pelletized, residential-use products, without the phrase relating to hard surfaces.

EPA believes the aquatic hazard statement is warranted, regardless of metaldehyde’s LC₅₀, since it is a molluscicide, for which toxicity to nontarget mollusks is likely. The Agency will amend the aquatic hazard statement for both the agricultural and residential use labels to reflect the concern for these types of organisms.

5. Application of residential use products resulting in piles of pellets

RED text: NA

Comment: Residential metaldehyde products applied in a manner that results in piles of granular materials on the treated surface present a hazard by concentrating material that might be ingested by pets.

Amendment: The labeling is amended to require that users avoid applying residential products in ways that result in piles of pellets.

6. Cultural practices statement for residential product labels

RED text: “Certain cultural practices may reduce damage from snails and slugs, and may make metaldehyde applications more effective. Examples of cultural methods to reduce snail and slug populations include:

- removing leaf litter and debris to eliminate places for slugs and snails to hide during the day;
- looking for and removing slugs and snails during daylight hours in leaf litter, mulch, or other protected areas adjacent to plants they feed on;
- watering in the morning rather than the evening to reduce humidity during the night when snails and slugs are active.”

Comments: Comments were received in support and in opposition of this language. Labels should refer users to garden experts for information on complementary cultural practices. Outreach materials could be developed to communicate additional cultural control information.

Amendment: The Agency continues to believe that information on relevant cultural practices can help consumers reduce damage by target pests while also reducing potentially hazardous exposures to metaldehyde. However, the Agency sees an opportunity to address the concern articulated in the public comments about the volume of text on the residential product labels, and is requiring an abbreviated cultural practices statement, one with specific, easy-to-implement practices. In addition, the Agency will discuss options in public outreach, including additional information on cultural practices, with the metaldehyde registrants.

7. Application methods and equipment

RED text: “Broadcast or foliar applications of this product are prohibited.”

Comment: Broadcast applications are needed for grass grown for seed.

Amendment: Broadcast applications were the basis for the Agency’s risk assessment for grass grown for seed, and are the norm for that crop. Labeling will be revised to allow broadcast applications for grass grown for seed.

RED text: NA

Comments: Allowable uses must be listed on all product labels. Allowable application methods and equipment and special application instructions should be listed on the product label.

Amendment: In addition to previous requirements for labeling that completely describes the maximum application rate, maximum number of applications per growing season, and minimum retreatment intervals for each use site, labels must also incorporate information on application methods, equipment, and any specialized application instructions.

8. Differentiation of formulation types

RED text: “Do not apply this product in a way that will contact other persons or pets either directly or through drift. Keep people and pets out of the area during application.”

Comment: The General Application Restrictions for residential use products contains a drift statement that is not applicable to granular formulations.

Amendment: The drift statement is amended to be more applicable to such formulations.

9. Grouping nonresidential sites with other nonagricultural, nonresidential sites

RED text: The following phrase appears in several places within the metaldehyde label table: "...residential sites (i.e., in yards or gardens, around homes, apartments, schools, daycare facilities, athletic fields, playgrounds, parks, recreation areas, etc.)..."

Comment: Residential use sites should not include athletic fields, playgrounds, parks, and recreation areas.

EPA response: The intent of this language is to impose the same requirements on residential uses and use on the listed sites, which are not truly examples of residential sites, but sites for which the Agency believes the potential for exposure (esp. to children, pets, and wildlife) is similar. The RED is amended so that these use sites are not named as types of residential use sites, but retains the same labeling requirements for both.

10. Setback for fruit and vegetable plants

RED text (residential product labels): "Application is permitted only as a barrier around gardens or individual plants. Application is prohibited within one foot of vegetable plants or fruit-bearing plants not listed on this label."

Comment: The setback statement for residential labels should be emphasized.

Amendment: Residential product labels are required to incorporate these two sentences in a way that will draw the attention of users to the change in use practices, i.e., in boldface type or another contrasting color that is readily distinguishable from the surrounding text.

11. Misleading statements on existing end-use product labels

RED text: NA

Comment: Phrases such as "ideal for vegetable gardens" and "can be used around fruit and vegetable plants, lawns and ornamental plants" on metaldehyde product labels may be construed to allow use on a broad range of use sites (including sites not appearing on the labels).

Amendment: Label submissions will be rejected if they are found to bear inappropriate or misleading statements.

12. Application parameters for blueberries

RED text: The RED requires that labels specify that the maximum application rate and number of application for blueberries must be no more than 0.8 lb ai/A per individual application and two applications/year. The minimum retreatment interval must be no less than 14 days.

Comment: The number of applications/year for blueberries should be increased to three.

Amendment: EPA has been advised by an expert in the field that three applications/season may be needed for blueberries in years of high rainfall and high pest pressure, which is significantly fewer than the assessed number of applications (five). Labeling will be amended to reflect a maximum of three applications per season on blueberries

13. Labeling for official use in eradicating invasive mollusks

RED text: NA

Comments: The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) uses metaldehyde as a cornerstone in its National program for controlling exotic, invasive snails and slugs that pose threats to plants and human health. This program includes treatments with metaldehyde on additional use sites not among those identified as eligible for reregistration by the RED, including fallow land, barrier strips; and railroad, pipeline, highway, power, and telephone rights of way.

Amendment: The mollusk eradication program is a high-benefit activity which addresses not just potential plant damage, but also threats to the public health, as some of the target species can transmit diseases to humans. The usage of metaldehyde in this program is relatively small. The Agency is requiring that any formulators who have previously included the additional use sites on their product labeling and wish to retain them for the use in the mollusk eradication program, or who later supplies product for use in the program, must include instructions within a special use box on the product label. Text within the special use box must include directions for use only in response to State and/or Federal invasive mollusk eradication operations.

14. Metaldehyde/carbaryl combination products

RED text: "...labels for metaldehyde-carbaryl combination products must bear language advising users that such products must not be applied unless both snails or slugs and target pests for carbaryl are present."

Comments: New labeling is not likely to prevent misuse of these products. To draw attention to the new restrictions, the combination products should be packaged differently, and prominent labeling should warn against using the product unless both types of pests are present.

Amendment: The Agency is amending the labeling requirements of the RED so that the requirement for using these products only when both types of pests are present is emphasized, both by placing the text on the front of the label and using boldface or other contrasting type to draw attention to subject language.

AMENDMENTS TO THE RED TEXT OTHER THAN LABELING REQUIREMENTS

15. Formulating metaldehyde end-use products with a blue dye

RED text: “Based on evidence that brightly colored granules may be less attractive to animals, formulators must incorporate a coloring agent into their granular formulations... The Agency is specifically seeking public input on this issue in the comment period after the RED becomes available.”

Comments: Bright non-natural colors could be effective in discouraging ingestion of granules by birds, especially if coupled with a taste-conditioned aversion. Colored pellets would make it easier for users to determine when applied material is no longer visible so that children and pets can regain access to yards. Blue-dyed pellets might appeal to children who would mistake them for candy. Conflicting comments were submitted on whether or not the dye would affect the appearance of produce and ornamentals.

Amendment: The Agency is withdrawing its requirement for colored pellets, primarily because of the possible risks to children and a body of literature which is not conclusive about the aversion of birds to colored pellets.

16. Relative costs of using metaldehyde and iron phosphate products

RED text: “Growers may be reluctant to use iron phosphate because they consider it to be new and untested, and because it is more expensive (\$1.55/lb vs. \$1.25 for metaldehyde).”

Comment: The discussion of relative treatment costs does not account for the higher application rate of iron phosphate.

Amendment: The Agency has more thoroughly explored the issue of the relative costs of metaldehyde and iron phosphate based on maximum and typical application rates. The Agency agrees that there are cost differentials for agricultural uses and higher cost differentials for residential uses. The RED is amended to include the following text:

“The labeled application rate for metaldehyde for most crops is 10 to 40 lb/acre (with the exception of artichokes where application rate is 20 to 75 lb/acre). Similarly, the label application rate for iron phosphate is 10 to 44 lb/acre. According to Washington State Pest Management Resource Service, iron phosphate costs \$0.36 more per pound than metaldehyde. At the maximum labeled rates noted above (excluding the rate for artichokes), this amounts to a difference of about \$21 per acre. Data from the California Department of Pesticide Regulation Data for 2005 (http://www.cdpr.ca.gov/docs/pur/pur05rep/05_pur.htm) indicate that actual application rates do not approach the label maximum and that application rates for metaldehyde and iron phosphate are generally comparable.

“Labeling directions for residential use products suggest that iron phosphate be applied at two and a half to four times the rate of metaldehyde. Prices for residential use products vary, with iron phosphate typically being slightly more expensive than metaldehyde. Applying metaldehyde at the rates shown in the directions for use on residential product labels would make the use of iron phosphate approximately two to five times more costly than the use of metaldehyde.”

17. Animal exposures via routes other than ingestion

RED text: “Labels for residential-use products must prominently display language advising users that...metaldehyde ingestion or other exposures to metaldehyde can be lethal to domestic animals.” (Even though this text includes requirements for label language, the metaldehyde label table did not reflect such a requirement.)

Comment: Exposure of domestic animals to metaldehyde by routes other than ingestion is not known to be lethal.

Amendment: Although domestic animals may be exposed to metaldehyde through other routes (e.g., dermal), there are no data to support the statement in the RED. The RED is amended to exclude this statement.

CONTACT INFORMATION

If you have questions on the metaldehyde RED, the amendments listed in this document, or questions about the Generic DCI, please contact the Chemical Review Manager, Jill Bloom, at (703) 308-8019, or via email at bloom.jill@epa.gov.

Sincerely,

Peter Caulkins
Acting Director
Special Review and Reregistration Division

Attachment: Revised Metaldehyde Label Table
Protocol for Incident Data Collection

Labeling Changes for Products Containing Metaldehyde

Description	Amended Labeling Language	Placement on Label
Manufacturing-Use Products		
For all Manufacturing- Use Products	<p>“This product may be formulated into a molluscicide for the following use(s) only: artichokes, blueberries, caneberries (bingleberry, black raspberry, blackberry, boysenberry, dewberry, lowberry, marionberry, olallieberry, red raspberry, youngberry) and other berries (currant, elderberry, gooseberry, huckleberry, loganberry, lingonberry, juneberry, salal), citrus, lettuce, cole crops and other leafy greens (broccoli, Brussels sprouts, cabbage, cauliflower, cavalo, broccolo, collards, kale, kohlrabi, mizuna, mustard greens, spinach, rape greens), grass grown for seed, ornamentals, tomato, and strawberry (grown as perennials only), except those use sites with directions for use in State and/or Federal invasive mollusk eradication operations.”</p> <p>“This product may not be formulated into end-use products for use on turf (except grass grown for seed and those use sites with directions for use in State and/or Federal invasive mollusk eradication operations), dichondra lawns, or strawberries grown as annuals.”</p> <p>“This product may not be formulated into end-use granular or pelletized products unless formulated to contain more than 35 pellets per gram.”</p> <p>“This product may not be formulated into end-use granular or pelletized products with directions for use at residential sites (i.e., in yards, gardens, around homes and apartments) and other sites such as the exterior areas around schools and daycare facilities, and athletic fields, playgrounds, parks, recreation areas, etc., unless such products contain the current bittering agent at 300 ppm or another bittering agent approved by the Agency. The bittering agent must be of sufficient concentration to deter ingestion by children and domestic</p>	Directions for Use

Description	Amended Labeling Language	Placement on Label
	<p>animals.”</p> <p>“This product may not be formulated into end-use products with directions for use at residential sites (i.e., in yards, gardens, around homes and apartments) and other sites such as the exterior areas around schools and daycare facilities, and athletic fields, playgrounds, parks, recreation areas, etc., unless the labels of such products contain a graphic that depicts the prohibition on allowing children and domestic animals access to treated areas and specific warnings designed to reduce the numbers of incidents involving children and domestic animals.”</p>	
<p>One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group</p>	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	<p>Directions for Use</p>
<p>Environmental Hazards Statements Required by the RED and Agency Label Policies</p>	<p>"This pesticide is toxic to birds and mammals. This pesticide is toxic to mollusks (e.g., clams, oysters, scallops, mussels). Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."</p>	<p>Precautionary Statements</p>
<p>End Use Products Intended for Agricultural Use or Use under State and/or Federal Invasive Mollusk Eradication Operations</p>		
<p>For any products that will</p>	<p>“This product may be used only on the following use sites in response to State</p>	<p>Text must be placed</p>

Description	Amended Labeling Language	Placement on Label
<p>potentially be used in State and/or Federal Invasive Mollusk Eradication operations</p> <p>NOTE: In addition to providing application rates in terms of pounds of active ingredient, labels also must provide application rate information in pounds of formulated product.</p>	<p>and/or Federal invasive mollusk eradication operations.</p> <p>“Broadcast applications of this product may be made to the following use-sites for State and/or Federal invasive mollusk eradication operations: fallow land; barrier strips; uncultivated non-agricultural areas; recreational areas; non-food or non-feed brush; weed or dense vegetative areas; railroad, pipeline, highway, power and telephone rights of way and roadsides; guardrails and fences; lumberyards; storage areas; seaports; industrial facility sites, including yards and walkways around industrial buildings, parking areas, parks, golf courses, other public areas; and airport and similar industrial non-crop areas.”</p> <p>“This product may be applied for State and/or Federal invasive mollusk eradication operations at an individual application rate of no more than 2 lb ai/A, and at no more than six applications/year. “</p>	<p>within a Special Use Box in the Directions for Use section of the label</p>
<p>Domestic Animal Precautionary Statements</p>	<p>“IMPORTANT: This product can be harmful to children and fatal to domestic animals when ingested. Children and dogs may be attracted to the product. Application of this product is prohibited unless children and domestic animals can be excluded from the treated area from the start of the application until applied material is no longer visible.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED¹</p>	<p>“Mixers, loaders, applicators, and other handlers must wear: long-sleeved shirts and long pants, and shoes plus socks.”</p>	<p>Immediately following/ below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

¹ PPE 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.

Description	Amended Labeling Language	Placement on Label
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>
User Safety Recommendations	<p>“User Safety Recommendations”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>“Users should remove PPE immediately after handling this product.</p> <p>“Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazard Statements	<p>“This pesticide is toxic to mollusks (e.g., clams, oysters, scallops, mussels). Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate.</p> <p>“This pesticide is toxic to birds and mammals. Granules on soil surface may be</p>	<p>Precautionary Statements immediately following the User Safety Recommendations</p>

Description	Amended Labeling Language	Placement on Label
	hazardous to terrestrial wildlife. Cover or collect any such materials spilled during loading.”	
Poisoning Hotline	<p>“Seek medical care as soon as possible after exposure. For incidents involving animals, seek veterinary care as soon as possible after exposure. Have the product container or label with you when you call a poison control center or doctor or veterinarian, or when going for treatment. For information on this pesticide product (including health concerns, medical emergencies, treatment advice, or pesticide incidents), call <i>[enter contact name as instructed below]</i> at 1-<i>[enter toll-free number as instructed below]</i>.”</p> <p><i>Instruction to the registrant:</i> The registrant must enter the contact information, including a toll-free telephone number, for the entity that 1) will provide information to callers, and as needed, refer callers for treatment advice (including instruction to see a medical or veterinary professional as soon as possible), and 2) collect incident information for reporting to EPA for both animal and human incidents. Requirements for call centers identified on the metaldehyde labels are detailed in an attachment to this amendment to the metaldehyde RED.</p>	Precautionary Statements, under “First Aid” : Poisoning Hotline
Note to Physician; Note to Veterinarian	<p>“Metaldehyde is a systemic toxin. There is no antidote. The following instructions are not intended for laypeople. There is no home treatment. Exposed individuals and animals should receive emergency care as quickly as possible.</p> <p>“NOTE TO PHYSICIAN: Dust inhalation is usual route of accidental exposure; the product is rarely ingested. Treatment is symptomatic and supportive. Monitor severe exposures closely: seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature have been reported.</p> <p>“NOTE TO VETERINARIAN: Animals typically are exposed via ingestion. Treatment is symptomatic and supportive. If significant ingestion suspected, and</p>	Precautionary Statements, under “First Aid” : Poisoning Hotline

Description	Amended Labeling Language	Placement on Label
	<p>the animal is asymptomatic, consider induction of emesis or gastric lavage and administration of activated charcoal, cathartic and enema to limit absorption. Monitor asymptomatic and symptomatic animals closely. Treat seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature. Monitor liver function post recovery.”</p> <p>Note to the registrant: The text appearing in boldface type above must appear on the product label in boldface or other contrasting type that is readily distinguishable from the surrounding text.</p>	
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated.”	Directions for Use, under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material” 	Directions for Use, under Agricultural Use Requirements Box
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Directions for Use, immediately above the Agricultural Use Requirements Box
Other Application Restrictions	“This product is intended solely for use on agricultural crops grown for commercial or research purposes, and in State and/or Federal invasive mollusk	Directions for Use

Description	Amended Labeling Language	Placement on Label
	<p>eradication operations. This product may not be applied to residential sites (i.e., in yards, gardens, around homes and apartments) and other sites such as the exterior areas around schools and daycare facilities, and athletic fields, playgrounds, parks, recreation areas, etc.”</p> <p>“Broadcast applications and applications of this product directed to plant parts are prohibited except to grass grown for seed and as specified for use in State and/or Federal invasive mollusk eradication operations.”</p>	
<p>Crop Specific Directions for Use</p> <p>NOTE: Maximum application rates must be expressed in pounds of formulation per acre in addition to pounds active ingredient per acre</p>	<p>End-use product labels must be amended to contain directions for use only on the following crop- and use-sites and only with the maximum application rate, maximum number of applications per growing season, and minimum retreatment intervals as listed below. All other crop- and use-sites must be removed from end-use product labels.</p> <p>Artichokes:</p> <ul style="list-style-type: none"> - When grown as a perennial, the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 18 days. - When grown as an annual, the maximum application rate is 1.0 lb ai/A per application. A maximum of 2 applications are permitted per growing season at a minimum of retreatment interval of 18 days. <p>Blueberries: the maximum application rate is 0.8 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Caneberries (bingeberry, black raspberry, blackberry, boysenberry, dewberry, lowberry, marionberry, olallieberry, red raspberry, youngberry) and Other Berries (currant, elderberry, gooseberry, huckleberry, loganberry, lingonberry,</p>	<p>Directions for Use, associated with the specific crop- or use-site</p>

Description	Amended Labeling Language	Placement on Label
	<p>juneberry, salal): the maximum application rate is 0.8 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Citrus: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Lettuce, Cole Crops, And Other Leafy Greens: (broccoli, Brussels sprouts, cabbage, cauliflower, cavalo, broccolo, collards, kale, kohlrabi, mizuna, mustard greens, spinach, rape greens): the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Grass grown for seed: the maximum application rate is 0.8 lb ai/A per application. A maximum of 4 applications are permitted per growing season at a minimum of retreatment interval of 21 days. Applications to turfgrass (other than grass grown for seed or in State and/or Federal invasive mollusk eradication operations) are prohibited.</p> <p>Ornamentals: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 21 days.</p> <p>Tomatoes: the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Strawberries (grown as perennials only): the maximum application rate is 1.0 lb</p>	

Description	Amended Labeling Language	Placement on Label
	<p>ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Applications to strawberries grown as annuals are prohibited.</p> <p><i>Note to the registrant:</i> Application methods and/or types of application equipment must be specified for each use site on the label, along with any specialized application instructions for any of the uses.</p>	
Storage Restrictions	<p>“This product can be harmful to children and fatal to dogs and other domestic animals if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets.”</p>	Storage and Disposal
<p>Products Intended for Use at Residential Sites and Other Sites such as exterior areas around schools and daycare facilities, athletic fields, playgrounds, parks, recreation areas</p>		
Precautionary Statement and Graphic Depiction for Products Intended for Use at Residential Sites	<p>The label of any end-use product with directions for use residential sites (i.e., in yards, gardens, around homes and apartments) and other sites such as the exterior areas around schools and daycare facilities, and athletic fields, playgrounds, parks, recreation areas, etc. must contain a graphic that depicts the prohibition on allowing children and domestic animals access to treated areas. The required graphic is in the form of a red circle with the words “Children” and “Pets” within the circle and with a red bar running diagonally through it from upper left to lower right.</p> <p>The following specific warning statements must be added to the label in close association to the above graphic:</p> <p>“Keep out of reach of children and domestic animals. This pesticide may be harmful to children and fatal to domestic animals if ingested. Exclude children and pets from treated areas until the applied product is no longer visible. For additional precautionary measures, see “Directions for Use” and “Storage and</p>	Front panel

Description	Amended Labeling Language	Placement on Label
	Disposal.””	
Precautionary Language	“IMPORTANT: This product may be harmful to children and fatal to domestic animals if ingested. Children and dogs may be attracted to metaldehyde products and their packaging. Keep children and pets out of treated areas from the start of application until the applied product is no longer visible.”	Precautionary Statements: Hazards to Humans and Domestic Animals
Poisoning Hotline	<p>“Seek medical care as soon as possible after exposure. For incidents involving animals, seek veterinary care as soon as possible after exposure. Have the product container or label with you when you call a poison control center or doctor or veterinarian, or when going for treatment. For information on this pesticide product (including health concerns, medical emergencies, treatment advice, or pesticide incidents), call [enter contact name as instructed below] at 1-[enter toll-free number as instructed below].”</p> <p>Instruction to the registrant: The registrant must enter the contact information, including a toll-free telephone number, for the entity that 1) will provide information to callers, and as needed, refer callers for treatment advice (including instruction to see a medical or veterinary professional as soon as possible), and 2) collect incident information for reporting to EPA for both animal and human incidents. Requirements for call centers identified on the metaldehyde labels are detailed in an attachment to this amendment to the metaldehyde RED.</p>	Precautionary Statements, under “First Aid” : Poisoning Hotline
Note to Physician; Note to Veterinarian	<p>“Metaldehyde is a systemic toxin. There is no antidote. The following instructions are not intended for laypeople. There is no home treatment. Exposed individuals and animals should receive emergency care as quickly as possible.</p> <p>“NOTE TO PHYSICIAN: Dust inhalation is usual route of accidental exposure; the product is rarely ingested. Treatment is symptomatic and</p>	Precautionary Statements, under “First Aid” : Poisoning Hotline

Description	Amended Labeling Language	Placement on Label
	<p>supportive. Monitor severe exposures closely: seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature have been reported.</p> <p>“NOTE TO VETERINARIAN: Animals typically are exposed via ingestion. Treatment is symptomatic and supportive. If significant ingestion suspected, and the animal is asymptomatic, consider induction of emesis or gastric lavage and administration of activated charcoal, cathartic and enema to limit absorption. Monitor asymptomatic and symptomatic animals closely. Treat seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature. Monitor liver function post recovery.”</p> <p><i>Note to the registrant:</i> The text appearing in boldface type above must appear on the product label in boldface or other contrasting type that is readily distinguishable from the surrounding text.</p>	
Environmental Hazard Statement for Residential Use Products	<p>“This product is toxic to mollusks (e.g., clams, oysters, scallops, mussels). Do not apply product near water (including garden ponds) or storm drains. Do not apply if heavy rain is expected. Apply this product only around gardens and ornamental plants.”</p> <p>For granular or pelletized product, add:</p> <p>“This pesticide is toxic to birds and mammals. Collect and remove any product that is spilled.”</p>	Precautionary Statements
General Application Restrictions	“Keep people and pets out of the area during application.”	Directions for Use under General Precautions and Restrictions
Other Application	“This pesticide may be harmful to children and fatal to dogs and other domestic	Directions for Use

Description	Amended Labeling Language	Placement on Label
Restrictions	<p>animals if ingested. Children and dogs may be attracted to metaldehyde products, both in the package and when applied. Children and domestic animals must be kept out of treated areas from the start of application until the applied product is no longer visible.”</p> <p>“Application of this metaldehyde product is prohibited unless children and domestic animals can be excluded from the treated areas from the start of application until the applied product is no longer visible.”</p> <p>“Applications to turf and dichondra are prohibited. Application is permitted only to non-turf areas (i.e., on soil or mulch) directly surrounding plants listed for use on the label.”</p> <p>“Broadcast and foliar applications of this product are prohibited. Application is permitted only as a barrier around gardens or individual plants. Application is prohibited within one foot of vegetable plants or fruit-bearing plants not listed on this label.”</p> <p>“Avoid applying pellets in piles that may attract pets.”</p> <p>“Certain cultural practices may reduce damage from snails and slugs. These practices include: -- eliminating hiding places by removing leaf litter and debris in the garden; -- removing slugs and snails during daylight hours from nearby leaf litter, mulch, and other protected areas; -- watering in the morning to reduce humidity during the night when snails and slugs are active.”</p> <p>The labels of end-use products containing both metaldehyde and carbaryl must</p>	under General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
	<p>bear this statement on the front of the container: “Do not use this product unless both insect pests and slugs or snails are present. Pests targeted by this product are listed under ‘Directions for Use.’”</p> <p><i>Note to the registrant:</i> The text appearing in boldface type above must appear on the product label in boldface or other contrasting type that is readily distinguishable from the surrounding text.</p>	
<p>Crop- and Use-Site Specific Directions for Use</p> <p>NOTE: Application rates must be provided in user-friendly terms, for example, “Apply pellets as a barrier around plants by distributing pellets evenly in a line at a rate of X tablespoons of product per X linear foot.”</p>	<p>End-use product labels must be amended to allow use only on the crop- and use-sites identified below. Use instructions must be consistent with the maximum application rate, maximum number of applications per growing season, and minimum retreatment intervals listed below. All other crop- and use-sites must be removed from end-use product labels.</p> <p>Artichokes:</p> <ul style="list-style-type: none"> - When grown as a perennial, the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 18 days. - When grown as an annual, the maximum application rate is 1.0 lb ai/A per application. A maximum of 2 applications are permitted per growing season at a minimum of retreatment interval of 18 days. <p>Blueberries: the maximum application rate is 0.8 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Caneberries (bingleberry, black raspberry, blackberry, boysenberry, dewberry, lowberry, marionberry, olallieberry, red raspberry, youngberry) and Other Berries (currant, elderberry, gooseberry, huckleberry, loganberry, lingonberry, juneberry, salal): the maximum application rate is 0.8 lb ai/A per application.</p>	<p>Directions for Use associated with the specific crop- or use-site</p>

Description	Amended Labeling Language	Placement on Label
	<p>A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Citrus: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Lettuce, Cole Crops, And Other Leafy Greens (broccoli, Brussels sprouts, cabbage, cauliflower, cavalo, broccolo, collards, kale, kohlrabi, mizuna, mustard greens, spinach, rape greens): the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Ornamentals: the maximum application rate is 1.0 lb ai/A per application. A maximum of 6 applications are permitted per growing season at a minimum of retreatment interval of 21 days.</p> <p>Tomatoes: the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days.</p> <p>Strawberries (grown as perennials only) the maximum application rate is 1.0 lb ai/A per application. A maximum of 3 applications are permitted per growing season at a minimum of retreatment interval of 14 days. Applications to strawberries grown as annuals are prohibited.</p> <p>Note to the registrant: Application methods and/or types of application equipment must be specified for each use site on the label, along with any specialized application instructions for any of the uses.</p>	

Description	Amended Labeling Language	Placement on Label
Storage Restrictions	“This product can be harmful to children and fatal to domestic animals if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets.”	Storage and Disposal

**ATTACHMENT TO THE AMENDMENT TO THE METALDEHYDE RED
REQUIREMENTS FOR CALL CENTERS IDENTIFIED ON METALDEHYDE PRODUCT LABELS**

The Agency's has several objectives for the metaldehyde poisoning hotlines:

1. To provide callers with prompt, helpful, and appropriate information for responding to human or domestic animal poisoning incidents in order to minimize the adverse effects of exposure. These calls may come from the general public or from health or veterinary care providers.

Callers from the general public will be advised to contact and go to a doctor, emergency room, veterinarian, or veterinary emergency room, as appropriate. If a health or veterinary care provider is not available or if the caller indicates that he or she will not take the affected individual or animal to a provider, the caller should be referred to an entity qualified to provide emergency care information (such as a local poison control center or the Animal Poison Control Center), as needed.

2. To collect information on these poisoning incidents, in a manner consistent with the process outlined in this attachment, so that statistics on incidents are comparable and can be compiled with those reported by other metaldehyde poisoning hotline services.

3. To respond to callers who are not reporting a pesticide poisoning emergency with the information they seek or to refer them to entities that can do so. Examples of inquiries that might be expected include requests for interpreting label directions, for information on how long after a metaldehyde is applied pets can be allowed to return to the treated area, and for information on how to remediate treated areas so that the hazard to potentially exposed animals is minimized. NPIC is one source for such information.

Process for Handling Hotline Calls

In order to address these objectives, the Agency is requiring that the poisoning reports required to be submitted by the registrant come from call centers using a protocol substantially similar to the one used by NPIC and the certified poison control centers. The required elements of this protocol are listed below. They cover both the disposition of the call by the call center and data collection from the caller.

Disposition

1. Each call must be assigned a unique identifier (ex., log or case number). The date and time of call must be recorded.
2. If the call is about an exposure to a person or domestic animal via ingestion, the call center must advise the caller that such exposures can be quite serious, and strongly encourage the caller to take the exposed individual or animal to a hospital emergency room or medical or veterinary care clinic as soon as possible.

3. If the call center believes that such a caller does not have access to a hospital emergency room or medical or veterinary care clinic, or believes that the caller should utilize such a service but will not do so, the caller should be transferred or referred to the Animal Poison Control Center or a certified Poison Control Center as he or she allows.

4. As part of the record of the call, the call center must include information on how the call was handled (answered questions directly, advised medical care, referred elsewhere, etc.).

Data collection

The technician or operator from the hotline service must attempt to get information from the caller and record responses for the following prompts and questions:

(Note: People calling about situations they consider to be emergencies may not wish to stay on the phone for very long. Assume the caller is willing to give no more than 3-5 minutes for answering these questions.)

1. Product of concern (Registration Number and/or Product Name, if possible)
2. Is the caller a member of the general public, a veterinary care provider, or other?
3. Formulation of metaldehyde product of concern (ex., liquid, granular, dust)
4. Where did the application or exposure take place (State, county, city)?
5. In what area did the application or exposure occur (ex., yard, park, storage shed)?
6. Type of Question (ex., seeking treatment advice, remediation of treated area)

If the call relates to a possible exposure, the caller should be asked:

7. What are the exposed individual's age, weight, and gender? *OR*
What are the exposed animal's species and breed, age, weight, and gender?
8. What was the likely route of exposure (ex., oral, inhalation, dermal, ocular)?
9. What symptoms have been observed?
10. When did the exposure occur?
11. How long did animal have access to the treated area or material in question? *OR*
How much was person exposed to?
12. How long after the exposure did symptoms develop (if known)?

13. How was the pesticide of concern applied? How much was applied? OR How was the individual or animal otherwise exposed (ex., torn bag)?
14. If an animal was exposed via an open or torn bag, where was that bag located at the time of the exposure (ex., garage floor, unlocked shed, high or low shelf)?

Any additional narrative explanation of the incident provided by caller should be recorded as it may be informative.