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The Ins and Outs of the Pesticide Registration Process and Why It's Important to the End-User

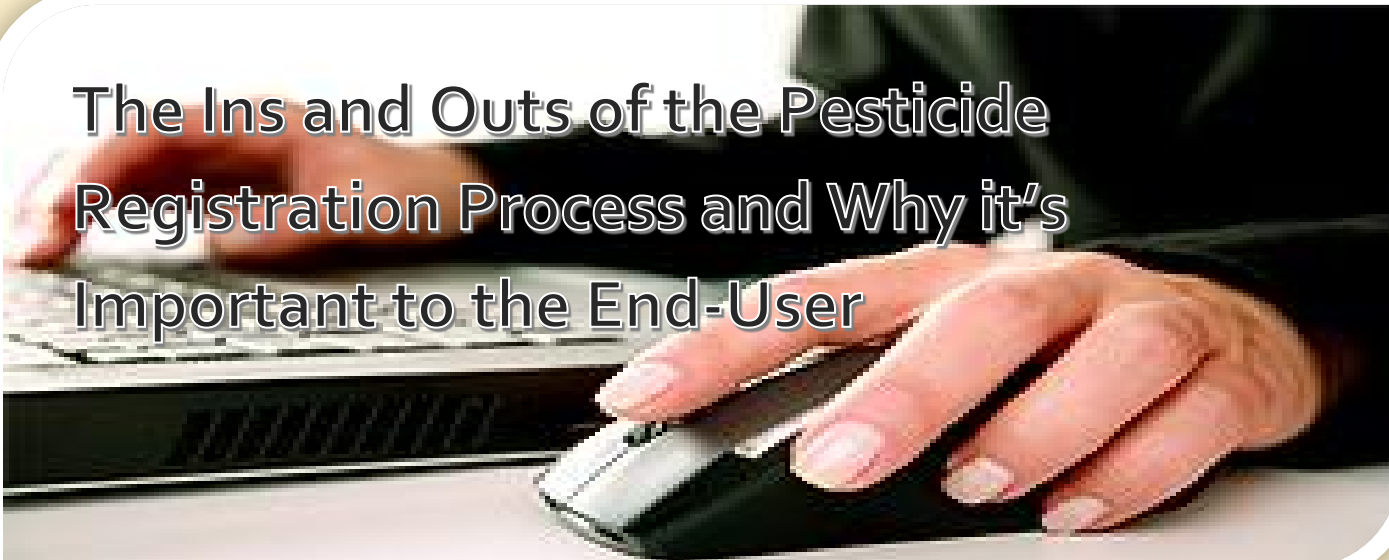
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The Ins and Outs of the Pesticide Registration Process and Why it's Important to the End-User

SECTION 3, SECTION 5, SECTION 24C (SLN), SECTION 18, SECTION 25B, 2(EE)...WHAT'S THE DIFFERENCE?

Types of Pesticide Registrations

The four major categories that are important for registration by **Type of Pesticide:**

- ✚ Conventional pesticides that include all ingredients
- ✚ Antimicrobial pesticides are mixtures of substances used to suppress or destroy growth of harmful microorganisms (fungi, viruses, bacteria, etc.)
- ✚ Biopesticides are derived from natural materials
- ✚ Inert ingredients are substances in a pesticide along with the active ingredient(s)

SECTION 3

Section 3 Pesticides are for use throughout the United States with some pesticides for more limited use in certain states. States, tribes and territories can place further restrictions on pesticides used or sold within their own jurisdictions.

SECTION 5

Section 5 Experimental Use Permits (EUP) allows manufacturers to test pesticides under development in field environments of 10 acres or more of land, or one acre or more of water.

SECTION 18

Section 18 Emergency Exemptions allows state and federal agencies to permit an unregistered use of a pesticide for a specific purpose in a specific geographic area within a limited time frame when emergency conditions exist.

SECTION 24(C)

Section 24(c) State-Specific allows states to register a federally registered product for an additional use, or a new pesticide product for any use in a “special local need” situation as long as the tolerances have been demonstrated. EPA can disapprove 24 (c) registrations.

SECTION 25(B)

Section 25(b) pesticides are considered minimum risk pesticides and are exempt from federal registration; however, state registration can be required where 25(b) products cannot be sold in the state prior to being registered.

2EE RECOMMENDATIONS

Section 2(ee) recommendations allow pesticide users to apply pesticides under limited conditions not specified on the product label. While the recommendations do not require additional state registrations, they are considered part of the label and must be consistent with FIFRA Section 3 labeling requirements.



The United States


Environmental Protection Agency (US EPA)

Registration Process

The US EPA registration process evaluates pesticides through legal, administrative and scientific procedures that encompass the pesticide ingredients (inert and active); the crop or site pertaining to where the pesticide will be used; the amount, timing and frequency of the pesticide to be used; the disposal and storage practices for the pesticide; and the potential human health and environmental effects that could be associated with the pesticide.

The US EPA evaluates and approves all label language that appears on a pesticide label, thus ensuring proper use patterns and that safety measures have been met to reduce any potential risks. All pesticide product labels are reviewed and approved before being distributed or sold in the U.S. with the intent that the label will provide clear and concise directions for use with effective

performance that minimizes any risks to the environment and human health. Companies and/or registrants wishing to register a new pesticide active ingredient, a new product for an existing pesticide, or need to add a new use to an existing label must submit an application for registration to the US EPA with at least the following information.



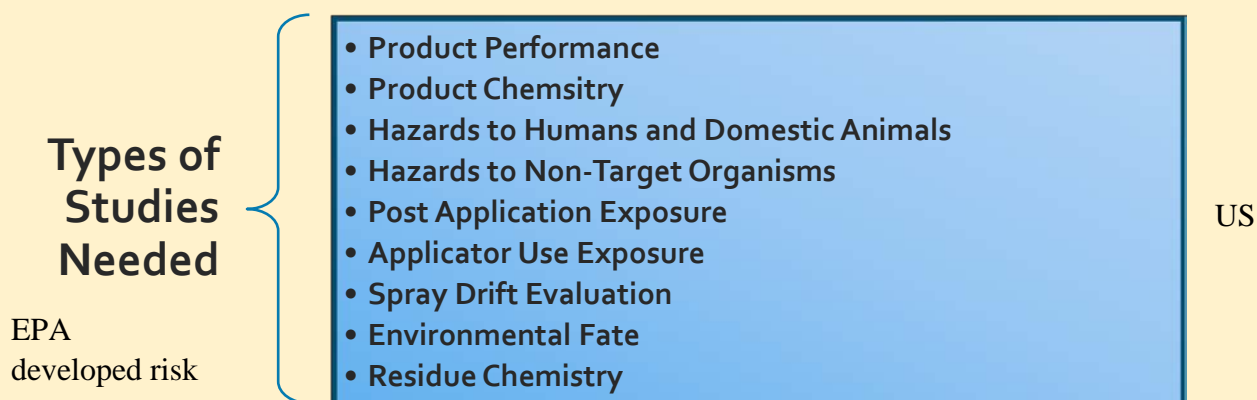
Product Label with	<ul style="list-style-type: none"> • signal word(s) • contents • directions for use
Identity and Quantity	<ul style="list-style-type: none"> • chemicals in product
Technical and Scientific Data on Risks to	<ul style="list-style-type: none"> • environment • human health • residues on food

Registrants and/or Manufacturers must submit review information to US EPA concerning health effects of pesticides that include information pertaining to:

- ✚ Cancer,
- ✚ Reproductive effects,
- ✚ Neurological effects, and
- ✚ Acute and chronic toxic effects.

The Evaluation Process and Overview of Risk Assessments

US EPA evaluates pesticides thoroughly to ensure that safety standards to protect the environment and human health have been met before allowing a pesticide to be sold in the U.S. Registration of a product is approved after all scientific and regulatory data requirements have been met addressing potential adverse effects and environmental fate of a pesticide that involve humans, wildlife, plants, surface water and ground water. EPA prefers that all data from tests conducted following their specific guidelines.



assessments to evaluate any potential harm to humans, fish, wildlife, plants, endangered species, non-target organisms and contamination to surface and ground water from spray drift, runoff or leaching. The human risk factors range for short-term to long-term effects that can include cancer and disorders to the reproductive system. The data reviewed pertains to:

- ✚ Aggregate Risks: through water, food, and residential uses
- ✚ Cumulative Risks: from different pesticides with the same effects
- ✚ Occupational Risks: to those applying the product while working
- ✚ Potential to ground water contamination
- ✚ Risks to endanger and threatened species
- ✚ Potential for endocrine-disruption effects

A ecological risk assessment determines if the use of a pesticide can pose any risks to the environment by evaluating the possibility of exposure through direct (e.g. fish die from pesticide exposure in waterways) or indirect (e.g. bird becomes sick after eating prey contaminated with pesticides) means. The risk management decision determines if additional protective measures are necessary to limit exposure to a pesticide by:

- ✚ Limiting the amount of pesticide applied to food crops that result in unacceptable risks to consumers
- ✚ Limiting the use in specific geographical areas to protect groundwater and other drinking sources
- ✚ Requiring workers to wear more personal protective equipment (PPE)
- ✚ Prohibiting workers from entering treated crop sites until specific timer periods have passed.

Ecological Risk Assessment

- ✚ How a pesticide affects Wildlife and Aquatic organisms.
 - ✚ How a pesticide affects various Plant Species.
 - ✚ How a pesticide affects soil, water, and air after being released into the environmental.
 - ✚ How a pesticide affects non-target species other than the one the pesticide is intended to kill.
 - ✚ How much of the pesticide residue remains in the environment over time.
 - ✚ How much of a pesticide drifts off-site when applied.
-
-

The RISK to human health from pesticide exposure depends on the TOXICITY of the pesticide and the probability of a human being EXPOSED to the pesticide.

$$\text{RISK} = \text{TOXICITY} \times \text{EXPOSURE}$$

At least some level of TOXICITY and EXPOSURE must occur to result in a RISK. For example,

- ✚ Exposure to a non-toxic pesticide poses no risk, or
- ✚ Alternately, if a pesticide is very toxic but no exposure occurred, there is no risk.

Human Health Risk Assessment

- ✚ What type of health problems are caused by pesticide?
 - ✚ Is there a low level established that the pesticide won't pose human health risks?
 - ✚ What are the legal limits for pesticide residues in food?
 - ✚ Are humans more likely to be susceptible because of age, genetics, pre-existing health conditions, gender, etc.?
 - ✚ What is the chance that humans will experience problems when exposed to different levels of pesticides?
 - ✚ Are there probabilities of adverse health effects in humans?
-

Re-evaluation of Registered Pesticides

The US EPA will review each registered pesticide at least every 15 years to determine whether it continues to meet the standards for registration that ensures no unreasonable risks to human health and the environment has evolved while policies and practices may have changed through this time period. If new concerns arise, EPA can choose to change the conditions for use or choose to cancel the registration.



Montana Department of Agriculture (MDA)

State Registration Process

The Montana Pesticide Act requires that any pesticide sold, distributed, offered for sale, purchased, given away, used or applied in the state must be registered by the Montana Department of Agriculture. This includes the following types of registrations:

SECTION 3

The majority of pesticides registered in the United States fall under FIFRA Section 3. Each pesticide registration is for a specific, labeled use of a particular formulation which is supported by research data. Before receiving EPA registration, pesticides are required to go through an extensive environmental, health and safety evaluation by the EPA. Once a pesticide has received EPA approval and registration, it can be registered in the state.

SECTION 25(B)

Section 25(b) pesticides are considered minimum risk pesticides and are exempt from federal registration; however, they still require state registration in Montana. 25(b) products may not be sold in the state prior to being registered, refer to the Montana Requirements for 25(b) Product Registrations for more details. The Montana Department of Agriculture requires the following in order to register and market 25(b) pesticide products in Montana:

- ✚ A label for each product registered, preferably in PDF format on a compact disc.
- ✚ Listing of the company name and contact information on the printed label. Product labels must not contain any EPA registration or establishment numbers.
- ✚ The active ingredients in the product must be listed in the Code of Federal Regulations, 40 CFR 152.25, and must be exempt from federal registration. Inert or other ingredients must be listed on the most current EPA Inert 4A List contained in Pesticide Registration (PR) Notice 2000-6 or in compliance with 40 CFR 180.950.
- ✚ Under the heading of “Active Ingredients,” the product label must contain the name and percentage (by weight) of each active ingredient. Under the heading “Inert Ingredients,”

the label must list all inert ingredients by name. The combined percentages of active and inert ingredients must equal 100 percent.

- ✚ A statement that the product is EPA exempt must appear on the label. Examples of label wording are as follows:

- ✚ “This product is exempt from registration with the federal Environmental Protection Agency under FIFRA Section 25(b) regulations.”

- ✚ “This product has not been registered by the U.S. Environmental Protection Agency. (The name of the company) represents that this product qualifies for exemption from registration under FIFRA.” Or

- ✚ An acceptable equivalent statement for review and acceptance by Montana Department of Agriculture.

- ✚ A Confidential Statement of Formula (CSF) may be required if the department determines that additional information is necessary to complete the registration request. If additional information is needed, a CFS form will be sent by regular mail or by email to the registrant for completion.

- ✚ Product labels must not include any false or misleading statements, including those listed on 40 CFR 156.10(a)(5)(i) through (viii).

- ✚ Labels and other product information must not claim to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease-transmitting bacteria or viruses. Claims to control insects or rodents that carry specific diseases, such as Lyme disease, also are prohibited.

SECTION 24(C)

24(c) registrations are for state specific pesticide uses that do not have a Section 3 registration. These registrations require a more extensive review process than Section 3 and 25(b) registrations as they include product uses that have not been reviewed and approved by the EPA. The Montana Pesticides Act requires that all 24(c) application be reviewed by three agencies- the Department of Agriculture, the Department of Public Health and Human Services, and the Department of Fish, Wildlife and Parks. Additionally, the department requests that the U.S. Fish and Wildlife Service and representatives from our seven Native American Reservations review the applications.

When a complete application package is received, we will document that a special local need exists and submit copies of the package to the review partners. We will notify you of our decision after the review is completed. After the application package is complete, it generally takes about a month for a full review. Additional information may be requested of the applicant by the reviewers before a final decision is made. The following information is typically needed to evaluate proposed special local need, 24(c) registration requests:

- ✚ A completed EPA Application/ Notification form (EPA Form 8570-25).
- ✚ A copy of the proposed supplemental labeling. For new products, a copy of the complete proposed labeling.
- ✚ A copy of the current EPA-approved FIFRA Section 3 labeling.

- ✚ Describe the special local need – the existing or imminent pest problem within Montana for which there is no appropriate federally registered pesticide product available. Include requests for the product from user groups that documents the need for the pesticide to use the product if the registration is approved.
- ✚ Technical data sheets, an MSDS, or other information to assess potential health hazards, including recognized chronic effects. Additional safety data may be needed to determine whether the pesticide poses less risk than EPA-registered alternatives.
- ✚ Documentation of a tolerance or exemption from tolerance if necessary for the proposed use (e.g. a copy of the Federal Register notification).
- ✚ Residue data to insure that residues from the proposed use pattern or rates do not exceed established tolerances.
- ✚ Efficacy data to demonstrate that the pesticide is more effective than EPA-registered alternatives or to insure that claims made for the pesticide are warranted. If data are not available, expert evaluations may be acceptable.
- ✚ A summary of environmental information, including toxicity to fish and wildlife, phytotoxicity, degradation mechanisms, persistence, and mobility. Information from nearby areas will be considered if Montana information is not available.
- ✚ Information regarding status of any Reregistration Decision, Special Review, or data-call-in by EPA including a summary of data gaps identified and any plans or studies in progress to support continued registration.
- ✚ Documentation for why alternative products are not available in sufficient quantity, if applicable.
- ✚ New products need a certified statement of formula.
- ✚ New products may need additional information that might be useful in making a “no unreasonable adverse effects” determination.

SECTION 18

Section 18 registrations provide exemptions from pesticide registration under emergency conditions. An emergency is considered an urgent, non-routine situation that may be remedied through the use of a pesticide(s) and shall be deemed to exist when:

- ✚ No effective, registered pesticides are available that have labeled uses for control of the pest.
- ✚ No economically feasible alternative practices which provide adequate control are available.
- ✚ The situation involves the introduction or dissemination of a pest new to or not previously known to be widely prevalent or distributed in the state or specific area.
- ✚ It must be substantiated that this (new) pest or problem will cause a significant economic loss.

In Montana, the Montana Department of Agriculture (MDA) is the responsible agency for making an application request to the EPA. After review of the application, the EPA approves or denies the request.

The MDA makes application for a specific exemption after receiving requests from individual producers and/or producer organizations that an emergency pest condition exists or can be expected to occur. The MDA proceeds with the application request when it has: 1) confirmed the emergency pest condition exists or can be expected, 2) determined there will be significant economic loss without control of the pest, 3) determined that no other registered pesticide is available or effective and 4) obtained cooperation of the pesticide registrant to support the application request.

The persons or organizations desiring the exemption should complete the information outlined below and submit it to the Montana Department of Agriculture. The Department prepares this information in final form and submits it to the EPA.

SECTION 5

Experimental Use Permits are available under FIFRA Section 5 to do field-testing on products before they receive Section 3 registration. EUPs establish conditions for the transportation, application, and disposal of pesticide material used in tests. Pesticides with EUPs are not to be sold or distributed other than through approved participants in the test program.

2(EF) RECOMMENDATIONS

Section 2(ee) recommendations allow pesticide users to apply pesticides under limited conditions not specified on the product label. While the recommendations do not require additional state registrations, they are considered part of the label. Montana does not require registration or approval of section 2(ee) use recommendations. We request that registrants send us all 2(ee) bulletins for our records.





Why We Use Pesticides and How it relates to Public Health Concerns

Over the years, the use of pesticides have caused concern amongst our society, especially when evaluating the risks associated with their use, but it's important to remember that there may be grave risks associated with letting certain pests go uncontrolled. A few examples where pesticides have played a major role in making our lives safer and protecting our economic well-being by balancing the act of risk vs. benefit.

- + **Health benefits:** Mosquito-vectored diseases such as West Nile Virus and the problems associated with it, Bubonic Plague vectored by fleas, Lyme disease vectored by ticks, rabies vectored by rodents, Typhus vectored by lice, and Asthma and Allergies from indoor household pests like cockroaches.
- + **Agricultural benefits:** Agricultural production is producing more food and fiber on less land than ever in history and pesticides are partly responsible. Controlling pests in feed and forage has encouraged a more efficient means of livestock production. Protecting bee hives with miticides for control of the devastating parasitic Varroa mite is vital to the industry.
- + **Structural benefits:** Termites and carpenter ants that cause widespread damage by feeding on structures. The preservation of wood from damaging insects and rot microorganisms is critical to the construction industry in building homes, decks, fences, and docks.
- + **Rights-of-way benefits:** Rights-of way are vital to our economy and provide a major conduit to the flow of goods and services. Management of nearly all rights-of-way involves worker safety, reduced fire hazards, road surface preservation, and utility and pipe lines. The use of herbicides makes obtaining all of these objectives realistic.
- + **Trade commodity benefits:** Cargo ships, aircraft, rail cars, and trucks cross our state borders on a daily basis. Pesticides protect our commodities prior to, and while being imported and provide for favorable trade relationships with foreign markets.
- + **Recreational benefits:** Golf course turfgrass which is free of disease-blighted areas, insect damage, and unsightly weeds attract golfers from all over the world. The dollar value of aesthetics can't be estimated and pesticides can help preserve the aesthetic appearance of our landscapes. Aquatic weed control by the judicious use of herbicides allows our fishing waters to be used by those who enjoy fishing and boating, while still supporting a healthy fish populations.



Pesticide labels contain information on how to use products legally and correctly, contain information on potential hazards associated with the products, and instructions in the event of a poisoning or spill. Following label instructions will allow you to minimize the risks and maximize the benefits.

The End-User and

Always read the label

- **Before purchasing the pesticide. It must be registered for your intended use, and you must make sure there are no restrictions that would prohibit its use.**
- **Before mixing and applying the pesticide. Understand how to mix and safely apply the pesticide, and know the first aid needed if an accident should occur.**
- **When storing pesticides. To prevent breakdown, contamination, and fire hazards know how to properly store pesticides. The farm chemical storage center should also be securely locked.**
- **Before disposing of unused pesticide and empty containers. To prevent environmental contamination and human health hazards.**

Make sure the product is intended for its specific use.

Do not use pesticides in any manner other than those specifically listed on the label; it is against the law.

Never remove a pesticide label from the container, or use unlabeled pesticides.

Store all pesticides safely out of reach of children and pets.

Main sections of a pesticide label:

Brand Name:


The brand or trade name is the name on the front panel of the label that you commonly used to identify the product.


EPA Registration Number:

Number tells you that EPA has reviewed the product and determined that it can be used with minimal or low risk if you follow the directions on the label properly.

Ingredients Statement:

 Active ingredients are the chemicals in the pesticide that kill or control the target pest(s).

 Inert ingredients often improve the effectiveness or safety of a pesticide.

 This section provides the chemical name of each active ingredient, the percentage by weight of each active ingredient, and the percentage by weight of all inert ingredients. Inert ingredients are not listed individually nor identified by name.

Signal Words:

Caution, Warning, or Danger - indicate the acute toxicity of the product to humans, based on one or more potential routes of exposure. The statement “keep out of reach of children” must also appear with signal words on the label of all pesticides.

Precautionary Statements:

This part describes the protective clothing that you should wear when using the pesticide. The section also tells you how to protect children or pets by keeping them away from areas treated with pesticides.

First Aid Instructions:

The label tells you what to do if someone is accidentally poisoned by the pesticide.

Personal Protective Equipment (PPE):

The label lists PPE needed to prevent exposure to the pesticide. Be sure to read this section before purchasing the pesticide.

Environmental Hazards:

This section indicates if the product can cause environmental damage, if it's harmful to wildlife, fish, pollinators, endangered plants or animals, or water bodies such as ponds, lakes, rivers and wetlands.

Directions for Use:

Make sure that the product is labeled for use against the pest(s) that you are trying to control. (For example, products labeled only for termites cannot be used to control fleas.) Use only the amounts indicated, and follow the directions exactly.

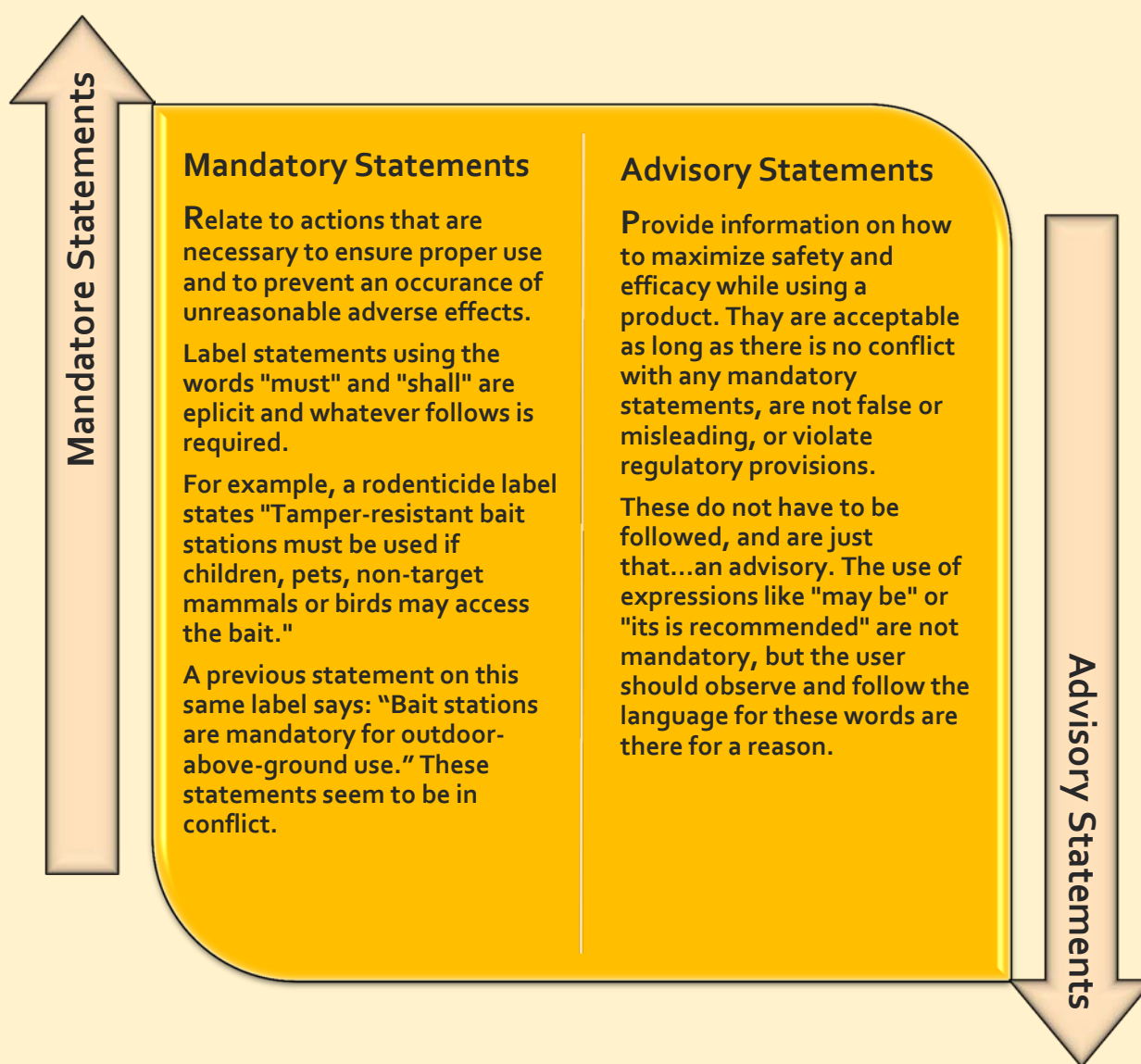
Storage and Disposal:

Safe storage and disposal of pesticide products. Always keep products in the original container and out of reach of children, in a locked cabinet or locked garden shed. Disposal of pesticide containers in a manner not listed by the label could lead to contamination of the environment or harm to other people.

CLARITY ON LABEL LANGUAGE

Labeling is defined as “all labels and other written, printed or graphic matter accompanying the pesticide at any time or to which reference is made on the label, or in literature.” It seems logical that if one can read and understand the written word this legal requirement should be easy to comply with, but this is where the problem often arise. Labels are not always clear and concise and can often cause confusion and misinterpretation.

Labels language must be clearly stated in either Mandatory or Advisory statements to avoid confusing language that may lead to misuse or adverse effects to the environment and/or human health.



Keeping “Tools in the Toolbox” and how EPA, States, and Associations collaborate on label language

The Association of Structural Pest Control Regulatory Officials (ASPCRO) website <http://www.aspcro.org/documents.html> has a page dedicated to documents that address the importance of working relationships when establishing clear and concise label language. The most recent example is the Rodenticide Labeling Restrictions for Commensal Rodent Use Only and how ASPCRO worked with EPA to modify the language to include more species of concern.

EPA implemented the Rodenticide Mitigation Decision (RMD) in 2008 that limited commensal rodenticide use exclusively for control of the Norway rat, Roof rat, and the House mice. As a result, the regulated community was left with few options for control of other rodents that habitually enter structures causing health concerns such as Hantavirus. The label language was updated in 2015, through the collaboration of ASPCRO and EPA to include the Norway rat, Roof rat, House mice, Cotton mouse, Cotton rat, Deer mouse, Eastern Harvest mouse, Golden mouse, Pack rat, Polynesian rat, Meadow vole, and White footed mouse. This process offered clarification to EPA that rodenticides need to be available to control commensal rodent species and non-commensal rodent species in and around manmade structures.

ASPCRO also works alongside the National Pest Management Association (NPMA) to conduct trainings for EPA registration and reregistration personnel. The trainings focus on products that are currently going through the reregistration review process.

- ✚ In 2015, a training was hosted at the Rollins Learning Center in Atlanta, Georgia that offered EPA staff a hands-on glimpse at how products for structural fumigation are used. The training covered all aspects of structural fumigation for EPA to learn and consider future fumigation registration decisions that will affect all states.
- ✚ In 2016, a training was hosted by the New Mexico Department of Agriculture in Albuquerque, New Mexico that offered EPA staff a glimpse at how products for rodent fumigation and livestock predation work and how important these products are for effective control of pests that have the ability to destroy environments and human health.

The two examples above also illustrated the importance of how the end-user must read and follow the LABEL if their intention is to keep the much needed “TOOLS in the TOOLBOX”.

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