HERBICIDE EVALUATION TECHNICAL UPDATE No. 1

Methods for the Evaluation of Herbicides for Use in Sensitive Areas of Rights-of-Way
June 2010

Update to: DEQE-DFA Cooperative Agreement relative to section 4(1)E of 333 CMR 11.00 Rights of Way Management Regulations – Appendix A (Narrative for Herbicide Evaluation Flow Chart) and Appendix B (List of Characteristics for Evaluation)

In 1988, the Massachusetts Department of Environmental Protection (MassDEP) and the Massachusetts Department of Agricultural Resources (MDAR) signed a Cooperative Agreement Relative to Section 4(1)(E) of 333 CMR 11.00 Rights-of-Way Management Regulations. The purpose of this agreement was to establish criteria and procedures that the MassDEP and MDAR would use to establish a listing of recommended herbicides for use within sensitive areas of rights-of-way. The "Narrative for Herbicide Evaluation Protocol" written in 1988 sets forth the written protocol that was created with the inception of the Rights-of-Way program in order to process a number of herbicide reviews at the start of the program. The present document represents an updated Narrative that more accurately represents the review procedure used today for evaluating herbicides petitioned for use in Sensitive Areas of Rights-of-Way where requests are infrequent and usually are for only one or two products at a time.

Herbicides approved for use on Rights-of-Way are products that have been registered with both the Federal EPA and the Commonwealth of Massachusetts. Products are composed of active ingredients and formulants. Label regulations require formulants to be referred to as "other ingredients" on product labels. However, formulants are also referred to as "inert" ingredients in informational exchanges related to pesticide products The active ingredients are the agents that are designed to produce an effect on the target organism e.g., broadleaf weeds. The "other" or "inert" ingredients can be solvents, surfactants etc. These agents, among other actions, increase the efficacy of the active ingredients.

EPA requires the manufacturer of the herbicide to submit data on environmental fate and transport parameters as well as toxicological information for both active ingredients and products. Product specific data requirements vary with the end use of the product. Most of the environmental fate and toxicological data available have been generated for the active ingredient. The data and studies submitted to EPA for registration are typically available upon request to state regulatory agencies for use in independently evaluating the active ingredients and formulated products.

While EPA requires the manufacturer to disclose information on the nature and composition of "inert" ingredients contained in formulated products, EPA does not routinely request the range of environmental fate and toxicological testing requirements it imposes on active ingredients, other than to require that limited acute mammalian toxicity tests be submitted on the formulated product. Because the composition of "inert" ingredients is treated as

proprietary information by EPA, state regulatory agencies cannot routinely obtain this information.

Historically, MassDEP and MDAR approved herbicides for use on Rights-of-Way based mainly on the acceptability of the herbicide active ingredient but also considering any available information on the formulated product. Surfactants and other inert ingredients were not evaluated based on the lack of information for these compounds. This protocol was established because there is typically a relative abundance of data available for the active ingredient, very limited information for its formulated product and no information for the inert component of the formulation. This protocol is still followed today based upon the same data limitations.

However, in recent years, an increasing number of studies from the scientific literature have been finding that certain classes of surfactants may have the potential to produce increased lethality and other effects on sensitive ecological receptors such as amphibians and may also have potential toxicological effects on humans. These compounds are not necessarily "inert" as their name implies and the use of "other" ingredients is more appropriate in this case. As a result of increasing concern on the potential toxicity of surfactants, the US EPA is seeking public comment on increasing public disclosure on all inert ingredients in pesticides which would make it possible to consider the potential toxicity of surfactants and other "inerts" during our evaluations. MassDEP and MDAR have agreed to incorporate a surfactants policy into this Narrative.

Evaluation Protocol for Active Ingredients and Formulated Product

The review of herbicides petitioned for use in Sensitive Areas of Rights-of-Way involves an evaluation of environmental fate and transport parameters as well as toxicological information for the active ingredient. Available information on the toxicity of the formulated product is also evaluated in the context of the information for the active ingredient.

Environmental Fate and Transport

Evaluation of environmental fate and transport for the active ingredient involves a consideration of its chemical and physical properties and how these properties influence the mobility and persistence of the chemical in the environment. The following list of chemical/physical parameters is employed in the review and evaluation of the environmental fate for the herbicide's active ingredient.

Transport
Water solubility
Octanol/water partition coefficient (K_{ow})
Soil/water partition coefficient (K_d)
K_d divided by soil organic carbon (K_{oc})
Vapor Pressure
Speciation at ambient pH

Persistence
Hydrolysis Half-life
Photolysis Half-life
Soil Half-life

If necessary and appropriate and if data permit, a modeling simulation will be conducted using a Pesticide Root Zone Model (PRZM) or similar model to simulate chemical movement in soil within and immediately below the plant root zone. PRZM is often used in conjunction with the Exposure Analysis Modeling System (EXAMS) that evaluates the fate, transport and exposure concentration of a chemical in aquatic environments.

Toxicology

An evaluation of toxicological data involves a compilation of available toxicological studies for that chemical, including studies conducted by the manufacturer or studies obtained from the scientific literature. The following list of toxicological endpoints should be represented in the review and evaluation of the herbicide's active ingredient.

Mammalian Toxicity

Acute:

Lethal Dose for 50% of the test animal population (LD50)
(routes of administration; oral, dermal and inhalation if relevant)
Data for at least 2 species required.

Irritant effects (eye, skin, upper and lower respiratory tracts)

Chronic - Subchronic:

Toxicological endpoint and resulting No Observed Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL), No Observed Effect Level (NOEL) or Lowest Observed Effect Level. (LOEL).

Reproductive toxicity/developmental toxicity

Carcinogenicity: oncogenicity

Mutagenicity

Aquatic Species Toxicity

Acute:

Lethal Concentration for 50% of test animal population (LC50) or Effective Concentration for 50% of test population (EC50) for
cold water fish, warm water fish and invertebrates.

Chronic -Subchronic:
NOEC (No Observed Effect Concentration) or LOEC (Lowest Observed Effect Concentration) or Equivalent for cold water fish, warm water fish and invertebrates

Reproductive toxicity/developmental toxicity:
cold water fish, warm water fish, invertebrates

Avian Species Toxicity

Acute:
LD50, LC50, EC50

Chronic- Subchronic:
NOEL or LOEL or equivalent

Reproductive toxicity/developmental toxicity:
NOEL or LOEL or equivalent

Invertebrates (colonies and individuals)

Acute:
LD50, LC50, EC50

Chronic: - Subchronic:
NOEC or LOEC or equivalent

Reproductive toxicity/developmental toxicity
NOEC or LOEC or equivalent

Amphibian Toxicity

Acute:
LD50, LC50, EC50

Chronic: - Subchronic:
NOEL or LOEL or equivalent

Endocrine Effects
NOEL or LOEL or equivalent

Reproductive toxicity/developmental toxicity
NOEL or LOEL or equivalent

Available data will be compiled for the active ingredient for each toxicological endpoint. Chemicals will be evaluated for mammalian, aquatic, avian, invertebrate and amphibian toxicity based on available data.

When data for a particular endpoint are available for more than one species, data from the most sensitive species will be used in the evaluation.

When evaluating the data to determine whether an herbicide can be recommended for use in sensitive areas on Rights-of-Way, the decision regarding its approval will consider the potential for toxicity and the concentration at which the chemical has been found to pose a hazard to mammals and other organisms with respect to one of the endpoints itemized above.

When the toxicological endpoint under investigation has a recognized threshold, an estimate of exposure will be made using the label application rates and estimated mobility to predict environmental concentration. The predicted concentration will be compared to toxicological "no observed effect levels" (NOELs) and lowest observed effect levels" (LOELs) for mammals and birds (or "no observed effect concentrations" (NOECs) and lowest observed effect concentrations" (LOECs) for aquatic species, invertebrates and amphibians) to evaluate the potential for toxicity (i.e., threshold risk). If none of the chronic criteria referenced above are available, then comparison will be done to available LC50 (for aquatic species) and/or LD50 acute toxicity values for mammals and birds. A Hazard Index will be developed as a ratio of the modeled exposure concentration over the toxicity criteria. In general, if this ratio is greater than 1.0, a potential for toxicity is indicated; if it is less than 1.0, toxicity is unlikely. However, the interpretation of potential toxicity is dependent on the toxicity criteria used for evaluation. If only lethality endpoints are available (e.g., LC50s), then HIs less than one do not necessarily mean an unlikely chance toxicity, since sublethal, but detrimental systemic responses can and do occur at concentrations less than those causing lethality. In keeping with this consideration, U.S. EPA provides different HI levels of concern for different receptors and toxicity criteria used to calculate the His. Their approach is found in the Office of Pesticide Program's Risk Quotient Method and Levels of Concern and will also be considered in the interpretation of the evaluation results (EPA, 2008). In cases where no threshold is recognized (e.g., carcinogenicity and mutagenicity), weight of evidence and potency information will be considered. An estimate of Excess Lifetime Cancer Risk (ELCR) will also be made for potential human exposures when information permits and will be compared to MassDEP excess lifetime cancer risk acceptability criteria of 1×10^{-6} for individual chemicals and 1×10^{-5} for mixtures of compounds.

Formulated Product

Once the active ingredient is evaluated, available environmental fate and/or toxicological data for the formulated product are also identified. The toxicological characteristics of a mixture of compounds may differ from those of its constituent compounds due to possible interactive effects. Any product-specific characteristics that significantly alter the exposure potential or toxicity of the product will be identified and evaluated. Toxicity and environmental fate data for the product are compared to the parent compound, when data are available. If no substantial toxicity is indicated, the herbicide will be placed on the "List of Approved Herbicides for Use in Sensitive Areas on Rights-of-Way". If the review identifies substantial toxicity, products will be listed with restrictions on use, or, if not recommended, will not be placed on the list. Guidelines may include, but are not limited to slope or wind restrictions, setback distances, limits on intervals between repeat applications, or application methods.

Surfactants Policy

Review of selected surfactant compounds will be conducted for compounds that are present in one or more formulated products in the "List of Approved Herbicides for Use in Sensitive Areas on Rights-of-Way", hereinafter referred to as "the List", or have been used in a tank mix with active ingredients from the List.

General Policy

In general, compounds will be designated for review when available fate/transport and/or toxicity information indicates a potential for increased exposure or toxicity to non-target species. As is described for active ingredients, fate and transport parameters as well as toxicological information will be considered in the review. With compounds for which there are limited data, available information may be supplemented with modeled information obtained through use of several fate/transport and toxicity prediction tools available through EPA.

Compounds that have been reviewed and for which potential exposure and toxicity are low will be placed on the "List of Approved or Evaluated Surfactants for Use in Sensitive Areas on Rights-of-Way", hereinafter referred to as "the Surfactant List". The Surfactant List will be updated periodically as review of additional surfactants is conducted.

New Requests

For review of a surfactant in a new herbicide product request (i.e., either a new active ingredient/surfactant product or a repack product in which a previously approved active ingredient is formulated with a new surfactant), the review process to be used for evaluating the surfactant component of an herbicide will be as follows:

a. When a formulated product contains only surfactant[s] that match a surfactant on the Surfactant List or is/are contained in a surfactant class on this List, it does not have to undergo additional review and will pass the surfactant portion of the review process for having a product added to the List of Approved Herbicides on the Sensitive Areas of Rights-of Ways;

b. When the identity of surfactants in a product is not disclosed, nor does the applicant certify that all the surfactants in the product come from the Approved List, the applicant must disclose the class or identity of those surfactants that are not on the list (along with their percent composition of the final product) and submit environmental fate and transport characteristics and toxicity data* for these surfactants and/or for the formulated product. The final decision regarding the acceptability of the product with surfactants will be based upon review of the data supplied ;

* At a minimum, these data must include LC50 and EC50 toxicity values for warm water and cold water fish, invertebrates and amphibians. Additional information on endocrine-disrupting effects and developmental effects should be identified if available.

c. Surfactants or products not meeting a or b above will not be approved for use in Sensitive Areas of Rights-of-Way.

References

EPA, 2008. Technical Overview of Ecological Risk Assessment Risk Characterization. URL: http://www.epa.gov/oppefed1/ecorisk_ders/toera_risk.htm#Deterministic