

Review Process for Addition of Herbicides to the Sensitive Area Materials List

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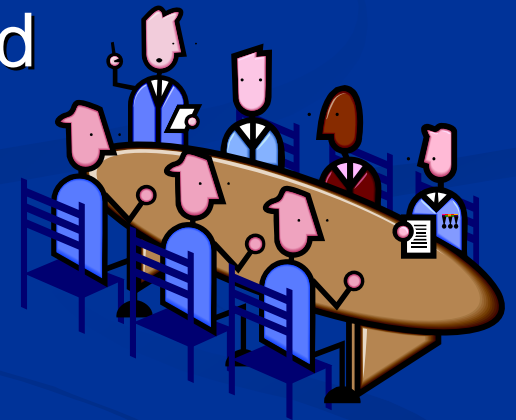
Sensitive Area Materials List

- Herbicides specified to be acceptable for use in sensitive areas in rights-of-way
- Purpose is to provide extra protection to prevent unreasonable adverse effects to humans and the environment
- Special collaborative review process for review and addition of herbicides to this list



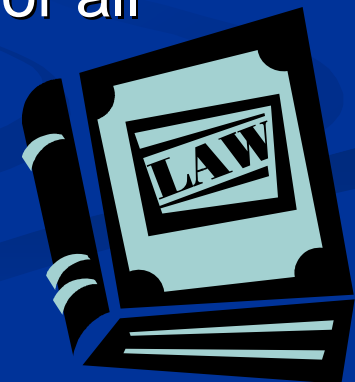
Levels of Review and Registration Relative to Listed Herbicides

1. At the federal level by US EPA
2. At the state level by Pesticide Board
Subcommittee
3. Joint review by MDAR and
MassDEP for Sensitive Area
Materials List



1. EPA Regulates Pesticides Under Authority From:

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Requires registration of all pesticides by EPA
- Federal Food, Drug and Cosmetic Act (FFDCA)
 - Requires EPA to set pesticide tolerances for all pesticides used in or on food



EPA Regulatory Authority for Pesticides

- Food Quality Protection Act (FQPA)
 - Amended both FIFRA and FFDCA
- EPA must find that a pesticides poses a "*reasonable certainty of no harm*" before that pesticide can be registered for use on food/feed.
- Analysis of aggregate exposure, cumulative effects, sensitive populations (infants), and endocrine-disrupting effects



EPA Registration Program

- Evaluation of new and existing pesticides
- Registration of products for pest control
- Ensure protection of human health and the environment
- Registration permits the distribution, sale, and use according to specific use directions and requirements on the product label
 - A product label is a legal document



Registration Process at EPA

- Scientific, legal, and administrative procedures
- Examination of ingredients, use pattern, storage and disposal practices
- Evaluation of a wide variety of potential human health and environmental effects
- EPA requires more than 100 scientific studies done according to strict EPA guidelines



Data Requirements

Scientific data needed to address concerns related to :

- Identity and composition of pesticide product
- Potential adverse effects to humans and non-targets organisms
- Environmental fate



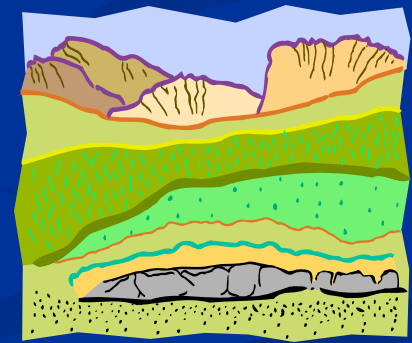
Types of Studies Required

- Product performance
- Hazard to humans and domestic animals
- Hazard to other non-target organisms
- Post-application exposure studies
- Applicator/User exposure studies
- Pesticide spray drift assessment
- Environmental fate
- Residue chemistry (food/feed tolerances)



Environmental Fate Studies

- Degradation studies
 - Hydrolysis
 - Photolysis (water, soil, air)
- Metabolism studies (biodegradation)
 - Aerobic/Anaerobic (soil/water)
- Mobility studies
 - Leaching; adsorption/desorption
- Volatility
- Field dissipation (terrestrial, aquatic)
- Ground and surface water exposure



Evaluation for Registration

- Human health risk

- Short-term acute effects
- Long-term effects such as cancer and reproductive
- Aggregate exposure (food, water and residential)
- Cumulative risks (includes other pesticides)
- Occupational risks



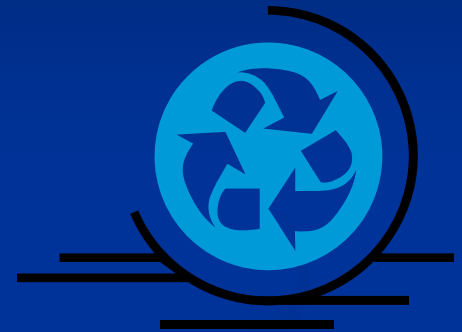
- Effects on wildlife, fish and plants

- Acute and chronic
- Including endangered species



Evaluation of Environmental Effects

- Consideration of environmental fate characteristics
- Consideration of metabolites
- Assessment of exposure to groundwater and surface water
 - Exposure Modeling
 - Monitoring studies



Risk Assessment

- Comprehensive health and environmental risk assessment based on the compiled data sets
 - Does labeled use cause unreasonable adverse effects?
 - More information EPA risk assessment procedures available at:
 - http://www.epa.gov/risk_assessment/
- Risk assessment undergoes a process of peer review by scientific experts



Risk Management and Regulatory Decisions

- Consideration of risk assessment and peer review
- Consideration of risk mitigation measures
 - General Use or Restricted Use
- Consideration of existing alternative pesticides
- Coordination of risk management with registrants
- Label Review and Approval

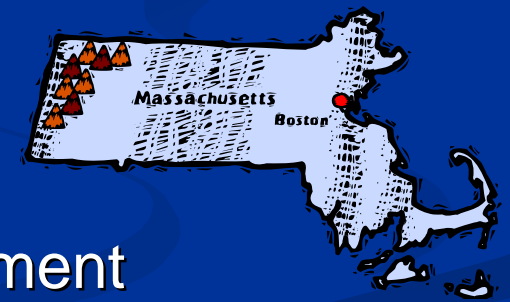


Review of Registered Pesticides

- Programs for re-evaluation of registered pesticides
 - Ensure adherence to the highest standards for protection of human health and the environment
- Registration review
 - Reevaluation on a regular cycle
- Special review
 - Initiated when unreasonable adverse effects occur

2. Pesticide Regulation at the State Level

- MDAR is responsible for regulating the use of pesticides in Massachusetts
 - Registration of pesticides
 - Licensing and certification of applicators
 - Enforcing federal and state laws and regulations
- Pesticide Program Objectives
 - Regulate the use of pesticides
 - Protect human health and the environment



State Laws Related to Registration of Pesticides

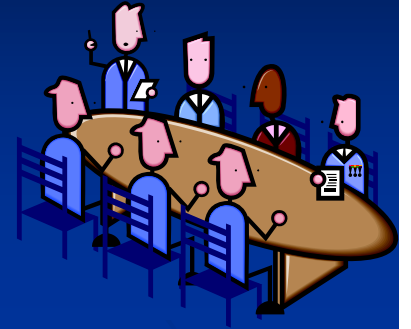
- 333 CMR 2.02 (3)
 - Subcommittee of the Pesticide Board

- 333 CMR 8.00 Registration of Pesticide Products
 - 8.01 Registration requirement
 - 8.02 Application for registration
 - 8.03 Individual review
 - Other sections 8.04 – 8.09



Pesticide Board Subcommittee

- MGL Ch. 132B Section 3A
- Five members from the Pesticide Board
 - Director of Food Protection Program, MDPH – Chairperson
 - Commissioner of MDAR or designee
 - Commissioner of MDPH or designee
 - Commissioner of MDCR or designee
 - Commercial Applicator



Subcommittee Review Process

- MDAR staff prepares review documents for subcommittee to consider
 - EPA factsheet
 - Supplemental information requested from registrant
 - Scientific studies available in the open literature
 - MDAR staff presents review at the Subcommittee meeting
- Subcommittee discusses information
 - Determines if data are sufficient to make decisions



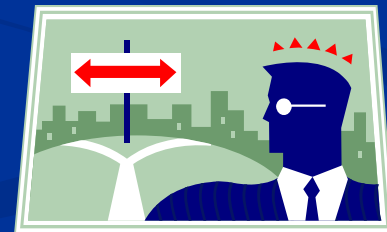
Subcommittee Registration Classification

- Subcommittee determines potential to cause unreasonable adverse effects when used as labeled
- Classification of registration
 - Refuse to register
 - Register – unclassified/ General Use
 - Register and classify for Restricted Use (e.g. classification as a potential groundwater contaminant)
 - Register for Special Local Need



Subcommittee Motions

- The Subcommittee votes and decides registrations by majority vote
- Decisions are recorded and motions may be repeatedly employed, e.g. the following:
 - Products containing chemicals on the Departments Potential Groundwater Contaminant List
 - Containing 20% or more 2,4-D
 - Subsurface Termiticides
 - Experimental Use Permits
 - State registration of Special Local Needs



Registration Classification

- Classification as State Restricted Use Pesticide based on:
 - Potential for groundwater contamination
 - Subsurface termiticide use
 - Toxicity concerns
 - Other Subcommittee concerns



Groundwater Protection Program

- Regulation: 333 CMR 12.00 Protection of Groundwater Sources of Public Drinking Water Supplies from Non-Point Source Pesticide Contamination
- Applies to products with active ingredients on Groundwater Protection List
- Ground Water Protection List
 - Active ingredients with potential to cause groundwater contamination
 - Assessment based on leaching potential and toxicological concerns



Additional Resources

- Crop Inspectional/Pest Home
- Groundwater Regulations (333 CMR 12:00)

Pesticide Program Fees
Increase - Effective 02/01/2010

Spotlight



Groundwater Protection List 2009

Contact: Hotze Wijnja at hotze.wijnja@state.ma.us - 617.626.1771

The Groundwater Protection List refers to a list of pesticide active ingredients that could potentially impact groundwater due to their chemical characteristics and toxicological profile. [Click here](#) to search for registered products in Massachusetts

Herbicides	Insecticides	Fungicides
Acetochlor*	Aldicarb	Chlorothalonil
Acifluoren	Carbofuran	Cyproconazole
Alachlor	Dinotefuran	Folpet
Aldicarb	Disulfoton	Kresoxim-Methyl
Atrazine	Fenamiphos	Triticonazole
Bentazon	Fonofos	
Bromacil	Lindane	
Cyanazine	Methoxyfenozide	
Chlorthal-Dimethyl**	PCP	
Dimethanamid	Propoxur	
Diuron	Terbufos	
Flufenacet	Thiamethoxam	
MCPA		
Metolachlor		
Metribuzin		
PCP		

Communications with Registrants

- MDAR staff regularly communicate with product registrants relative to the following:
 - Products pulled for individual review
 - Labeling issues
 - Supplemental data requests
 - Subcommittee registration decisions – letters are sent to product registrants subsequent to the Subcommittee Meeting.



Pesticide Product Label Review

- Registration of new pesticide products
- Ensure that product label information meets standards
- Pulled for individual (special) review
 - New active ingredients
 - Special local need
 - Emergency exemption
 - Products labeled for mosquito control and aquatic weed control



3. Review for Rights-of-Way

- Specific Regulations for Rights-of-Way management
- Sensitive Area Materials List
- Special review process for herbicides to be added to list
 - Require EPA registration
 - Require State registration



Rights-of-Way Management Regulations (333 CMR 11.00)

- Provide provisions for sensitive areas within rights-of-way
- Sensitive area restrictions include:
 - Only herbicides listed on the “Sensitive Area Materials List” shall be used
- Criteria and procedures for review of herbicides for use within sensitive areas are established in a Cooperative Agreement between MDAR and MassDEP (1987)



Sensitive Area Materials List

- Herbicides specified to be acceptable for use in sensitive areas
- Currently Listed Active Ingredients:
 - Glyphosate
 - Metsulfuron-methyl
 - Sulfometuron-methyl
 - Fosamine
 - Imazapyr
 - Triclopyr



Review Process

- Cooperative review by MDAR and MassDEP
- Scientific review of herbicide products includes:
 - Physical and chemical characteristics
 - EPA registration standard and status
 - Primary and secondary data sources
 - If necessary, additional data will be requested from registrant
 - Review addresses both active ingredients and “other” or “inert” ingredients



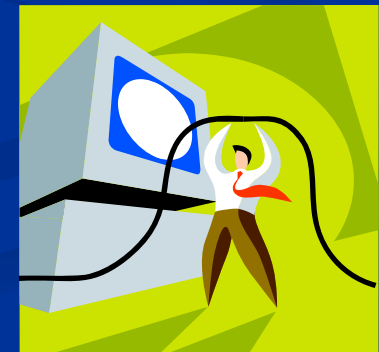
Protocol for Active Ingredients

- Environmental fate and transport characteristics
- Transport
 - Water solubility
 - Partitioning characteristics
 - Vapor pressure (volatility)
 - Speciation at ambient pH
- Persistence
 - Hydrolysis half-life
 - Photolysis half-life
 - Soil half-life

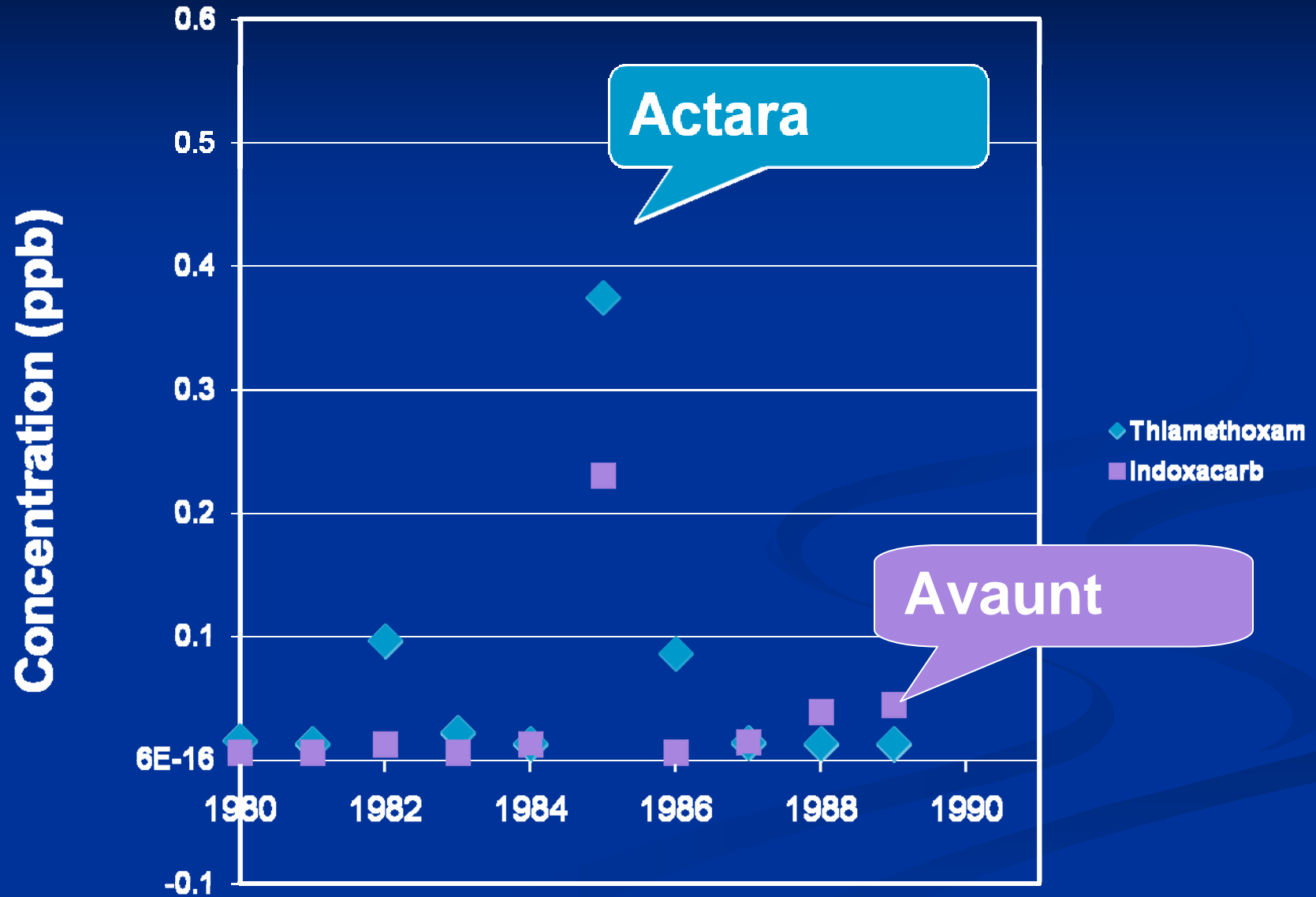


Environmental Fate Evaluation

- Evaluation may be supported by computer modeling by using EPA-approved models for environmental exposure assessments.
- Models generate predicted environmental concentrations in soil and water for situations specified with the input parameters, including
 - Chemical properties
 - Application characteristics
 - Soil and meteorological input



Example of Model-simulated Surface Water Concentrations



Toxicity Criteria

- Mammalian toxicity

- Acute: LD50 values; Irritant effects
- Chronic/ Subchronic
- No Observed Adverse Effect Levels (NOAEL)
- Lowest Observed Adverse Effect Levels (LOAEL)
- Reproductive and developmental toxicity
- Carcinogenicity
- Mutagenicity



Aquatic Life Toxicity Criteria

- Acute (fish and invertebrates)
 - Lethal Concentration (LC50) values
- Chronic/Subchronic
 - No Observed Effect Concentration
 - Lowest Observed Effect Concentration
- Reproductive and developmental toxicity



Avian Toxicity Criteria



- Acute
 - Lethal Dose (LD50) values
- Chronic/Subchronic
 - No Observed Effect Concentration
 - Lowest Observed Effect Concentration
- Reproductive and developmental toxicity

Amphibian Toxicity Criteria

- Acute
 - Lethal Dose (LD50) values
- Chronic/Subchronic
 - No Observed Effect Concentration
 - Lowest Observed Effect Concentration
- Reproductive and developmental toxicity



Risk Characterization

- Based on comparison of predicted environmental concentrations with:
 - “No Observed Effect Levels” or “Lowest Observed Effect Levels”
 - LC50 values
- Hazard Index (HI)
- Risk Quotient (RQ)
- Comparison of HI or RQ with Levels of Concern established for various classes of organisms



Cases where no threshold is recognized

- Carcinogenicity
- Weight of evidence and potency information will be considered
- An estimate of the Excess Lifetime Cancer Risk will be made for potential human exposures when information permits
- Will be compared to MassDEP excess lifetime cancer risk acceptability criteria

Sensitive Area Materials List

Examples of Active ingredients and approved products

<p>Metsulfuron Methyl Sulfometuron Methyl <i>Lowest Labeled Rate*</i></p>	<p>Oust Extra (352-622) <i>EI Dupont</i></p>	
<p>Ammonium Salt of Fosamine <i>Lowest Labeled Rate*</i></p>	<p>Krenite S (352-395) <i>EI Dupont</i></p>	
<p>Imazapyr <i>3 pints/acre every 3rd year OR</i> <i>2 pints/acre every other year</i> <i>for all Imazapyr Products</i></p>	<p>Arsenal (241-346) Arsenal Powerline (241-431) Arsenal Railroad Herbicide (241-273) <i>BASF</i></p>	<p>POLARIS HERBICIDE (241-346-228) POLARIS RR HERBICIDE (241-273-228) <i>NU FARM AMERICAS</i></p>

Formulated Product

- Toxicity and environmental fate of the formulated will be identified
- Will be compared to toxicity and fate of active ingredient
- Toxicity and fate characteristics of the formulated product will be considered in the final decision on the particular herbicide product



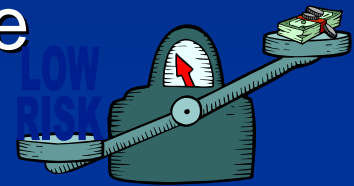
Review Criteria for “Other” Ingredients

- Surfactants and detergents are a common component of herbicide formulations
- Concerns for potential effects on aquatic organisms
- Review protocol similar to active ingredient protocol
 - Environmental fate and toxicological information will be considered
 - Supplemental information may be obtained through use predictive tools approved by EPA



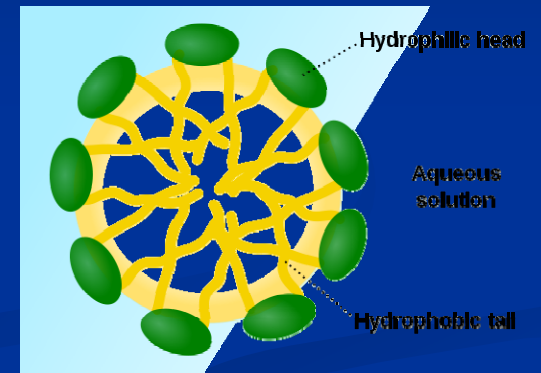
List of Approved Surfactants

- Recently completed a risk assessment of commonly used surfactants in herbicide products
- Resulted in a list of approved surfactants for use in Sensitive Areas of Rights-of-Way
- New requests for herbicide products containing surfactants that are not listed will have to undergo a review following the same criteria

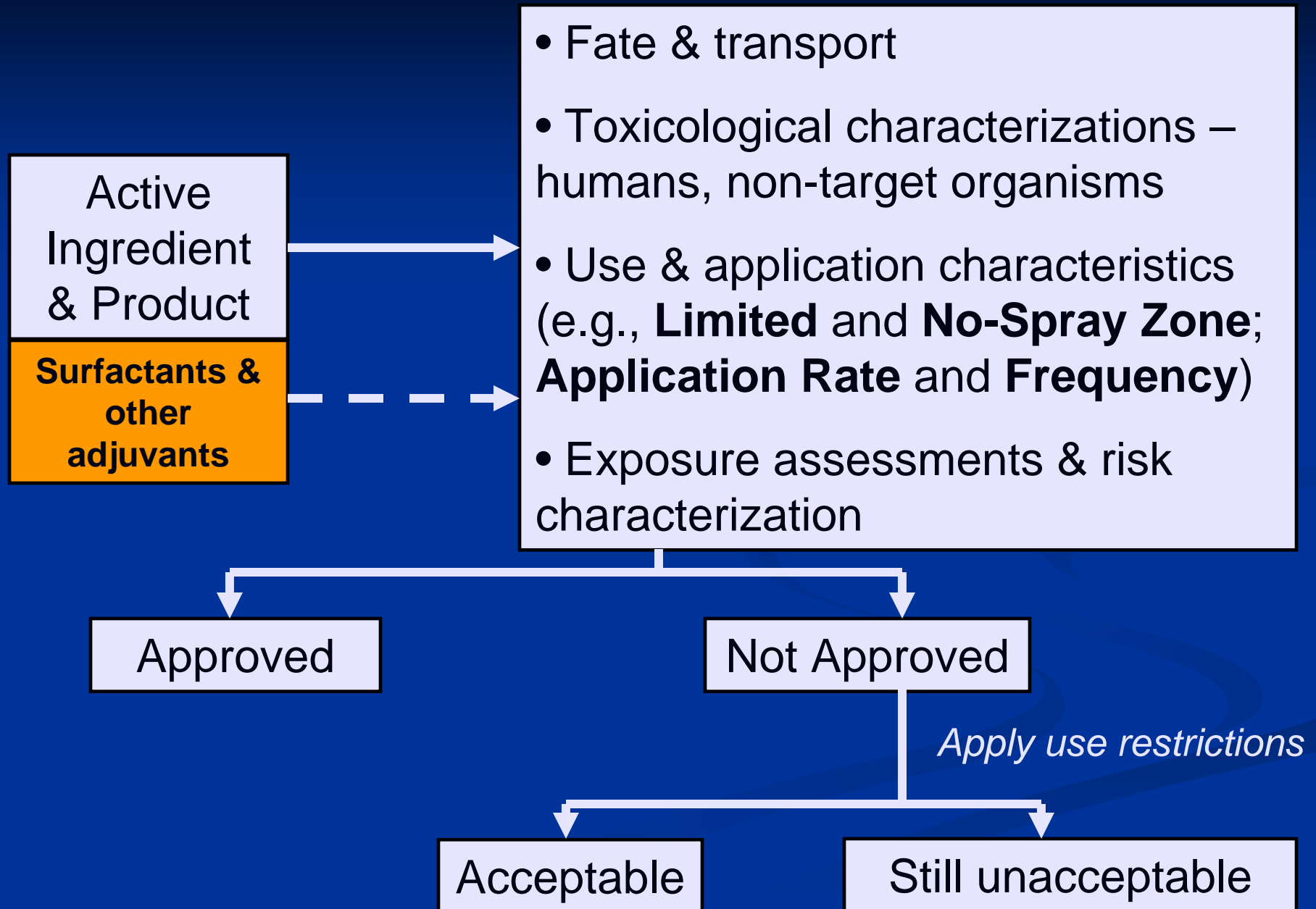


List of Approved Surfactants

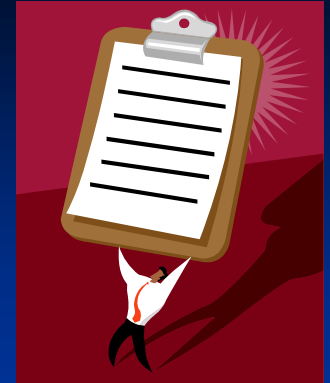
- Polyethoxylated ethylamines (POEA)
 - Alkylphenol ethoxylates (APE)
 - Alcohol ethoxylates (AE)
 - Phosphate ester ethoxylates (PE)
 - Organosilicones (OS)
-
- The need for re-evaluation will be considered when new data become available



Herbicide Reviews for ROW



Summary



- Extensive data requirements and review for registration at the federal level
- Review and Registration at state level by Pesticide Board Subcommittee
- Additional review process for Rights-of-way by MDAR and MassDEP

Summary



- These levels of review and evaluation for registration and addition to the Sensitive Area Materials List and the rigorous regulatory process for rights-of-way are in place to ensure:
- Protection from potential impacts on human health and the environment from the selective use of these herbicides
- Allow the benefits of selective use of herbicides to maintain rights-of-way

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