PESTICIDE BOARD SUBCOMMITTEE MEETING

MINUTES OF MEETING

April 28, 2020

Meeting held via remote participation

MEMBERS PRESENT

- Michael Moore, Chairperson, Director of Food Protection Program
  - Department of Public Health
- Taryn LaScola, Alternate Designee for Commissioner John Lebeaux
  - Department of Agricultural Resources
- Marc Nascarella, Designee for Commissioner Monica Bharel
  - Department of Public Health
- Nicole Keleher, Designee for Commissioner Jim Montgomery
  - Department of Conservation and Recreation
- Richard Berman
  - Commercial Applicator

ALSO PRESENT:

- Susie Reed, Department of Agricultural Resources
- Hotze Wijnja, Ph.D., Department of Agricultural Resources
- Members of the public attended

I. PRODUCT REGISTRATIONS

VOTED

That the Pesticide Board Subcommittee registers the pesticide products listed on the EIPAS PR April 28, 2020 Subcommittee cover letter with the exception of the following products:

1. Versagard Fungicide G, EPA Reg. No. 9198-256, chlorothalonil
2. Hyvar X-L IVM Herbicide, EPA Reg. No.81927-77, bromacil
3. SpiruS EPA Reg. No. 91234-188, s-metolachlor
4. Triad TZ Select, EPA Reg. No. 89442-52, 2,4-D

Moved: Berman
Second: Keleher
Approved: 5-0

STATE RESTRICTED USE MOTIONS:

Restricted Use As Defined under the Groundwater Protection Regulations:

Move: That the Pesticide Board Subcommittee has determined that the use of the following products:

1. Versagard Fungicide G, EPA Reg. No. 9198-256, containing chlorothalonil,
2. Hyvar X-L IVM Herbicide,EPA Reg. No.81927-77, containing bromacil, and
3. SpiruS EPA Reg. No. 91234-188, containing *s*-metolachlor,

May cause an unreasonable risk to man or the environment, when taking into account the economic, social and environmental costs and benefits of their use. This determination is based upon the leaching potential and toxicological concern of this substance as defined in the "Protection of Groundwater Supplies from Non-Point Source Pesticide Contamination" Regulations. Therefore, the Subcommittee hereby modifies the registration classification of agricultural/commercial pesticide products containing ***Chlorothalonil, Bromacil*** and *s*-***Metholachlor*** from general to restricted use for groundwater concerns.

Moved: Berman
Second: LaScola
Approved: 5-0

2,4-dichlorophenoxyacetic Acid (2,4-D) Motion:

Move: That the Pesticide Board Subcommittee has determined that the use of the following product:

1. Triad TZ Select, EPA Reg. No. 89442-52, containing 2,4-D at 31.82%

as restricted use pursuant to the Subcommittee's decision on April 14, 1989, to register products containing 20% or more of **2,4-dichlorophenoxyacetic acid (2,4-D)** and/or its derivatives as state restricted use.

Moved: Berman
Second: Keleher
Approved: 5-0

III. NEW ACITIVE INGREDIENTS

Discussion of the new active ingredient **pyrasulfotole:**

Huskie Herbicide Pyrasulfotole is co-formulated with two forms of bromoxynil and labeled for use on cereal grains, and grass grown for seeds.

This post-emergent herbicide targets broadleaf weeds. Pyrasulfotole is an HPPD inhibitor and thereby inhibits photosynthesis in susceptible plants. Application is by foliar method, including ground boom and aerial application. The application on cereal crops is up to 0.045 lb/acre as a single application per year. On grass-grown-for-seed, two applications per year are allowed.

Label language includes groundwater and surface-water advisories statements to address the environmental characteristics of this chemical that indicates potential for leaching and runoff in certain situations. There is also detailed spray drift language to minimize non-target exposure and crop rotation language to address the potential for the herbicide to carry over to the next growing season.

The meeting packet included the pesticide factsheet for Pyrasulfotole (USEPA, 2007). This document and additional supporting documents are available at www.regulations.gov in docket "EPA-HQ-OPP- 2006-1026". Wijnja summarized the information at the meeting.

Active ingredient first registered by EPA in 2007 for wheat and barley. In 2011 the use on grass grown for seed was added. At that time, EPA also issued a revised human health risk assessment and revised language for toxicity information to address additional tolerances and information related to human health.

The toxicity information for human health risk assessment indicate that pyrasulfotole has low acute toxicity by oral and dermal inhalation exposure (Category 3 and 4), is a moderate eye irritant, and not a skin irritant or a dermal sensitizer. The eye is the primary target organ for this chemical which appears in some sub-chronic, and chronic studies where ocular toxicity was observed.

In the combined chronic carcinogenicity study in rats observed an increase in the corneal tumors at high doses. The Cancer Assessment Review Committee (CARC) considered that a rare type of tumors and consider to be treatment-related. In the carcinogenicity study in mice, an increase in the incidence of transitional cell carcinomas and papillomas of the urinary bladder were observed in males and females at the highest dose tested. However, these tumors were observed at doses that were considered excessive due to increased mortality caused by urinary bladder stones. Pyrasulfotole was negative for mutations and chromosomal aberrations across four in vitro/in vivo genotoxicity studies and was considered by the CARC not to pose a mutagenic concern. Overall the CARC classified pyrasulfotole as "Suggestive Evidence of Carcinogenicity". However, it was determined that a separate quantification of cancer risk is not required. The chronic risk assessment is considered protective for all chronic

risks, including carcinogenic risk.

Developmental studies showed skeletal variations and body weight effects in offspring in rat studies of offspring. Both effects were observed in the presence of maternal toxicity at the same dose. In the developmental neurotoxicity (DNT) study in rats, ocular toxicity as well as several adverse developmental effects were observed at the mid dose. Ocular toxicity was also observed at this dose in maternal animals; an identical no-observed-adverse-effect-level (NOAEL) was established in both dams and offspring. Reproductive study effects included ocular toxicity in dogs, and in offspring thyroid and kidney effects were observed in each generation. Metabolic studies showed that 60% is excreted in urine within 6 hours and 30% in feces within 52 hours.

Food Quality Protection Act safety factor was reduced from 10x to 1x based on various considerations. Overall the database is complete for risk assessment purposes. There is no residual uncertainties related to pre- and postnatal toxicity and there is an adequate exposure assessment for this chemical.

Dietary risk assessments show no concerns for acute and chronic effects; exposure are below the level of concern. The aggregate risk assessment occupational risk assessment considered acute and chronic exposures from food and drinking water. Occupational risk assessments considered dermal and inhalation exposure for short and intermediate terms. Exposures using baseline protection were determined to be below the level of concern.

The environmental fate of this chemical is characterized by being highly soluble in water, low vapor pressure, low potential to bioaccumulate, moderately mobile, and moderately persistence in the environment. Soil half-life values range between 60 to 63 days, while field dissipation studies showed surface horizon half-life from 6 to 18 days. Biodegradation is the major route of dissipation.

The overall profile is that this chemical has the potential to run off and leach. The label has language to inform applicators about this potential.

The ecological toxicity information shows that it is practically non-toxic to freshwater fish and freshwater invertebrate on an acute basis. However, it is classified as highly toxic to marine invertebrates. Chronic risk to freshwater organisms is below the level of concern. Pyrasulfotole is practically non-toxic to birds and mammals on acute basis. Chronic effects on growth at relatively high exposure levels, but risk was determined to be below the level of concern. Some chronic risks to mammals is indicated for high-end application rates. The active ingredient is non-toxic to terrestrial invertebrates. Vascular plant and aquatic vascular plants are sensitive to this herbicide.

Pyrasulfotole was conditionally registered by EPA. Conditionally data were needed to confirm a few regulatory requirements related to analytical methods and standards, dermal penetration and sediment toxicity to benthic organisms. Tolerance was established for food crops, feed, animal products. Required environmental label statements related to groundwater advisory, surface water advisory and spray drift management to protect non-target organisms.

Relative to the groundwater protection regulation (333 CMR 12.00), it was pointed out that pyrasulfotole does not meet the criteria for potential ground water pollutant.

Berman noted the difference in signal words when comparing product label 'Warning' and safety data sheet 'Danger'. Wijnja pointed out the criteria used by EPA for signal word differ from the criteria used by the authorities that issue the SDS. On most SDS documents, the regulatory information section points out this difference in regulatory criteria.

Berman also sought clarification on how EPA's carcinogenicity classification is used for evaluation of the regulatory criteria for groundwater and water supply protection [333 CMR 12]. This question was in the context of EPA's classification of pyrasulfotole as 'suggestive evidence of carcinogenicity'. Wijnja pointed out that in previous cases the Subcommittee has evaluated pesticides with that same classification as not meeting the toxicological criterion of groundwater protection regulations. Wijnja pointed out that the regulatory criteria in 333CMR12 were developed in the 1980s. EPA has updated the carcinogenicity classification over the years. The designations of carcinogenicity potential have changed and interpretation in the context of the regulatory criteria for groundwater criteria was necessary. In the case of classification of 'suggestive evidence of carcinogenicity' the Subcommittee determined that it does not to meet the criteria for toxicological concern as defined in 333CMR12.02.

LaScola sought clarification on what the designation of 'Suggestive evidence of Carcinogenicity' means. Wijnja responded that the designation is based on consideration of the data set from studies with the substance and the weight of evidence for carcinogenicity potential. 'Suggestive evidence' is one if the designations that is used and indicates that there some of the data show carcinogenicity effects, but consideration of all available data does not allow a higher carcinogenicity potential designation.

Nascarella stated that it may be helpful for the Subcommittee to look into how we are using carcinogenicity information in evaluating the criteria in the groundwater protection regulations. It would be helpful to have a rubric available that the Subcommittee can refer when conducting these evaluations.

Moore asks about conditional data requirements that were part of the conditional registration by EPA in 2008. Wijnja explained that the updated registration documents indicated that at least some of the data requirements were fulfilled. Some of the requirements were related to analytical aspects that are typically not included in published regulatory documents, and therefore are more difficult to verify.

Move that the Pesticide Board Subcommittee approve the product registration for the **Huskie Herbicide, EPA Reg. No. 264-1023**. This product contains the active ingredient **pyrasulfotole** and has never before been registered in Massachusetts.

Moved: Berman

Second: Keleher
Approved: 5-0

Discussion of the new active ingredient ***Aureobasidium pullulans*** **strains DSM 14940 and DSM 14941.**

Aureobasidium pullulans strains DSM 14940 and 14941 is a biopesticide substance formulated in the product **Blossom Protect**, EPA Reg. No. 86174-4, which is labeled for preventing fire blight in pome fruit and walnut blight in walnuts.

The product was developed in Austria. The product label has environmental hazard statement indicating it should not be used in water also precautionary language such as spray drift management requirements, buffer zone requirements, wind speed restriction, runoff management.

The active ingredient substance is a biopesticide that contains two strains of this organism. *Aureobasidium pullulans* is ubiquitous in the environment and is found in plants, soil and water.

Product is used as a preventative product to address blight infection in target crops. The mode of action is by colonization of blossom and compete with pathogenic organisms. The application rate 1.5 lbs. of this product in 50-200 gallons of water, applied by ground spray equipment only, up to 4 applications during bloom of pome fruits , and up to six application of walnuts trees during bloom.

Federal Food, Drug, and Cosmetic Act consideration document from 2015 entitled 'Considerations for Aureobasidium pullulans strains DSM 14940 and DSM 14941'; (www.regulations.gov; Docket ID Number: EPA-HQ-OPP-2010-0099) was included in the meeting packet. The document was issued relatd to the request for exemption from requirements of tolerance residue of this active ingredient in all food commodities. The document provides information related to human health effects and provides and an overview of information EPA considered for registration of this new active ingredient.

The overview of that document points out that it is a naturally occurring fungus, found in and on many plants, and has been isolated from grape, apple and other plants. This microorganism nourishes from non-living or decaying organic matter, and is a weak pathogen or parasite of certain plants. It is also known as an antagonist of several plant disease causing organisms.

The strains that make up this new biopesticide product were isolated from apple leaves, they are not mutant or genetically modified.

The microbial pesticide toxicity data requirements indicates that some of the test was done with 14941 strain only, but were used to support both strains because they are closely related. The

study results show that it is not toxic, ineffective or pathogenic. The temperature affect study show it does not grow at temperatures of 35 Celsius or above.

The exposure assessment indicate food exposure is possible, but based on the toxicity profile it is not likely that adverse effects will occur with the use of this product according to label instructions. Exposure through drinking water is unlikely as typical water treatment removes or inactivates this biopesticide. Other exposure situation, such as residential and agricultural use, were consideres as additional exposures, but are not expected to reach the levels to cause adverse effects.

Overall , EPA determined there is a reasonable certainty that there is no harm to U.S. population, including infants and children, from the use of this product according to label instructions. EPA conclude the exemption requirements for tolerance can be established for this active ingredient.

MDAR staff reviewed ecological effects information available in the European registration information for this active ingredient as a source of information to assess the ecological and environmental fate aspects of this active ingredient. The overall information indicates a low eco-tox profile. The ubiquitous presence of *Aureobasidium pullulans* in the environment was an important aspect in the ecological risk assessments. The use of this biopesticide is not expected to increase the exposure that is already present in the environment to levels that would cause adverse effects to non-target organisms.

EPA registered this active ingredient unconditionally. Relative to the Massachusetts groundwater protection regulations (333 CMR 12.00), it was pointed out that this active biopesticide does not meet the criteria for potential groundwater pollutant.

Move that the Pesticide Board Subcommittee approve the product registration for the **Blossom Protect, EPA Reg. No. 86174-4**. This product contains the active ingredients ***Aureobasidium pullulans*** **strains DSM 14940 and DSM 14941** and has never before been registered in Massachusetts.

Moved: Berman
Second: Keleher
Approved: 5-0

IV. New Business

LaScola proposed to schedule a Subcommittee meeting in May to allow additional products to be registered in light of the increased number of applications for disinfectant products. LaScola also provided an update on the plan for a statewide monitoring study that will be part of the individual review of glyphosate. MDAR will move forward with the plan when the

situation allows and will reach out to water departments across the state to select participants in this study.

LaScola provided a heads-up regarding the preparations for a potential invasion of the Spotted Lantern Fly. This invasive species is present in PA and has potential to spread to New England. MDAR interacted with USDA and other stakeholders to prepare for this invasive species in case it appears in Massachusetts. As part of the preparation, USDA staff inquired about the Special Local Needs registration process in MA, in case that is needed for the use of insecticide products as part of an effort to control and/or eradicate an invasion. Moore asked if there has been an invasion of this species in MA in the past. LaScola noted that a single dead Spotted Lantern Fly had been found on an imported nursery plant from PA in late 2019. No live insects have been found yet. Program staff in the invasive species program is very active on this front to prepare for a potential appearance of this insect in MA. In context of invasive species, Berman brought up that USDA released an updated manual on the Emerald Ash Borer. The updates included an assessment that the Emerald Ash Borer (EAB) eradication is deemed almost unsolvable and therefore this species may be delisted later this year. Keleher noted that there had been shifting in funding to modify control strategies for EAB.

MOTION TO ADJOURN THE MEETING

It was moved, seconded and passed unanimously.

VOTED
To adjourn the April 28, 2020 Subcommittee Meeting.
Moved: Berman
Second: Keleher
Approved: 5-0
Meeting adjourned at 9:40 a.m.