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TO: PESTICIDE REGISTRATION AND EVALUATION COMMITTEE

SUBJECT: ACTIVE INGREDIENTS PRIORITIZED FOR HUMAN HEALTH RISK ASSESSMENT INITIATION

On September 20, 2013, the Department of Pesticide Regulation (DPR) sought input from the Pesticide Registration and Evaluation Committee (PREC) on pesticide active ingredients (AIs) to be prioritized for risk assessment initiation and initiated. The process was initiated at the PREC meeting on that date. Members of the PREC and other interested parties were asked for their suggestions of AIs to be considered for addition to the list of AIs to be prioritized for risk assessment initiation.

The Risk Assessment Prioritization Work Group (RAPWG) was reconvened to carry out this process that would result in a ranked list of 10 AIs. The RAPWG is made up of two senior scientists from DPR's Medical Toxicology Branch (supervising risk assessment and toxicology data review), two senior scientists from the Worker Health and Safety Branch (supervising exposure assessment and pesticide illness reporting), and a senior scientist from the Environmental Monitoring Branch, as well as one senior scientist from the Air Resources Board (ARB) and one from the Office of Environmental Health Hazard Assessment (OEHHA).

Suggestions were received for 10 AIs, so there was not a need to reduce the number of AIs to 10, only to rank them. The list of 10 AIs, along with a brief description of each chemical, was sent to the members of the RAPWG for ranking. The brief descriptions are at the end of this notice. The ranking scores were tallied and a list of the composite ranking of the 10 AIs are:

1. Mancozeb
2. Paraquat dichloride
3. Dimethoate
4. Iprodione
5. Propylene oxide
Ziram
7. Glufosinate Ammonium
8. Cypermethrin
9. Glutaraldehyde
10. PCNB



There will be a 30-day public comment period. Submitted comments will be reviewed, and a final ranking will be generated. This list will be transmitted to DPR management for approval. DPR will then publish the final list and ranking on its web site.

Any comments must be submitted on or before February 17, 2014. Please send your comments by email to: <jay.schreider@cdpr.ca.gov>.

Cypermethrin

Cypermethrin is a pyrethroid insecticide. It is primarily used for structural pest control. Approximately 45,000 pounds out of a total of approximately 49,000 pounds were reported used for structural pest control in California in 2011. Approximately 22,000 pounds of S-cypermethrin were reported used on crops, primarily alfalfa. USEPA has classified cypermethrin as a Group C, possible human carcinogen. The primary toxicity concern, as with most pyrethroids, is for neurotoxicity caused by disruption of nerve conduction. DPR's Pesticide Illness Surveillance Program (PISP) shows an increase in illness reports over the time period of 2006-2010.

Dimethoate

Dimethoate is an organophosphate insecticide. Approximately 270,000 pounds were reported used in California in 2011 on a variety of crops including cotton, alfalfa, corn, tomatoes and wheat. USEPA has classified dimethoate as a Group C, possible human carcinogen. The primary toxicity concern for dimethoate is for neurotoxicity. This concern is heightened by dimethoate's low NOELs for neurotoxic effects.

Glufosinate Ammonium

Glufosinate ammonium is an herbicide used on a variety of crops, including almonds, grapes, pistachios, walnuts, and rights of way. A total of approximately 740,000 pounds were reported used in California in 2011. USEPA has classified glufosinate ammonium as not likely to be a human carcinogen. The primary toxicity concerns are developmental toxicity and neurotoxicity, with relatively low NOELs demonstrated in several animal studies. The effects include, but are not limited to increased fetal mortality in a rat developmental toxicity study, altered electrocardiograms and mortality in a chronic dog study, brain morphometric changes in a rat developmental neurotoxicity study, and retinal atrophy and behavioral alterations in a rat neurotoxicity study.

Glutaraldehyde

Glutaraldehyde is a disinfectant with approximately 126,000 pounds reported used for industrial water disinfection in 2011. Approximately 1,282,000 pounds were reported sold in California in 2011. The difference is due to the preponderance of non-industrial/agricultural uses, which

would not require use reporting. Currently, 125 products are registered in California, all with disinfectant uses. USEPA has classified Glutaraldehyde as not likely to be a human carcinogen. Glutaraldehyde is corrosive to eyes and skin and is a sensitizer. PISP reports a total of 375 illness cases in the period 1992-2010 (most of which involved irritation to eyes and mucous membranes). Oral animal studies have resulted in non-neoplastic lesions of the respiratory tract and stomach. Inhalation studies have resulted in pathological alterations of the nasal and respiratory tracts.

Iprodione

Iprodione is a fungicide used primarily on almonds, lettuce, carrots, peaches, and onions. Approximately 353,000 pounds were reported as used in 2011. USEPA has classified iprodione as likely human carcinogen due to liver tumors in mice and testicular (Leydig cell) tumors in rats. It is identified under Proposition 65 as known to the state to cause cancer. In addition, various animal studies have shown pathological changes in male sexual glands as well as perturbations of testosterone.

Mancozeb

Mancozeb is a fungicide used on a wide variety of crops including apples, grapes, landscape maintenance, lettuce, onions, pears, potatoes, tomatoes and walnuts. Approximately 1,045,000 pounds were reported used in 2011. Mancozeb is a “hazardous air pollutant” and is administratively listed as a toxic air contaminant. USEPA has classified mancozeb as a probable human carcinogen, and it is identified under Proposition 65 as known to the state to cause cancer. Mancozeb is an ethylene bisdithiocarbamate (EBDC) fungicide. EBDCs degrade to ethylenethiourea (ETU) which is primarily responsible for the potential carcinogenic, developmental, and thyroid effects. USEPA has examined these ETU-related effects in detail. In some recent open literature studies, scientists have raised questions regarding a connection between mancozeb exposure and Parkinson’s disease and regarding the potential effects from exposure to manganese.

PCNB

Pentachloronitrobenzene (PCNB) is a low-use fungicide in California, with less than 25,000 pounds applied per year. It is used primarily on Brussels sprouts and nursery grown ornamental plants. PCNB is moderately volatile, is identified as a “hazardous air pollutant,” and is administratively listed as a toxic air contaminant. USEPA classifies PCNB as a possible human carcinogen. The carcinogenicity concern is based on rat liver and rat thyroid tumors. While overall use may be low, there is concern regarding air levels that may be present at the sites of use. DPR has done some screening air modeling of the largest applications documented in pesticide use reports and assuming that 100% of the amount applied is released to the air. These

worst-case air concentrations may be high relative to health screening levels or reference concentrations.

Paraquat dichloride

Paraquat dichloride is a desiccant and herbicide. Approximately 915,000 pounds were reported used in 2011. The primary crops were alfalfa, almonds, cotton, and grapes. Paraquat is highly acutely toxic. Subchronic and chronic toxicity studies in rats, dogs, and mice showed lesions in the lungs, kidneys, and eyes, with the lungs being the primary target organ.

Propylene Oxide

Propylene oxide is a fumigant with food and non-food uses. A total of approximately 422,000 pounds were reported used in 2011. USEPA has classified propylene oxide as a probable human carcinogen, and it is also listed under Proposition 65 as known to the state to cause cancer. Propylene oxide is identified as a “hazardous air pollutant,” and is administratively listed as a toxic air contaminant. Animal studies have indicated developmental effects in the rat and rabbit (increased minor skeletal variations) and oncogenic effects (forestomach tumors in rats, hemangiomas and hemangiocarcinomas in mice).

Ziram

Zinc dimethyldithiocarbamate (Ziram) is a fungicide with a total of approximately 799,000 pounds reported used in 2011, primarily on almonds, nectarines, and peaches. Ziram is also used as a preservative in adhesives, caulks, sealants, latex paint, etc. USEPA has classified ziram as being “suggestive of carcinogenicity in humans based on the occurrence of hemangiomas and, possibly, preputial gland adenomas in male CD and F344 rats, respectively.” There is some evidence of reproductive effects (decreased body weight in pups) and evidence of decreased body weight gain in several animal studies. Ziram is a severe eye irritant and a moderate skin sensitizer. The primary target organs are the thyroid, nervous system, and liver.