Note to Reader
Endosulfan: Request for Additional Information on Usage and Availability of Alternatives
November 16, 2007

Dear Reader:

The purpose of this document is two-fold: 1) to summarize the updated human health and ecological effects risk assessments for endosulfan, and: 2) to solicit public comment on EPA's analysis of endosulfan usage information since the 2002 Reregistration Eligibility Decision (RED) and its preliminary determinations regarding endosulfan's importance to growers and availability of alternatives. The updated human health and ecological effects risk assessments and updated usage/alternatives information is being released for a 60-day public comment period, running from November 16, 2007 to January 16, 2008.

Background

Endosulfan is a broad spectrum contact insecticide and acaricide registered for use on a wide variety of vegetables, fruits, cereal grains, and cotton, as well as ornamental shrubs, trees, vines, and ornamentals for use in commercial agricultural settings. Endosulfan is formulated as a liquid emulsifiable concentrate and a wettable powder. There are currently three endosulfan registrants: Makhteshim-Agan of North America, Makheteshim Chemical Works, Ltd., and Drexel Chemical Company. Bayer CropScience recently cancelled all U.S. registrations of endosulfan products, effective July 16, 2007.

In its 2002 Reregistration Eligibility Decision, EPA identified use of endosulfan to pose dietary, occupational, and ecological risks of concern. However, the Agency determined that these risks could likely be mitigated to levels below concern through the deletion of use on five crops (grapes, pecans, spinach, succulent peas, succulent beans) and changes to pesticide labeling and formulation. Accordingly, EPA concluded that endosulfan was eligible for reregistration provided that: (1) additional required data were submitted by the registrants confirming this decision; and (2) the risk mitigation measures outlined in the RED were adopted, and label amendments made to reflect these measures.

Human Health Assessment

EPA's updated assessment of the potential human health effects of endosulfan is based on the review of a recently submitted developmental neurotoxicity (DNT) study, which was required in the 2002 Endosulfan RED.

Occupational Risks

Based on the toxicological effects observed in the DNT, the Agency selected a different endpoint than the one used in the 2002 RED assessment to evaluate short- and intermediate-term dermal exposure for occupational handlers. The updated occupational assessment for endosulfan indicates short- and intermediate-term risks for mixers, loaders, and applicators for the majority of uses, even with maximum Personal Protective Equipment (PPE) and engineering controls. In addition, postapplication risks are such that the majority of reentry intervals (REIs) would need to be extended by several to multiple days.

Dietary Risks

In the 2002 RED assessment, the Agency retained a 10x FQPA safety factor for the dietary assessment due to database uncertainties. As the post-RED submission and review of a developmental neurotoxicity study (DNT) and a subchronic neurotoxicity study address residual uncertainties for pre- and /or post-natal toxicity, EPA reduced the FQPA safety factor in its updated assessment from 10x to 1x. Based on the new assessment, the combined dietary (food and drinking water) does not exceed the Agency's level of concern for both acute and chronic exposures.

One area of uncertainty, however, regarding the Agency's assessment of dietary risk is the potentially unique risk-exposure scenario for indigenous, subsistence fishers/hunters because of the uncertainty in the potential for endosulfan to bioaccumulate. As specific residue data in/on commodities consumed in subsistence diets (e.g., fish, polar bear, walrus, caribou, moose) are not available for endosulfan, risk estimates for these population subgroups have not been evaluated by the Agency. However, based upon the detection of endosulfan in areas distant from use sites, such as the Arctic, and its potential to persist and bioaccumulate, the Agency has concerns for dietary exposure of indigenous populations to endosulfan.

Residential Risks

As there are no residential uses of endosulfan, the Agency did not include residential risks in its aggregate assessment of this chemical.

Ecological Risks

EPA has updated the ecological effects assessment for endosulfan based on studies required in the 2002 RED and on additional information drawn from the published literature on endosulfan bioaccumulation, persistence, monitoring and transport, and ecological incidents. In general, the new information suggests that parent endosulfan and its sulfate degradate may pose greater risks than the 2002 RED outlined. Additional studies on the sulfate degradate of endosulfan demonstrate its equal toxicity and increased persistence as compared to endosulfan parent. While the parent may readily undergo degradation under some environmental conditions, the sulfate degradate is

persistent and represents an additional source for total endosulfan residues to enter aquatic and terrestrial food chains. While endosulfan is not expected to biomagnify appreciably in aquatic food webs, the compound does bioconcentrate in aquatic organisms to a significant extent. Also, there is direct evidence (measured residues) that endosulfan bioaccumulates in terrestrial systems and indirect evidence (modeling) that endosulfan has a significant potential to biomagnify in certain terrestrial food webs.

EPA also continues to be concerned about endosulfan's volatility and its ability to migrate to sites distant from use areas. Endosulfan has been found to migrate over long distances through various environmental media such as air, water, and sediment. The occurrence of endosulfan in regions such as the Great Lakes, the Arctic, and mountainous areas is well documented. Once endosulfan is applied to crops, it can either persist in soil or dissipate from the site of application through several physical, chemical, and biological processes. Recent studies suggest that residues of endosulfan volatilize and continue to recycle in the global system through a process of migration and dry/wet deposition in the northern Hemisphere.

In addition to EPA updating its work on endosulfan, Canada, California, and international bodies are reviewing issues associated with endosulfan. EPA and its regulatory partners, Canada Pest Management Regulatory Agency (PMRA) and California Department of Pesticide Regulation (DPR), have been keeping each other informed on recent developments in their assessments of endosulfan. On October 16, 2007, Canada's PMRA released a *Preliminary Risk and Value Assessment of Endosulfan* for a 60-day comment period. In this Re-evaluation Note, PMRA has proposed that endosulfan meets the four criteria for a Track 1 substance under the Toxic Substances Management Policy, which calls for virtual elimination of these substances. California's DPR released a draft risk assessment in July 2007 for public comment. The European Commission (EC) has proposed that endosulfan be evaluated in a more detailed risk assessment to determine whether it should be listed as a Persistent Organic Pollutant (POP) under the Stockholm Convention on POPs, which prohibits most production and use of listed substances on a global basis. In addition, all uses of endosulfan are to be cancelled in the European Union for environmental risk concerns by the end of 2007.

The Agency anticipates working with national and international authorities to further characterize endosulfan in terms of persistence, bioaccumulation potential, toxicity, and the potential for long range transport.

Usage and Alternatives

EPA has updated its endosulfan usage information since the 2002 RED and has made preliminary determinations regarding endosulfan's importance to growers and the availability of alternatives. In general, endosulfan appears to provide low benefits for producers of many crops and moderate to high benefits for some crops in certain regions of the country.

Questions

The Agency is providing the following questions to help the public in preparing comments. Please provide as much detail and documentation in your comments as possible.

(1) Do you agree with the Agency's selection of a new endpoint to evaluate short- and intermediate-term dermal exposure for occupational handlers in the updated human health assessment? If not, why not? Please explain.

(2) Do you agree with the Agency's reduction of the FQPA safety factor from 10x to 1x in the updated human health assessment? If not, why not? Please explain.

(3) What information is the public aware of regarding endosulfan residues in/on commodities consumed by subsistence fishers/hunters? Please provide data and/or sources.

(4) What additional information on endosulfan is the public aware of regarding bioaccumulation, persistence, toxicity, monitoring and transport, and ecological incidents?

(5) What additional endosulfan usage information is the public aware of since the 2002 RED?

(6) What additional alternatives are available for the pests targeted by endosulfan?

(7) For registered uses not addressed in the Agency's usage and alternatives document, what are the pests targeted by endosulfan and what alternatives are available for their control?

(8) What effect would the extended REIs have on the ability of growers to perform the necessary postapplication activities for registered uses?

(9) For which crops, against which pests, and in which regions is use of endosulfan critical and why?