Extension of Conditional Registration of Iodomethane (Methyl Iodide)

Related Information

April 2, 2009 response letter from EPA to Washington State (16 pp, 1.3M, About PDF)
January 29, 2008 letter from Washington State to EPA (13 pp, 736K, About PDF)
February 3, 2009 letter from scientists to EPA (PDF) (1 pp, 68K, About PDF)
April 6, 2009 response letter from EPA to scientists (PDF) (3 pp, 3M, About PDF)
May 8, 2008 letter from scientists to EPA (PDF) (17 pp, 1.0 MB, About PDF)
June 4, 2008 response letter from EPA to scientists (PDF) (14 pp, 1.0 MB, About PDF)
September 24, 2007 letter from scientists to EPA (PDF) (5 pp, 234k, About PDF)
September 27, 2007 letter from Assistant Vice President, University of California to EPA (PDF) (4 pp, 209k, About PDF)
October 5, 2007 response letter from EPA to scientists (PDF) (3 pp, 217k, About PDF)

In October 2007, the Agency approved a time-limited (for one year) conditional registration of the soil fumigant iodomethane (methyl iodide) under highly restrictive provisions governing its use. On September 29, 2008, EPA issued new registration notices converting the one-year time-limited registrations to conditional registrations. All provisions governing its use and the conditions of registration were maintained. The conditions of registration were to ensure that the iodomethane registrant makes all changes to the iodomethane labels that are appropriate to ensure that all the fumigants are regulated in a consistent manner, when the reregistration process for the existing soil fumigants was concluded. The reregistration process has now concluded, as discussed below, and the registrant of Iodomethane will be required to submit label changes for each iodomethane product within the same timeframe imposed on other soil fumigant registrants for similar label changes.

Iodomethane is a methyl bromide alternative that can be used as a pre-plant soil fumigant to control:

- plant pathogens,
- nematodes,
- insects, and
- weeds.

Iodomethane can be used to control these pests on crops and plants such as strawberries, tomatoes and peppers, ornamentals, turf, trees, and vines.

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- Stringent Protection Measures
- Thorough Risk Assessment Process
- Peer-Reviewed Science and Technology
- Revised Human Health Risk Assessments
- Docket Information on Iodomethane

Mitigation Measures Protect Workers and the Public

EPA granted approval of iodomethane with conditions on the registration and mitigation measures to protect handlers and bystanders.

Conditions of Registration

The registrant agreed to the following conditions for registration: (1) to provide a training/stewardship program using criteria agreed with the Agency; (2) to satisfy any additional data requirements and to add any additional risk mitigation as required by the Agency once the Agency made a decision for the soil fumigant group, and to submit label amendments for each iodomethane product within the same timeframe imposed on other soil fumigant registrants for similar label amendments. (See update under Risk Management Decisions for Other Soil Fumigants.)

Risk Mitigation

1. End use products are classified as restricted use.

2. Buffer zones are specified on product labels. The buffer zones provide flexibility based on several factors such as application rate, field size, application method, type of tarp, and soil characterization. The buffer zones are as follows:

Application Rate (lb a.i./treated acre)	Size Of Contiguously Treated Area (acres)	Buffer Zone Distance in Feet If HDPE* or LDPE** Tarps are Used
175 (max)	>20 to 40	500
	>10 to 20	300
	>5 to 10	100
	Up to 5	50
131 (75%)	>20 to 40	375
	>10 to 20	225
	>5 to 10	75
	Up to 5	40
88 (50%)	>20 to 40	250
	>10 to 20	150
	>5 to 10	50
	Up to 5	25
44 (25%)	>20 to 40	125
	>10 to 20	75
	>5 to 10	25
	Up to 5	25

*High Density Polyethylene **Low Density Polyethylene

3. Buffer zone reductions of 10% each are allowed for applications where flat fume fumigation is used, when high barrier films are used, and the soil has an organic matter content of greater

than or equal to 3. The buffer zone for applications utilizing all 3 credits can be reduced by 30%. However, the minimum buffer zone is always 25 feet regardless of credits.

4. Application sites must be limited to = 40 acres/day, and the buffer zone of the field to be treated field cannot overlap the buffer zone of another field treated within the last 48 hours.

5. The certified applicator is responsible for establishing the buffer zone, ensuring that workers or bystanders do not enter the buffer zone for 48 hours following the end of the application. An exception will be allowed for transit through the buffer zone, e.g.; < 15 minutes for roads and vehicle passage ways where transit is unavoidable.

6. Currently, all certified applicators are required to maintain records related to their use of restricted use pesticides. In addition, for iodomethane, certified applicators must maintain records that demonstrate the method of buffer zone calculations, buffer zone size, how applications met sensitive site requirements, and how occupied structures were handled.

7. Use within ¼-mile of any occupied sensitive site such as a school, day care facility, nursing home, hospital, prison, or playground is prohibited.

8. Certified applicators must be on site within the line of sight of the field during application.

9. The registrant is instituting a training/stewardship program for certified applicators. Product labels require that the certified applicator must complete the registrant's training program and be certified by Arysta before using the iodomethane product. Sale of iodomethane will be limited to certified applicators that have completed the registrant's training and certification program.

10. The entry restricted period is five days.

11. Tarp monitors, shovelers, tractor drivers and co-pilots must wear a respirator that meets standards specified by the Occupational Safety and Health Standards Agency (OSHA). In addition, respirator users must be trained using a program that conforms to OSHA requirements and must be examined by a qualified medical practitioner to ensure physical ability to safely wear a respirator. Tractor drivers and co-pilots will have the option of using a ducted fan/blower in lieu of the respirator.

12. Non-handler entry is prohibited while tarps are being removed.

One of the Most Thorough Risk Assessment Processes Ever Completed by the Agency

EPA based its decision to approve the registration of iodomethane on risk assessments conducted over four years. On several occasions, the Agency required the applicant to generate additional data to address uncertainties resulting in one of the most thorough analyses ever completed by the Agency for a pesticide registration action. It incorporates state-of-the-art methods and extensive chemical-specific toxicology and exposure data.

The Agency reviewed over 50 chemical-specific studies for this assessment. The toxicity database includes studies on mutagenicity, cancer, birth defects, reproductive effects, neurotoxicity, and respiratory effects.

The potential for iodomethane to cause cancer has been evaluated. The only evidence of carcinogenicity following exposure to methyl iodide was related to thyroid cancer, and was attributable to the effects of the chemical on thyroid homeostasis similar to what is seen with other non-mutagenic iodinated compounds. The dose-response for these effects was considered in the risk assessments, and the exposures expected from this use are well below those that would cause thyroid effects leading to cancer. Based on this evaluation, the Agency concluded that there are adequate safety margins and these endpoints do not pose risks of concern.

Peer-Reviewed Science and Technology Applied to Assessing Risk

EPA's risk assessments employed a new and highly sophisticated, predictive biological model to translate iodomethane effects in test animals to humans. The Agency also estimated potential bystander exposure using a model that determines air concentrations to which individuals could be exposed at various distances around treated fields. These models have undergone extensive review. The air model was reviewed by the FIFRA Scientific Advisory Panel in 2004 and utilizes basic concepts that have served as the basis for Agency air permitting for many years.

The Agency has collected extensive information on potential human exposure, including studies on workers under actual field conditions involved in the application of iodomethane. EPA paid particular attention to potential exposures of those who live, work, or spend time in areas close to fields where iodomethane might be used. These data served as the basis for the evaluation of possible exposures to iodomethane in the general population (e.g., in homes, schools, and other locations near treatments) and were used to develop specific restrictions to protect bystanders. The Agency also evaluated the probability of being exposed to concentrations that could possibly lead to adverse health effects and found that those levels would not be reached under the stringent use conditions that will be imposed.

Risk Management Decisions for Other Soil Fumigants

In May 2009 , EPA concluded its reevaluation of a group of registered soil fumigants and issued Amended Reregistration Eligibility Decisions (REDs) for these pesticides, including:

- methyl bromide,
- metam sodium/potassium,
- dazomet, and
- chloropicrin.

Another soil fumigant, 1,3-dichloropropene (telone), was included in EPA's reevaluation for comparison purposes, but its reassessment was completed in 1998 and no regulatory changes are required in 2009.

In accordance with the process established in the iodomethane registration decision, now that the Agency has established the final risk mitigation measures and other reregistration requirements for the soil fumigant pesticides (including the timelines for the revision of the existing labels), the iodomethane registrant will be required to make all changes to the iodomethane labels that are appropriate to ensure that all the fumigants are regulated in a consistent manner. The registrant will be required to submit label changes for each iodomethane product within the same timeframe imposed on other soil fumigant registrants for similar label changes.

Further Review of Iodomethane and Other Soil Fumigants

As has been emphasized for the chemicals undergoing reregistration in the soil fumigant group, EPA's process is designed to ensure that pesticides continue to meet stringent health and safety standards, and this emphasis will continue in the Registration Review process.

New technologies to reduce emissions are emerging and new data are expected to improve the understanding of the factors that affect fumigant emissions. Thus, EPA plans to initiate registration review for the soil fumigants in 2013, four years earlier than previously planned.

This will allow EPA to consider new data and technologies sooner and to determine whether the mitigation required in the reregistration decisions for the soil fumigant group is effectively addressing the risks, as EPA believes it will, or if additional mitigation is needed.

In the case of iodomethane, EPA has recently completed a new human health risk assessment for iodomethane that evaluates the data that were collected in three field-scale emissions studies (from Georgia, Florida, and Michigan) that were completed under the last Experimental Use Permit. In these emissions studies, metalized and virtually impermeable films were used along with reduced application rates and a proprietary programmable application control system (Symmetry), which was developed by the registrant. Overall emissions were significantly reduced compared to typical practices which were quantified in previous iodomethane emissions studies.

Changes are likely to be made to the iodomethane labels in the near term to include consideration of these new data and application practices.

Information on Iodomethane in Dockets at Regulations.gov

FIFRA Scientific Advisory Panel

Pesticides not Requiring a Tolerance or an Exemption from Tolerance

Protection of Stratospheric Ozone: The 2008 Critical Use Exemption From the Phaseout of Methyl Bromide (docket includes an iodomethane evaluation)