



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 13 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PESTICIDE REGULATION (PR) NOTICE 95-4

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS
AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible For Registration of Pesticide Products

SUBJECT: Regulatory Status of Methyl Bromide and Priority Review of Methyl Bromide Alternatives

This notice is to inform registrants, producers, and users of methyl bromide about the Environmental Protection Agency's (EPA) policies and obligations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the U.S. Clean Air Act (CAA), and the Montreal Protocol to regulate methyl bromide. It is also intended to inform registrants of EPA's commitment to giving priority review to methyl bromide alternatives, consistent with the Agency's reduced risk initiative.

I. BACKGROUND

EPA regulatory changes will affect the continued availability of the pesticide methyl bromide, which is subject to regulation as an ozone depleting chemical under the CAA and as a pesticide under FIFRA. Action is also being taken under the Montreal Protocol, an international agreement on ozone depletion issues.

A. Status of Methyl Bromide Under FIFRA

Methyl bromide is a broad spectrum fumigant used against insects, fungi, bacteria, nematodes and weeds in soil, structural, and commodity/quarantine fumigation. Major commodities for preplant soil treatments are strawberries, tomatoes, peppers, eggplant, tobacco



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and ornamentals. Durable food commodities such as grain, coffee beans and nuts, as well as perishable food commodities, mainly fruits and vegetables, are fumigated predominantly to control insect pests. Forestry products, cut flowers, warehouses, railroad cars, grain mills, and domestic dwellings may also be fumigated.

As a pesticide, methyl bromide must be registered by EPA under FIFRA. Registration is intended to ensure that a pesticide, when used according to label directions, will not have unreasonable adverse effects on people or the environment. Registration entails the submission of data on the characteristics of a pesticide and its health and environmental effects, an assessment of risks and benefits, and a review of product labeling for adequacy.

Currently there are three major producers of methyl bromide and nearly 100 products registered for soil, structural, and commodity/quarantine fumigation. Because of its toxicity to humans and non-target organisms, methyl bromide is a restricted use pesticide, to be used only by trained and certified applicators or persons under their direct supervision.

Under FIFRA section 4, methyl bromide must undergo reregistration and the data supporting its registration must be brought up to current scientific standards. If registrants decline to support reregistration by not supplying the necessary data and paying the required fees, the pesticide may be suspended and/or canceled. Methyl bromide is being supported for reregistration, although some uses may be dropped. The last data required from registrants are due in late 1997.

B. Status of Methyl Bromide Under the Clean Air Act (CAA)

Independent of FIFRA reregistration requirements and decisions, methyl bromide is subject to the provisions of the CAA. The CAA, among other things, designates certain chemicals as "class I ozone depleting chemicals," depending upon their scientifically determined "ozone depletion potential" (ODP), a numerical comparison with the ODP of CFC-11 (Freon), which is defined as having an ODP of 1.

The CAA requires that if a chemical has an ODP greater than 0.2, as determined by the Administrator, EPA must add it to the class I list and propose a phase out schedule that eliminates production and importation within seven years. The latest international scientific assessment estimates the ODP of methyl bromide as 0.6. Therefore, under the CAA, EPA is obligated to phase out methyl bromide.

On December 10, 1993, EPA issued a final rule under the CAA that froze production at 1991 levels starting in 1994, makes no interim reductions, but eliminates methyl bromide production and importation by the year 2001. The scientific basis for the rule is supported by a consensus of atmospheric scientists, including experts at the National Aeronautics and Space Administration and the National Oceanic and Atmospheric Administration, as well as experts assembled under the Montreal Protocol. Scientists believe that in the short-term,

bromine from methyl bromide is a more significant ozone depleter than is chlorine from CFC's.

The CAA is more stringent on the phase out of methyl bromide than actions now planned under the Montreal Protocol, as described below. The Montreal Protocol contains an exemption for "essential uses," which allows methyl bromide use to continue in the absence of alternatives. The CAA does not allow for such exemptions. Unlike FIFRA, the CAA does not take into account the weighing of the risks and benefits of methyl bromide use.

C. Status of Methyl Bromide Under the Montreal Protocol

As a signatory of the Montreal Protocol, the United States must also list and regulate a chemical if the international community, through the Montreal Protocol Agreement, determines that it should be regulated. Methyl bromide has been identified by the United Nations Environmental Programme (UNEP) as a significant ozone depleting chemical.

At their November 1992 meeting, the parties to the Protocol listed methyl bromide as an ozone depleter and agreed to freeze production at 1991 levels beginning in 1995, except for quarantine and pre-shipment applications. The parties also agreed to make every effort to reduce methyl bromide emissions and to decide on a general control scheme no later than the 1995 meeting. An international expert assessment team has reviewed methyl bromide issues in preparation for the upcoming meeting this fall.

II. DISCUSSION

Based on the above, production and availability of methyl bromide will be severely restricted in the future. Both the EPA Office of Pesticide Programs (OPP) and the Office of Air and Radiation have urged registrants and users to invest resources in identifying alternatives and ways of recycling or reducing the atmospheric emissions of methyl bromide. The U.S. Department of Agriculture (USDA) has made a major research commitment to finding alternatives to methyl bromide.

A. Methyl Bromide Alternatives Task Force

EPA has established a Methyl Bromide Alternatives Task Force comprised of representatives of the Office of Pesticide Programs, with active participation from the Office of Air and Radiation and EPA Region 9. The mission of this Task Force is to coordinate FIFRA, CAA and Montreal Protocol activities and to work with USDA, commodity groups, and others to give priority to the development, registration, and adoption of alternatives to methyl bromide, including both chemical and non-chemical pest control strategies. Members of the Task Force also meet quarterly with representatives of the U.S. Department of Agriculture concerned about methyl bromide alternatives development.

B. Opportunities to Replace Methyl Bromide

EPA recognizes the technical challenges to replacing methyl bromide. No one alternative will likely replace the wide array of uses that methyl bromide currently covers. Methyl bromide users need to prioritize key uses for research purposes so that alternative pest control methods can be found.

EPA intends to take an active role in managing the regulatory process for the development of suitable alternatives to methyl bromide use. There are several possible mechanisms for replacing methyl bromide, or reducing its use. In addition to proposals to expand registration of existing chemicals, registrants and users also need to investigate new use practices (e.g., recycling, capture, better tarping, and improved injection methods), new pesticide active ingredients, new combinations of active ingredients, and non-chemical control methods.

In terms of chemical alternatives to methyl bromide, the practical short-term focus may be on chemicals already registered that have substantially complete data bases. However, a number of potential alternative chemicals may also face regulatory difficulties in the future. Therefore, efforts toward development of less risky alternatives are being encouraged by the Agency through an expedited review process.

C. Priority Review of Methyl Bromide Alternatives

EPA is committed to expediting review of potential methyl bromide alternatives, in particular those judged to be reduced risk alternatives. The Agency will also expedite requests for information about registration of methyl bromide alternatives and all related registration requests.

In order to ensure that registration applications receive expedited review, applicants should include with their submissions a statement of the methyl bromide use sites for which the pesticide represents a potential alternative and a request for expedited review. Where all necessary data have been submitted, EPA will work to ensure that decisions for registration of biological pesticides are made within eight months; decisions on petitions for a new food use of a registered pesticide are made within six months; and decisions on registration of new active ingredients as reduced risk pesticides are made within 12 months. These time frames are consistent with an August 1994 Memorandum of Understanding (MOU) between EPA and USDA, designed to expedite research, development, education, and registration of products which meet key pest control needs. The Agency will work to meet these time frames to the maximum extent possible.

D. Policies on Reregistration and Emergency Exemption Requirements for Methyl Bromide under FIFRA

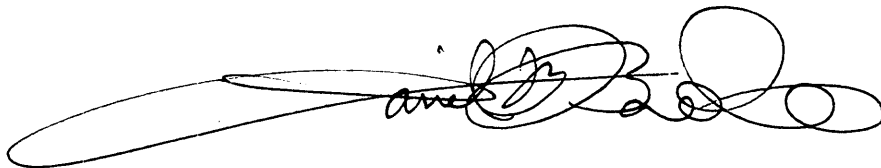
EPA is looking broadly at the possibilities for reducing risks from methyl bromide emissions and fostering development of alternatives in the context of emergency exemption applications under section 18 of FIFRA and its registration and reregistration policies.

On January 13, 1995, OPP issued a memorandum to state pesticide agencies and federal agencies informing them of OPP's position on the continued use of methyl bromide under section 18 of FIFRA. The memorandum states that future emergency exemption requests for methyl bromide must document the steps taken to find an appropriate alternative and include a commitment to pursue work on alternatives as a condition of the requested exemption. These steps may include, but are not necessarily limited to, a summary of the results of completed comparative product performance evaluations of methyl bromide alternatives. Where possible, these studies should include an assessment of the relative economic values of the alternatives tested. EPA believes these requirements are essential and in the best interest of requestors, given the fact that methyl bromide will not be produced or imported after the 2001 CAA phase out date and, thus, cannot be relied upon to meet future pest control needs.

With respect to reregistration, as noted above, methyl bromide is currently being supported for reregistration and the last data required from registrants are due in late 1997. The Agency must require and process data to evaluate whether methyl bromide is eligible for reregistration under FIFRA, regardless of activities under the CAA or the Montreal Protocol. Therefore, registrants must continue to fulfill reregistration data requirements even though methyl bromide will be phased out by 2001 under the CAA.

III. FURTHER INFORMATION

Questions regarding this notice can be directed to Paul F. Schuda, Chairperson of the Methyl Bromide Alternatives Task Force, at (703) 305-7565 or Tracy Perry of the Policy and Special Projects Staff, OPP at (703) 305-7461.

A handwritten signature in black ink, appearing to read 'Daniel M. Barolo', with a long horizontal flourish extending to the left.

Daniel M. Barolo, Director
Office of Pesticide Programs

