

REGISTRATION STATUS OF BARK BEETLE SEMIOCHEMICALS

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ABSTRACT: Tests of the semiochemicals verbenone and 3-methyl-2-cyclohexen-1-one (MCH) are continuing under experimental use permits. It is hoped that results will lead to registration consistent with the Federal Insecticide, Fungicide, and Rodenticide Act and the National Environmental Policy Act and use of these bark beetle semiochemicals as alternatives to conventional chemical pesticides.

INTRODUCTION

A full understanding of the processes leading to the registration of a compound as a pesticide requires the definition of several terms and the placement of them in proper context with their associated laws and regulations. This paper defines terms such as: a pesticide, pesticide research, experimental-use permit, pesticide registration, and exemption in the context of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. It also defines environmental analysis, scoping, categorical exclusion, environmental assessment, and environmental impact statement as related to the National Environmental Policy Act (NEPA). The paper concludes with an update of the registration status of two semiochemicals--verbenone, the antiaggregating pheromone of the mountain pine beetle (MPB), and methylcyclohexenone (MCH), the antiaggregating pheromone of the Douglas-fir beetle (DFB).

FIFRA

FIFRA is a Federal law that was passed by Congress in 1972 and substantially amended in 1974 and 1978. New revisions were considered in 1987 and 1988 but Congress has been unable to reach agreement on new changes to the Act. FIFRA is administered by the U.S. Environmental Protection Agency (EPA) and it provides national guidance for and regulation of the registration, manufacture, transportation, and use of all pesticides (herbicides, fungicides, fumigants, insecticides, rodenticides, etc.). FIFRA defines a pesticide as

any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest (insect, rodent, plant, or other unwanted organism).

Section 3 of FIFRA provides guidance on the data required to register a pesticide. Data gathering is research. Preliminary research or testing is usually done in the laboratory and is called screening for potential pesticidal activity. Later, greenhouse and/or limited outdoor tests are done to further confirm pesticidal activity. While testing is being done to determine the value of a substance for pesticidal purposes, and when applications are on a cumulative total of less than 10 acres, a material is not considered a pesticide and no paperwork under FIFRA is required. However, once an active ingredient is determined to be efficacious and there is an interest in examining its potential for future operational use, then an experimental use permit (EUP) is required.

The purpose of EUP's is to provide EPA some oversight (FIFRA Section 5) during the generation of data necessary to support an application for full registration (FIFRA Section 3). The process is also intended to prevent adverse environmental impact by preventing the indiscriminate use of potentially dangerous materials without the restraint and control of regulatory protocols that prescribe plot size, geographic location, and amount of active ingredient intended to be used under the EUP. When a material is being evaluated for its pesticidal potential on more than 10 acres, EUP's are essential. This goes for conventional chemical pesticides, biologicals, and semiochemicals. Exceptions exist when the Administrator of EPA grants an exemption.

Such was the case in 1987 when EPA, after long negotiations with the USDA Forest Service and Phero Tech, Inc., changed its policy and allowed tree baits, which had previously required registration, to be exempt. EPA has not, however, exempted semiochemicals that are sometimes formulated as beads and used in broadcast applications.

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NEPA

NEPA is a Federal law passed by Congress in 1969 to encourage Federal agencies to conduct their programs in ways that will create and maintain conditions under which people and nature can exist in productive harmony now and in the future. It also requires a systematic, interdisciplinary approach to planning and decision making for

actions that may affect the quality of the human environment. Federal agencies are required to study, develop, and describe appropriate alternatives to proposed courses of action under NEPA.

The process of analyzing a proposed course of action and developing alternatives is called environmental analysis. The method of collecting public input (in terms of issues, concerns, and opportunities) is called scoping. Scoping determines the extent of environmental analysis necessary. The result of these two activities leads to documentation of a decision.

Depending on the nature of a proposed Federal agency project, NEPA documentation may take one of three forms: (1) categorical exclusion (CE), (2) environmental assessment (EA), or (3) environmental impact statement (EIS). Categorical exclusions are reserved for actions that, based on both experience and environmental analysis, will have no significant impact on the quality of the human environment, individually or cumulatively (e.g., administrative road closures, construction of low-impact facilities, repair and maintenance, etc.). It is not a good practice to use CE's for most pesticide-related activities. Environmental assessments are used to document the analysis of an action not categorically excluded from documentation but for which the need for a more extensive environmental impact statement has not been determined. EIS's are comprehensive reviews of factual information that provide a responsible official with all of the information, necessary to make an informed decision. Some EIS's contain risk assessments and worst case analyses when they deal with subjects about which there is scientific uncertainty or unknown information. This is often the case with pesticides.

BARK BEETLE SEMIOCHEMICAL REGISTRATION STATUS

The USDA Forest Service (FS) has pioneered or assisted in pioneering research on the identification and development of several bark beetle semiochemicals. For example, in the early 1970's FS researchers identified, isolated, and synthesized 3-methyl-2-cyclohexen-1-one (MCH), the antiaggregating pheromone of the Douglas-fir beetle. More recently the FS cooperated in the research and development of 4,6,6-trimethylbicyclo (3.1.1) hept-3-en-2-one or verbenone, the antiaggregating pheromone of the mountain pine beetle.

MCH

Initial laboratory testing of MCH by the FS did not require FIFRA paperwork; however, in 1978 the FS requested an EUP from EPA. The EUP was granted (No. 27586-EUP-23) and the FS expects to continue operating under an extension to this EUP until May 1990.

In 1986, the FS, based on data collected under the EUP, requested full registration of MCH. In 1988, EPA notified the FS that additional research was needed. Unable to conduct the necessary research itself, the FS requested input from interested parties in the private sector by advertising in the Commerce Business Daily (June 8, 1988). Four firms expressed interest in production and marketing of MCH and negotiations are in progress to transfer this technology under the auspices of the Stevenson-Wydler Technology Transfer Act. Use of MCH is very limited at present, and no NEPA documents covering use of this compound have been prepared to date.

VERBENONE

Basic research on verbenone has been conducted primarily in Canada at Simon Fraser University and at Phero Tech, Inc.; however, the FS has been an active cooperator in the research and development of this MPB-antiaggregating pheromone. In 1988, Phero Tech, Inc. requested and was granted an EUP (No. 56261) for evaluation of bubble cap (EUP-1) and bead (EUP-2) formulations. These EUP's will serve to facilitate small-scale field studies of verbenone over the next 2 years. Currently the FS is cooperating on a replicated research study in Regions 1, 2, 4, and 6 as described by Amman and others at this meeting. An EA was developed by the Intermountain Research Station for this effort.

It is hoped that, consistent with FIFRA and NEPA, the results of these efforts will lead to the future registration and use of bark beetle semiochemicals as viable alternatives to conventional chemical pesticides.