hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his/her own motion, this determination shall become final and effective September 29, 1995.

Any request for a public hearing shall include the following: (1) the name, address, and telephone number of the individual, organization, or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; and (3) the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

Alabama Department of Environmental Management, Public Water Supply Section, 1751 Congressman W.L. Dickinson Drive, Montgomery, Alabama 36109

Environmental Protection Agency, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30365

FOR FURTHER INFORMATION CONTACT: Philip H. Vorsatz, EPA, Region IV, Drinking Water Section at the Atlanta address given above or telephone (404) 347–2913.

(Sec. 1413 of the Safe Drinking Water Act, as amended (1986), and 40 CFR 141 and 142 of the National Primary Drinking Water Regulations)

Dated: June 27, 1995.

Patrick M. Tobin,

Acting Regional Administrator, EPA, Region 4.

[FR Doc. 95–21283 Filed 8–29–95; 8:45 am]

BILLING CODE 6560–50–P

[OPP–50810; FRL–4972–2]

Lepidopteran Pheromones; Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is expanding the minimum acreage from 10 acres to 250 acres for when an experimental use permit (EUP) is required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for certain biological pesticides. This policy includes the majority of Lepidopteran pheromones, regardless of formulation or mode of application, when used at a maximum use rate of 150 grams active ingredient (ai)/acre/year. Tests conducted on these pheromones under the conditions specified in this notice would not require an EUP at acreages up to and including 250 acres. Tests conducted with other arthropod pheromone products on food crops entering commerce would still require an EUP and a temporary tolerance or exemption from the requirement of a temporary tolerance. Similarly, testing on acreages exceeding 250 acres for all pheromones (food and non-food uses) still requires an EUP.

EFFECTIVE DATE: This policy becomes effective August 30, 1995.

FOR FURTHER INFORMATION CONTACT By mail: Phil Hutton, Product Manager (PM–90), Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor, Crystal Station 1, 2805 Crystal Drive, Arlington, VA, (703) 308–8260, e-mail: hutton.phil@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, in this policy, is providing additional regulatory relief for manufacturers, researchers and developers of certain Lepidopteran pheromones regardless of formulation or mode of application when used at rates less than or equal to 150 grams ai/acre/year. For the purposes of this policy, Lepidopteran pheromones are defined as naturally occurring compounds designated by the unbranched aliphatics (with a chain between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone. This definition encompasses the majority of Lepidopteran pheromones. While other types of chemical compounds have been demonstrated to be Lepidopteran pheromones, the Agency believes the type described here represents not only the majority of Lepidopteran pheromones but also those with the most complete toxicological data base.

Section 5 of FIFRA, 7 U.S.C. 136c, and 40 CFR part 172 provide for issuance by EPA of EUPs for the testing of new, unregistered pesticides or new uses of existing pesticides for product performance and registration purposes. Such permits are generally issued for large-scale testing of pesticides on more than 10 acres. Accompanying a food-use EUP is the requirement that any treated crops be destroyed or a temporary tolerance or exemption from the requirement of a temporary tolerance for residues in or on the crop be in place.

Due to the unique characteristics of pheromones, EPA believes that pheromone products used for food purposes need to be tested at acreages greater than 10 acres and as high as 250 acres to determine the products' value for pesticidal purposes. Many pheromone uses are effective as mating disruptants to the adult insects. Larger test acreages are needed to sufficiently evaluate the disruption of the natural flight range of the adult target insect. An additional factor necessitating larger acreages is the volatile nature of most pheromone compounds. Separate treatments in adjoining small plots is unfeasible, and test plot sizes ranging from 20 to 60 acres are usually required depending upon the nature of the treated site and the pest in question. EPA believes that 250 acres should be sufficient to determine the value for pesticidal purposes of most pheromones.

I. Background

Biochemical pesticides are naturally occurring substances that elicit pesticidal effects by a nontoxic mode of action to the target pest. A pheromone is defined by EPA as a compound produced by an arthropod (insect, arachnid, or crustacean) that modifies the behavior of other individuals of the same species (40 CFR 152.25(b)(1)). Lepidopteran pheromones (a subset of arthropod pheromones) are those produced by a member of the order Lepidoptera, which includes butterflies and moths. One physical-chemical feature common to all these compounds is their volatility which is the basis for the signalling and homing mechanism. The Agency has registered 17 arthropod pheromones active ingredients, 11 of which are Lepidopteran pheromones.

The Agency recognizes that pheromones are inherently different from conventional synthetic pesticides in their nontoxic pesticidal mode of action, low use rate, and target species specificity, and is employing various measures to facilitate their development and ultimate registration. In January 1994, EPA expanded the minimum acreage required for an EUP to 250 acres for arthropod pheromones in polymeric matrix dispensers with an annual application rate limitation of 150 grams/acre (59 FR 3681; January 26, 1994). The following July, EPA broadened the regulatory scope of the EUP minimum acreage limit to include broadcast applications and sprayable formulations of non-food uses of arthropod pheromones (59 FR 34182; July 7, 1994). EPA is now in the position to broaden

the scope even further by including food uses of broadcast or sprayable applications of Lepidopteran pheromones under certain conditions outlined in this notice. It is important to note that this policy is only applicable to Lepidopteran pheromone products where the pheromone(s) is the sole active ingredient(s). Lepidopteran pheromone products formulated to include non-pheromone pesticide active ingredients, and non-lepidopteran pheromone products still require an EUP, when the treated area exceeds 10 acres and the formulation does not utilize a retrievable matrix.

II. Risk Considerations

A. Ecological Effects

In regard to nontarget organism effects, the risks from broadcast applications to crop lands should not be greater than from forestry or other non-crop use if the same environmental hazard restrictions apply. Experimental use of broadcast applications are limited to terrestrial use only and experimental application does not include use in or around marshes, swamps, rivers, streams, ponds, lakes, estuaries, flood plains, or drainage ditches, nor should the product be allowed to wash or drain into water. Low rates of experimental application, high volatility, limited acreage, and the current extent of knowledge indicating generally low orders of toxicity are all justifications to overcome potential increased risks to nontarget organisms due to exposure to foliar residues. The Agency has previously determined that exposure to wildlife will be minimal when release of the pheromone is confined to experimental purposes only and applications are limited to a maximum of 150 grams ai/acre/year on a maximum of 250 acres.

B. Human Health

The need for further regulatory relief above that provided for non-food uses prompted the Agency to reconsider the human dietary exposure for broadcast applications. In its previous policy notice, EPA was not able to make a no unreasonable adverse effects finding for arthropod pheromone pesticides for use on food crops because of insufficient data on the levels of exposure from pheromones applied in a broadcast manner. For pheromone products, especially those directly applied to food, one problem has been a lack of subchronic toxicity studies and an estimate of the actual pheromone residues occurring with use. The Agency has contended that sprayable formulations or other modes of application of pheromones to raw agricultural commodities had the potential to increase the likelihood of human dietary exposure. The Agency, at this time, still does not have adequate data to support the inclusion of all uses of arthropod pheromones in its EUP policy. It does possess enough information, however, to include the straight-chained Lepidopteran pheromones, a significant subset.

Human health concerns arise for any experimentally treated crops that may enter the food supply. From the data submitted, the Agency was able to conclude that the potential for residues from Lepidopteran pheromones, as described in this notice, is not a dietary hazard. This conclusion is based on: (1) The low acute toxicity seen in the data review of the Lepidopteran pheromones registered to date; (2) the known metabolism of long-chain fatty acids that predicts these compounds would be metabolized either by beta-oxidation yielding a series of paired carbon losses or by complexing with glucuronide and excretion by the kidneys; and (3) low exposure subsequent to application from product aging, volatilization, and the results of the field residue studies. Elsewhere in this issue of the **Federal Register**, EPA is proposing an exemption from the requirement of a permanent tolerance for these straight-chained Lepidopteran pheromones under the Federal Food, Drug, and Cosmetic Act.

The Agency has found that given the generally low expected toxicity and high volatility of arthropod pheromones, an upper limit of 150 grams ai/acre/year is adequate for testing the Lepidopteran pheromone product performance while still protecting the public health, nontarget organisms and the environment from unreasonable risks. These application rates encompass the majority of pheromone uses seen by the Agency to date.

III. Conclusion

Today's notice sets forth that for food uses of the majority of Lepidopteran pheromone pesticides, regardless of formulation or mode of application, EPA is permitting the acreage expansion from 10 to 250 acres for experimental testing at a maximum use rate of 150 grams ai/acre/year before triggering the requirement of an EUP under FIFRA. For the purposes of this policy, Lepidopteran pheromones are defined as naturally occurring compounds which are unbranched aliphatics (with a chain between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the carbon chain. Synthetically produced compounds that are identical to a known Lepidopteran pheromone as described above, and those that differ only in that their molecular structures are stereochemical isomers (or ratios of such isomers) also are included in this notice. The Agency contends, that for experimental uses involving food crops and all other non-aquatic uses, this change in policy provides significant flexibility to determine product efficacy without resulting in significant risk to human health or the environment due to the active ingredient's low use rate, high volatility, and lack of dietary exposure. Upon meeting the above conditions, the Agency has determined that pheromones of the type described do not present an unreasonable adverse effect to human health or the environment due to unlikely exposure.

The above policy applies to only the experimental phase of pheromone product development and not to registration of the product. The intent of this regulatory relief policy is to permit adequate conditions for practical research and development, while protecting the food supply and nontarget species from higher pheromone levels than occur naturally. The current set of studies listed in 40 CFR 158.690 are still required for the registration and sale of the final product.

With the implementation of this policy, EPA hopes to encourage the development and use of environmentally acceptable biological pesticides as alternatives to more toxic conventional synthetic chemical pesticides. The aim is to ease the testing requirements of these products, to speed their market entry, and promote their integration into pest management strategies.

List of Subjects

Environmental protection, Experimental use permits.

Dated: August 18, 1995.

Janet L. Andersen,

Acting Director, Biopesticide and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 95–21038 Filed 8–29–95; 8:45 am]

BILLING CODE 6560–50–F