§4-66-45 Experimental use permits; generally.

Experimental use permits may be issued for the intrastate shipment, delivery or use of a pesticide product that is to be tested further to determine the scope and limitations of its usefulness and the effect of its use on humans and the environment.

Permits may be

issued for products for use in experimental programs under the supervision of applicators certified in demonstration and research pest control and broad scale testing under normal conditions of use.

The head may

require the information and data concerning the product and the proposed testing program that is deemed necessary to make determinations on the merits of the proposals. [Eff 7/13/81; am and comp 12/16/06; am and comp

] (Auth: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §\$172.20 to 172.26) (Imp: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §\$172.20 to 172.26)

§4-66-46 Experimental use permits; prohibitions.

No permits shall be issued for any of the following:

- (1) A product containing an active or inert ingredient that is currently subject to an EPA cancellation or suspension of registration order, or that is currently subject to an EPA notice of intent to suspend or cancel registration because of human health, environmental, or efficacy consideration; except that a permit may be issued for such a product for a purpose or in a formulation that:
 - (A) Is not specifically considered in, or that is not subject to, suspension or cancellation proceedings, after consultation with appropriate EPA officials; or
 - (B) Was specifically considered during the proceedings but not suspended, canceled, or subject to a notice of intent to suspend or cancel.
- (2) A use of a product that has been the subject of a notice of denial of registration under FIFRA; and
- (3) A use of a product, which may involve use in or on food or feed other than as authorized in section 4-66-47. [Eff 7/13/81; am and comp 12/16/06; am and comp] (Auth: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.24) (Imp: HRS §\$149A-19, 149A-22, 149A-33;

\$4-66-47 Experimental use permits; exceptions. Upon written notification of the head, no experimental use permit is required for the intrastate shipment or use of a substance or mixture of substances being put through laboratory, enclosed space production, or limited field trials of less than one-fourth acre, in which the following three criteria have been met: (1) the purpose of the laboratory, enclosed space production, or limited field trials is to determine the value of a substance or mixture of substances as a pesticide or to determine its toxicity, or other properties; (2) the tests will be conducted by recognized research personnel; and (3) the research personnel conducting the tests do not expect to receive any benefit, other than the research, in pest control from the use of the substance or mixture of substances.

If these three criteria are met, the substances or mixture of substances are not considered to be pesticides within the meaning of the Act or these rules. No State experimental use permit is required if an experimental use permit has been issued by the EPA for the proposed trial(s).

Written notification shall be submitted on forms prescribed by the head. [Eff 7/13/81; am and comp 12/16/06; am and comp] (Auth: HRS \$\$149A-19, 149A-22, 149A-33; 7 USC \$136v (a)) (Imp: HRS \$\$149A-19, 149A-22, 149A-33)

- §4-66-48 Experimental use permits; provisions for issuance. (a) A permit is required for a pesticide intended for experimental use that is not exempt under section 4-66-47. If a pesticide is to be tested for a use, which is likely to result in a residue on or in food or feed, a permit for experimental use may be issued provided:
 - (1) A tolerance or exemption from the requirements of a tolerance has been established under section 408 of the Federal Food, Drug, and Cosmetic Act, codified at title 21 United States Code section 346a (2017); or a regulation established under section 409 of the Federal Food, Drug, and Cosmetic Act, codified at title 21 United States Code section 348 (2017); or
 - (2) The food or feed product derived from the experimental use permit shall be destroyed or used as feed only for laboratory or experimental animals for testing purposes; or
 - (3) Convincing evidence is submitted by the applicant

that the proposed use shall not result in residues in or on food or feed that would be in excess of that authorized under section 408 of the Federal Food, Drug, and Cosmetic Act, codified at title 21 United States Code section 346a (2017), or a regulation established under section 409 of the Federal Food, Drug, and Cosmetic Act, section 348 of title 21, United States Code (2017), which would be hazardous to humans, other animals, or the environment.

- (b) A permit shall be issued only if it is clearly shown in the permit application that the applicant's instructions for use reasonably assure the protection of humans and the environment.
- (c) All applications for an experimental use permit shall be filed by a qualified person on a form prescribed by the head. Each application shall contain the following:
 - (1) Name and address of the shipper, the consignee, and place or places from which the shipment shall be made;
 - (2) Proposed date of shipment, or proposed shipping period that shall not exceed one year from the permit application date, and quantity to be shipped;
 - (3) A statement of the composition of material to be covered by the permit, which shall apply to a single material or similar formulations of the material;
 - (4) The name, address and telephone number and qualification of the person responsible for conducting the test;
 - (5) Available data or reference to available data on the analytical method and toxicity of the pesticide;
 - (6) The purpose or objective of the proposed tests; a description of the proposed testing program including test parameters; a designation of the pest organism or organisms involved; the amount of pesticide product proposed for use; the crops, fauna, flora, sites, modes, dosage rate, and situation of applications on or in which the pesticide is to be used; the number of acres, number of structure sites, or number of animals to be treated or included in the area of experimental use; the proposed dates, or period, or periods during which the testing program is to be conducted and the manner in which supervision of the program shall be accomplished; and the method

- of destruction or disposal of treated food or feed;
- (7) A statement that the pesticide is intended for experimental use only;
- (8) Proposed labeling that shall bear:
 - (A) The prominent statement "For Distribution and Experimental Use Only Within Hawaii" in the container label and any accompanying circular or other labeling;
 - (B) A warning or caution statement that may be necessary and if complied with is adequate for the protection of those who may handle or be exposed to the experimental formulations;
 - (C) The name and address of the applicant for the permit;
 - (D) The name or designation of the formulation; and
 - (E) If the pesticide is to be sold to experimental use program participants, a statement of the names and percentages of the principal active ingredients in the product; provided that, if the shipper submits a copy of a valid experimental use permit issued under the provisions of FIFRA, and the accepted labeling related thereto, at the head's discretion, the head may exempt the shipper from the requirement of submitting a part of the application, the data, and information specified in this subsection; and
- (9) A statement as to the disposal of any unused portions of the experimental pesticide. [Eff 7/13/81; am and comp 12/16/06; am and comp] (Auth: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.24) (Imp: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.24)

§4-66-49 Experimental use permits; restrictions.

- (a) The head may limit the quantity of a pesticide covered by an experimental use permit to a lesser quantity than requested if available information on effectiveness, toxicity, or other hazards is not sufficient to justify the scope of experimental use proposed in the application, or make other limitations in the permit as may be determined to be necessary for the protection of the public.
- (b) A pesticide shipped or delivered solely for experimental use shall not be offered or advertised for general sale or use.
 - (c) Unless revoked by the head, experimental use

permits shall be effective for a specified period of time, depending upon the crop or site to be treated and the testing program submitted.

Permits may be renewed upon request if circumstance warrants.

Applications for renewal of experimental use permits shall be submitted no less than thirty days prior to the permit expiration dated.

[Eff 7/13/81; comp 12/16/06; am and comp

] (Auth: HRS \$\$149A-19, 149A-22, 149A-33; 40 CFR \$172.25) (Imp: HRS \$\$149A-19, 149A-22, 149A-33; 40 CFR \$172.25)

§4-66-50 Experimental use permits; reports. At specific intervals to be prescribed by the head, the experimental use permittee shall submit periodic reports to the head regarding the status of the experimental program.

The permittee shall immediately report to the head any incidents of unreasonable adverse effects on the environment from use, or from exposure to pesticides covered by an experimental use permit. These periodic reports shall include the following information:

- (1) Quantity of the pesticide shipped and used during the reporting period;
- (2) Name and address of consignee and ultimate destination and amount of each shipment;
- (3) A summary of data on effectiveness, phytotoxicity, or other pertinent information regarding usefulness obtained during the permit period;
- (4) Any additional data obtained on residue or analytical methods obtained;
- (5) Any additional data obtained on toxicity or unreasonable adverse effects to humans, non-target animals, or the environment;
- (6) Any residue data obtained on the treated crop or site on which determination can be made regarding reentry into the treated area;
- (7) Disposition of unused pesticide; and
- (8) Such other information and data as may be prescribed by the head. [Eff 7/13/81; am and comp 12/16/06; am and comp]
 (Auth: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.25) (Imp: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.25)

§4-66-51 Experimental use permits; monitoring and revocation. (a) The head shall monitor the testing program if it is determined necessary for protection of the public

health and environment. It shall be the responsibility of the permittee or person supervising the experiment to immediately report to the head any incidents or adverse reaction from use of, or exposure to the pesticide covered by an experimental use permit.

- (b) The head shall revoke an experimental use permit if it is determined that the permit terms or conditions are being violated, or that the permit terms or conditions are inadequate to avoid unreasonable adverse effects on humans or the environment.
- (c) Failure to comply with the terms or conditions of any State issued experimental use permit may subject the permittee, or person supervising the experiment, or both, to additional penalties as provided by law. [Eff 7/13/81; am and comp 12/16/06; am and comp]

 (Auth: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.25)

 (Imp: HRS §\$149A-19, 149A-22, 149A-33; 40 CFR §172.25)