EPA Reg. No. 6735-201. Tide Products, Inc., Box 1020, Edinburg TX 78533. TIDE MALATHION 5 DUST. Active Ingredients: Malathion (0,0-dimethyl dithiophosphate of diethyl mercaptosuccinate) 5%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM16

EPA File Symbol 6962-LR. Madison Bionics, 11250 W. Addision St., Franklin Park, IL 60131. PROPER. Active Ingredients: Ammonium Oxalate 1.30%; 2,2'-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4' - Trichloro-2' - hydroxydiphenylether 0.10%; Ammonium Ortho Phenylphenate 0.05%. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 6962-LE. Madison Bionics. DISINFECTANT 4045. Active Ingredients: Isopropanol 15.00%; Potassium orthophenylphenate 4.40%; Potassium o-benzyl-p-chlorophenate 4.05%; Tetrasodium ethylenediamine tetraacetate 1.60%. Method of Support: Application proceeds under 2(a) of interim policy. PM32

EPA File Symbol 8075-A. Allen Chemical Co., 3235 N. W. 37th St., Miami FL 33142. ALCO TOWER BIOCIDE #13. Active Ingredients: Disodium cyanodithiomidocarbonate 3.68%; Potassium N-methyldithiocarbamate 5.07%. Method of Support: Application proceeds under 2(b) of interim policy. PM33

[FR Doc.76-34122 Filed 11-18-76;8:45 am]

[FRL 646-5]

PEST CONTRAL DEVICES AND DEVICE PRODUCERS

Consolidation and Clarification of Requirements

I. Purpose

• Requirements applicable to pest control devices and device producers have been set forth in various regulations promulgated pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136 et seq.) ("FIFRA" or "the Act"). The purpose of this notice is to provide a consolidation and clarification of all such requirements. •

II. Definitions

At section 2(h) of FIFRA (7 U.S.C. 136(h)) the term "device" is defined to mean:

* * * any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separtely therefrom.

To more clearly identify the types of products to which the requirements discussed in this Notice apply, the term "device" must be contrasted with the term "pesticide," which is defined at section 2(u) of FIFRA to mean:

* * * any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as plant regulator, defoliant, or desiccant.

Thus, if an article uses physical or mechanical means to trap, destroy, repeal, or mitigate any plant or animal life declared to be a pest at 40 CFR 162.14, it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide.

III. Devices Subject to the Act

Section 25(c)(4) of FIFRA (7 U.S.C. 136w(c)(4)) provides that the Administrator may specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) (7 U.S.C. 136(q)(1)) or section 7 (7 U.S.C. 136e) of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act. On July 3, 1975, the Administrator promulgated regulations (40 F.R. 28242) amending 40 CFR Part 162 pursuant to this authority. 40 CFR 162.15 now provides that devices as defined in FIFRA section 2(h) are subject to the requirements of FIFRA section 2(q)(1)(A)-(G) and to those provisions of FIFRA section 7 which are necessary to effectuate the purposes of FIFRA with respect to devices.

The preamble to these regulations at 40 F.R. 28266 declared that to effectuate the purposes of the Act, devices subject to sections 2(q)(1) and 7 include but are not limited to:

(A) Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites; (B) certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds; (C) black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and (D) mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

The preamble further specifies those instruments declared to be of a character unnecessary to be subject to this Act in order to carry out the purposes of the Act. These include:

(1) Those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and

(2) Those which operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps.

Section 8 of FIFRA (7 U.S.C. 136f) provides for such record-keeping and record inspection requirements as the Administrator determines necessary for effective enforcement of the Act. Section 17 specifies the requirements to be placed on the import and export of devices. In neither of these sections is there a provision that the Administrator declare those classes of devices subject to these sections of the Act; and in the attendant regulations, no specification is made. For purposes of enforcement, the Agency will consider those classes of devices declared to be subject to regulation under section 25(c)(4) of the Act as subject to regulation under sections 8 and 17 as well.

IV. Summary of FIFRA Provisions Applicable to Devices

Any instrument declared to be a device under 40 CFR 162.15 is, upon introduction into channels of trade, subject to the provisions discussed below. Those provisions of the amended FIFRA which pertain to devices are in many respects similar to those under the 1947 FIFRA (61 Stat. 163; 7 U.S.C. 135-135k). In both Acts the Agency is authorized to inspect records showing the delivery, movement, or holding of devices (7 U.S.C. 135c, 136f); to obtain samples of any device in the marketplace (7 U.S.C. 135d, 136g); to seize any misbranded device (7 U.S.C. 135g, 136k); to initiate criminal proceedings against any person violating any provision of the Act (7 U.S.C. 135f, 136l); and, in cooperation with the Secretary of the Treasury, to sample, examine, and detain any imported device which violates the provisions of the Act (7 U.S.C. 135h, 136o).

The differences in the provisions of the two Acts with respect to requirements applicable to devices, lie primarily in the greater specification of jurisdiction and regulatory requirements provided by the 1972 amendments. For example, while a device, unlike a pesticide, is not subject to the section 3 registration requirement of FIFRA, section 12 of the Act makes clear the intent of the Act that subject devices and persons dealing with devices be held responsible for those obligations, other than registration, that are imposed by the Act. Jurisdiction to regulate devices is expanded to intra- as well as interstate commerce (7 U.S.C. 136j(a)(1)). Similarly, section 9(a) of the amended FIFRA specifies that entry for the purpose of inspecting and obtaining samples of devices "packaged, labeled, and released for shipment is permitted into "any establishment or other place where * * * devices are held for distribution or sale (7 U.S.C. 136g(a)).

With respect to affirmative regulatory requirements, section 2(q)(1) of the amended FIFRA expands the definition of misbranding as it applies to devices subject to the Act (7 U.S.C. 136(q)(1)). Section 7 of the amended FIFRA is totally new, requiring the registration of establishments which produce devices declared subject to the Act (7 U.S.C. 136e). In addition to the provisions of the Act allowing the inspection of records kept by producers and distributors of devices, section 8(a) of the amended FIFRA requires producers of devices subject to the Act to maintain such books and records as the Administrator requires by regulation (7 U.S.C. 136f(a)). Finally, section 17(a) of FIFRA, as amended, specifically imposes the same recordkeeping requirements on producers of devices intended for export by making such producers subject to the requirements of section 8.

V. ELABORATION OF SPECIFIC REQUIREMENTS APPLICABLE TO DEVICES

A. *Section 2(q)(1), Misbranding Provisions (7 U.S.C. 136(q)(1)).* With promulgation of the regulations at 40 CFR 162.15, which invoked the authority of section 25(c)(4) to specify devices subject to sections 2(q) and 7 of the Act, the labeling requirements of the 1947 FIFRA to which devices had been subject were expanded (7 U.S.C. 135(z)(1)). Those misbranding provisions of section 2(q)(1) of the amended FIFRA which the Administrator has made applicable to devices are listed at 40 CFR Part 162.15(b). In summary, a device will be subject to enforcement action if

2(q)(1)(A): Its labeling bears any statements, designs, or graphic representations relative thereto or to its ingredients which are false or misleading in any particular;

2(q)(1)(B): Its packaging or wrapping fails to conform with standards established pursuant to section 25(c)(3) (Such standards have not, as of this date, been issued by the Administrator; at such time as they are, the question of their applicability to devices will be addressed);

2(q)(1)(C): It is an imitation of, or is offered for sale under the name of another device;

2(q)(1)(D): Its label fails to bear the establishment number;

2(q)(1)(E): Required information is not prominently displayed on the label;

2(q)(1)(F): It lacks adequate directions for use; or

2(q)(1)(G): It lacks an adequate warning or caution statement.

40 CFR 162.10(a)(5) provides an interpretation of what the term "false and misleading" may include in the context of FIFRA section 2(q)(1)(A) misbranding:

A false or misleading statement concerning the composition of the product;

A false or misleading statement concerning the effectiveness of the product;

A false or misleading statement about the value of the product for purposes other than as a device;

A falle or misleading comparison with other devices;

Any statement directly or indirectly implying that the device is recommended or endorsed by any agency of the Federal Government;

A true statement used in such a way as to give a false or misleading impression to the purchaser;

Label disclaimers which negate or detract from labeling statements required under the Act and regulations; or

Non-numerical and/or comparative statements on the safety of the product.

B. Section 7, Registration of Establishments (7 U.S.C. 136e). On November 6, 1973, regulations (40 CFR Part 167) for the implementation of section 7, Registration of Establishments, were published in the FEDERAL REGISTER (38 F.R. 30557). The scope of the requirements is set forth at § 167.2(a): "All establishments, as defined in this part, which produce any pesticide or device subject to the provisions of this section, must be registered pursuant to the requirements of these regulations * * *" At § 167.1(k) the term "device" is defined as "* * * any device or class of devices as defined by the Act and determined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act."

Section 7 imposes three basic requirements: (1) Registration of device-producing establishments, (2) labeling which reflects the EPA establishment number assigned to the establishment in which the device was produced, and (3) submission of annual production reports.

All establishments in which devices subject to the Act are produced must be registered with the Environmental Protection Agency as producing establishments. This includes foreign establishments in which devices shipped to the United States are produced, as well as establishments located in the United States which produce devices for export.

To register establishments, producers should obtain from an EPA regional office the Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8). The applications require such information as the name and address of the company headquarters and the names and addresses of all device-producing establishments owned and operated by the company. This application must be submitted to the regional office on or before January 18, 1976. Upon receipt of a completed application, the regional office shall register each establishment listed and shall assign each establishment an EPA establishment number. This EPA establishment number must be displayed on all devices released for shipment by the establishment after 90 days after the producer is notified of the assigned number.

The production reports (EPA Form 3540-16) must be submitted to the regional office within thirty days after notification of registration and by February 1 each year thereafter.

C. *Section 8, Books and Records (7 U.S.C. 136f).* On September 18, 1974, regulations (40 CFR Part 169) for the implementation of section 8, Books and Records, were published in the FEDERAL REGISTER (39 F.R. 33512). Pursuant to the authority of section 8(a) of the Act, these regulations (at 40 CFR 162.2) specify those records pertaining to development, testing, production, holding, and distribution, which all producers of devices declared subject to the Act are required to maintain and submit to inspection. These requirements apply to domestic and foreign persons producing devices for sale and distribution in the United States and to domestic producers who export devices.

Specifically, producers of devices subject to the Act are required to maintain the following records:

169.2(b): Records showing the brand names and quantities of devices produced. These records shall be retained for two years.

169.2(c): Records showing the following information regarding the receipt of devices: (1) Brand name of device, (2) Name and address of shipper, (3) Name of delivering carrier, (4) Date received, and (5) Quantities received.

These records shall be retained for two years.

169.2(d): Records showing the following information regarding the shipment of devices: (1) Brand name of device, (2) Name and address of the consignee, (3) Name of originating carrier, (4) Date shipped or delivered for shipment, and (5) Quantities shipped or delivered for shipment.

These records shall be retained for two years.

169.2(e): Inventory records with respect to the types and amounts of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

169.2(h): In the case of devices intended solely for export to any foreign country, copies of the specifications or directions of the foreign purchaser for the production of the devices. These records shall be retained for two years after expiration of the contract.

Pursuant to the authority of section 8(b) of the Act, 40 CFR 169.3(b) requires that distributors, carriers, dealers or other persons who sell or deliver (or offer to sell or deliver) devices declared subject to the Act, allow inspection of the records they have pertaining to the following:

(1) The delivery or holding of the device and quantity held; (2) Date of shipment and receipt; (3) Name and address of consignee and consignor; and (4) Any guarantees received pursuant to section 12(b)(1).

D. *Section 17, Imports and Exports (7 U.S.C. 136o).* On August 1, 1975, regulations (19 CFR Part 12.1) for the implementation of section 17, Imports and Exports, were published in the FEDERAL REGISTER (40 FR 32321). These regulations require that devices produced by foreign manufacturers and imported into the United States comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, available at any EPA office) for review and determination as to whether the shipment should be sampled and/or permitted entry into the United States. The Act also provides that samples may be collected and examined and that shipments may be permitted entry, detained until brought into compliance, destroyed, or re-exported.

With respect to devices produced in this country for export, section 17(a) of the FIFRA as amended requires that such devices must be prepared or packed in accordance with the specifications or directions of the foreign purchaser and that producers of such devices must maintain books and records pursuant to section 8(a).

VI. ENFORCEMENT AUTHORITIES

Section 9(a) (7 U.S.C. 136(g)(a)) of the Act authorizes officers of the Agency to inspect any establishment or other place where a device is held for distribution or sale in order to obtain a sample of the device as packaged, labeled and released for shipment, and samples of any containers or labeling for the device. Officers of the Agency are also authorized

to inspect books and records required to be maintained under section 8(a) and copies of records which are available under section 8(b).

Pursuant to section 12(a)(2)(B) of the Act, it is unlawful for any person to refuse to keep or to permit inspection of books and records, or to refuse to permit inspection of an establishment. Pursuant to section 12(a)(1)(F) of the Act, it is unlawful to sell or distribute any device which is misbranded. Finally, pursuant to section 12(a)(2)(L) of the Act, it is unlawful to violate any provision of section 7.

Upon a finding of any unlawful act, the Administrator may assess a civil penalty pursuant to section 14(a) of the Act or initiate criminal proceedings pursuant to section 14(b) of the Act. If, upon inspection or tests, a device is believed to be in violation of the Act, or if it is believed that a device is intended to be distributed or sold in violation of the Act, a Stop Sale, Use or Removal Order may be issued pursuant to section 13(a). Additionally, section 13(b) authorizes in rem seizure proceedings in a federal district court against any device which is misbranded or which, when used in accordance with the requirements imposed under the Act causes unreasonable adverse effects upon the environment. Finally, the Administrator may seek injunctive relief pursuant to section 16(c) to prevent and restrain violations of the Act.

VII. Public Comment

The Administrative Procedure Act (5 U.S.C. 533(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." EPA has determined that this Notice falls within this exemption from the requirement to solocit public comment. Nonetheless, interested persons may submit written comments regarding the policy set forth in this Notice to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: November 8, 1976.

Stanley W. Legro,
Assistant Administrator for Enforcement.

[FR Doc.76-34119 Filed 11-18-76;8:45 am]

[FRL 646-2; OPP-30114A]

PESTICIDE PROGRAMS

Approval of Application to Register Pesticide Product Containing A New Active Ingredient and Waiver of Data

On April 21, 1976, the Environmental Protection Agency (EPA) gave notice (41 FR 16692) that the United States Forest Service (USFS), 1205-B (RPE), 14th and Independence Ave. SW, Washington, D.C. 20250, had filed an application with the EPA to register the pesticide product TM BIOCONTROL-1 containing 3.5 percent of the active ingredient polyhedral inclusion bodies of Douglas Fir Tussock Moth nucleopolyhedrosis virus which was not previously registered at the time of submission. The application received from the USFS proposed that the product be used in aerial application to control Douglas Fir Tussock Moth and that the product be classified for general use. PM17.

Having considered the evidence submitted by USFS in their application for registration and the data submitted in support thereof, the Administrator has made a written finding pursuant to the regulations (40 CFR 180.6(a)(3)) with respect to whether such properties of TM Biocontrol-1 are fundamentally different from the factors considered by EPA in establishing the data requirements set forth in the Registration Guidelines. Although the Guidelines were published as proposed rules in the Federal Register on June 25, 1975 (40 FR 26802), and have not as yet been promulgated in their final form, the basic data requirements set forth in the proposed Guidelines represent the data currently considered necessary to support the registration of a pesticide product. Accordingly, the notification of data waiver will apply to the supporting data now required by the Agency and set forth in the proposed Guidelines.

The Administrator has found that the submission of certain data is not necessary for determining whether TM Biocontrol-1 will generally cause unreasonable adverse effects on man or the environment. Specifically, the following required data have been waived by the Administrator for the polyhedral inclusion bodies of the nucleopolyhedrosis virus of the Douglas Fir Tussock Moth:

1. Avian 8-day dietary LC_{50} study utilizing a native upland game bird, preferably bobwhite quail.
2. Acute LC_{50} studies to 96 hours on a native cold and warm water species of fish, preferably utilizing trout and bluegill sunfish.
3. Acute aquatic invertebrate LC_{50} to 48 hours, preferably utilizing *daphnia* sp.

The primary basis of this waiver is due to the natural presence of the nucleopolyhedrosis virus in the environment and its role in bringing about the collapse of epizootic Douglas Fir Tussock Moth populations. During outbreaks of the Tussock Moth, large amounts of this virus are naturally released into the environment. Moreover, data presented by the registrant demonstrate that a much greater amount of this virus is released naturally into the environment through the collapse of Douglas Fir Tussock Moth populations than is released through the application of this product as a suppression measure.

Finally, it should be noted that this product can be used against only one pest, the Douglas Fir Tussock Moth, and that infestations of this pest are cyclic in nature; the maximum use of this product would likely be once in 6 to 10 years, and therefore exposure of fish and wildlife to this product would be minimal. Because the data submitted by the registrant have adequately demonstrated that this product is fundamentally different from the products for which the fish and wildlife testing requirements were designed, a waiver of the data listed above is both appropriate and acceptable.

This application was approved August 11, 1976, and the product has been assigned the EPA Registration No. 27586-1. Notice of registration is given in accordance with the regulations (40 CFR 180.7(d)(2)) for the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (*86 Stat. 973; 89 Stat. 751, 7 U.S.C. 136(a)* et seq.).

Test data and other information submitted in support of this registration as well as such other scientific information deemed relevant to the registration decision, except for such material protected by section 3(c)(1)(D) and section (10) of FIFRA, will be available for public inspection in the office of the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, Room EB-31, East Tower, 401 M St., Washington, D.C. 20460.

It is suggested that persons interested in viewing these data notify the Information Coordination Section, either by letter at the above address or by telephone at 202/426-2690, prior to visiting the EPA Headquarters Office so that clearance procedures may be instituted and the appropriate data made available for review purposes pursuant to the regulations for section 3(c)(2) of FIFRA (40 CFR 162.7(f)).

Dated: November 15, 1976.

Edwin L. Johnson,
Deputy Assistant, Administration for Pesticides Program.

[FR Doc.76-34120 Filed 11-18-76;8:45 am]

[FRL 647-2; OPP-30000/9]

PESTICIDE PROGRAMS

Intent to Process Pesticide Products for Reregistration—Sperm Whale Oil

The Deputy Assistant Administrator, Office of Pesticide Programs, Environmental Protection Agency (EPA) has determined that the use of pesticide products containing sperm whale oil which has already been stockpiled does not result in fatality to members of endangered species; accordingly, such product registrations will be returned to the Registration Division, Office of Pesticide Programs, for processing according to normal reregistration and classification procedures.

I. *Regulatory provisions.* On July 3, 1975 (40 FR 28242), EPA promulgated regulations (40 CFR 162) for the registration, reregistration, and classification of pesticides, pursuant to Section 3 of the Federal Insecticide, Fungicide and