Thus, if an article uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 122.14, it is considered a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repel, 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 25(c) (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 at 40 F.R. 28262 amending 40 CFR Part 125 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 both of these sections if (1)-(2) and to those provisions of 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) moles, thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain subspecies of mole.

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 upon the performance of the person using the device than on the performance of the device itself, and
(2) Those which entrap or entrap verminate animals.

Products generally falling within these categories include traps, fly swatters,illage equipment for weed control and fish traps.

Section 8 of FIFRA (7 U.S.C. 136i) 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 the preamble to these requirements, there is 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 to be regulated 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 in this Notice, as well as those of the amended FIFRA which pertain to devices 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, 136l); 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, 136f); and, in accordance with the provisions of the Treasury, to sample, examine, and detain any imported device which violates the provisions of the Act (7 U.S.C. 135n, 136g).

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. 136c(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 any 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 a device 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 7 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.

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V. ELABORATION OF SPECIFIC REQUIREMENTS APPLICABLE TO DEVICES

A. Section 2(q) (1), Misbranding Provisions (7 U.S.C. 136(g) (1)). With promulgation of the regulations at 40 CFR 162.14, which invoked the authority of section 2(b) of the Act, the labeling requirements of the 1947 FIFRA to which devices had been subject were expanded (7 U.S.C. 135(e) (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. To any party, 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 to standards established pursuant to section 25(e) (8) (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 of the manufacturer, importer, or domestic producer.

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

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

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" as used 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 false 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, 1972, regulations (40 CFR Part 169) for the implementation of section 7, Registration of Establishments, were published in the Federal Register (38 FR. 35057).

The scope of the requirements is set forth at § 167.3(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) The 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 pesticide-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 the 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 applications on EPA Form 3540-10 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 (40 FR. 32321). 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 (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) Data 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 most 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 15.

D. Section 17, Import and Exports (7 U.S.C. 136o). On August 1, 1975, regulations (19 CFR Part 121.1) 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) to the nearest EPA regional 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 of the foreign purchaser and that producers of such devices 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

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

Pursuant to section 12(a)(2)(B) of the Act, it is unlawful for any person to refuse to keep or permit inspection of books and records, or to refuse to permit inspection of an establishment. Pursuant to section 12(a)(1)(B) of the Act, it is unlawful to 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 2.

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, 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, Ban Sale, Rem Seizure Order may be issued pursuant to section 13(a).

Additionally, section 13(b) authorizes in rem seizure proceedings in a federal district court to enjoin and restrain any person from distributing, using, dispensing, or handling 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. 553(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 solicit 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.

EDWIN L. JOHNSON
Deputy Assistant, Administration for Pesticides Program.

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

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 (RFES), 14th and Independence Ave. SW, Washing-