

application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Transco to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-00086A; FRL 1350-4]

### Pesticide Use and Production by Veterinarians; Statement of Policy on the Applicability of the Federal Insecticide, Fungicide, and Rodenticide Act to Veterinarians

AGENCY: Office of Pesticide Programs/ Office of Enforcement, Environmental Protection Agency (EPA).

ACTION: Notice of a policy for implementation of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, with respect to veterinarians.

**SUMMARY:** This notice explains EPA's policy for enforcement of various provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136 et seq.), and regulations thereunder, with regard to Doctors of Veterinary Medicine (veterinarians) who use, mix, or prescribe pesticides.

**FOR FURTHER INFORMATION CONTACT:** Ralph Colleli (TS-766), Office of Pesticide Programs, (202) 755-8030.

**SUPPLEMENTARY INFORMATION:** On Thursday, March 15, 1979, EPA's Office of Pesticide Programs and Office of Enforcement published a proposed statement of policy for the regulation of veterinarians who use or dispense pesticides in the course of their practice (44 FR 15768). That proposed policy statement pointed out that veterinarians who deal with pesticides are subject, to some extent, to legal responsibilities imposed by FIFRA and regulations thereunder, including regulations for pesticide applicator certification, product registration, establishment registration, and special (child-resistant) packaging. The March 15 notice also

stated that the purpose of the proposed policy was to describe EPA's plan for applying these statutory and regulatory requirements to veterinarians. This plan would allow veterinarians to continue their usual practices without having to comply with all the procedural requirements to which they are technically subject, provided that they comply with certain minimal safety precautions specified in the policy statement. These conditions would not extend or augment in any way the legal responsibilities or liabilities of veterinarians. However, compliance with these precautions would permit EPA to allow beneficial and customary veterinary practices to continue, free from restraints which would otherwise apply.

The March 15 notice invited the public to comment on the proposed policy. The deadline for submitting comments was April 30, 1979. Only two commenters responded to this notice. One commenter (No. 1(00086)), speaking for the California Department of Food and Agriculture, objected generally to the idea that veterinarians should be treated any differently under this policy than other pesticide users. The commenter specifically stated that "Veterinarians should comply with applicator certification requirements and use registered pesticides in accordance with registered labeling."

EPA must reject this objection since, as the March 15 notice pointed out, veterinarians are exempted from certification requirements by regulations promulgated in 1975 (40 CFR 171.4(e)), and *not* by this policy. Also, as the proposed policy statement, and this final notice, expressly state, "veterinarians, like all other persons, must use all pesticides . . . consistently with their registered labeling."

The other commenter (No. 2(00086)) raised several points. First, he stated that this policy might set a precedent for other pesticide user and producer groups, and that the policy statement should be written with that consideration in mind. EPA has considered this issue and notes that this policy is not intended as a precedent for treatment of any persons other than practicing veterinarians. This policy was specifically developed to recognize the special status granted to veterinarians by regulation, and to obtain for the public the unique benefits this group can provide, while maintaining an acceptable level of safety in the use, production, and distribution of pesticides by veterinarians. This statement cannot, therefore, be extended to any other groups.

The same commenter also suggested that veterinarians who mix and

dispense special pesticide blends for treating unusual cases should be required to keep special records on such treatments. This comment was rejected since most of the information specified by the commenter is routinely kept by veterinarians in their office files, and since the incremental benefits obtainable from such records would not justify imposing such a requirement on veterinarians.

These comments are available for public inspection in the Chemical Information Division (TS-793), Office of Toxic Substances, EPA, Room E-447, 401 M Street, S.W., Washington, D.C. 20024, from 9:00 a.m. to 4:00 p.m., Monday through Friday.

Certain minor changes in the policy statement have been made since its proposal, however, in order to clarify or correct certain deficiencies in the proposed policy. For example, the sections relating to *Repackaging and Dispensing of Pesticides and Production of Special Pesticide Formulas* have been modified to require that the basic labeling information described therein be physically attached to the pesticide package, if space permits. In addition, in cases where the size of the package precludes insertion of human safety precautionary statements on the package itself, certain specific precautions must appear on a tag attached to the package.

Also, the final policy statement clarifies that veterinarians dispensing special pesticides formulations will be covered by the exemptions described herein only when the special blend is formulated for use on an affected animal. Special blends intended for other purposes (e.g., space sprays) are not covered by the exemption and must be registered by the veterinarian.

Accordingly, notice is hereby given that the Office of Pesticide Programs and the Office of Enforcement intend to implement immediately a policy on the subject of veterinarians using and dispensing pesticides, as described below.

#### Use of Restricted Use Pesticides

Under sections 3, 4, and 12(a)(2)(F) of FIFRA, no individual may use a restricted use pesticide unless he is an applicator certified under a plan approved by EPA, or is under the direct supervision of a certified applicator, or is expressly exempted from the certification requirement. Regulations promulgated under section 4 in 1974 established an exemption from the certification requirement for veterinarians who use restricted use pesticides in "the course of their normal practice" (40 CFR 171.4(e)). The regulations explained, however, that this

exemption does *not* apply to veterinarians who are "in the business of applying pesticides for hire, publicly holding themselves out as pesticide applicators, or engaged in large-scale use of pesticides" (40 CFR 171.3(b)(1)(ii)). Activities such as these would not be part of "normal practice," and veterinarians would have to be certified to use restricted use pesticides for such purposes. Although the meaning of a "normal practice" is broad and may vary according to local needs, some activities clearly do not come within the scope of that term. For instance, application of pesticides by a veterinarian as a "principal or regular occupation" (39 FR 36447 (October 1, 1974)), or solicitation of pesticide application business by veterinarians, is not considered part of a "normal practice." Veterinarians who use restricted use pesticides for such purposes, or in any other manner which is not part of their "normal practice," are required to become certified under an appropriate approved State or Federal certification plan, unless they use such pesticides under the direct supervision of a certified applicator.

Although EPA strongly recommends that veterinarians keep abreast of advances in pesticide use and technology through appropriate professional continuing education, veterinarians who practice within the bounds of 40 CFR 171.4(e) are exempt from the certification requirement. EPA interprets this exemption as also extending to regular employees of a veterinarian when applying restricted use pesticides "under the direct supervision" of the veterinarian. Such supervision requires, unless the pesticide labeling specifies otherwise, that the employee be a competent individual, acting under the supervision and control of a veterinarian who is available if and when needed, even though the veterinarian is not physically present at the time (section 2(e)(4) of FIFRA). Veterinarians are, however, subject to civil and criminal penalties for violations of FIFRA, including misuse of pesticides, committed by employees under their supervision (see section 14(b)(4) of FIFRA). Additionally, veterinarians (unless they have become certified applicators) are not authorized to supervise the use of restricted use pesticides by uncertified persons other than their employees.

Similarly, under section 12(a)(2)(F) of FIFRA, veterinarians, as all other persons, are forbidden to dispense restricted use pesticides to uncertified persons, including their clients, unless expressly allowed by EPA regulations.

However, EPA will consider the need of veterinarians to dispense a particular pesticide to clients as part of any future decision on whether to restrict use of such a pesticide.

Finally, veterinarians, like all other persons, must use all pesticides, including those not classified for restricted use, consistently with their registered labeling. As authorized by section 2(e) of FIFRA, this includes use against a pest not specified on the labeling as long as the animal or site treated *is* so specified, unless use against that pest is expressly forbidden by the Administrator of EPA.

Any veterinarian who uses or dispenses pesticides in violation of the provisions of FIFRA, as described above, may be penalized under section 14 of FIFRA for such actions.

#### Repackaging and Dispensing of Pesticides

Sections 3(a) and 7(a) of FIFRA, and regulations thereunder, require every "producer" of pesticides to register all pesticides produced by him, and to register the establishment in which they are produced, prior to sale or distribution of such pesticides. By regulation, the term "producer" includes all persons who "repackage or otherwise change the container of any pesticide \* \* \*" (40 CFR 167.1(c) and (d)). Therefore, a veterinarian who prescribes or otherwise dispenses a pesticide in a new container, or a container which he has altered by changing the package or its labeling, after receipt of the original product, is considered a "producer." The veterinarian is then legally responsible for registering such a product with EPA (even though the original product may already have been registered by its producer); for registering his establishment; for complying with all applicable labeling and packaging standards established by EPA; and for keeping all records required of producers under section 7(c) of FIFRA and 40 CFR 167.5.

However, EPA recognizes the substantial benefits which may be gained by permitting veterinarians who obtain pesticides in bulk containers to dispense such pesticides to clients in individual containers better suited to the specific case for which each pesticide is prescribed. EPA also recognizes the care with which most veterinarians prescribe, repackage, and distribute pesticides. Therefore, EPA, as a matter of policy, will not subject veterinarians who prescribe and dispense repackaged pesticides to the requirements imposed on "producers," provided that the following minimal conditions are met:

1. The repackaged pesticide is registered by EPA for a use consistent with the use for which the pesticide is prescribed, and the EPA registered use is not classified as restricted.

2. The veterinarian supplies the client with labeling for the pesticide which contains:

- (a) The common or trade name(s) and percentage(s) of the active ingredient(s);
- (b) The EPA product registration number;
- (c) Use directions for the use prescribed;
- (d) The name and address of the veterinarian;
- (e) An antidote statement;
- (f) Directions for disposal of the pesticide and the package dispensed to the client; and
- (g) Human safety precautionary statements, including but not limited to:
  - (i) "For application to animals only."
  - (ii) "Keep out of reach of children."
  - (iii) "In case of accident, contact local physician immediately."

If there is sufficient space on the package dispensed to the client, all of the information specified in (a)-(g) above must be physically attached to the package.

If space on the package is not sufficient to permit direct attachment of labeling containing all the information in (a)-(g), then, at a minimum, the information specified in (a), (b), (c), and (d) must be physically attached to the package. In addition, in such a case, the human safety precautionary statement specified in (g) above must be physically affixed to the container by wire, plastic, or similar means.

The information required by (e) and (f) above may be supplied to the client in the form of supplemental labeling, which may, if appropriate, consist of the original labeling of the pesticide as received by the veterinarian.

3. The container in which the pesticide is dispensed to the client is a child-resistant package as described in 40 CFR 162.16 of the "Special Packaging" rule (44 FR 7695), unless the veterinarian has determined that there is no reasonable possibility that the package will come within the reach of children.

4. The pesticide is prescribed and dispensed to the client for the treatment of a specific pest problem, on a case-by-case basis, as part of the veterinarian's "normal practice."

In addition to meeting the above requirements, all veterinarians distributing pesticides are urged to discuss labeling directions with the client at the time the pesticide is dispensed.

Any veterinarian who repackages and dispenses pesticides, and who does not satisfy conditions (1) through (4) above, must comply with all federal registration and recordkeeping requirements for "producers," and may be penalized under section 14 of FIFRA for failure to do so.

#### Producing and Dispensing Special Pesticide Formulas

Veterinarians who prepare their own special products for treatment of pests, other than by mere dilution of a registered pesticide in accordance with its labeling, may also be "producers." If the product formulated by the veterinarian is a "new animal drug" (as defined in 21 U.S.C. 321(w) and 321(g)(1)), the product and the veterinarian are subject to regulations of the U.S. Food and Drug Administration. If, however, the product is not a "new animal drug," or an animal feed containing a new animal drug, and is intended to prevent, repel, mitigate, or destroy any pest, it is a pesticide (section 2(u) of FIFRA) and is subject to the primary jurisdiction of EPA. The veterinarian is then considered a "producer" under FIFRA section 2(w).

As described above, "producers" are ordinarily required to register products and establishments, to keep records, and to meet labeling and packaging standards. If, however, the veterinarian produces a special pesticide blend solely for his own use, or use by persons in his presence and under his immediate supervision, then the veterinarian is exempt from these requirements (see, e.g., 40 CFR 162.3(gg); 162.5(a); 167.2(a)). Nevertheless, when mixing or using special pesticide blends, veterinarians are still required to comply with the labeling directions of any registered pesticides used. In addition, EPA recommends that labeling meeting the minimum standards of 40 CFR Part 162 accompany the special blend, in order to promote safe use, storage, and disposal of such pesticides by the veterinarian and his employees. Also, when applying a special blend which may leave a residue in or on an animal intended for use as food, the veterinarian must ensure that the ingredients used have been granted necessary clearances under the Federal Food, Drug, and Cosmetic Act.

On the other hand, veterinarians who formulate special pesticide mixtures for distribution to others are legally subject to all registration, labeling, and packaging requirements imposed on producers. However, EPA recognizes the benefits which may be obtained by allowing veterinarians to formulate products to meet unusual cases.

Therefore, EPA will not subject veterinarians who dispense such products to these requirements if:

1. The special pesticide blend is produced by mixing two or more pesticides already registered by EPA, or by adding new substances to an EPA registered pesticide.

2. Special blends made from registered pesticides classified for restricted use by EPA are not dispensed to uncertified persons.

3. The special blend is formulated and dispensed in accordance with recognized clinical practices and not primarily for purposes of experimentation.

4. The product is prescribed solely for application to an affected animal consistent with the labeling of any registered product used as an ingredient, and the use directions in the labeling for the registered ingredient do not prohibit the mixing performed by the veterinarian.

5. The special product is prescribed and dispensed to individual clients of the veterinarian on a case-by-case basis to meet specific pest problems.

6. The veterinarian supplies the client with labeling for the special product which contains:

(a) The common or trade name(s) and percentage(s) of active ingredient(s);

(b) The EPA registration number for each registered product used as an ingredient;

(c) Use directions for the use prescribed, which are consistent with the directions found in the original labeling for the registered products used as ingredients;

(d) The name of the veterinarian;

(e) An antidote statement;

(f) Directions for disposal of the pesticide and its container; and

(g) Human and environmental safety precautionary statements including, but not limited to:

(i) "For application to animals only."

(ii) "Keep out of reach of children."

(iii) "In case of accident, contact local physician immediately."

If there is sufficient space on the package dispensed to the client, all of the information specified in (a)-(g) above must be physically attached to the package.

If space on the package is not sufficient to permit attachment of labeling containing all the information in (a)-(g), then, at a minimum, the information specified in (a), (b), (c), and (d) must be physically attached to the package. In addition, in such a case, the human safety precautionary statements specified in (g) above must be physically affixed to the container by wire, plastic, or similar means.

If the original labeling or any of the ingredients would satisfy the requirements of (e) and (f), copies of that labeling may be supplied to the client to fulfill those requirements.

7. The container in which the special product is sold to the client is a child-resistant package, as described by the "Special Packaging" rule, unless the veterinarian has determined that there is no reasonable possibility that the package will come within the reach of children.

In addition to meeting the above requirements, all veterinarians distributing their own special products are encouraged to discuss labeling instructions for the special product with the client at the time the pesticide is dispensed.

Veterinarians who do not meet these conditions when distributing specially formulated pesticides must comply with all registration, recordkeeping, labeling, and packaging requirements established for "producers." Failure to comply may result in the imposition of penalties under section 14 of FIFRA.

#### Special Packaging

As mentioned above, it is expected that veterinarians who "produce" pesticides for their clients' use will frequently be subject to the requirements of the "Special Packaging" rule by its own terms. That is, a veterinarian producing a pesticide which meets the toxicity requirements of the "Special Packaging" rule, and which is intended for "residential application", as defined by that rule, *must* package the product in a child-resistant container before dispensing it to a client.

In addition, in those cases where that rule will not apply by its own terms, but the prescribed pesticide may come within the reach of children, use of child-resistant packaging by the veterinarian is a prerequisite to exemptions from registration, recordkeeping, and labeling requirements described in the preceding sections of this policy.

These facts, coupled with the practical difficulty that some veterinarians may have in determining whether a prescribed pesticide is subject to the terms of the "Special Packaging" rule, make it to the veterinarians' advantage to comply with the rule whenever there is a reasonable possibility that a prescribed pesticide may come within the reach of children. Therefore, EPA strongly encourages veterinarians to voluntarily comply with packaging standards established by the rule when dispensing any repackaged or specially blended pesticides.

**State Regulation of Veterinarians**

This policy statement concerns only EPA policy under FIFRA and federal regulations. It does not affect State or local regulatory restrictions covering veterinarians who deal with pesticides. Therefore, all veterinarians should consult their local professional associations, licensing offices, and State and local pesticide regulatory agencies for detailed information on local requirements.

Dated: October 16, 1979.

Edwin L. Johnson,  
Deputy Assistant Administrator for Pesticide Programs.

Dated: October 24, 1979.

Richard O. Wilson,  
Deputy Assistant Administrator for General Enforcement.

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[OPP-30000/33A; FRL 1350-1]

**Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing EPN; Extension of Period for Submission of Rebuttal Evidence and Comments**

**AGENCY:** Environmental Protection Agency (EPA), Office of Pesticide Programs.

**ACTION:** Extension of comment period.

**SUMMARY:** EPA has extended the period for submittal of rebuttal evidence and other comments in regard to the

rebuttable presumption against registration (RPAR) of pesticide products containing O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (EPN).

**DATE:** The comment period closes on December 28, 1979.

**FOR FURTHER INFORMATION CONTACT:** Mr. Patrick Miller, Special Pesticide Review Division (TS-791), Office of Pesticide Programs, Room 722, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Crystal City, Virginia 22202, Telephone: 703/557-7973 Ext. 24. The file supporting the Agency's presumption against EPN is available for public inspection at this location.

**SUPPLEMENTARY INFORMATION:** On September 4, 1979, EPA issued an RPAR against EPN. This notice was published in the Federal Register on September 19, 1979 (44 FR 54384). The regulations governing RPAR's provide that the applicant or registrant of these pesticide products shall have forty-five days from the date this notice is sent to submit evidence in rebuttal of the presumption. If good cause is shown, however, an additional sixty days may be granted in which to submit evidence (40 CFR 162.11(a)(1)(i)).

The deadline for submitting rebuttal evidence in the RPAR notice was October 29, 1979. Requests for an additional sixty days in which to submit evidence to EPA have been received from registrants and others who were affected by the notice of presumption. They have specified a need for additional time to respond to the risk

presumptions set forth in the September 19 notice (i.e., delayed neurotoxicity in test animals and acute toxicity to aquatic organisms) and to assess properly the benefits of EPN.

The Agency concludes that additional time would be beneficial to ensure the submission of complete and accurate responses to this notice of presumption. Therefore, all registrants, applicants, for registration, and other interested persons shall have until December 28, 1979, to submit rebuttal evidence and other comments or information. These submissions should be sent to the Document Control Officer, Chemical Information Division (TS-793), Office of Toxic Substances, EPA, Room 447, East Tower, 401 M Street, SW., Washington, D.C. 20460.

All comments should bear the identifying notation "OPP-30000/33A." Comments received on or before December 28, 1979, will be considered before the Agency decides whether a notice shall be issued under 40 CFR 162.11(a)(5)(ii) and 7 U.S.C. 136(d)(B)(1). Comments received after December 28, 1979, shall be considered only to the extent feasible, consistent with the time limits imposed by 40 CFR 162.11(a)(5)(ii). All written comments filed will be available for public inspection in the office of the Document Control Officer at the above address from 8:30 a.m. to 4 p.m. on normal business days.

Dated: October 26, 1979.

Edwin L. Johnson,  
Deputy Assistant Administrator for Pesticide Programs.

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**FEDERAL COMMUNICATIONS COMMISSION****Canadian Standard Broadcast Stations; Notification List**

List of new stations, proposed changes in existing stations, deletions, and corrections, in assignments of Canadian standard broadcast stations modifying the assignments of Canadian broadcast stations contained in the appendix to the recommendations of the North American Regional Broadcasting Agreement Engineering Meeting Jan. 30, 1941.

September 19, 1979.

**Canadian List No. 389**

Call letters	Location	Power kW	Antenna	Schedule	Class	Antenna height (feet)	Ground system		Proposed date of commencement of operation
							Number of radials	Length feet	
CBQ	Thunder Bay, Ontario, N. 48°18'38", W. 89°21'30" (In operation with changed antenna radiation pattern)	10D/5N	DA-1	630 kHz U	II				
CHRS	Longueuil, Quebec, N. 45°19'17", W. 73°18'36" (Change of studio location from St. Jean)	10	ND-180	1630 kHz D	II		120	350 (ave)	