TABLE 1.—Record and Reporting Requirements By Product—Continued

Products	Manufacturer: Product reports § 1002.10	Manufacturer: Supplemental reports § 1002.11	Manufacturer: Abbreviated reports § 1002.12	Manufacturer: Annual reports § 1002.13	Manufacturer: Test records § 1002.30(a)[1]	Manufacturer: Distribution records § 1002.30(b)[2]	Dealer & Distributor: Distribution records §§ 1002.40 and 1002.41
Diagnostic ultrasound			X				
Medical ultrasound other than therapy or diagnostic	X	X					
Nonmedical ultrasound			X				

[1]However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2]The requirement includes §§ 1002.31 and 1002.42, if applicable.
[3]Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR 1020.30(d)(1) through (d)(3).
[4]Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 1020.30(c).
[5]Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (1020.10(c)(3)(iii)).
[6]Annual report is for production status information only.
[7]Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

§ 1002.3 [Corrected]

3. On page 48385, in the first column, in § 1002.3, in line 6, the comma is removed after the word ''product'' and in line 7, a comma is added after the word ''purchaser''.

Dated: March 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–7313 Filed 3–26–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH48

Examinations

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, without change, an interim rule that amended the Department of Veterans Affairs (VA) adjudication regulations concerning compensation and pension claims filed by veterans, surviving spouses, or parents. With respect to language for authorizing VA examinations, this final rule provides that a VA examination will be authorized where there is a well-grounded claim for disability compensation or pension but the medical evidence accompanying the claim is not adequate for rating purposes. This final rule reflects statutory language and caselaw requirements concerning such VA examinations.

EFFECTIVE DATE: This final rule is effective March 27, 1996. (The interim rule was effective October 11, 1995.)

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: On October 11, 1995, VA published in the Federal Register (60 FR 52863) an interim final rule intended to clarify the circumstances under which a VA examination will be authorized. Interested parties were invited to submit written comments on or before December 11, 1995. We received no comments.

Based on the rationale set forth in the interim final rule, the provisions of the interim final rule are adopted as a final rule without change.

The Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will directly affect VA beneficiaries but will not affect small businesses. Therefore, pursuant to 5 U.S.C. 606(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program numbers are 64.100, 64.104, 64.105, 64.106, 64.109, and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans, Vietnam.

Approved: March 18, 1996.

Jesse Brown,

Secretary of Veterans Affairs.

[FR Doc. 96–7326 Filed 3–26–96; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 5F4509/R2221; FRL–5357–9]

Meat Meal and Red Pepper; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the active ingredients meat meal and red pepper in or on all raw agricultural commodities when applied as animal repellants in accordance with good agricultural practices. This exemption was requested by Lakeshore Enterprises.

EFFECTIVE DATE: The regulation becomes effective on March 27, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [PP 5F4509/R2221], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental

Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mai l) to: opp-docket@epamail.epa.gov

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 5F4509/R2221] . No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Julie Fry, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7501W), U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor CS1, 2800 Crystal Drive, Arlington, VA 22202, Telephone 703–308–8673, e-mail: fry.julie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 7, 1996, EPA issued a notice that Lakeshore Enterprises had submitted pesticide petition 5F4509 to EPA, proposing to amend 40 CFR part 180 by establishing a regulation pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) to exempt from the requirement of a tolerance the residues of the biochemicals meat meal and red pepper (synonyms include capsicum, cayenne pepper, chile pepper) in or on all raw agricultural commodities when applied as animal repellants in accordance with good agricultural practices. The Agency received one comment opposing tolerance levels proposed for the pesticides described primarily based on possible roles of pesticides in neurotoxicity. The commentor also supported the promotion of ''safe/safer'' alternatives to toxic chemicals. The Agency believes that the subject active ingredients, meat meal and red pepper, don't pose a risk including risk of neurotoxicity based on their extended use without any reported adverse effects. Furthermore, both meat meal and red pepper fall in the category of ''safe/safer'' pesticides, as supported by the response of the commentor.

Product Chemistry

Meat Meal

Meat meal is a sterilized, animal food by-product produced at livestock rendering plants from clean, fresh animal proteins. It is composed of greater than or equal to 85% crude protein, greater than or equal to 8% crude fiber, less than or equal to 3% fat, and less than or equal to water. This composition may vary from the batch-to-batch, depending on the by-products rendered (traces of hair, stomach belchings and urine might occur unavoidably in good manufacturing processes.) The moisture is removed from the crude product and the dried meat meal is sterilized at a temperature ranging from 210 °F to 250 °F for at least 1 1/2 hours. No chemicals are added to the meat meal. The resulting product is an unconsolidated fibrous powder.

Red Pepper

Red pepper is natural, processed vegetable matter that has been part of the human diet for many years. Red pepper is made by dehydrating fresh red chili pepper pods (*Capsicum spp.*), processing the dried pods through a mill and sifter, then blending the varieties of pepper powder into a final product. Known constituents of red pepper include capsaicin oil (0.1 - 1%), the source of red pepper's pungent effect and capsanthin, a carotenoid pigment.

Human Health Risk Assessment

EPA waived the data requirements for residue chemistry and toxicology data pursuant to 40 CFR 177.110(b) because it was unnecessary. As discussed below, EPA already has adequate information to determine that meat meal and red pepper do not pose a human health hazard without the waived data.

Meat Meal

Meat meal is available from livestock rendering plants nationwide; it is widely distributed in commerce and available to the general public. It is used as an animal food/feed supplement and as organic fertilizer. No significant adverse effects from exposure to meat meal have been reported. The expected uses of meat as an olfactory animal repellant will include meat meal packaged in bags and applied in powder form around the base of plants. Meat meal will not be applied directly to the plant. Negligible human exposure is anticipated.

Meat meal is composed mainly of sterilized animal proteins and fats. These natural components do not persist in the environment because they biodegrade rapidly. Furthermore, meat meal has been identified by EPA as a List 4A-Minimum Risk Inert. This list, published in the Federal Register, September 28, 1994 (59 FR 49400), identifies substances ''considered to be of minimal risk in pesticide products to human health when used as inert ingredients.'' These substances are also exempt from the requirement of tolerance when used as an inert ingredient. EPA believes that the risk from the use of meat meal on food is comparable whether it is used as an active or as an inert ingredient.

Red Pepper

Lack of toxicity of red pepper is supported by its long history of use by humans as a food additive/component without any indication of deleterious effects. Red peppers are ubiquitous in the cooking of many African countries and most of India, Ceylon and S.E. Asia. (*Capsicum spp*). Pepper exports amount to 176,000 tons annually (Ref. 1) (Rehm, S. and G. Espig. 1991. The Cultivated Plants of the Tropics and Subtropics - Cultivation, Economic Value, Utilization. Verlag Josef Margraf Scientific Books. Berlin, Germany. Pages 279–280). Red pepper is listed by the Food and Drug Administration as Generally Regarded as Safe (GRAS) in 21 CFR part 182. Furthermore, red pepper, a common food additive/component, also falls within the scope of the policy announced in the Federal Register, September 28, 1994 (59 FR 49400) which states ''... EPA is announcing that substances commonly consumed as food will also be considered minimal risk, List 4A, even if they have previously not been used in pesticide products and are therefore not currently on the list. Substances commonly consumed as foods will be considered acceptable for use in all pesticide products, both food and nonfood use, and will not require a specific exemption from tolerance.'' EPA believes the risk from the use of red pepper on food is comparable whether it is used as an active or as an inert ingredient.

Conclusion

Based on the low toxicity of meat meal, a sterilized food by-product and

red pepper, a common additive/component of the human diet, the Agency concludes that establishment of a tolerance is not necessary to protect the public health. Therefore, the exemption from tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP 5F4509/R2221] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

References Cited

The following reference is cited in this tolerance rule:

(1) Rehm, S. and G. Espig. (1991). The Cultivated Plants of the Tropics and Subtropics - Cultivation, Economic Value, Utilization. Verlag Josef Margraf Scientific Books. Berlin, Germany. pp. 279-280.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995, Pub. L. 104–4, EPA has determined that this regulation does not impose a Federal mandate upon State, local, or tribal governments or the private sector and does not contain any regulatory requirements that might significantly or uniquely affect small governments because the regulation does not impose any enforceable duties upon those entities.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 18, 1996.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding § 180.1164, to read as follows:

§ 180.1164 Food and food by-products; exemption from the requirement of a tolerance.

(a) Meat meal, a sterilized food by-product, is exempt from the requirement of a tolerance on all raw agricultural commodities when used as an olfactory animal repellent.

(b) Red pepper (*Capsicum spp.*) is exempt from the requirement of a tolerance on all raw agricultural commodities when used as a gustatory animal repellent.

[FR Doc. 96–7444 Filed 3–26–96; 8:45 am]

BILLING CODE 6560–50–F