Proposed Rules

Federal Register
Vol. 64, No. 85
Tuesday, May 4, 1999

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Chapter I

[Docket 98–085–1]

RIN 0579–AB09

Aquaculture: Farm-Raised Fin Fish

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: We are considering establishing programs and regulations for farm-raised fin fish. A national program could help protect the health of farm-raised fin fish, help producers of farm-raised fin fish meet international trade requirements, and help encourage international trade in U.S. aquaculture products. We are asking for comments on whether we should establish such programs and, if so, the type and extent of the programs. We are also asking for comments on whether to use negotiated rulemaking to develop regulations for any programs that we may establish.

DATES: Consideration will be given only to comments received on or before July 6, 1999.

ADDRESSES: Please send an original and three copies of your comment to Docket No. 98–085–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 98–085–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Otis Miller, Jr., National Aquaculture Coordinator, National Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231, (301) 734–6954.

SUPPLEMENTARY INFORMATION:

Background

The United States Department of Agriculture (USDA) has received 21 petitions asking us to promulgate animal health regulations and perhaps other regulatory programs to deal with farm-raised fin fish as livestock. These petitions are from State farm bureaus, industry associations, individual producers, State officials, and businesses that serve aquaculture industries.

One petition requested that we define domesticated farm-raised fish as livestock ''so that USDA can provide farmers with needed services identical to those received by other American farm raised animals.''

Most of the petitions we have received addressed only farm-raised fin fish. However, several addressed a broader range of aquatic species. One letter stated that we should recognize the entire industry—''clams, aquatic plants, alligators, tropical fish, and fish raised for human consumption''—as ''general farming.'' One stated that we should define ''farmed aquatic animals, such as fish and shrimp,'' as livestock. Another asked us to define ''domesticated farm-raised fish and shellfish'' as livestock. Other letters suggested that we consider domestically raised fish and shellfish as livestock, and stated that ''[a]quatic farmers are a diverse group growing a number of species of fish, crustaceans, and mollusks.''

The petitioners are concerned mainly with receiving the same services that domestic producers of livestock receive for animals moving in interstate and foreign commerce. Examples are diagnostic and certification services, protecting the industry by preventing importation of pests and diseases, and supporting commerce by simplifying interstate movement (now, each State sets its own requirements).

Based on the petitions, it is difficult for us to determine what segments of the aquaculture industry want services and exactly what sevices they want. It is also difficult to determine what the different petitioners want to accomplish by inviting Federal regulation.

The Animal and Plant Health Inspection Service (APHIS) is authorized to regulate to protect the health of livestock and poultry in the United States. We have many regulatory programs covering poultry, horses, swine, cattle, and other livestock. Our regulatory programs also cover animals that could transmit diseases or pests of livestock or poultry. Our programs for ''traditional'' livestock are intended to: (1) Prevent the importation of diseases and pests; (2) regulate interstate movement in a uniform manner; (3) provide diagnostic laboratory services; (4) regulate vaccines and biologic reagents used in animals; and (5) control and/or eradicate diseases and pests already found in the United States.

Based on the petitions we have received, we are considering whether to expand services to farm-raised fin fish. We already provide some services to aquaculture industries. Specifically, we provide laboratory diagnostic services, endorse export health certificates for aquatic animals and aquatic animal products, and license vaccines and biologic reagents for use in aquatic animals. We also control damage done by wild birds and other animals to farmed aquatic animals. Some of these services are paid for through user fees and cooperative agreements. If we were to offer additional services and programs, we would need funds to pay for them. We are interested in comments on how such services and programs should be funded.

What Programs and Regulations Should We Establish?

Before we decide whether to propose regulations covering farm-raised fin fish, we want the views and recommendations of all interested persons on the following specific issues:

1. We have received petitions to promulgate rules and regulations concerning domesticated farm-raised fin fish. However, as many of the petitions acknowledge, U.S. aquaculture industries include more than just domesticated fin fish. Letters referred not only to fish, but to clams, alligators, tropical fish (for aquariums), fish raised for human consumption, shrimp, mollusks, and crustaceans. Should we consider regulating only domesticated farm-raised fin fish, or should we consider regulating other aquatic animals as well? If we should consider a broader regulatory program, what species should we include, and why?

2. We already provide some services to aquaculture industries. We provide laboratory diagnostic services, endorse export health certificates for aquatic animals and aquatic animal products, and license vaccines and biologic reagents for use in aquatic animals. We also control damage done by wild birds and other animals to farmed aquatic animals. Should we expand the range of our services? If we expand our services to aquaculture industries, what new or additional services should we consider providing?

3. We currently regulate the importation of livestock and poultry and livestock and poultry products. These regulations are designed to prevent diseases and pests of livestock and poultry from being introduced into the United States. Should we consider adopting regulations to prevent the introduction of diseases and pests of aquatic animal species? If so, should the regulations be similar to those we have for livestock and poultry? If not, how should the regulations be different?

4. We work closely with industry and State representatives to administer many of our current disease control programs. For example, we work with industry and State representatives to control and eradicate brucellosis, tuberculosis, and other livestock diseases. If we develop any regulatory programs for aquatic animal species, what form should our cooperation take?

5. We currently regulate the interstate movement of livestock and poultry and livestock and poultry products. These regulations are designed to prevent diseases and pests of livestock and poultry from being spread within the United States. Currently, we administer several voluntary programs designed to help producers control and eliminate certain diseases in their livestock. The goal of these programs is to eliminate sources of infection, while helping producers improve their stock. For example, we have a program covering scrapie in sheep and goats called the Voluntary Scrapie Flock Certification Program. Should we consider adopting regulations to prevent the interstate spread of diseases and pests of any aquatic species? If we were to adopt regulations covering interstate movement of any aquatic animal species, should we include voluntary programs to help producers control and eliminate certain diseases? If so, what species and diseases should be covered? What should we include in such programs?

How Should We Conduct Rulemaking?

Developing a new regulatory program can be very complicated. It is important that we establish reasonable goals and adopt workable programs to achieve them. We will need to collect reliable information on the costs and benefits of any program. Public participation and input in the rulemaking process is vital to success.

In the rulemaking process, we can either draft proposed regulations ourselves or use negotiated rulemaking to develop the proposals. In negotiated rulemaking, an agency brings together the groups that are interested in or would be affected by proposed regulations. Working together, agency employees and representatives of interested and affected groups negotiate the text of a draft proposed rule.

Whether we draft a proposed rule ourselves, or use negotiated rulemaking, later steps in the rulemaking process would be the same. We would publish any proposed rule in the **Federal Register**, including an analysis of the costs and benefits, and invite the public to submit comments. After reviewing all the comments we receive, we would decide upon what further action to take.

Therefore, we are asking for comments from interested persons regarding the desirability of using a negotiated rulemaking process should we decide to proceed with rulemaking affecting farm-raised fin fish or other aquatic animals.

Authority: 5 U.S.C. 5542; 7 U.S.C. 147b; 21 U.S.C. 111–114a, 114b–114c, 114h, 115, 117–130, 134, 134(a)–134(h), 135a, 136, and 136a; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 28 day of April 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–11130 Filed 5–3–99; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

[Docket No. PRM–32–5]

Metabolic Solutions, Inc.; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking dated March 5, 1999, filed by Metabolic Solutions, Inc. (petitioner). The petition has been docketed by the Commission and has been assigned Docket No. PRM–32–5. The petitioner is requesting that the NRC regulations be amended to extend a regulatory distribution exemption to the petitioner's product, an ''Erythromycin Breath Test.'' That test uses a three-microcurie dose of carbon-14 (C14)-erythromycin to measure the rate of drug metabolism in the human liver. Current NRC regulations permit distribution of radioactive drug capsules that contain one microcurie of C14-urea to persons exempt from licensing. Dose regulations also permit any person exempt from the requirements of a license to use the capsules for diagnostic tests in humans. The petitioner believes that exempting the C14-erythromycin from regulatory control would make the breath test more widely available and reduce the costs of clinical trials without increasing the radiation risk to the public.

DATES: Submit comments by July 20, 1999. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (e-mail: CAG@nrc.gov).

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–7162 or Toll Free: 1–800–368–5642 or E-mail: *DLM1@NRC.GOV*.

SUPPLEMENTARY INFORMATION:

Background

On December 2, 1997 (62 FR 63634), the NRC published a final rule in the **Federal Register** that permitted the