

# Proposed Rules

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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

#### 7 CFR Part 330

[Docket No. 95-095-1]

RIN 0579-AA80

#### Plant Pest Regulations; Review of Current Provisions

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Advance notice of proposed rulemaking and notice of public meeting.

**SUMMARY:** We are soliciting public comment on several issues pertaining to our current regulations regarding the importation and interstate movement of plant pests. Specifically, we are seeking public comment on the criteria used to determine whether an organism is a plant pest; what types of direct and indirect injury or damage to plants and plant products should be regulated; how to facilitate the interstate movement and use of biological control organisms; and how to best evaluate the safety of proposed releases into the environment of organisms with plant pest characteristics. The information gathered through this advance notice of proposed rulemaking will be used by the Animal and Plant Health Inspection Service as we consider the need for regulatory changes and weigh alternative methods of addressing plant pest risk as it pertains to the importation, interstate movement, and release into the environment of plant pest or potential plant pest organisms.

**DATES:** Consideration will be given only to comments received on or before December 26, 1996. We will also consider comments made at a public hearing to be held on November 7, 1996, from 10 a.m. until 5:00 p.m.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 95-095-1, 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. 95-095-1. 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. The public hearing will be held on November 7, 1996, at the USDA Center at Riverside, 4700 River Road, Riverdale, MD.

**FOR FURTHER INFORMATION CONTACT:** Dr. Sally McCommon, Science Advisor, OA, APHIS, P.O. Box 96464, Washington, DC 20090-6464, (202) 720-8014, E-mail: smccommon@aphis.usda.gov; or Dr. Robert Flanders, Entomologist, Biological Assessment and Taxonomic Support, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236, (301) 734-8896, E-mail: bflanders@aphis.usda.gov.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Federal Plant Pest Act (FPPA), as amended (7 U.S.C. 150aa through 150jj), grants the Secretary of Agriculture broad authority to carry out operations or measures to detect, eradicate, suppress, control, or to prevent or retard the spread of plant pests; that authority gives the United States Department of Agriculture (USDA) the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against foreign plant pests. The FPPA defines a *plant pest* as "any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants."

The Secretary's authority under the FPPA and the Plant Quarantine Act, as amended (7 U.S.C. 151 through 164a, 167) has been delegated to the Administrator of the USDA's Animal and Plant Health Inspection Service

(APHIS), which administers regulations and conducts activities for the purpose of controlling and eradicating plant pests. APHIS' Plant Protection and Quarantine program area bears primary responsibility within the agency for those plant pest control and eradication activities.

Many of APHIS regulations in title 7, chapter III, of the Code of Federal Regulations focus on the importation or interstate movement of plants or plant products—e.g., nursery stock, seeds, fruits and vegetables, logs and lumber—as a means of preventing the introduction and dissemination of plant pests that are new to or not widely distributed within and throughout the United States. Those regulations are based on the premise that certain plants or plant products may be a vector of, or be infected or infested with, a plant pest. Similarly, 7 CFR chapter III also contains regulations that restrict or prohibit the movement of articles such as soil, stone, and quarry products, garbage, packing materials, and soil-moving equipment due to the risks that those articles may introduce or disseminate plant pests. Still other regulations in 7 CFR chapter III focus on organisms that may be a vector of, or be infected or infested with, plant pests. Examples of such organisms are live bees other than honeybees of the genus *Apis* regulated under 7 CFR 319.76; live honeybees of the genus *Apis* regulated under 7 CFR part 322; and organisms genetically engineered through recombinant DNA techniques regulated under 7 CFR part 340. Finally, there are regulations that focus on assessing and mitigating the plant pest risks associated with the movement of plant pests themselves.

APHIS' plant pest regulations in 7 CFR 330.200 (referred to below as the plant pest regulations) are for the stated purpose of preventing the dissemination of plant pests into the United States, or interstate, by regulating the movement of plant pests into or through the United States and interstate. When these regulations were first promulgated in 1959, they adequately addressed the needs of the regulated community, which at the time consisted mostly of government and academic researchers. In the years since 1959, however, the range of research and applications involving organisms that present plant pest risk has broadened enormously. In

addition to applications to move the "traditional" plant pests, APHIS now regularly receives requests to import or move interstate organisms such as parasites and predators for the biological control of arthropod pests; centipedes, walking sticks, praying mantises, butterflies, giant cockroaches, etc. for insect zoos; and microbes for soil treatment.

Although the range of organisms for which plant pest permits are requested has changed dramatically since 1959, APHIS' plant pest regulations have not been substantively amended to keep pace with those changes.

#### Nonindigenous Species Report

APHIS did propose to supplement its plant pest regulations following the September 1993 release of a report by the U.S. Congress' Office of Technology Assessment (OTA) entitled "Harmful Non-Indigenous Species in the United States" (OTA-F-565, Washington, DC; U.S. Government Printing Office, September 1993, referred to below as the OTA report). The OTA report examined pathways through which harmful nonindigenous organisms enter the United States, the harmful effects and economic consequences of many introduced organisms, and the State/Federal regulatory framework in place to prevent their introduction. One conclusion of the OTA report was that Federal agencies, including APHIS, should reevaluate, within their respective areas of responsibility, their approaches to dealing with introductions into the United States of nonindigenous organisms. The OTA report also highlighted the benefits that could accrue as a result of the increased use of biological control in pest management.

In response to the OTA report, APHIS published a proposed rule in the Federal Register on January 26, 1995 (60 FR 5288-5307, Docket No. 93-026-1) to establish new regulations to provide a means of screening certain nonindigenous organisms prior to their introduction to determine the potential plant pest risks associated with their introduction. We received over 250 comments on that proposed rule, none of which supported the proposed rule as written. After considering all the comments, we determined that the revisions needed to reconcile the proposed regulations with the very diverse views expressed in the comments would be so significant that any final rule would be substantially different from the proposed rule on which the public had the opportunity to comment. Therefore, on June 16, 1995,

we withdrew the proposed rule (60 FR 31647, Docket No. 93-026-4).

#### Regulatory Reform

In addition to any issues that may remain unresolved with regard to the recommendations of the OTA report, we have also made a commitment to reassess our plant pest regulations in response to the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals. To further both of those objectives, we have prepared this advance notice of proposed rulemaking to identify and seek input on several issues that we believe must be addressed in order for us to improve the service we provide to our stakeholders and move forward with a long overdue revision of the plant pest regulations. These issues are:

- The criteria used to determine whether an organism is a plant pest;
- What types of direct and indirect injury or damage to plants and plant products should be regulated;
- APHIS' role in facilitating the interstate movement and use of biological control organisms; and
- How to best evaluate the safety of proposed releases into the environment of organisms with plant pest characteristics.

These issues, and our questions regarding them, are discussed in detail below.

#### Determination of Plant Pest Status

The provisions of the plant pest regulations are most often implemented when a person requests a permit for the importation or interstate movement of an organism that is, or may be, a plant pest or that presents a risk of introducing or disseminating a plant pest. When a person seeks to import such an organism into the United States for the first time, APHIS will generally allow it to enter the country provided the organism is consigned directly to a containment facility inspected by APHIS, particularly if the organism is unidentified or field-collected. Such facilities are designed and operated to minimize the risk that the organisms contained in them could escape. Once in containment, an imported organism is separated from any contaminants (e.g., other organisms or plant materials) and evaluated in terms of the potential it has to directly or indirectly injure or cause damage or disease in plants or plant products. The same evaluation is applied to organisms already present in the United States, i.e. those organisms

for which a plant pest permit for interstate movement has been requested.

To determine whether or not an organism is a plant pest or poses a risk of introducing or disseminating a plant pest, APHIS conducts what we refer to as a first-tier pest risk assessment. First, because the identity of an organism is the key to subsequent research, we seek to establish whether the organism has been identified by a recognized authority or, if the species is undescribed or if it belongs to a group poorly understood by taxonomists, whether voucher materials have been deposited in a major U.S. repository, such as the collection at a major university. Once that consideration has been addressed, we then look at the organism in light of five questions; an affirmative answer to any one of these questions would give us reason to believe that the subject organism is a plant pest. Those questions are:

- Does the organism feed on, infect, or parasitize living plant tissues?
- Does the organism feed on, infect, or contaminate plant products such as stored grain, stored fruit, or lumber?
- Does the organism transmit plant pathogens?
- Does the organism develop as a secondary parasite, pathogen, or predator of a primary natural enemy of a herbivore or plant pathogen?
- Does the organism adversely affect commercially important pollinators or important herbivores or plant pathogens that control weeds?

In that those five questions dictate, in large measure, the questions that we would ask on an application for a plant pest permit or in some sort of pre-application guidance document, we would like your comments on those questions. Do they constitute an adequate measure of plant pest risk, or should additional criteria be included?

#### Indirect Injury or Damage

Many of the commenters who responded to our January 1995 proposed rule were critical of our lack of specificity when it came to what we might consider "indirect" injury or damage to plants or plant products. The tone of the proposed rule implied that we considered potential injury very broadly to include all negative impacts of all organisms within food chains where plants are the primary producers. Under such a scheme, herbivores and plant pathogens cause direct plant injury, while parasites and predators at higher trophic levels may cause indirect injury; any proposed insertion of an organism into a food web would require an evaluation of all potential disturbances within that food web.

While some groups may support an approach that requires an evaluation of all potential significant environmental impacts of introducing new organisms into an established food web, other groups strongly oppose that approach because it means that many parasites, predators, and pathogens that have traditionally been released to control herbivores and plant pathogens (i.e., biological control organisms) would be defined as plant pests because their effects on their intended targets could be construed as causing indirect injury or damage to plants or plant products.

In order that we may more clearly delineate the types of effects that could be considered "indirect" injury or damage to a plant or plant product and thus bring a greater degree of clarity or predictability to the plant pest permitting process, we are offering the following interpretation of "indirect" injury or damage for your consideration:

Direct and indirect injury or damage refers only to impacts within a food chain that negatively affect plants or plant products. Thus, for example, parasites or predators that inflict population-level damage on herbivorous invertebrates would not themselves be considered plant pests because their actions cause a reduction in direct injury or damage to plants or plant products. However, organisms at the next higher trophic level (e.g., hyperparasites) would be seen as causing indirect injury or damage to plants or plant products if they suppress the actions of the parasites, predators, or pathogens that would otherwise reduce the degree of direct injury or damage to plants or plant products. Similarly, because organisms such as honey bees, bumblebees, etc. are critical pollinators, any parasites, predators, or pathogens that adversely impact those pollinators would be seen as causing indirect injury or damage to plants or plant products due to the potential negative impact of reduced pollination.

Considering all the ramifications, is this interpretation of indirect injury or damage too narrow, or would a broader interpretation of indirect injury or damage unnecessarily hinder or delay the resolution of plant pest problems?

#### Voluntary Standards

When, as a result of our review, we determine that an organism is not a plant pest, we will inform the applicant that a plant pest permit is not required for the importation or interstate movement of the organism. In many cases, an applicant will request that APHIS issue a courtesy permit for the movement of such an organism. The plant pest regulations provide for the

issuance of courtesy permits for the movement of organisms that are not subject to regulation under the FPPA or any other act, as a courtesy to facilitate movement when the movement might otherwise be impeded because of the similarity of the organisms with others regulated under the FPPA. Such permits are most frequently requested for the interstate movement of parasites, predators, and pathogens that are intended for use in the biological control of plant pests.

APHIS deals regularly with State plant health officials who wish to see some Federal regulatory oversight for the interstate movement of such organisms. That is one of the reasons that courtesy permits are so often issued to facilitate the interstate movement of parasites, predators, and pathogens that are intended for use in the biological control of plant pests. Indeed, it may be desirable for there to be some degree of regulatory oversight on the part of APHIS to address the plant pest risks related to the movement of field-collected biological control organisms and host material.

One idea that has been raised that might fill any potential regulatory void while promoting the use of biological control is the formation of a cooperative program involving Federal and State agencies, biological control producers and distributors, and the biological control research community. The goal of the cooperative program would be to establish and promote compliance with a set of voluntary or consensus standards for the interstate movement and release into the environment of organisms used in the biological control of plant pests.

Under the FPPA, the Secretary of Agriculture is authorized to carry out measures to prevent or retard the spread of plant pests, either independently or in cooperation with States, farmers' associations and similar organizations, or individuals. In that the voluntary program would be a cooperative effort to facilitate research into and the movement of organisms used to prevent or retard the spread of plant pests, we believe that it could be established under our existing statutory authority.

A benefit of the plan would be that it could serve as a "seal of approval" for biological control researchers, producers, and distributors in the sense that its guidelines would be considered optimal for the research community and the industry. The voluntary plan could be operated under standards produced through consensus by its participants, i.e., government, industry, and the research community; a document drafted and widely distributed by the

National Biological Control Institute, a non-regulatory unit within APHIS, entitled "Options for Changes in Biological Control Regulations and Guidelines in the United States: A Strawman for Comment" is one example of the form that the voluntary plan's guidelines could take. Because participation in the plan would be voluntary, individuals would be likely to participate in the program as long as the benefits they derive from the program outweigh any added costs they might incur through their participation.

Would the level of support and participation from industry and the research community be great enough to justify the formation of such a program?

We are interested in receiving any ideas at all about the membership, leadership, responsibilities, funding, authority, etc. of a voluntary, cooperative program for organisms intended for the biological control of plant pests.

#### Releasing Plant Pests

When we have reason to believe that an organism is a plant pest or poses the risk of introducing or disseminating plant pests, that organism will be held in containment or refused permission to be moved interstate. However, there are organisms that possess plant pest characteristics but that have potential applications outside the laboratory or containment that would recommend their eventual release into the environment. Specifically, such organisms may have use in the biological control of weeds.

APHIS would only consider allowing such an organism to be released into the environment after it has been determined that the organism causes population-level injury, damage, or disease in a demonstrably narrow range of closely related plant species. The targeted plant species must also be overwhelmingly considered undesirable weeds before APHIS would consider allowing the release of an organism displaying plant pest characteristics.

We believe that a case can be made for the considered release into the environment of certain organisms that manifest plant pest characteristics; indeed, APHIS has, on a case-by-case basis, considered and granted approval for such releases. However, our current plant pest regulations make no provisions for such releases.

The demonstrated benefits accruing from the public and private use of integrated pest management principles make it likely that the use of organisms for the biological control of weeds will only increase. Therefore, we believe that it is necessary to develop standards that

would allow us to determine whether an organism could be safely employed for the biological control of weeds. Through our previous experience with determining the safety of potential biological control organisms of weeds, we have developed several questions that speak to the primary factor that must be considered in assessing such releases, i.e., host specificity. Those questions are:

- Does the organism feed upon, infect, or suppress only the target plant species or a few closely related species?

- If an arthropod, does the organism deposit eggs on plant species besides the target? If so, how closely are these plant species related to the target? Similarly, if the organism is a plant pathogen, can its spores or other propagules germinate and penetrate the tissues of plants other than the target?

- If the organism deposits eggs on plant species other than the target, do those eggs hatch and can the resulting immature stages significantly feed on them and complete their development? For plant pathogens, does penetration of the plant tissues lead to disease symptoms or signs in the plant?

- If the organism is an arthropod, are its immature stages capable of completing development on plants other than the target, and are the resulting adults fertile? Similarly, if the organism is a plant pathogen, does infection of nontarget plants result in the subsequent production of viable spores or other infective units?

- Does the probable ecological range (especially those related to tolerances for physical environmental parameters, especially temperature and humidity) of the organism overlap the distribution of native plant species that are related to the target in the United States and that are attacked in laboratory tests?

- Is the organism closely related to other species or strains that exhibit narrow or broad host specificities?

- Can the organism feed upon, attack, infect, or otherwise adversely impact endangered or threatened plant or animal species in the United States?

We are seeking your input on the appropriateness of these questions for assessing the risks of releasing organisms with plant pest characteristics for the biological control of weeds. What other considerations might be appropriate for such an assessment? Should any special requirements be imposed on organisms proposed for release on islands such as Puerto Rico or the State of Hawaii? Should APHIS require applicants to submit post-release monitoring data regarding possible attacks on nontarget plant species?

## Public Hearing

APHIS will host a public hearing to provide interested persons a full opportunity to present oral presentations of data, views, arguments, and questions regarding this advance notice of proposed rulemaking. The hearing will be held on November 7, 1996, at the USDA Center at Riverside, 4700 River Road, Riverdale, MD.

A representative of APHIS will preside at the public hearing. Any interested person may appear and be heard in person, by attorney, or by other representative. Persons who wish to speak at the public hearing will be asked to sign in, listing their names and organizations.

The public hearing will begin at 10 a.m. local time and is scheduled to end at 5 p.m. local time. However, the hearing may be terminated at any time after it begins if all persons desiring to speak have been heard. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing. If the number of speakers at the hearing warrants it, the presiding officer may limit the time for each presentation so that everyone wishing to speak has the opportunity.

We welcome all comments on the scope, approach, criteria, and issues outlined above and encourage the submission of ideas on any associated topics or other suggestions for the evaluation of plant pest risk and the improvement of the evaluation and permitting process. APHIS will consider all comments and recommendations in developing any revisions to the current FPPA regulations and will initiate rulemaking for any changes deemed appropriate.

Authority: 7 U.S.C. 149, 150bb, 150dd, 150ee, 150ff, 154, 159, 160, 162, and 2260; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 24th day of September 1996.

Terry L. Medley,

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 96-24847 Filed 9-26-96; 8:45 am]

BILLING CODE 3410-34-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. 95P-0337/CP1]

#### Food Labeling: Saccharin and Its Salts; Retail Establishment Notice; Revocation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revoke the food labeling regulation that prescribes conditions for the display by a retail establishment of a notice concerning the sale of products containing saccharin and its salts. This action is being taken in response to the enactment of Pub. L. 104-124, which amended the Federal Food, Drug, and Cosmetic Act (the act), and a citizen petition submitted by the Calorie Control Council. This action is intended to reduce the burden on small businesses.

**DATES:** Comments by December 11, 1996.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS-151), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

**SUPPLEMENTARY INFORMATION:** FDA is proposing to amend its food labeling regulations by revoking § 101.11 *Saccharin and its salts; retail establishment notice* (21 CFR 101.11). In the Federal Register of March 3, 1978 (43 FR 8793), FDA adopted § 101.11 to implement a provision of the Saccharin Study and Labeling Act (Pub. L. 95-203) (hereinafter referred to as the SSLA). Among other things, the SSLA amended the act by adding section 403(p) (21 U.S.C. 343(p)), which provided that a food would be misbranded if it contained saccharin and was offered for sale, but not for immediate consumption, at a retail establishment unless the retail establishment displayed specific information relative to saccharin and its salts.

On October 11, 1995, FDA received a citizen petition from the Calorie Control Council requesting that the agency revoke § 101.11. The petition claimed