States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. The phytosanitary treatments regulations contained in 7 CFR part 305 (referred to below as the regulations) set out standards for treatments required in parts 301, 318, and 319 of 7 CFR chapter III for fruits, vegetables, and other articles.

In §305.2, paragraph (b) states that approved treatment schedules are set out in the Plant Protection and Quarantine (PPQ) Treatment Manual. 1  Section 305.3 sets out the processes for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. In that section, paragraph (b) sets out the process for adding, revising, or removing treatment schedules when there is an immediate need to make a change. The circumstances in which an immediate need exists are described in §305.3(b)(1). They are:

- PPQ has determined that an approved treatment schedule is ineffective at neutralizing the targeted plant pest(s).
- PPQ has determined that, in order to neutralize the targeted plant pests(s), the treatment schedule must be administered using a different process than was previously used.
- PPQ has determined that a new treatment schedule is effective, based on efficacy data, and that ongoing trade in a commodity or commodities may be adversely impacted unless the new treatment schedule is approved for use.
- The use of a treatment schedule is no longer authorized by the U.S. Environmental Protection Agency or by any other Federal entity.

In accordance with §305.3(a)(1), we published a notice 2 in the Federal Register on March 28, 2014 (79 FR 17496–17497, Docket No. APHIS–2013–0009), announcing our determination that several additions to the PPQ Treatment Manual were necessary to mitigate the risk from various plant pests, based on evidence presented in treatment evaluation documents (TEDs) we made available with the notice. We also determined that the ongoing trade of commodities would be adversely impacted unless the new and revised treatment schedules were approved for use. The treatments were added to the PPQ Treatment Manual, but subject to change or removal based on public comment.

We solicited comments on the notice for 60 days ending on May 27, 2014. We received one comment by that date, from an importers association representative who raised concerns about the revised treatment schedule for asparagus.

Specifically, the commenter stated that there have been no pests detected during post-fumigation inspections to justify the revision of the fumigation process from 2 hours to 2.5 hours. Furthermore, the commenter stated that the additional 30 minutes of fumigation would have a negative impact on the quality of the asparagus. The commenter suggested that Animal and Plant Health Inspection Service (APHIS) and Peru collaborate to develop a systems approach to mitigate the plant pest risks, rather than use the prescribed fumigation treatment.

As noted in the TED, in 2007, live Copitarsia spp. larvae were detected on Peruvian asparagus during a post-fumigation inspection. As an interim measure to ensure trade would continue uninterrupted, PPQ increased the treatment duration by 30 minutes for all temperature ranges and monitored its effectiveness against all stages of the pest. Since the revision was made there have been no interceptions of Copitarsia spp. larvae on asparagus imported into the United States from Peru.

We understand the commenters’ concern regarding the negative effects the fumigation process has on the quality of the vegetables. We acknowledge that there is a potential risk of negative impacts on the quality or shelf life of commodities treated with fumigation and seek to minimize those efforts to the extent possible, but note that our primary concern must be to prevent the introduction of plant pests into the United States. We will, however, add a statement to the treatment T101–b–1 regarding the potential reduction in the shelf life of the treated asparagus.

We welcome and encourage opportunities to collaborate with our stakeholders and trading partners to further mitigate the risks associated with the importation of commodities. If we receive scientific information that supports the development of a systems approach, we would consider the information and make appropriate recommendations based on that information.

Therefore, in accordance with our regulations in §305.3(b)(3), we are affirming our addition of the new and revised treatment schedules for use for the various plant commodities for the PPQ Treatment Manual.


Done in Washington, DC, this 15th day of July 2015.

Kevin Shea,
Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–17840 Filed 7–20–15; 8:45 am]
BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0097]

Monsanto Co.; Availability of Preliminary Plant Pest Risk Assessment and Draft Environmental Assessment of Maize Genetically Engineered for Increased Ear Biomass

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is making available for public comment a preliminary plant pest risk assessment and draft environmental assessment for maize designated as event MON 87403, which has been genetically engineered for increased ear biomass.

DATES: We will consider all comments that we receive on or before August 20, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2014–0097, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents for this petition and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0097 or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851–3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 14–213–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of maize (Zea mays) designated as event MON 87403, which has been genetically engineered for increased ear biomass. The Monsanto petition states that information collected during field trials and laboratory analyses indicates that MON 87403 maize is not likely to be a plant pest and therefore should not be a regulated article under APHIS’ regulations in 7 CFR part 340.

According to our process for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice published in the Federal Register on January 20, 2015 (80 FR 2674–2675, Docket No. APHIS–2014–0097), APHIS announced the availability of the Monsanto petition for public comment. APHIS solicited comments on the petition for 60 days ending on March 23, 2015, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. APHIS received 20 comments on the petition. Issues raised during the comment period include the contamination of conventional crop production, the potential for disruption of trade due to the presence of unwanted genetically engineered commodities in exports, the potential for negative impacts on plant fitness and the environment, and health concerns. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our draft environmental assessment (EA).

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 1), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, APHIS will follow Approach 2. Under Approach 2, APHIS first solicits written comments from the public on a draft EA and preliminary PPRA for a 30-day comment period through the publication of a Federal Register notice. Then, after reviewing and evaluating the comments on the draft EA and preliminary PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). For this petition, we are using Approach 2.

As part of our decisionmaking process regarding a GE organism’s regulatory status, APHIS prepares a PPRA to assess the plant pest risk of the article. APHIS also prepares the appropriate environmental documentation—either an EA or an environmental impact statement—in accordance with NEPA, to provide the Agency and the public with a review and analysis of any potential environmental impacts that may result if the petition request is approved.

APHIS has prepared a preliminary PPRA and has concluded that maize designated as event MON 87403, which has been genetically engineered for increased ear biomass, is unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, “plant pest” is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data submitted by Monsanto, a review of other scientific data, field tests conducted under APHIS oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of maize designated as event MON 87403, or (2) make a determination of nonregulated status of maize designated as event MON 87403.

The EA was prepared in accordance with (1) NEPA, as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS’ NEPA
Implementing Procedures (7 CFR part 372).

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments on our draft EA and our preliminary PPRA regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 30 days from the date of this notice. Copies of the draft EA and the preliminary PPRA, as well as the previously published petition, are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft EA and the preliminary PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the Federal Register announcing the regulatory status of the GE organism and the availability of APHIS’ final EA, PPRA, FONSI, and our regulatory determination.


Done in Washington, DC, this 15th day of July 2015.

Kevin Shea,
Administrator, Animal and Plant Health Inspection Service.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2015–0007]

Notice of Affirmation of Addition of a Treatment Schedule for Methyl Bromide Fumigation of Figs

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are affirming our earlier determination that it was necessary to immediately add to the Plant Protection and Quarantine Treatment Manual a treatment schedule for methyl bromide fumigation of figs for certain pests, including Chilean false red mite. In a previous notice, we made available to the public for review and comment a treatment evaluation document that described the new treatment schedule and explained why we have determined that it is effective at neutralizing these pests.

DATES: Effective July 21, 2015, we are affirming the addition to the Plant Protection and Quarantine Treatment Manual of the treatment described in the notice published at 80 FR 10661–10662 on February 27, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Inder P.S. Gadh, Senior Risk Manager—Treatments, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851–2018.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR chapter III are intended, among other things, to prevent the introduction or dissemination of plant pests and noxious weeds into or within the United States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. These regulations set out standards for treatments required in 7 CFR parts 301, 318, and 319 for fruits, vegetables, and other articles.

In § 305.2, paragraph (b) states that approved treatment schedules are set out in the Plant Protection and Quarantine (PPQ) Treatment Manual.1 Section 305.3 sets out a process for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. In that section, paragraph (b) sets out the process for adding, revising, or removing treatment schedules when there is an immediate need to make a change. The circumstances in which an immediate need exists are described in § 305.3(b)(1). They are:

• PPQ has determined that an approved treatment schedule is ineffective at neutralizing the targeted plant pest(s).
• PPQ has determined that, in order to neutralize the targeted plant pest(s), the treatment schedule must be administered using a different process than was previously used.

• PPQ has determined that a new treatment schedule is effective, based on efficacy data, and that ongoing trade in a commodity or commodities may be adversely impacted unless the new treatment schedule is approved for use.
• The use of a treatment schedule is no longer authorized by the U.S. Environmental Protection Agency or by any other Federal entity.

In accordance with § 305.3(b), we published a notice2 in the Federal Register on February 27, 2015 (80 FR 10661–10662, Docket No. APHIS–2015–0007), announcing our determination that a new methyl bromide fumigation treatment schedule to control certain pests, including Chilean false red mite (Brevipalpus chilensis), on figs (Ficus carica) is effective, based on evidence presented in a treatment evaluation document (TED) we made available with the notice. We also determined that ongoing trade in figs would be adversely impacted unless the new treatment is approved for use. The treatment was added to the PPQ Treatment Manual, but was subject to change based on public comment.

We solicited comments on the notice for 60 days ending on April 28, 2015. We received one comment by that date, from a private citizen. The commenter stated that methyl bromide is known to deplete the stratospheric ozone layer, and that authorizing its use for treating figs violates the Montreal Protocol, in which the United States agreed to gradually reduce and ultimately eliminate use of methyl bromide.

The United States Government encourages methods that do not use methyl bromide to meet phytosanitary standards where alternatives are deemed to be technically and economically feasible, practical, and effective. At present, methyl bromide fumigation is the only authorized treatment that meets the above criteria for the treatment of external pests on figs. In addition, in accordance with Montreal Protocol Decision XI/13 (paragraph 7), APHIS is committed to promoting and employing gas recapture technology and other methods whenever possible to minimize harm to the environment caused by methyl bromide emissions.

Paragraph 5 of Article 2H of the Montreal Protocol does allow for quarantine and preshipment uses of methyl bromide, and does not specify a maximum number of such applications. Therefore, the application of this treatment is not in conflict with the


2 To view the notice, the TED, and the comment we received, go to http://www.regulations.gov/