



Animal and Plant Health Inspection Service, Plant Protection and Quarantine

Questions and Answers

Standardizing Phytosanitary Treatment Regulations: Approval of Cold Treatment and Irradiation Facilities; Cold Treatment Schedules; Establishment of Fumigation and Cold Treatment Compliance Agreements

What is APHIS proposing to change?

APHIS is proposing to standardize the treatment regulations related to the approval process for cold treatment (CT) facilities located in the southern and western States of the United States, and to establish generic criteria that all cold treatment facilities in these States must follow to safely treat commodities to meet U.S. entry requirements. This approval process would be similar to the one APHIS uses to approve irradiation facilities in the southern United States.

Currently, cold treatment facilities are only allowed to operate in the continental United States north of 39° latitude and east of 104° longitude as specified in 7CFR 305.6(b). This geographic limitation was enacted to protect southern and western states where exotic fruit flies could establish. To approve a cold treatment facility outside of these parameters APHIS must grant a special exemption through rulemaking. Through rulemaking APHIS has approved seven cold treatment facilities: the maritime ports of Corpus Christie, TX, Gulfport, MS, Seattle, WA, and Wilmington, NC, and the airports at Atlanta, GA, Mascoutah, IL and Seattle, WA.

U.S. industry has shown considerable interest in having additional CT facilities in the southern and western United States. Given APHIS' experience with cold treatment and the successful history of safeguarding at existing cold treatment facilities, we are confident that safeguards can be maintained to allow domestic cold treatment of fruit fly host material regardless of location.

This proposed rule would also expand the fruit cutting and inspection requirements to give U.S. Customs and Border Protection Agriculture Specialists (CBP-AS) the authority to sample and cut fruit from any cold treated consignment to inspect for any pest of concern. Currently, the regulations in § 305.6(d)(15) stipulate that an inspector will sample and cut fruit only for Mediterranean fruit fly (Medfly) to monitor treatment effectiveness. This provision is intended to provide CBP-AS more flexibility during the inspection process, but will not modify existing fruit cutting requirement or operational procedures related to fruit cutting.

We are also proposing to remove an obsolete cold treatment schedule (T 107-f) from the APHIS Plant Protection and Quarantine (PPQ) Treatment Manual.

Lastly, APHIS is proposing to standardize the regulations related to Compliance Agreements for treatment facilities. APHIS' current regulations require cold treatment facilities that are located in the United States to have compliance agreements. This proposed rule would also require operators of cold treatment facilities located outside the U.S. to have compliance agreements with APHIS when treating commodities destined to the U.S. Likewise, this proposed rule would require any person/facility operator providing fumigation treatments in the U.S., as well as those located outside the U.S. to obtain a compliance agreement. Other facilities such as heat treatment and irradiation treatment facilities in the U.S. already require a facility compliance agreement as a regulatory requirement. These additional compliance agreement requirements will make this consistent across all treatment types, transparent to stakeholders, and enforceable.

With regard to irradiation facilities, the regulation currently states that APHIS and the irradiation treatment facility operator must agree on all parameters, such as time, routing and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. We would propose to add that if APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached. This proposal harmonizes with what is being proposed for the cold treatment facility approval process described in the remainder of this document.

Why is APHIS proposing changes to the cold treatment facility approval process?

Currently, each request to authorize a cold treatment facility south of 39° latitude and west of 104° longitude must be approved through rulemaking, preventing APHIS from quickly responding to shifting trends in agricultural trade. With the increase in agricultural trade, there is a need to build these types of facilities where the demand for product is greatest. Thus, over the years, APHIS has allowed cold treatment facilities to be located at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; Hartsfield-Atlanta International Airport, Atlanta, GA; and, most recently, MidAmerica St. Louis Airport, Mascoutah, IL. This has resulted in establishing six different sets of criteria for eight different locations approved for cold treatment.

Approval on a case-by-case basis is an inefficient way to do the business which costs time and money to the stakeholders. The proposed changes would establish a set of safeguarding criteria that the new facility must follow to safeguard American agriculture from exotic pests. This will eliminate the need to publish rules or notices in the Federal Register to approve these facilities thus saving considerable time and resources. Additionally having one or two generic sets of criteria for facility approval and operation, will be less confusing, create consistency, and result in less demand of APHIS resources to implement these requirements. APHIS will still evaluate each proposed location for pest risks and approve that location only after APHIS identified sufficient safeguards.

What is the generic criteria for the approval of cold treatment facilities that is being proposed?

The regulations in 7 CFR Part 305.6 provide requirements that all northern cold treatment facilities must follow to treat articles to meet U.S. entry requirements. These facilities do not require rulemaking for approval, but they are held to certain criteria. The requirements stipulate that the facility is certified by APHIS, capable of keeping treated articles separate from the untreated, has the necessary equipment, enclosures, and expertise to effectively perform cold treatment, and that treated articles be sampled and cut by a CBP-AS to verify effectiveness of the cold treatment.

In addition to what is required for northern cold treatment facilities, APHIS is proposing that, facilities located in the area south of 39° latitude and west of 104° longitude, comply with the following:

- Maintain records of facility specific information including maps of the crops grown within 4 square miles of the facility,
- Schedule treatments in advance of that commodity being imported,
- Transport untreated articles to the facility in pest-proof boxes and refrigerated containers,
- Maintain a contingency plan to properly dispose of untreated articles should treatment fail, using approved disposal methods under the direction of APHIS,
- Take all precautions to prevent re-infestation of treated fruit,
- Lock facility during non-operational hours,
- Comply with any additional requirements that APHIS identified to prevent the escape of plant pests from the time the shipment arrives at the facility until the articles are successfully treated or otherwise properly disposed of.

How will the new cold treatment facility approval process differ from the current one?

With the application of the new generic criteria, no rulemaking or Notice in the *Federal Register* will be required to approve new facilities. Instead, facilities must submit an application and enter into a compliance agreement with APHIS. After we have reviewed the application and evaluated pest risks related to the facility, the pertinent State will be consulted for its concurrence before a facility is approved. Once a facility is approved, States will not have an ability to decertify a facility unless there are other issues outside the scope of APHIS regulations.

Will the establishment of generic criteria for approving cold treatment facilities replace options for cold-treating articles (i.e. treatment at origin or in-transit prior to arrival)?

No, if a commodity is already approved to undergo cold treatment at origin or in-transit, importers may continue to choose those treatment options. This rule will only affect the method

by which APHIS approves facilities in the southern and western States of the United States and establishes a transparent set of generic criteria for the facilities located in these States.

Will the proposed rule affect APHIS' market access approval process?

No, the commodity must be admissible to enter, or its domestic movement authorized, before it can be treated at the facility located on the mainland USA.

Will the proposed rule alter the commodity clearance process at ports of entry?

No, this proposed rule will not alter the current commodity entry requirements or the clearance process at ports of entry. In general, CBP-AS will continue performing the activities related to cold treatment as they are currently performing, including such things as:

- Inspecting the commodity and containers for hitch hiking pests,
- Sealing containers carrying the untreated commodity,
- Allowing movement to the pre-approved facility for cold treatment with proper safeguards,
- Sampling and cutting fruit for verification of the treatment.

The requirements are further detailed in the importer's compliance agreement and the import permit. At each facility, PPQ will ensure integrity of the containers, initiate the treatment, monitor the treatment on-site or remotely, and verify data received at the end of the treatment. CBP-AS will then visit the facility, carry out fruit cutting as determined necessary for fruit flies or other pests, and clear the consignment once all treatment requirements have been met.

Will the proposed rule increase the workload of CBP-AS?

We do not anticipate a significant increase in the work load of CBP-AS. Under existing requirements all cold treated commodities, whether treated in transit or on arrival require fruit cutting. This proposed rule would not alter those procedures or existing requirements. Prior to authorizing a new facility APHIS would work closely with CBP to assess the operational feasibility of that location.

When will the proposed changes take effect?

The proposed changes would take effect no sooner than 30 days after the final rule is published.

How will APHIS ensure facilities are adequately safeguarding untreated commodities?

During the approval process, the facility operator must agree to requirements in the compliance agreement. Thereafter, each time a treatment is initiated an inspector must visit the facility to

verify pre-cooling of fruit and check compliance with other treatment requirements. During the treatment, data are continuously logged on secure data loggers that APHIS may audit anytime and receive a copy at the end of treatment. Once APHIS has verified the data being acceptable, a CBP-AS visits the facility to verify completion of the treatment which involves checking the fruit temperature, sampling and cutting of fruit to make sure no live pest of concern survived the treatment. Regulations require re-certification of every cold treatment facility once every three years or as often as APHIS directs.

Will APHIS have oversight of the treatments?

APHIS is required to monitor each treatment. As a routine, depending upon the location, an APHIS inspector visits the facility once at pre-cooling time (i.e. prior to start of the treatment) to ensure all requirements for cold treatment including calibration of temperature sensors are in place, monitors treatment on site or remotely through the information being recorded on the data loggers, and then at the end of treatment visits to verify completion of the treatment. APHIS or CBP has the right to visit the facility unannounced at any time, and to take action when there are treatment failures or issues of non-compliance. As provided in the facility compliance agreement, facilities tampering with data are subject to heavy penalties and denial/withdrawal of certification.

What if the cold treatment fails?

Because of different temperature options available to meet cold treatment requirements, chances of treatment failures are remote. For example, cold treatment T107-a provides three temperature options to complete a treatment, at or below 34° F, 35° F and 36° F, for 14 days, 16 days, 18 days, respectively. If the treatment did fail the importer has the choice of either re-treating with cold treatment, destroying the commodity using an approved disposal method, or re-exporting the commodity to another country.

Why is APHIS now requiring compliance agreements from domestic fumigation facilities?

Compliance agreements between APHIS and domestic chemical treatment facilities have always been required per APHIS policy. However, the compliance agreement requirement was never codified into the code of federal regulations. Other facilities such as cold treatment, heat treatment, irradiation, etc. all specifically require a facility compliance agreement. These additional compliance agreement requirements will make this consistent across all treatment types, transparent to stakeholders, and enforceable.

How will APHIS maintain oversight for fumigation facilities located outside the United States?

If a fumigation treatment of imported articles is conducted outside the United States, the fumigation treatment facility operator or the person who conducts the fumigation must sign a compliance agreement or an equivalent agreement with APHIS and the national plant protection organization (NPPO) of the country in which the facility is located. In this agreement, the fumigation treatment facility operator or person conducting the fumigation must agree to comply with the requirements, and the NPPO of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance. Similar to the safeguarding measures for cold treatment the fumigation facility compliance agreement will contain requirements for equipment, temperature, air circulation and other measures to ensure the treatment is administered properly.

How will APHIS maintain oversight for cold treatment facilities located outside the United States?

Currently, cold treatment facilities located outside the United States operate under a bilateral workplan. The workplan must be signed by a representative of the cold treatment facility, National Plant Protection Organization (NPPO) of the country of origin and APHIS. The bilateral workplan may contain some of the same requirements as a domestic compliance agreement with the potential addition of a trust fund agreement information regarding payment of salaries and expenses of APHIS employees on the overseas site. We are proposing to combine these requirements into a single paragraph in the regulation that would set out the requirements that both domestic and foreign cold treatment facilities and importers would have to meet in order to enter into a compliance agreement with APHIS. These requirements are consistent with those required under regulation of importers shipping articles to irradiation facilities located in the Southern United States and are necessary to ensure that articles are not diverted to any destination other than an approved treatment facility, to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival into the United States to the approved cold treatment facility and to ensure that APHIS is aware of the time, route and conveyance by which consignments will move to the treatment facility.