

Prior Notice of Imported Food Contingency Plan for System Outages: Guidance for Industry

Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to <https://www.regulations.gov/>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with docket number FDA-2004-D-0042.

For questions regarding this document contact Food and Drug Administration, Office of Regulatory Affairs, Office of Enforcement and Import Operations, Division of Food Defense Targeting, Element Bldg., HFC-180, 12420 Parklawn Dr., Rockville, MD 20857-20993, e-mail: prior.notice@fda.hhs.gov, phone number: 866-521-2297.

**U.S. Department of Health and Human Services
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Prior Notice of Imported Food Contingency Plan for System Outages: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) and U.S. Customs and Border Protection (CBP) on this topic. It does not establish any rights for any person and is not binding on FDA, CBP, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document provides recommendations for submitting prior notice of imported food during system outages affecting the applicable FDA and U.S. Customs and Border Protection (CBP) program systems.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added section 801(m) to the Federal Food, Drug, and Cosmetic Act (the Act) to require that FDA receive prior notice for food imported or offered for import into the United States. An article of food imported or offered for import without prior notice in accordance with the Act shall be refused admission into the United States under section 801(m)(1) of the Act.

Prior notice regulations (21 CFR 1.276-1.285) set out the requirements for submitting prior notice of imported food. All submissions must be made electronically and must be submitted through the CBP Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS) or the FDA Prior Notice System Interface (PNSI) at <https://www.access.fda.gov> (21 CFR 1.280). If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (OASIS) is not working, FDA will post prominent notification and instructions at <https://www.access.fda.gov> (see log-in page) (21 CFR 1.280(c)).

FDA and CBP have identified seven system downtime scenarios that could impact transmission, confirmation, and processing of prior notice submissions and have developed alternative submission options for each of the identified scenarios. In these situations, FDA will accept prior

¹ This guidance has been prepared by the Office of Regulatory Affairs at the U.S. Food and Drug Administration in cooperation with the U.S. Customs and Border Protection at the Department of Homeland Security.

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notice submissions in the format it deems appropriate at the time (21 CFR 1.280(c)), such as by e-mail or fax (telephonic facsimile). When the alternate submission options include both e-mail and fax transmissions, e-mail transmission is encouraged as the more efficient means.

Any reference to ACE as not working only refers to the CBP ACE itself. If a filer/transmitter's ABI system is not working, arrangements should be made to transmit prior notice via another filer or via PNSI (21 CFR 1.280(b)).

III. PRIOR NOTICE CONTINGENCY PLAN

1. Scenario 1: ACE, OASIS, and PNSI are working, but the link between ACE and OASIS is down.

The outage described in this scenario would prevent submitters who filed via ABI/ACE from receiving prior notice confirmation and would prevent CBP from auto-checking the prior notice confirmation for ABI/ACE and PNSI filers.

If deemed appropriate, FDA will post a notice at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message through the Cargo Systems Messaging Service (CSMS) website advising of any available downtime specifics.

If prior notice has not been submitted, ABI filers may decide to wait out the ACE/OASIS interface downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

Alternatively, filers may submit prior notice via PNSI, in which case the prior notice confirmation number must accompany the article of food and must be provided to CBP or FDA upon arrival (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be provided to CBP officers for cargo release. If the PNSI confirmation page is not provided, it may delay cargo release.

If prior notice was submitted via ABI/ACE and a prior notice confirmation number has been received before the interface outage, the submitter may proceed with prior notice using the standard process. However, if prior notice was submitted via ABI/ACE but a prior notice confirmation number has not been received before the interface outage, submitters should provide a signed copy of the ABI transmission or other evidence to show that prior notice has been submitted via ABI/ACE, to CBP officers at the time of cargo release.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.

2. Scenario 2: ACE, PNSI, and the link between ACE and OASIS are working, but OASIS is down.

The outage described in this scenario would prevent submitters who filed via ABI/ACE from receiving prior notice confirmation and would prevent CBP from auto-checking the prior notice confirmation for ABI/ACE and PNSI filers.

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If deemed appropriate, FDA will post a notice at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message through the Cargo Systems Messaging Service (CSMS) website advising of any available downtime specifics.

If prior notice has not been submitted, ABI filers may decide to wait out the OASIS downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

Alternatively, filers may submit prior notice via PNSI, in which case the prior notice confirmation number must accompany the article of food and must be provided to CBP or FDA upon arrival (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be provided to CBP officers for cargo release. If the PNSI confirmation page is not provided, it may delay cargo release.

If prior notice was submitted via ABI/ACE and a prior notice confirmation number has been received before the interface outage, the submitter may proceed with prior notice using the standard process. However, if prior notice was submitted via ABI/ACE but a prior notice confirmation number has not been received before the interface outage, submitters should provide a signed copy of the ABI transmission or other evidence to show that prior notice has been submitted via ABI/ACE, to CBP officers at the time of cargo release.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.

3. Scenario 3: ACE and the link between ACE and OASIS are working, but OASIS and PNSI are down.

The outage described in this scenario would prevent submitters from filing prior notice via PNSI, prevent submitters who filed via ABI/ACE from receiving prior notice confirmation, and prevent CBP from auto-checking the prior notice confirmation for ABI/ACE and PNSI filers.

If deemed appropriate, FDA will post a notice at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message through the Cargo Systems Messaging Service (CSMS) website advising of any available downtime specifics.

If prior notice has not been submitted, filers may decide to wait out the OASIS and PNSI downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

If prior notice was submitted via ABI/ACE and a prior notice confirmation number has been received before the system outage, the submitter may proceed with prior notice using the standard process. However, if prior notice was submitted via ABI/ACE but a prior notice confirmation number has not been received before the outage, submitters should provide a signed copy of the ABI transmission showing the prior notice submission, or other evidence to show

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that prior notice has been submitted via ABI/ACE, to CBP officers at the time of cargo release.

If prior notice was submitted via PNSI, the confirmation number must accompany the article of food and must be provided to CBP or FDA upon arrival (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be provided to CBP officers for cargo release. If the PNSI confirmation page is not provided, this may delay cargo release.

If prior notice was not submitted via PNSI or ABI/ACE, prior notice must be submitted by either e-mail or fax. FDA will not accept prior notice submitted by these methods other than during a PNSI downtime.

1. E-mail Submission

FDA will provide a link to the contingency submission form (FDA 3540) at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message on the CSMS website. When this option is activated, the FDA's Division of Food Defense Targeting (DFDT) intends to send an automated receipt response, including the prior notice confirmation number, to the e-mail address from which the prior notice was submitted. A paper copy of the e-mail receipt confirmation should be presented to the CBP officer for cargo release. CBP intends to enforce prior notice submission time frames based on the e-mail receipt confirmation time stamp.

2. Fax Submission

FDA will publish the fax number to the DFDT at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message on the CSMS website. When this option is activated, DFDT intends to return a fax acknowledgement report, including the prior notice confirmation number. The fax acknowledgement report should be presented to the CBP officer for cargo release. CBP intends to enforce prior notice submission time frames based on the fax acknowledgement report confirmation time stamp.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.

4. Scenario 4: ACE, OASIS, and the link between ACE and OASIS are working, but PNSI is down.

The outage described in this scenario would prevent submitters from filing prior notice via PNSI and prevent CBP from auto-checking the prior notice confirmation for PNSI filers.

If deemed appropriate, FDA will post a notice at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message through the Cargo Systems Messaging Service (CSMS) website advising of any available downtime specifics

In this situation, prior notice may be submitted through ABI/ACE. If prior notice has not been submitted, PNSI filers may decide to wait out the PNSI downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

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If prior notice was submitted via PNSI and a confirmation number has been received before the system outage, the confirmation number must accompany the article of food and must be provided to CBP or FDA upon arrival (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be provided to CBP officers for cargo release. If the prior notice confirmation page is not provided, it may delay cargo release.

If prior notice was not submitted before the system outage, it may be submitted by either e-mail or fax. FDA will not accept prior notice submitted by these methods other than during PNSI downtime.

1. E-mail Submission

FDA will provide a link to the contingency submission form (FDA 3540) at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message on the CSMS website. When this option is activated, the FDA's Division of Food Defense Targeting (DFDT) intends to send an automated receipt response, including the prior notice confirmation number, to the e-mail address from which the prior notice was submitted. A paper copy of the e-mail receipt confirmation should be presented to the CBP officer for cargo release. CBP intends to enforce prior notice submission time frames based on the e-mail receipt confirmation time stamp.

2. Fax Submission

FDA will publish the fax number to the DFDT at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message on the CSMS website. When this option is activated, DFDT intends to return a fax acknowledgement report, including the prior notice confirmation number. This fax acknowledgement report should be presented to the CBP officer for cargo release. CBP intends to enforce prior notice submission time frames based on the fax acknowledgement report confirmation time stamp.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.

5. Scenario 5: OASIS, PNSI and the link between ACE and OASIS are working, but ACE is down.

The outage described in this scenario would prevent submitters who filed via ABI/ACE from receiving prior notice confirmation and prevent CBP from auto-checking the prior notice confirmation for ABI/ACE and PNSI filers.

If deemed appropriate, FDA will post a notice at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message through the Cargo Systems Messaging Service (CSMS) website advising of any available downtime specifics.

If prior notice has not been submitted, ABI filers may decide to wait out the ACE downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

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If prior notice was submitted via ABI/ACE and a prior notice confirmation number has been received before the system outage, the submitter may proceed with prior notice using the standard process. However, if prior notice was submitted via ABI/ACE but a prior notice confirmation number has not been received before the outage, submitters should provide a signed copy of the ABI transmission, or other evidence to show that prior notice has been submitted via ABI/ACE, to CBP officers at the time of cargo release.

Filers that need to submit prior notice while ACE is down must submit through PNSI (21 CFR 1.280(b)). If prior notice has been submitted via PNSI, the confirmation number must accompany the article of food and must be provided to CBP or FDA upon arrival (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be provided to CBP officers for cargo release. If the PNSI confirmation page is not provided, it may delay cargo release.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.

6. Scenario 6: ACE and PNSI are down.

The outage described in this scenario would prevent submitters from filing prior notice via PNSI, prevent submitters who filed via ABI/ACE from receiving prior notice confirmation, and prevent CBP from auto-checking the prior notice confirmation for ABI/ACE and PNSI filers.

If deemed appropriate, FDA will post a notice at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message through the Cargo Systems Messaging Service (CSMS) website advising of any available downtime specifics.

If prior notice has not been submitted, filers may decide to wait out the downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

If prior notice was submitted via ABI/ACE and a prior notice confirmation number has been received before the system outages, the submitter may proceed with prior notice using the standard process. However, if prior notice was submitted via ABI/ACE but a prior notice confirmation number has not been received before the outages, submitters should provide a signed copy of the ABI transmission or other evidence to show that prior notice has been submitted via ABI/ACE, to CBP officers at the time of cargo release.

If prior notice was submitted via PNSI and a confirmation number has been received before the system outage, the confirmation number must accompany the article of food and must be provided to CBP or FDA upon arrival (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be provided to CBP officers for cargo release. If the PNSI confirmation page is not provided, it may delay cargo release.

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If prior notice was not submitted before the outages, prior notice may be submitted by either e-mail or fax. FDA will not accept any prior notice submitted by these methods other than during PNSI downtimes.

1. E-mail Submission

FDA will post a link (URL) to the contingency submission form (FDA 3540) at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message on the CSMS website. When this option is activated, the FDA's Division of Food Defense Targeting (DFDT) intends to send an automated receipt response, including the prior notice confirmation number, to the e-mail address from which the prior notice was transmitted. A paper copy of the e-mail receipt confirmation should be presented to the CBP officer for cargo release. CBP intends to enforce prior notice submission time frames based on the e-mail receipt confirmation time stamp.

2. Fax submission

FDA will publish the fax number to the DFDT at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a message on the CSMS website. When this option is activated, DFDT intends to return a fax acknowledgement report including the prior notice confirmation number. The fax acknowledgement report should be presented to the CBP officer for cargo release. CBP intends to enforce prior notice submission time frames based on the fax acknowledgement report confirmation time stamp.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.

7. Scenario 7: Localized or regional power failure or other emergencies.

If possible, FDA will post a notice that includes a link to the prior notice contingency submission form (FDA 3540) at <https://www.access.fda.gov> (see log-in page) and will request that CBP issue an administrative message to brokers through CBP's Cargo Systems Messaging Service (CSMS) website.

If prior notice has not been submitted prior to the outage, filers may decide to wait out the downtime if the timeliness of prior notice will not be affected. Filers who choose this option remain responsible for filing timely prior notice under section 801(m) of the Act and under the prior notice final rule.

For the duration of this contingency scenario, filers should submit the required prior notice information to FDA at the port of arrival or if there is no FDA officer at a given port, to CBP via a paper copy of the contingency submission form at the time of cargo release.

FDA intends to post a notice once normal processing has resumed at <https://www.access.fda.gov> (see log-in page) and will request that CBP post a similar message on the CSMS website.