

August 12, 2004

Guidance for Industry

Prior Notice of Imported Food Contingency Plan for System Outages

This guidance represents the Food and Drug Administration's (FDA) and Customs and Border Protection's (CBP) current thinking on alternative submission options for prior notice of imported food in the event of system outages. It does not create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Comments and suggestions regarding this guidance may be submitted at any time. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Domenic Veneziano, Office of Regulatory Affairs (HFC-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703-621-7809.

Additional copies are available from:
U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition

Department of Homeland Security
U.S. Customs and Border Protection (CBP)

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TABLE OF CONTENTS

1. [INTRODUCTION](#)
2. [BACKGROUND](#)
3. PRIOR NOTICE CONTINGENCY PLAN
 1. [Scenario 1 -- ACS, OASIS, and PNSI are all operational but the link between ACS and OASIS is down.](#)
 2. [Scenario 2 -- ACS, PNSI, and the link between ACS and OASIS are operational, but OASIS is down.](#)
 3. [Scenario 3 -- ACS and the link between ACS and OASIS are operational but OASIS and PNSI are down.](#)
 1. Prior notice submitted via ABI/ACS
 2. Prior notice submitted via PNSI
 3. Prior notice submitted via e-mail or fax
 1. E-mail Submission
 2. Fax Submission
 4. [Scenario 4 -- ACS, OASIS, and the link between ACS and OASIS are operational but PNSI is down.](#)
 1. E-mail Submission
 2. Fax Submission
 5. [Scenario 5 -- OASIS, PNSI, and the link between ACS and OASIS are operational but ACS is non-operational.](#)
 6. [Scenario 6 -- ACS and PNSI are down.](#)
 1. E-mail Submission
 2. Fax Submission
 7. [Scenario 7 -- Localized or regional power failure or other emergencies.](#)

Guidance for Industry⁽¹⁾

Prior Notice of Imported Food Contingency Plan for System Outages

This guidance represents the Food and Drug Administration's (FDA's) and Customs and Border Protection's (CBP) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA

staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This document is intended to provide guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and CBP program systems.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency'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 Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), section 307, 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. Section 801(m) provides that if an article of food arrives at the port of arrival with inadequate prior notice (e.g., no prior notice, inaccurate prior notice, or untimely prior notice), the food is subject to refusal of admission under section 801(m)(1) of the Act and may not be delivered to the importer, owner, or consignee. If an article of food is refused under section 801(m)(1) of the Act, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

On October 10, 2003, FDA and CBP issued an interim final regulation requiring that FDA receive prior notice of the importation of food beginning on December 12, 2003 (68 FR 58974). The interim final rule provides that any person with knowledge of the required information may submit prior notice or have it transmitted on their behalf (21 CFR 1.278). The interim final rule also provides that prior notice must be submitted electronically, in English (except an individual's name, the name of a company, or the name of a street), through either CBP's ABI/ACS or the FDA PN System Interface (PNSI) (21 CFR 1.280(a)). The interim final rule eliminates submission of duplicative information to FDA by those who can file import entry information through ABI/ACS. FDA and CBP upgraded and interfaced their respective electronic systems so that information required for prior notice can be submitted through ABI/ACS. Information required by the interim final rule also can be submitted through PNSI. The interim final rule further provides that if a customs broker's or self-filer's system is not working or if ABI/ACS is not working, prior notice must be submitted through PNSI; and that if PNSI or FDA's Operational and Administrative System for Import Support (OASIS) is not operating, prior notice information must be submitted by e-mail, or by fax to the FDA (21

CFR 1.280(b)-(e)).

FDA and CBP have identified seven potential 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 any of the scenarios described, where the alternate submission options include both email and fax (telephonic facsimile) transmissions, email transmission is strongly encouraged as the more efficient means.

Any reference to ACS as non-operational refers only to the CBP ACS itself. If a filer/transmitter's ABI system is non-operational, arrangements should be made to transmit prior notice via another filer or via PNSI (21 CFR 1.280(b)).

III. PRIOR NOTICE CONTINGENCY PLAN

A. Scenario 1: ACS, OASIS, and PNSI are all operational, but the link between ACS and OASIS is down on FDA's or CBP's side of the system interface.

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

In this situation, if deemed appropriate, CBP will issue an administrative message to brokers and FDA will post a notice at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, advising of any available downtime specifics. If prior notice has not already been submitted, ABI filers may decide to wait out the ACS/OASIS Interface downtime if they determine that the timeliness of prior notice will not be adversely affected. Filers who choose this option should understand that they remain responsible under section 801(m) of the Act and under the prior notice interim final rule for filing timely prior notice.

Alternatively, filers may submit prior notice via PNSI, in which case the prior notice confirmation number must accompany the article of food (21 CFR 1.279(g)). If prior notice is submitted through PNSI, FDA and CBP recommend that the submitter present the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the PNSI confirmation page is not presented, this may delay cargo release while the CBP officer, without being able to access OASIS, contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

If prior notice has already been submitted via ABI/ACS prior to the interface outage, and confirmation has already been received, the submitter may proceed with prior notice using the standard process. If prior notice has already been submitted via ABI/ACS and confirmation has not been received prior to the interface outage, FDA and CBP

recommend that, rather than resubmitting via PNSI, submitters should provide to CBP officers, at the time of cargo release, an endorsed (signed) copy of the ABI transmission or some other evidence adequate to show that prior notice has been submitted via ABI/ACS.

Upon restoration of the interface FDA intends to provide notice, via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html>, that normal processing has resumed.

B. Scenario 2: ACS, PNSI, and the link between ACS and OASIS are operational, but OASIS is non-operational.

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

In this situation, notice advising of any available downtime specifics will be posted at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, and through messages in ABI/ACS (see 21 CFR 1.280(d)).

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

Alternatively, filers may submit prior notice via PNSI, in which case the prior notice confirmation number must accompany the article of food (21 CFR 1.279(g)). If prior notice is submitted through PNSI, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be presented to CBP officers for cargo release. If the PNSI confirmation page is not presented, this may delay cargo release while the CBP officer, without being able to access OASIS, contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

If prior notice has already been submitted via ABI/ACS prior to the interface outage, and confirmation has already been received, the submitter may proceed with prior notice using the standard process. If prior notice has already been submitted via ABI/ACS and confirmation has not been received prior to the interface outage, FDA and CBP recommend that, rather than resubmitting via PNSI, submitters should provide to CBP officers, at the time of cargo release, an endorsed (signed) copy of the ABI transmission or some other evidence adequate to show that prior notice has been submitted via

ABI/ACS.

Upon restoration of the system FDA intends to issue a notice via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html>, that normal processing has resumed.

C. Scenario 3: ACS and the link between ACS and OASIS are operational but OASIS is non-operational and PNSI is non-operational or unavailable due to Internet service interruptions.

If deemed appropriate, notice advising of any available downtime specifics will be posted at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, and through messages in ABI/ACS (see 21 CFR 1.280(c) and (d)).

1. Prior Notice Submission submitted via ABI/ACS

If prior notice has already been submitted via ABI/ACS prior to the system outage, and a prior notice confirmation number has been received, the submitter may proceed with prior notice using the standard process. However, if prior notice is submitted via ABI/ACS and a prior notice confirmation number is not received prior to the outages, submitters should provide to CBP officers, at the time of cargo release, either an endorsed (signed) copy of the ABI transmission showing the prior notice submission, or some other evidence adequate to show that prior notice has been submitted via ABI/ACS.

2. Prior Notice Submission submitted via PNSI

If prior notice has been submitted via PNSI, the confirmation number must accompany the article of food (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the submitter also provide the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the PNSI confirmation page is not provided, this may delay cargo release while the CBP officer, without being able to access OASIS, contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

3. Prior Notice Submission via e-mail or fax

If prior notice has not been submitted via PNSI or ABI/ACS, prior notice must be submitted by either e-mail or fax (21 CFR 1.280(c), (d)). FDA does not intend to accept prior notice submitted by these methods other than during a PNSI downtime (21 CFR 1.280(e)).

1. E-mail Submission

FDA will publish a location (URL) linking to the email submission form for FDA's Prior Notice Center at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, and through messages in ABI/ACS (see 21 CFR 1.280(c) and (d)). When this option is activated, FDA intends to transmit back to the e-mail address from which the prior notice was submitted an automated receipt response, including the prior notice confirmation number. A paper copy of FDA's e-mail receipt confirmation should then be presented to the CBP officer for cargo release processing. CBP officers intend to enforce prior notice submission based on the e-mail receipt confirmation time stamp.

2. Fax Submission

FDA will publish the fax telephone number for the Prior Notice Center at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, and through messages in ABI/ACS (see 21 CFR 1.280(c) and (d)). When this option is activated, the Prior Notice Center intends to return a fax acknowledgement report, including the prior notice confirmation number.

The fax acknowledgement report should then be presented to the CBP officer for cargo release processing. CBP officers intend to enforce prior notice submission time frames based on the fax received confirmation time stamp.

Upon restoration of the systems, FDA intends to issue a notice, via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html>, that normal processing has resumed.

D. Scenario 4: ACS, OASIS, and the link between ACS and OASIS are operational but PNSI is non-operational or unavailable due to Internet service interruptions.

If deemed appropriate, CBP intends to issue an administrative message to brokers and notice will be posted advising of any available downtime specifics at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html> (see 21 CFR 1.280(c)).

In this situation, prior notice may continue to be submitted through ABI/ACS.

If prior notice has been submitted via PNSI prior to the system outage and a confirmation number has already been received, the confirmation number must accompany the article of food (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the submitter also

provide the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the prior notice confirmation page is not provided, this may delay cargo release while the CBP officer contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

Otherwise, if prior notice has not been submitted prior to the system outage, it may be submitted by either e-mail or fax (21 CFR 1.280(c)). FDA does not intend to accept any prior notice submitted by these methods other than during PNSI/OASIS downtime (21 CFR 1.280(e)).

1. E-mail Submission

FDA will publish a location (URL) linking to the email submission form for the Prior Notice Center at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html> (see 21 CFR 1.280(c)). For e-mail submissions, FDA intends to transmit back to the e-mail address from which the Prior Notice was submitted an automated receipt response, including the confirmation number. A paper copy of FDA's e-mail receipt confirmation should be presented to the CBP officer for cargo release processing. CBP intends to enforce prior notice submission timeframes based on the e-mail receipt confirmation time stamp.

2. Fax Submission

FDA will publish the fax telephone number for FDA's Prior Notice Center at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html> (see 21 CFR 1.280(c)). In cases of fax transmissions, the Prior Notice Center 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 processing. CBP officers intend to enforce prior notice submission time frames based on the fax received confirmation time stamp.

Upon restoration of the system FDA intends to issue a notice, via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html>, that normal processing has resumed.

E. Scenario 5: OASIS, PNSI and the link between ACS and OASIS are operational but ACS is non-operational.

In this situation, if deemed appropriate, FDA intends to post a notice at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and

<http://www.cfsan.fda.gov/~pn/pnoview.html> (see 21 CFR 1.280(c)), advising of any available downtime specifics.

If prior notice has already been submitted via ABI/ACS prior to the system outage, and a prior notice confirmation number has been received, the submitter may proceed with prior notice using the standard process. However, if prior notice is submitted via ABI/ACS and a prior notice confirmation number is not received prior to the outage, submitters should provide to CBP officers, at the time of cargo release, an endorsed (signed) copy of the ABI transmission or some other evidence adequate to show that prior notice has been submitted via ABI/ACS.

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

Alternatively, filers may submit prior notice via PNSI, in which case the prior notice confirmation number must accompany the article of food (21 CFR 1.279(g)). If prior notice is submitted through PNSI, FDA and CBP recommend that the PNSI confirmation page, including the prior notice confirmation number and time stamp, be presented to CBP officers for cargo release. If the PNSI confirmation page is not presented, this may delay cargo release while the CBP officer, without being able to access OASIS, contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

While ACS is non-operational, prior notice must be submitted through PNSI (21 CFR 1.280(b)). If prior notice has been submitted via PNSI, the confirmation number must accompany the article of food (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the submitter also provide the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the PNSI confirmation page is not provided, this may delay cargo release while the CBP officer, without being able to access OASIS, contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

Upon restoration of the system FDA intends to issue a notice, via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html>, that normal processing has resumed.

F. Scenario 6: ACS is non-operational, PNSI is non-operational or unavailable due to Internet service interruptions, and OASIS and the link between ACS and OASIS are either operational or non-operational.

A notice advising of any available downtime specifics will be posted at <http://www.access.fda.gov>, <http://www.fda.gov>,

<http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, and, if OASIS is down, through messages in ABI/ACS (see 21 CFR 1.280(c) and (d)).

If prior notice has already been submitted via ABI/ACS prior to the system outages, and a prior notice confirmation has been received, the submitter may proceed with prior notice using the standard process. However, if prior notice is submitted via ABI/ACS and a prior notice confirmation number is not received prior to the outages, submitters should provide to CBP officers, at the time of cargo release, either an endorsed (signed) copy of the ABI transmission or some other evidence adequate to show that prior notice has been submitted via ABI/ACS.

If prior notice has been submitted via PNSI prior to the system outage and a confirmation number has been received, the confirmation number must accompany the article of food (21 CFR 1.279(g)). In addition, FDA and CBP recommend that the submitter also provide the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the PNSI confirmation page is not provided, this may delay cargo release while the CBP officer contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

If prior notice has not been submitted prior to the outages, prior notice may be submitted by either e-mail or fax (21 CFR 1.280(c) and (d)). FDA does not intend to accept any prior notice submitted by these methods other than during PNSI/OASIS downtimes (21 CFR 1.280(e)).

1. E-mail Submission

FDA will publish a location (URL) linking to the email submission form for the Prior Notice Center at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html> (see 21 CFR 1.280(c) and (d)). For e-mail submissions, FDA intends to transmit back to the e-mail address from which the Prior Notice was transmitted an automated receipt response from FDA, including the prior notice confirmation number. A paper copy of FDA's e-mail receipt confirmation should be presented to the CBP officer for cargo release processing. CBP intends to enforce prior notice submission timeframes based on the e-mail receipt confirmation time stamp.

2. Fax submission

FDA will publish the fax telephone number for the Prior Notice Center at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html> (see 21 CFR 1.280(c) and (d)). In cases of fax transmissions, the Prior Notice Center intends to return a fax acknowledgement report including the prior notice confirmation number. The fax acknowledgement report should

then be presented to the CBP officer for cargo release processing. CBP officers intend to enforce prior notice submission time frames based on the fax received confirmation time stamp.

Upon restoration of the system FDA intends to issue a notice, via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html>, that normal processing has resumed.

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

If possible, CBP will issue an administrative message to brokers and FDA will post a notice at <http://www.access.fda.gov>, <http://www.fda.gov>, <http://www.cfsan.fda.gov/~furls/fisstat.html> and <http://www.cfsan.fda.gov/~pn/pnoview.html>, advising of any available downtime specifics.

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 prior notice e-mail contingency form (FDA 3540) at the time of cargo release. Upon restoration of the system, FDA intends to issue a notice via web page posting at <http://www.cfsan.fda.gov/~furls/fisstat.html> that normal processing has resumed.