

Guidelines for Penalty Assessment and Mitigation for Bioterrorism Act Violations

James Doran Barnes, Richardson & Colburn Washington, D.C

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("BTA") requires prior notice ("PN") of the importation of food and food products to be provided electronically to the Food and Drug Administration ("FDA"). U.S. Customs and Border Protection ("CBP") has now published a Memorandum on Procedures for Implementation of Enforced Compliance and Penalties for the Bioterrorism Act, which includes Guidelines for Penalty Assessment and Mitigation.

The previously issued joint CBP-FDA <u>Compliance Policy Guide for Food Imports</u> identifies three categories of BTA violations:

<u>Category 1 violations</u>, those violations where available information indicates that the article presents a threat of serious adverse health consequences or death to humans or animals;

<u>Category 2 violations</u>, those violations which either reflect a history of repeated, similar conduct by a person who has been notified or such violations which appear to be intentional or flagrant; and

<u>Category 3 violations</u>, violations other than as described above.

Current Enforcement Phase

CBP-FDA's current phase of enforcement runs from June 4 until August 12 of this year. Under this phase, CBP may assess monetary penalties equal to the domestic value of the cargo against a party aiding or abetting in the importation of any merchandise contrary to law, and may take the following actions, depending on the specific violation: Customs may refuse entry and assess monetary penalties for all Category 1 violations and those Category 2 violations involving failure to provide PN; for Category 2 violations involving inaccurate or untimely PN or the importation food or food products from an unregistered facility, monetary penalties are considered but CBP will not refuse entry; and, for Category 3 violations involving failure to provide PN, the merchandise is subject to refusal but no monetary penalties are considered. Informed compliance notices will be issued during this phase for other Category 3 violations.

On August 13, 2004, CBP will begin the full enforcement of the BTA. All violations, regardless of category or type, may be subject to civil monetary penalties, and associated merchandise will be refused entry into the United States.

Penalty Assessment and Mitigation

The penalty assessment guidelines for failure to provide PN, untimely presentation of PN, or inaccurate information in a PN, allow the port director to issue a civil monetary penalty equal to the domestic value of the cargo. The mitigation guidelines provide for pre-set mitigated penalties if the violator agrees to waive the right to file a petition for relief. Alternatively, the charged party may petition for relief, and full relief will be granted when the petitioner demonstrates that there was no violation or that the violation occurred solely as a result of government error, but by so petitioning will no longer be afforded the reduced penalty option.

Available mitigated penalties, depending on the violation, are as follows:

Failure to submit PN

- First violation: penalty may be mitigated upon payment of \$750;
- Second or subsequent violation: penalty may be mitigated upon payment of an amount between \$1,000 and \$5,000;
- If a petition for relief is filed, the penalty will be mitigated to an amount equal to no less than \$500 more than the pre-set reduced amount option.

Untimely submission of PN

- First violation: penalty may be mitigated upon payment of \$250;
- Second or subsequent violation: penalty may be mitigated upon payment of an amount between \$500 and \$2,000;
- If a petition for relief is filed, the penalty will be mitigated to an amount equal to no less than \$250 more than the pre-set reduced amount option.

Inaccurate information on a PN

- First violation: penalty may be mitigated upon payment of \$500;
- Second or subsequent violation: penalty may be mitigated upon payment of an amount between \$750 and \$3,000;
- If a petition for relief is filed, the penalty will be mitigated to an amount equal to no less than \$500 more than the pre-set reduced amount option.

Cargo Security

Note that CBP indicates that, before any penalty assessments are made, consideration may be given to the level of cooperation received regarding cargo security from the party to be charged. Specifically, the fines, penalties and forfeitures officer ("FPFO") may consider whether the party is a participant in the Customs-Trade Partnership Against Terrorism ("C-TPAT") and weigh the level of cooperation received regarding cargo

security as a mitigating factor in any case. The FPFO may mitigate a subsequent violation as a first violation in the case of a penalty assessed against a cooperating party.