For the Nuclear Regulatory Commission.

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Executive Director for Operations.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 766

[Docket No. 151204999–5999–01]

RIN 0694–AG73

Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases, Revision of Supplement No. 1 to Part 766 of the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise Bureau of Industry and Security's (BIS) guidance regarding administrative enforcement cases based on violations of the Export Administration Regulations (EAR). The rule would rewrite Supplement No. 1 to part 766 of the EAR, setting forth the factors BIS considers when setting penalties in settlements of administrative enforcement cases and when deciding whether to pursue administrative charges or settle allegations of EAR violations. This proposed rule would not apply to alleged violations of part 760—Restrictive Trade Practices and Boycotts, which would continue to be subject to Supplement No. 2 to part 766. BIS is proposing these changes to make administrative penalties more predictable to the public and aligned with those promulgated by the Department of the Treasury, Office of Foreign Assets Control (OFAC).

DATES: Comments must be received no later than February 26, 2016.

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

Federal eRulemaking Portal: http://www.regulations.gov. The identification number for this rulemaking is BIS–2015–0051.

By email directly to: publiccomments@bis.doc.gov. Include RIN 0694–AG73 in the subject line.

By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Refer to RIN 0694–AG73.

FOR FURTHER INFORMATION CONTACT: Norma Curtis, Assistant Director, Office of Export Enforcement, Bureau of Industry and Security. Tel: (202) 482–5036, or by email at *norma.curtis@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The mission of the Office of Export Enforcement (OEE) at BIS is to enforce the provisions of the Export Administration Regulations (EAR), secure America's trade, and preserve America's technological advantage by detecting, investigating, preventing, and deterring the unauthorized export and reexport of U.S.-origin items to parties involved with: (1) Weapons of mass destruction programs; (2) threats to national security or regional stability; (3) terrorism; or (4) human rights abuses. Export Enforcement at BIS is the only federal law enforcement agency exclusively dedicated to the enforcement of export control laws and the only agency constituted to do so with both administrative and criminal export enforcement authorities. OEE's criminal investigators and analysts leverage their subject-matter expertise, unique and complementary administrative enforcement tools, and relationships with other federal agencies and industry to protect our national security and promote our foreign policy interests. OEE protects legitimate exporters from being put at a competitive disadvantage by those who do not comply with the law. It works to educate parties to export transactions on how to improve export compliance practices, supporting American companies' efforts to be reliable trading partners and reputable stewards of U.S. national and economic security. BIS also discourages, and in some circumstances prohibits, U.S. companies from furthering or supporting any unsanctioned foreign boycott (including the Arab League boycott of Israel).

OEE at BIS may refer violators of export control laws to the U.S. Department of Justice for criminal prosecution, and/or to BIS's Office of Chief Counsel for administrative prosecution. In cases where there has been a willful violation of the EAR, violators may be subject to both criminal fines and administrative penalties. Administrative penalties may also be imposed when there is no willful intent, allowing administrative cases to be brought in a much wider variety of circumstances than criminal cases. BIS has a unique combination of administrative enforcement authorities including both civil penalties and denials of export privileges. BIS may also place individuals and entities on lists that restrict or prohibit their involvement in exports, reexports, and transfers (in-country).

In this rule, BIS is proposing to amend the EAR to update its Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases (the ''Guidelines'') found in Supplement No. 1 to part 766 of the EAR in order to make civil penalty determinations more predictable and transparent to the public and aligned with those promulgated by the Treasury Department's Office of Foreign Assets Control (OFAC). OFAC administers most of its sanctions programs under the International Emergency Economic Powers Act (IEEPA), the same statutory authority by which BIS implements the EAR. OFAC uses the transaction value as the starting point for determining civil penalties pursuant to its Economic Sanctions Enforcement Guidelines. Under IEEPA, criminal penalties can reach 20 years imprisonment and $1 million per violation, and administrative monetary penalties can reach $250,000 or twice the value of the transaction, whichever is greater. Both agencies coordinate and cooperate on investigations involving violations of export controls that each agency enforces, including programs relating to weapons of mass destruction, terrorism, Iran, Sudan, Specially Designated Nationals and Specially Designated Global Terrorists. This guidance would not apply to civil administrative enforcement cases for violations under part 760 of the EAR—Restrictive Trade Practices and Boycotts. Supplement No. 2 to Part 766 continues to apply to enforcement cases involving part 760 violations.

The Guidelines would provide factors by which violations could be characterized as either egregious or non-egregious and describe the difference in the base penalty amount likely to apply in an enforcement case. The base penalty would depend on whether the violation is egregious or non-egregious and whether or not the case resulted from a voluntary self-disclosure that satisfies all the requirements of § 764.5 of the EAR. Base penalty amounts would be described in terms of the applicable statutory maximum, the transaction value, or the applicable schedule amount. The terms ''transaction value'' and ''applicable schedule amount'' would be defined in the Guidelines. The ''statutory maximum'' would be the maximum permitted by § 764.3(a)(1) of the EAR

(15 CFR 764.3(a)(1)) subject to adjustment under the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461). Additional information about the changes proposed here and how they differ from the current Guidelines set forth in Supplement No. 1 to Part 766 is described below.

Once the base penalty amount has been determined, Factors set forth in these Guidelines would be applied to determine whether the base penalty amount should be adjusted downward or, subject to the statutory maximum, upward. Factors set forth in the current Guidelines would be reorganized into the following categories: (1) Aggravating Factors (*e.g.,* willfulness or recklessness); (2) General Factors that could be considered either aggravating or mitigating depending upon the circumstances (*e.g.,* the absence or presence and adequacy of an internal compliance program); (3) Mitigating Factors (*e.g.,* remedial measures taken); and (4) other Relevant Factors on a case-by-case basis (*e.g.,* additional violations or other enforcement actions). Voluntary self-disclosures (VSDs) would no longer be listed as mitigating factors in and of themselves, but credit accorded to VSDs would be built into the determination of the base penalty amount. This credit would no longer be characterized as constituting ''great weight'' mitigation, but violations disclosed in a complete and timely VSD may be afforded a deduction of 50 percent of the transaction value or, in egregious cases, the statutory maximum in determining the base penalty amount. Mitigating Factors would also be assigned specific percentages off the base penalty amount, as further described below. Mitigating Factors may be combined for a greater reduction in penalty but mitigation will generally not exceed 75 percent of the base penalty.

Willfulness, recklessness and concealment would be set forth as Aggravating Factor A—*Willful or Reckless Violation of Law* in the revised Guidelines. The degree to which these actions are present would determine the degree of aggravation factored into the penalty calculation. Aggravating Factor B—*Awareness of Conduct at Issue* would be listed as a separate factor in the revised Guidelines to address situations where the Respondent knew or had reason to know of the violation(s), and took no action to address them. Currently, knowing violations are subsumed within consideration of the ''Degree of Willfulness.'' Harm to regulatory program objectives would be listed as Aggravating Factor C—*Harm to Regulatory Program Objectives.* This factor would take into account all of the following: The destination involved, the end use and end user, and the sensitivity and control level of the item(s) involved in the transaction. Aggravating Factors A–C would be considered key in determining whether a violation was egregious or not, as further discussed below. Other aggravating facts, whether relating to the General Factors or Other Relevant Factors discussed below, may also be pertinent in determining whether a violation was egregious.

Under this proposed rule, General Factors could either be mitigating or aggravating depending upon the circumstances. Two General Factors would be set forth in the revised Guidelines: General Factor D, involving an assessment of the individual characteristics of a Respondent; and General Factor E, assessing the presence and adequacy of a compliance program. General Factor D—*Individual Characteristics*—would encompass an evaluation of the Respondent's commercial sophistication, exporting experience, volume and value of transactions, and regulatory history. General Factor E—*Compliance Program*—would involve a determination of whether or not the Respondent had an effective risk-based BIS compliance program in place at the time of the apparent violation, including an assessment of the extent to which it complied with BIS's Export Management System (EMS) Guidelines. Under General Factor E, if the Respondent's compliance program served to uncover the violation and led to prompt and comprehensive remedial measures taken to ensure against future violations, additional mitigation may be accorded to the Respondent under Mitigating Factor F, *Remedial Response.* That factor looks at whether the Respondent took corrective action in response to the apparent violation, such as stopping the conduct at issue.

Mitigating Factor G—*Exceptional Cooperation with OEE* may result in a 25 percent to 40 percent reduction of the base penalty amount. This level of cooperation goes beyond what would be considered minimally necessary to address a violation and take corrective measures. In cases not involving a VSD, the Respondent must have provided substantial additional information regarding the apparent violation and/or other apparent violations caused by the same course of conduct. Exceptional cooperation in cases involving VSDs may also be considered as a further mitigating factor.

Transactions that would likely have received a license had one been sought, as set forth in Mitigating Factor H—*License Was Likely To Be Approved* also may result in up to a 25 percent reduction of the base penalty amount. First offenses, addressed in the context of calculation of the base penalty amount, may also result in a reduction of that amount by up to 25 percent.

Finally, proposed Factors I–M pertain to factors that may be relevant in certain circumstances and considered on a case-by-case basis. Factor I—*Related Violations* would address situations in which a single export transaction can give rise to multiple violations. Factor J—*Multiple Unrelated Violations* would address situations where multiple unrelated violations, as described in this proposed rule, could warrant a stronger enforcement response, including a denial order. Factor K—*Other Enforcement Action* would provide that corresponding enforcement action taken by federal, state, or local agencies in response to the apparent violation or similar apparent violations may be considered, particularly with regard to global settlements or criminal convictions and/or plea agreements.

Factor L—*Future Compliance/Deterrence Effect* would address the impact that the administrative action may have with regard to promoting future compliance and deterring such conduct by other similar parties, particularly in the same industry sector. Factor M—*Other Factors That BIS Deems Relevant* would serve as a ''catch-all'' category to retain flexibility to consider factors not already specifically addressed in the Guidelines, whether proposed by the Respondent or BIS.

Consideration of these Factors would not dictate a particular outcome in any particular case, but rather is intended to identify those Factors most relevant to BIS's decision and to guide the agency's exercise of its discretion. The Guidelines would provide sufficient flexibility to allow for the consideration of the Factors most relevant to a particular case. Penalties for settlements reached after the initiation of an enforcement proceeding and litigation through the filing of a charging letter will usually be higher than those described by these Guidelines.

In accordance with OEE's existing posture that enhanced maximum civil penalties authorized by the International Emergency Economic Powers Enhancement Act (Enhancement Act) (Pub. L. 110–96, 50 U.S.C. 1701, *et seq.*) should be reserved for the most serious cases, the Guidelines would formally account for the substantial

increase in the maximum penalties for violations of IEEPA and distinguish between egregious and non-egregious civil monetary penalty cases. Egregious cases would be those involving the most serious violations, based on an analysis of all applicable Factors, with substantial weight given to considerations of willfulness or recklessness, awareness of the conduct giving rise to an apparent violation, and harm to the regulatory program objectives, taking into account the individual characteristics of the parties involved. As described below, the Guidelines generally would provide for significantly higher civil penalties for egregious cases. OEE anticipates that the majority of apparent violations investigated by OEE will fall in the non-egregious category. OEE does not expect that adoption of these guidelines will increase the number of cases that are charged administratively rather than closed with a warning letter.

The Guidelines define the ''transaction value'' to mean the dollar value of a subject transaction. Where the dollar value cannot be determined with certainty, the Guidelines would provide sufficient flexibility to allow for the determination of an appropriate transaction value in a wide variety of circumstances. The applicable schedule amounts, which would provide for a graduated series of penalties based on the underlying transaction values, reflect appropriate starting points for penalty calculations in non-egregious cases not involving VSDs. The base penalty amount for a non-egregious case involving a VSD would equal one-half of the transaction value, capped at $125,000, for an apparent violation of the EAR. Such calculation would ensure that the base penalty for a VSD case will not be more than one-half of the base penalty for a similar case that is not voluntarily self-disclosed. This difference is intended to serve as an additional incentive for the submission of VSDs. In the interest of providing greater transparency and predictability to BIS administrative enforcement actions, BIS would also allot penalty reductions—all from the base penalty amount—of between 25 and 40 percent for exceptional cooperation, and up to an additional 25 percent for first offenses and for transactions where a license was likely to be approved.

BIS encourages the submission of VSDs by persons who believe they may have violated the EAR. The purpose of an enforcement action includes raising awareness, increasing compliance, and deterring future violations, not merely punishing past conduct. VSDs are a compelling indicator of a person's present intent and future commitment to comply with U.S. export control requirements. The purpose of mitigating the enforcement response in voluntary self-disclosure cases is to encourage the notification to OEE of apparent violations about which OEE would not otherwise have learned. OEE's longstanding policy of encouraging the submission of VSDs involving apparent violations is reflected by the fact that, over the past several years, on average only three percent of VSDs submitted have resulted in a civil penalty. The majority of cases brought to the attention of OEE through VSDs result in the issuance of warning letters, containing a finding that a violation may have taken place. With respect to VSDs generally, OEE will issue warning letters in cases involving inadvertent violations and cases involving minor or isolated compliance deficiencies, absent the presence of aggravating factors.

Finally, in appropriate cases in the context of settlement negotiations, BIS may suspend or defer payment of a civil penalty, taking into account whether the Respondent has demonstrated a limited ability to pay, whether the matter is part of a global settlement with other U.S. government agencies, and/or whether the Respondent will apply a portion or all of the funds suspended or deferred for purposes of improving its internal compliance program.

Cases will continue to be processed in accordance with the enforcement guidelines and precedents currently in existence until the new Guidelines are issued in final form after review of public comments.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a currently valid OMB Control Number. This rule does not contain any collections of information.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities.

Number of Small Entities

Under the Regulatory Flexibility Act, the term ''small entities'' encompasses small businesses, small (not for profit) organizations and small governmental jurisdictions. The Bureau of Industry and Security (BIS) does not collect data on the size of entities that apply for and are issued export licenses pursuant to the Export Administration Regulations (EAR). However, in this instance, no small entities would be impacted by this rule because this rule would not require any person to change its behavior, nor would it alter any rights that any person has pursuant to the EAR. Only BIS would be directly affected by this proposed rule and BIS is not a small entity for purposes of the Regulatory Flexibility Act.

Economic Impact

This proposed rule would revise Bureau of Industry and Security's guidance regarding administrative enforcement cases based on violations of the EAR. The rule would set forth the factors BIS would consider when setting penalties in the settlement of administrative enforcement cases, when deciding whether to pursue administrative charges or settle allegations of EAR violations, and when

deciding what level of penalty to seek in settlements of administrative cases. As with the existing guidelines, consideration of these factors would not dictate the outcome in a particular case. Instead the guidelines are intended to identify those factors most relevant to BIS's decision and to guide BIS in the exercise of its discretion. The guidelines themselves would provide sufficient flexibility for consideration of the factors most relevant in a particular case. Publication of this proposed rule and any resulting final rule is intended to make BIS decisions related to administrative enforcement of the Export Administration Regulations more transparent and predictable to the public. The rule would not require any party other than BIS to alter its behavior, nor would it alter any right that any person (including any small entity) currently has under the Export Administration Regulations. BIS is not a small entity for purposes of the Regulatory Flexibility Act.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 7, 2015, (80 FR 48233 (Aug. 11, 2015)), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

List of Subjects in 15 CFR Part 766

Administrative practice and procedure, Confidential business information, Exports, Law Enforcement, Penalties.

Accordingly, this proposed rule proposes to amend part 766 of the Export Administration Regulations (15 CFR parts 730–774) (EAR) as follows:

PART 766—[AMENDED]

■ 1. The authority citation for part 766 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 48233 (August 11, 2015).

■ 2. Supplement No. 1 to Part 766 is revised to read as follows:

Supplement No. 1 to Part 766—Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases

Introduction

This Supplement describes how the Bureau of Industry and Security (BIS) responds to apparent violations of the Export Administration Regulations (EAR) and, specifically, how BIS makes penalty determinations in the settlement of civil administrative enforcement cases under part 764 of the EAR. This guidance does not apply to enforcement cases for violations under part 760 of the EAR—Restrictive Trade Practices or Boycotts. Supplement No. 2 to Part 766 continues to apply to civil administrative enforcement cases involving part 760 violations.

Because many administrative enforcement cases are resolved through settlement, the process of settling such cases is integral to the enforcement program. BIS carefully considers each settlement offer in light of the facts and circumstances of the case, relevant precedent, and BIS's objective to achieve in each case an appropriate penalty and deterrent effect. In settlement negotiations, BIS encourages parties to provide, and will give serious consideration to, information and evidence that parties believe are relevant to the application of this guidance to their cases, to whether a violation has in fact occurred, or to whether they have an affirmative defense to potential charges.

This guidance does not confer any right or impose any obligation regarding what penalties BIS may seek in litigating a case or what posture BIS may take toward settling a case. Parties do not have a right to a settlement offer or particular settlement terms from BIS, regardless of settlement positions BIS has taken in other cases.

I. Definitions

Note: See also: Definitions contained in § 766.2 of the EAR.

Apparent violation means conduct that constitutes an actual or possible violation of the Export Administration Act of 1979, the International Emergency Economic Powers Act, the EAR, other statutes administered or enforced by BIS, as well as executive orders, regulations, orders, directives, or licenses issued pursuant thereto.

Applicable schedule amount means:

1. $1,000 with respect to a transaction valued at less than $1,000;

2. $10,000 with respect to a transaction valued at $1,000 or more but less than $10,000;

3. $25,000 with respect to a transaction valued at $10,000 or more but less than $25,000;

4. $50,000 with respect to a transaction valued at $25,000 or more but less than $50,000;

5. $100,000 with respect to a transaction valued at $50,000 or more but less than $100,000;

6. $170,000 with respect to a transaction valued at $100,000 or more but less than $170,000;

7. $250,000 with respect to a transaction valued at $170,000 or more.

Transaction value means the U.S. dollar value of a subject transaction, as demonstrated by commercial invoices, bills of lading, signed Customs declarations, or similar documents. Where the transaction value is not otherwise ascertainable, BIS may consider the market value of the items that were the subject of the transaction and/or the economic benefit derived by the Respondent from the transaction, in determining transaction value. In situations involving a lease of U.S.-origin items, the transaction value will generally be the value of the lease. For purposes of these Guidelines, ''transaction value'' will not necessarily have the same meaning, nor be applied in the same manner, as that term is used for import valuation purposes at 19 CFR 152.103.

Voluntary self-disclosure means the self-initiated notification to OEE of an apparent violation as described in and satisfying the requirements of § 764.5 of the EAR.

II. Types of Responses to Apparent Violations

OEE, among other responsibilities, investigates apparent violations of the EAR, or any order, license or authorization issued thereunder. When it appears that such a violation has occurred, OEE investigations may lead to a warning letter or an administrative enforcement proceeding. A violation may also be referred to the Department of Justice for criminal prosecution. The type of enforcement action initiated by OEE will depend primarily on the nature of the violation. Depending on the facts and circumstances of a particular case, an OEE investigation may lead to one or more of the following actions:

A. *No Action.* If OEE determines that there is insufficient evidence to conclude that a violation has occurred, determines that a violation did not occur and/or, based on an analysis of the Factors outlined in Section III of these Guidelines, concludes that the conduct does not rise to a level warranting an administrative response,

then no action will be taken. In such circumstances, if the investigation was initiated by a voluntary self-disclosure (VSD), OEE will issue a letter in response indicating that the investigation is being closed with no administrative action being taken. OEE may issue a no-action letter in non-voluntarily disclosed cases at its discretion. A no-action determination represents a final determination as to the apparent violation, unless OEE later learns of additional information regarding the same or similar transactions or other relevant facts.

B. *Warning Letter.* If OEE determines that a violation may have occurred but a civil penalty is not warranted under the circumstances, and believes that the underlying conduct could lead to a violation in other circumstances and/or that a Respondent does not appear to be exercising due diligence in assuring compliance with the statutes, executive orders, and regulations that OEE enforces, OEE may issue a warning letter. A warning letter may convey OEE's concerns about the underlying conduct and/or the Respondent's compliance policies, practices, and/or procedures. It may also address an apparent violation of a technical nature, where good faith efforts to comply with the law and cooperate with the investigation are present, or where the investigation commenced as a result of a voluntary self-disclosure satisfying the requirements of § 764.5 of the EAR, provided that no aggravating factors exist. In the exercise of its discretion, OEE may determine in certain instances that issuing a warning letter, instead of bringing an administrative enforcement proceeding, will achieve the appropriate enforcement result. A warning letter will describe the apparent violation and urge compliance. A warning letter represents OEE's enforcement response to the apparent violation, unless OEE later learns of additional information concerning the same or similar apparent violations. A warning letter does not constitute a final agency determination as to whether a violation has occurred.

C. *Administrative enforcement case.* If BIS determines that a violation has occurred and, based on an analysis of the Factors outlined in Section III of these Guidelines, concludes that the Respondent's conduct warrants a civil monetary penalty or other administrative sanctions, BIS may initiate an administrative enforcement case. The issuance of a charging letter under § 766.3 of the EAR initiates an administrative enforcement proceeding. Charging letters may be issued when there is reason to believe that a violation has occurred. Cases may be settled before or after the issuance of a charging letter. *See* § 766.18 of the EAR. BIS may prepare a proposed charging letter which could result in a case being settled before issuance of an actual charging letter. *See* § 766.18(a) of the EAR. If a case does not settle before issuance of a charging letter and the case proceeds to adjudication, the resulting charging letter may include more violations than alleged in the proposed charging letter. Civil monetary penalty amounts for cases settled before the issuance of a charging letter will be determined as discussed in Section IV of these Guidelines. A civil monetary penalty may be assessed for each violation. The maximum amount of such a penalty per violation is stated in § 764.3(a)(1), subject to adjustments under the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461), which are codified at 15 CFR 6.4. BIS will afford the Respondent an opportunity to respond to a proposed charging letter. Responses to charging letters following the institution of an enforcement proceeding under part 766 of the EAR are governed by § 766.3 of the EAR.

D. *Civil Monetary Penalty.* BIS may seek a civil monetary penalty if BIS determines that a violation has occurred and, based on the Factors outlined in Section III of these Guidelines, concludes that the Respondent's conduct warrants a monetary penalty. Section IV of these Guidelines will guide the agency's exercise of its discretion in determining civil monetary penalty amounts.

E. *Criminal Referral.* In appropriate circumstances, BIS may refer the matter to the Department of Justice for criminal prosecution. Apparent violations referred for criminal prosecution also may be subject to a civil monetary penalty and/or other administrative sanctions or action by BIS.

F. *Other Administrative Sanctions or Actions.* In addition to or in lieu of other administrative actions, BIS may seek sanctions listed in § 764.3 of the EAR. BIS may also take the following administrative actions, among other actions, in response to an apparent violation:

License Revision, Suspension or Revocation. BIS authorizations to engage in a transaction pursuant to a license or license exception may be revised, suspended or revoked in response to an apparent violation as provided in §§ 740.2(b) and 750.8 of the EAR.

Denial of Export Privileges. An order denying a Respondent's export privileges may be issued, as described in § 764.3(a)(2) of the EAR. Such a denial may extend to all export privileges, as set out in the standard terms for denial orders in Supplement No. 1 to part 764 of the EAR, or may be narrower in scope (*e.g.,* limited to exports of specified items or to specified destinations or customers). A denial order may also be suspended in whole or in part in accordance with § 766.18(c).

Exclusion from practice. Under § 764.3(a)(3) of the EAR, any person acting as an attorney, accountant, consultant, freight forwarder or other person who acts in a representative capacity in any matter before BIS may be excluded from practicing before BIS.

Training and Audit Requirements. In appropriate cases, OEE may require as part of a settlement agreement that the Respondent provide training to employees as part of its compliance program, adopt other compliance measures, and/or be subject to internal or independent audits by a qualified outside person. In those cases, OEE may suspend or defer a portion or all of the penalty amount if the suspended amount is applied to comply with such requirements.

G. *Suspension or Deferral.* In appropriate cases, payment of a civil monetary penalty may be suspended or deferred during a probationary period under a settlement agreement and order. If the terms of the settlement agreement or order are not adhered to by the Respondent, then suspension or deferral may be revoked and the full amount of the penalty imposed. *See* § 764.3(a)(1)(iii) of the EAR. In determining whether suspension or deferral is appropriate, BIS may consider, for example, whether the Respondent has demonstrated a limited ability to pay a penalty that would be appropriate for such violations, so that suspended or deferred payment can be expected to have sufficient deterrent value, and whether, in light of all of the circumstances, such suspension or deferral is necessary to make the impact of the penalty consistent with the impact of penalties on other parties who committed similar violations. BIS may also take into account when determining whether or not to suspend or defer a civil penalty whether the Respondent will apply a portion or all of the funds suspended or deferred to audit, compliance, or training that may be required under a settlement agreement and order, or the matter is part of a ''global settlement'' as discussed in more detail below.

III. Factors Affecting Administrative Sanctions

Many apparent violations are isolated occurrences, the result of a good-faith misinterpretation, or involve no more than simple negligence or carelessness. In such instances, absent the presence of aggravating factors, the matter frequently may be addressed with a warning letter. If the violations are of such a nature and extent that a monetary fine alone represents an insufficient penalty, a denial or exclusion order may also be imposed to prevent future violations of the EAR.

While some violations of the EAR have a degree of knowledge or intent as an element of the offense, OEE may regard a violation of any provision of the EAR as knowing or willful if the facts and circumstances of the case support that conclusion. For example, evidence that a corporate entity had knowledge at a senior management level may mean that a higher penalty may be appropriate. OEE will also consider, in accordance with Supplement No. 3 to part 732 of the EAR, the presence of any red flags that should have alerted the Respondent that a violation was likely to occur. The aggravating factors identified in the Guidelines do not alter or amend § 764.2(e) or the definition of ''knowledge'' in § 772.1, or other provisions of parts 764 and 772 of the EAR.

As a general matter, BIS will consider some or all of the following Factors in determining the appropriate sanctions in administrative cases, including the appropriate amount of a civil monetary penalty where such a penalty is sought and is imposed as part of a settlement agreement and order. These factors describe circumstances that, in BIS's experience, are commonly relevant to penalty determinations in settled cases. Factors that are considered exclusively aggravating, such as willfulness, or exclusively mitigating, such as situations where remedial measures were taken, are set forth below. This guidance also identifies General Factors—which can be either mitigating or aggravating—such as the presence or absence of an internal compliance program at the time the apparent violations occurred. Other relevant Factors may also be considered at the agency's discretion.

Aggravating Factors

A. *Willful or Reckless Violation of Law:* BIS will consider a Respondent's apparent willfulness or recklessness in violating, attempting to violate, conspiring to violate, or causing a violation of the law. Generally, to the extent the conduct at issue appears to be the result of willful conduct—a deliberate intent to violate, attempt to violate, conspire to violate, or cause a violation of the law—the OEE enforcement response will be stronger. Among the factors BIS may consider in evaluating apparent willfulness or recklessness are:

1. *Willfulness.* Was the conduct at issue the result of a decision to take action with the knowledge that such action would constitute a violation of U.S. law? Did the Respondent know that the underlying conduct constituted, or likely constituted, a violation of U.S. law at the time of the conduct?

2. *Recklessness/gross negligence.* Did the Respondent demonstrate reckless disregard or gross negligence with respect to compliance with U.S. regulatory requirements or otherwise fail to exercise a minimal degree of caution or care in avoiding conduct that led to the apparent violation? Were there warning signs that should have alerted the Respondent that an action or failure to act would lead to an apparent violation?

3. *Concealment.* Was there a deliberate effort by the Respondent to hide or purposely obfuscate its conduct in order to mislead BIS, federal, state, or foreign regulators, or other parties involved in the conduct, about an apparent violation?

Note: Failure to voluntarily disclose an apparent violation to OEE does not constitute concealment.

4. *Pattern of Conduct.* Did the apparent violation constitute or result from a pattern or practice of conduct or was it relatively isolated and atypical in nature?

5. *Prior Notice.* Was the Respondent on notice, or should it reasonably have been on notice, that the conduct at issue, or similar conduct, constituted a violation of U.S. law?

6. *Management Involvement.* In cases of entities, at what level within the organization did the willful or reckless conduct occur? Were supervisory or managerial level staff aware, or should they reasonably have been aware, of the willful or reckless conduct?

B. *Awareness of Conduct at Issue:* The Respondent's awareness of the conduct giving rise to the apparent violation. Generally, the greater a Respondent's actual knowledge of, or reason to know about, the conduct constituting an apparent violation, the stronger the BIS enforcement response will be. In the case of a corporation, awareness will focus on supervisory or managerial level staff in the business unit at issue, as well as other senior officers and managers. Among the factors OEE may consider in evaluating the Respondent's awareness of the conduct at issue are:

1. *Actual Knowledge.* Did the Respondent have actual knowledge that the conduct giving rise to an apparent violation took place, and remain willfully blind to such conduct, and fail to take remedial measures to address it? Was the conduct part of a business process, structure or arrangement that was designed or implemented with the intent to prevent or shield the Respondent from having such actual knowledge, or was the conduct part of a business process, structure or arrangement implemented for other legitimate reasons that consequently made it difficult or impossible for the Respondent to have actual knowledge?

2. *Reason to Know.* If the Respondent did not have actual knowledge that the conduct took place, did the Respondent have reason to know, or should the Respondent reasonably have known, based on all readily available information and with the exercise of reasonable due diligence, that the conduct would or might take place?

3. *Management Involvement.* In the case of an entity, was the conduct undertaken with the explicit or implicit knowledge of senior management, or was the conduct undertaken by personnel outside the knowledge of senior management? If the apparent violation was undertaken without the knowledge of senior management, was there oversight intended to detect and prevent violations, or did the lack of knowledge by senior management result from disregard for its responsibility to comply with applicable regulations and laws?

C. *Harm to Regulatory Program Objectives:* The actual or potential harm to regulatory program objectives caused by the conduct giving rise to the apparent violation. This factor would be present where the conduct in question, in purpose or effect, substantially implicated national security or other essential interests (*e.g.,* foreign policy, nonproliferation) protected by the U.S. export control system, in view of such factors as the reason for controlling the item to the destination in question; the sensitivity of the item; the prohibitions or restrictions against the recipient of the item; and the licensing policy concerning the transaction (such as presumption of approval or denial). BIS, in its discretion, may consult with other U.S. agencies or with licensing and enforcement authorities of other countries in making its determination. Among the factors BIS may consider in evaluating the harm to regulatory program objectives are:

1. *Implications for U.S. National Security:* The impact that the apparent violation had or could potentially have on the national security of the United States. For example, if a particular export could undermine U.S. military superiority or endanger U.S. or friendly military forces or be used in a military application contrary to U.S. interests, BIS would consider the implications of the apparent violation to be significant.

2. *Implications for U.S. Foreign Policy:* The effect that the apparent violation had or could potentially have on U.S. foreign policy objectives. For example, if a particular export is, or is likely to be, used by a foreign regime to monitor communications of its population in order to suppress free speech and persecute dissidents, BIS would consider the implications of the apparent violation to be significant.

General Factors

D. *Individual Characteristics:* The particular circumstances and characteristics of a Respondent. Among the factors BIS may consider in evaluating individual characteristics are:

1. *Commercial Sophistication:* The commercial sophistication and experience of the Respondent. Is the Respondent an individual or an entity? If an individual, was the conduct constituting the apparent violation for personal or business reasons?

2. *Size and Sophistication of Operations:* The size of a Respondent's business operations, where such information is available and relevant. At the time of the violation, did the Respondent have any previous export experience and was the Respondent familiar with export practices and requirements? Qualification of the Respondent as a small business or organization for the purposes of the Small Business Regulatory Enforcement Fairness Act, as determined by reference to the applicable standards of the Small Business Administration, may also be considered.

3. *Volume and Value of Transactions:* The total volume and value of transactions undertaken by the Respondent on an annual basis, with attention given to the volume and value of the apparent violations as compared with the total volume and value of all transactions. Was the quantity and/or value of the exports high, such that a greater penalty may be necessary to serve as an adequate penalty for the violation or deterrence of future violations, or to make the penalty proportionate to those for otherwise comparable violations involving exports of lower quantity or value?

4. *Regulatory History:* The Respondent's regulatory history, including BIS's issuance of prior penalties, warning letters, or other administrative actions (including settlements), other than with respect to antiboycott matters under part 760 of the EAR. BIS will generally only consider a Respondent's regulatory history for the five years preceding the date of the transaction giving rise to the apparent violation. When an acquiring firm takes reasonable steps to uncover, correct, and voluntarily disclose or cause the voluntary self-disclosure to OEE of conduct that gave rise to violations by an acquired business before the acquisition, BIS typically will not take such violations into account in applying these Factors in settling other violations by the acquiring firm.

5. *Other illegal conduct in connection with the export:* Was the transaction in support of other illegal conduct, for example the export of firearms as part of a drug smuggling operation, or illegal exports in support of money laundering?

6. *Criminal Convictions:* Has the Respondent has been convicted of an export-related criminal violation?

Note: Where necessary to effective enforcement, the prior involvement in export violation(s) of a Respondent's owners, directors, officers, partners, or other related persons may be imputed to a Respondent in determining whether these criteria are satisfied.

E. *Compliance Program:* The existence, nature and adequacy of a Respondent's risk-based BIS compliance program at the time of the apparent violation. BIS will take account of the extent to which a Respondent complies with the principles set forth in BIS's Export Management System (EMS) Guidelines. Information about the EMS Guidelines can be accessed through the BIS Web site at *www.bis.doc.gov*. In this context, BIS will also consider whether a Respondent's export compliance program uncovered a problem, thereby preventing further violations, and whether the Respondent has taken steps to address compliance concerns raised by the violation, including steps to prevent reoccurrence of the violation, that are reasonably calculated to be effective.

Mitigating Factors

F. *Remedial Response:* The Respondent's corrective action taken in response to the apparent violation. Among the factors BIS may consider in evaluating the remedial response are:

1. The steps taken by the Respondent upon learning of the apparent violation. Did the Respondent immediately stop the conduct at issue?

2. In the case of an entity, the processes followed to resolve issues related to the apparent violation. Did the Respondent discover necessary information to ascertain the causes and extent of the apparent violation, fully and expeditiously? Was senior management fully informed? If so, when?

3. In the case of an entity, whether it adopted new and more effective internal controls and procedures to prevent the occurrence of similar apparent violations. If the entity did not have a BIS compliance program in place at the time of the apparent violation, did it implement one upon discovery of the apparent violation? If it did have a BIS compliance program, did it take appropriate steps to enhance the program to prevent the recurrence of similar violations? Did the entity provide the individual(s) and/or managers responsible for the apparent violation with additional training, and/or take other appropriate action, to ensure that similar violations do not occur in the future?

4. Where applicable, whether the Respondent undertook a thorough review to identify other possible violations.

G. *Exceptional Cooperation with OEE:* The nature and extent of the Respondent's cooperation with OEE, beyond those actions set forth in Factor F. Among the factors BIS may consider in evaluating exceptional cooperation are:

1. Did the Respondent provide OEE with all relevant information regarding the apparent violation at issue in a timely, comprehensive and responsive manner (whether or not voluntarily self-disclosed), including, if applicable, overseas records?

2. Did the Respondent research and disclose to OEE relevant information regarding any other apparent violations caused by the same course of conduct?

3. Did the Respondent provide substantial assistance in another OEE investigation of another person who may have violated the EAR?

4. Did the Respondent enter into a statute of limitations tolling agreement, if requested by OEE (particularly in situations where the apparent violations were not immediately disclosed or discovered by OEE, in particularly complex cases, and in cases in which the Respondent has requested and received additional time to respond to a request for information from OEE)? If so, the Respondent's entering into a tolling agreement will be deemed a mitigating factor.

Note: A Respondent's refusal to enter into a tolling agreement will not be considered by BIS as an aggravating factor in assessing a Respondent's cooperation or otherwise under the Guidelines.

H. *License Was Likely To Be Approved:* Would an export license application have likely been approved for the transaction had one been sought? Some license requirements sections in the EAR also set forth a licensing policy (*i.e.,* a statement of the policy under which license applications will be evaluated), such as a general presumption of denial or case by case review. BIS may also consider the licensing history of the specific item to that destination and if the item or end-user has a history of export denials.

Other Relevant Factors Considered on a Case-by-Case Basis

I. *Related Violations:* Frequently, a single export transaction can give rise to multiple violations. For example, an exporter who inadvertently misclassifies an item on the Commerce Control List may, as a result of that error, export the item without the required export license and file Electronic Export Information (EEI) to the Automated Export System (AES) that both misstates the applicable Export Control Classification Number (ECCN) and erroneously identifies the export as qualifying for the designation ''NLR'' (no license required) or cites a license exception that is not applicable. In so doing, the exporter commits three violations: one violation of § 764.2(a) of the EAR for the unauthorized export and two violations of § 764.2(g) of the EAR for the two false statements on the EEI filing to the AES. It is within the discretion of BIS to charge three separate violations and settle the case for a penalty that is less than would be appropriate for three unrelated violations under otherwise similar circumstances, or to charge fewer than three violations and pursue settlement in accordance with that charging decision.

J. *Multiple Unrelated Violations:* In cases involving multiple unrelated violations, BIS is more likely to seek a denial of export privileges and/or a greater monetary penalty than BIS would otherwise typically seek. For example, repeated unauthorized exports could warrant a denial order, even if a single export of the same item to the same destination under similar circumstances might warrant just a civil monetary penalty. BIS takes this approach because multiple violations may indicate serious compliance problems and a resulting greater risk of future violations. BIS may consider whether a Respondent has taken effective steps to address compliance concerns in determining whether multiple violations warrant a denial in a particular case.

K. *Other Enforcement Action:* Other enforcement actions taken by federal, state, or local agencies against a Respondent for the apparent violation or similar apparent violations, including whether the settlement of alleged violations of BIS regulations is part of a comprehensive settlement with other federal, state, or local agencies. Where an administrative enforcement matter under the EAR involves conduct giving rise to related criminal or civil charges, OEE may take into account the related violations, and their resolution, in determining what administrative sanctions are appropriate under part 766 of the EAR. A criminal conviction indicates serious, willful misconduct and an accordingly high risk of future violations, absent effective administrative sanctions. However, entry of a guilty plea can be a sign that a Respondent accepts responsibility for complying with the EAR and will take greater care to do so in the future. In appropriate cases where a Respondent is receiving substantial criminal penalties, BIS may find that sufficient deterrence may be achieved by lesser administrative sanctions than would be appropriate in the absence of criminal penalties. Conversely, BIS might seek greater administrative sanctions in an otherwise similar case where a Respondent is not subjected to criminal penalties. The presence of a related criminal or civil disposition may distinguish settlements among civil penalty cases that appear otherwise to be similar. As a result, the factors set forth for consideration in civil penalty settlements will often be applied differently in the context of a ''global settlement'' of both civil and criminal cases, or multiple civil cases, and may therefore be of limited utility as precedent for future cases, particularly those not involving a global settlement.

L. *Future Compliance/Deterrence Effect:* The impact an administrative enforcement action may have on promoting future compliance with the regulations by a Respondent and similar parties, particularly those in the same industry sector.

M. *Other Factors That BIS Deems Relevant:* On a case-by-case basis, in determining the appropriate enforcement response and/or the amount of any civil monetary penalty, BIS will consider the totality of the circumstances to ensure that its enforcement response is proportionate to the nature of the violation.

IV. Civil Penalties

A. Determining What Sanctions Are Appropriate in a Settlement

OEE will review the facts and circumstances surrounding an apparent violation and apply the Factors Affecting Administrative Sanctions in Section III above in determining the appropriate sanction or sanctions in an administrative case, including the appropriate amount of a civil monetary penalty where such a penalty is sought and imposed. Penalties for settlements reached after the initiation of litigation will usually be higher than those described by these guidelines.

B. Amount of Civil Penalty

1. *Determining Whether a Case is Egregious.* In those cases in which a civil monetary penalty is considered appropriate, OEE will make a determination as to whether a case is deemed ''egregious'' for purposes of the base penalty calculation. This determination will be based on an analysis of the applicable Factors. In making the egregiousness determination, substantial weight will generally be given to Factors A (''willful or reckless violation of law''), B (''awareness of conduct at issue''), C (''harm to regulatory program objectives''), and D (''individual characteristics''), with particular emphasis on Factors A, B, and C. A case will be considered an ''egregious case'' where the analysis of the applicable Factors, with a focus on Factors A, B, and C indicates that the case represents a particularly serious violation of the law calling for a strong enforcement response. A determination by OEE that a case is ''egregious'' must have the concurrence of the Assistant Secretary of Commerce for Export Enforcement.

2. *Monetary Penalties in Egregious Cases and Non-Egregious Cases.* The civil monetary penalty amount shall generally be calculated as follows, except that neither the base amount nor the penalty amount will exceed the applicable statutory maximum:

a. Base Category Calculation and Voluntary Self-Disclosures

i. In a non-egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base amount shall be one-half of the transaction value, capped at a maximum base amount of $125,000 per violation.

ii. In a non-egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base amount shall be the ''applicable schedule amount,'' as defined above

(capped at a maximum base amount of $250,000 per violation).

iii. In an egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base amount shall be one-half of the statutory maximum penalty applicable to the violation.

iv. In an egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base amount shall be the statutory maximum penalty applicable to the violation.

The following matrix represents the base amount of the civil monetary penalty for each category of violation:

BASE PENALTY MATRIX

		Egregious Case: NO	Egregious Case: YES
Voluntary Self-Disclosure	YES	(1) One-Half of Transaction Value (capped at $125,000 per violation)	(3) One-Half of Applicable Statutory Maximum
	NO	(2) Applicable Schedule Amount (capped at $250,000 per violation)	(4) Applicable Statutory Maximum

b. Adjustment for Applicable Relevant Factors

The base amount of the civil monetary penalty may be adjusted to reflect applicable Factors for Administrative Action set forth in Section III of these Guidelines. A Factor may result in a lower or higher penalty amount depending upon whether it is aggravating or mitigating or otherwise relevant to the circumstances at hand. Mitigating factors may be combined for a greater reduction in penalty, but mitigation will generally not exceed 75 percent of the base penalty. Subject to this limitation, as a general matter, in those cases where the following Mitigating Factors are present, BIS will adjust the base penalty amount in the following manner:

In cases involving exceptional cooperation with OEE as set forth in Mitigating Factor G, but no voluntary self-disclosure as defined in § 764.5 of the EAR, the base penalty amount generally will be reduced between 25 and 40 percent. Exceptional cooperation in cases involving voluntary self-disclosure may also be considered as a further mitigating factor.

In cases involving a Respondent's first violation, the base penalty amount generally will be reduced by up to 25 percent. An apparent violation generally will be considered a ''first violation'' if the Respondent has not been convicted of an export-related criminal violation or been subject to a BIS final order in five years, or a warning letter in three years, preceding the date of the transaction giving rise to the apparent violation. A group of substantially similar apparent violations addressed in a single Charging Letter shall be considered as a single violation for purposes of this subsection. In those cases where a prior Charging Letter or warning letter within the preceding five years involved conduct of a substantially different nature from the apparent violation at issue, OEE may consider the apparent violation at issue a ''first violation.'' In determining the extent of any mitigation for a first violation, OEE may consider any prior enforcement action taken with respect to the Respondent, including any warning letters issued, or any civil monetary settlements entered into with BIS. When an acquiring firm takes reasonable steps to uncover, correct, and disclose or cause to be disclosed to OEE conduct that gave rise to violations by an acquired business before the acquisition, OEE typically will not take such violations into account as an aggravating factor in settling other violations by the acquiring firm.

iii. In cases involving charges pertaining to transactions where a license would likely have been approved had one been sought as set forth in Mitigating Factor H, the base penalty amount generally will be reduced by up to 25 percent.

In all cases, the penalty amount will not exceed the applicable statutory maximum. Similarly, while mitigating factors may be combined for a greater reduction in penalty, mitigation will generally not exceed 75 percent of the base penalty.

C. Settlement Procedures

The procedures relating to the settlement of administrative enforcement cases are set forth in § 766.18 of the EAR.

Dated: December 22, 2015.

David W. Mills,

Assistant Secretary for Export Enforcement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2014–N–1207]

Use of the Term ''Natural'' in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a docket to receive information and comments on the use of the term ''natural'' in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. A notice requesting comments on this topic appeared in the **Federal Register** of November 12, 2015. We initially established February 10, 2016, as the deadline for the submission of comments. We are taking this action