



OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Interim Consolidated Enforcement Response and Penalty Policy (CERPP) for the Toxic Substances Control Act (TSCA) New and Existing Chemicals Program

FROM: Gregory Sullivan, Director
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TO: Regional Counsels
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DATE: January 17, 2025

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Attached is the interim Consolidated Enforcement Response and Penalty Policy (CERPP) for the Toxic Substances Control Act (TSCA) New and Existing Chemicals Program. This policy is intended to be used by the EPA in calculating the penalty that the Agency will seek in administrative enforcement actions for violations of the new and existing chemicals programs under the Toxic Substances Control Act (TSCA).

This policy establishes a framework the EPA expects to use in determining the appropriate enforcement response and penalty amounts for cases to which it applies. It is immediately effective and supersedes any prior TSCA Enforcement Response Policy that has been updated with a corresponding Core TSCA program module. The policy applies to all administrative actions initiated after this date, and all pending actions in which the government has not yet transmitted a proposed settlement penalty amount. It may be applied in pending cases in which penalty negotiations have commenced, at the discretion of the litigation team.

If you have any questions about this policy, please contact James Miles (202-564-5161), Branch Manager, in the Waste and Chemical Enforcement Division of the Office of Civil Enforcement, or

James' staff members, Lindsay Simmons (202-564-3223), Attorney-Advisor, or Valarie Franklyn (202-564-1596), Environmental Engineer.

cc: Tom Mariani, Chief, DOJ-EES
Environmental Appeals Board
Regional Judicial Officers
National New and Existing Chemicals (Core) TCSA Practitioners Group

Attachment: Interim Consolidated Enforcement Response and Penalty Policy (CERPP) for the Toxic Substances Control Act (TSCA) New and Existing Chemicals Program



**Interim Consolidated Enforcement Response
and Penalty Policy
(CERPP)
for the
Toxic Substances Control Act (TSCA)
New and Existing Chemicals Program
(Core TSCA Program)**

January 2025

United States Environmental Protection Agency
Office of Enforcement and Compliance Assurance
Office of Civil Enforcement
Waste and Chemical Enforcement Division

Foreword

This Consolidated Enforcement Response and Penalty Policy (CERPP or Policy) is intended solely for the guidance of personnel of the United States Environmental Protection Agency (EPA or the Agency). This Policy sets forth factors for consideration that will guide the Agency in the exercise of its civil enforcement prosecutorial discretion.

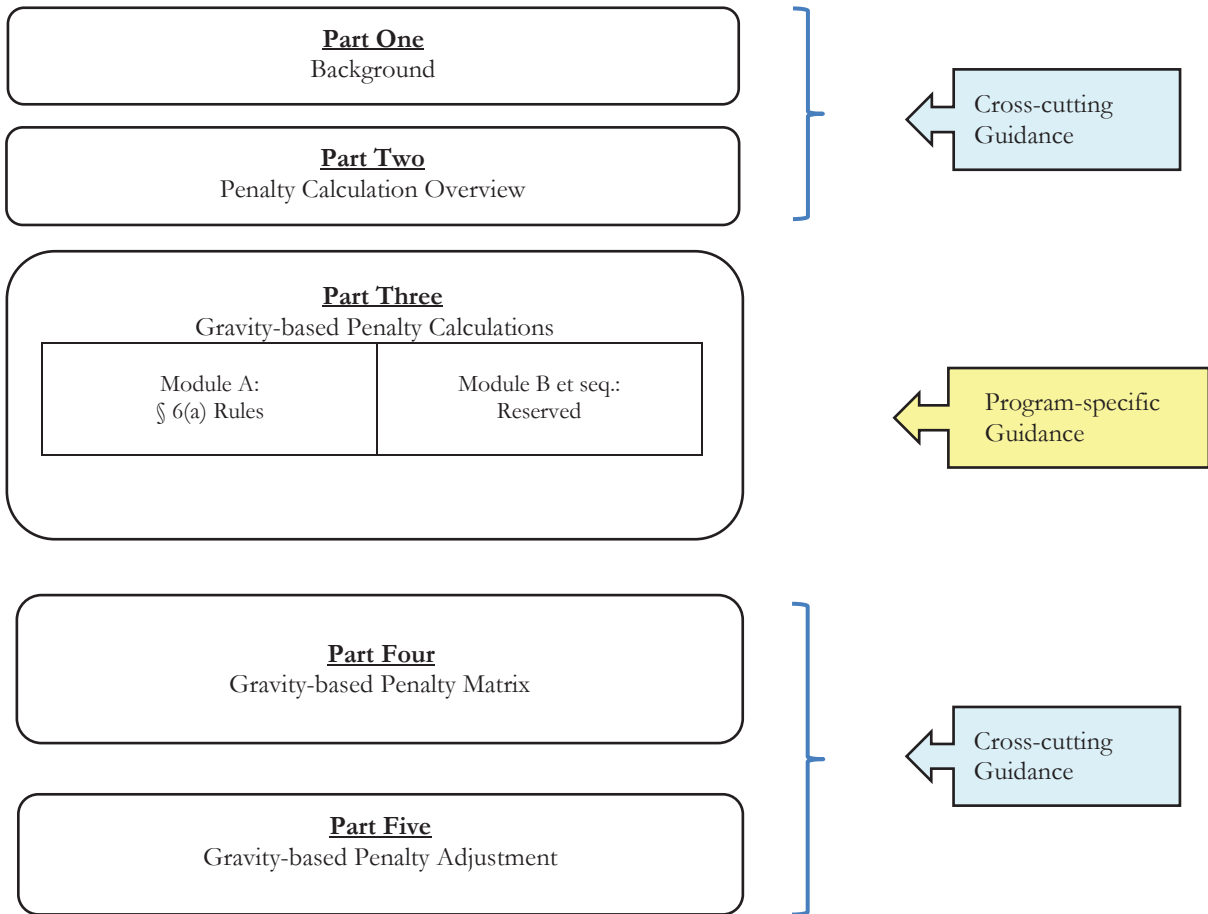
The CERPP does not constitute rulemaking by EPA. It is not intended to, and cannot be relied upon, to establish any right or benefit, substantive or procedural, enforceable at law or equity by any party.

The Agency reserves the right to act at variance with this policy and to change it any time without public notice. This policy is not binding on the Agency. Agency personnel should continue to make appropriate case-by-case enforcement judgments, guided by, but not restricted or limited to, the policies contained in this document.

EPA reserves the right to take enforcement action for any violation of the Toxic Substances Control Act (TSCA), even if it is not specifically identified in the CERPP. The Agency may hold any regulated entity, whether a natural person or business enterprise, responsible for violations.

This policy is immediately effective and applicable, regardless of the date of violation, and supersedes any civil enforcement response or penalty guidance previously issued for the programs covered by the Policy.

Introductory Figure: How the CERPP is Organized



Core TSCA

Consolidated Enforcement Response and Penalty Policy (CERPP)

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GLOSSARY

Acronyms

| | |
|----------|---------------------------------------------------------------------------------------------------|
| ATP | Ability to Pay |
| CADG | Control-associated Data-gathering |
| CAFO | Consent Agreement and Final Order |
| CC | Chemical Control |
| CID | Criminal Investigation Division |
| CDR | Chemical Data Reporting |
| CDX | Central Data Exchange |
| CERPP | Consolidated Enforcement Response and Penalty Policy for TSCA New and Existing Chemicals Programs |
| CFR | Code of Federal Regulations |
| DOJ | U.S. Department of Justice |
| EBN | Economic Benefit of Noncompliance |
| e-CDRweb | Electronic, web-based tool for the submission of Chemical Data Reporting (CDR) information |
| ERP | Enforcement Response Policy |
| FR | Federal Register |
| GBP | Gravity-based Penalty |
| GEM | Graduated Enumeration Method |
| GLP | Good Laboratory Practice |
| HA | Hazard Assessment |
| MIPUD | Manufacturing, Importation, Processing, Commercial Use, and Disposal |
| MIPDUD | Manufacturing, Import, Processing, Distribution in Commerce, Use, and Disposal |
| NOC | Notice of Commencement |
| NON | Notice of Noncompliance |
| NOV | Notice of Violation |
| OCE | Office of Civil Enforcement, OECA |
| OCSP | EPA Office of Chemical Safety and Pollution Prevention |
| OECA | EPA Office of Enforcement and Compliance Assurance |
| OPPT | Office of Pollution Prevention and Toxics, OCSP |
| PAIR | Preliminary Assessment Information Rule |
| PCBs | Polychlorinated biphenyls |
| PIA | Penalty Inflation Adjustment |
| PIE | Potentially Impacted Entities |
| PMN | Pre-manufacture Notification |
| PBT | Persistent, bioaccumulative, and toxic |
| R&D | Research and Development |
| SEP | Supplemental Environmental Project |
| SNUR | Significant New Use Rule |
| TSCA | Toxic Substances Control Act, 15 U.S.C. §§ 2601 et seq. |
| USC | United States Code |

WCED Waste and Chemical Enforcement Division, Office of Civil Enforcement, OECA
WCPP Workplace Chemical Protection Program

Terms

The CERPP uses certain generic terms for convenience and to encompass concepts that are comparable across TSCA programs. These terms are not official Agency nomenclature or legally defined terms.

Chemical means any material that is regulated by TSCA which, depending on the particular Core TSCA Program, may be specified as a “chemical substance,” “mixture,” “article,” or an item that contains a chemical.

Company means any entity subject to regulation under a Core TSCA Program, including any alleged violator or respondent, whether an individual, business enterprise (corporation, LLC, partnership, non-profit organization, etc.), governmental unit, or any other regulated entity.

Core TSCA Program (or Program) means the TSCA New and Existing Chemicals Program as described in this CERPP.

Initial Gravity-based Penalty (Initial GBP) refers to the dollar amount *per violation*, as shown on the Core TSCA Gravity-based Penalty Matrix. The Initial GBP is also called the “base” Gravity-based Penalty in some TSCA guidance.

Total Unadjusted Gravity-based Penalty (Total GBP) refers to the total GBP for *all violations* in a case, after applying any relevant “calculation factors” to the initial GBP – but *before* applying any TSCA-required adjustment factors to determine the final civil administrative penalty.

Final Gravity-based Penalty (Final GBP) refers to the final assessed GBP after adjusting the Total GBP upward or downward based on the following TSCA § 16 factors as applicable to the violator:

- “Ability to pay.”
- “Effect on ability to continue to do business.”
- “Any history of prior such violations.”
- “The degree of culpability.”
- “Such other matters as justice may require.”

Region generally refers to any Core TSCA enforcement case team, unit, or office, whether located in a Region or Headquarters.

TSCA Inventory refers to the [TSCA Chemical Substance Inventory](#).

TSCA regulatory office refers to an appropriate *non-enforcement* EPA office (also referred to as the TSCA “program” office). As of the date of publication of the CERPP, this generally means the Office of Pollution Prevention and Toxics (OPPT) within EPA’s Office of Chemical Safety and Pollution Prevention (OCSPP).

I. INTRODUCTION

A. Overview

This Consolidated Enforcement Response and Penalty Policy (CERPP) sets forth guidance for civil administrative enforcement by the United States Environmental Protection Agency (EPA or the Agency¹) for violations of the New and Existing Chemicals Program under the [Toxic Substances Control Act](#) (TSCA).² The TSCA New and Existing Chemicals Program is known also as the “Core TSCA” enforcement program.

The Core TSCA enforcement program addresses noncompliance with the following TSCA provisions and regulations thereunder, respectively:

- Title I § 4 Good Laboratory Practice (GLP) standards and specific chemical test rules and orders;
- Title I § 5 for new chemicals and existing chemicals with significant new uses;
- Title I § 6 for existing chemicals;
- Title I § 8 for chemical reporting requirements;
- Title I § 12 for chemical import requirements;
- Title I § 13 for chemical export requirements; and
- Title VI for Formaldehyde.

Over time, the Agency may promulgate additional rules that fall under the Core TSCA program.

The CERPP is guidance for TSCA civil enforcement practitioners and case teams (collectively, “the Region”).³ This guidance is intended to help ensure that enforcement actions and the assessment of civil administrative penalties (herein simply, penalties)⁴ are appropriate, nationally consistent and promote compliance among TSCA-regulated entities (herein, companies).

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¹ This means “the Administrator” and his/her delegees within the meaning of TSCA.

² [15 U.S.C. §§ 2601 et seq.](#), as amended in 2016 by The Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182 from House Bill 2576).

³ This includes TSCA practitioners and case teams located at Headquarters. Headquarters generally refers to the Chemical Risk & Reporting Enforcement Branch (CRREB), within the Waste and Chemical Enforcement Division (WCED), Office of Civil Enforcement (OCE) in EPA’s Office of Enforcement and Compliance Assurance (OECA).

⁴ References in the CERPP to “penalties” means *civil administrative* penalties since the CERPP does not cover criminal enforcement, and there are no civil *judicial* penalties (see § II, TSCA Legal Background).

Relation to Prior Core TSCA Enforcement Response Policies

The CERPP incorporates the overarching principles of the [1980 TSCA Penalty Policy](#).⁵ It also will consolidate and update the following Core TSCA enforcement response policies (ERPs):

- The [§ 4 GLP Standard](#) ERP (04/09/1985).⁶
- The [§ 4 Test Rules](#) ERP (05/28/1986).⁷
- The § 5 Rules ERP (1988 version; amended version 06/08/1989 and [amended version 07/01/1993 for NOC violations](#)).⁸
- The [§§ 8/12/13 Rules](#) ERP (03/31/1999).⁹

Until a module for a specific Core TSCA program is added to the CERPP, use the current ERP for that Core TSCA program.

B. Effectiveness of the CERPP

The CERPP is effective immediately and supersedes any prior ERP that has been updated with a corresponding Core TSCA program module. EPA TSCA practitioners should use the CERPP to calculate penalties sought in Complaints, or accepted in settlements, civil administrative enforcement actions that EPA initiates after the effective date of the CERPP (regardless of the date of the violation), and all pending actions where EPA has not transmitted a proposed penalty.

The Agency reserves the right to act at variance with this policy and to change it any time without public notice. This policy is not binding on the Agency. Enforcement staff should continue to make appropriate case-by-case enforcement choices, guided by, but not restricted or limited to, the policies contained in this document.

This policy is immediately effective and applicable, regardless of the date of the violation(s), and it supersedes any enforcement response or penalty guidance previously issued for TSCA Subtitle I.

C. How the CERPP is Organized

The CERPP encompasses both cross-cutting and program-specific guidance. Also, the CERPP is organized to follow the process for computing a final civil administrative penalty (See Foreword, Introductory Figure).

⁵ *Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act*, 45 Fed. Reg. 59770 (Sept. 10, 1980)(*TSCA Penalty Policy*), <https://www.epa.gov/sites/default/files/documents/tscapen.pdf>.

⁶ Final TSCA GLP Enforcement Response Policy. <https://www.epa.gov/enforcement/final-tsca-glp-enforcement-response-policy>.

⁷ Enforcement Response Policy for TSCA Section 4 Test Rules. <https://www.epa.gov/enforcement/enforcement-response-policy-tsca-section-4-test-rules>.

⁸ Amended TSCA Section 5 Enforcement Response Policy. <https://www.epa.gov/enforcement/amended-tsca-section-5-enforcement-response-policy>.

⁹ Issuance of Revised Enforcement Response Policy for TSCA Sections 8,12 & 13. <https://www.epa.gov/enforcement/issuance-revised-enforcement-response-policy-tsca-sections-812-13>.

To address commonalities across Core TSCA programs, the CERPP consolidates and accords cross-cutting guidance, such as penalty dollar amounts (CERPP Part Four) and the principles for applying TSCA’s penalty adjustment factors (CERPP Part Five).

Generally, to encompass cross-cutting concepts, the CERPP uses **generic terms**, such as “chemical” to cover any TSCA-regulated material. See Glossary.

To address variations among Core TSCA Programs in computing the Gravity-based Penalty (GBP) for their respective violations, the CERPP provides program-specific GBP Modules (CERPP Part Three). The CERPP is organized to incorporate additional GBP Modules to accommodate future Core TSCA rules (i.e., new, separate ERPs will not be necessary for new rules).

Also, the CERPP is organized to follow the two-stage process for determining the penalty, i.e.: first compute the Final GBP for all violations in the case (CERPP Part Three and Part Four); and then adjust the Final GBP in accordance with TSCA factors with respect to the violator (CERPP Part Five). See CERPP Part Two, Penalty Calculation Overview.

The CERPP contains the following Parts:

- **CERPP Part One** provides *cross-cutting* background information: Introduction; TSCA Legal Background; Enforcement Response Options; and Regulatory Responses.
- **CERPP Part Two** provides a *cross-cutting* overview of the process for determining penalties: Introduction; General Principles; Steps in Computing Civil Penalties; Factors as to Violation; Factors as to Violator.
- **CERPP Part Three** encompasses Modules for computing Gravity-based Penalties for specific Core TSCA programs, including:
 - o Module A for the § 6(a) Rules.
- **CERPP Part Four** presents the *cross-cutting* Gravity-based Penalty Matrix, which states the “initial” (per violation) Gravity-based Penalty dollar amount applicable in all Core TSCA programs.
- **CERPP Part Five** provides *cross-cutting* guidance for adjusting (or remitting) the Gravity-based Penalty to derive the final civil administrative penalty in a case: Overview; Preliminary Information; Ability to Pay/Continue in Business; Prior Violation; Culpability; Other Matters Justice May Require; Penalty Remittance.

II. TSCA LEGAL BACKGROUND

The information in the CERPP is provided for convenience and is not a replacement for close review of the applicable law.

A. Overview

The [Toxic Substances Control Act](#) of 1976, amended by the [Frank R. Lautenberg Chemical Safety for the 21st Century Act](#) (Lautenberg Chemical Safety Act or the 2016 Amendments) in 2016, 15 U.S.C. § 2601 *et seq.*, authorizes EPA to require reporting, record-keeping and testing; and impose

restrictions relating to chemicals and mixtures. TSCA also addresses the production, importation, distribution in commerce, use, and disposal of specific chemicals including [polychlorinated biphenyls \(PCBs\)](#), [asbestos](#), radon, and [lead-based paint](#).¹⁰

Among other things, TSCA provides authority to:

- [Require, under § 5, notification pre-manufacture for “new chemical substances” and pre-manufacture or processing for a “significant new use” of a chemical substance.](#)
- [Require, under § 4, testing](#) of chemical substances or mixtures by manufacturers, importers, and processors where risks or exposures of concern are found.
- Issue [Significant New Use Rules \(SNURs\)](#), under § 5, when it identifies a “significant new use” that could result in exposures to, or releases of, a substance of concern.
- [Maintain the TSCA Inventory](#) under § 8. The Inventory contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, they are placed on the list. That is generally, the absence of a chemical on the Inventory serves as notice to industry that the chemical must be reviewed by EPA under § 5 before it can be manufactured legally.
- Require, under § 8, reporting and record-keeping by persons who manufacture, import, process, and/or distribute in commerce chemical substances and mixtures.
- Require, under § 8(e), that any person who manufactures (including imports), processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment to immediately inform EPA (except where EPA has been adequately informed of such information).
- Require those [importing or exporting chemicals](#), under §§ 12(b) and 13, to comply with certification reporting and/or other requirements.
- Require EPA under § 6 to evaluate existing chemicals with clear and enforceable deadlines.
- Risk-based chemical assessments and evaluations under § 6.

The program-specific Modules in CERPP Part Three provide further information relevant to each Core TSCA program.

B. Compliance Monitoring and Enforcement Provisions

The following TSCA provisions establish EPA’s compliance monitoring and enforcement authorities:

- TSCA § 7 authorizes initiating civil enforcement actions to provide injunctive relief as may be necessary to protect health or the environment, including but not limited to seizure and condemnation of imminently hazardous chemical substances, mixtures, and articles.
- TSCA § 11 empowers EPA to conduct inspections and issue subpoenas.
- TSCA § 15 provides that it is unlawful to fail or refuse to comply with any TSCA requirement.
- TSCA § 16 empowers EPA to pursue civil administrative penalty enforcement, enter into settlements, and remit penalties; and establishes factors for determining civil penalties. Section 16 also authorizes a court to impose criminal enforcement for knowing or willful violations of TSCA.

¹⁰ There are separate TSCA ERPPs for the PCB, asbestos and lead-based paint programs.

- TSCA § 17 empowers EPA to seek judicial action by the appropriate U.S. District Court to compel compliance with TSCA (but not to assess penalties).¹¹

III. ENFORCEMENT RESPONSE OPTIONS

A. Overview

The principles below apply to all Core TSCA Programs. The program-specific Gravity-based Penalty Modules (CERPP Part Three) may present additional considerations or limitations. The CERPP specifies most, but not necessarily every, potential TSCA violation.

Once the Region has determined that a violation has occurred, the Region must determine the appropriate enforcement response. The options for the civil enforcement program include the following:

- Notice of Noncompliance (NON) no-penalty action.¹²
- Civil administrative penalty action, which could include the filing of an administrative complaint or the filing of a Consent Agreement and Final Order (CAFO).
- Civil judicial action, through a referral to the U.S. Department of Justice (DOJ).
- Referral to EPA’s Criminal Investigation Division (CID)¹³ for investigation and a potential criminal referral to DOJ.

Certain conduct is addressed via a regulatory response from the Agency’s TSCA regulatory office, rather than via enforcement (see § IV, below).

1. General Considerations

An appropriate enforcement response should achieve a timely return to compliance and serve as a deterrent to future noncompliance. Generally, EPA should seek penalties to address noncompliance, through either a civil administrative action or a referral to DOJ for civil judicial action. In limited circumstances, a no-penalty administrative action such as a NON may be sufficient. An enforcement action may be resolved via either litigation or settlement.

2. Potential Notice to the Public

EPA may, at its discretion, issue a press release, advisory, or alert to notify the public regarding an enforcement action filing, settlement, or adjudication. These notices can help educate the public regarding TSCA compliance obligations and EPA’s response to noncompliance. Such notice may be particularly valuable and appropriate where the violations may have affected a disproportionately impacted community or potentially exposed or susceptible subpopulations.

¹¹ Since penalties are available only under through EPA’s administrative authority, the CERPP generally refers to “civil penalties” (rather than “civil administrative penalties”) for simplicity.

¹² Generally, an instrument styled as a NON aims to *resolve* an alleged violation through a no-penalty action, distinguished from a “Notice of Violation” (NOV) which aims to *commence* an action and will be followed by a complaint or other enforcement action.

¹³ CID is an office within EPA’s Office of Enforcement and Compliance Assurance (OECA), Office of Criminal Enforcement and Forensics Training (OCEFT).

EPA may make such notification via a press release, advisory or other appropriate means of communication. The issuance of such notices, as well as the nature of their contents, are within EPA's sole discretion and shall not be subject to negotiation with the violator.¹⁴

B. Enforcement Options

1. Notice of Noncompliance and Other No-Penalty Actions

A Notice of Noncompliance (and any other no-penalty action¹⁵) is an exception to the principle that a penalty action is appropriate for most Core TSCA violations. A NON may be issued under most Core TSCA programs if outlined for a particular program or type of violation. See CERPP Part Three.

Generally, a NON is appropriate only where all three of the following conditions apply:

- The offense(s) is a non-substantive, de minimis or technical violation that (a) presented no actual or potential risk of harm or injury to human health or the environment; or (b) either separately or collectively, presented minimal or no impact upon EPA's regulatory or decision-making functions;
- The violator has not received a previous NON for noncompliance with a same, similar or closely related requirement (no matter how minor or technical the prior offense); *and*
- The violation does not otherwise warrant a penalty assessment for any other reason.

A NON should not be used in conjunction with another type of enforcement response. Therefore, a NON should not be used where a situation involves several violations, some of which merit a NON and others warrant civil penalties. Instead, the Region should initiate an administrative penalty action, pleading all of the violations but assessing no penalties for non-substantive, de minimis, or technical infractions that merit a NON.

The NON, or any settlement instrument¹⁶ that includes NON-eligible violations as discussed above, should explicitly require that the company complete specific corrections within a stated period of time (typically within 30 days of receipt of the NON or settlement instrument). Failure to correct any violation for which a NON is issued may be the basis for issuance of a Complaint for penalty action. With or without having first issued a NON, EPA retains discretion to pursue a penalty action for any violation based on the facts of a case.

2. Civil Administrative Penalty Action

A civil administrative penalty action under TSCA § 16 is the appropriate response for most Core TSCA violations, and for failure to correct violation(s) cited in a NON (discussed above). Civil

¹⁴ See generally, Memorandum, G. Nakayama, *Restrictions on Communicating with Outside Parties Regarding Enforcement Actions* (Mar. 8, 2006), http://www2.epa.gov/sites/production/files/documents/commrestrictions-nakayamamemo030806_0.pdf.

¹⁵ Alternative no penalty actions include instruments styled as a warning or a compliance assistance letters.

¹⁶ Administrative settlement "instruments" are styled variously as "CAFOs" (Consent Agreement & Final Orders) or "Super-CAFOs" depending upon the prevailing regional practice and nomenclature.

administrative penalty actions typically commence with the filing of a Complaint. The Region, however, may issue notice to the violator prior to filing a Complaint, typically in the form of a pre-filing letter.¹⁷

3. Civil Judicial Action

Usually, a civil administrative penalty action under TSCA § 16 is sufficient to obtain compliance. In certain cases, however, it may be appropriate to invoke TSCA § 17 by referring the matter to DOJ to petition the court for injunctive relief to compel compliance with TSCA; for the collection (not assessment) of a civil administrative penalty;¹⁸ or to enforce a TSCA § 11 subpoena. There does not need to be an imminent hazard or recalcitrant respondent in order to invoke TSCA § 17. Additionally, EPA may seek seizure and/or relief to address imminently hazardous chemical substances from a judicial district court under TSCA § 7.

For example, it may be appropriate to refer actions that involve multiple media or injunctive relief that can't be achieved. Also, situations such as the following may merit referral for injunctive relief:

- For seizure or other relief concerning a chemical substance that presents imminent and unreasonable risk of serious or widespread injury to human health or the environment.
- Ongoing violations of Sections 5 or 6 of TSCA that cannot successfully be resolved in an administrative settlement, including, but not limited to:
 - o Violations of TSCA § 5(e) or § 5(f) orders, Low Volume Exemptions, or Test Marketing Exemptions that involve failure to use personal protective equipment or chemical control measures;
 - o Ongoing manufacture or processing of a chemical substance subject to notice requirements under Section 5 without cessation or implementation of appropriate controls during the notice submission and review period; and
 - o Ongoing violations concerning a prohibited condition of use¹⁹ of a chemical substance under Section 6.
- Contumacy, undue delay or refusal to comply with TSCA requirements, such as refusal to respond to a Section 11 subpoena, or to maintain records where circumstances indicate that the company would not otherwise do so or where there is a repeated failure to do so.
- Repeat offenders for whom the penalty increase under the TSCA adjustment factor for a prior violation is unlikely to deter future violations (see CERPP Part Five) (presuming the offense is of a nature where injunctive relief is being sought).

Although TSCA § 17 can be an effective tool in the appropriate circumstance, typically it is more efficient to resolve penalty and compliance simultaneously in an administrative action. Therefore, use of § 17 should be reserved for cases in which a civil penalty action seems unlikely to obtain the sufficiently swift compliance necessary to mitigate a hazardous situation, obtain timely compliance, or protect human health or the environment.

¹⁷ This may be in the form of a "Notice of Violation" (NOV) or other writing.

¹⁸ Note that EPA may obtain penalties through a judicial settlement wherein the respondent agrees to pay a penalty under the judicial settlement in lieu of EPA prosecuting a concurrent civil administrative penalty action.

¹⁹ TSCA § 3(4); 15 U.S.C. § 2602(3). The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

4. Criminal Referral

The CERPP applies only to civil enforcement and, thus, does not address criminal enforcement for Core TSCA violations. In some instances, however, offenses may warrant criminal enforcement under TSCA § 16, Title 18 and/or other federal laws. EPA also may pursue parallel civil and criminal enforcement, as discussed below.

When there are potential criminal violations, the Region should promptly refer the matter to EPA's Criminal Investigation Division (CID). CID has the lead for investigating alleged criminal misconduct and deciding whether to refer a matter to DOJ.

To prove a TSCA criminal charge, the government must generally establish that a person knowingly or willfully violated a TSCA requirement.²⁰ (The exception relates to TSCA's felony endangerment provision, which requires the government to prove that a person knowingly **and** willfully violated a TSCA provision, and also knew that such conduct placed one or more other persons at imminent risk of death or serious bodily injury).²¹ A person in these contexts includes companies.

Several factors to consider whether criminal enforcement may be appropriate include the following:

- The nature of the misconduct is among the most serious considering (a) the gravity of harm or risk to human health or the environment resulting from or threatened by the prohibited conduct; or (b) the actual or potential impact on EPA's statutory, regulatory and/or decision-making functions.
- The company's past non-compliance and/or repeat violations history. Criminal enforcement may be appropriate as the incidents increase, or the severity or character of noncompliance worsens.
- Other indicators reflect a general intent to undermine statutory or regulatory requirements.

In addition to potential TSCA violations, there may be violations of other federal criminal statutes to consider. For example, pursuant to 18 U.S.C. § 1001, it is illegal to knowingly and willfully make a false or fraudulent statement to the government. This crime may have occurred where a company's management makes an affirmative decision to violate the TSCA § 4 Test Rules or § 4 Good Laboratory Practice Standard by falsifying material data or intentionally concealing data through omission or selective reporting, which could result in prosecution under both TSCA § 16 and 18 U.S.C. § 1001.


C. Concurrent (Parallel) Actions

In certain cases, concurrent (parallel) administrative and judicial responses may be appropriate for the distinct benefit that each venue provides. Parallel proceedings are concurrent enforcement actions under distinct authorities (e.g., TSCA § 16 versus § 17), and led by separate (but cooperating) units. For example, parallel civil administrative and judicial enforcement may be appropriate where violations merit both civil penalties (administrative) and injunctive relief (judicial). Also, parallel civil and criminal proceedings may be appropriate where noncompliance merits both civil penalties and criminal action (fine and/or imprisonment). When the Region deems either form of concurrent

²⁰ TSCA § 16(b)(1); 15 U.S.C. § 2615(b)(1).

²¹ TSCA § 16(b)(2)(A); 15 U.S.C. § 2615(b)(2)(A).

action to be appropriate, the Region should confer with Headquarters before bringing either action.²² See Figure 1-2.

| Fig. 1-2: Enforcement Options | | |
|------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|
| | Civil Enforcement (Remedy Available) | Criminal Enforcement (Remedy Available) |
| Administrative Action | Yes (civil penalties) | N/A (all criminal enforcement is judicial) |
| Judicial Action (via DOJ referral) | Yes (injunctive relief) | Yes (criminal action) |
| Parallel actions allowed  | | |

1. Parallel Civil Actions

For civil enforcement, the Region would typically first attempt to return the company to compliance and resolve the violations administratively before seeking injunctive relief judicially. However, there may be cases for which the concurrent use of these remedies is appropriate. The Region is to consult Headquarters before bringing either action.

2. Parallel Civil and Criminal Proceedings

Although most EPA's enforcement actions are brought as either a civil action or a criminal action, there are instances when it is appropriate to bring both a civil and a criminal enforcement response.²³ These include situations where the violations merit the deterrent and retributive effects of criminal enforcement, yet a civil action is also necessary to obtain an appropriate remedial result, and where the magnitude or range of the environmental violations and the available sanctions make both criminal and civil enforcement appropriate.

Active consultation and cooperation between EPA's civil and criminal programs, in conformance with all legal requirements, EPA's *Strategic Civil-Criminal Enforcement Policy*,²⁴ and with OECA's Parallel Proceedings Policy (September 24, 2007),²⁵ is critical to the success of EPA's overall enforcement program. The success of any parallel proceeding depends upon coordinated decisions by the civil and criminal programs as to the timing and scope of their activities. For example, it will often be important for the criminal program to notify the civil enforcement program managers that an investigation is about to become overt or known to the subject. Similarly, the civil program should notify the criminal program when there are significant developments that might change the scope of

²² In accordance with the November 1, 1994, memorandum entitled, "Final List of Nationally Significant Issues and Process for Raising Issues to TPED." This final implementation guidance was developed in follow-up to Steve Herman's July 11, 1994 memorandum on "Redelegation of Authority and Guidance on Headquarters' Involvement in Regulatory Enforcement Cases."

²³ Simultaneous civil and criminal enforcement proceedings are legally permissible and, on occasion, clearly warranted. See United States v. Kordel, 397 U.S. 1, 11 (1970.) The Supreme Court considered the double jeopardy clause in Hudson v. United States, 522 U.S. 93 (Dec. 10, 1997), and held that an administrative proceeding is not a bar to later criminal prosecution since administrative proceedings are civil, not criminal. Thus, there may be situations where an administrative action precedes a criminal prosecution.

²⁴ See OECA's *Strategic Civil-Criminal Enforcement Policy*, (Apr. 17, 2024) [Strategic Civil-Criminal Enforcement Policy \(epa.gov\)](https://www.epa.gov/strategic-civil-criminal-enforcement-policy).

²⁵ See TSCA Enforcement Policy and Guidance Documents, Memorandum, Parallel Proceedings Policy, Grant Y. Nakayama, September 24, 2007 OECA Memorandum, <http://www2.epa.gov/sites/production/files/documents/parallel-proceedings-policy-09-24-07.pdf>.

the relief. In every parallel proceeding, communication and coordination should be initiated at both the staff and manager levels and should continue until resolution of all parallel matters.

IV. REGULATORY RESPONSES

In addition to or in lieu of enforcement, the Agency may respond to certain performance deficiencies through regulatory action, such as requiring study invalidation or re-testing for purposes of making regulatory decisions. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) has purview for the TSCA regulatory program.

For example, OCSPP may determine that data from a study that was not performed in compliance with TSCA § 4 Good Laboratory Practice Standards is unreliable for purposes of showing that the tested chemical is unlikely to pose an unreasonable risk.²⁶ If a sponsoring company submits such data under a § 4 Test Rule or Order, then EPA may require the sponsor to re-test. If the study is submitted as a requirement under TSCA § 5 or a negotiated testing agreement, then EPA may deem the study unreliable or consider the data insufficient to evaluate the health/environmental effects or the fate of the chemical and could prohibit or limit manufacture or use of the chemical under TSCA § 5. Whereas the testing deficiency itself may not constitute a violation, noncompliance with the TSCA § 5 restriction could be a violation.

²⁶ 40 C.F.R. § 792.17.

I. INTRODUCTION

TSCA provides for civil penalties only in administrative enforcement actions.¹ TSCA § 16 requires that in determining a civil penalty, EPA consider specific factors concerning the violation and the violator.

TSCA § 16 states:

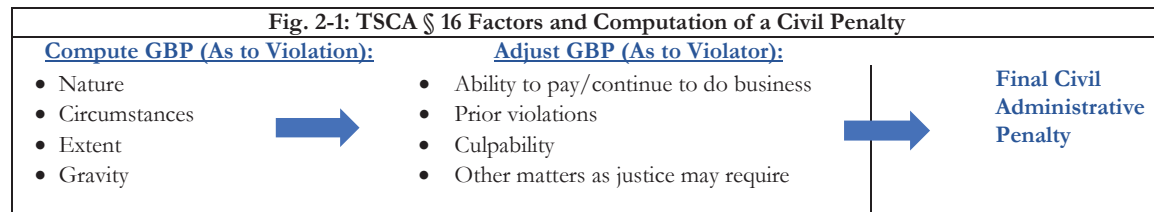
EPA “shall take into account the *nature, circumstances, extent, and gravity* of the violation or violations and, with respect to the violator, *ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.*”²

Therefore, the civil penalty process accommodates these factors via an initial stage concerning the violation(s), and a second stage concerning the violator – and each stage includes multiple steps.

- **First Stage: Compute the Gravity-based Penalty (GBP)** by applying the TSCA § 16 factors relevant to the violation(s) – nature, circumstances, extent, and gravity – using program-specific guidance in the pertinent CERPP Part Three Module, and the CERPP Part Four GBP Penalty Matrix (dollar amount).
- **Second Stage: Adjust the Unadjusted GBP**, upward or downward, based on the TSCA § 16 factors relevant to the violator – ability to pay/continue to do business, history of prior violations, culpability, and such other matters as justice may require – using the cross-cutting guidance in CERPP Part Five.

See Figure 2-1, below. See also Reference #1 and Introductory Figure.

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| #1 Summary: Steps in Computing Civil Penalties |



¹ See CERPP Part One § II.

² 15 U.S.C. § 2615(a)(2)(B)(emphasis added).

II. GENERAL PRINCIPLES

The following principles apply to penalty computations under all Core TSCA programs.

A. Violations Cited in the CERPP

The CERPP does not identify every possible Core TSCA violation that may occur. That is, where a program specific Module (CERPP Part Three) may list the most commonly occurring violations in that program, the list is illustrative and not necessarily exclusive. To determine the appropriate response to a non-listed violation, the Agency should look to how the CERPP handles generally comparable requirements and consider overarching principles in the CERPP.

B. Gravity-based Penalty - Statutory Maximum

The Initial GBP dollar amount per violation (CERPP Part Four Penalty Matrix) constitutes the foundation for determining the final civil penalty in a case but may be subject to program-specific Calculation Factors (CERPP Part Three Module), TSCA adjustment factors (CERPP Part Five), and limitation (statutory maximum).

The Initial GBP per violation may not exceed the statutory maximum, but the maximum is adjusted each year in accordance with EPA's annual Penalty Inflation Adjustment (PIA) Rule. Also, EPA periodically adjusts the penalty amounts shown on the GBP Matrix in accordance with the prevailing PIA guidance.

C. Penalty Assessment: Per Requirement, Per Chemical, Per Unit of Violation

Per Requirement, Per Chemical. In all cases, a separate penalty is to be assessed for each distinct requirement (regulatory or statutory) that is violated, *and* for each unit of violation (e.g., number of occurrences of the offense), *and* for each chemical involved in each such violation. For an illustration, see Figure 2-2, below (3 violations involving 2 chemicals).

Fig. 2-2: Hypothetical: Assessing Penalties Per Requirement, Per Chemical

A company conveys **two chemicals** (A and B) to a third party in violation of a prohibition against distribution in commerce. The Company also disposed of Chemical A in violation of a prohibition requiring disposal in a specific manner. Penalties would be assessed for **3 violations**, as follows:

| | |
|---------------------------------------------|----------------------|
| Chemical A: Distribution in commerce | = 1 violation |
| Chemical A: Disposal in a prohibited manner | = 1 violation |
| Chemical B: Distribution in commerce | = <u>1 violation</u> |
| | 3 violations |

(Note: For purposes of illustration only, this hypothetical computes each violation as a **one-day occurrence** (one "unit of violation" for each requirement violated). Depending upon the applicable program-specific Module (CERPP Part Three), however, these offenses might be computed as "per day of violation" (potentially multiple "units of violation" for each requirement violated). See "Unit of Violation," below.

Per Unit of Violation. Each unit of violation equates to an independently assessable violation. A separate penalty is to be assessed per unit of violation.

Depending upon the Core TSCA program and offense, the unit of violation may be counted on the basis of days of noncompliance; number of violative transactions or items; number of batches; or on some other basis. The Calculation Factors in each program-specific Module in CERPP Part Three provides guidance regarding the unit of violation for each type of offense. See also Figure 2-3, below (Per Transaction Unit of Violation).

| Fig. 2-3: Hypothetical: Assessing Penalties Per Requirement, Per Chemical and Per Transaction | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| A company illegally conveys two chemicals (A and B) to a third party via four (4) transactions . In each transaction, the company violated the requirement : prohibition against distribution in commerce. Penalties would be assessed for 8 violations as follows: | |
| Chemical A: Distribution in commerce @ 4 transactions | = 4 violations |
| Chemical B: Distribution in commerce @ 4 transactions | = <u>4 violations</u> |
| | 8 violations |

III. STEPS in COMPUTING CIVIL PENALTIES

A. Compute the Gravity-based Penalty

The first stage in determining the appropriate civil penalty involves computing the GBP, i.e.:

- Identify the **Initial GBP** dollar amount for each particular violation, respectively, based on the TSCA violation factors applied to the GBP Matrix; then
- Compute the **Total GBP** for each type of violation, respectively, based on the number of occurrences or other Calculation Factors; and then
- Derive the **Final GBP** for all of the violations in the case by adding together the Total GBPs for all violations.

See e.g., Figure 2-4, below.

| Fig. 2-4: Illustration: Initial GBP vs. Total GBP vs. Final GBP | | | | |
|--------------------------------------------------------------------------------------------------------|--------------------------------|---|--------------------|--------------------------------|
| A case involves two (2) types of violations. There is an Initial GBP and Total GBP for each violation. | | | | |
| Violation A | \$ Initial GBP (per violation) | x | No. of occurrences | = \$ Total GBP - Violation A** |
| Violation B | \$ Initial GBP (per violation) | x | No. of occurrences | = \$ Total GBP - Violation B** |
| | | | | \$ FINAL GBP |

** Calculation Factors (CERPP Part Three Modules), such as the units of violation, also may apply.

1. Initial Gravity-based Penalty (for Each Type of Violation)

Use the program-specific Module in CERPP Part Three to identify the **Nature, Circumstances, Extent and Gravity** for the particular violation. Section III, below, explains each factor.

On the GBP Matrix in CERPP Part Four, **locate the Initial GBP dollar amount** per violation for the particular offense. The proper amount appears at the intersection of the “Circumstances Level” (row) and “Extent Level” (column) that the Agency has determined for the violation. See Figure 2-5, below.

| Fig. 2-5: Hypothetical – Initial GBP vis-à-vis GBP Matrix | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|---------------------|
| Here, the Agency has determined that a violation has a “ Medium ” Circumstances Level and a “ Significant ” Extent Level. The Initial GBP (per violation) appears in the cell at the intersection of the applicable row and column. | | | |
| Gravity-based Penalty Matrix (CERPP Part Four) | | | |
| Circumstances | Extent | | |
| | Major | Significant | Minor |
| High | \$ (Statutory Max.) | \$ | \$ |
| Medium | \$ | \$ | \$ |
| Low | \$ | \$ | \$ (Lowest Penalty) |

Note: The dollar amounts in the Matrix apply to every Core TSCA program.

Repeat this process to identify the Initial GBP for each type of violation in the case.

2. Total Gravity-based Penalty (for Each Type of Violation)

Next, compute the Total GBP for each type of violation by applying pertinent program-specific Calculation Factors to the Initial GBP. For example, multiple occurrences of the same violation generally equate to multiple units of violation; and the Calculation Factor may call for simply multiplying the Initial GBP by the number of units.

Depending on the Core TSCA program, Calculation Factors may include:

- Guidance on counting the units of violation, whether one-day, per-day of violation, per transaction, etc.
- Approaches to generate a Modified Total GBP for certain types of violations.
- “Caps” (limitations) on the Total GBP for certain types of violations
- Guidance on special situations such as imminent hazards, multiple establishments, studies/reports, etc.

Note

The Agency must use both CERPP Part Three and Part Four to compute the Total GBP for each violation:

- Part Three to determine the violation’s Circumstances Level and Extent Level.
- Part Four to locate the Initial GBP on the GBP Matrix (Circumstances column and Extent row).
- Part Three, again, to apply any Calculation Factors to the Initial GBP and compute the violation’s Final GBP.

Repeat the process of determining the Total GBP for each type of violation in the case. See Figure 2-5, above.

3. Final Gravity-based Penalty (for All Violations)

Compute the Final GBP for the case by adding together the Total GBP for every type of violation in the case. The Final GBP is adjusted in the second stage of the civil penalty process. See Figure 2-4, above.

Reminder

- The *Initial* GBP for a violation from the GBP Matrix (CERPP Part Four) will not be the *Total* GBP for that offense if the *violation* is affected by any CERPP Calculation Factor, such as multiple occurrences.
- If a case involves more than one type of violation, then Total GBP for any particular violation will not be the *Final* GBP in the case, because the Final GBP is the sum of every Total GBP in the case.

B. Adjust the Gravity-based Penalty

Adjust the Final GBP, upward or downward, in accordance with the guidance in CERPP Part Five for the TSCA § 16 factors applicable to the violator. The adjusted Final GBP is the final civil penalty in the case.

IV. TSCA FACTORS for VIOLATION

As discussed above, the confluence of a violation’s Nature, Circumstances, Extent and Gravity determines its Initial GBP. The general function of each TSCA factor is explained below. See also Figure 2-6, below.

Since these factors are statutory, they apply to every Core TSCA program. The guidance for these factors, however, varies by program. Therefore, CERPP Part Three provides separate Modules for interpreting these factors with respect to the violations under the particular program.

Fig. 2-6: TSCA Factors – General Principles

| TSCA Factor | Factor Pertains to: |
|-----------------------------------------------------------|---------------------------------------------------------------------|
| Nature | Essential purpose of the requirement that was violated.* |
| Circumstances | Probability that harm <i>could have</i> occurred due to violation.* |
| Extent | Degree, range or scope of violation in relation to potential harm. |
| Gravity | Overall seriousness of the violation. |
| * Generally, the CERPP <i>assigns</i> the classification. | |

A. Nature

Nature pertains to the essential purpose of the requirement that was violated. The CERPP *assigns* each violation to one of three classifications:

- Hazard Assessment (HA) (known also as “Hazard/Risk Assessment”).³

³ Note that earlier Core TSCA ERPs may have used the term “Hazard/Risk Assessment.”

- Chemical Control (CC); or
- Control-associated Data-gathering (CADG).

Whereas some Core TSCA programs use the same classification for all violations, other programs assign different classifications to particular violations.

1. Hazard Assessment (HA)

The purpose of HA requirements is to enable EPA to develop and gather information necessary to weigh the risks and benefits of a chemical and impose control requirements when appropriate. For example, this category includes violations for failure to notify EPA and violations for withholding information from, or submitting false or misleading information to, EPA.

2. Chemical Control (CC)

CC restrictions aim to minimize risks presented by a chemical by placing constraints on how a chemical is handled. For example, CC violations include noncompliance with:

- § 5(a)(1)(A)'s prohibition of the manufacture and/or processing of new chemical substances and "significant new uses" of chemical substances without complying with § 5(a)(1)(B)'s notice-and-review scheme;
- § 5(e) and (f) requirements such as labeling restrictions and environmental release restrictions, manufacturing bans;
- § 5(h)(1) restrictions on the manufacture or processing of a test marketed chemical
- § 5(h)(3) requirements to give employees adequate warning when producing a chemical under a certain Research and Development (R&D) exemptions; and
- § 6(a)(1) requirements limiting the manufacture/importation, processing, or distribution in commerce of a chemical substance.

3. Control-associated Data-Gathering

CADG requirements are the recordkeeping requirements associated with a chemical control regulation. These requirements enable EPA to evaluate the effectiveness of the regulation and monitor compliance. This category applies to certain § 5(e) and 5(f) violations, such as violation of a § 5(e) order requirement to keep records of all purchases of a regulated chemical test marketing exemption restrictions with recordkeeping requirements; and to certain § 6 recordkeeping violations.

Note that Nature classification is *not* an axis on the GBP Matrix (CERPP Part Four). See Figure 2-5, above. Depending on the Core TSCA program, however, Nature may be integral to determining a violation's Circumstances Level and Extent Level, both of which *are* axes on the Matrix.

B. Circumstances

The Circumstances factor reflects EPA's determination regarding the probability of potential harm that occurred as a result of non-compliance.

The CERPP *assigns* the Circumstances Level of a violation (High, Medium, or Low), so that the Agency need not make a violation-specific determination. Also, depending upon the particular Core TSCA Program, each Circumstances Level may be divided into sub-levels:⁴

- High (Level 1 and 2) - high probability of harm.
- Medium (Levels 3 and 4) - intermediate probability of harm.
- Low (Levels 5 and 6) - lower probability of harm.

An after-the-fact determination whether harm actually occurred is irrelevant. The probability of harm may be potential injury to human health and/or the environment (e.g., risk of exposure to an unregulated chemical); or potential impairment to EPA's decision-making or regulatory functions (e.g., jeopardy to the integrity of the TSCA Inventory or other EPA data).⁵

Circumstances Levels are represented as the vertical axis of the GBP Matrix (CERPP Part Four). See also Figure 2-5, above.

C. Extent

Extent considers the degree, range or scope of the violation in relation to *potential* harm to human health or the environment from non-compliance. Extent is expressed in three levels of potential harm, damage, or injury:

- Major - serious harm to human health, or major environmental damage.
- Significant - significant harm to human health or the environment.
- Minor - a lesser amount of harm to human health or environmental damage.⁶

Generally, the Agency must determine the appropriate Extent Level for a violation, based on program-specific guidance in the pertinent CERPP Part Three Module. For instance, for certain § 6 violations, the Agency must compute the Extent Level based on the Circumstances Level of the violation and the potential exposure to humans and/or the environment of the chemical involved.

Extent Levels are represented as the horizontal axis of the GBP Matrix (CERPP Part Four). See also Figure 2-5, above.

D. Gravity

No calculation is required for Gravity. Gravity is a “dependent variable,” derived from the Nature, Circumstances and Extent factors and, thus, is implicit in the Core TSCA GBP Matrix (CERPP Part Four).

⁴ The § 4 Test Rule does not use Level 2. The § 4 GLP Standard does not include any sub-levels.

⁵ For certain violations (e.g., § 4 GLP and § 8(e) violations), it may be appropriate to consult with the Agency's TSCA regulatory office for clarification regarding the violation's effect on regulatory functions.

⁶ 47 Fed. Reg. 59771 (Sept. 10, 1980).

V. TSCA FACTORS for VIOLATOR

The TSCA § 16 factors for adjusting the Final GBP as to the violator are:

- Ability to pay / Ability to continue to do business.
- Prior violations.
- Culpability.
- Other matters justice may require. (This factor is reflected in several policies, such as recovery of economic benefit, voluntary disclosure, good faith/attitude, environmentally beneficial projects, and special circumstances.)

CERPP Part Five explains each factor and provides cross-cutting guidance for applying each.

REFERENCES

CERPP Part Two - Reference #1

Summary: Steps in Computing Civil Penalties

- **Preliminary Step:** Confirm the appropriate enforcement response (CERPP Part One).
- **STAGE ONE: Calculate the GBP for each type of violation, following the program-specific guidance** (CERPP Part Three):
 - **Step 1: Nature** - Identify the Nature assigned to the violation.
 - **Step 2: Circumstances** – Identify the Circumstances Level for the violation.
 - **Step 3: Extent** – Identify the Extent Level for the violation.
 - **Step 4: Initial GBP** – Using the GBP Matrix (CERPP Part Four), locate the initial (per violation) GBP for the violation, at the intersection of the Circumstances Level (from Step 2) and Extent Level (from Step 3).
 - **Step 5: Total GBP** – Multiply the number of violations by the Initial GBP (from Step 4) and apply any pertinent “CERPP Calculation Factors” (CERPP Part Three) to determine the Total GBP for the violation

Repeat Steps 1-5 to determine the Total GBP for any other type of violation in the case.

- **Step 6: Final GBP.** If the case involves only one type of violation, then the Total GBP for that violation (from Step 5) is also the Final GBP in the case. If the case involves more than one type of violation, then add together the Total GBPs for every violation (from Step 5) to derive the Final GBP for all violations in the case.

STAGE TWO: Adjust the Final GBP in accordance with TSCA adjustment factors (CERPP Part Five) to derive the **final civil penalty** in the case.

Part Three

Module A

§ 6(a) Rules

Gravity-based Penalty Calculation

I. INTRODUCTION

A. Purpose

Use this Module to compute the Gravity-based Penalty (GBP) for violations of rules for “unreasonable risk” chemical substances and mixtures (herein, chemicals) promulgated under TSCA § 6(a), as well as rules for persistent, bioaccumulative and toxic (PBT) chemicals under TSCA § 6(h).

B. Legal Background

TSCA § 6, [15 U.S.C. § 2605](#), governs the prioritization, risk evaluation, and regulation of chemicals that present an “unreasonable risk of injury to health or the environment.”¹ In brief, § 6(a) states that if the Administrator determines that the manufacture, processing, distribution in commerce, use, and/or disposal of a chemical presents an unreasonable risk of injury, then the Administrator shall apply one or more of the following requirements:

- **Prohibit**, limit the amount, or otherwise restrict manufacturing, processing, or distribution in commerce of the chemical (§ 6(a)(1)); or prohibit or otherwise restrict manufacturing, processing, or distribution in commerce of the chemical for a particular use or for a particular use in a concentration exceeding a specified level (§ 6(a)(2)).
- **Require** appropriate warnings and instructions for use, distribution in commerce, and/or disposal to be marked on or accompany the chemical or any article containing the chemical (§ 6(a)(3)).
- **Require** manufacturers and processors to make and retain records of the processes used to manufacture or process the chemical and monitor or conduct tests to assure compliance with applicable requirements (§ 6(a)(4)).
- **Prohibit or regulate** commercial use of the chemical (§ 6(a)(5)).

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¹ This summary is not a substitute for close review of the law. Reference #1 provides the statutory text. Regulations promulgated under TSCA § 6(a) are set forth in 40 C.F.R. Part 751.

- **Prohibit or regulate disposal** of the chemical or of any article containing the chemical by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes (§ 6(a)(6)).
- **Direct** manufacturers or processors to (a) give notice of the unreasonable risk of injury to distributors in commerce and, to the extent reasonably ascertainable, to other persons in possession of, or exposed to, the chemical; (b) give public notice of such risk; and (c) replace or repurchase the chemical (§ 6(a)(7)).

Also, TSCA § 6 establishes chemical-specific requirements:

- TSCA § 6(h) for promulgating rules under § 6(a) for persistent, bioaccumulative and toxic (PBT) chemicals. This CERPP Module covers PBT violations.
- TSCA § 6(f) for mercury. Mercury will be addressed in CERPP Part Three.
- TSCA § 6(e) for polychlorinated biphenyls (PCBs), for which there is a separate ERPP.

See Module A Reference #1, and TSCA § 6 statutory text.

II. Preliminary Information

Readers should be familiar with CERPP Parts One and Two which detail enforcement response options, and the process and principles for computing Gravity-based Penalties and final civil penalties in a case.

Enforcement Response for this Program. A penalty action is the appropriate enforcement response for most violations of a TSCA § 6(a) requirement.

Terminology in this Module. In this Module, the term “chemical” means a chemical substance or mixture within the meaning of TSCA § 6(a); and encompasses any product or “article” that contains such chemical substance or mixture in accordance with § 6(a)(3) and § 6(a)(6) or as otherwise defined by rule.

Manufacturing, Importation, Processing, Commercial Use, and Disposal are referred to collectively as “MIPUD” activities. See e.g., [Calculation Factors](#), below.

III. Nature *(essential purpose of requirement that was violated)*

The Nature classification for all § 6(a) violations is Chemical Control (CC), excluding recordkeeping violations. The Nature classification for recordkeeping violations under § 6(a) is Control-associated Data-Gathering (CAGD).

IV. Circumstances (probability of harm or injury to Human Health or Environment, or impede an EPA function)

Identify the Circumstances Level classification for the violation using Figure 3-A-1. The Circumstances Level depends on the type of requirement that was violated.

| Figure 3-A-1. Circumstances Levels by § 6(a) Violations | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Level | Requirement Violated |
| High Range | Prohibition, limitation, regulation or restriction on: <ul style="list-style-type: none"> • Manufacture/importation, processing, or distribution in commerce. § 6(a)(1). • Manufacture/importation, processing, or distribution in commerce for a particular use, or a particular use in a concentration exceeding a specified level. § 6(a)(2). • Disposal. § 6(a)(6)). • Commercial use. § 6(a)(5)). • Testing. § 6(a)(4). • Replace or repurchase. § 6(a)(7)(C) See Note, below. |
| Medium Range | Complete noncompliance, or <i>materially</i> deficient partial compliance, of the following requirements: <ul style="list-style-type: none"> • Warnings and instructions on use, distribution, or disposal. § 6(a)(3). • Notice of risk of injury. § 6(a)(7)(A) and (B). • Recordkeeping. § 6(a)(4). |
| Low Range | Deficient compliance where the deficiency is <i>less than a material deficiency</i> *: <ul style="list-style-type: none"> • Recordkeeping. § 6(a)(4). • Warnings and instructions on use, distribution, or disposal. § 6(a)(3). • Notice of risk of injury. § 6(a)(7)(A) and (B). <p>*For example, the compliance may be slightly tardy, or fail to meet the precise regulatory standard in a minor or de minimis way that does not merit a higher Circumstances Level.</p> |
| <p>Note: It is important to distinguish the precise requirement related because the Circumstances Levels may differ for seemingly comparable requirements. For instance, where a rule pertains to manufacturing, importation, processing, commercial use and/or disposal (MIPUD activities), the Circumstances Level is High Range where the rule:</p> <ul style="list-style-type: none"> • Dictates how to lawfully conduct a MIPUD activity (e.g., process a chemical only when using a hood to capture fumes); or • Requires corollary health/safety precautions (e.g., <i>develop and implement</i> an Exposure Control Plan) where MIPUD activities may occur at a facility. <p>By contrast, the Circumstances Level may be Low Range (or Medium Range) for violation of a recordkeeping requirement, such as to <i>maintain a record</i> of an Exposure Control Plan.</p> <p>When calculating the appropriate sub-level in the Circumstance Level Range, (i.e., Level 1 for High Range), EPA personnel should consider the specific circumstance of the violation (e.g., partial compliance, etc.) If the records specified above are unavailable, the penalty is to be assessed from the records that are available if possible or at the high circumstance level.</p> <p>The selection of the exact penalty amount within each circumstance level is left to the discretion of enforcement personnel in any given case. The range of numbers provided in each circumstance level allows enforcement personnel to better adapt the penalty amount to the gravity of the violation and its surrounding circumstances. Enforcement personnel should analyze and rely on case-specific factors in selecting a dollar figure from this range.</p> <p>Also, the “unit of violation” for seemingly comparable requirements may differ (e.g., one day versus per day). See Calculation Factors, below.</p> | |

V. Extent (degree, range, scope of violation in relation to potential harm from noncompliance)

A. Overview

Use the Extent Level Matrix to determine the Extent Level for a violation that involves human health or the environment. See Figure 3-A-2, below.

The Agency has determined that chemicals regulated pursuant to TSCA § 6(a) pose an unreasonable risk of injury to human health or the environment. For purposes of assessing penalty, however, the Extent Level Matrix establishes classifications - Major, Significant or Minor - to distinguish among violations. The Matrix also bases those classifications on two factors relevant to the unreasonable risks from § 6(a) chemicals, i.e.:

- **Potential Injury** – i.e., the scope of the violation in relation to the potential injury from noncompliance; and
- **Potentially Impacted Entity (PIE)** – i.e., the population or environment that could be subject to the potential injury from the violation.

See Figure 3-A-2, below, Extent Level Matrix. The classifications are explained below. See also the illustration in Module A, Reference #2.

The violative conduct need not have resulted in actual injury from, or exposure to, the chemical. The conduct need only have posed a potential risk of injury or exposure (i.e., “potential” is implicit throughout the discussion herein, if not explicit).

| Figure 3-A-2. § 6(a) Extent Level Matrix | | | | |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| | | Potentially Impacted Entity (PIE) | | Extent Level |
| | | A | B | |
| Row Ref. No. | Potential Injury | POPULATION: Massive population with or without vulnerable members OR POPULATION: Non-massive population <u>with</u> vulnerable member OR ENVIRONMENT: Widespread Impact | POPULATION: Non-massive population <u>without</u> vulnerable member OR ENVIRONMENT: Localized Impact OR POPULATION / ENVIRONMENT: Unknown Impact | |
| 1 | Acute Human Lethality/ Toxicity | X | X | Major |
| 2. | Chronic specific target organ toxicity/ carcinogenicity/ re productive toxicity | X | X | Major |
| 3 | Skin Irritation/Corrosion/ Sensitization | X | | Significant |
| | | | X | Minor |
| 4 | Other Acute/ Chronic Injury | X | | Major |
| | | | X | Significant |
| 5 | Hazardous to Environment | X | | Major |
| | | | X | Significant |
| Note: If information is available, EPA personnel should consider the appropriate injury at the exposure level. | | | | |

B. Extent Level Classifications

1. Potential Injury - Vertical Axis (Rows)

The Potential Injury classifications on the Extent Level Matrix are as follows:

- Acute² human lethality/ toxicity; or Chronic specific target organ toxicity/carcinogenicity/reproductive toxicity (Rows 1-2).
- Skin Irritation/Corrosion/Sensitization (Row 3).
- Other Acute/ Chronic Injury (Row 4).
- Hazardous to Environment/ (Row 5).

Generally, EPA's determination regarding the classification of a chemical's potential injury (e.g., acute versus chronic) is stated in the Agency's risk evaluation and/or risk management rule for the chemical.³ If the applicable classification for purposes of the Extent Level Matrix is not clear from these sources, then the appropriate EPA risk management office should be consulted for an opinion.⁴

² Generally, "acute" refers to effects that occur after a single or short-term exposure to a chemical; whereas "chronic" refers to effects that occur after repeated exposures.

³ EPA provides Ongoing and Completed Chemical Risk Evaluations under TSCA on its website. See <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under>.

⁴ As of the publication of this CERPP, the applicable office is the Office of Pollution Prevention and Toxics (OPPT), in EPA's Office of Chemical Safety and Pollution Prevention (OCSPP).

2. Potentially Impacted Entities (PIEs) – Horizontal Axis (Columns)

The classifications for Potentially Impacted Entities distinguish populations and environments by size and/or composition (Columns A and B). These classifications do not impose artificial numerical or demographic boundaries. Generally, investigation to confirm the precise size or composition of a population is not necessary or merited. The Agency is to employ objective professional judgment, as supported by the evidence, to determine the appropriate PIE classification.

a. PIE is a Human Population (Group or Individual)

The classifications are as follows:

- “Massive population” (Column A).
- “Non-massive population *with* ‘vulnerable’ member” (Column A).
- Non-massive population *without* vulnerable member (Column B).
- Population Unknown (Column B).

Note that each column on the Matrix covers multiple PIE categories.

“Massive population” (Column A) covers potentially vast national or multi-regional populations, such as the general public, where virtually anyone may access the chemical and, thus, potentially be impacted by the violation. For instance, this category is appropriate where the violation involves distribution of a chemical via an Internet site or another national distribution operation.

“Non-massive population *with* ‘vulnerable’ member” (Column A) covers any size human population (other than “massive”), including a single person, where the potentially impacted population may include a vulnerable member or members. For purposes of this CERPP, “vulnerable” member means (a) any group defined as a “potentially exposed or susceptible subpopulation” by TSCA § 3(12)⁵ or EPA’s risk evaluation or risk management rule for the chemical;⁶ or (b) any other individual or group that is reasonably foreseeable to be at greater risk of injury from the violation than the general public (e.g., hospital patients).⁷

⁵ TSCA § 3(12), [15 U.S.C. § 2602\(12\)](#), defines the term “potentially exposed or susceptible subpopulations” to mean “a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” See also <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>.

⁶ Generally, the “Exposures” section of the Agency’s risk evaluation for a chemical states the determination regarding the “potentially exposed or susceptible subpopulations.” For example, for carbon tetrachloride the Agency has identified workers, occupational non-users, and certain other individuals. See Section 5.2.1 in Final Revised Unreasonable Risk Determination for Carbon Tetrachloride, December 2022 https://www.epa.gov/system/files/documents/2022-12/9948-02_Revised_RD_CTC_12.12.22_for%20RSB.pdf.

⁷ For instance, otherwise healthy individuals may be vulnerable to greater risk of injury temporarily or under certain circumstances, such as persons at a health care facility or hospital.

Presumption Regarding Vulnerable Member(s)

Consistent with the foregoing definition and because EPA has already determined that all § 6(a) chemicals present an unreasonable risk to human health, the CERPP establishes the presumption that any population potentially impacted by a § 6(a) violation included (or could have included) at least one vulnerable member. This presumption may be rebutted based on information *to the Agency's satisfaction* that the population likely did *not* include a vulnerable member or members. (If the presumption does not apply, then Column B, rather than Column A, applies. See below.)

“Non-massive population *without* ‘vulnerable’ member” (Column B) covers any size population (other than “massive”), including a single person, where the Agency determines that the population does *not* include a vulnerable member or members (i.e., the CERPP presumption, above, does not apply). For example, this classification may apply where the potentially impacted population was limited to a few adult visitors to a company office (non-massive population, non-workers, no apparent vulnerable members). The Extent Level is **Major** or **Significant**, depending upon the chemical’s Injury classification on the Extent Level Matrix.

“Population unknown” (Column B) applies where EPA has insufficient evidence to reasonably ascertain any size and/or composition of the population potentially impacted by the violation. The Extent Level is **Major** or **Significant**, depending upon the chemical’s Injury classification on the Extent Level Matrix.

b. PIE is the Environment

The classifications are based on the extent of impacts as follows:

- Widespread Environmental Impact (Column A).
- Localized Environmental Impact (Column B).
- Unknown Environmental Impact (Column B).

“Widespread Environmental Impact” (Column A) covers, for instance, violations that affect multiple environmental media (e.g., air emissions that result in chemical depositions to soil, sediments or water); or violations that affect areas beyond the company’s fence-line or facility, such as water bodies or expansive areas of land. The Extent Level is **Major** for all Injury classifications on the Extent Level Matrix.

“Localized Environmental Impact” (Column B) covers, for instance, violations that affect a single environmental media only within one small geographical area. The Extent Level is **Significant**.

“Unknown Environmental Impact” (Column B) applies where EPA lacks sufficient evidence to reasonably ascertain the extent of the potentially impacted environment. The Extent Level is **Significant**.

Conflicting Extent Levels

If the PIEs include both a human population (or individual) and the environment, and the Extent Levels for each are in conflict, then apply the higher Extent Level to the violation applicable to the human population.

VI. Initial Gravity-based Penalty

Locate the *Initial* Gravity-based Penalty (dollar amount *per violation*) on the GBP Matrix in CERRP Part Four based on the violation's Circumstances Level and Extent Level (above).

Note that the CERPP Calculation Factors, below, are used to determine how many multiples of the Initial GBP to count for each type of violation. That product (the Initial GBP times the applicable multiples) will result in the *Total* GBP for each type of violation.

VII. Calculation Factors

A. Overview

Determine the *Total* Gravity-based Penalty for each type of violation by applying any pertinent CERPP Calculator Factor(s) to the Initial GBP for the violation.

For this program, the Calculation Factors are as follows:

- The “unit of violation” which, depending upon the violation, may be counted as per transaction, per item, per day, or one-day.
- Methods for modifying (reducing) the Total GBP for certain product-based violations.
- Computations for imminent hazards.

B. Units of Violation




1. Units of Violation Generally

A penalty is to be assessed for each unit of violation (i.e., each independently assessable violation), per requirement violated, and per chemical. See CERPP Part Two (General Principles).

The TSCA § 6(a) requirements govern three broad classes of activities. The CERPP establishes different bases for ascertaining the unit of violation for each class, as follows:

- For **product-based activities** – e.g., distribution in commerce, notice, warning/instructions, replacement/repurchase - the unit of violation is **per transaction, or per item** under certain circumstances. See § 2, below.
- For **MIPUD Activities** – e.g., manufacturing/importation, processing, commercial use, disposal - the unit of violation is **per day of violation, including per calendar day** under certain circumstances. See § 3, below.
- For **occurrence-based activities** – e.g., recordkeeping, testing, and other requirements – the unit of violation is **one day, per day of violation, including per calendar day** under certain circumstances. See § 4, below.

See Figure 3-A-3.

| Fig. 3-A-3: Unit of Violation via-a-vis Requirement Violated | | | |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Regulated Activity | <u>Product-based Activities</u> <ul style="list-style-type: none"> • Distribution in commerce • Notice • Warning / Instructions • Replacement/repurchase  | <u>MIPUD Activities</u> <ul style="list-style-type: none"> • Manufacturing, Importation • Processing • Commercial Use • Disposal  | <u>Occurrence-based Activities</u> <ul style="list-style-type: none"> • Recordkeeping • Testing • Other requirements (e.g., health/safety plans)  |
| Unit of Violation | Per transaction (or per item) | Per day of violation (including per calendar day) | One day (or per day of violation, including calendar day) |

2. Product-based Requirements

a. Generally

Certain TSCA § 6(a) requirements govern **distribution in commerce, warnings, instructions, notice, and replacement/repurchase**.⁸ Violations of these requirements are known as “product-based” violations (Figure 3-A-3, above) because the offense typically involves distribution in commerce of a chemical (or product containing the chemical) to a third party. The third party could be within the same unit of a company; within another unit of the same company; or a customer or other outside entity. Noncomplying distribution in commerce is itself a violation; and may give rise to other product-based violations (i.e., for warning, instruction, notice, and/or replacement/repurchase).

The unit of violation for assessing penalties for a product-based violation is:

- **Per transaction**, generally; or
- **Per item** under certain circumstances.

Both computation methods enable EPA to consider the potential for widespread injury to vast populations due to the possibility of the chemical/product becoming widely accessible via iterative downstream distributions in commerce (and otherwise). Also, each transaction/item constitutes a unit of violation and merits an independently assessable penalty because each invokes the pertinent requirement anew; each creates a distinct opportunity for potential injury; and each could result in placement of the chemical/product at a separate location at which entities in the vicinity are put at risk of injury.

⁸ TSCA § 6(a)(1)(distribution), 6(a)(3)(warnings, instructions), 6(a)(7)(notice of risk, replacement/repurchase).

b. Per Transaction Penalty Assessment

Generally, penalties for a product-based offense, especially distribution in commerce violations, should be assessed **per transaction**. A “transaction” is any type of arrangement through which an entity distributes in commerce (or otherwise illegally transfers)⁹ a chemical or a chemical-containing product so as to violate any product-based requirement.

The **per transaction** approach is particularly appropriate where a product-based violation involves distribution via an Internet-based platform because of the vast magnitude of potentially impacted populations.

Any party engaged in the transaction chain may be subject to enforcement, in accordance with the applicable regulatory provision. This includes, but is not limited to, an entity that operates a physical outlet or store; operates or controls an Internet site; or is otherwise involved in the violation, such as broker, distributor, vendor, processor, or manufacturer.¹⁰

The per transaction unit of violation generally does not consider the size or cost of the transaction; the identity of the purchaser or whether the purchaser is involved in multiple transactions; or the number or size of items or containers in the transaction. (See below for “per item” unit of violation.)

c. Per Item Penalty Assessment

Under certain circumstances, penalties for a product-based violation should be assessed **per item**. Where noncompliance involved only one or a few transactions through which an entity (e.g., wholesaler) distributed numerous individual items which could have been widely distributed and caused extensive potential injury (e.g., one transaction for a truck-load of product which contained hundreds of individually-packaged units). In such a case, assessing a penalty based only on the single transaction would be incongruent with the potential injury from thousands of individual units.

The per item unit of violation considers the number of items involved, and generally does not consider the number of transactions, the size or cost of each item, or the identity and number of entities to whom the items were or could have been ultimately distributed.

d. Records to be Used

The Agency should use the records required by the applicable regulation to help determine the units of violation (the number of transactions or items). The Agency also may use other reliable information, such as ordinary business records (e.g., invoices, sales records) and reliable public data (e.g., government or authoritative non-governmental reports or studies).

⁹ For instance, “distribution in commerce” may take the form of selling, dispersing, supplying, making available, purveying or otherwise facilitating the transfer, passing on or handing over of the chemical (or product) to another party.

¹⁰ For these TSCA violations, this group generally excludes independent entities that only transport the chemical/product, such as third-party logistics, trucking or delivery companies. Such entities typically have no specific dominion over the chemical/product beyond transporting it.

e. Total Gravity-Based Penalty

Compute the Total GBP *per requirement violated* by multiplying the Initial GBP for the violation (dollar amount from CERPP Part IV Matrix) by the number of transactions or items. Figure 3-A-4.

| Fig. 3-A-4: Computing Total Gravity-Based Penalty for a Product-based Violation | | | | |
|---------------------------------------------------------------------------------|---|------------------------------|---|---------------------------------------|
| Initial GBP for particular violation | X | # Transactions Or # Items | = | Total GBP for particular violation |

Compute the Total GBP for each chemical. Add together all of the Total GBPs (per requirement, per chemical), and apply any other pertinent Calculation Factors, to derive the Final GBP in the case. See CERPP Part Two.

f. Modified Gravity-based Penalty (Reference #3)

The Total GBP for a product-based violation may be significant when a case involves numerous transactions or items. Moreover, the Final GBP for all violations in the case may be further enlarged beyond involving multiple units of violation when the case involves chemicals and types of violations.

When the Total GBP for a violation seems exorbitant, enforcement practitioners may consider whether to generate a Modified Gravity-based Penalty. The guidance in Reference #3 provides an objective basis for modifying the GBP; and describes the applicability, methods, and conditions for this option. Note that modifying the Total GBP is distinct from applying the TSCA penalty adjustment factors to the Final GBP (CERPP Part Five).

3. Manufacturing, Importing, Processing, Commercial Use, Disposal (MIPUD) Activities

a. Generally

Certain TSCA § 6(a) requirements govern **manufacturing/importing, processing, commercial use, or disposal**¹¹ (collectively, MIPUD). See Figure 3-A-3, above.

Generally, assess penalties **per day of violation** for a MIPUD violation. Some circumstances may warrant that these per day violations are assessed per calendar day when the evidence supports that the MIPUD restriction was violated on a per calendar day basis.¹²

¹¹ Note that a rule may define processing to include recycling.

¹² Note that this unit of violation computation applies to *operational* MIPUD requirements that dictate how to legally conduct a MIPUD activity. As discussed elsewhere, such operational MIPUD requirements are distinguished from corollary health/safety requirements and recordkeeping obligations, which use a different unit of violation computation (see Occurrence-based Requirements, below) and may have a different Circumstances Level (see Circumstances Table, above).

b. Per Day of Violation Penalty Assessment

The penalty is calculated for the first day of noncompliance; for each subsequent day of noncompliance; and through and including the date on which noncompliance is confirmed to have ceased. The days of violation counted need not be successive or uninterrupted; there may be intervening days of inactivity or compliance over the course of the entire time period considered.

For example, when a company is charged with illegal manufacturing or processing, then each day on which such activity occurs (in whole or in part) constitutes a violation, regardless of whether the function being performed reached its conclusion since every day of handling a § 6(a) chemical presents an opportunity for exposure to an unreasonable risk. Also, the amount of chemical involved is not relevant.

For improper disposal, generally assess the penalty for each day of disposal, regardless of the amount of chemical disposed of in a day. Assess a penalty for each batch disposed of in a day if the violation occurred via disposal of multiple batches of the chemical in a day, rather than per day of disposal.

c. Records to be Used

The Agency should use the records required by the applicable regulation to help determine the units of violation (number of days). The Agency also may use other reliable information, such as ordinary business records (e.g., manufacturing, batch, or waste logs; and transport manifests)¹³ and reliable public reports (e.g., government or authoritative non-governmental reports or studies).

4. Occurrence-Based Requirements

Certain TSCA § 6(a) requirements govern **recordkeeping, testing**,¹⁴ and other requirements such as for health and safety plans. See Figure 3-A-3, above. Depending upon the specific requirement, the unit of violation may be counted for a single occurrence or counted for a continuing obligation.

Generally, for a single occurrence requirement - e.g., *establish, develop, or create* a plan or record, or *commence* a test by a date certain - assess penalties as a **one-day** offense (one unit of violation).

For a continuing obligation – e.g., *continuously implement* a health/safety plan, *maintain* a record, or *complete* a test and report by a date certain – assess penalties **per day of violation** (multiple units of violation). There may be intervening days of inactivity or compliance.

¹³ See also e.g., Core TSCA Inspection Manual, EPA (May 1, 2022) <https://www.epa.gov/system/files/documents/2022-04/tscanewandexistingchemicalinspectionsmanual.pdf>.

¹⁴ OPPT may require testing to determine compliance with certain sections of the rule such as the exposure monitoring measurements required in the Workplace Chemical Protection Program (WCPP).

For certain continuing obligations, it may be appropriate to assess penalties **per calendar day**, such as where the Agency needs information for an urgent or critical function, or the violation presents an imminent hazard under TSCA¹⁵ or other imminent endangerment authority.

Reminder

As discussed elsewhere, it is important to distinguish between seemingly comparable requirements, because the unit of violation, and Circumstances Levels, may differ. For instance, a rule may impose several distinct obligations for health and safety plans:

- A duty to *establish, develop or create* a plan (High Circumstances Level, one-day assessment) - versus
- A duty to *continuously implement* a plan (High Circumstances Level, generally assessed per day of violation) - versus
- A duty to *maintain* a record of a plan (Low Circumstances Level, generally assessed per day of violation).

These are distinct obligations, and compliance with one does not necessarily substantiate compliance with another. Each violation is separately assessable. See also Circumstances Level Table, above.

5. Use of Chemicals Subject to § 6 Violations or that Present Imminent Hazard or Endangerment

Section 15 of TSCA also makes it a violation of TSCA to use for commercial purposes of a chemical that the company knew or had reason to know was manufactured, processed, or distributed in commerce in violation of § 6. It is also a violation to use a chemical that presents an imminent hazard under TSCA and is subject to an action brought under § 7.¹⁶ Each day the company uses the chemical should be assessed as a separate day of violation.

VIII. Total Unadjusted Gravity-based Penalty

Derive the Total Unadjusted Gravity-based Penalty for *all* violations in the case by adding up the *Total* GBP for *each type* of violation (the Initial GBP per violation as modified by applicable CERPP Calculation Factors).

The Total Unadjusted GBP may be subject to adjustment upward or downward based on TSCA § 16 adjustment factors set forth in CERPP Part Five, if appropriate, to calculate the Final GBP. The Final GBP will constitute the final civil penalty in the case.

¹⁵ Under TSCA § 7(f), 15 U.S.C. § 2606(f), “imminently hazardous chemical substance or mixture” means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other non-risk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 [TSCA § 6] of this title can protect against such risk.

¹⁶ Under TSCA § 7(f), 15 U.S.C. § 2606(f), “imminently hazardous chemical substance or mixture” means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other non-risk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 [TSCA § 6] of this title can protect against such risk.

REFERENCES

Module A – Reference #1: TSCA § 6, 15 U.S.C. § 2605 (Excerpt)

Note: Regulations promulgated under TSCA § 6(a) are set forth at 40 C.F.R. Part 751.

Prioritization, risk evaluation, and regulation of chemical substances and mixtures

(a) Scope of regulation

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, **presents an unreasonable risk of injury** to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

- (1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.
- (2) A requirement-
 - (A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or
 - (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.
- (3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.
- (4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.
- (5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.
- (6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.
 - (B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.
- (7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) Risk evaluations [omitted]

(c) Promulgation of subsection (a) rules [omitted]

(d) Effective date [omitted]

(e) Polychlorinated biphenyls [omitted]

(f) Mercury [omitted]

(g) Exemptions

(h) Chemicals that are persistent, bioaccumulative, and toxic

(1) Expedited action

Not later than 3 years after June 22, 2016, the Administrator shall propose **rules under subsection (a)** with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments-

(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under [section 2603 of this title](#), prior to June 22, 2016; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) No risk evaluation required

The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

(3) Final rule

Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

(4) Selecting restrictions

In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

(5) Relationship to subsection (b)

If, at any time prior to the date that is 90 days after June 22, 2016, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

(i) Final agency action [omitted]

(j) Definition

For the purposes of this chapter, the term "requirement" as used in this section shall not displace statutory or common law.

Module A – Reference #2

Extent Level Matrix Illustration

| Fig. 3-A-5: Illustrations of § 6(a) Extent Levels | | | | |
|-------------------------------------------------------|---|---------------------------------------------------------------------------------------------|---|--------------|
| Injury: | | Potentially Affected Entity: | | Extent Level |
| Chemical X – Acute Human Toxicity (Row 1) | + | Non-massive Population <u>with</u> vulnerable member (e.g., nearby school)(Column A) | = | Major |
| Chemical Y – Skin Irritation (Row 3) | + | Non-massive Population <u>without</u> vulnerable member (Column B) | = | Minor |
| Chemical Z Hazardous to Environment (Row 6) | + | Environment – Localized Impact (Column B) | = | Significant |

The Extent Level determinations for these chemicals is highlighted on the Table below.



| Fig. 3-A-6: Illustration of § 6(a) Extent Level Matrix | | | | |
|--------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| | | Potentially Impacted Entity (PIE) | | Extent Level |
| | | A | B | |
| Row Ref. No. | Potential Injury | POPULATION: Massive population with or without vulnerable members OR POPULATION: Non-massive population <u>with</u> vulnerable member OR ENVIRONMENT: Widespread Impact | POPULATION: Non-massive population <u>without</u> vulnerable member OR ENVIRONMENT: Localized Impact OR POPULATION / ENVIRONMENT: Unknown Impact | |
| Chem. X → | 1 Acute Human Lethality/ Toxicity | X | X | Major |
| | 2 Chronic specific target organ toxicity/ carcinogenicity/ reproductive toxicity | X | X | Major |
| Chem. Y → | 3 Skin Irritation/Corrosion/ Sensitization | X | | Significant |
| | | | X | Minor |
| | 4 Other Acute/ Chronic Injury | X | | Major |
| | | | X | Significant |
| Chem. Z → | 5 Hazardous to Environment | X | | Major |
| | | | X | Significant |

Module A – Reference #3

Modified Gravity-Based Penalty for Product-based Violations

1. Background

A TSCA § 6(a) “product-based” violation means noncompliance with a requirement that governs **distribution in commerce, warning, instructions, notice, or replacement/repurchase**. The unit of violation is per transaction (or per item under certain circumstances), which may result in a very large Total GBP for each type of violation. See above.

2. Purpose

This guidance provides an objective basis and mechanisms by which to modify (reduce) the Total Gravity-based Penalty (GBP) for a product-based violation when the standard GBP is deemed to be exorbitant, as described below.

The option to generate a Modified GBP is distinct from, and does not obviate the Agency’s ability to apply, appropriate TSCA adjustment factors (including ability-to-pay), prosecutorial discretion and other enforcement policies.

Depending upon the computation method used (below), the Modified GBP could result in counting, and assessing penalties on, as few as 45 violations per 100 actual violations. In no case is it mandatory to compute a Modified GBP. The Agency maintains its authority to assess penalties of up to the statutory maximum per violation, as appropriate.

3. Applicability

The option to generate a Modified GBP applies to assessing penalties for a product-based violation where the standard Total GBP for a violation could be exorbitant solely because the case involves numerous identical units of violation (transaction/items), such as where distribution of a specific chemical or product occurs via an Internet platform or nationwide outlet.¹⁷

The Agency may consider the standard Total GBP to be exorbitant where the dollar amount is (a) excessive in relation to the totality of facts and circumstances in the case; and (b) likely would result in a final civil penalty that grossly exceeds the amount required for effective deterrence even after application of appropriate TSCA adjustment factors (CERPP Part Five). The Modified Total GBP is used in lieu of the larger, standard Total GBP to determine the Final GBP in the case.

¹⁷ A Modified GBP is not appropriate where the penalty is high for another reason (e.g., an imminent hazard or endangerment), or for any other type of TSCA § 6(a) violation; or where there are material differences among the transactions or items being counted. TSCA adjustment factors such as ability to pay are not relevant to generating a Modified Total GBP.

4. Methods for Generating a Modified Total GBP

Subject to the conditions below, one of the following two methods should be used to generate a Modified Total GBP:

- Sample Size Method; or
- Graduated Enumeration Method (GEM).

The Sample Size Method counts an appropriate percentage of the actual number of violative transactions/items, whereas GEM “merges” redundancies in tabulating identical units. See below.

5. Conditions

- Modify the Total GBP in cases that involve at least 100 identical units (100U), i.e., 100 transactions/100 items. The option generally is not necessary or appropriate for cases with fewer than 100 units of violation.
- All of the actual transactions/items should be tabulated to compute the full standard Total GBP. This computation is needed for evidentiary purposes and for comparison to the Modified Total GBP.
- **OECA approval is required** where the proposed modification reduces the Total GBP to less than 60 percent (60%) of the standard (unmodified) Total GBP.

6. Sample Size Approach

An appropriate sample size is to be selected, generally no less than 50 percent (50%) of the actual number of units (transactions/items). The Modified GBP is based on only the sample size, i.e., the sample size is not extrapolated to a larger number of units. Therefore, the sample size should account for a sufficient number of units so as to accurately reflect the extent of noncompliance. For example, a sample size that accounts for only ten percent (10%) of the actual number of units may suggest de minimis noncompliance whereas the actual number of violations could have been substantial.

7. Graduated Enumeration Method (GEM)

GEM reduces the number of identical units tabulated by merging duplicative tabulations. GEM's graduated counting methodology results in counting as follows:

- For every *full set of 100U* (100 transactions/units), only 45 units are counted.
- For a *partial set of 100U* (less than 100U), fewer units are counted depending on the number of actual units.

See Formula, below.

GEM Formula.

The GEM formula for graduated counting ranges *from counting every actual unit to counting only 20 percent of actual units* per 100U as follows:

- The first 20 units are counted at 100% (counted as 20 units).
- The next 30 units (Units #21-50) are counted at 50% (counted as 15 units).

- The final 50 units (Units # 51-100s) are counted at 20% (counted as 10 units).
See Figure 3-A-7.

| Figure 3-A-7: GEM Formula Per 100U | | | |
|------------------------------------|-------------------------|---------------------------------------------------|------------------------------------------------------------------|
| Actual # Units | % of Units Counted | Maximum # Assessable Violations | |
| #1 to #20 (≤ 20 units) | @ 100% of units counted | = | Penalties assessed for ≤ 20 units (100% of ≤ 20 units) |
| #21 to #50 (≤ 30 units) | @ 50% of units counted | = | Penalties assessed for ≤ 15 units (50% of ≤ 30 units) |
| #51 to #99 (≤ 50 units) | @ 20% of units counted | = | Penalties assessed for ≤ 10 units (20% of ≤ 50 units) |
| ≤ 100 Actual Units | | Penalties assessed for ≤ 45 Units out of 100 | |

For each **full set of 100U**, the formula results in counting only 45 units. (Example 3, below, illustrates a streamlined approach that involves considering only the full sets of 100U.)

For a **partial set less than 100U** (1-99 100U), the same GEM methodology applies so that fewer units are counted depending upon the number of units in the partial set.

GEM Examples:

Example 1. Case Involves Only Full Sets of 100Us

Derive the number of units (violations) counted: (a) determine the number of *full sets of 100U*; and then (b) multiply that number by 45 units (GEM counts only 45 units per 100U).

| Example 1 | | | |
|------------------------------------------------------------------------------------|--------------|-----------------------------|-----------------------------------------|
| A case involves 42,000 actual units (transactions/items) I.e., 420 sets of 100U | | | |
| Actual Units | Sets of 100U | X Units Counted Per 100U | Total # Units (Violations) using GEM |
| 42,000 → | 420 | x 45 per 100U = | 18,900 |
| 42,000 Actual Units (Violations) <i>versus</i> 18,900 Units (Violations) Using GEM | | | |

Example 2. Case Involves *Full Sets of 100U* and a *Partial Set* (Less than 100U)

Derive the number of units (violations) counted: (a) determine the number of *full sets of 100U* and multiply that number by 45 units (GEM counts 45 units per 100U) – then (b) apply the GEM formula to the partial set of 100U to determine the number of units counted in the partial set – then (c) add together the results of steps (a) and (b).

| Example 2 | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------|--------------------------------|
| A case involves 42,030 actual units (transactions/items) I.e., 420 full sets of 100U & a partial set of 30 Units | | | |
| Actual Units | Sets of Units | X Units Counted | Total # GEM Units (Violations) |
| 42,030 | 420 <i>Full Sets of 100U</i> | x 45 per 100U = | 18,900 |
| | 30 <i>in Partial set</i> | 25** | + 25** |
| | | | 18,925 |
| 42,030 Actual Units (Violations) <i>versus</i> 18,925 GEM Units (Violations)** | | | |
| ** Using GEM formula (above) for partial set of 30 units results in 25 GEM units – I.e.: Actual Units #1-20 counted at 100% - so, 20 GEM Units Actual Units #21-30 counted at 50% - so, 5 GEM Units | | | |

| |
|-------------------------|
| $20 + 5 = 25$ GEM Units |
|-------------------------|

Example 3. Streamlined Approach for Very Large Cases

Where a case involves thousands of units, a streamlined approach that counts *only the full sets of 100U* is simpler and may not be unreasonable where a remaining partial set of 100U is de minimis compared to many full sets of 100U.

This approach involves (a) rounding *down* the number of actual units to the nearest hundred; (b) multiplying the number of full sets of 100U by 45 (GEM counts 45 units per 100U); and disregard the remaining partial set of less than 100U.

| Example 3 – Streamlined Approach | | | |
|----------------------------------------------------------------------------------------------------|------------------------------|-----------------|------------------------------------|
| A case involves 42,030 actual units (transactions/items) | | | |
| I.e., 420 sets of 100U Plus a Partial Set of 30 Units | | | |
| Actual Units | Sets of Units | X Units Counted | Total # Units (Violations) Counted |
| 42,030 | 420 <i>Full Sets of 100U</i> | x 45 per 100U = | 18,900 |
| | 30 <i>in Partial set</i> | Disregard | -0- |
| 42,030 Actual Units <i>versus</i> 18,900 Units Using Gem (18,900 Units of Violation) | | | |

Module A – Reference #4

Examples

Distribution in Commerce

Example 1

A company qualified as a “retailer” and unlawfully distributed in commerce a chemical in violation of a § 6 rule prohibition. The chemical was prohibited for retail distribution in commerce due to its acutely lethal effect. The retailer distributed in commerce ten products containing the chemical via six transactions. Because the type of activity is a prohibition, the violation should be assessed as at the High Range for Circumstances. Because the violation presented a risk of potential injury of acute human lethality, it should be assessed at the Major Extent, regardless of the Potentially Impacted Entity. A Level 1,¹⁸ Major violation would be assessed at \$49,772 under the 2025 Penalty Inflation Adjustment (PIA) Rule.¹⁹

The appropriate unit of violation for most product-based violations, such as most retailer violations, is per transaction. Because this retailer sold the ten items in six transactions, the number of violations is six. Because the total number of violations is fewer than 100, it is not appropriate to use the Modified Gravity-Based Penalty approach.

$\$49,772 \times 6 = \$298,632$ is the Total Unadjusted GBP.

Example 2

A company unlawfully distributed in commerce a chemical in violation of a § 6 rule prohibition. The chemical was prohibited for retail distribution in commerce due to its acutely lethal effect. The company distributed in commerce 215 cases of products containing the chemical via 47 transactions. Because the type of activity is a prohibition, the violation should be assessed as at the High Range for Circumstances. Because the violation presented a risk of potential injury of acute human lethality, it should be assessed at the Major Extent, regardless of the Potentially Impacted Entity. A Level 1,²⁰ Major violation would be assessed at \$49,772 under the 2025 PIA Rule.

Although the appropriate unit of violation for most product-based violations is per transaction, the transactions in this scenario involved dozens of products, each one posing the risk of serious potential injury. As such, it would be more appropriate to assess the unit of violation on a per item basis—in this scenario for each case or product sold, for a total of 215 violations. Because the total number of violations is greater than 100, it is appropriate to use the Modified Gravity-Based Penalty approach.

¹⁸ For the purposes of this example, the violations were assessed as a Level 1 violation, but case teams should the specific circumstances of the violation and the case to determine if a Level 1 or Level 2 violation is appropriate.

¹⁹ See <https://www.epa.gov/enforcement/enforcement-policy-guidance-publications#penalty>.

²⁰ For the purposes of this example, the violations were assessed as a Level 1 violation, but case teams should the specific circumstances of the violation and the case to determine if a Level 1 or Level 2 violation is appropriate.

| Actual Units | Sets of 100U | X Units Counted Per 100U | Total # Units (Violations) using GEM |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-----------------------------|-----------------------------------------|
| 215 → | 2 <i>Full sets of 100U</i> | x 45 per 100U = | 90 |
| | 15 <i>in Partial set</i> | 15* | 15 |
| 215 Actual Units (Violations) versus 105 Units (Violations) Using GEM | | | |
| * Using GEM formula (above) for partial set of 15 units results in 15 GEM units – I.e.: Actual Units #1-20 counted at 100% - so, 15 GEM Units | | | |

$$\$49,772 \times 105 = \$5,226,060$$

Notices of Risk of Injury

Example 3

A company distributed in commerce a chemical without including the required notice of risk of injury under a § 6 rule. The notice of risk of injury specified that the chemical substance must not be distributed in commerce to retailers. The chemical was prohibited for retail distribution in commerce due to its acutely lethal effect. The company distributed in commerce on 47 occasions (transactions) without the required notice of risk of injury. Because each distribution of the chemical was completely unaccompanied by the required notice of risk of injury, the violation should be assessed at the Medium Range for Circumstances. Because the violation presented a risk of potential injury of acute human lethality, it should be assessed at the Major Extent, regardless of the Potentially Impacted Entity. A Level 3,²¹ Major violation would be assessed at \$29,107 under the 2025 PIA Rule.

$$\$29,107 \times 47 = \$1,368,029.$$

²¹ For the purposes of this example, the violations were assessed as a Level 3 violation, but case teams should the specific circumstances of the violation and the case to determine if a Level 3 or Level 4 violation is appropriate.

Part Four

Gravity Based Penalty Matrix

This Gravity-based Penalty (GBP) Matrix provides the dollar amount per violation applicable to every Core TSCA Program. The GBP for a particular violation is located at the intersection of the violation's Circumstances Level and Extent Level, as computed in accordance with the program-specific guidance in CERPP Part Three.

The dollar amounts shown below were in effect as of the date of CERPP publication. Penalties are subject to adjustment pursuant to EPA's 2025 Penalty Inflation Adjustment (PIA) Rule and guidance.¹

| Core TSCA Gravity-based Penalty Matrix | | | | |
|----------------------------------------|---|---------------|------------------|------------|
| Circumstances Levels | | Extent Levels | | |
| | | A Major | B Significant | C Minor |
| High Range | 1 | \$49,772 | \$32,988 | \$9,702 |
| | 2 | \$38,810 | \$25,226 | \$5,821 |
| Medium Range | 3 | \$29,107 | \$19,405 | \$2,911 |
| | 4 | \$19,405 | \$11,643 | \$1,940 |
| Low Range | 5 | \$9,702 | \$5,821 | \$970 |
| | 6 | \$3,881 | \$2,523 | \$388 |

¹ See <https://www.epa.gov/enforcement/enforcement-policy-guidance-publications#penalty>.

Part Five

Gravity-based Penalty Adjustment

I. INTRODUCTION

Use this CERPP Part Five to determine the Final Gravity-based Penalty in a civil administrative case. To do so, adjust the Unadjusted Gravity-based Penalty (GBP) for all violations in the case upward or downward based on the following TSCA § 16 factors as applicable to the violator:

- “Ability to pay.”
- “Effect on ability to continue to do business.”
- “Any history of prior such violations.”
- “The degree of culpability.”
- “Such other matters as justice may require.”¹

TSCA § 16 also authorizes EPA to remit an assessed penalty, with or without conditions.

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¹ 15 U.S.C. § 2615(a)(2)(B).

II. PRELIMINARY INFORMATION

Readers should be familiar with CERPP Parts One and Two which detail the process and principles for computing the unadjusted gravity-based penalty in a case.

Penalty Inflation Rule. It is Agency policy to adjust the Unadjusted GBP for inflation, round to the nearest \$1,² and then apply the pertinent TSCA adjustment factors. (Hereinafter, references to Gravity-based Penalty means the rounded Unadjusted Gravity-based Penalty GBP).

Exclusivity. The TSCA adjustment factors, and the corresponding CERPP policies herein, are exclusive, and not merely illustrative. Any adjustment to the Gravity-based Penalty must fall under a statutory factor and is expected to be consistent with the CERPP guidance for that factor.³

Downward Adjustments. Prior to issuing a proposed penalty and dependent on the facts of the case, the Agency may not make downward adjustments, except for voluntary disclosure and immediate disclosure. In most cases, EPA will try to obtain public information on ability to pay (ATP), but this information may not become known before initiating settlement negotiations or litigation.

Upward Adjustments. The Agency may make appropriate upward adjustments prior to announcing the proposed penalty to the violator. Typically, there is no need to wait for information from the violator because the Agency can estimate upward adjustments based on the facts in the case, enforcement history, and publicly available information. However, information relevant to prior violations, culpability/attitude, history of violation, or economic benefit, may become relevant subsequent to the initial penalty proposal. Also, early disclosure of the potential maximum penalty puts the violator on early notice of its possible maximum penalty exposure. Total upward adjustments cannot exceed the statutory maximum *per violation*.

Adjustment Amount Per Factor. Depending upon the adjustment factor, the CERPP establishes either a specific adjustment percentage or, more often, provides a percentage range. See Figure 5-1, below.

TSCA § 16 requires that EPA “take into account” each adjustment factor⁴ but does not dictate any adjustment amount or value. Thus, for instance, where the CERPP establishes an adjustment percentage range, there is a maximum allowable percentage, but no minimum percent and no entitlement to the maximum downward adjustment. Thereby, percentage range enables the Agency to more fully take into account the specific facts in the case related to the violator.

² Amendments to the EPA’s Civil Penalty Policies to Account for Inflation, <https://www.epa.gov/enforcement/enforcement-policy-guidance-publications#penalty>.³ Note that certain Core TSCA programs may have other policies by which to resize a Gravity-based Penalty, such as Calculation Factors for mitigation, or the policy for a Modified Total Gravity-based Penalty for certain § 6(a) violations. See CERPP Part Three Modules.

³ Note that certain Core TSCA programs may have other policies by which to resize a Gravity-based Penalty, such as Calculation Factors for mitigation, or the policy for a Modified Total Gravity-based Penalty for certain § 6(a) violations. See CERPP Part Three Modules.

⁴ See *In re: New Waterbury, Ltd.*, 5 E.A.D. 529 (EAB 10/20/1994) (TSCA; in administrative enforcement actions under statutes that specify ATP as a factor in determining penalties, EPA must consider the appropriateness of the penalty in light of all of the statutory factors).

| Fig. 5-1. TSCA Adjustment Factors | |
|-------------------------------------------------|-----------------------------------------------------|
| Factor | Adjustment to GBP |
| • Ability to pay / Continue to do business | <i>Downward</i> , based on financial analysis |
| • Prior violations | <i>Upward</i> , 25%, 50% or 100% |
| • Culpability | <i>Upward</i> , 25%, or <i>no</i> adjustment |
| • Other matters as justice may require | |
| • Attitude | <i>Downward</i> , 15%, or <i>Upward</i> , 15% |
| ➤ Recovery of Economic Benefit | <i>Upward</i> , up to the statutory maximum |
| ➤ Voluntary Disclosure of Violations | |
| ▪ EPA Audit Policy, Small Business Policy, etc. | <i>Downward</i> , determined by Policy requirements |
| ▪ CERPP Voluntary Disclosure | <i>Downward</i> , up to 65% |
| ➤ Supplemental Environmental Project | <i>Downward</i> up to 75% |
| ➤ Special Circumstances | <i>Downward</i> up to 30% |

Calculating Final Civil Penalty. Each GBP adjustment factor requires a separate analysis, consistent with the guidance for that factor. Also, the adjustments are *not* cumulative. Each reduction or increase is computed against the Unadjusted GBP and not calculated from any previously reduced or increased amount. See Figure 5-2, below.

| Fig. 5-2: Hypothetical | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <ul style="list-style-type: none"> • An Unadjusted GBP is \$100,000. • The downward adjustments are Voluntary Disclosure @ 25% and Good Faith/Attitude @ 15%. • The Adjusted civil penalty is \$60,000, as shown below: | |
| GBP | → \$100K |
| Voluntary Disclosure @ 25% = \$100K x 25% = \$25K | |
| Good Faith/Attitude @ 15% = \$100K x 15% = \$15K | |
| Total Reduction @ 40% = \$100K x 40% = \$40K | → - \$40K |
| Adjusted Civil Penalty | → \$60K |

III. ABILITY TO PAY / CONTINUE TO DO BUSINESS

A. Overview

TSCA § 16 requires EPA to take into account “ability to pay” and “effect on ability to continue to do business” with respect to the violator. Generally, the CERPP treats these two factors through a single analysis (collectively, “ability to pay” or ATP), because both factors pertain to a violator’s finances and rely on comparable data.

In order to satisfy these statutory factors, EPA has the burden of proving the proposed penalty is “appropriate.”⁵ In determining whether the penalty is appropriate, EPA can analyze financial data that is publicly available. For publicly traded companies, EPA can analyze annual financial reports

⁵40 C.F.R. § 22.24(a).

(Form 10-K) in SEC's EDGAR website or the company's website. Unlike publicly traded companies, privately held companies do not have financial data publicly available. EPA can review online sources, such as Dun & Bradstreet,⁶ but many online sources require subscriptions. For the online sources that EPA has access to, many sources estimate private companies' financial data, and the data may not be accurate or have been verified. EPA should take into account the facts known about the violator and the violations in determining whether the proposed penalty is "appropriate."

B. EPA Policies

The following ATP policies should be consulted:

- *A Framework for Statute-Specific Approaches to Penalty Assessments: Implementing EPA's Policy on Civil Penalties* (EPA's General Enforcement Policy, GM-22) (Feb. 16, 1984);
- Thomas L. Adams, Jr., *Guidance on Determining a Violator's Ability to Pay a Civil Penalty* (Dec. 16, 1986) (PT.2-1 previously codified as GM-56); and
- Susan Shinkman, *Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action* (June 29, 2015).

C. Financial Information

After EPA presents a proposed penalty to the violator in its Answer to an EPA Complaint or during settlement negotiations, the violator may assert an inability to pay claim. If so, then the Agency should require the violator to provide appropriate documentation supports the inability to pay claim, at the violator's request⁷ such as:

- A written, narrative statement explaining why the violator has an inability to pay the proposed penalty.
- Federal tax returns, including all schedules and attachments, for the last three to five years.
- The violator's internal financial statements for the last 3-5 years, including income statements, balance sheets, and statements of cash flow, if available.
- Statement of changes in financial position.
- Statement of operations, including information on business and corporate structure.
- Loan applications, financing agreements, security agreements, if applicable to the inability to pay claim.
- Any other documents, such as audit reports or financial analyses that EPA may deem necessary. See e.g., ATP policies (above).

⁶ See *In re: New Waterbury, Ltd.*, 5 E.A.D. 529 (EAB 10/20/1994)(TSCA; EPA may obtain information of ATP/continue to do business from independent commercial financial reports, or other credible sources).

⁷ EPA may request financial data *during an inspection* only if *the nature and extent of such data are described with reasonable specificity* in the required inspection notice. TSCA § 11(b)(2), 15 U.S.C. § 2610 (b)(2). This limitation does not apply to obtaining such data for settlement purposes.

D. Ability to Pay Computer Models

EPA has three computer models to help assess whether a violator can afford proposed civil penalties and/or compliance costs:

- ABEL for corporations and partnerships.
- INDIPAY for individuals.
- MUNIPAY for local governments.

These models do not mandate an amount that the Agency must use as the proposed penalty. Instead, the models calculate an estimated ATP that the Agency should consider, along with other factors in the case.

ABEL is applicable for most ATP analyses in Core TSCA actions because ABEL applies to the types of entities typically subject to Core TSCA enforcement, e.g., corporations, partnerships, and other companies. ABEL estimates future cash flow based on past performance and analyzes ability to pay based on future excess cash flow, i.e., the funds coming into and going out of a business; and whether that cash flow is sufficient in relation to the proposed penalty.

Excess cash flow, however, is only one financial metric. The Agency should consider additional sources of revenue to determine a violator's ATP, including:

- Cash or other liquid assets that are immediately available, such as certificates of deposit and money market funds.
- Ability to raise funds through debt or equity.

EPA should conclude an inability to pay if the violator establishes that paying the penalty would cause it to suffer undue financial hardship and prevent it from paying its ordinary and necessary business expenses.⁸

E. ATP Analyses

As noted above, the ATP computer models do not render a mandatory penalty but rather, provide data to inform the Agency's determination regarding the proper penalty in light of the inability to pay claim. Also, in as much as the models generate objective data, they can provide justification and support for the penalty amount that is ultimately assessed. If EPA reduces a penalty based on an inability to pay and the violator states that it cannot pay the reduced penalty, EPA should ask the violator to provide additional documentation or justification for a lower penalty. EPA can also request the violator what it can pay because the violator knows its financial circumstances better than EPA. However, EPA must ensure that the ultimate penalty is appropriate.

There may be instances where the violator can pay the entire penalty, but the financial data indicates that it needs to pay overtime. In such cases, the Agency may consider a delayed payment schedule

⁸ See *Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action* (Jun. 29, 2015) (Section B.), <https://www.epa.gov/sites/default/files/2015-06/documents/atp-penalty-evaluate-2015.pdf>

calculated in accordance with EPA regulations⁹ and Section V. of the *Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action*, mentioned above. While unique, there may be ATP analyses that indicate a reduced penalty and delayed payment plan are warranted.

When analyzing a violator's inability to pay a penalty claim, EPA will take into the violator's current and future compliance costs. While EPA will reduce a penalty and/or offer a delayed payment plan based on an ATP analysis, EPA will not reduce costs required for violators to be compliant with the law.

Generally, EPA will not collect a penalty that exceeds a violator's ability to pay as indicated by ATP analyses. However, in appropriate circumstances, EPA reserves the option to seek a penalty that might exceed a violator's ability to pay, cause bankruptcy, or result in an inability to continue to do business. Such circumstances may exist where the violations are egregious (e.g., the prohibited act resulted in significant, widespread or permanent harm to human health or the environment) or there is a long history of previous violations.

IV. PRIOR VIOLATIONS

A. Overview

TSCA § 16 requires EPA to take into account “any history of prior such violations” with respect to the violator. The Unadjusted Gravity-based Penalty establishes the Unadjusted GBP for *first offenders*. A history of prior violations indicates that a violator was not deterred by a previous enforcement response.

Therefore, the Agency is to adjust the Unadjusted GBP for a repeat violator *upward*, unless the previous violation was caused by factors entirely beyond the violator's control (e.g., force majeure or Act of Nature).¹⁰ The upward adjustment aims to increase the violator's motivation to comply going forward. Note that any consideration regarding control over prior violations is distinguished from considerations of control, willfulness and knowledge under the Culpability factor, below.

⁹ See 40 C.F.R. § 13.18.

¹⁰ The adjustment also is appropriate in consideration that the Agency had to devote limited enforcement resources to the same violator; *Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act*, 45 Fed. Reg. 59770, at 59773, (Sept. 10, 1980) (*TSCA Penalty Policy*), <https://www.epa.gov/sites/default/files/documents/tscapen.pdf>.

B. Adjustment Percentage

This factor provides for an upward adjustment, by 25%, 50% or 100% for all Core TSCA programs, where there is a prior same, similar or closely related violation of TSCA or a requirement thereunder that resulted in a final order within five years (5) of the instant violation. The adjustments are as follows:

- First repetition (second occurrence): 25 or 50% upward adjustment.
- Second repetition (third occurrence): 50 or 100% upward adjustment.

A penalty may not exceed the statutory maximum *per violation*.

A third repetition (fourth occurrence) of a violation generally warrants a referral for criminal sanctions or a petition for injunctive relief. See CERPP Part One.

C. Same, Similar or Closely Related Violation

If the “prior such” TSCA violation is not related to the same section of the TSCA Subchapter I provision or regulation, then the penalty should be upwardly adjusted 25 percent for the first repetition and 50 percent for additional repetitions of the violation. If the “prior such” violation is of any corresponding section, the penalty should be upwardly adjusted by 50 percent for the first repetition and 100 percent of the second repetition.

D. Prior Enforcement Action

Considering all prior violations (self-disclosed and EPA-discovered), the prior violation must have resulted in a final order within five years (5) of the present violation.¹¹ Note that because the prior order could have occurred up to five years ago, the prior *violation* which was the basis of such order may have occurred much earlier than five years ago, i.e., to account for the duration between commission of the violation, inspection, and conclusion of the prior enforcement action.

The final order may be in any of the following instruments:

- An administrative or judicial order, based on an uncontested Complaint.
- An administrative or judicial settlement order, including consent agreements and consent decrees.
- A contested Complaint resolved against the violator via litigation.
- A Notice of Determination under the audit policy
- A judgment establishing liability.

For purposes of this adjustment factor, a Notice of Noncompliance does not constitute a prior violation, since the violator is given no opportunity to contest a NON.¹² However, both EPA-

¹¹ TSCA Penalty Policy, 45 Fed. Reg. at 59774.

¹² TSCA Penalty Policy, 45 Fed. Reg. at 59773-4.

discovered violations and violations that the violator discloses may qualify as prior violations that merit upward adjustments, if orders have been issued since both situations put the violator on notice of its compliance obligations.

E. Multiple Establishments

A prior violation may involve multiple establishments (e.g., locations, sites, facilities, laboratories) of a company. Generally, a company with multiple establishments is considered a single entity when determining prior enforcement history. If one establishment of a company commits a TSCA violation, then it counts as history when another establishment of the same company, anywhere in the nation, commits a TSCA violation.

In most cases of violations by wholly- or partly-owned subsidiaries, the history of the parent corporation shall apply to its subsidiaries, and the subsidiaries' violations shall impute to the parent, particularly when the parent has a majority share of ownership of the subsidiary. The exception would be where two companies are held by the same parent corporation. Such “sibling” companies may not necessarily affect each other’s compliance history if they are in substantially different lines of business, and their respective management and Boards of Directors are substantially independent of each other.

Note that the foregoing principles for adjustments based on prior violations by multiple *establishments* of the same company are distinguished from the guidance for the Culpability factor (below) concerning adjustments where *independent entities* are associated with the *same* violation (e.g., laboratories versus test sponsors).

V. CULPABILITY

A. Overview

TSCA § 16 requires EPA to take into account “the degree of culpability” with respect to the violator. Since TSCA imposes strict liability, culpability (blameworthiness) is not a factor in determining whether a violation has occurred.¹³ Culpability, however, may provide a basis for adjusting the Gravity-based Penalty upward.

¹³ *TSCA Penalty Policy*, 45 Fed. Reg. 59770, at 59773.

B. Adjustment Criteria

The primary criteria for assessing a violator's culpability are its knowledge and degree of control over the violative conduct, as follows:

- Level I – Upward Adjustment for either of the following:
 - o The violation is willful, i.e., the violator intentionally committed an act which it knew or had reason to know would be a violation, or knew would be hazardous to human health or the environment (regardless whether the violator knew it would be a violation). Also, this type of violation may merit a referral for criminal sanctions.
 - o The violator had sufficient knowledge to recognize the hazard created by its conduct and significant control over the situation to avoid committing the violation.
 - o The GBP is to be adjusted upward up to 25 percent (25%).
- Level II – No Adjustment. The violator had either sufficient knowledge to recognize the hazard created by its conduct, or significant control over the situation to avoid committing the violation. This is the default level of culpability; and no adjustment is made to the GBP.

C. Good Faith Efforts to Comply / Attitude or Quick Settlement

The fact that a violator exhibits good faith efforts to comply or to obtain settlement may qualify for a Gravity-based Penalty adjustment, *upward or downward*.¹⁴ Generally, attitude is used to adjust the Gravity-based Penalty in a Level II culpability finding.

The Agency may reduce the GBP by *up to* 15% for good faith efforts to comply with the applicable requirements, good attitude, or quick settlement. For example, if a violator had a system in place to track and comply with TSCA § 13 import certification requirements but a chemical inadvertently “slips through,” then a 15% good faith/attitude reduction may be appropriate *provided* the violator demonstrates to the Agency's satisfaction that such bypasses are rare and the violator has established measures to further prevent such slips going forward.

Typically, the Agency considers reductions based on good faith/attitude during settlement negotiations, since a violator usually does not demonstrate behavior worthy of a penalty reduction where EPA must resolve the case via litigation. Quick settlement means that a settlement in principle is reached by no more than six (6) months from the beginning date of negotiations.

Conversely, the Agency may make an upward adjustment of up to 15 percent based on objective evidence of poor attitude as expressed by the violator's statements, actions or inactions. For instance, a violator may demonstrate poor attitude by continuing the noncomplying activity, not acting in good faith, hindering EPA's progress, causing increased government expenditures, or otherwise being unreasonable or uncooperative.

¹⁴ TSCA Penalty Policy, 45 Fed. Reg. at 59773.

In assessing good faith/attitude, the Agency may consider factors such as whether the violator:

- Timely takes steps to come into compliance, or to take corrective action, such as promptly preparing required documents or initiating proper disposal;
- Promptly takes actions to minimize potential harm caused by the violation;
- Promptly takes steps to avoid future such violations, such as instituting new corporate controls or practices; and/or
- Cooperates throughout the Agency's compliance monitoring and enforcement process.

D. Multiple Entities

Certain violations may involve multiple independent entities wherein each entity was involved in the violation but each qualifies for different penalty adjustment. For example, TSCA § 4 Good Laboratory Practice violations may involve a sponsor of the study and an independent laboratory.¹⁵ The CERPP generally treats these entities as a single enterprise since both are expected to have the knowledge or control necessary for the default Culpability Level (Level II).¹⁶ If, however, it is clear that only one of these entities willfully committed a violation, then an upward adjustment for Level I culpability may be appropriate only for the offending entity.

Note that this Culpability guidance for multiple *entities* is distinguished from the guidance, above, for prior violations by multiple *establishments*.

VI. MATTERS AS JUSTICE MAY REQUIRE

A. Overview

TSCA § 16 requires EPA to take into account “other matters as justice may require” with respect to the violator. This factor is reflected in the following policies:

- Recovery of the Economic Benefit of Noncompliance (EBN).
- Voluntary Disclosure of Violations.
- Supplemental Environmental Projects (SEPs).
- Special Circumstances.

Any adjustment based on this statutory factor must fall under at least one of these policies.

B. Economic Benefit of Noncompliance

¹⁵ See CERPP Part Three, Module B.

¹⁶ Although an independent laboratory generally has direct control over a violative condition, the sponsor can dictate the laboratory's protocol, performance and environment through its contractual arrangement with and oversight of the laboratory. Also, since the sponsor must certify compliance with TSCA GLP standards, it is incumbent upon the sponsor to ensure that the laboratory abides by those standards. See also *TSCA Penalty Policy*, 45 Fed. Reg. 59770, at 59773.

1. Background

The principle that a regulated entity should not profit from its non-compliance is a matter as justice may require. For example, noncompliance with a TSCA § 4 Test Rule may enable a violator to accrue significant economic gains because the violator may not have expended funds to test properly or test at all; and a chemical may remain unregulated pending EPA's receipt and evaluation of proper testing data.¹⁷

As explained below, a violator may derive an Economic Benefit of Noncompliance (EBN) from delayed or avoided compliance costs, from wrongful profits from an unfair competitive advantage based on noncompliance, or from both. To calculate economic gain from delayed/avoided costs, EPA can use the "BEN" computer model for settlement purposes. To determine wrongful profits, the assistance of a financial or industry expert may be required.

2. General Principles

EPA's 1984 *Policy on Civil Penalties* (EPA General Enforcement Policy, GM-21)(Feb. 16, 1984) establishes principles for recovery of EBN. The following general considerations apply:

- The Agency should evaluate a violator's economic gain from noncompliance and adjust accordingly for the period of noncompliance.
- Generally, the Agency should add the EBN amount after making other statutory adjustments (e.g., for prior violations, culpability).
- The final civil penalty calculated for a case should equal or exceed the EBN, and in only limited instances should be less than the EBN. (*Settlement* at less than the EBN is allowed under certain circumstances, as discussed below.)
- If the Initial Gravity-based Penalty (per violation) is less than the EBN, then the Agency may impose penalties up to, but not exceeding, the statutory maximum per violation to ensure that the penalty is not less than the EBN.
- The final civil penalty, including any significant EBN, cannot exceed the statutory maximum penalty per violation.

3. Forms of Economic Benefit of Noncompliance

A violator may realize an EBN via delayed or avoided costs and/or wrongful profits. If both types of EBNs apply in a case, then EPA should make separate adjustments for both types. For example, when the Agency has sufficient evidence to determine wrongful profits, the Agency may calculate the EBN from those profits and add it to EBN based on delayed or avoided costs.¹⁸

Since different analyses are required for the distinct forms of EBN, the Agency should distinguish the calculations for each type of EBN to avoid double-counting any economic gain.

¹⁷ For example, for TSCA § 4 Test Rule violations likely to result in economic gain, penalties may be assessed for each day the chemical is manufactured, processed, or imported. See CERPP Part Three, Module A.

¹⁸ *Calculation of the Economic Benefit of Noncompliance in EPA's Civil Penalty Enforcement Cases*, 70 Fed. Reg. 50,326, at 50,327 (Aug. 26, 2005).

- Delayed or Avoided Costs. Delayed costs are expenditures that have been deferred by the violator's failure to comply with its environmental obligations. The EBN is the investment return on the money saved during the period of noncompliance. For example, delayed costs could result from failure to install necessary equipment or maintain required practices.

Avoided costs are expenditures that have not been incurred. The EBN would be saving the full cost of compliance. For instance, improper disposal of a material that can never be retrieved for proper disposal would constitute an avoidance of the entire cost of proper disposal.

For settlement purposes, EPA uses the BEN computer model to calculate the economic gain from delayed/avoided costs. BEN is appropriate for users with no background in economics. Webinar trainings are available on FedTalent. Also, BEN has a Help System that is located within the model. Assistance from a financial expert, however, may be necessary in certain complex cases.

- Wrongful Profits. Wrongful profits are economic benefit based on profits generated by violating the law, such as receiving profit proceeds from the sale of an illegally manufactured substance. The Agency should ensure that any economic benefit calculation for wrongful profits does not include profits attributable to lawful operations. Generally, the assistance of a financial and/or industry expert is necessary to determine wrongful profits.

4. EBN In Settlements

When a case is resolved via settlement, the Agency should recover any "significant" EBN. For the purposes of this CERPP a significant EBN is one that exceeds \$10,000.

Also, the Agency should not settle for an amount less than the EBN, unless one or more of the following circumstances apply:¹⁹

- The EBN is not significant, as described above.
- There are compelling public concerns that would not be served by taking a case to trial, so that settlement is highly desirable.
- Based on the facts of the case, it is unlikely that EPA will be able to recover the EBN in litigation.
- The violator has documented an inability to pay the total penalty, including the EBN.

¹⁹ Three exceptions are provided in *A Framework for Statute-Specific Approaches to Penalty Assessments* (Feb. 16, 1984)(GM-22), <https://www.epa.gov/enforcement/framework-statute-specific-approaches-penalty-assessments-implementing-epas-policy> ; The fourth exception comes from *Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action* (Jun. 29, 2015), <https://www.epa.gov/enforcement/guidance-evaluating-ability-pay-civil-penalty-administrative-enforcement-actions>

C. Voluntary Disclosure

1. Disclosure Generally

The fact that a violator voluntarily discloses violations to the Agency presents a matter as justice may require. Companies that promptly self-disclose violations in writing to EPA may qualify for a downward penalty adjustment under several alternative policies, such as:

- The Agency’s Policy for Self-Policing,²⁰ the Interim Approach to Applying the Audit Policy for New Owners²¹ or Small Business Compliance Policy.²²
- CERPP’s voluntary disclosure guidance, below.

To encourage voluntary disclosure, the Agency may make reductions for disclosure before issuing the Complaint; and state in the Complaint the original penalty, the reduced penalty, and that the reduction is based on self-disclosure.

These policies are exclusive; a violator may receive a reduction under only one of these policies (unless explicitly allowed otherwise under the applicable policy). Thus, if a violator has already received a penalty reduction under any one of these policies, then no adjustment should be made for disclosure of the same, similar or a closely-related violation²³ under another of these policies.

2. CERPP Voluntary Disclosure

A violator that voluntarily self-discloses its noncompliance to EPA in writing may qualify for a downward adjustment of the Unadjusted Gravity-based Penalty by *up to* 25% or 50%, depending upon the rapidity at which the disclosure is made. The Agency may make a further reduction of *up to* 15% where the violator takes steps to mitigate the violation, as explained below. That is, the potential total downward adjustment is *up to* 65% for qualified disclosure and mitigation. See Figure 5-4, below.

| Fig. 5-4: Reductions under CERRP Voluntary Disclosure | |
|--------------------------------------------------------------|--------------------------|
| | Maximum Reduction |
| Disclosure of Violation | |
| Voluntary disclosure | 25% |
| “Immediate” disclosure (within 30 days) | 25% |
| Mitigation of Violation | |
| Steps taken to mitigate the violation | 15% |
| TOTAL REDUCTION (Maximum) | 65% |

²⁰ Incentives for Self- Policing: Discovery, Disclosure, Correction and Prevention of Violations, 65 Fed. Reg. 19618. See generally *EPA’s Audit Policy* at <https://www.epa.gov/compliance/epas-audit-policy>

²¹ Interim Approach to Applying the Audit Policy to New Owners, 73 Fed. Reg. 44991, at 44991-45001

²² Small Business Compliance Policy, 65 Fed. Reg. 19630, at 19630-4

²³ See the Culpability factor (§ V above) for discussion of same, similar or closely-related violations.

- Voluntary Disclosure - Criteria (Downward Adjustment Up to 25%)

The Agency may adjust a Gravity-based Penalty downward by *up to* 25% for a voluntary disclosure that meets the following conditions:

- o The violator must submit a signed statement of voluntary disclosure to EPA describing the alleged violation(s) with appropriate specificity.
- o The disclosure must not be the result of governmental or otherwise legally required action.
- o The disclosure must be made before EPA receives any information related to the violation or EPA alerts the violator to potential compliance monitoring (e.g., via notice of a forthcoming inspection or a subpoena). If, however, the disclosed violations are clearly outside the scope of EPA's inquiry, then reductions for self-disclosure may be made.

- "Immediate" Disclosure (Additional Downward Adjustment Up to 25%)

The Agency may provide an additional reduction *up to* 25% for "immediate" disclosure. See Figure 5-4, above. "Immediate" disclosure means the violator made disclosure within thirty (30) calendar days of knowing or having reason to believe that a violation may have occurred.

For example, a violator has reason to believe it may be in violation when the violator cannot locate a chemical on the public TSCA Inventory and nonetheless proceeds to manufacture the chemical without submitting a TSCA § 5 Premanufacture Notification (PMN).²⁴ The 30-day time limit begins the moment the violator knows or has reason to suspect that the chemical may not be listed on the Inventory, regardless of whether or when EPA confirms the Inventory status of the chemical. In other words, the additional reduction for "immediate" disclosure does not apply if the violator knew or suspected the potential violation but awaited confirmation (from EPA or through its own devices) and delayed disclosure past 30 days of first suspecting the potential violation.

- Mitigation of Violations (Additional Downward Adjustment Up to 15%)

The Agency may make an additional penalty reduction of up to 15% when a violator mitigates a voluntarily disclosed violation. Generally, this reduction is limited to violations that are assessed on a per-day basis.

This reduction may be available when a violator mitigates the violation by promptly taking all steps requested, or reasonably expected to be requested, by EPA to mitigate the violation and all potential adverse impacts on human health or the environment, such as by ceasing all routes of potential exposure. For example, if a violator fails to file a TSCA § 5 Premanufacture Notification yet proceeds to manufacture a chemical that is not on the TSCA Inventory, then the mitigation reduction may be appropriate if (a) the violator discloses the possible violation to EPA, (b) immediately ceases all manufacture, processing and distribution until it files a PMN, and (c) quarantines all existing stocks.

²⁴ See 40 C.F.R. § 720.22.

The following conditions apply:

- o The violator must have voluntarily disclosed the violation.
- o The violator must submit to EPA the information that the Agency needs to assess the violation either (a) within 30 days of the violator acquiring knowledge, or reason to believe, that a violation may have occurred; or (b) within a time period to which the Agency and violator agree.
- o The reduction ceases to be available if the violator has not taken the steps expected or requested by EPA by the time of settlement.²⁵ In some cases, however, the Agency may determine that cessation of the noncompliance is sufficient and no additional corrective actions are necessary.
- o No reduction can be made where mitigation is impossible. For example, if the product has already been distributed in commerce and used, then there might be nothing the violator can do to rectify the situation and there is no basis for a mitigation reduction.

The mitigation reduction is an alternative to, not in addition to, any reduction for a Supplemental Environmental Project (SEP).²⁶ The reduction, however, may be taken in addition to adjustments under other statutory factors, such as Good Faith/Attitude.

- Prior Violations - Additional Violations. To encourage disclosure and prospective compliance, EPA generally may disregard a violator's prior violations for purposes of applying a downward adjustment to an otherwise eligible disclosure under CERPP's voluntary disclosure policy. (By contrast, for purposes of applying the TSCA adjustment factor for history of prior violations, above, the Agency should consider both self-disclosed and EPA-discovered violations.)

If EPA initiates an enforcement action and the violator discloses additional violations after the Agency has issued a Complaint, then the Agency may address the additional violations through an amendment to the original Complaint, through an additional Complaint, or by including additional charges in any settlement order.

- Successor Companies

The reduction for voluntary disclosure is available to companies which have changed ownership, i.e., incoming owners may qualify for a reduction based on voluntary disclosure of violations committed by prior ownership.

D. Supplemental Environmental Project (SEP)

The fact that EPA may consider that a violator voluntarily undertakes a Supplemental Environmental Project (SEP) is assessed as matter as justice may require. Under a SEP, a violator voluntarily agrees to undertake a project that it is not otherwise legally obligated to perform.

²⁵ The Agency may address future mitigation activities in accordance with EPA's policy for penalty remittance under a TSCA Settlement with Conditions. See § VII Penalty Remittance.

²⁶ See Memorandum, Cynthia Giles, *Issuance of the 2015 Update to the 1998 U.S. Environmental Protection Agency Supplemental Environmental Projects Policy* (Mar. 10, 2015), as revised ("SEP Memorandum").

The Agency may apply some percentage of the cost of the SEP to reduce the adjusted penalty in a case. The Agency has extensive guidance governing SEPs.²⁷ SEPs are an important tool in EPA's enforcement program but may not be appropriate in settlement of all cases. Among other things, it is important to consider the particular violator's commitment and ability to perform a SEP.

Whether to include a SEP as part of an enforcement settlement is within EPA's sole discretion. A violator may not receive reductions for both a SEP and, for instance, the additional 15% reduction for mitigation of a voluntarily disclosed violation. See Section C., above.

E. Special Circumstances

The fact that a case may involve special circumstances presents a matter as justice may require. Occasionally, a case may present factors that warrant a penalty reduction not addressed under any of the forgoing factors.

For example, a case may present certain litigation considerations. In such situations, the Agency may reduce the Unadjusted Gravity-based Penalty by up to 30% at settlement. The Agency, however, should still obtain a penalty sufficient to remove any economic benefit from noncompliance (EBN), as discussed above.

VII. PENALTY REMITTANCE

TSCA § 16(a)(2) provides that EPA “may compromise, modify or remit, with or without conditions, any civil penalty.”²⁸ Penalty remittance is not a reduction to the Gravity-based Penalty. Instead, it is a conditional forbearance from demanding some, or all, of the final civil penalty based upon the violator's performance of an EPA-approved “condition” (project) under a remittance agreement.

The remittance agreement is incorporated into (or appended to) the settlement in accordance with any EPA applicable policies. Thus, the settlement memorializes the assessed civil penalty, the agreed-upon condition, and the penalty amount remitted for performance of the condition. EPA forebears immediately demanding the remitted portion of the penalty *provided* the violator satisfactorily fulfills the condition; but the Agency may subsequently demand the remitted penalty if the respondent fails to do so.

Remittance agreements include a compliance program (project plan) and a schedule with which the violator must comply in order to maintain its remittance. Also, the settlement should include provisions that ensure sufficient fiscal accountability to ensure that remitted funds are spent as intended. When considering a potential remittance of an assessed penalty, the Agency is expected to work with Headquarters to ensure the settlement is consistent with the prevailing guidance on TSCA SWCs and the policy for Nationally Significant Issues.

²⁷ See e.g., *SEP Memorandum*.

²⁸ 15 U.S.C. § 2615(a)(2)(C).