UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 8 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amendment to the TSCA §5 Enforcement Response Policy

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

This memorandum amends the TSCA §5 Enforcement Response Policy by revising the penalty for falsification of a Notice of Commencement (NOC). This change would apply to those instances where a company has submitted a Notice of Commencement in anticipation of production or importation, the event does not occur, and the company never does produce or import the substance.

This change has been made in response to numerous comments that the policy issued on August 5, 1988, created a large inequity in penalty when a company submits a Notice of Commencement but does not produce a substance, as compared to a company that produces a substance without submitting a Notice of Commencement. In the first situation, the current ERP requires that the violation be charged as a false NOC and would subject the violator to per day penalties from the day the false NOC was submitted to the day of discovery of the violation with the potential of very large penalties. The provision to allow for per day penalties for each calendar day a falsification occurs, was created for those situations where the falsification prevents the Agency from making a reasoned evaluation of the chemical substance. This is not the case for a false NOC. The chemical has been reviewed and mistakenly placed on the Inventory. A reasoned evaluation of the chemical substance has been made.

Attached are the two pages affected by the change with the necessary revisions incorporated. These pages may be inserted into the TSCA §5 ERP in the appropriate places. If you have any questions concerning the revisions please contact David Stangel of my staff at 382-3477.

Attachments

JUN 8 1989

AMENDED

TSCA SECTION 5

ENFORCEMENT RESPONSE POLICY

OFFICE OF COMPLIANCE MONITORING

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

THE U. S. ENVIRONMENTAL PROTECTION AGENCY

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INTRODUCTION

Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires chemical manufacturers and importers to notify EPA 90 days prior to manufacturing or importing a new chemical substance in the United States. EPA will evaluate the new chemical substance within 90 days based on the information supplied by the submitter. If the Agency finds that the information supplied is insufficient to permit a reasoned evaluation of the health or environmental effects of the chemical substance and that in the absence of such information the manufacture, distribution, use or disposal of the chemical substance may pose an unreasonable risk of injury to health or the environment, or that the chemical substance may be produced in substantial amounts which may result in significant human or environmental exposure, the Agency may issue an order under TSCA §5(e) to prohibit or limit the manufacture, distribution, use or disposal of the chemical substance. TSCA §5(a)(2) allows the Agency to identify uses of a chemical substance which EPA has determined are significant new uses and to require notification of those significant new uses. Certain exemptions from the full reporting and notification requirements are allowed under TSCA §5(h). These exemptions may be found at 40 CFR 720.30 through 720.38 and at 40 CFR Part 723. The major exemptions from notification are research and development, test marketing, small quantities (less than 1,000 kg per year), certain polymers and substances used in instant photographic and peel-apart film articles.

Failure to comply with the provisions of TSCA §5 is a violation of TSCA §15 and subject to the remedies found in TSCA §16.

Summary of TSCA §5 Requirements

Premanufacturing Notification (PMN) - Under TSCA §5(a)(1) and 40 CFR 720, manufacturers and importers of new chemical substances are required to submit, 90 days prior to manufacturing or importing, a notice of their intention to conduct such activities as well as any test data in their posession or control in accordance with 40 CFR Part 720.50.

Significant New Use Rules (SNUR) - Under TSCA §5(a)(2) and 40 CFR 721, EPA specifies by rule the use(s) of chemical substances which it considers to be significant new uses. EPA must be notified prior to commencement of any significant new use.

Notice of Commencement(NOC) - Under 40 CFR 720.102, EPA requires that any person who commences the manufacture or importation of a new chemical substance for which that person had previously submitted a PMN, must submit a notice of commencement of manufacture or import on or no later than 30 days after the first day of manufacture or import.

TSCA §5(e) Order - Under TSCA §5(e), if EPA determines that the information available in support of a PMN is insufficient to make a reasoned evaluation of the health or environmental effects of a chemical substance, EPA will issue an order imposing controls, restrictions or prohibitions on the manufacture of the substance in order to address the concerns of EPA.

TSCA §5(f) Order - Under TSCA §5(f), if EPA finds that the manufacture, import, processing, distribution, use or disposal of a chemical substance presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under TSCA §6 can protect against such risk, the Administrator may issue an immediately effective proposed rule to impose controls or restrictions to protect against such risk or may issue an Order to prohibit manufacture, processing, or distribution in commerce.

TSCA §5(h) Exemptions - TSCA §5(h) and 40 CFR 720.30 through 720.38 and 40 CFR 723 exempt certain substances and classes of substances from the full notification and reporting requirements of TSCA §5.

DETERMINING THE LEVEL OF ACTION

Enforcement alternatives include civil penalties, injunctive relief, criminal action or some combination of these actions. Notices of noncompliance are not appropriate for TSCA §5 violations.

Administrative Civil Penalty

An administrative civil penalty will be the appropriate response for most violations of these regulations.

Concurrence

Civil penalties are to be assessed according to this policy. Regional enforcement personnel must obtain written concurrence from the Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances prior to initiating a civil administrative penalty for TSCA §5 violations. Reductions for settlement purposes require the concurrence of OCM as well and must be in accordance with the TSCA Penalty Policy and this Enforcement Response Policy.

Each reduction must be based on the TSCA Penalty Policy or this policy and justified in the Consent Agreement and Final Order with specific dollar amounts attributed to each reduction. Headquarters may relax concurrence requirements on a Region by Region basis after the Regions have gained experience with actions under these rules and this policy.

Injunctive Action

In most circumstances, a TSCA §16 administrative action will provide a complete and timely remedy for TSCA §5 violations. However, certain cases may present the need for the types of injunctive relief available under TSCA §17 in addition to TSCA §16 administrative actions.

Section 17 provides the U.S. District Courts with the jurisdiction to:

- Restrain persons from taking actions prohibited by TSCA §§ 5, 6, and 15.
- Compel persons to take actions required by TSCA.
- Direct manufacturers, importers, or processors in violation of TSCA to: provide notice of the violation or risk of injury to, or repurchase the product from, the consumers of the violative product.
- Seize any chemical substance manufactured, imported, processed, or distributed in commerce in violation of TSCA.

It is important to note that TSCA §17 does not require an imminent hazard or recalcitrant respondent as a condition to its use. However, the Agency believes that the use of TSCA §17 should be limited to those instances where a civil penalty action will not mitigate a hazardous situation, is not likely to result in timely compliance, or where penalties alone do not provide a complete remedy. Injunctive action is appropriate in the following examples:

- illegal production/use which presents a hazard to human health or the environment;
- violations of TSCA §5(e) or 5(f) orders, Low Volume Exemptions, or Test Marketing Exemptions which involve the failure to use personal protective equipment or chemical control measures;
- contumacy, undue delay, or refusal of a violator to comply with TSCA requirements and regulations; or
- repeat offenders for whom the penalty adjustments for past history of violations is unlikely to deter future violations.

Criminal Sanctions

Criminal sanctions pursuant to TSCA §16(b) are the most serious sanctions available for violations of TSCA §5. Accordingly, criminal sanctions may be sought in situations that, when measured by the nature of the conduct, the compliance history of the subject(s) and the gravity of the consequences to human health or the environment, reflect the most serious cases of misconduct.

ASSESSING A CIVIL ADMINISTRATIVE PENALTY

Summary of the Penalty Policy

Background

The TSCA Civil Penalty Policy, published in the Federal Register on September 10, 1980, establishes a system for determining penalties in administrative actions brought pursuant to TSCA §16. Under that system, penalties are determined in two stages: (1) determination of a "gravity based penalty" (GBP), and (2) adjustments to the gravity based penalty.

To determine the gravity based penalty, the following factors affecting a violation's gravity are considered:

- The "nature" of the violation.
- The "circumstances" of the violation.
- The "extent" or potential for harm that could result from a given violation.

These factors are incorporated into a matrix which allows determination of the appropriate gravity based penalty.

Once the gravity based penalty has been determined, upward or downward adjustments to the penalty amount are made in consideration of these other factors:

- culpability,
- history of such violations,
- ability to pay,
- ability to continue in business, and
- such other matters as justice may require.

The TSCA Civil Penalty Policy system provides a framework for the development of individual penalty guidances for each rule promulgated under TSCA. This document sets forth Agency policy for the use of the Gravity Based Penalty Matrix to assess penalties for specific violations of TSCA §5 and regulations promulgated pursuant to this section.

Applicability

This policy is immediately applicable and should be used to calculate penalties for all administrative actions concerning TSCA §5 instituted after the date of this policy, regardless of the date of violation. Pending cases should be reviewed to determine whether the penalty calculated under this policy is lower than the penalty in the civil complaint. If this policy yields a lower penalty, an amendment to the complaint should be made to substitute the lower penalty. This policy should not be used to raise penalties in existing actions. No case should be settled for an amount higher than the penalty which this policy would yield.

Calculation of the Gravity Based Penalty

Penalties for TSCA §5 violations vary depending on the nature, extent, circumstances and whether penalties are to be calculated as one-day assessments or per-day assessments. In establishing each of these, the Agency considered the following factors in a comparative manner:

- Potential for and/or the relative degree of harm to human health or the environment caused by failure to comply. This directly relates to the impact on the Agency's mandate to evaluate and control the potential for human health or environmental effects of a new chemical substances prior to its production or import.

- Potential exposure of the public or the environment to an unregulated new chemical substance.

- Impact on the validity of the Inventory, which the statute mandates the Administrator to keep current.

- Deterrent effect the penalty would have or the likelihood that the penalty will deter future violations.

Nature

The nature of the TSCA violation depends on whether the violation relates to chemical control, control-associated data-gathering, or hazard assessment. It is important to make this determination first. Determining the nature of the violation is necessary prior to using the extent matrix. The following list places the violation types in their respective categories.

1) Chemical Control Violations

- Noncompliance with TSCA §5(e) or 5(f) orders, rules, or injunctions and significant new use rules (those aspects dealing with the actual control of the substance, i.e., production, commercial use, disposal, production restrictions, etc.).
- Noncompliance with research and development exemption restrictions (noncompliance with the adequate warning and supervision of a technically qualified individual requirement).
- Noncompliance with test marketing exemption restrictions (those aspects dealing with the actual control of the substance).
- Noncompliance with exemption restrictions under 40 CFR 723 (those aspects dealing with the actual control of the substance).

2) Control-Associated Data-Gathering Violations

- Noncompliance with the recordkeeping provisions of TSCA §5 orders, rules, or injunctions.
- Noncompliance with the recordkeeping provisions of exemption restrictions under 40 CFR 723.
- Noncompliance with the recordkeeping provisions of the research and development and test marketing exemption restrictions.

3) Hazard Assessment Violations

- All failures to notify EPA when such notification is required by law.
- Withholding material information from or submitting false or misleading information in a TSCA §5 notice or exemption request.
- Commercial use of a substance produced without a PMN or valid exemption.

- Noncompliance with the reporting provisions of TSCA §5(e) or 5(f) orders, rules, or injunctions.
- Any violation not listed previously.

Circumstances

Once the nature of the violation has been determined, the second step in calculating the penalty is determining the circumstances of the violation. The circumstances determination is based upon the probability that harm could have taken place - an a priori potential for harm to the environment or the Agency's decisionmaking or ability to regulate, i.e., potential exposure to an unregulated chemical substance or harm to the integrity of the Inventory. Any after the fact determination that harm did or did not take place is irrelevant to the initial circumstance level determination. The gravity based penalty matrix provides for six circumstance levels. Levels one and two represent the Agency's determination of circumstances where there exists a high probability of harm. Levels five and six represent circumstances of low probability of harm and levels three and four fall between these high and low probabilities.

The circumstance level of a violation is designated in the following manner. Please note that many of the levels refer to a PMN being subject to a TSCA §5(e) or 5(f) action. Please refer to page 22 for a further explanation of when a substance is subject to a TSCA §5(e) or 5(f) action.

Failure to Notify

Failure to submit a PMN not subject to a TSCA §5(e) or 5(f) order or exemption when the substance was not distributed to others or further processed for commercial use by the company is a level 4 violation, per-day.

Failure to submit a PMN not subject to a TSCA §5(e) or 5(f) order or exemption when the substance was distributed to others or further processed for commercial use by the company is a level 3 violation, per-day.

Failure to submit a PMN when the substance is or would have been the subject of a TSCA §5(e) or 5(f) action but was not either distributed to others or further processed for commercial use by the company is a level 2 violation, per-day.

Failure to submit a PMN when the substance is or would have been the subject of a TSCA §5(e) or 5(f) action and the substance was either distributed to others or further processed by the company is a level 1 violation, per-day.

Failure to submit a PMN for a chemical substance which would meet all requirements for a polymer exemption under 40 CFR 723.250, except that the company did not file for an exemption, will be assessed as a level 5 violation, per-day.

Failure to submit a PMN for a chemical substance which would meet all requirements for a polymer exemption under 40 CFR 723.250, except that the company did not file for an exemption and the substance was further processed for commercial use, distributed to consumers, or released uncontrolled into the environment will be assessed as a level 4 violation, per-day.

Failure to submit a Notice of Commencement is a level 3 violation, one-day.

Failure to submit a timely Notice of Commencement (early or late submission, up to 30 days prior to manufacture or 30 to 60 days after manufacture) is a level 6 violation, one-day.

Failure to submit a timely Notice of Commencement (early or late submission, more than 30 days prior to manufacture or more than 60 days after manufacture) is a level 4 violation, one-day.

Withholding information or submitting false or misleading information with regard to a PMN, Significant New Use Notice, or exemption request is a level 1 violation, per-day.

Submission of a false Notice of Commencement is a level 1 violation, one-day.

<u>Noncompliance with TSCA §5(e) or 5(f) Orders, Rules or Injunctions and Significant New Use Rules</u>

Violation of on-site restrictions is a level 2 violation, per-day.

Violation of off-site restrictions where the substance was either processed by another firm <u>or</u> distributed to consumers <u>or</u> released uncontrolled into the environment is a level 1 violation, per-day.

Failure to submit a Significant New Use Notice when the substance was not distributed is a level 2 violation, per-day.

Failure to submit a Significant New Use Notice when the substance was distributed to consumers is a level 1 violation, per-day.

Violation of production ban or restriction is a level 1 violation, per-day.

Failure to generate reports as required is a level 2 violation, per-day.

Failure to generate reports as required, where the substance was either processed by another firm or distributed to consumers or released uncontrolled into the environment is a level 1 violation, per-day.

Late submission of required reports where the substance was not distributed or processed is a level 4 violation, per-day.

Late submission of required reports where the substance was either processed by another firm or distributed to consumers or released uncontrolled into the environment is a level 3 violation, per-day.

Withholding information or submitting false or misleading information is a level 1 violation, per-day.

Violation of the recordkeeping provisions where the firm produces the missing records within 5 days of a written EPA request is a level 4 violation, one-day.

Violation of the recordkeeping provisions where the firm cannot produce the missing records within 5 days of an EPA request is a level 3 violation, one-day except as specified on page 26 of the policy.

Commercial Use of a Substance Produced Without a PMN or Valid Exemption

Commercial use violations will be charged in two circumstances:

1. Where a company processes or uses a chemical substance which it did not manufacture and it has reason to know is not on the Inventory.

2. Where a chemical substance was manufactured or imported illegally on just a few occasions and processed over a long period of time, the substance would have been subject to a TSCA §5(e) or 5(f) order, and the activity could have caused substantial endangerment to health or the environment.

Commercial use violations will be assessed as follows:

Violation where the substance was not processed by or distributed to others after receipt by the user is a level 4 violation, per-day.

Violation where the substance was further processed by or distributed to others is a level 3 violation, per-day.

Violation where the substance is or would have been the subject of a TSCA §5(e) or 5(f) action but was not processed by or distributed to others is a level 2 violation, per-day.

Violation where the substance is or would have been the subject of a TSCA §5(e) or 5(f) action and was either processed by others or released uncontrolled into the environment is a level 1 violation, per-day.

In cases involving imminent hazard the Agency reserves the right to charge a manufacturer with both failure to submit a PMN and illegal commercial use of the substance.

Noncompliance with Test Marketing Exemption Restrictions

Overproduction by 10% or less is a level 3 violation, per-day.

Overproduction of more than 10% would be charged as a failure to submit a PMN.

Violation of exposure related, on-site restrictions is a level 2 violation, per-day.

Violation of recordkeeping provisions is a level 4 violation, one-day except as specified on page 26 of the policy.

Violations of the off-site control provisions of a TME where the substance was either distributed to consumers or was released uncontrolled into the environment is a level 1 violation, per-day.

Noncompliance with Research and Development Exemption Restrictions

Violations regarding the labeling of the R&D substance where the substance was further processed by another firm is a level 2 violation, per-day.

Violations regarding the labeling of the R&D substance where the substance was either distributed to consumers or was released uncontrolled into the environment is a level 1 violation, per-day.

Please note that any violation of an R&D exemption other than failure to adequately label the R&D substance, would cause the charge to be a failure to submit a PMN.

Noncompliance with Low Volume Exemption Restrictions

Violations regarding the notification of customers of the restrictions on use of the substance is a level 2 violation, per-day.

Violations regarding the failure to notify EPA of any changes in site or use of the exempted chemical is a level 2 violation, per-day.

Violations of the recordkeeping provisions of the low volume exemption is a level 3 violation, one-day except as specified on page 26 of the policy.

Violations of the 1,000 kg. production limit would be viewed as a failure to submit a PMN.

Violations regarding the failure to maintain required exposure controls is a level 2 violation, per-day.

Noncompliance with the Instant Photographic and Peel-Apart Film Article Exemption Restrictions

Failure to limit manufacturing and processing to site(s) listed in the exemption application is a level 5 violation, per-day.

Distribution in commerce or use of a peel-apart film article containing a new chemical substance prior to its being cleared through the PMN process would be considered a failure to submit a PMN and subject to the penalties thereunder.

Failure to follow the conditions of manufacture for instant photographic or peel-apart film articles where the substance would not have been subject to a TSCA §5(e) or 5(f) order is a level 2 violation, per-day.

Failure to follow the conditions of manufacture for instant photographic or peel-apart film articles where the substance would have been subject to a TSCA §5(e) or 5(f) order is a level 1 violation, per-day.

Violation of the recordkeeping provisions of this exemption is a level 3 violation, one-day except as specified on page 26 of the policy.

Noncompliance with Polymer Exemption Restrictions

Violations regarding the submission of test data with the exemption application is a level 1 violation, per-day.

Violations of the recordkeeping provisions of the polymer exemption is a level 4 violation, one-day.

All other violations of the polymer exemption would be charged as a failure to submit a PMN.

Production

Production of a chemical substance not subject to a TSCA §5(e) or 5(f) order or exemption after submission of a PMN but prior to the expiration of the PMN review period is a level 3 violation, per-day.

Production of a chemical substance after submission of a PMN but prior to the expiration of the PMN review period when the substance becomes or would have been the subject of a TSCA §5(e) or 5(f) action or the substance was distributed to consumers is a level 2 violation, per-day.

Production of a chemical substance prior to the expiration of the PMN review period when the substance becomes or would have been the subject of a TSCA §5(e) or 5(f) action and the substance was distributed to consumers is a level 1 violation, per-day.

Other Violations

Any other violation not listed above is a level 4 violation, per-day.

Extent

The third step in selecting the base penalty for a specific violation from the matrix is to determine the violation's position on the extent axis. Extent is based on the amount of substance involved in the violation and the nature of the violation. The following table is to be used to determine the extent of a violation.

EXTENT MATRIX*

Nature	Extent Level		
	A Major	B Significant	C Minor
Chemical Control	>2,500 lbs >1,134 kg	>250 lbs to 2,500 lbs >113.4 kg to 1,134 kg	>0 to 250 lbs >0 to 113.4 kg
Control-Associated Data-Gathering	>10,000 lbs >4,536 kg	>1,000 lbs to 10,000 lbs >453.6 kg to 4,536 kg	>0 to 1,000 lbs >0 to 453.6 kg
Hazard Assessment	>7,500 lbs >3,402 kg	>750 lbs to 7,500 lbs >340.2 kg to 3,402 kg	>0 to 750 lbs >0 to 340.2 kg

* Note exceptions listed on page 14 and 15 under Notes for determining extent.

Notes for determining extent

1) Production records will generally serve as the extent basis in the following violation categories:

   - All failures to notify EPA when such notification is required by law.
   - Noncompliance with TSCA §5(e) or 5(f) orders, rules, or injunctions.
   - Noncompliance with exemptions under 40 CFR Parts 720 and 723.

   Where there are no production records, the penalty will be assessed at the major extent and may be adjusted if the firm provides data which can be used to determine the extent. If the underlying violative conduct does not relate to production, another more appropriate basis should be employed to determine extent. If, for example, the violator disposes of 5,000 pounds of the substance in violation of the terms of a TSCA §5(e) order, then the amount of the substance disposed, as evidenced in disposal records, is the basis of the penalty.

2) The basis of extent in a commercial use violation will be the amount of illegally produced substance processed or used by the violator on a given day.

3) If the records specified above are unavailable, the penalty is to be assessed from those records that are available if possible or at the major extent level.

4) Violations for withholding information, submitting false or misleading information, or failure to submit reports required by a TSCA §5(e) or 5(f) order, rule or injunction do not lend themselves to extent determinations based on production amounts. For the purposes of determining per-day penalties under this ERP, if the the study which is the subject of the violation involved human monitoring data, the extent is major. If the study which is the subject of the violation involved animal laboratory data, the extent is significant. If the study involved physical or chemical properties or environmental fate data, the extent is minor. This is consistent with the TSCA §§8, 12, and 13 Enforcement Response Policy.

5) Violations involving genetically engineered microorganisms do not lend themselves to extent determinations based on the matrix, due to the extremely small amounts involved. These microorganisms may have the ability to reproduce, creating a larger environmental hazard.

Therefore, any violation involving a genetically engineered microorganism will be considered major in extent. Likewise, violations involving any genetically altered or naturally occurring organisms subject to a SNUR or TSCA §5(e) order will be considered major in extent. In the event the Agency identifies low-risk categories of organisms, violations involving low-risk organisms will be considered significant.

6) All Notice of Commencement violations will be considered major in extent.

Gravity

Gravity, as used in this ERP, is dependent upon the nature, extent and circumstances of the violation.

Per-Day Assessments

Where per-day assessments are provided for in the Circumstances Level section, the base penalty is calculated for the first occurrence of a violative activity and assessed for each day of subsequent occurrence. For example, a manufacturer or importer is responsible for notifying EPA prior to production or importation of a new chemical substance. Each day of production or importation of a new chemical substance in violation of the notification requirements of TSCA §5 constitutes a new violation. A day of violation is counted for each day a chemical substance is produced regardless of the number of batches produced on a given day. The total amount produced on a given day would be used when determining extent. If production of a chemical substance takes place over a number of days before the manufacturing process is complete, production occurs only when the manufacturing process has been completed. Likewise, a manufacturer or importer subject to an order, rule or injunction under TSCA §5 which directs him to dispose of the substance or wastes in a particular manner, is in violation for each day disposal occurred contrary to the requirements of the order, rule or injunction. Illegal commercial use violations are assessed under the same principles. Commercial use violations, however, are based on the amount of illegally produced chemical substance used.

Per-day penalties assessed on a daily basis (i.e., calendar days vs. days of actual production) are generally reserved for violations of the data-gathering provisions of TSCA §5 where the Agency needs the data to assess the risks presented by a chemical substance, or situations involving imminent hazard.

One-Day Violations

Violations of the recordkeeping provisions of TSCA §5 are assessed on a one-time basis only except where compliance cannot be determined or noncompliance was intentional. See pages 22 and 26 for a further discussion of these issues.

Imminent Hazard

Upon review of the facts surrounding a violation, the Agency may make a finding that continued production, sale and distribution of a substance may present an imminent hazard to health and the environment. In the event of such a finding, the Agency may take steps to halt further production, sale and distribution of the product as well as assess the maximum penalty of $25,000 per day for each calendar day the exposure from manufacturing and/or commercial use occurred. Thus, if the Agency determined that exposure to a substance found to be an imminent hazard occurred for 90 days, the penalty would be 90 X $25,000 or $2,250,000.

Gravity Based Penalty

The Gravity Based Penalty (GBP), a function of the nature, circumstances and extent of each violation, is to be determined by using the following matrix:

GRAVITY BASED PENALTY MATRIX

Circumstances		Extent		
		A	B	C
		Major	Significant	Minor
	Levels			
High Range	1	$25,000	$17,000	$5,000
	2	$20,000	$13,000	$3,000
Mid Range	3	$15,000	$10,000	$1,500
	4	$10,000	$ 6,000	$1,000
Low Range	5	$ 5,000	$ 3,000	$500
	6	$ 2,000	$ 1,300	$200

Whether a penalty is to be assessed as a one-day assessment or as a continuing violation on a per-day basis is addressed in the Circumstances section and on page 15.

Adjusting the Gravity Based Penalty

Follow the adjustment factor application instructions as presented in the general TSCA penalty policy document, "TSCA Civil Penalty System" of September 10, 1980 at pages 9-16.

Adjustment factors specific to this policy are discussed below.

Other Factors As Justice May Require

Voluntary Disclosure

Penalty amounts for violations of TSCA §5 will be reduced when the violations are voluntarily disclosed by the company. For TSCA §5 violations the penalty reductions for voluntary disclosure are as follows.

Voluntary disclosure	25%
Immediate disclosure within 30 days of discovery	25%
Takes all steps reasonably expected	up to 15%
Total	up to 65%

The reduction for voluntary disclosure and immediate disclosure may be made prior to issuing the Civil Complaint. The Civil Complaint should state the original penalty and the reduced penalty and the reason for the reduction.

The Agency wants to encourage voluntary disclosures for TSCA §5 violations. In order to do this, an automatic penalty reduction may be made. To be eligible, a firm must make the disclosure prior to being notified of a pending inspection and the disclosure cannot be one that is required by TSCA §8(e) or that is made after EPA has received information relating to the alleged violation. Voluntary disclosure of a violation will result in a 25% reduction of the penalty.

In some cases, companies have delayed 9-12 months in reporting a violation. An additional 25% penalty reduction may be given to those companies which report the potential violation to EPA within 30 days of having reason to believe that they may be in violation. This reduction is also applicable to firms which have changed ownership.

If a company realizes it cannot find a chemical which it is manufacturing on the non-CBI Inventory, and for which it did not submit a PMN, it has reason to believe that it may be in violation. The time limit begins the moment the company has reason to believe that the chemical may not be on the Inventory, not after EPA has confirmed the Inventory status of the chemical.

Environmentally beneficial expenditures above and beyond those specifically required under TSCA are allowable penalty reductions at the Agency's discretion. Generally, environmentally beneficial expenditures may be deducted from the penalty at the Agency's discretion in accordance with the TSCA Civil Penalty Policy for recall costs and special disposal costs, if such action is requested by EPA or undertaken by the company independently, but not required by TSCA, a regulation, order, or TSCA §§7 or 17 and such action is conducted in a manner satisfactory to EPA.

As an alternative to the deduction of costs for environmentally beneficial expenditures, a penalty reduction of up to 15% may be made for voluntarily disclosed violations at the Agency's discretion if the company takes all steps reasonably expected/requested by EPA to mitigate the violation. This includes timely submission of information necessary for EPA to assess a violation. Timely submission means within 30 days or a time period agreed upon by EPA and the company. This reduction is not in addition to reductions for environmental expenditures above and beyond that required by the law, but is an alternative. This reduction of up to 15% is only applicable to companies which have voluntarily disclosed the violation and may be taken in addition to the Attitude of the Violator adjustment found in the TSCA Civil Penalty Policy. If the steps expected/requested by EPA have not been taken at the time of settlement, this section does not apply. Future activities may be addressed in accordance with the Settlement with Conditions Policy.

In some cases, mitigation may not be possible. For example, if the product was distributed in commerce and has already been used, there may be nothing the company can do to rectify the situation. In these cases, no reduction will be given under this heading. In other cases, if no steps are expected because cessation of the violative action is sufficient, i.e., the chemical clears the PMN process and OTS makes a finding that no corrective actions are necessary, EPA may still give the added 15% reduction for companies that have voluntarily disclosed the violation, provided the penalty exceeds any economic benefit gained by the company.

An example of a situation in which EPA may give the additional 15% reduction is one in which a company manufactures a chemical not on the Inventory and does not file a PMN. The company notifies EPA of the possible violation, immediately ceases all manufacture, processing, and distribution until it files a PMN and the chemical clears the review period without being a candidate for a TSCA §5(e) or 5(f) action.

Economic Benefit

In no cases shall reductions be given if the reduced penalty does not exceed the economic benefit gained from non-compliance. EPA should require the company to present information concerning economic benefits gained from the violative action prior to the reduction of the penalty except for the 25%/50% off for voluntary disclosure. In all cases, EPA wishes to encourage voluntary disclosure.

Attitude

The existing adjustment provision for the Attitude of the Violator in the TSCA Civil Penalty Policy (Septemeber 10, 1980) may also be applied to adjust the penalty by up to 15%. Please note that this adjustment may decrease or increase the penalty by 15%. This adjustment applies equally to companies that voluntarily disclosed violations and those that did not. A company would generally qualify for a downward adjustment if it immediately halts the violative activity, takes steps to rectify the situation and there is no finding of culpability. However, such a reduction is at the discretion of EPA.

History of Prior Violation

The Agency will disregard the firm's prior history of violations in calculating the penalty for a self-disclosed violation. However, for violations discovered by the Agency, the Agency will address history of prior violations as indicated in the TSCA Civil Penalty Policy, even if the prior history results from a violation which was voluntarily disclosed.

Culpability

The culpability of a violator may be taken into account when a violator does not have control over the violation charged. An example would be a company importing a chemical substance from a foreign manufacturer where the foreign manufacturer falsely certifies that the substance is on the TSCA Inventory and the company importing the substance only knows the trade name of the substance. The importing company must be able to provide a copy of the written false certification and show that they were unable to ascertain the identity of the substance by any other means. The Agency can reduce the penalty by up to 25% in such situations. In the event of further violations of this type, history of prior violation would not be considered when determining the penalty.

Explanation of the Penalty Policy

Nature

The nature of a TSCA §5 violation depends on whether the violation deals with chemical control, control-associated data-gathering, or hazard assessment.

1. Chemical control regulations are aimed at minimizing the risk presented by a chemical substance by placing constraints on how the substance is handled. Section 5(a)(2) authorizes the Administrator to make a determination that use of a chemical is a significant new use and require the manufacturer or importer to notify EPA prior to initiating such a use. Sections 5(e) and 5(f) authorize a wide variety of chemical control requirements from labeling restrictions to manufacturing bans. Section 5(h)(1) authorizes the Administrator to impose restrictions upon the manufacture or processing of a test marketed substance. Violations of those restrictions that place constraints on how a substance is handled fall into this category. Section 5(h)(3) obligates a firm producing a substance under a research and development exemption to give adequate warning to employees if that substance is dangerous. This is also a constraint on a substance's handling and is included in this category.

2. Control-associated data-gathering requirements are the recordkeeping and/or reporting requirements associated with a chemical control regulation. These requirements enable the Agency to evaluate the effectiveness of the regulation and to monitor compliance. Some requirements in TSCA §5(e) and 5(f) orders, rules, or injunctions would fall into this category (i.e., a section 5(e) order that requires the manufacturer to keep records of all purchases of the regulated substance). Some test marketing exemption restrictions would also fall into this category as section 5(h)(1)(B) authorizes the Administrator to impose, among other things, recordkeeping and/or reporting requirements.

3. Hazard assessment requirements are used to develop and gather information necessary to weigh the risks and benefits presented by particular chemical substances and to impose chemical control requirements when appropriate. This category includes violations for failure to notify, withholding information from EPA or submission of false or misleading information.

Circumstances

Circumstances are used in the penalty policy to determine the probability of potential harm. In other words, a variety of facts surrounding the violation as it occurred are examined to determine whether the circumstances of the violation are such that there is a high, medium, or low potential for harm. To calculate the penalty first use the nature determination list to select the appropriate nature category and then select the appropriate circumstance.

Application of the Circumstances Factor to Section 5

1) Chemical control. Chemical control violations include noncompliance with TSCA §5(e) or 5(f) actions, failure to submit a significant new use notice, noncompliance with a research and development exemption restriction on adequate warning, noncompliance with test marketing exemption restrictions on the actual control of the substance, improper commercial use of a substance produced in violation of a TSCA §5(e) or 5(f) order, or noncompliance with any exemption restriction on the use of a substance found under 40 CFR Part 723. For these violations, the initial circumstance level is based on the severity of the violation. Circumstance evaluations are adjusted by the degree of potential environmental exposure and potential risk posed by the chemical.

2) Control-associated data-gathering. Control-associated data-gathering violations include noncompliance with the recordkeeping provisions of TSCA §5(e) or 5(f) actions and exemption restrictions under 40 CFR Parts 720 and 723. For these violations the circumstances are dependent on the extent to which the Agency's ability to monitor and/or evaluate the risks posed by the substance or the company's compliance with the substantive legal requirements is impaired.

3) Hazard assessment. Hazard assessment violations include failure to submit a premanufacturing notification and associated commercial use, failure to submit a notice of commencement, withholding information, submitting false or misleading information, and noncompliance with the reporting provisions of TSCA §5(e) or 5(f) actions.

When determining whether a PMN is subject to a TSCA §5(e) or 5(f) action, there are instances where rather than imposing controls under a TSCA §5(e) order with testing triggered at a particular production volume or time, EPA requires testing upfront before manufacture may commence. If the company refused to either do the testing or withdraw the PMN, EPA would then unilaterally issue an "adversarial" TSCA §5(e) order prohibiting any manufacture. This type of case would be treated as a TSCA §5(e) or 5(f) action and subject to higher penalties.

When determining the circumstance level for recordkeeping violations when EPA has requested the missing records, EPA must be able to determine compliance from the records which are provided or the charge would be considered failure to produce the missing records. Where records are necessary to determine compliance with a requirement of a TSCA §5 action, rule, or injunction and the records cannot be produced, EPA reserves the right to charge per day penalties.

PMN violations involving chemical substances which meet all requirements for a polymer exemption under 40 CFR 723.250, except the company did not file for an exemption, will be assessed at a level 5 circumstance. EPA has determined that chemicals which qualify for these exemptions are of less concern as a hazard.

Extent

Extent is used to take into consideration the degree, range, or scope of the violation. The Extent Matrix (pg. 13) provides for three levels of extent: Major, Significant, and Minor. The three levels are generally based upon the amount of substance involved in the violative conduct.

Production records will generally serve as the penalty basis in the following violation categories:

- All failures to notify when such notification is required by law.
- Noncompliance with TSCA §5(e) or 5(f) orders, rules, or injunctions and significant new use rules (except for reporting violations).
- Noncompliance with test marketing or research and development exemption restrictions.
- Noncompliance with exemption restrictions under 40 CFR Parts 720 and 723.

If a chemical substance is manufactured for commercial purposes as part of a chemical mixture, the amount of the chemical substance from which the mixture is made is used to calculate the penalty. If a chemical mixture made from a chemical substance is incorporated into an article, the penalty is calculated from the amount of the chemical substance used to manufacture the chemical mixture. If the amount of chemical substance used to manufacture the chemical mixture is unknown, the amount of chemical mixture will be used to determine extent. If a portion of a batch containing an illegally manufactured chemical substance is sold/distributed for commercial purposes, the entire batch is considered to be manufactured for commercial purposes and the amount of the chemical substance used to manufacture the entire batch is used to calculate the penalty. Likewise, if one batch of an illegally manufactured chemical substance is sold/distributed for commercial purposes, all other batches of the chemical substance are considered to be manufactured for commercial purposes.

If a firm disposes of a substance in violation of a test marketing restriction or a section 5(e) injunction, then the amount illegally disposed is the basis of the penalty.

Violations involving genetically altered, naturally occurring or genetically engineered microorganisms will all be placed in the major extent category due to the Agency's general level of concern over the potential for harm from unregulated environmental release. In the event the Agency identifies low risk categories of organisms, violations involving low risk organisms will be placed in the significant extent level.

It should be noted that if those records specified above are unavailable, the penalty should be assessed on those records that are available or where there are no records, assume the violation is major in extent.

Determining extent for violations involving withholding information, submitting false or misleading information, or failure to generate reports as required by a TSCA §5(e) or 5(f) action requires different criteria. These violations are assessed for each day the violation occurred beginning from the day the information was submitted or should have been submitted. While the amount of a substance produced has an effect on the potential exposure of the public or environment to that substance, the harm is caused by the failure to submit the data or submit true and complete data. Consistent with the TSCA §§8, 12 and 13 Enforcement Response Policy, extent is determined by the type of data involved in the violation. If the subject study involves laboratory animal data, the extent is determined to be significant. If the subject study involves physical/chemical properties or environmental fate data, the extent level is minor.

The three levels of extent (major, significant and minor) are based on the potential for harm to health or the environment. As stated previously, chemical control violations are considered the most serious due to the fact that risks have largely been identified and steps have been taken to mitigate those risks. Thus, the amount of production/disposal necessary to place a violation into the major and significant categories is substantially less than the amounts which place a violation into those same categories for hazard assessment violations or control-associated data-gathering violations. Hazard assessment violations impair the Agency's ability to determine the risks presented by a particular new chemical substance and impose control requirements. Because the Agency has no way of knowing whether the substance presents a risk to health or the environment, hazard assessment violations are placed between chemical control violations and control-associated data-gathering violations in terms of the amount of substance necessary to place a violation in the various extent levels. Control-associated data-gathering violations impair the Agency's mission to mitgate threats to health and and the environment the least. These violations involve the recordkeeping provisions of a TSCA §5 action. Nonetheless, they are important for the Agency to assure compliance.

Application of the Extent Factor to Section 5

1) Chemical control violations. The Agency will have either knowledge or concerns that the substance may be harmful. Thus the potential for harm is greatest in this category. An amount of a substance that is considered minor or significant in the two other categories may be considered major here. A minor designation covers amounts from 0 to 250 lbs. (0 to 113.4 kg.); a significant designation covers amounts greater than 250 lbs. to 2,500 lbs. (113.4 kg. to 1,134 kg.); the major designation is assigned to amounts greater than 2,500 lbs. (1,134 kg.).

2) Control-associated data-gathering. Since production, distribution, etc. is always allowed, the penalties escalate more slowly than for the chemical control category violations: minor is 0 to 1,000 lbs. (0 to 453.6 kg.); significant is greater than 1,000 lbs. to 10,000 lbs. (453.6 kg. to 4,536 kg.); major is greater than 10,000 lbs. (4,536 kg.).

3) Hazard assessment. In this category, the Agency can neither assume that the substance is harmless nor harmful. The violations, however, are more serious than those in the control-associated data-gathering category: minor is 0 to 750 lbs. (0 to 340.2 kg.); significant is greater than 750 lbs. to 7,500 lbs. (340.2 kg. to 3,402 kg.); and major is greater than 7,500 lbs. (3,402 kg.).

Gravity of the Violation

Gravity refers to the overall seriousness of the violation. As used in this penalty system, gravity is a dependent variable (i.e., the evaluation of nature, extent, and circumstances will yield a dollar figure in the matrix that is the gravity based penalty).

Imminent Hazard

Imminent hazard violations require the Agency to make a finding that a particular violative substance presents an imminent hazard to health or the environment. Penalties for violations involving imminent hazards are assessed for each day the violation continues at the maximum penalty allowable when a company manufactures and uses the hazardous chemical. In these cases separate charges, one for manufacturing and one for commercial use may be assessed.

Per-Day Penalties or One-Day Assessments

TSCA §16(a)(1) provides not only that civil penalties may be assessed up to $25,000 but that each day a violation continues is a separate violation for which penalties may be assessed. For the purposes of this ERP, per-day penalties will be assessed for each day a violation of TSCA §5 occurs. If, for example, a firm is charged with the illegal manufacture of a chemical substance, each separate day of manufacture constitutes a violation regardless of the number of batches produced during that day. The total amount produced in a day would be used as the basis for the extent of the violation if a company has more than one facility illegally producing a substance on a given day. Likewise, if a firm illegally disposed of a substance, the penalty is based on the number of days the disposal occurred regardless of the number of shipments for disposal on a given day. The total amount of a substance produced or disposed of on a given day is used when determining extent. Where the manufacture or processing of a substance takes several days to complete, the penalty is based only on the day the manufacturing or processing was completed. For example, if it takes 3 days to manufacture a substance in violation of TSCA §5, the penalty would be assessed for the day the manufacture of the substance was completed (day 3).

Violations which warrant daily penalties are those which impair the Agency's ability to assess the risks to public health or the environment. These penalties are assessed from the date of occurrence to the date of discovery.

Per-day penalties will be assessed for the following violations:

- Withholding information or submitting false or misleading information
- Failure to generate reports as required by a TSCA §5(e) or 5(f) action
- Noncompliance with TSCA §5(e) and 5(f) orders, rules, and injunctions (chemical control aspects)
- Noncompliance with research and development exemption restrictions (violation of adequate warning and expert supervision requirements)
- Commercial use of an illegally produced substance
- Noncompliance with exemption restrictions under 40 CFR Parts 720 and 723 (chemical control aspects)
- Failure to notify

Penalties for recordkeeping violations will be assessed on a one-time basis. Violations of these types do not generally pose as great a risk to public health or the environment. The violations arise from a single violative act.

One-day penalties will be assessed for the following violations:

- Noncompliance with section 5(e) and 5(f) orders, rules, and injunctions recordkeeping provisions only. The Agency reserves the right to assess per day penalties for recordkeeping violations when compliance with a requirement of a TSCA §5 action, rule or injunction cannot be verified.
- Noncompliance with exemption restrictions under 40 CFR Parts 720 and 723 involving recordkeeping provisions.
- Notice of Commencement violations. The Agency reserves the right to charge a per day violation in those cases where the notice was intentionally withheld by the company.

Multiple Violations/Chemicals

Multiple violations of a TSCA §5 action, rule, or injunction will be assessed separately for each distinct violation. Where more than one chemical substance is in violation, penalties will be assessed for each violative chemical.

Adjustment Factors

Voluntary Disclosure

This is an activity which the Office of Compliance Monitoring (OCM) wants to encourage. If EPA receives a voluntary disclosure, the Agency can proceed with action to rectify a situation even if the manufacturer is reluctant. Actions by EPA to convince a violator to do the "right thing" may include penalties issued on a per-day basis, TSCA §§7 or 17 actions, or other additional rule-making.

Although OCM considered including the condition that the manufacturer acted in good faith prior to the violation and that he ceased the violative act as soon as he had reason to know of the violation, OCM decided not to include this as a condition for the 25% reduction for the following reasons: 1) If the violation continues, EPA may assess penalties against the manufacturer for each day of violation. 2) In calculating the penalties for violations after the violator knew of the violation, a culpability factor for those days may be added. 3) If the violator intended to violate TSCA prior to disclosing the violation, the penalties for the entire period of violation may be increased based on a culpability finding. 4) If the violator does not act to rectify the situation, his penalties may be increased based on attitude if no finding of culpability is made. 5) Irrespective of the circumstances of the violation, the Agency wants the manufacturer to report it.

Immediate Voluntary Disclosure

OCM wants to further encourage prompt reporting. Therefore, an added incentive is provided so that the Agency is notified soon after the manufacturer has reason to know of a potential violation.

History of Noncompliance

As a further incentive for the voluntary disclosure of violations, the Agency has decided to forego the imposition of penalty increases for a history of noncompliance in assessing penalties for voluntarily disclosed violations.

However, a voluntarily disclosed violation does constitute a violation and is to be used to increase penalties for future violations which the Agency discovers.

Definitions

Consumer - Any person who uses a chemical substance for any purpose.

Off-site Restrictions - Off-site restrictions are those restrictions placed on a substance after it leaves the original site of manufacture or processing.

On-site Restrictions - On-site restrictions are those restrictions imposed upon a Company by EPA through a TSCA §5 action, rule, or injunction at the site of manufacture or processing.

Recordkeeping - Recordkeeping is that information the Agency requires the Company to retain at its premises and provide to EPA upon request.

Reports - Reports are those data the Agency is requiring the Company to submit to EPA under TSCA §5.

APPENDIX 1

EXAMPLES

Failure to Notify

Example 1

A company has produced a chemical substance, which is not on the Inventory, for 5 years, with production occurring on 50 days each year, and 1,000 pounds of the substance produced on each day of production. The chemical substance is consumed in another chemical reaction. The company stops production immediately upon discovery of the violation, voluntarily discloses the violation within 30 days, submits a PMN within 30 days and takes all the steps EPA requests of them. The PMN goes through review without any health or environmental concerns being raised. The company is charged with a failure to submit a PMN, level 4, significant, per-day.

$6,000 X 5 X 50 = $1,500,000

80% reduction in penalty warranted - $1,200,000

Final Penalty - $300,000

Example 2

A company has produced a chemical substance, which is not on the Inventory, for 4 years with production occurring 50 days per year, and 8,000 pounds of the substance produced on each day of production. The chemical substance is further processed by the company on 100 days per year, 4,000 pounds processed on each day and sold in an end-use product. The company discovers the violation, immediately stops production, voluntarily discloses the violation within 30 days, submits a PMN within 30 days and takes all steps EPA asks of them. The PMN review identifies a substantial environmental concern and the company subsequently enters into a TSCA §5(e) consent order to address this concern. The company is charged with a failure to submit a PMN, level 1, major, per-day.

4 X 50 X $25,000 = $5,000,000

80% reduction in penalty warranted - $4,000,000

Final Penalty - $1,000,000

Example 3

A company has produced a chemical substance, which is not on the Inventory, for 8 years, with production taking place 25 days a year, and 3,000 pounds of the substance produced on each day of production. The chemical substance is incorporated into a product which is sold to its customers for use in a consumer product. The company discovers the violation and reports it to EPA 75 days later, after it has developed a legal substitute for the illegal chemical substance and has been notified of a pending inspection. A PMN is not filed as the company has no intention of making the illegally produced substance again. The company produces production records for the substance only after missing two deadlines for submitting the records. The company is charged with a failure to submit a PMN, level 3, significant, per-day.

$10,000 X 8 X 25 = $2,000,000

15% penalty adjustment upward for attitude - $300,000

Final Penalty - $2,300,000

Example 4

A company failed to submit a Notice of Commencement to EPA. The first day of production yielded 3,000 pounds of the substance. EPA discovered the violation. The company is charged with a failure to submit a Notice of Commencement, level 3, significant, one-day.

The company would be charged $10,000.

Example 5

A company produced a chemical substance regulated by a SNUR, for a significant new use as defined by the SNUR, without submitting a Significant New Use Notice to EPA. The substance was incorporated into a consumer use product. The company produced the chemical 9 times, with 3,000 pounds produced on each occasion. EPA discovered the violation. The company is charged with a failure to submit a Significant New Use Notice, level 1, major, per-day.

9 x $25,000 = $225,000

Example 6

An inspector discovers a study that should have been submitted in conjunction with a PMN application. The study involved animal testing data. The chemical substance was produced for 1 year before the violation was detected. The company is charged with witholding information, level 1, significant, per-day.

$17,000 X 365 = $6,205,000

Example 7

A company produces a chemical substance under a TSCA §5(e) order. The order requires the company to train workers and requires the employees to wear respirators while engaged in the manufacture of the substance. The inspector discovers that the company has not conducted training as required and that the workers do not wear respirators, or have them available, while engaged in the manufacture of the substance. Production has taken place on 30 days with 5,000 pounds of the substance produced each day. The company is charged with two counts, failure to provide training and failure to require their employees to wear respirators, level 2, major, per-day.

$20,000 X 2 X 30 = $1,200,000

Example 8

A company produces a chemical substance under a TSCA §5(e) order. The order requires the company to incinerate all wastes derived from the production of the chemical substance. An inspector discovers that the company has not incinerated the wastes as required, but has been releasing the wastes to water after primary treatment. Disposal took place on 50 days with 2,000 pounds disposed of each day. The company is charged with failure to follow the restrictions of the TSCA §5(e) order regarding disposal, level 1, significant, per-day.

$20,000 X 50 = $1,000,000

Example 9

A company produces a chemical substance under a TSCA §5(e) order. The order requires the company to either stop production or submit a study to EPA after producing 400,000 pounds of the substance. The company submits the study to the Agency and the study is approved. A subsequent inspection reveals that the company had produced 450,000 pounds of the substance prior to submitting the study, producing 5,000 pounds of the substance on 10 different days. The company is charged with violation of a production ban, major, level 1, per-day.

$25,000 X 10 = $250,000

Example 10

A company has manufactured and processed a chemical substance, which is not on the Inventory, for 8 years with manufacturing occurring 100 days each year, 5,000 pounds manufactured each day and processing occurring 200 days each year, with 2,500 pounds processed each day. The processed chemical substance is incorporated into an end use product. An inspector discovers the violation. A review of the chemical by EPA identifies a substantial environmental concern which would have placed the the substance as TSCA §5(e) order candidate. The company is charged with a failure to submit a PMN, level 1, significant, per-day.

$20,000 X 8 X 100 = $16,000,000

Example 11

A company applied for and recieved a low volume exemption for a chemical substance. An inspector discovers that the company produced 1500 kg of the substance in 3 different years with production occurring on 3 days each year, 500 kg produced each day. The chemical substance would have had a TSCA §5(e) order issued if it had not been granted a low volume exemption. The chemical substance was distributed to customers. The company would be charged with a failure to file a PMN, level 1, significant, per-day.

$20,000 X 3 X 3 = $180,000

Example 12

A company produced a chemical substance which is not on the Inventory, for 5 years, with production occurring on 50 days, 5,000 pounds produced each day. The chemical substance was further processed for 100 days each year with 2,500 pounds of the substance processed each day. The finished product containing the chemical substance was distributed to consumers. The chemical substance was a polymer that otherwise would have qualified for a polymer exemption. The company is charged with failure to file a PMN, level 5, significant, per-day.

$3,000 X 5 X 50 = $750,000

Example 13

Company A solicited several manufacturers to produce a chemical substance for them. They were advised by one company that the substance did not appear on the Inventory and that a PMN would have to be filed prior to manufacturing. Another company agreed to produce the chemical for Company A. Company A commercially used the chemical substance for 5 years, 100 days per year, processing 3,000 pounds of the substance on each occasion. EPA discovered the violation at the manufacturing company and charged the manufacturing company with a failure to file a PMN. The PMN was filed and no problems were found with the chemical substance during the PMN review. A subsequent inspection of Company A discovered the letter from the manufacturer who had advised Company A of the status of the chemical. Company A was charged with commercial use of an illegally manufactured substance, level 3, major, per-day.

5 X 100 X $15,000 = $7,500,000

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Failure to Notify			
Failure to submit a PMN not subject to a TSCA §5(e) or 5(f), order or exemption when the substance was not distributed to consumers or further processed for commercial use by the company.	4	Per-day	HA
Failure to submit a PMN not subject to a TSCA §5(e) or 5(f) order or exemption when the substance was distributed to consumers or further processed for commercial use by the company.	3	Per-day	HA
Failure to submit a PMN when the substance is or would have been the subject of a TSCA §5(e) or 5(f) action but was not either distributed to consumers or further processed for commercial use by the company.	2	Per-day	HA
Failure to submit a PMN when the substance is or would have been the subject of a TSCA §5(e) or 5(f) action and the substance was either distributed to consumers or further processed by the company.	1	Per-day	HA
Failure to submit a PMN for a chemical substance which would meet all requirements for a polymer exemption under 40 CFR 723.250, except that the company did not file for an exemption.	5	Per-day	HA
Failure to submit a PMN for a chemical substance which would meet all requirements for a polymer exemption under 40 CFR 723.250, except that the company did not file for an exemption and the substance was further processed for commercial use, distributed to consumers, or released uncontrolled into the environment.	4	Per-day	HA
Failure to submit a Notice of Commencement.	3	One-day	HA

HA - Hazard Assessment CC - Chemical Control CADG - Control-Associated Data-Gathering

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Failure to submit a timely Notice of Commencement (early or late submission, up to 30 days prior to manufacture or 30 to 60 days after manufacture).	6	One-day	HA
Failure to submit a timely Notice of Commencement (early or late submission, more than 30 days prior to manufacture or more than 60 days after manufacture).	4	One-day	HA
Withholding information or submitting false or misleading information with regard to a PMN, Significant New Use Notice, or exemption request.	1	Per-day	HA
Submission of a false Notice of Commencement.	1	One-day	HA
<u>Noncompliance with TSCA §5(e) or 5(f) Orders, Rules or Injunctions and Significant New Use Rules</u>			
Violation of on-site restrictions.	2	Per-day	CC
Violation of off-site restrictions where the substance was either processed by another firm <u>or</u> distributed to consumers <u>or</u> released uncontrolled into the environment.	1	Per-day	CC
Failure to submit a Significant New Use Notice when the substance was not distributed.	2	Per-day	CC
Failure to submit a Significant New Use Notice when the substance was distributed to consumers.	1	Per-day	CC
Violation of production ban or restriction.	1	Per-day	CC
Failure to generate reports as required.	2	Per-day	HA

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Failure to generate reports as required, where the substance was either processed by another firm or distributed to consumers or released uncontrolled into the environment.	1	Per-day	HA
Late submission of required reports where the substance was not distributed or processed.	4	Per-day	HA
Late submission of required reports where the substance was either processed by another firm or distributed to consumers or released uncontrolled into the environment.	3	Per-day	HA
Withholding information or submitting false or misleading information.	1	Per-day	HA
Violation of the recordkeeping provisions where the firm produces the missing records within 5 days of an EPA request.	4	One-day	CADG
Violation of the recordkeeping provisions where the firm cannot produce the missing records within 5 days of an EPA request except as specified on page 26 of the policy.	3	One-day	CADG

Commercial Use of an Illegally Produced Substance

Commercial use violations will be charged in three circumstances:

1. When a company processes or uses a chemical substance which it did not manufacture and it has reason to know is not on the Inventory.

2. When a chemical substance was manufactured or imported illegally on just a few occasions and processed over a long period of time, the substance would have been subject to a TSCA §5(e) or 5(f) order, and the activity could have caused substantial endangerment to health or the environment.

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Commercial use violations will be assessed as follows:			
Violation where the substance was not processed by or distributed to others after receipt by the user.	4	Per-day	CC
Violation where the substance was further processed by or distributed to others.	3	Per-day	CC
Violation where the substance is or would have been the subject of a TSCA §5(e) or 5(f) action but was not processed by or distributed to others.	2	Per-day	CC
Violation where the substance is or would have been the subject of a TSCA §5(e) or 5(f) action and was either processed by others or released uncontrolled into the environment.	1	Per-day	CC
Noncompliance with Test Marketing Exemption Restrictions			
Overproduction by 10% or less.	3	Per-day	CC
Overproduction of more than 10% would be charged as a failure to submit a PMN.			
Violation of exposure related, on-site restrictions.	2	Per-day	CC
Violation of recordkeeping provisions except as specified on page 26 of the policy.	4	One-day	CADG
Violations of the off-site control provisions of a TME where the substance was either distributed to consumers or was released uncontrolled into the environment.	1	Per-day	CC
Noncompliance with Research and Development Exemption Restrictions			
Violations regarding the labeling of the R&D substance where the substance was further processed by another firm.	2	Per-day	CC

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Violations regarding the labeling of the R&D substance where the substance was either distributed to consumers or was released uncontrolled into the environment.	1	Per-day	CC
Please note that any violation of an R&D exemption other than failure to adequately label the R&D substance, would cause the charge to be a failure to submit a PMN.			
Noncompliance with Low Volume Exemption Restrictions			
Violations regarding the notification of customers of the restrictions on use of the substance.	2	Per-day	CC
Violations regarding the failure to notify EPA of any changes in site or use of the exempted chemical.	2	Per-day	CC
Violations of the recordkeeping provisions of the low volume exemption except as specified on page 26 of the policy.	3	One-day	CADG
Violations of the 1,000 kg. production limit would be viewed as a failure to submit a PMN.			
Violations regarding the failure to maintain required exposure controls.	2	Per-day	CC
Noncompliance with the Instant Photographic and Peel-Apart Film Article Exemption Restrictions			
Failure to limit manufacturing and processing to site(s) listed in the exemption application.	5	Per-day	CC
Distribution in commerce or use of a peel-apart film article containing a new chemical substance prior to its being cleared through the PMN process would be considered a failure to submit a PMN and subject to the penalties thereunder.			

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Failure to follow the conditions of manufacture for instant photographic or peel-apart film articles where the substance would not have been subject to a TSCA §5(e) or 5(f) order.	2	Per-day	CC
Failure to follow the conditions of manufacture for instant photographic or peel-apart film articles where the substance would have been subject to a TSCA §5(e) or 5(f) order.	1	Per-day	CC
Violation of the recordkeeping provisions of this exemption except as specified on page 26 of the policy.	3	One-day	CADG
<u>Noncompliance with Polymer Exemption Restrictions</u>			
Violations regarding the submission of test data with the exemption application.	1	Per-day	HA
Violations of the recordkeeping provisions of the polymer exemption except as specified on page 26 of the policy.	4	One-day	CADG
All other violations of the polymer exemption would be charged as a failure to submit a PMN.			
<u>Production</u>			
Production of a chemical substance after submission of a PMN but prior to the expiration of the PMN review period.	3	Per-day	HA

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Production of a chemical substance after submission of a PMN but prior to the expiration of the PMN review period when the substance becomes or would have been the subject of a TSCA §5(e) or 5(f) action <u>or</u> the substance was distributed to consumers.	2	Per-day	HA
Production of a chemical substance prior to the expiration of the PMN review period when the substance becomes or would have been the subject of a TSCA §5(e) or 5(f) action <u>and</u> the substance was distributed to consumers.	1	Per-day	HA
<u>Other Violations</u>			
Any other violation not listed above.	4	Per-day	HA

EXTENT MATRIX

Nature	Extent Level		
	A Major	B Significant	C Minor
Chemical Control	>2,500 lbs >1,134 kg	>250 lbs to 2,500 lbs >113.4 kg to 1,134 kg	>0 to 250 lbs >0 to 113.4 kg
Control-Associated Data-Gathering	>10,000 lbs >4,536 kg	>1,000 lbs to 10,000 lbs >453.6 kg to 4,536 kg	>0 to 1,000 lbs >0 to 453.6 kg
Hazard Assessment	>7,500 lbs >3,402 kg	>750 lbs to 7,500 lbs >340.2 kg to 3,402 kg	>0 to 750 lbs >0 to 340.2 kg

GRAVITY BASED PENALTY MATRIX

Circumstances		Extent		
		A	B	C
		Major	Significant	Minor
	Levels			
High Range	1	$25,000	$17,000	$5,000
	2	$20,000	$13,000	$3,000
Mid Range	3	$15,000	$10,000	$1,500
	4	$10,000	$ 6,000	$1,000
Low Range	5	$ 5,000	$ 3,000	$500
	6	$ 2,000	$ 1,300	$200

Failure to submit a PMN for a chemical substance which would meet all requirements for a polymer exemption under 40 CFR 723.250, except that the company did not file for an exemption, will be assessed as a level 5 violation, per-day.

Failure to submit a PMN for a chemical substance which would meet all requirements for a polymer exemption under 40 CFR 723.250, except that the company did not file for an exemption and the substance was further processed for commercial use, distributed to consumers, or released uncontrolled into the environment will be assessed as a level 4 violation, per-day.

Failure to submit a Notice of Commencement is a level 3 violation, one-day.

Failure to submit a timely Notice of Commencement (early or late submission, up to 30 days prior to manufacture or 30 to 60 days after manufacture) is a level 6 violation, one-day.

Failure to submit a timely Notice of Commencement (early or late submission, more than 30 days prior to manufacture or more than 60 days after manufacture) is a level 4 violation, one-day.

Withholding information or submitting false or misleading information with regard to a PMN, Significant New Use Notice, or exemption request is a level 1 violation, per-day.

Submission of a false Notice of Commencement is a level 1 violation, one-day.

<u>Noncompliance with TSCA §5(e) or 5(f) Orders, Rules or Injunctions and Significant New Use Rules</u>

Violation of on-site restrictions is a level 2 violation, per-day.

Violation of off-site restrictions where the substance was either processed by another firm <u>or</u> distributed to consumers <u>or</u> released uncontrolled into the environment is a level 1 violation, per-day.

Failure to submit a Significant New Use Notice when the substance was not distributed is a level 2 violation, per-day.

Failure to submit a Significant New Use Notice when the substance was distributed to consumers is a level 1 violation, per-day.

Violation of production ban or restriction is a level 1 violation, per-day.

Failure to generate reports as required is a level 2 violation, per-day.

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
Failure to submit a timely Notice of Commencement (early or late submission, up to 30 days prior to manufacture or 30 to 60 days after manufacture).	6	One-day	HA
Failure to submit a timely Notice of Commencement (early or late submission, more than 30 days prior to manufacture or more than 60 days after manufacture).	4	One-day	HA
Withholding information or submitting false or misleading information with regard to a PMN, Significant New Use Notice, or exemption request.	1	Per-day	HA
Submission of a false Notice of Commencement.	1	One-day	HA
<u>Noncompliance with TSCA §5(e) or 5(f) Orders, Rules or Injunctions and Significant New Use Rules</u>			
Violation of on-site restrictions.	2	Per-day	CC
Violation of off-site restrictions where the substance was either processed by another firm <u>or</u> distributed to consumers <u>or</u> released uncontrolled into the environment.	1	Per-day	CC
Failure to submit a Significant New Use Notice when the substance was not distributed.	2	Per-day	CC
Failure to submit a Significant New Use Notice when the substance was distributed to consumers.	1	Per-day	CC
Violation of production ban or restriction.	1	Per-day	CC
Failure to generate reports as required.	2	Per-day	HA