



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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Amendment to the TSCA Section 5 Enforcement Response Policy - Penalty Limit For Untimely NOC Submissions

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

TO: Addressees

This memorandum amends the TSCA Section 5 Enforcement Response Policy by placing a limit on the penalty amount that can be assessed for failure to submit timely Notices of Commencement. In addition, the extent levels for these violations are to be reduced from major to significant. These changes would apply to those instances where a company submitted several Notices early and/or late. The penalties collected for untimely Notices of Commencement, for a single case, shall not exceed \$100,000. For example, an inspection reveals that a facility submitted twenty Notices of Commencement 75 days after commencing manufacture and six were submitted 45 days after commencing manufacture. This would be calculated as twenty level 4 (significant extent) violations at \$6,000 per count and six level 6 (significant extent) violations at \$1,300 per count for a total penalty of \$127,800. Pursuant to this amendment the total assessed penalty would be \$100,000.

This change has been made in response to comments that the policy issued on August 5, 1988, created a large inequity in penalties, in some cases, when a company fails to submit timely Notices of Commencement. This amendment is based on the premise that the risk associated with these violations is not as great as originally believed because the chemicals have been reviewed by, and cleared through the PMN process. This amendment applies to the failure to submit timely Notices of Commencement only. This amendment does not apply for violations of either failing to submit a Notice of Commencement, or withholding or submitting false or misleading information with regard to a Notice of Commencement.

This amendment is immediately applicable and should be used to calculate penalties for all administrative actions concerning the failure to submit timely Notices of Commencement 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 amendment is lower than the penalty in the civil complaint. If this amendment yields a lower penalty, an amendment to the complaint should be made to substitute the lower penalty.

If you have any questions concerning the amendment contact Peter Pagano of my staff at (202) 260-6747.

attachment

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.

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

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 or distributed to consumers or 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.

** - The total penalty for multiple counts of failure to submit timely NOC is limited to \$100,000 per case.

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, except for failure to submit timely ones which will be considered significant 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.

VIOLATION	LEVEL	PER-DAY/ ONE-DAY	NATURE
<u>Failure to Notify</u>			
Failure to submit a PMN not subject to a TSCA §5(e) or 5(f) order or exemption when the substance was <u>not</u> distributed to consumers <u>or</u> 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 <u>not</u> either distributed to consumers <u>or</u> 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 C:ADG - 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	IIA
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	IIA
Withholding information or submitting false or misleading information with regard to a PMN, Significant New Use Notice, or exemption request.	1	Per-day	IIA
Submission of a false Notice of Commencement.	1	One-day	IIA
<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 or distributed to consumers or 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	IIA

** - The total penalty for multiple counts of failure to submit timely NOC is limited to \$100,000 per case.