The Constantly Pending PMN: Low Volume Exemption Applications Are Living Documents

When available, a Low Volume Exemption ("LVE") is an attractive and quicker path to commercial marketing than filing a full premanufacture notification ("PMN") pursuant to the Toxic Substances Control Act ("TSCA"). Specifically, because LVE substances are never listed on the TSCA Chemical Substances Inventory ("Inventory"), having an LVE is akin to operating under a constantly pending PMN, obligating an LVE holder to submit to the United States Environmental Protection Agency ("EPA") information on changes to the process of manufacturing the LVE substance and on significant new information about the substance for the life of the exemption. As described below, the on-going notice requirement is a point worth noting when considering the advantages and disadvantages of filing an application for an LVE.

Premanufacture Notices

Pursuant to TSCA section 5, anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required to provide EPA with notice before initiating the activity.\[^1\] This notice, the PMN, must be submitted at least 90 days prior to the manufacture or import of the chemical.\[^2\] An obligation exists for the submitter during review of the PMN to provide relevant new information on the PMN substance to EPA. As such, while approval of a PMN is pending, the submitter is obligated to provide additional information to EPA if the information "materially adds to, changes, or otherwise makes significantly more complete" the information included in the PMN notice.\[^3\] Time constraints exist on submission of new information to EPA during the PMN review as follows: the submitter must provide information to EPA within ten days of receiving the new information, but no later than five days before the end of the notice review period (save where new information becomes available during the last five days of the notice review period, in which case the submitter must immediately inform EPA of the information by telephone).\[^4\]

Once the PMN review period has ended, its content is largely irrelevant, barring the need to correct the chemical identity or as potential evidence that the notice was not submitted in good faith. Process conditions, anticipated end uses and markets may all change without any need to alert EPA as long as the PMN substance (or any not otherwise regulated Inventory-listed substance) is produced. The submitter must provide notice to EPA within 30 calendar days of the date the substance is first manufactured or imported for nonexempt commercial purposes and comply with on-going obligations to report substantial risk information under section 8(e) and other reporting and data requirements that arise.\[^5\] Notice takes the form of a Notice of Commencement (NOC) of Manufacture or Import. The chemical substance is considered to be on the TSCA Inventory as soon as a complete NOC is received by EPA. Actual EPA processing of the NOC to complete the transaction takes about four weeks.

Low Volume Exemption Applications

Not every substance requires the filing of a full PMN. Specifically, certain categories of new chemical substances are exempted from full PMN review pursuant to regulations under TSCA section 5(h)(4), viz., chemicals manufactured at 10,000 kg/year or less.\[^6\] The advantage of filing an LVE application is that it undergoes only a 30-day review and is not subject to user fees. It is an attractive option for high-toxicity substances since risks are
mitigated by the limitations on exposure. If submitted as a PMN, the same substance might well wind up being regulated under section 5(e).

Reliance on an LVE can be problematic from a customer assurance standpoint because the substance never becomes an "existing" chemical substance listed on the TSCA Inventory. Moreover, the right to manufacture is limited to the LVE holder, although EPA can approve more than one LVE per chemical substance. Furthermore, the conditions of approval must be followed. At times this may require manufacturers to notify processors and industrial users of the LVE substance that the substance can only be used for specific purposes and with specific controls.

PMN-like data obligations also continue to apply to the manufacturer of an LVE substance even after approval of the LVE. Specifically, LVE regulations state: "[i]f the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information." Further, similar to PMN requirements, the LVE submitter is obligated to provide additional information to EPA during the LVE review period if the information "materially adds to, changes, or otherwise makes significantly more complete" the information included in the LVE application.

The conditions of an LVE can be materially changed by more than just new health and safety information. Namely, a holder of an LVE is bound to the conditions described in the LVE application, including:

- Use;
- Site of manufacture;
- Exposure and release controls;
- Physical form, such that the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the LVE application or in a physical form which will not increase the human exposure to or environmental release of the chemical substance over those exposures or releases resulting from physical form specified in the LVE application;
- Importation only, if so specified; and
- Production volume of less than 10,000 kg per year, if the submitter agrees to be bound to that volume.

As such, material changes to conditions listed above may need to be submitted to EPA in the form of a new LVE submission, save under limited circumstances pursuant to 40 C.F.R. § 723.50(j)(6).

The (j)(6) provision carves out an exception to the requirement that changes in the manufacturing site necessitate the filing of a new submission, provided there is no greater exposure of individual workers to the LVE substance and releases to water are negligible or zero. In that case, the manufacturer need only notify EPA of the new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance at the new manufacturing site.
Failure to comply with any provision discussed above is deemed a violation of TSCA and could subject the violator to a maximum penalty of up to $37,500 per violation. [16] Moreover, EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of LVE requirements, or EPA may act to seize any chemical substance manufactured or processed in violation of LVE requirements.

Manufacturers that rely upon LVE’s should take care to implement tracking systems and standard operating procedures that take into account that the termination of the notice period for an LVE application is only the end of the beginning of the life of the LVE.

[4] Id.
[14] 40 C.F.R. §§ 723.50(j)(6)(i)(A) and (B)
[15] 40 C.F.R. § 723.50(j)(6)(ii). The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, a statement that the notification is an amendment to the original exemption application, and an original signature of an authorized official of the manufacturer.
[16] 40 C.F.R. § 723.50(o).