

Chemical Compliance Challenges For US Battery Makers

By **Marshall Morales, Maureen Gorsen and Andrew Stewart** (October 18, 2022)

Battery production in the U.S. is expected to grow drastically in coming years — especially production of batteries for electric vehicles.

The Biden administration has made a substantial commitment to increasing domestic battery production capacity. Federal agencies and state governments have made special grant and tax incentive programs available for battery manufacturing facilities.

Most recently, the Inflation Reduction Act includes key provisions related to tax credits for EVs. These are expected to further incentivize domestic production of batteries for EVs.

Battery manufacturing uses a range of innovative chemicals that may require approvals by the U.S. Environmental Protection Agency under the Toxic Substances Control Act, or TSCA. These approvals can be complex and cause substantial delay.

Many battery manufacturers, or those investing in such facilities or who are part of the supply chain, may be unaware of how the TSCA applies to their operations — and how it could present risk of supply chain or business interruptions.

The EPA announced in early October that it will create a streamlined process for one category of chemicals that battery manufacturers use — mixed metal oxides.[1] But manufacturers use many other types of specialized chemicals to produce batteries that may also be regulated by TSCA.

Chemical Regulatory Requirements

The TSCA regulates the manufacture and import of new chemical substances. It defines a "new chemical substance" as one that is not identified on the TSCA Chemical Substance Inventory, which is a list maintained by the EPA of the thousands of chemicals actively used in commerce in the U.S.

A manufacturer or importer of a new chemical substance generally must file a premanufacture notice, or PMN, with the EPA — essentially equivalent to a registration or permit application — unless an exemption applies.

Industries like battery manufacturing, with highly specialized chemical needs, often wish to use chemicals produced or used overseas that are not yet listed on the TSCA inventory — and which therefore may be considered new chemical substances.



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Under the statutory text of the TSCA, PMN reviews by the EPA are intended to be completed in under 90 days. But the agency is currently taking 12 months or more to complete most PMN reviews. This is generally due to chronic understaffing of the EPA's TSCA office, as well as the highly technical and intensive nature of the agency's chemical risk assessments.

The finer details of the EPA's new plan to streamline reviews of mixed metal oxides — which include new and modified cathode active materials — have not been announced yet, so it remains to be seen what kind of acceleration will be available. Other EV battery-related chemicals are not included in the plan, so approvals for those, unfortunately, may still present risk of delays in ramping up battery production.

EV battery manufacturers should also be mindful that beyond the PMN requirements, additional regulations, called significant new use rules, may apply to existing chemicals, depending on the manner of usage.

Furthermore, the TSCA also establishes a range of reporting and record-keeping requirements for chemical manufacturers, importers and processors. The TSCA additionally requires that each import of chemicals have an import certification filed with U.S. Customs and Border Protection, which certifies whether the shipment complies with the TSCA, or is not subject to it.

Companies have an independent obligation under the TSCA to make good faith efforts to confirm TSCA compliance for every chemical. Relying on supplier information alone may not be enough to comply.

Promoting Chemical Compliance

In most companies, the separate functions of purchasing, import documentation and regulatory compliance need to work in sync to ensure TSCA compliance.

For any chemical manufactured or imported, a company should verify that the substance is on the TSCA inventory prior to importation, and determine whether any special rules, such as significant new use rules, apply to each chemical.

Additionally, staff responsible for import documentation need to ensure that the correct TSCA certification is filed for each import. And compliance staff need to maintain sufficient records to meet the TSCA's periodic reporting obligations.

For a chemical that is not on the TSCA inventory, a company should first confirm whether any exemptions are available — such as those for low volumes, test marketing, or research and development. Some of these exemptions are self-executing — i.e., no filing with the EPA is necessary — but others require a written submission to claim the exemption.

Companies can often find ways to begin manufacturing or importing under certain exemption on a temporary basis, while a PMN is being reviewed. For any submission to the EPA, an efficient resolution depends heavily on preparing a complete package that anticipates any questions or concerns from the agency staff.

Mitigating Compliance Risk

The Biden administration has signaled a greater interest in environmental enforcement, and the EPA has focused chemical enforcement resources on where there are risks to human

health or the environment.

TSCA civil violations can carry penalties of up to about \$43,000 per day, and the EPA has authority to bar the use of any stocks of chemicals manufactured or imported out of compliance. For imported chemicals, shipments can be seized and held at ports. Any enforcement action by the EPA can also bring potential reputational risk once an enforcement action or settlement is made public.

Companies can take steps to mitigate TSCA compliance risk with two key strategies. First, an internal compliance audit can identify ways to resolve areas of potential noncompliance.

Second, implementing written policies and procedures regarding chemical regulatory compliance is an important measure to promote effective cooperation between different functions within the company. Additionally, for companies looking to invest in or acquire battery manufacturing facilities, special attention should be paid during the diligence process to the status of TSCA compliance.

Where an audit identifies potential noncompliance, the EPA maintains policies that allow for voluntary disclosure of past violations for substantial or complete penalty reductions, depending on the circumstances.

Additionally, the agency has a policy for new owners of facilities with even more favorable terms for disclosure of past violations following soon after a transaction. The voluntary disclosure process can act to provide assurance against a later EPA investigation or enforcement action.

While chemical regulatory compliance will present some challenges to the domestic battery manufacturing industry, appropriate planning can mitigate compliance risks and promote efficient resolutions for submissions to the EPA. Many in the industry welcome the agency's recent effort to expedite reviews for mixed metal oxides, and manufacturers should engage with the agency to make sure the process is effective.

Clarification: This article has been updated to clarify that there were three authors.

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[1] <https://www.epa.gov/newsreleases/epa-announces-innovative-effort-bring-new-chemicals-used-electric-vehicle>.