EPA Announces SNPRM On Strengthening Transparency In Regulatory Science

On March 3, 2020, EPA announced that a supplemental notice of the proposed rulemaking (SNPRM) titled “Strengthening Transparency in Regulatory Science” will be published in the Federal Register in the near future. While the notice would only modify EPA internal procedures, industry stakeholders are asked to comment on the proposed rule during a 30-day period after the date of publication in the Federal Register. The supplemental notice proposes the following changes to the 2018 proposed rulemaking:

- A scope that applies to influential scientific information and significant regulatory decisions;
• A modified approach to the availability provisions for data and models that would underlie influential scientific information and significant regulatory decisions as well as an alternate approach;

• Clarification on the ability of the EPA Administrator to grant exemptions; and

• Definitions and clarifications that the proposed rule applies to data and models underlying both pivotal science and pivotal regulatory science.

These proposed modifications are in response to some of the public comments received by EPA on the 2018 proposed rulemaking. Under the alternate approach to the use of data and models, EPA will also use restricted studies that are not available to the public. The proposal would apply to reviews of data, models, and studies regardless of when the data and models were generated. EPA plans to identify studies that are given greater consideration and provide a short explanation of why greater consideration was given.

EPA is seeking comment on each of the proposed changes. In particular, EPA is asking for feedback on whether this approach may improve consistency between this proposed rulemaking and certain provisions of those statutes that refer to standards for data availability.

EPA’s announcement includes a pre-publication version of the proposed supplemental rulemaking, which can be accessed here. Interested parties may wish to review Bergeson & Campbell, P.C.’s (B&C®) March 9, 2020, memorandum on the SNPRM.

**EPA Publishes Final Rule Establishing CBI Claims Review For TSCA Inventory**

On March 6, 2020, EPA announced via the Federal Register its final rule on requirements for regulated entities to substantiate certain confidential business information (CBI) made under TSCA. The substantiation requirements describe the applicable procedures and provide instructions for regulated entities, providing the review criteria and related procedures that EPA will use to complete the reviews within the five-year time frame set in TSCA. The final rule will be effective on May 5, 2020.

**EPA Announces Latest Update To TSCA Inventory**

On March 11, 2020, EPA announced the availability of the latest TSCA Inventory. EPA states that this biannual update to the public TSCA Inventory is part of its regular posting of non-confidential TSCA Inventory data. According to EPA, this update adds 81 new chemicals, and the Inventory as a whole now contains 86,405 chemicals, of which 41,484 are active in U.S. commerce. Other updates to the TSCA Inventory include:
• Updates to commercial activity data, or active/inactive status;

• Updated regulatory flags, such as consent orders and significant new use rules (SNUR); and

• Additional unique identifiers.

EPA notes that the TSCA inventory is a list of all existing chemical substances manufactured, processed, or imported in the United States that do not qualify for exemption or exclusion under TSCA. More information on the TSCA Inventory is available on EPA’s website.

**EPA Adds Two Microorganisms To List Of Microorganisms Eligible For Exemption From Certain TSCA Reporting Requirements**

On March 10, 2020, EPA announced that it issued a final rule to add two strains of microorganisms to the list of microorganisms eligible for an exemption from certain reporting requirements under the Toxic Substances Control Act (TSCA). EPA states that manufacturers of new intergeneric *Trichoderma reesei* (strain QM6a) and *Bacillus amyloliquefaciens* (subspecies *amyloliquefaciens*) may now be eligible to undergo a streamlined review process under TSCA’s new chemicals review program with reduced TSCA fees. The final rule is intended to ensure the safety of human health and the environment while reducing regulatory burden for the biotechnology industry.

EPA states that after reviewing all relevant health and safety data, it determined that the two microorganisms can be added to the list of microorganisms eligible for exemption. Under TSCA, manufacturers of a new intergeneric microorganism may be eligible to submit an exemption request in lieu of a microbial commercial activity notice (MCAN) if the organism is on the list of species eligible for an exemption and meets other criteria. EPA is including these two microorganisms on the list because it determined that the microorganisms “will not present an unreasonable risk of injury to health or the environment provided that the other criteria relating to the introduced genetic material and the physical containment of the new microorganisms have been met."

According to EPA, both microorganisms have a long history of safe use to produce a variety of commercial enzymes used in industrial and food-related industries. *Trichoderma reesei* is used by the animal feed, baking, beverages, textile processing, detergent, pulp and paper, industrial chemicals, and biofuels industries. *Bacillus amyloliquefaciens* has been used to produce commercial enzymes for more than 50 years. It produces carbohydrases, proteases, nucleases, xylanases, and phosphatases that have applications in the food, brewing, distilling, and textile industries.

The final rule will be effective **April 9, 2020**.
EPA Announces Grant Opportunity Supporting Innovative Solutions For Reducing Pollution, Including In The Chemical Manufacturing, Processing, And Formulation Sector

On March 5, 2020, the U.S. Environmental Protection Agency (EPA) announced that it is seeking grant applications through the Source Reduction Assistance Grant Program from states, federally recognized tribes, universities, local governments, and other groups to support innovative solutions for source reduction or pollution prevention (P2) through research, education, training, or certain other methods. EPA notes that as it highlights chemical safety during the month of March, “these grants support that goal by providing information, training, and tools to improve public health and the surrounding environment, reduce pollutants, and decrease resource use (e.g., water and energy).” EPA anticipates awarding individual grants in the range of $20,000 - $200,000 for a two-year funding period (or between $10,000 and $100,000 per year), though award amounts may vary based on EPA region. EPA anticipates awarding 20 grants in total. EPA states that grant applications should focus on at least one of the following P2 priority areas, also referred to as National Emphasis Areas (NEA) that support several of the EPA’s Smart Sectors. Through these grants, technical assistance and projects should encourage businesses to identify, develop, and adopt P2 practices and reduce waste in the following sectors:

- Food and Beverage Manufacturing and Processing (NEA #1);
- Chemical Manufacturing, Processing, and Formulation (NEA #2);
- Automotive Manufacturing and Maintenance (NEA #3);
- Aerospace Product and Parts Manufacturing and Maintenance (NEA #4); and
- Metal Manufacturing and Fabrication (NEA #5).

Proposals are due by **April 30, 2020**. Additional information is available on [www.grants.gov](http://www.grants.gov), under Funding Opportunity Announcement EPA-HQ-OPPT-2020-002.

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