"New" Microorganisms Subject to the Toxic Substances Control Act (TSCA) - Section 5

New Microorganism = "intergeneric"

- Microorganism formed by the deliberate combination of genetic material from organisms classified in different taxonomic genera
- Microorganism constructed with synthetic genes that are not identical to genetic material that would be derived from the same genus as the recipient
  - Not on the TSCA Inventory of Chemical Substances
  - Used in TSCA applications

Microorganisms Excluded from TSCA Reporting Requirements

- Naturally occurring microorganisms – implicitly listed on the TSCA Inventory
- Intrageneric – those formed by the introduction of genetic material from organisms within the same genus
- Those containing only well-characterized, non-coding regulatory sequences

Submissions – Reporting Mechanisms

Microbial Commercial Activity Notice (MCAN)

- Any manufacturer, importer, or processor must file an MCAN at least 90 days prior to initiating manufacture/import (unless eligible for an exemption)

TSCA Experimental Release Application (TERA)

- Persons who wish to introduce a new microorganism into the environment, including those at the R&D stage if deemed commercial R&D, must submit a TERA 60 days prior to initiation of the field test
    - Commercial R&D means that the activities are conducted with the purpose of obtaining an immediate or eventual commercial advantage

Risk Assessment

Risk = Hazard x Exposure

- **Taxonomic Identification Report**
- **Genetic Construction Report – product characterization/ genetic construction process**
- **Human Health Hazard Assessment * – pathogenicity/toxicity and allergenicity including to potentially exposed or susceptible subpopulations**
- **Ecological Hazard Assessment * – animal & plant pathogenicity, ecological interactions**
- **Construct Hazard Analysis – potential hazards of inserted genes, potential for horizontal gene transfer (HGT)**
- **Engineering Report – use, worker exposure, production volume, releases to the environment**
- **Exposure Assessment – consumer, general population, and environmental exposures**

* largely based on information available on the recipient microorganism with an evaluation of how the genetic modifications affect the characteristics/behavior of the microorganism