

S6T2**Achieving Regulatory Approval for Microbial Inoculants or Soil Additives**

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Abstract

Modern genetic technologies have led to increased interest in developing microbial products to improve plant growth or crop yield, including efforts to enhance nitrogen fixation or uptake of other nutrients, or to generally enhance the phytobiomes of important crop species. Those products utilizing genetically modified microorganisms may face regulatory barriers in many countries of the world; and in the U.S., those products not meeting the definition of pesticides might be regulated by the Environmental Protection Agency under its biotechnology regulations under the Toxic Substances Control Act (TSCA). Under these regulations, such products might require agency approval not only for commercial sale, but also prior to any outdoor field testing. Although projects involving the outdoor uses of modified microorganisms will trigger enhanced regulatory scrutiny, it is possible to obtain such approvals through proper planning. This presentation will review the regulations of the U.S. and other countries that would govern development of enhanced microbial inoculants and soil additives, it will discuss applicable precedents of successful approvals, and will present strategies for obtaining needed regulatory clearances for new inoculant or soil additive products.

