



2nd Public Meeting

EPA's Draft Algae Guidance for the Preparation of TSCA Biotechnology Submissions

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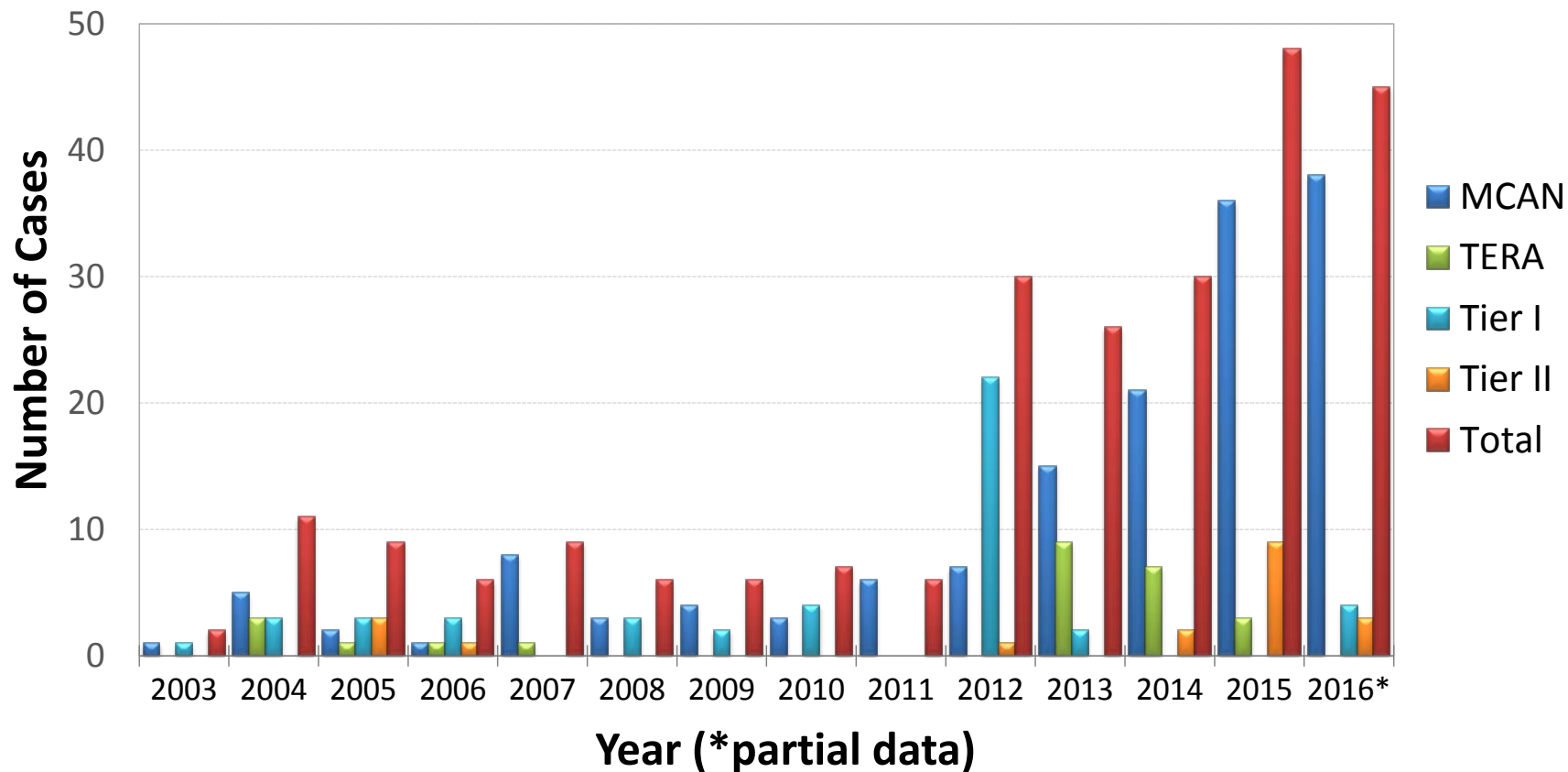


Statutory Authority

- **The US EPA Office of Pollution Prevention and Toxics (OPPT) implements microorganisms regulations under Section 5 of the Toxic Substances Control Act (TSCA)**
 - **Enacted in 1976, and amended in 2016**
 - **For regulating certain new (i.e., intergeneric) genetically engineered microorganisms (GEMs)**
- **TSCA regulates the manufacture, import, processing, distribution in commerce, use and disposal of new GEMs for commercial purposes.**
- **Manufacturers are required to report certain information to EPA within 90 days before commencing the manufacture of GEMs**



Biotech Submissions





1st Public Meeting: Background

- EPA needed to know what science questions to be asked regarding pre-commercialization submissions for GE algae
- 1st “Workshop for Public Input and Considerations for Risk Assessments of Genetically Engineered Algae”
 - Hosted on September 30, 2015 in Washington DC
 - Employed a transparent process to gather information from stakeholders
 - Well-attended
 - Published a final summary report on December 21, 2015
- Comments received during the workshop/docket as well as public input were considered in developing the “Draft Algae Guidance”
 - A supplement to the current “Points to Consider” Guidance Document





2nd Public Meeting: Purpose

- Stakeholders have a desire to understand EPA's need for data and information to enable robust review of biotechnology submissions
 - *Genetically engineered (GE) algae and cyanobacteria that are subject to TSCA oversight*
- The public needs to be confident that EPA is using appropriate data and information resources during the course of risk assessments
- This public meeting provides a forum to engage relevant stakeholders and to receive public input and comments on the "Draft Algae Guidance"



2nd Public Meeting: An Overview

- **Dr. Carolina Penalva-Arana: “Risk Assessment of Biotechnology Products Under TSCA”**
 - Overview of TSCA/Coordinated Framework
 - Biotechnology Program under TSCA
 - Review of Risk Assessment Framework
- **Dr. Gwen McClung: “Draft Algae Guidance for the Preparation of TSCA Biotechnology Submissions”**
 - An update to the 1997 “Points to Consider” guidance document addressing GE algae
 - Public input and comments during this meeting/until Nov 30, 2016
- **Dr. Mark Segal: Public input/discussions during three sessions using charge questions:**
 - Ecological Effects of GE Algae
 - General Charge Questions
 - Draft Algae Guidance
- **Closing Remarks**



Acknowledgements

- **Organizers of the Algae Biomass Summit**
- **Arizona State University**
- **Attendees in-person/via webinar**
- **EPA Panel Members for the Public Meeting**
- **EPA Biotechnology Technical Team**
- **Eastern Research Group, Inc./Battelle**