RISK ASSESSMENT OF BIOTECHNOLOGY PRODUCTS UNDER TSCA

CAROLINA PEÑALVA-ARANA, PHD

RISK ASSESSMENT DIVISION
OFFICE OF POLLUTION PREVENTION AND TOXICS
U.S. ENVIRONMENTAL PROTECTION AGENCY

PURPOSE OF PRESENTATION

- Overview of TSCA & Coordinated Framework
- Overview of the Biotechnology Program under TSCA
- Review the Risk Assessment Framework

TOXIC SUBSTANCES CONTROL ACT (TSCA)
AND
THE COORDINATED FRAMEWORK

TOXIC SUBSTANCES CONTROL ACT (TSCA)

- Enacted in 1976
- Amended by Frank R. Lautenberg Chemical Safety for the 21st Century Act, 6/22/16
- Under TSCA, EPA has authority to regulate the manufacture, use, distribution in commerce, and disposal of chemical substances and mixtures
- Covers chemical substances (industrial, environmental, or consumer products) not specifically excluded

FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

- This Act is an amendment to TSCA - signed on June 22, 2016
- It requires EPA to make an affirmative finding that addresses whether or not the substance (microorganism) is likely to present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation
- This determination must be made without consideration of costs or other non-risk factors

POSSIBLE DETERMINATIONS UNDER TSCA

- The microorganism [significant new use] presents an unreasonable risk;
- The information available is insufficient;
- The microorganism [significant new use] may present an unreasonable risk;
- The microorganism [significant new use] may have substantial or significant environmental release or human exposure; or
- The microorganism [significant new use] is not likely to present an unreasonable risk

TSCA AND THE COORDINATED FRAMEWORK

- In 1986 EPA issued a final policy statement as part of the Federal "Coordinated Framework for the Regulation of Biotechnology" (OSTP)
  - Confirmed TSCA oversight and gap-filling function
  - Formed the basis of the final TSCA biotechnology rule: Microbial Products of Biotechnology, 1997 (40 CFR Parts 700, 720, 721, 723, and 725)
- The Update to the Coordinated Framework (September 2016) clarifies roles and responsibilities of lead agencies

https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_coordinated_framework.pdf

BIOTECHNOLOGY PROGRAM UNDER TSCA

1997's MICROBIAL PRODUCTS OF BIOTECHNOLOGY RULE

- Rule retained EPA's interpretation of "new" (intergeneric) microorganisms as stated in the 1986 Coordinated Framework Policy Statement
- Rule established mechanisms for reporting to EPA, including a number of specific exemptions
- For clarity, EPA consolidated all requirements and procedures into one part of the CFR (40 CFR 725)
- Applies to "new" microorganisms that are manufactured, imported, or processed for commercial activities, including R&D activities

“NEW” MICROORGANISMS UNDER TSCA SECTION 5

“New” microorganisms are:

- Formed through the deliberate combination of genetic material from organisms classified in different taxonomic genera (intergeneric), or;
- Constructed with synthetic genes that are not identical to DNA derived from the same genus as the recipient cell, and;
- Used in TSCA applications

TSCA APPLICATIONS: EXAMPLES & EXCLUSIONS

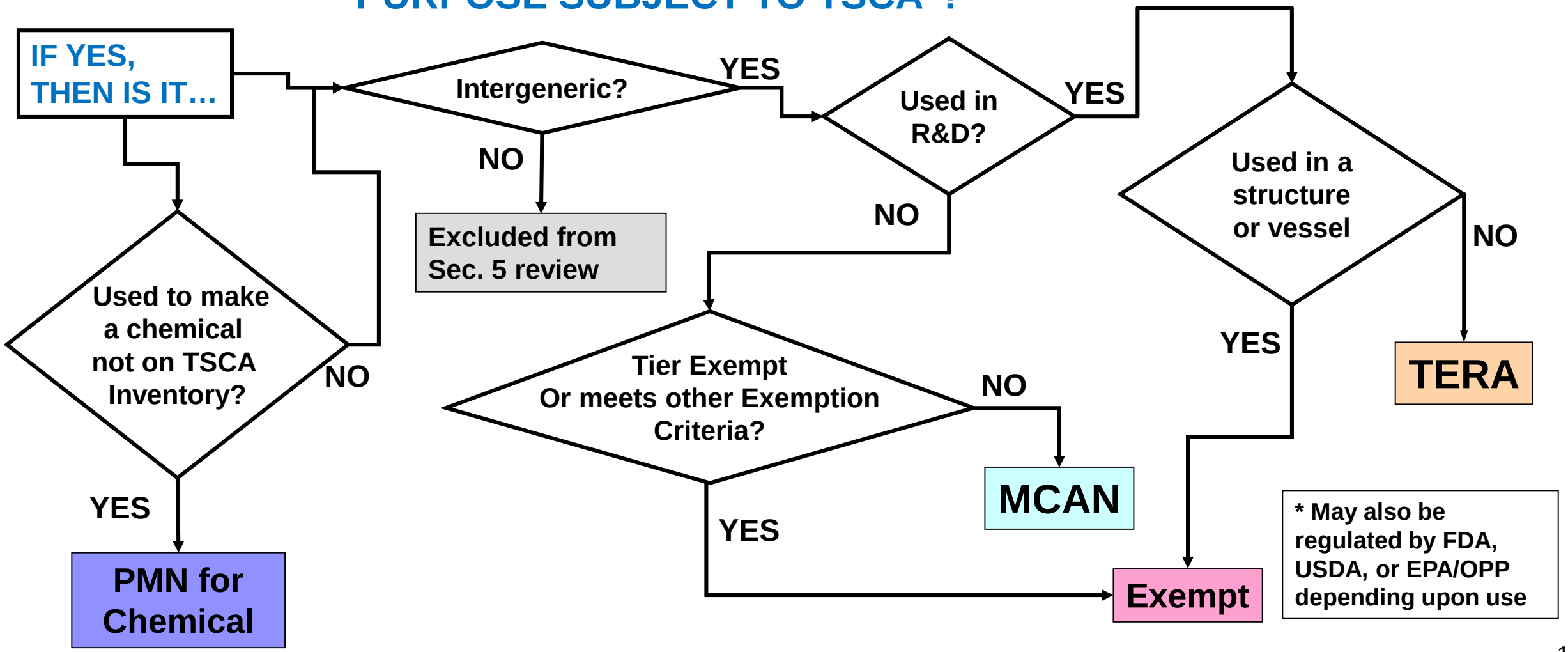
REGULATED USES
Biomass conversion for chemical production
Microbial fuel cells
Mining and resource extraction
Building materials
Waste remediation and pollution control
Non-pesticidal agriculture
Weather and climate modification
Other

EXCLUSIONS
Food and food additives
Drugs
Cosmetics
Medical Devices
Pesticides (but not intermediates)
Tobacco
Nuclear materials
Firearms

MECHANISMS FOR REPORTING TO EPA

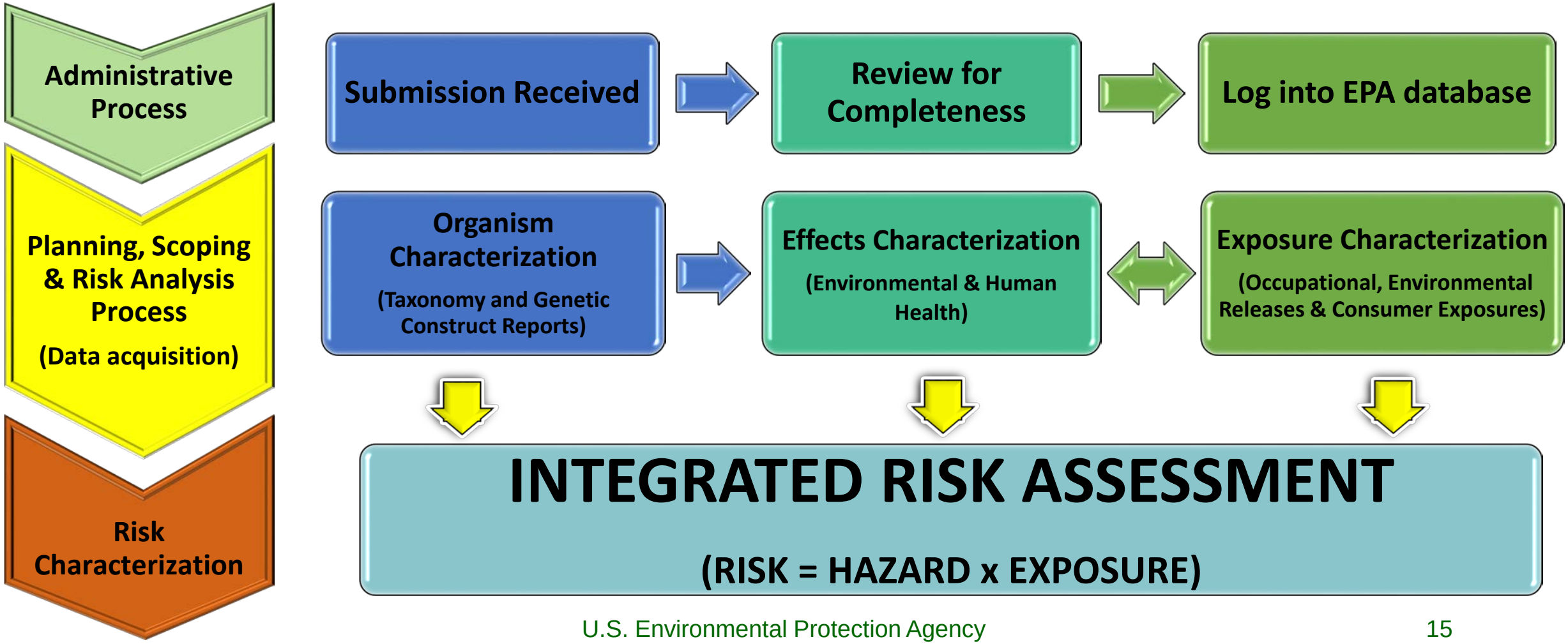
- MCAN - Any manufacturer, importer, or processor must file a *Microbial Commercial Activity Notice* (MCAN) 90 days prior to initiating manufacture/import (unless the activity is eligible for an exemption)
- TERA - Persons who wish to introduce a new microorganism into the environment for commercial R&D purposes must submit a *TSCA Experimental Release Application* (TERA) 60 days prior to initiation of the field test
- Tier I and Tier II Exemptions - Exemptions from MCAN filing are available for closed system commercial activities utilizing approved recipient organisms (40 CFR 725.420), meeting certain criteria for the introduced genetic material, and specific containment/control technologies

IS THE MICROORGANISM USED FOR A COMMERCIAL PURPOSE SUBJECT TO TSCA*?



RISK ASSESSMENT FRAMEWORK

RISK ASSESSMENT FRAMEWORK



PARTS OF A BIOTECH RISK ASSESSMENT

- Microbial Identification Report - (verifies taxa of donor and recipient organisms)
- Genetic Construction Report - (product characterization, genetic modifications)
- Construct Hazard Analysis - (hazards posed by of the genetic modifications and potential for horizontal gene transfer)
- Exposure Report - (environmental, general population, and consumer exposures, including potentially exposed and susceptible subpopulations)
- Engineering Report - (worker exposure, releases from facility)
- Human Health Hazard Assessment
- Ecological Hazard Assessment

INTEGRATED RISK ASSESSMENT

- A final Risk Assessment makes a qualitative risk call based on any Hazard and Exposure(s) detected
  - It considers the potential risk posed to the environment, workers and the general public, including susceptible subpopulations
  - It also takes into consideration any other potential uses of the regulated product

AVAILABLE RESOURCES

EPA strongly encourages companies at any stage of production to contact the agency for a Pre-Notice Consultation

- **For more information on the regulatory determinations for microorganisms**
  https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-pre-manufacture-notice-review
- **Draft Algae Guidance and information on submitting comments**
  https://projects.erg.com/conferences/oppt/workshophome.htm
- **Biotechnology Resources**
  http://www2.epa.gov/regulation-biotechnology-under-tsca-and-fifra
- **Overview of Biotechnology under TSCA**
  http://www2.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-biotechnology-under-tsca