BERGESON & CAMPBELL PC

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Key Federal Chemical Use Laws

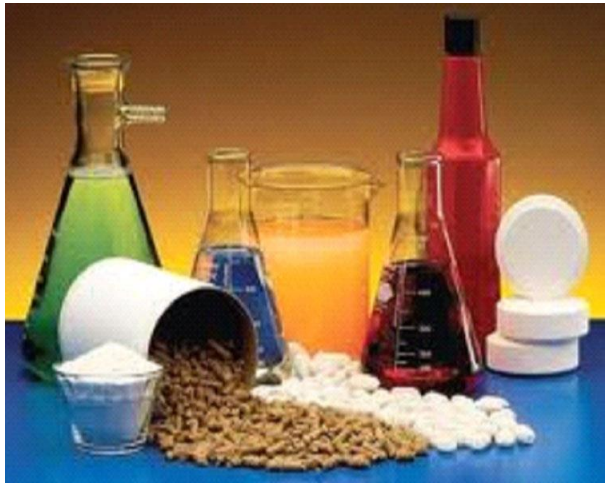
- Toxic Substances Control Act (TSCA)
  - Regulation of industrial chemicals

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Regulation of pesticides (agricultural chemicals, biocides)

Other Consumer Product Regulations

- Federal Hazardous Substances Act (FHSA)
- Consumer Product Safety Improvement Act (CPSIA)
- Federal Trade Commission (FTC) Green Guides
- California Safer Consumer Product Regulations (SCPR)
- State Consumer Protection Laws

TSCA



Overview

- Passed in 1976 following several years of debate and revisions
- Almost four decades passed without substantive amendment
- Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted on June 22, 2016 (Pub. L. No. 114-182)

Overview

- TSCA provides a chemical safety net
- TSCA is one of several statutes that regulate chemicals
- TSCA's unique focus is on industrial chemicals in commerce
- New TSCA dramatically changes how industrial chemicals are introduced and regulated in the U.S.

Purposes

- To encourage or require industry to develop adequate information on the human health and environmental effects of chemicals
- To regulate chemicals and mixtures that may present unreasonable risk of injury to health or the environment under intended conditions of use, and to take action against imminent hazards
- No regulation should unduly impede or create unnecessary economic barriers to technological innovation

Key Sections of TSCA

- Section 4 – Testing of Chemical Substances and Mixtures
- Section 5 – Manufacturing and Processing Notices (New Chemicals)
- Section 6 – Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures (Existing Chemicals)
- Section 8 -- Reporting and Retention of Information
- Section 9 -- Relationship to Other Federal Laws
- Section 14 -- Confidential Information
- Section 26 -- Administration of the Act

Definitions

- "Chemical substance" covers industrial chemicals and excludes pesticides, food additives, drugs, cosmetics, and preparations



- Regulates both manufacturers and processors (including importers)
- Distinguishes "new" from "existing" substances
  - A new chemical substance is "any chemical substance which is not included in the chemical substance list compiled and published under [TSCA Section 8(b)]"
  - TSCA Inventory is a list of all chemical substances in commerce prior to 1979 and those that have been commercialized since (about 86,000 chemicals)

Major Changes Over Current Law

- Mandatory duty on the U.S. Environmental Protection Agency (EPA) to evaluate existing chemicals with clear and enforceable deadlines
  - *Old TSCA -- No duty to review; no deadlines for action*
- Chemicals assessed against a risk-based safety standard with no consideration of nonrisk factors
  - *Old TSCA -- Risk-benefit balancing standard*
- Unreasonable risks identified in the risk evaluation must be eliminated
  - *Old TSCA -- Significant risks might not be addressed due to cost/benefit balancing and no mandate to act*
- Expanded authority to compel development of chemical information when needed by order, rule, or consent agreement
  - *Old TSCA -- Required lengthy rulemaking*

Major Changes Over Current Law

- Requires EPA to make an affirmative determination on new chemicals before entry into the marketplace
  - *Old TSCA -- New chemicals enter the market in the absence of EPA action*
- Requires substantiation of certain confidential business information (CBI) claims
  - *Old TSCA -- No statutory substantiation requirements for CBI claims*
- New funding source (up to $25 million total in annual user fees plus costs for manufacturer-requested risk evaluations), to be supplemented by Congressional appropriations
  - *Old TSCA -- Cap on individual user fees at $2,500 and limited fee collection authority*

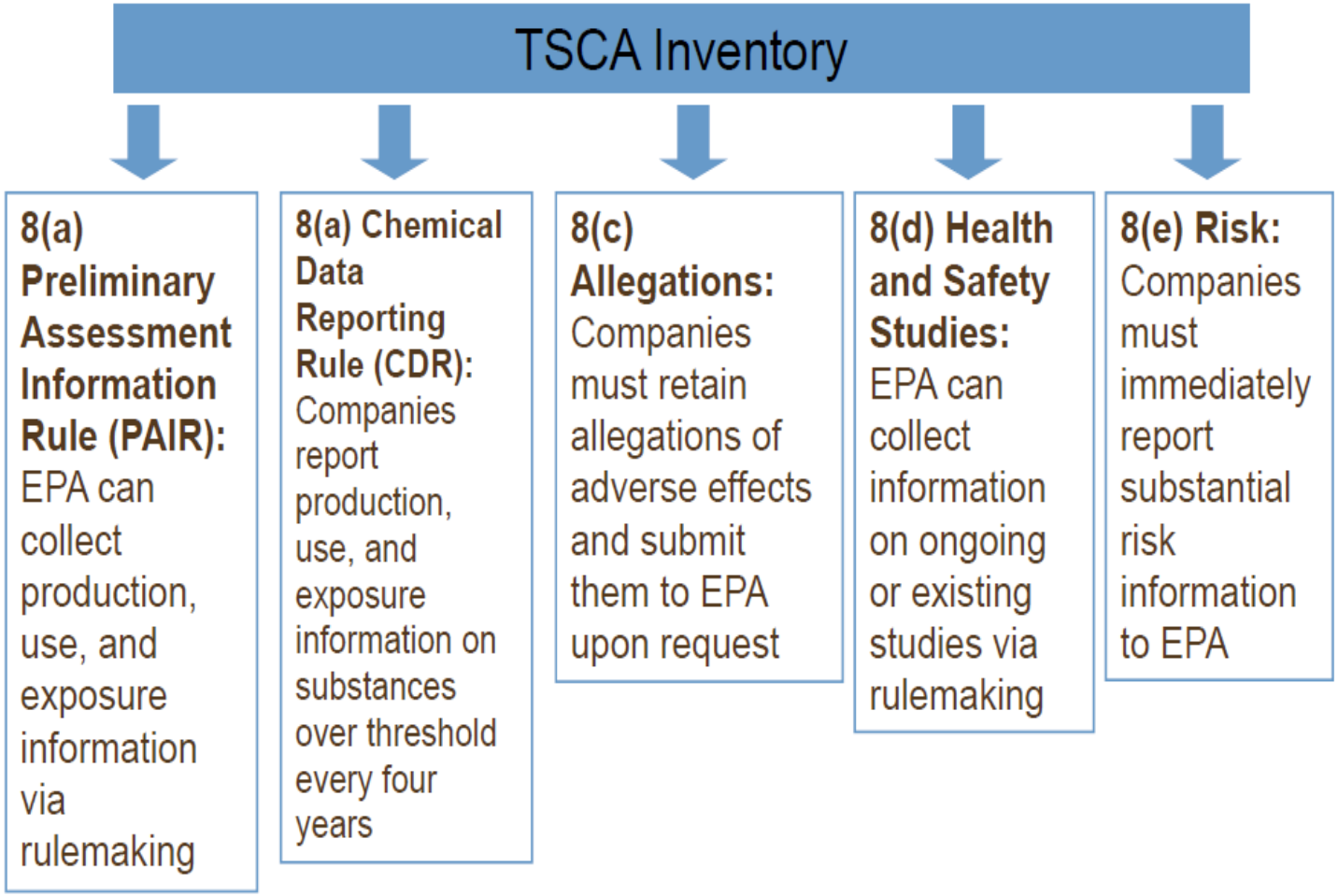
Section 8 -- Information Gathering

- Authorizes EPA to require chemical manufacturers and processors to maintain records and report data to EPA -- established through rulemaking (small manufacturers exempt)
  - Chemical identity, use categories, health and environmental information, people exposed
  - Chemical Data Reporting (CDR) rule -- Requires manufacturers of non-polymeric chemicals over 25,000 pounds listed on Inventory every four years to report current data on production use, exposure, and related information (2,500 pounds if subject to certain restrictions)

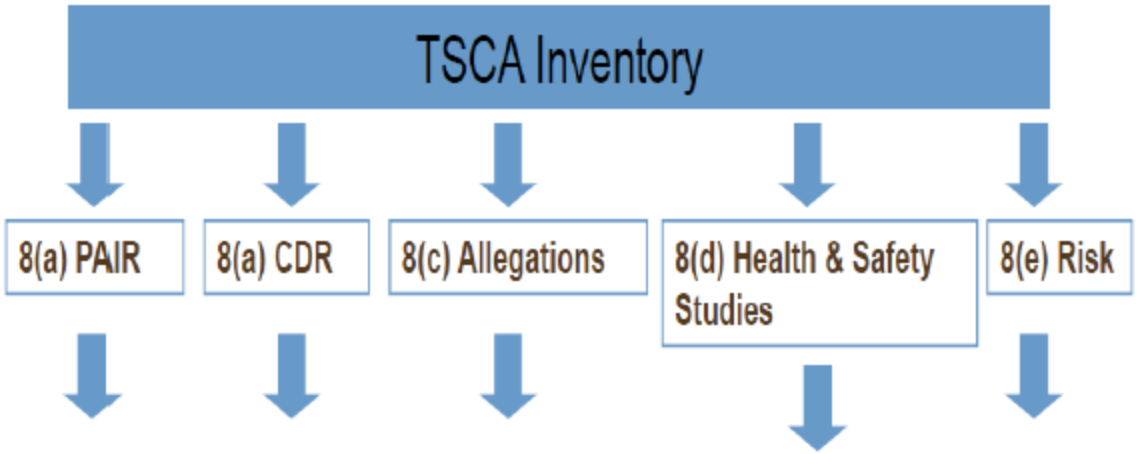
Section 8 -- Information Gathering

- Requirement that companies immediately notify EPA of substantial risk information
- Requirement that companies record and retain "allegations" of adverse effects and submit them to EPA upon request
- EPA can require companies to submit information on ongoing or existing health and safety studies

Information Collection on Existing Chemicals



Testing on Existing Chemicals

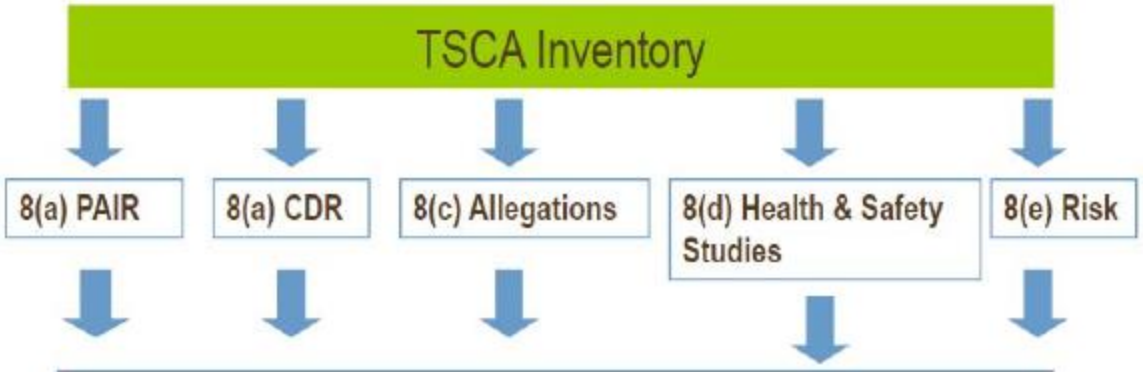


If available information is not sufficient or raises concerns, Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemaking to require the development of information

Testing on Existing Chemicals

- New TSCA expands EPA's authority to require development of information
  - Authorizes administrative orders and consent agreements in addition to rulemakings
  - Permits EPA to require testing needed for prioritization
  - New authority does not require EPA findings
  - May not be used to establish "a minimum information requirement of broader applicability"
- New Section 4(h) concerns vertebrate animal testing and requires EPA to:
  - Reduce and replace such testing to the extent practicable, scientifically justified, and consistent with policies of diminished animal testing
  - Develop, within two years of enactment, and implement a strategic plan to promote alternative test methods

Risk Management on Existing Chemicals



Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemakings

If concerns continue after testing and information collection: Section 6 authorizes EPA to address unreasonable risk through restrictions, warning labels, recordkeeping, and product bans

Specific Requirements -- Existing Chemicals

- New TSCA -- Prioritizing Chemicals for Assessment
  - Establish a risk-based process to identify “high” and “low” priority substances
  - High-priority -- The chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations
  - Low-priority -- The chemical use does not meet the standard for high-priority
- Procedural rule issued on June 22, 2017, established a process for prioritizing chemicals

Specific Requirements -- Existing Chemicals

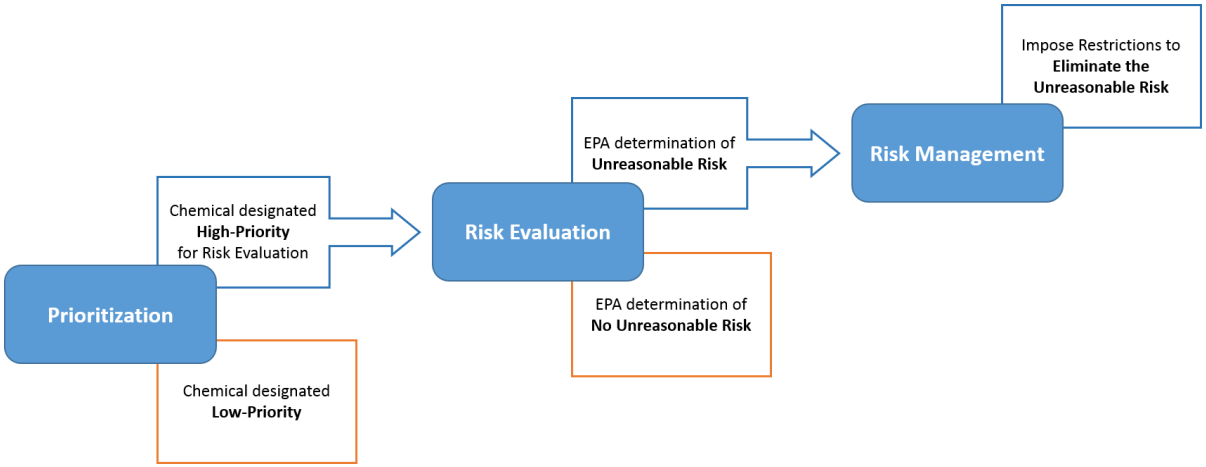
- Initial Set of Risk Evaluations from Work Plan Chemical Assessments
  - EPA identified a list of ten TSCA Work Plan chemicals and formally initiated risk evaluations last December
  - Scope of each assessment was released on June 22, 2017

Specific Requirements -- Existing Chemicals

- Risk-Based Safety Standard
  - Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an “unreasonable risk”
  - The risk determination is to be made without consideration of costs or other nonrisk factors
  - Risks to susceptible and highly exposed populations must be considered
- EPA must take risk management action to address unreasonable risks
  - Costs and availability of alternatives to be considered when selecting among risk management options
  - Exemption process for critical uses
  - Risk management actions must be promulgated within two years of completing risk evaluation, with extension of up to two additional years

Specific Requirements -- Existing Chemicals

- EPA issued Final Risk Evaluation Process Rule on June 22, 2017



Specific Requirements -- Existing Chemicals

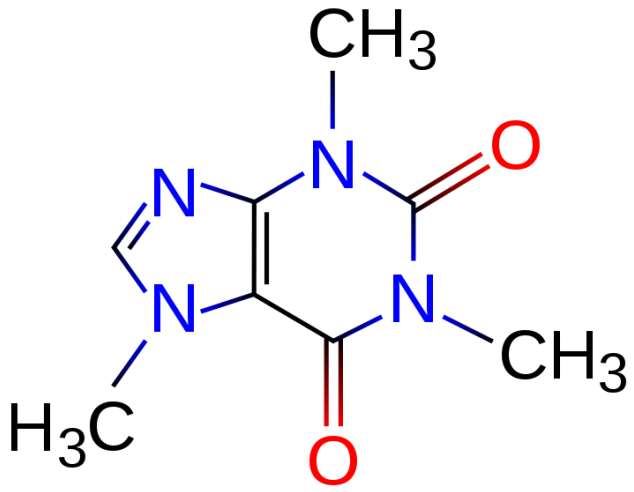
- Persistent, Bioaccumulative, and Toxic Chemicals (PBT)
  - The new law establishes fast-track process to address certain PBT chemicals already on TSCA Work Plan
  - No risk evaluation; only a use and exposure assessment
  - Rules to reduce exposure to the extent practicable must be proposed within three years of enactment and issued in final 18 months later, unless a manufacturer requested a risk evaluation by September 22, 2016
  - Additional requirements encourage prioritization of PBTs in overall risk evaluation process

Specific Requirements -- Existing Chemicals

- TSCA Inventory
  - Requires industry to report on the chemicals they manufactured or processed in the previous ten years to determine if chemicals are currently "active" in the marketplace
  - The chemicals on the TSCA Inventory will not change
  - Chemicals will be designated as "active" or "inactive"
  - Only "active" chemicals may be prioritized
  - No premanufacture notification (PMN) required to move from "inactive" to "active"
- Final Inventory Notification rule issued on June 22, 2017

Section 5 -- New Chemical Review

- Company submits PMN
  - Chemical identity information
  - Production volume
  - Intended categories of use
  - Description of byproducts
  - Molecular formula
  - Available information



- EPA conducts initial review
- EPA develops hazard profile
  - Structure Activity Team (SAT) uses analogs

Section 5 -- New Chemical Review

- Evaluates health effects, environmental effects, environmental fate
- Establishes health and environmental hazard potential

- EPA develops Exposure/Release Profile
- EPA holds Focus Meeting -- drop or full review
- *Prior bullets = "old" EPA new chemical review process. Mandate for affirmative finding has adjusted process and outcomes*

New Chemicals/Significant New Uses

- Retains certain basic requirements for new chemicals (NC) and significant new uses (SNU)
  - 90-day review period, extensions permitted
- Requires EPA determination on all notices
- Three alternative determinations:
  1. NC/SNU *presents* an unreasonable risk
  2. Available information is *insufficient* **or** NC/SNU *may present* unreasonable risk **or** NC/SNU chemical has *substantial production and exposure*, or
  3. NC/SNU *not likely* to present unreasonable risk

New Chemicals/Significant New Uses

- EPA required to regulate under determinations 1 and 2
- EPA has limited ability to regulate articles/category of articles compared to prior TSCA, but requires EPA also to apply a SNU rule (SNUR) under determinations 1 and 2 or "make public" a statement explaining its findings
- Under determination 3, the submitter can begin to commercialize immediately, and EPA will later publish in the *Federal Register* a notice that the chemical is most likely to pose an unreasonable risk

FIFRA

FIFRA

- Who Implements the Program?
  - EPA
    - Office of Pesticide Programs (OPP)
      - Antimicrobials Division (AD)
      - Biological and Economic Analysis Division (BEAD)
      - Biopesticides and Pollution Prevention Division (BPPD)
      - Environmental Fate and Effects Division (EFED)
      - Field and External Affairs Division (FEAD)
      - Health Effects Division (HED)
      - Information Technology and Resources Management Division
      - Pesticide Re-Evaluation Division
      - Registration Division

FIFRA

- Where a state has a federally-approved pesticide program, the state is the primary enforcement authority
- Several states have developed separate state programs that are quite mature and pose formidable market entry challenges -- California, New York, Florida

California Environmental Protection Agency
dpr Department of Pesticide Regulation

DEPARTMENT OF ENVIRONMENTAL CONSERVATION • NEW YORK STATE •

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES EST. 1868

What Is a Pesticide?

- Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest
- A substance is considered to be intended for a pesticidal purpose requiring registration if the person who distributes or sells the substance claims, states, or implies that the substance can or should be used as a pesticide

Regulatory Scope

- Active Ingredients
  - Ingredients that prevent, destroy, repel, or mitigate pests
  - Plant regulators, defoliants, desiccants, and nitrogen stabilizers
- Inert Ingredients
  - “Other ingredients” in pesticide formulations
- Pesticide Types
  - Conventional pesticides
  - Minimum-risk pesticides
  - Biopesticides
  - Antimicrobials
  - Treated articles

Regulatory Framework

- Premarket Approval
- Risk-Based Safety Standard
  - No unreasonable risk (non-food uses)
  - Reasonable certainty of no harm (food uses)
- Burden on registrant to meet safety standard
- Unlike TSCA, FIFRA is “use” specific, not “chemical” specific

Regulatory Framework

- EPA reviews registrant-submitted data against applicable standard
- Data requirements codified at 40 C.F.R. Part 158
  - Battery of testing requirements
  - EPA has authority to require additional data
  - EPA discretion to waive data requirement
- Data development can cost millions and it can take years before an application can be submitted to EPA

Regulatory Framework

- Protections for trade secrets and CBI
- EPA has adopted a narrow interpretation of protected information; enhanced transparency
- Compensation provisions for third-party use of proprietary data

Regulatory Framework

ATTENTION:
This specimen label is provided for general information only.

RESTRICTED USE PESTICIDE

BULLET
Herbicide by Monsanto

Complete Directions For Use

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

Keep out of reach of children.

CAUTION!

- Mandatory Label Requirements
  - Ingredients
  - Approved claims
  - Use directions
  - Warning statements
  - Registrant information
- Use inconsistent with label prohibited
- Labeling covers all written materials (and then some)

Regulatory Framework

- New Actives/Products/Uses
  - Review timeframes established by statute (Pesticide Registration Improvement Extension Act (PRIA 3))
  - Four months to 24 months review standard, but can be longer
- Existing Actives/Products/Uses
  - Review older pesticides against current health standards
  - This review typically yields label amendments, use restrictions, or other legal redress (cancellation)

Regulatory Framework

- Promote “Safer” or “Reduced-Risk” Pesticide Alternatives
  - Reduced fees
  - Expedited reviews
  - Dedicated resources

- Various Programs to Register Reduced-Risk Pesticides
  - Minimum-risk pesticides
  - Reduced-risk conventional pesticides
  - Biopesticides

Enforcement Framework

- Restrict Future Sale of Products
- Stop Sale, Use, or Removal Orders (SSURO)
- Civil Penalties
- Criminal Penalties

Current FIFRA Issues

- Endangered Species Act (ESA)
  - ESA litigation ongoing since 2001
  - Litigation resulted in long list of promised consultations with Services (U.S. Fish and Wildlife Service (FWS)/National Marine Fisheries Service (NMFS))
  - Species review by EPA delaying registration decisions
  - Consultation process unsustainable
  - December 2017 Biological Opinions released by NMFS; comment period ended July 23, 2018
  - January 31, 2018, Memorandum of Agreement between EPA, U.S. Department of Interior (including FWS), and U.S. Department of Commerce (including NMFS) regarding process improvements
- PRIA Reauthorization?

Thank You

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