TSCA in 2017
What You Need to Know

Society for Chemical Hazard Communication – Fall Meeting

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TSCA Reform Overview

- The Toxic Substances Control Act (TSCA) regulates the manufacture, import and use of chemical substances in the US
- On June 22, 2016 "The Frank R. Lautenberg Chemical Safety for the 21st Century Act" (LCSA) became effective; the new law makes several changes impacting companies that manufacture, import or process chemical substances in the US
  - Review of existing chemicals
  - New chemicals review
  - Testing
  - Confidentiality claims
  - Fees
  - Relationship to other US federal and state laws
- Will look at the key changes and their implementation status

TSCA Reform Overview

- LCSA made changes to the implementation of the TSCA standard that "such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment"
- The regulatory threshold includes consideration of whether the chemical's conditions of use would attain the safety standard
- The threshold explicitly includes potentially exposed or susceptible populations in evaluating risks
  - Infants, children, pregnant women, workers and the elderly
- EPA is prohibited from considering cost and other non-risk factors in determining if a substance creates an unreasonable risk
- Impacts the evaluation of existing substances and new substances.
- Provides risk management tools

TSCA Reform Overview

- If EPA determines there is an unreasonable risk, it must issue a risk management rule
- Options range from labeling and notification to a ban
- In choosing regulatory options EPA must consider the effects of a chemical on health and the environment, the chemical's benefits, and economic consequences of the regulation including effects on the national economy, small business, and technology innovation
- When deciding whether to ban or restrict a chemical, EPA must consider the availability of feasible alternatives
- Articles may be restricted only to the extent necessary to address risk from exposure to that article
- Critical uses of a chemical may be exempt from restriction if there is no safer alternative, the restriction would disrupt the economy, national security or critical infrastructure, or the chemical provides a substantial benefit to health, safety, or the environment

Overview-Timing

- For existing substances:
  - EPA must initiate risk evaluations of at least 20 “high priority” chemicals within 3.5 years after enactment
  - The Agency will need to designate at least 20 chemicals as “low priority” within 3.5 years of enactment
  - Each risk evaluation is to be completed within three years of initiation, with a potential extension of an additional six months
  - Manufacturers and processors can request EPA prioritize specific chemicals for an evaluation, subject to the payment of fees
  - EPA is required to initiate risk evaluations of at least 10 chemicals included in the 2014 Update of the TSCA Work Plan within 180 days of enactment
- For new substances
  - changes effective on enactment
  - All ongoing PMN reviews were reset on June 22, 2016
- Confidential Business Information
  - Changes effective on enactment

Existing Chemicals: Inventory Reset

- Under LCSA, EPA must screen existing chemicals to determine which are still "active" and warrant additional review and regulation
  - Currently approximately 85,000 chemicals on the TSCA Inventory, but likely far fewer actively in commerce in 2017

PMNACC_072016

ID	NO	AN	GN	FL
1	P000005	232689	Polymeric MDI based polyurethane (PRO\	P; S
2	P000006	278489	Polymeric MDI based polyurethane (PRO\	P; S
3	P000008	164331	Emulsion polymer (PROVISIONAL)	P; XU
4	P000009	257944	Copolymer of acrylic esters, acrylic acid a	P; XU
5	P000010	155421	Polyurethane (PROVISIONAL)	P; XU
6	P000012	238676	Reaction product of cashew nutshell liqui	P
7	P000015	245502	Polyoxyalkylene polyester urethane block	P; XU
8	P000024	260470	Aluminum alkylamide (PROVISIONAL)	P
9	P000028	173354	Acrylic copolymer (PROVISIONAL)	P; XU
10	P000030	235279	Modified polyacrylate (PROVISIONAL)	P; XU
11	P000035	250396	Isocyanate-terminated polyurethane prej	P; XU
12	P000038	245411	Urethane acrylate (PROVISIONAL)	P; XU
13	P000042	242490	N-Alkyl-4-alkylaminonaphthalene (PROVI	P

Final Rule on TCSA Inventory Reset

- LCSA gave EPA one year to issue a rule requiring manufacturers, and potentially processors, to identify all chemicals they are currently manufacturing/importing into the US, so that EPA can "reset" the inventory and review only substances that are currently in commerce
- EPA issued a final Inventory Reset Rule on June 22, 2017
- The rule establishes both "retrospective" and "forward-looking" reporting requirements
- EPA made several changes in response to comments on the proposal:
  - Expanded retrospective reporting exemptions
  - Removed requirements to report commercial activity type and date range
  - Added a 90-day transition period before a substance is designated inactive
  - Extended the optional reporting period for processors to 420 days

LCSA Inventory Reset Rule

10-Year Look-Back:

- The rule requires a retrospective electronic notification for chemical substances on the TSCA Inventory that were manufactured (including imported) for nonexempt commercial purposes **between June 2006 and June 2016**
  - If EPA receives notice: Chemical designated active
  - If EPA does not receive notice: Chemical designated inactive
- Manufacturers have **180 days from publication in Federal Register** to submit notice: **February 7, 2018**
- **Chemicals reported under 2012 or 2016 Chemical Data Reporting (CDR) cycles are exempt from retrospective notice requirement**

LCSA Inventory Reset Rule

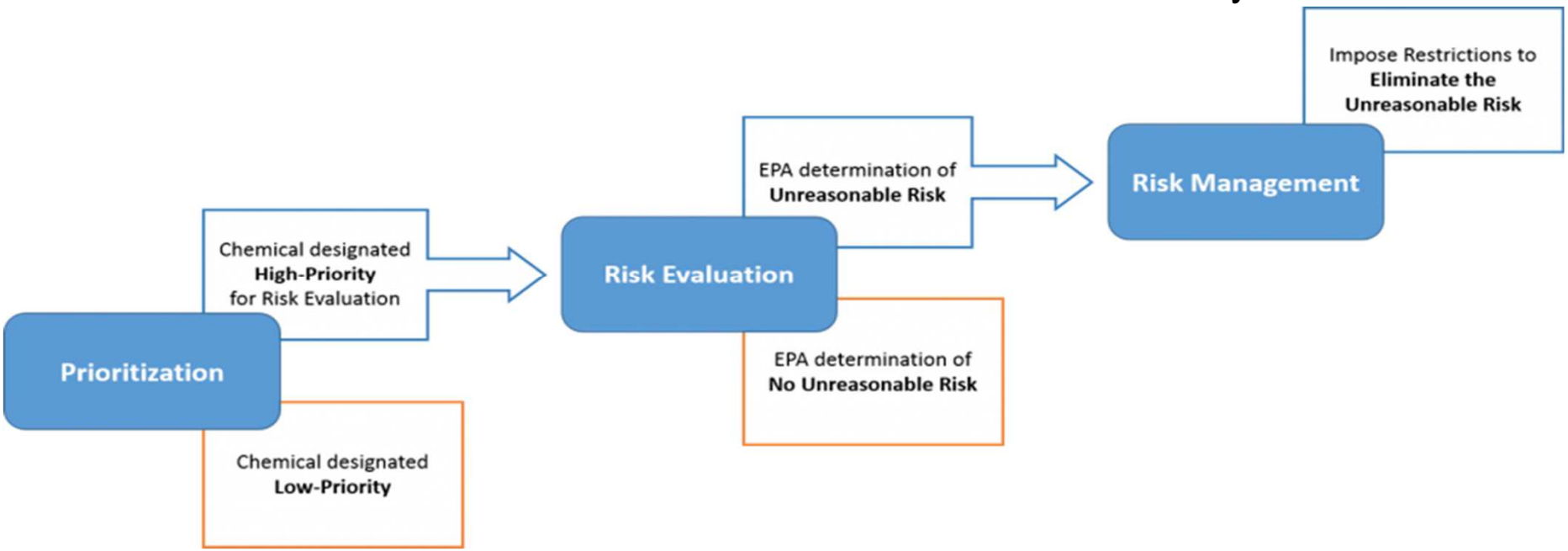
- Initial "retrospective reporting" period applies to **manufacturers** and **importers**, but **processors** also need to monitor to ensure the substances they are processing are designated as "active"
  - The rule allows processors to file any necessary supplemental reports in an "extended submission period" – 420 days after publication in Federal Register (October 5, 2018)
  - This provision allows processors time to search the interim active and inactive designations EPA makes based on CDR and manufacturers' submissions and fill any gaps
- Rule also includes a **forward-looking** electronic notification procedure for chemical substances designated as inactive
  - If manufacturing or processing of such substances is expected to resume, notice must be submitted within 90 days of initiating manufacture or processing
  - Upon receipt of a valid notice, EPA would change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active
  - EPA has announced a webinar regarding the rule: https://www.epa.gov/tsca-inventory

Existing Chemicals: Prioritization for Risk Evaluation

- LCSA requires EPA to prioritize existing chemicals in order to identify high-priority chemical substances that must undergo a risk evaluation
- On June 22, 2017 EPA issued its final "prioritization" rule, which establishes a risk-based screening process and criteria to designate existing chemical substances as either:
  - **"High-Priority Substances"** requiring comprehensive risk evaluations, or
  - **"Low-Priority Substances"** that do not warrant additional risk evaluation

Existing Chemicals: Prioritization for Risk Evaluation

- This rule represents the first step in the implementation of an extended process under which EPA will assess health and safety risks of existing chemical substances listed as “active” on the TSCA Inventory



Source: https://www.epa.gov/assessing-and-managing-chemicals-under-LCSA/how-epa-evaluates-safety-existing-chemicals

Procedures for Prioritization of Chemicals for Risk Evaluation

- **Initiation:**
  - EPA will initiate process once all information required has been made "reasonably available"
  - EPA announces the candidate chemical substance in the Federal Register
  - **90-day period** to submit comments
- **Proposed Designation:**
  - EPA will propose a rule designating a chemical substance as either High-Priority or Low-Priority and allow a **second 90-day comment period**
  - By statute, EPA will consider:
    - Hazard and exposure potential of the chemical substance
    - Persistence and bioaccumulation
    - Potentially exposed/susceptible subpopulations
    - The conditions of use of the chemical substances
    - Volume of the chemical substance manufactured or processed

Procedures for Prioritization of Chemicals for Risk Evaluation

- **Final Designation:**
  - EPA either finalizes a:
    - **High-Priority Substance designation** and initiates a full-scale risk evaluation, or a
    - **Low-Priority Substance designation** and takes no further action
- **LCSA Requires:**
  - Timing: Under the statute, the Initiation, Proposed Designation, and Final Designation phases must last at least 9 months to ensure sufficient public input, but may last no longer than one year
  - By December 2019, EPA must designate at least 20 substances as High-Priority and at least 20 chemical substances as Low-Priority
  - Upon the completion of an individual risk evaluation, EPA must immediately designate an additional High-Priority Substance, which will ensure that there will be a constant stream of substances undergoing risk evaluation

Existing Chemicals: Procedures for Risk Evaluation

- Risk **evaluation** follows chemical **prioritization**
- By statute, the risk evaluations must:
  - Determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under conditions of use
  - **Not** consider costs or other non-risk factors, and
  - Consider unreasonable risks to a potentially exposed or susceptible subpopulation
- Process would apply to:
  - Chemical substances designated as High-Priority Substances during the prioritization process
  - The first ten chemical substances to be evaluated from the 2014 update of the TSCA Work Plan for Chemical Assessments, and
  - Chemical substances for which EPA has initiated a risk evaluation in response to manufacturer requests

Existing Chemicals: Procedures for Risk Evaluation

1) Scope:
   - EPA identifies the conditions of use, hazards, exposures, and any potentially exposed or susceptible subpopulations that the EPA expects to consider
   - Draft Scope published 3 months after initiation with opportunity for public comment; Final Scope document published within 6 months of the beginning of risk evaluation

2) Hazard Assessment:
   - Identifies the types of adverse health or environmental effects that can be caused by exposure to some agent in question, and to characterize the quality and weight of evidence supporting this identification

3) Exposure Assessment:
   - Where relevant, will take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure assessment

Existing Chemicals: Procedures for Risk Evaluation

4) Risk Characterization:

- LCSA requires that a risk evaluation "integrate and assess available information on hazards and exposures"

5) Peer Review:

- EPA will conduct peer reviews using the guidance provided in OMB and EPA peer review directives

6) Risk Determination:

- EPA must make an affirmative determination:
  - **Does not present an unreasonable risk of injury** to health or the environment under the conditions of use: Publish in Federal Register
  - **Presents an unreasonable risk of injury** to health or the environment under the conditions of use: EPA must initiate a Section 6(a) rulemaking in order to impose requirements to the extent necessary so that the substance no longer presents such risk

Timing: A risk evaluation can last **no longer than three years** from High-Priority Designation, with possibility for **six month extension**

Guidance for Third-Party Risk Evaluations

On June 22, 2017, EPA released the "Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under TSCA"

- The guidance is intended to help parties submit draft chemical risk evaluations to be considered by EPA as part of its risk evaluation for a particular chemical
- EPA states that this guidance will be re-evaluated every five years and could be used as a means for providing additional transparency regarding the risk evaluation process
- The guidelines are consistent with the steps outlined in the risk evaluation rule, including consideration of best available science, weight of evidence evaluations, systematic review and data quality considerations
- Although there is no comment period for the guidance, EPA states that external parties can submit comments to the docket (EPA-HQ-OPPT-2017-0314) at any time to strengthen the guidance

Existing Chemicals: Procedures for Risk Evaluation

Major Changes in Final Rule Published on June 22, 2017 and the Proposed Rule:

- Narrowing scope of "Conditions of Use"
  - Proposed rule required EPA to consider all known, intended, and reasonably foreseen activities associated with the substance
  - Final rule gives EPA discretion to focus on uses that may present the greatest concern. EPA need not evaluate legacy uses, impurities, non-commercial use
  - Substantial Guidance for Industry-Requested Evaluations
- Manufacturer can only request evaluations for its own uses; EPA has discretion to consider all uses
  - Must submit a substantial amount of evidence re risk
- Incorporates TSCA "good science" standards into regulation
  - TSCA § 26(h-i) requires EPA to make decisions consistent with "best available science" and "based on the weight of the scientific evidence"
- EPA simultaneously published guidance for third parties that conduct risk evaluation – closely mirrors rules for EPA-led evaluations

Existing Chemicals: Procedures for Risk Evaluation

LCSA created statutory deadlines for the risk evaluation process:

- **Within six months of initiation of risk evaluation,** EPA shall "publish the scope of the risk evaluation to be conducted, including the hazard(s), exposure(s), conditions of use, and the potentially exposed or susceptible subpopulation(s) the agency plans to consider for the evaluation"
- **Within three years,** EPA must complete a risk evaluation, though it may obtain one six-month extension
- If it is determined that the chemicals "present an unreasonable risk to humans and the environment," EPA must mitigate that risk **within two years through promulgating a Section 6(a) mitigation rule**

Existing Chemicals: Initial Risk Evaluations

- On June 22, 2017, EPA published scoping documents for the 10 priority chemicals it had identified for initial risk evaluations
  - Scoping documents contain:
    - Conditions of use that will be evaluated (legacy uses sometimes evaluated)
    - Nature of exposures:
      - Human Exposures: Occupational, Consumer, General Population Exposures, Potentially Exposed/Susceptible Subpopulations
      - Environmental Exposures
    - Nature of hazards:
      - Human Hazards: Cancer and non-cancer hazards
      - Environmental Hazards
    - Proposed conceptual models for analysis
    - Initial analysis plan for exposure and hazards

Existing Chemicals: Initial Risk Evaluations

- As EPA was unable to publish draft scoping documents, it will instead publish and take public comment on **Problem Formulation documents** that will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation
  - **Will be published in approximately December 2017**
- Final determination for 10 initial chemicals due by **December 2019**

1,4-Dioxane	Methylene Chloride
1-Bromopropane	N-Methylpyrrolidone
Asbestos	Pigment Violet 29
Carbon Tetrachloride	Tetrachloroethylene
Cyclic Aliphatic Bromide Cluster	Trichloroethylene

New Chemicals

- New Substances are added to the Inventory via a notice to EPA's new chemical group generally through a PMN
- As of June 22, 2016 in assessing a new chemical or significant new use, EPA must make one of the following findings:
  - The chemical is "not likely to present an unreasonable risk"
  - "Information…is insufficient to permit a reasoned evaluation…"
  - "May present an unreasonable risk" or
  - "Presents an unreasonable risk"
- Assessment of unreasonable risk:
  - Without consideration of costs and other non-risk factors
  - Includes exposure under the conditions of use to susceptible subpopulations
- EPA stated in a public stakeholder meeting the Agency will broadly interpret "conditions of use" to include not only the uses specified in the PMN, but any "reasonably foreseeable use" not specified in the PMN

New Chemicals

- For finding other than “unlikely to present an unreasonable risk” EPA may:
  - Require additional data collection/testing
  - Impose use restrictions or other risk management steps
  - Limit or prohibit manufacture
- Section 5 Consent Order
  - May allow limited manufacture/import during data generation
  - Manufacture/import may be limited to certain volumes, types of uses, etc.
  - Testing may be triggered by production (including import) volumes
  - Testing must follow protocols
- Consent Order is only applicable to the company that signed the Consent Order
- EPA issues a Significant New Use Rule (SNUR) to make condition applicable to others.

New Chemicals

- No standard data set required
  - Substance specific determination
  - EPA uses available data
  - In absence of data EPA uses estimates of toxicity and exposure
    - Structure activity relationships
    - EPA website on screening tools (www.epa.gov/tsca-screening-tools)
- EPA has stated interested in
    - Data quality/breadth
    - Information on intended use
    - Disposal Information

New Chemical Requirements

- Timing issues
- EPA announced on September 5 that it had completed 1,058 new chemical reviews since June 2016, and had 386 cases under review:

Pre-Manufacture Notices (PMNs), Microbial Commercial Activity Notices (MCANs), Significant New Use Notices (SNUNs), Low-Volume and other Exemptions (Exemptions)

Statistics from June 22, 2016 – September 5, 2017

Total Cases	1, 528
Total Reviews Completed	1,058
Cases Determined to be Invalid or Incomplete	84
Cases Under Review as of September 5, 2017	386**

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review

Testing Changes

- EPA's authority to require development of information is expanded
  - Authorizes administrative orders and consent agreements in addition to rule making
  - Permits EPA to require testing needed for prioritization, risk evaluation, PMN review
- EPA cannot use to establish "a minimum information requirement of broader applicability"
- Preference for tiered screening and testing process and explain basis for requiring use of vertebrate animals
- EPA required to reduce and replace vertebrate animal testing to extent practicable, scientifically justified, and consistent with policies of diminished animal testing
  - EPA to encourage formation of industry consortia to conduct joint testing to avoid unnecessary duplicative testing

Testing

- If information required is equivalent to information that has been submitted or is being developed in accordance with a rule, order, or consent agreement then EPA may grant an exemption from testing
  - Those who developed the information and those seeking the exemption should agree on an amount and method of reimbursement for a portion of the costs to those who developed the information
  - If the parties do not reach agreement, then EPA will determine the equitable reimbursement
- Limited reimbursement period

Confidentiality Claim Changes

- CBI protections will remain for ten years unless:
  - The party claiming CBI notifies EPA that it is withdrawing the claim or
  - EPA becomes aware that the information does not qualify for protection
- After 10 years, the party claiming CBI will have to re-substantiate the claim of confidentiality
- EPA is required to develop a retroactive review plan for evaluating whether chemicals on the existing confidential list require CBI protection
- Some information is not protected from disclosure e.g.
  - Banned or phased-out chemicals, with certain limitations
- EPA issued an interpretation (https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01235.pdf)

Fees

- LCSA provides authority to collect fees from manufacturers and processors who:
  - Submit notification of intent to manufacture a new chemical or new use of a chemical;
  - Are required to submit test data;
  - Manufacture or process a substance subject to a risk evaluation; or
  - Request EPA to conduct a risk evaluation on an existing chemical
- EPA is authorized to collect total fees of up to 25% of the program costs up to $25 million annually
- EPA has sought and received input from stakeholders, but has yet to publish a proposed Fee Rule

Preemption – Good News and Bad News

- The Good News:
  - LCSA will preempt some state regulations
- The Bad News:
  - Preemption will not kick in until EPA has taken action on a particular chemical
  - Preemption is subject to various exceptions, limitations, and potential waiver
  - Some existing state laws/actions will be grandfathered

What Will Be Preempted?

For future state regulatory actions, states will be preempted from:

- Requiring data that is likely to produce the same information required by federal guidelines (“anti-duplication” provision)
- Restricting the use of a chemical which EPA has determined does not pose an unreasonable risk of injury to health or the environment, or for which EPA has issued a TSCA Rule

What Will Be Preempted? Preemptive Pause

- From the time EPA publishes the scope of a risk evaluation for a chemical that EPA has designated as high priority, until the evaluation is completed or the deadline for completion arrives, states cannot take action to regulate that chemical
- The pause does not apply to chemicals undergoing a “requested” risk evaluation or to the first 10 evaluations of Work Plan chemicals
- By temporarily limiting states’ ability to regulate a chemical that EPA is currently evaluating, EPA has the ability to conduct a risk evaluation, secure information from any interested state, and reach a conclusion and possibly mandate restrictions that will be imposed nationwide

What Won't Be Preempted?

- Grandfathering
  - Any requirement enacted before April 22, 2016
  - Any action taken pursuant to a state law that was in effect on August 31, 2003
    - E.g. California Proposition 65
- State programs pursuant to federal statutes
- State monitoring or reporting requirements
- State laws relating to air, waste, or water, as long as they do not impose a TSCA type risk-management restriction
- State laws that are identical to federal laws

Preemption Waivers

- States may seek a mandatory waiver from pause preemption or a discretionary waiver from general preemption
- Discretionary waivers from the general preemption provisions require rulemaking by EPA based on a determination that:
  - Compelling conditions warrant granting the waiver to protect health or the environment,
  - Compliance with the proposed state requirement would place no undue burden on interstate commerce, and
  - The proposed state requirement is designed to address a risk that was identified using the best available science
- Given the requirement for rulemaking and the required substantive determination, discretionary preemption waivers are likely to be rare
- However, there are many open questions regarding the role of discretionary waivers

Conclusion – Takeaways

- The standards and process for evaluating chemicals have changed
  - The new provisions have a more distinct focus on use of and exposure to chemicals
- New requirements for CBI
  - EPA is directed to scrutinize confidentiality claims, including those for active substances whose chemical identities are on the confidential inventory
- Preemption is limited
  - Many existing state programs are grandfathered, and there is still room for states to regulate chemical safety

Next Steps for Companies

- Make sure your procedures address changes to PMNs and CBI claims
- Examine chemical substances manufactured, processed or imported into the US to identify which need to remain on the TSCA Inventory and take appropriate action
  - Also check the nomenclature used to identify those chemicals
  - Identify existing toxicity and exposure data
- Consider how to address potential data needs
- Consider potential advantages of requesting that EPA prioritize specific chemicals, subject to the payment of fees
- Be aware of potential changes to avoid disruptions in supply chain

Questions

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