The Current Status of TSCA

ORC HSE Webinar

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Overview

- TSCA basics and 2016 amendments
- New chemicals, including PMNs and SNURs
- Existing chemicals, including prioritization, risk evaluation, and risk management
- Reporting requirements
- Confidential information
- Current issues: PFAS, risk evaluations, risk management

TSCA Basics and the 2016 Amendments

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TSCA basics

Enacted in 1976

Amended in 2016

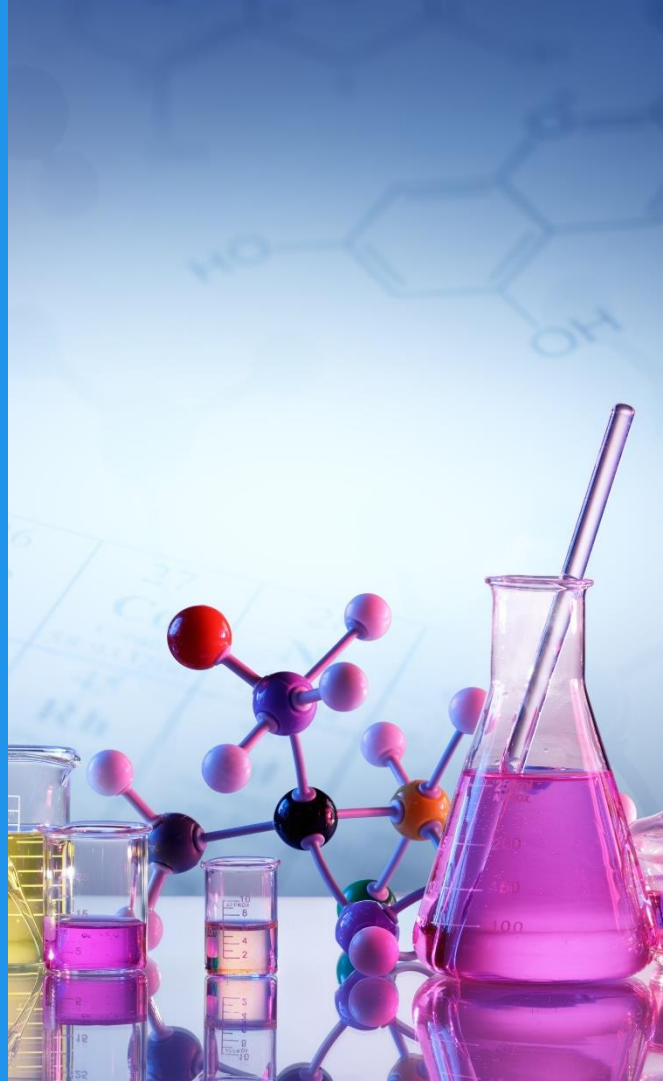
Section 4 – testing

Section 5 – new chemicals and new uses

Section 6 – existing chemicals

Section 8 – reporting

Section 14 – CBI



TSCA basics

- TSCA Inventory
  - If listed on the Inventory, "existing" – relatively difficult for EPA to regulate (mainly under section 6)
  - If not, "new" – relatively easy to regulate (section 5)
- As of Feb. 18, 2019
  - 86,228 chemicals on the Inventory
  - 40,655 (47%) identified as active
  - 7,757 substances with identities withheld as confidential (19% of the total active substances)

2016 amendments

1976 TSCA hobbled by 1991 asbestos case

- 25 years of no section 6 risk management rules
- Concern by some about other provisions
- REACH made TSCA feel outdated

Frank R. Lautenberg Chemical Safety for the 21st Century Act (June 22, 2016) (LCSA)

- Substantial revisions throughout

Almost 3 years later …

Major changes to EPA section 5 practices

First section 6 rule in 30 years issued

10 risk evaluations underway

20 risk evaluations to start in December

Fees in place

Litigation challenges

More to come

New Chemicals

New chemical basics

To manufacture (or import) a chemical, it:

- Must be on Inventory (and active); or
- Must be exempt (e.g., R&D, impurity); or
- Must be covered by an EPA-approved exemption application (e.g., low volume - < 10,000 kg/year) ($4,700 fee, 30-day review period); or
- Must be subject of premanufacture notice (PMN) reviewed by EPA for which EPA makes a final determination ($16,000 fee, "90-day" review period)

Timing for PMN review

- Statutory: 90 days, unless extended
  - After EPA shutdown ended, formal extension
- In practice, series of "voluntary" extensions
- Can be < 90 days for "not likely"
- Can be 1 year or longer for "may present"
- Current backlog: > 500 PMNs, etc.

PMN determinations

- Restrictions under § 5(e) or § 5(f):
  - Presents an unreasonable risk
  - **May present an unreasonable risk**
  - Insufficient information
  - Substantial quantities + substantial release
- No restriction:
  - **Not likely to present an unreasonable risk**

PMN determination considerations

- Without regard to cost or other non-risk factors
- Consider risks to potentially exposed or susceptible subpopulations (e.g., workers, children)
- Under the "conditions of use"

"Conditions of use"

"the circumstances, as determined by the Administrator, under which a chemical substance is **intended, known, or reasonably foreseen** to be manufactured, processed, distributed in commerce, used, or disposed of"

Application to PMNs

- Intended – described in PMN or amended PMN
- Known – from exempt activities (e.g., LVE)
- Reasonably foreseen (not speculation)
  - Case-by-case; factors to consider may include:
    - Current use outside the U.S.
    - Use of structurally analogous chemicals
    - Conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN

New chemical determinations

- Exemption applications (as of Feb. 26, 2019)
  - Granted 824 (not added to Inventory), denied 128
- PMNs (as of Feb. 10, 2019)
  - 564 final determinations (not invalid or withdrawn)
  - 441 led to restrictions (78%)
  - 123 “not likely to present” (22%)

"Not likely to present"

- Has low potential for human and environmental toxicity and the substance is not both persistent and bioaccumulative
- Toxicity is higher but all exposure scenarios do not present unreasonable risks
- May have the potential for higher toxicity but there is little potential for exposure due to its physical-chemical properties

Evaluating exposure scenarios

- First 2 years – little reliance on PPE in PMN or amended PMN
  - PMNs not binding
- Since September 2018 – assume compliance with PPE recommendations and requirements
  - SDS
  - OSHA requirements: "EPA's identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise."
  - "Not likely" determinations with that assumption increasing
  - Criticized at March 13 House subcommittee hearing as not "reasonably foreseen"

Improving chances of "not likely"

Provide at least basic health and environmental fate data with PMN

Control human exposure and releases

Submit complete and accurate PMN

Consult "Points to Consider" document

Have a Pre-notice Conference

New Uses

Significant new use rules (SNURs)

Based on changes, EPA can designate use of a chemical (new or existing) as a "significant new use" in a SNUR

- Use must not be "ongoing"
- Mainly used for PMN chemicals after EPA review of PMN
- Illegal to engage in a significant new use for which EPA has a final SNUR without prior EPA review and approval of a significant new use notice (SNUN)

SNURs since LCSA enactment

TSCA § 5(f)(4) – EPA must initiate SNUR rulemaking for any restricted PMN substance within 90 days

- Restrictions apply only to PMN submitter
- SNUR extends restrictions to other manufacturers and processors (does not apply to PMN submitter)

EPA has initiated SNUR rulemaking for 403 restricted PMN substances

- ~85% of the total number of restriction orders
- But not within 90 days, and has many to finalize

SNURs since LCSA enactment

- 13 proposed SNURs for PMN substances with "not likely to present" determinations
- More coming?
- Updated "Framework Document" promised for later this year

Existing Chemicals

LCSA rewrote section 6

EPA may finish pre-LCSA reviews

EPA must –

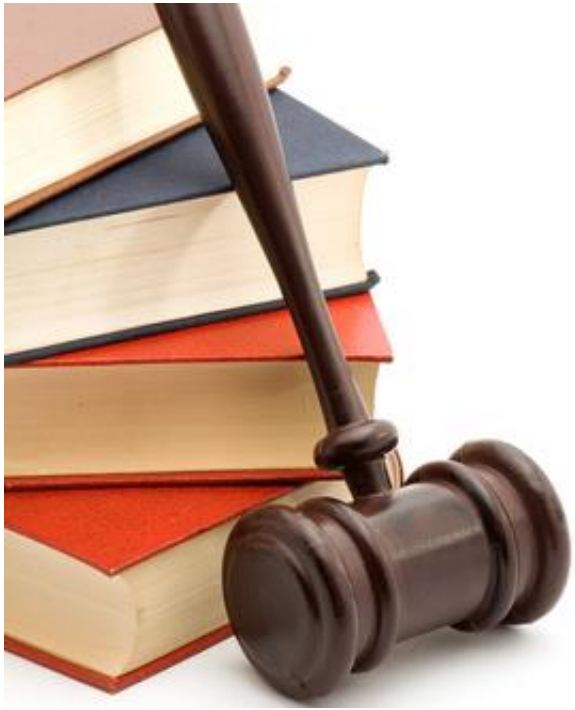
- Adopt prioritization and risk evaluation framework rules
- Identify chemicals for risk evaluations and/or restrictions (9-12 months for prioritization)
- Conduct risk evaluations (3 years from initiation)
- Make determinations about unreasonable risk (1 year from determination)
- Adopt risk management rules for chemicals that present unreasonable risks (2 years from determination)

Finishing pre-LCSA reviews

- Jan. 2017 – EPA published proposed rules for methylene chloride, N-methylpyrrolidone (NMP), trichloroethylene (TCE) based on 2014 TSCA work plan
- EPA deferred NMP and TCE rules for risk evaluations
- Mar. 22, 2019:
  - Publication of final rule banning consumer use of methylene chloride in paint stripping; first section 6 rule in 30 years
  - ANPR for training and certification program for commercial paint stripping
  - Litigation expected by NGOs

Framework rules

- 40 C.F.R. Part 702 adopted 1 year after enactment
- EPA may select the conditions of use to be addressed (e.g., exclude legacy uses)
- 9th Circuit NGO litigation challenging this proposition – oral argument May 16, 2019



Initial identification – PBTs

- § 6(h) – EPA identified 5 chemicals as PBTs:
  - Decabromodiphenyl ethers (decaBDE)
  - Hexachlorobutadiene (HCBD)
  - Pentachlorothiophenol (PCTP)
  - Phenol, isopropylated, phosphate (3:1)
  - 2,4,6-Tris(tert-butyl) phenol

Regulation of PBTs

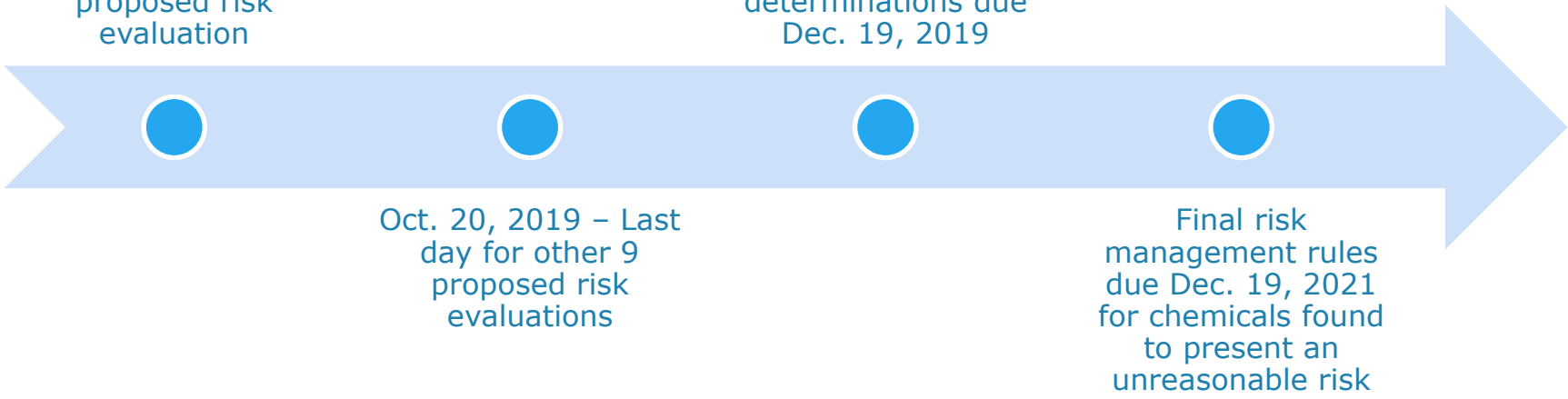
- No risk evaluation
  - Use and exposure evaluation
- EPA must propose risk management rules by June 22, 2019
- EPA must adopt final risk management rules by December 22, 2020
- Rules must "reduce exposure to the substance to the extent practicable"

Initial risk evaluations

EPA identified 10 chemicals for risk evaluations:

- Asbestos (not legacy uses)
- 1,4-Dioxane (not as an impurity)
- 1-Bromopropane
- Carbon tetrachloride
- Cyclic aliphatic bromide cluster (HBCD) (not legacy uses)
- N-Methylpyrrolidone (NMP) (including proposed rule)
- Methylene chloride (uses other than proposed rule)
- Pigment Violet 29 (most likely to get "does not present" determination)
- Trichloroethylene (TCE) (including proposed rule)
- Tetrachloroethylene (perchloroethylene)

Timing for first 10 chemicals



Prioritization

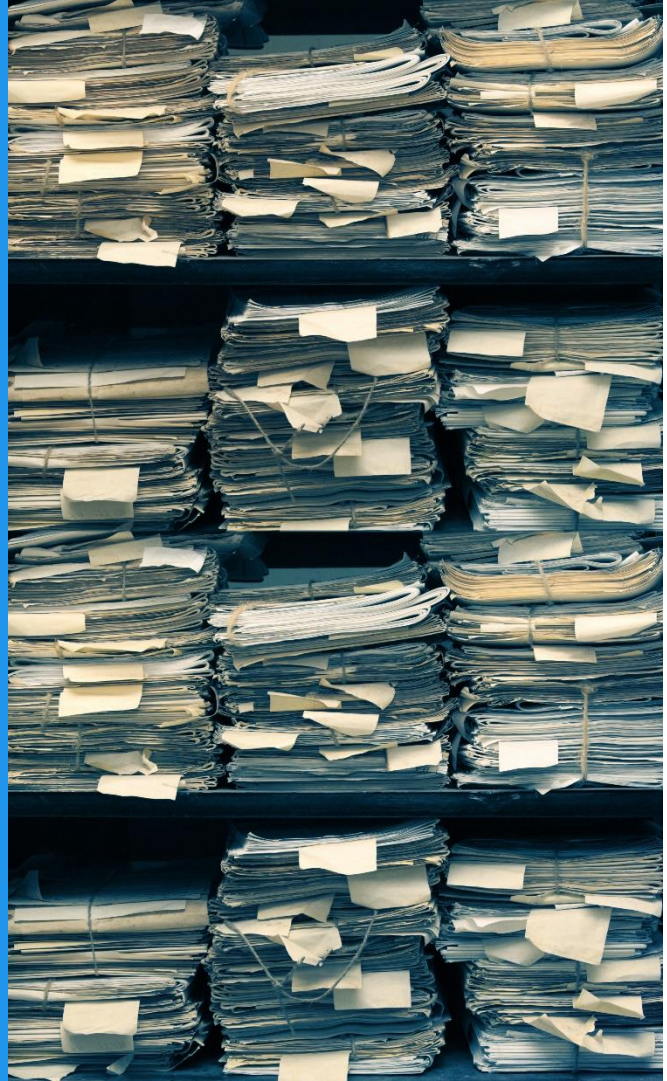
By Mar. 22, 2019, EPA must identify:

- 20 candidates for high-priority substances
- 20 candidates for low-priority substances

By Dec. 22, 2019, EPA must:

- Make final designations
- Begin risk evaluations for 20 high-priority substances

Reporting Requirements



Inventory reset

- In 2018, manufacturers had to report all chemicals they manufactured over a recent period; processors could do so
  - Reported chemicals and EPA-designated chemicals are "active"
  - 40,655 listed as active as of Feb. 19, 2019
  - Others are "inactive"
- Beginning May 19, 2019, illegal to manufacture or process an "inactive" chemical without first notifying EPA (to make it "active")

Chemical data reporting rule

- Proposed CDR amendments pending review at OMB since Jan. 29, 2019
- Final rule due Dec. 22, 2019
  - Expand to processors?
  - Lower threshold from 25,000 lbs.?
    - 8,707 chemicals reported for 2016 CDR (21% of 40,655 chemicals listed as "active")
  - Relief for inorganic byproducts that are recycled, reprocessed, or reused?
- CDR reporting period June – Sept. 2020
  - 2019 is primary reporting year

Confidentiality Requirements

Substantiation of CBI claims

- Must assert CBI claims at time of submission
- Must substantiate then also
- Optional templates available
- EPA must review 100% of substantiations for chemical identity CBI claims and 25% of others
  - Proposed rule for EPA review all chemical identity CBI claims pending review at OMB since Feb. 28, 2019
  - Final rule due Feb. 19, 2020

Additional CBI developments

- Generic names updated guidance issued June 2018
- EPA must assign unique identifiers to chemical identities claimed CBI
  - Guidance issued June 2018
  - Unique identifiers to be added to Inventory by around July 2019

EPA to post PMNs and attachments

Except for information claimed CBI

As soon as possible after final determination

Commitment in Dec. 2018 letter to Sen. Carper

Expected at some point in 2019

Current Issues

PFAS

- EPA PFAS action plan issued Feb. 14, 2019
  - **TSCA**, CWA, SDWA, RCRA, CERCLA
  - Discontinued PFASs – 2010/2015 PFOA Stewardship Program + SNURs
  - New PFASs
    - > 300 PMNs or SNUNs for PFASs have been reviewed by EPA since the PFOA Stewardship Program began
    - ~ 200 regulated by EPA
    - > 300 Low Volume Exemption applications reviewed, most granted subject to restrictions in applications

Risk evaluations

Mar. 22, 2019 – 20 high-priority candidates

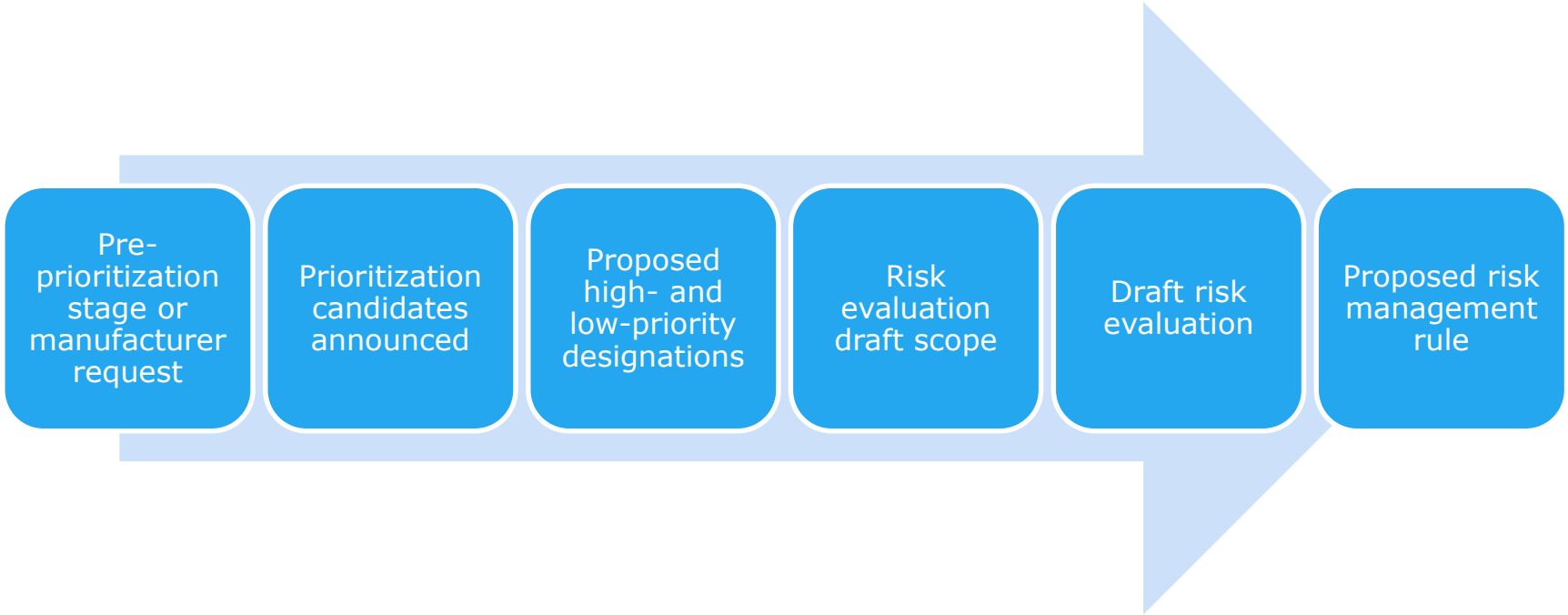
Dec. 22, 2019 – 20 high-priority designations

- Preliminary list of manufacturers subject to fee of $1,350,000
- Risk evaluations begin

June 22, 2020 – scope for risk evaluations

- Fee payments due

Timing for stakeholder actions



Most effective stakeholder actions

Submit or develop hazard data

- Review studies reasonably available to EPA
- Submit additional existing studies – REACH?
- Conduct new studies

Submit or develop use and exposure data

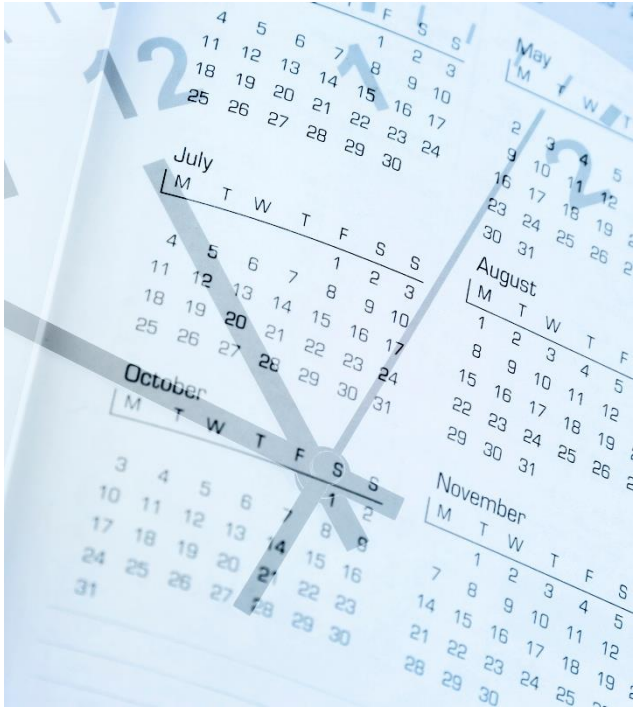
- Potential for consumer use
- PPE used
- IH monitoring, environmental monitoring

Prepare and submit your own risk evaluation

Advocacy

Risk management

- June 22, 2019 – proposed rules for 5 PBTs
- Dec. 19, 2020 – proposed rules for first 10 chemicals if found to "present an unreasonable risk"



EPA must consider non-risk factors

EPA must factor in these issues to the extent practicable:

- Benefits of the substance for various uses
- Economic consequences of the rule, e.g., effect on national economy, small business, and technological innovation
- Costs and benefits of rule and an alternative

Additional factors

Replacement parts

Use in articles

For a ban, whether alternatives that benefit health and environment will be reasonably available

Compliance dates: ASAP to 5 years

Questions?

Thank you!

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