

Status of Efforts to Modernize TSCA

Presented by

Michael Boucher

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Background

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- The United States' Toxic Substances Control Act ("TSCA") became law in 1976
- Since then, the core provisions of TSCA (Title I) have remained essentially unchanged
- But pressure to update TSCA has grown significantly in the past few years

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Legislative History

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- On Apr. 15, 2010, U.S. Senator Frank Lautenberg introduced the Safe Chemicals Act of 2010 (S. 3209) in the U.S. Senate
- On July 22, 2010, U.S. Representatives Henry Waxman and Bobby Rush introduced companion legislation, the Toxic Chemicals Safety Act of 2010 (H.R. 5820), in the U.S. House of Representatives, following stakeholder comments and meetings
- Neither bill attracted enough support to complete the legislative process before the 111th Congress ended on Jan. 3, 2011

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Legislative History

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- On Apr. 14, 2011, Senator Lautenberg introduced the Safe Chemicals Act of 2011 (S. 847) in the U.S. Senate, with changes intended to gain Republican support
- After negotiations broke down between Republicans and Democrats, Senator Barbara Boxer, Chair of the Senate Environment and Public Works (“EPW”) Committee, convened a markup on S. 847

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Legislative History

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- During the markup of S. 847, Senator Lautenberg offered a manager's amendment, which included significant changes intended to attract Republican support
- On July 25, 2012, the Senate EPW Committee passed the amended S. 847 along party lines
- The full Senate did not consider S. 847 before the 112th Congress ended on Jan. 3, 2013

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Current Outlook

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- Senator Lautenberg will reintroduce the Safe Chemicals Act in the Senate, probably soon
- Senator David Vitter, the Ranking Member on the Senate EPW Committee, is discussing an alternative to the Safe Chemicals Act with industry stakeholders
 - Senator Vitter intends to introduce his own bill in the Senate during 2013, perhaps this spring

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Current Outlook

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- Representative John Shimkus, Chair of House Energy and Commerce Subcommittee on the Environment and the Economy Chair, says that he will consider any TSCA bill that the Senate passes but will not pursue his own bill in the House of Representatives
- Thus, legislation to amend TSCA will originate, if at all, in the Senate
 - And focus is on the Senate EPW Committee

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Overview of S. 847

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- § 8 – Declarations of chemical substances in commerce and creation of new inventories
- § 4 – Minimum information sets and test rules and orders
- § 5 – New chemicals, categorization, new uses, and exemptions

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Overview of S. 847

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- § 6 – batching, categorization, and prioritization of, and safety standard determinations for, existing chemicals
- § 8 – Reporting and recordkeeping
- § 14 – Confidential business information
- Other provisions of interest

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§ 8(b) – Declarations of Chemical Substances in Commerce

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- Within 180 days after S. 847's enactment, each importer and manufacturer of a chemical must file a declaration of "current commercial interest" in such chemical
 - Must be currently importing or manufacturing the chemical, or have done so in the past and expect to do so again "in the near future"
 - Declarations are required for all chemicals of current commercial interest, without exclusions or exemptions
 - Processors may voluntarily file within one year

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§ 8(b) – Declarations of Chemical Substances in Commerce

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- Within 180 days after S. 847' s enactment, an importer, manufacturer, or processor may voluntarily file a declaration of “potential commercial interest” in a chemical
 - Must not have a current commercial interest
 - The declared chemical must have the potential to serve as a “reasonable substitute” for a chemical of current commercial interest

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§ 8(b) – Declarations of Chemical Substances in Commerce

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- Within 180 days after S. 847' s enactment, a current or former importer, manufacturer, or processor may voluntarily file a declaration of cessation of manufacture or processing for a chemical
 - Must have ceased all import, manufacture, processing, and export, or
 - Must do so within 180 days after filing the declaration

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§ 8(b) – Declarations of Chemical Substances in Commerce

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- Declarations apply only to chemicals in commerce when S. 847 is enacted
- Contents of declaration
 - Chemical identity
 - Any “special substance characteristics” (determined by EPA, by rule or order)
 - Identity and primary business location of the importer, manufacturer, or processor, as applicable
 - Documentation of “current commercial interest” or “potential commercial interest,” as appropriate

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§ 8(h) – New Inventories

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- Active inventory
 - Initially, this inventory will consist of solely of existing chemicals declared to be of “current commercial interest”
 - Such chemicals can be imported, manufactured, or processed in accordance with categorization, prioritization, and safety determinations conducted under section 6
 - R&D and section 6(h)(2)(B) chemicals excluded
 - EPA must publish an initial active inventory within one year after S. 847’s enactment

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§ 8(h) – New Inventories

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- Active inventory
 - In addition, this inventory will include chemicals for which the importer, manufacturer, or processor has filed a notice of commencement following new chemical notification and assessment under section 5
 - A dynamic inventory that will grow
- Inactive inventory
 - Will consist solely of existing chemicals declared as being of “potential commercial interest”
 - A dynamic inventory that may shrink but will not grow
 - Listed chemicals cannot be imported, manufactured, or processed without a 30-day advance notification

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§ 8(h) – New Inventories

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- Inactive inventory
 - Contents of notification
 - Chemical identity and any “special substance characteristics”
 - Identity and primary business location of the manufacturer
 - A list of health and safety studies conducted or initiated by or for, known to, or reasonably ascertainable by the notifier (and copies to EPA upon request)
 - Projected annual import, manufacture, or processing volumes for the three years following notification
 - Name and location of downstream processors, distributors, and users
 - All other existing information known to, in the possession or control of, or reasonably ascertainable by the notifier regarding toxicological properties, uses, exposures, or fate

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§ 8(h) – New Inventories

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- Inactive inventory
 - Upon receipt of a valid notification, EPA will move the chemical to the active inventory and treat it accordingly
- Both new inventories exclude
 - Chemicals without declarations
 - Chemicals with only declarations of cessation of manufacture or processing
- Import, manufacture, or processing of a chemical not listed on either inventory requires new chemical notification and assessment under section 5

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§ 4 – Minimum Information Sets

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- Within one year after S. 847's enactment, EPA must promulgate a rule to establish "minimum information sets" for evaluating chemicals under sections 5 and 6
 - Must provide for varied or tiered information for different chemicals
 - Must specify information quality and reliability requirements
 - Must accommodate alternative testing methods and strategies to generate information quickly, and at low cost, and to minimize animal testing

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§ 4 – Minimum Information Sets

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- Minimum information sets
 - Must permit a screening-level risk assessment by EPA
 - Must include information on
 - “Characteristics”
 - Toxicological properties
 - Environmental and biological fate and behavior
 - Exposure and uses
- For any failure to submit a minimum information set when required, EPA may issue an order to ban or limit import, manufacture, processing, use, distribution, or disposal of a chemical

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§ 4 – Test Rules and Orders

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- EPA may issue a test rule or order to facilitate any determination or carry out any part of TSCA
 - EPA may seek information not provided in minimum information sets *and* from persons not required to submit minimum information sets
- For any failure to submit testing when required by rule or order, EPA may issue an order to ban or limit import, manufacture, processing, use, distribution, or disposal of a chemical
- EPA also may request chemical samples by rule or order, to conduct any tests needed to make any determination or carry out any part of TSCA

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§ 4 – Test Rules and Orders

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- Procedures for test rules and orders are similar to current section 4 with two exceptions
 - EPA can prescribe standards for the development of information about exposure (including information about the presence of chemicals in humans) and bioaccumulation
 - EPA can prescribe biomonitoring and environmental monitoring as acceptable methodologies for any required testing

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§ 4 – Test Rules and Orders

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- Persons who submit information under test rules or orders must certify that each statement
 - Is accurate and reliable
 - Includes all material facts known to, in the possession or control of, or reasonably ascertainable by the person
- Other U.S. federal agencies can request EPA to issue test rules or orders or to collect existing chemical information
 - Within 60 days after any such request, EPA must take responsive action, or publish an explanation for not doing so in the *Federal Register*

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§ 5 – New Chemicals

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- To import or manufacture a new chemical, or to process one for uses described in section 6(h)(2)(B), a person must file a notice including
 - The chemical's identity and any "special substance characteristics"
 - The identity and primary business location of the importer or manufacturer
 - The information required in a notification for a chemical listed on the inactive inventory
 - Any required minimum information set and any other information owed under a section 4 test rule or order
 - A statement that the chemical is likely to meet the safety standard (§ 6(d)), or that one or more proposed uses meets the criteria of section 6(h)(2)(B), as applicable

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§ 5 – New Chemicals

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- In addition, EPA must find that
 - The chemical is likely to meet the safety standard, or
 - The person has clearly established that one or more proposed uses meets the criteria in section 6(h)(2)(B)
 - Of paramount interest to national security
 - Lack would cause significant disruption in the national economy, or
 - Critical or essential and
 - No feasible safer alternative, or
 - Compared to all available alternatives, provides a substantial net benefit to human health, the environment, or public safety

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§ 5 – New Chemicals

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- Within 30 days after commencing import, manufacture, or processing of a new chemical, the person will file a notice of commencement (“NOC”)
 - Causes EPA to add the chemical to the active inventory
- A new chemical that EPA does not approve following notification is handled in accordance with the “category” to which EPA assigns it

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§ 5 – Categorization of New Chemicals

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- Within one year after S. 847’s enactment, EPA must promulgate a rule to categorize new chemicals that are notified
 - Substances of very high concern (“SVHCs”)
 - Substances likely to meet the safety standard
 - Substances of very low concern (“SVLCs”)
 - Substances designated to undergo safety standard determinations
 - Substances with insufficient information
 - Substances unlikely to meet the safety standard

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§ 5 – Categorization of New Chemicals

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- SVHCs are persistent, bioaccumulative, and toxic (“PBT”) or “highly hazardous”
 - Can be imported, manufactured, or processed only by the notifier and solely for uses described in section 6(h)(2)(B)
- Substances likely to meet the safety standard
 - SVLCs possess intrinsic low-hazard properties based on the minimum information set (with exceptions)
 - EPA can designate a substance to undergo safety standard determination based on “sufficiently robust” information that the chemical is not SVHC or SVLC and does not lack sufficient information

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§ 5 – Categorization of New Chemicals

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- Substances likely to meet the safety standard
 - Following submission of an NOC, EPA will add the chemical to the active inventory
 - For chemicals designated to undergo safety standard determination, EPA also will schedule (“batch”) the chemical for prioritization under section 6
 - Processors must file a report under new section 8(e) before processing

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§ 5 – Categorization of New Chemicals

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- Substances with insufficient information
 - EPA must request the applicable minimum information and then re-categorize the chemical
 - Meanwhile, import, manufacture, and processing is prohibited
- Substances unlikely to meet the safety standard
 - EPA can determine based on available information
 - As with SVHCs, can be imported, manufactured, or processed only by the notifier and solely for uses described in section 6(h)(2)(B)

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§ 5 – New Uses of Existing Chemicals

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- For existing chemicals prior to a safety standard determination, no person may import, manufacture, or process the chemical for a “new use,” unless the person
 - Submits a notice, any information owed under a section 4 test rule or order, and an NOC (for importers and manufacturers) or section 8(e) report (for processors)
 - “New use” is any use not ongoing at the time that S. 847 is enacted or any volume that increases “significantly” after such date

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§ 5 – New Uses of Existing Chemicals

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- For existing chemicals following a safety standard determination, no person may import, manufacture, or process the chemical for a “new use,” unless the person
 - Submits a notice and satisfies EPA that the new use will continue to satisfy the safety standard
 - EPA will amend the safety standard to include the new use
 - “New use” is any use not covered by the existing safety standard determination for the chemical

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§ 5 – Exemptions

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- New exemption for “intrinsically safe” chemicals
- Within 180 days after S. 847’s enactment, EPA will review existing PMN exemptions granted under TSCA § 5(h)(4)
 - Excludes other section 5(h) exemptions, for test marketing, equivalent chemicals, R&D, and chemicals with “temporary existence”
 - Exemptions under review stay in force during EPA’s review

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§ 5 – Exemptions

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- Changes to specific exemptions
 - Polymer exemption is retained pending EPA's review
 - NOC is required both immediately and following EPA's review, if EPA retains this exemption
 - Exemptions for test marketing, equivalent chemicals, R&D, and chemicals with “temporary existence” also are retained but with a new NOC requirement

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§ 6 – Batching of Existing Chemicals

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- EPA must assign chemicals on the active inventory to a “batch” every five years, until all listed chemicals have been assigned to a batch
- EPA must create the first batch within 270 days after S. 847 is enacted
- The first batch will contain all chemicals (on the active inventory) for which Chemical Data Reporting (“CDR”) Rule reports have been filed to date
 - Exclusions and inclusions apply
- EPA may create later batches in any way that reflects “the extent to which chemicals warrant earlier or later evaluation”

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§ 6 – Categorization of Chemicals within Batches

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- Within one year after S. 847's enactment, EPA must promulgate a rule to categorize batched substances, and to prioritize chemicals designated to undergo safety standard determinations
- Within a further 180 days, EPA must categorize all chemicals in the first batch
- For each subsequent batch, EPA must categorize all chemicals in the batch within 180 days after creating the batch

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§ 6 – Categorization of Chemicals within Batches

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- The categories for batched chemicals mirror the categories that EPA will create for new chemicals (differences noted below)
 - SVHCs are PBTs, highly hazardous, or subject to section 6 or 7 rules or voluntary phase-out under the “old” TSCA
 - EPA can categorize a chemical as an SVHC without a minimum information set
 - Within 18 months of assigning a chemical to this category, EPA must issue an order to achieve “maximum practicable reduction in human or environmental exposure”
 - A one-time compliance extension of five years is available in “exceptional circumstances”

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§ 6 – Categorization of Chemicals within Batches

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- The categories for batched chemicals mirror the categories that EPA will create for new chemicals (differences noted below)
 - SVLCs require no further risk management action
 - Substances designated to undergo safety standard determination are not SVHC or SVLC, based on information that is sufficiently robust to inform prioritization decisions
 - Substances with insufficient information require the submission of a minimum information set within five years after being batched

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§ 6 – Prioritization of Chemicals for Safety Standard Determinations

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- Within 270 days after promulgating regulations to categorize and prioritize batched chemicals, EPA must assign priority classes to first-batch chemicals designated to undergo safety standard determinations, based on
 - Hazard potential, including identification of hazard characteristics by other authorities
 - Exposure potential
 - Direct measurements of exposure for a given pathway, if available and reliable, and in preference to indicators or surrogates
- For later batches, EPA must prioritize designated chemicals within 270 days after creating each batch

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§ 6 – Prioritization of Chemicals for Safety Standard Determinations

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- Priority Class 1 includes chemicals that EPA decides warrant evaluation “in the near term,” due to relatively greater hazard potential and evidence of significant or widespread exposure
 - EPA does not require a minimum information set to put a chemical in this priority class
- Priority Class 2 includes chemicals that EPA decides are of a lower priority than Priority Class 1 with respect to the timing of evaluation
 - EPA must require a minimum information set within five years after placing a chemical in this priority class

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§ 6 – Prioritization of Chemicals for Safety Standard Determinations

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- Priority Class 3 includes chemicals that EPA decides may be set aside until the chemicals in Priority Classes 1 and 2 have been evaluated, or new information places a chemical in Priority Class 1 or 2
 - EPA cannot request a minimum information set for chemicals in this priority class
- As EPA completes safety standard determinations for chemicals in Priority Class 1, EPA may reassign to Priority Class 1 chemicals initially assigned to Priority Classes 2 and 3

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§ 6 – Safety Standard Determinations

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- For each chemical in Priority Class 1, EPA needs to determine whether the chemical meets the following safety standard
 - There is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance
- EPA must make a safety standard determination for each chemical within five years after assigning it to Priority Class 1

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§ 6 – Safety Standard Determinations

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- EPA will apply a full range of risk mitigation measures to chemicals that do not meet the safety standard
- Unless exempted, risk mitigation measure go into effect 18 months after the safety standard determination is made
 - One-time, five-year compliance extension is available for “compelling technological need” or for any reason that prevents compliance and is beyond the importer’s, manufacturer’s, or processor’s control
- Based on new information or significant changes in exposure, any person may petition EPA for a new safety standard determination

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§ 8 – Reporting and Recordkeeping

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- The Chemical Data Reporting Rule remains in effect until EPA amends or replaces it, which EPA is required to do within 180 days after S. 847's enactment
- Persons must maintain records to support declarations and periodic reports and must submit such records upon request by EPA
- Within one year after S. 847's enactment, EPA must promulgate a rule to establish periodic reporting by processors
- Periodic reporting by importers, manufacturers, and processors must be updated at least every four years, and upon receipt of any significant new information

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§ 8 – Reporting and Recordkeeping

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- EPA may by rule or order require any importer, manufacturer, processor, distributor, user, or disposer of any chemical substance, mixture, or article to maintain and submit records of existing information to assist various EPA decisions
- Within one year after S. 847's enactment, EPA must establish a public database of chemical information and all significant decisions and submissions under TSCA
- Current sections 8(c) and 8(e) renumbered but otherwise retained without change

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§ 14 – Confidential Business Information

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- Information that is always eligible for protection
 - Precise information describing the import, manufacture, processing, or distribution of a chemical substance or mixture
 - Marketing and sales information
 - Information identifying the customers of an importer, manufacturer, processor, or distributor
 - Details of the full composition of a mixture of a particular importer, manufacturer, or processor
 - Precise information about the use, function, or application of a chemical substance or mixture in a process, mixture, or product of a particular importer, manufacturer, or processor
 - Precise production or import volumes of a particular importer, manufacturer, processor, or distributor

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§ 14 – Confidential Business Information

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- Information that may be eligible for protection
 - The precise identity of a chemical substance
 - Notice, justification, and EPA approval required
 - Degree of purity or identity of impurities present in a chemical substance or mixture, if EPA determines that such information would reveal processes to manufacture or process the chemical substance or mixture

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§ 14 – Confidential Business Information

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- Information that is never eligible for protection
 - The identity of a chemical substance, unless protected
 - Safety standard determinations and supporting analyses
 - Health and safety study data submitted under TSCA, with qualifications
 - Health and safety data in notices of substantial risk submitted under section 8(l) (old section 8(e))
 - Information describing import and manufacturing volumes in ranges and industrial, commercial, or consumer functions and uses of a chemical substance or mixture
 - Information indicating a chemical substance in consumer products that may be used by children, with qualifications

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§ 14 – Confidential Business Information

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- Period of protection
 - For chemical identity information only, information is protected, upon EPA's approval of an application, for an initial period determined by EPA (can be anything)
 - EPA can grant one five-year extension upon approving a renewal application
 - Upon application to EPA, other information is protected for an initial period not to exceed five years
 - EPA can grant one extension of up to five years upon approving a renewal application

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化學工業日報 The Chemical Daily

McKenna Long
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Other Provisions of Interest

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- Eliminates export-only exemption (§ 12(a))
- Extends import certifications (§ 13) to cover substances and mixtures in articles
- Maximum civil penalties increased to \$37,500
- Preempts U.S. state law only when compliance with both U.S. federal and U.S. state law is impossible
- Citizen petitions (§ 21) will allow EPA to initiate any action authorized by TSCA
- Directs EPA to minimize the use of animals in testing (§ 30)

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Some Concerns with S. 847

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- Vastly increased scope and complexity
- Limited resources of EPA and industry
- Use of safety standard for food-use pesticides
- Effect on introduction of new chemicals
- Possible loss of established PMN exemptions
- Reduced protection of trade secrets
- No preemption of duplicative U.S. state laws

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