

The Frank R. Lautenberg Chemical Safety for the 21st Century Act: Frequent Questions

Q1. What are the key changes in the new law?

The new law includes a number of important improvements, consistent with the Administration's 2009 Principles for TSCA Reform. These changes include:

- For the first time, requiring EPA to evaluate the safety of existing chemicals in commerce, starting with those most likely to cause risks.
- Requiring EPA to evaluate new and existing chemicals against a new risk-based safety standard that includes explicit considerations for vulnerable populations;
- Empowering EPA to require the development of chemical information necessary to support these evaluations;
- Establishing clear and enforceable deadlines that ensure both timely review of prioritized chemicals and timely action on identified risks;
- Increasing the public transparency of chemical information by limiting unwarranted claims of confidentiality and allowing for the appropriate sharing of confidential information with States and health and environmental professionals; and
- Providing a source of funding for EPA to carry out these significant new responsibilities.

[Learn more about the new law, summary information, and frequently asked questions.](#)

Q2. What can the public expect from the new bill that will help ensure that the chemicals manufactured and used in this country are safe for them, their families, and the environment?

As described above, the law addresses fundamental flaws in TSCA that have, for nearly 40 years, limited EPA's ability to protect the public from dangerous chemicals. EPA views the law as a major victory for chemical safety, public health and the environment - particularly the mandatory duty to evaluate chemicals and the new risk-based safety standard. EPA is already taking steps necessary to carry out its new responsibilities, including identifying those chemicals actively in commerce, establishing procedures to prioritize chemicals and evaluate high-priority substances, and working with stakeholders on setting up a fee system to support implementation.

Q3. When does the new law take effect?

The law takes effect immediately upon signature by the President, which took place on June 22, 2014.

Q4. The new law contains a number of requirements that must be implemented within certain time frames. What are EPA's plans for meeting those deadlines?

EPA is developing an Implementation Plan to guide the agency's efforts on successfully meeting the deadlines in the new law, including among others:

- Identifying the initial ten Work Plan chemical risk assessments;
- Establishing a process and criteria for identifying high priority chemicals for risk evaluation; and
- Issuing a procedural rule that establishes EPA's process for evaluating risks from high-priority chemicals.

Q5. Is EPA going to seek stakeholder input on its implementation activities?

Yes. EPA believes that input from interested stakeholders and the public is critical to successful implementation of the new law. In the coming weeks, EPA plans to begin making information available on opportunities to learn more about the changes in the new law and how and when specific stakeholder engagement will begin to take place. Opportunities for input may include briefings, webinars, public meetings, comment periods, etc. [Please visit this link to sign-up for updates on EPA's stakeholder engagement efforts.](#)

Q6. Are there any areas immediately affected by changes in the new law?

The most immediate effects will be on the new chemicals review process. EPA is now required to make an affirmative determination on a new chemical or significant new use of an existing chemical before manufacturing can commence. For companies that submitted premanufacture notices (PMNs) prior to enactment and which are currently undergoing review, the new law effectively resets the 90-day review period. The agency will make every effort to complete its review and make a determination within the remaining time under the original deadline. EPA will be making additional information available on new chemical reviews in the very near future.

Q7. How might the new law impact State laws and regulations?

States can continue to act on any chemical, or particular uses or risks from a chemical that EPA has not yet addressed. States also retain authority to address local environmental concerns related to air, water, waste treatment and disposal. For State and Federal requirements that are identical, States retain the ability to partner with the Federal government on enforcement. Finally, the law preserves State laws already on the books (as of April 22, 2016).

Generally, State action on a chemical is preempted only when EPA has acted – either by finding a chemical to be safe, or regulating a chemical to address identified risks. State action is also temporarily “paused” when EPA is evaluating a chemical, although States can avail themselves of a mandatory waiver from the “pause” if they still seek to pursue their own regulation.

Q8. When will EPA decide how to collect fees to support implementation of the new law?

Section 26 of the act provides EPA authority to collect fees that help to defray the costs of administering the provisions on collecting and managing information, implementing the new chemicals program, and evaluating and regulating existing chemicals. Before collecting fees, EPA is required to publish a proposed rule, obtain public comment, address the comments, and then finalize the rule. Prior to proposing a rule, EPA will consult with parties subject to the fees, as required by the act. The Agency plans to begin this process in the coming weeks.

New Chemical Submissions and Reviews**Q9. Are there new requirements that affect EPA's review of new chemicals?**

The new law requires EPA to make an affirmative finding on new chemicals or new uses of existing chemicals before they can proceed to the marketplace.

Q10. What is the status of a PMN that was submitted to the Agency for review prior to enactment of the new law?

For companies that submitted premanufacture notices (PMNs) prior to enactment that are currently undergoing review, the new law effectively resets the 90-day review period, the agency will make every effort to complete its review and make a determination within the remaining time under the original 90-day review period. EPA will be making additional information available on new chemical reviews in the very near future.

Q11. What is the U.S. Environmental Protection Agency’s (EPA) authority for resetting the 90-day clock on all pending PMNs?

The revisions to TSCA section 5(a) impose not only new procedures regarding section 5 submissions, but also new determinations and authorities that apply to such submissions. Thus, the authority under which PMNs and other section 5 submissions have been filed no longer exists in its previous form, so that PMNs that were in process and whose review period had not expired upon enactment of the revisions to TSCA were not submitted under section 5(a).

TSCA section 5(i) defines the “applicable review period” as starting on the date the Administrator receives a notice “under subsection (a)(1).” EPA interprets this cross-reference as a reference to TSCA subsection (a)(1), as amended. In the case of a notice submitted prior to the date of enactment, the earliest possible date on which that notice could be viewed as submitted “under subsection (a)(1),” is June 22, 2016, the first date on which that subsection was in legal effect. EPA views all section 5(a) notices that were within the applicable review period as of June 22, 2016 – the date of the signing of the new law, as having been refiled on that date, thereby restarting the 90-day review clock.

Q12. How will EPA communicate 5(a)(3)(C) findings (that the PMN is “not likely to present an unreasonable risk”) to submitters, so that submitters may confidently commence manufacturing?

EPA will send a letter to the submitter notifying them of the section 5(a)(3)(C) decision. Attached to the letter will be a summary of the basis for the section 5(a)(3)(C).

Q13. What will be the role of Structure-Activity Relationships (SAR), categories, and nearest analog analysis in PMN review?

EPA expects to continue to use SAR, categories and analogs in PMN reviews, as appropriate.

Q14. Does EPA still see a continuing role for non-5(e) significant new use rules (SNUR) under the new law?

The Agency’s authority to issue SNURs derives from section 5(a)(2) – not section 5(e). Section 5(a)(2) was not changed under the recent amendments to TSCA. The Agency fully expects to continue to exercise its SNUR authority, as appropriate, in the context of both new and existing chemicals.

Q15. What information should submitters consider providing that would help EPA to evaluate concerns about potentially exposed or susceptible subpopulations?

To help EPA determine whether a chemical substance “may present an unreasonable risk ... under the conditions of use” to **potentially exposed or susceptible** subpopulations, most useful from submitters is precise and complete/detailed information about chemical manufacture, processing and especially uses of the PMN chemical in the original submission (rather than after EPA has conducted assessments using generic scenarios and default assumptions) . Submission of data or information regarding intrinsic (e.g., age, gender, genetic traits) or acquired (e.g., pre-existing disease, exposure) characteristics known to modify risks of related chemicals/analogs is also useful.

Q16. How will EPA take into account considerations such as Pollution Prevention (P2) statements, Green Chemistry aspects, energy efficiency, Sustainable Futures-based submissions, and relative risk determinations?

EPA will continue to consider these factors in deciding how to proceed with individual new chemical submissions.

Q17. In the case of polymers submitted as PMNs that otherwise satisfy the polymer exemption requirements (especially 40 C.F.R. § 723.250(e)(1) and (3) criteria), does EPA plan to continue to drop such polymers (i.e., to make a (C) determination under the new law)?

For polymers submitted as PMNs that otherwise meet the polymer exemption requirements in 40 CFR 723.250 and for which lower molecular weight species are unlikely to present an unreasonable risk, EPA expects to make a finding during the 90-day PMN review period that these chemical substances are “not likely to present an unreasonable risk.”

Q18. Does EPA anticipate any changes to the review and determinations for Section 5(h)(4) exemptions (LVEs, LoREX), other than considering possible vulnerable population concerns?

Because there were no changes to section 5(h)(4) other than consideration of a “potentially exposed or susceptible population” and because of the savings clause in section 26(p), the LVE and LOREX exemption regulations in 40 CFR.723.50 will remain in effect with the additional consideration by the Agency during its review of LVE and LOREX exemption applications of potential risks to any “potentially exposed or susceptible population.”

Q19. Will EPA still use voluntary suspensions if submitters need time to gather information to submit to EPA as an amendment to the PMN? Does EPA view that, under the new law, it is limited in the use of such voluntary suspensions?

EPA will continue to allow voluntary suspensions of the notice review period (as described in 40 CFR 720.75) so that submitters can develop, search for, and submit additional data for the new chemical substance.

Q20. Does EPA expect to continue to talk with notifiers throughout the entire review process for a given case as has been the practice historically under Section 5 “Initial” and “Standard Review?” Would this continue to be the case after issuing a Section 5(c) notice extending the review period?

EPA will continue to discuss new chemical notices in review with submitters as the Agency has done in the past. EPA will also continue to do this if the Agency extends the review period using the authority of section 5(c). For many cases, given the nature and extent of discussions, it would be important as in the past for the submitter to request and EPA agree to a suspension of the review period.

Q21. How will EPA communicate the Focus Meeting decision (or other status information) to submitters? For example, will EPA continue to post the initial Focus results on PMN and exemption cases?

EPA expects to post the interim and final results of its reviews of PMNs, SNUNs, MCANs and exemption applications on the web in a similar manner to that which has been used in the past. In addition, EPA intends to post, after the Agency has formally notified the submitter of its determination, any “not likely to present an unreasonable risk” determination, as well as the rationale for that finding. An EPA Program Manager will also continue to contact submitters individually when the outcome of the Focus Meeting suggests that the Agency’s determination may be something other than “not likely to present an unreasonable risk”.

Q22. The new law explicitly speaks to withdrawals in the context of Section 5. Does EPA envision any limitations for withdrawing a PMN?

A PMN may not be withdrawn once the applicable review period has expired.

Confidential Business Information

Q23. The Frank R. Lautenberg Chemical Safety for the 21st Century Act revised TSCA § 14 concerning confidential business information (CBI) claims for information submitted to EPA. What are the major changes for CBI claim submitters?

Summarized, there are new requirements relating to the submission of CBI, its management, and periodic reviews of CBI claims, including expiration of CBI claims.

The law requires that the submitter provide a statement concerning the need for the CBI claim and a certification that the statement of need is true and correct; EPA has collapsed the two requirements into a single certification statement. There is also a requirement that when a chemical identity is claimed as CBI, a non-CBI structurally descriptive generic name be provided. Certain information listed in the statute is exempt from substantiation requirements. Otherwise, the Agency has the authority to require substantiations to support CBI claims.

EPA must, with limited exceptions, review all CBI claims for chemical identity, as well as a representative sample of at least 25% of other claims. These reviews must occur within 90 days of receipt. Other CBI claims can also be reviewed by

the Agency based on specific events. For example, EPA may conduct a CBI review pursuant to a FOIA request, when a substance is designated as a high priority or active substance under the statute, or when the Agency believes that disclosure would be important in implementation of TSCA section 6. Most CBI claims expire after 10 years unless the business submitter reasserts and substantiates or re-substantiates the CBI claim. When EPA approves a CBI claim for chemical identity, the Agency must develop a unique identifier for the chemical.

TSCA CBI may also be shared under certain circumstances with non-federal authorities including states, subdivisions of states, tribes, emergency responders, and health care professionals.

Q24. Will substantiation of CBI claims be required with submission of information to EPA under TSCA?

Currently, EPA is using existing authorities to obtain CBI substantiations. This includes substantiation of CBI claims in submissions for which Agency rules currently require it, such as certain CBI claims under the Chemical Data Reporting (CDR) rule, and requests for comment (substantiation) on CBI claims under EPA general confidentiality regulations at 40 CFR § 2.204(e). These regulations allow EPA to request additional information, including substantiation, when making a CBI determination. EPA will use the substantiation provided to inform the confidentiality determinations for chemical identity and other CBI claims. The Agency may revise CBI substantiation requirements for specific types of information submissions by subsequent rulemaking.

Q25. TSCA now requires that when a CBI claim is made for specific chemical identity, the claim shall include a structurally descriptive generic name, developed consistent with EPA guidance. Will the EPA's reporting processes be modified to enable submitters to comply with this requirement?

There are existing generic name reporting requirements for some reports, and EPA anticipates no change for information submitters for these sections in the near term. For filing types where generic names were not previously required, submitters should use the existing guidance to develop these names. See <https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf>. EPA will develop further guidance regarding generic names as required by the new law.

Q26. TSCA § 14(c)(1)(B) requires that the assertion of a CBI claim be accompanied by a specific supporting statement. What is the impact of this requirement on filings submitted after June 22, 2016?

As of June 22, 2016, the effective date of the new law, all persons asserting CBI claims are required to include the supporting statement described in TSCA § 14(c)(1)(B) and the certification required in § 14(c)(5). EPA has revised TSCA electronic reporting systems to require persons making CBI claims to make the required statement and certification as a single certification that is part of the submission. Paper submitters must include this certification in their filings. The following required statement incorporates these requirements:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Q27. The new law provides for potential limitations on duration of CBI claims. What plans does the Agency have regarding implementing this provision?

Information submitters should be aware that the new TSCA § 14(e) limits the duration of many confidentiality claims to ten (10) years, unless those claims are timely reasserted and substantiated. EPA will develop policies, rules, and guidance to implement this provision.

Q28. Will the Agency initiate a review of CBI claims made in TSCA information submissions?

EPA will review and make determinations within 90 days on new CBI claims for chemical identity in submissions to the Agency filed after June 22, 2016, as required by TSCA § 14(g)(1)(C)(i). A representative subset of CBI claims for other kinds of information filed after June 22, 2016 will be reviewed in accordance with TSCA § 14(g)(1)(C)(ii). The Agency's procedures for CBI determinations are reflected in Agency confidentiality regulations at 40 CFR part 2 and in regulations for certain specific TSCA reporting obligations. The regulations at 40 CFR part 2 allow EPA to request additional information, including substantiation, when making a CBI determination. EPA will use the substantiation provided as part of the information considered when making a CBI determination.

Q29. TSCA § 14(c)(2) provides certain information are not subject to substantiation requirements, including “[s]pecific information describing the processes used in the manufacturing or processing of a chemical substance, mixture, or article,” and “[s]pecific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture or article” Do these provisions conflict with the existing substantiation requirements under the Chemical Data Reporting (CDR) Rule?

No. The information for which substantiation at the time of submission is required under CDR (e.g., chemical identity in health and safety studies as described in 40 CFR § 711.30 or general use and process information collected under 40 CFR § 711.15(b)(4) of CDR), is not the type of specific information referenced in TSCA § 14(c)(2).

Q30: EPA must review a representative sample of at least 25% of other, non-chemical identity CBI claims under § 14(g). How will the Agency be selecting its representative sample?

EPA is reviewing CBI claims in 25% of those TSCA submissions that include such claims. Submissions in which the only CBI claim is for chemical identity will not be reviewed as part of the 25% because chemical identity CBI claims are already to be reviewed under TSCA §14(g)(1)(C)(i). Also not included in the reviews will be CBI claims for the data elements identified in § 14(c)(2). The intended approach is that every fourth submission received, containing CBI claims, is to be reviewed. EPA may modify its selection and review procedures in the future, as it gains experience with the new law. TSCA CBI will be reviewed consistent with the provisions of TSCA, its implementing regulations and in accordance with the Agency procedures set forth in 40 CFR part 2. Pursuant to 40 CFR § 2.204(e), submitters of filings selected for this 25% review who have not previously been required to substantiate their CBI claims will be notified and provided an opportunity to comment (substantiate) on the claims. If the CBI claims are not waived and comments were received in a timely manner, EPA will proceed in making its final determination.

2016 Chemical Data Reporting (CDR)

Q31. Are there any changes from the new law that affect CDR reporting for 2016?

There are changes in the new law related to confidential information submitted under TSCA. For the 2016 CDR submitters, EPA changed the wording of the CBI certification statement to be consistent with the requirements in the new law. EPA is updating the guidance, instructions, and other information documents to be consistent with the new certification language.

Preemption

NOTE: These responses convey the EPA's general and preliminary interpretation of TSCA Section 18. They are intended to address the extent to which TSCA may preempt state law under a variety of general circumstances,

including how EPA's own actions may affect the potential scope of preemption. These responses also convey the EPA's preliminary interpretation of its own authorities and obligations to grant waivers from any such federal preemption. The Agency does not adjudicate disputes as to whether particular state laws are subject to federal preemption and these responses are not intended to resolve such disputes, or to otherwise establish the preemption status of a particular state law.

Q32 Are the first 10 Work Plan chemicals exempt from TSCA 18(b) pause preemption?

TSCA does not provide for “pause” preemption to occur while EPA is preparing risk evaluations for the initial batch of 10 Work Plan chemical substances (i.e., those that must be identified under TSCA § 6(b)(2)(A)). See TSCA § 18(b)(1), which specifies that pause preemption is only applicable with respect to a chemical substance “that is a high-priority substance designated under [TSCA § 6(b)(1)(B)(i)].” The designation of a chemical substance under TSCA § 6(b)(1)(B)(i) is distinct from the identification of a chemical substance under TSCA § 6(b)(2)(A). See TSCA § 6(b)(4)(C)(i). EPA’s interpretation is reflected in the legislative history of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“FRL21”): “The first 10 chemicals EPA evaluates under the bill are . . . exempted from preemption until the final rule is issued.” 162 Cong. Rec. S3511 (June 7, 2016). Similarly, “[Pause preemption] does not apply to the first 10 TSCA Work Plan chemicals the EPA reviews, and it does not apply to manufacturer-requested risk evaluations.” 162 Cong. Rec. S3521 (June 7, 2016).

Q33 TSCA 18(e)(1)(B) exempts from preemption “any action taken pursuant to a State law that was in effect on August 31, 2003.” Does “any action” include a state regulation (to be promulgated in the future) adopted pursuant to a state law in effect before August 31, 2003?

A state action “taken pursuant to a State law that was in effect on August 31, 2003,” is not preempted by TSCA. See § 18(e)(1)(B). In contrast to § 18(e)(1)(A), which is limited in scope to state actions taken prior to April 22, 2016, TSCA § 18(e)(1)(B) specifies no cutoff for when the state action in question must have been taken. Thus, EPA understands that TSCA § 18(e)(1)(B) applies irrespective of when the state action was taken, if it is “pursuant to a State law that was in effect on August 31, 2003.” EPA’s interpretation is reflected in the legislative history of the Frank R. Lautenberg Chemical Safety for the 21st Century Act: “Section 18(e) . . . grandfathers . . . requirements imposed now or in the future under the authority of state laws that were in effect on August 31, 2003.” 162 Cong. Rec. S3518 (June 7, 2016).

Q34 TSCA 18(d)(1)(A)(iii) exempts from preemption state regulations adopted pursuant to state law “related to water quality, air quality, or waste treatment or disposal,” except to the extent that a regulation meets certain narrow criteria. If a state regulation was adopted pursuant to a state law promulgated before 2003 (and so would otherwise be grandfathered under TSCA 18(e)(1)(B)), but falls within the exception to exemption from preemption under 18(d)(1)(A)(iii), is the state regulation preempted or not?

The grandfathering provision of § 18(e)(1)(B) applies even when other exceptions from preemption under § 18(d)(1)(A) are unavailable. Section 18(e)(1)(B) states that “[n]othing in this chapter . . . shall be construed to preempt or otherwise affect,” state actions that qualify for the grandfathering. TSCA indicates that grandfathering should be construed as “subject to subsection (g),” but is silent as to any interdependency with § 18(d)(1)(A). EPA therefore infers that the §§ 18(d)(1)(A) and 18(e)(1)(B) operate independently. A state action otherwise qualifying under § 18(e)(1)(B) should not be considered to have lost its grandfathering simply because it does not doubly qualify as exempt from preemption under one of the further grounds listed at § 18(d)(1)(A).

Q35 EPA has published risk assessments on a number of chemicals prior to enactment of new TSCA. Section 26(l)(4) gives EPA authority to proceed to risk management on these “completed risk assessment” chemicals. Would state actions or regulations involving these chemicals be subject to permanent preemption or pause preemption as a result of these rules?

We believe there is a reasonable argument that a state statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of a “completed

risk assessment” chemical will not be preempted under either Section 18(a)(1)(B) or 18(b). The extent of preemption under Section 18(a)(1)(B) is “consistent with the scope of the risk evaluation under section 6(b)(4)(D).” The extent of preemption under 18(b) is similarly tied to the “scope of the risk evaluation pursuant to section 6(b)(4)(D).” EPA’s rulemaking authority for the “completed risk assessment” chemicals is in Section 26(l)(4), which provides EPA authority to publish Section 6(a) rules for chemical substances for which completed risk assessments were published prior to the date of recent amendments to TSCA, “consistent with the scope of the completed risk assessment.” In EPA’s view, the risk assessments that have been completed prior to the recent amendments to TSCA that can form the basis of these rulemakings are not the equivalent of risk evaluations under 6(b)(4)(D). Therefore, it is reasonable to argue that a Section 6(a) rule promulgated under the authority of Section 26(l)(4) will not preempt a state law or action on that chemical under either Section 18(a)(1)(B) or Section 18(b).

Persistent, Bioaccumulative, and Toxic Chemicals Covered Under TSCA Section 6(h)

Q36. The Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), requires that EPA take expedited action on certain persistent, bioaccumulative, and toxic (PBT) chemicals listed on the Agency’s 2014 update of the TSCA Chemicals Work Plan for Chemical Assessment (2014 Work Plan). TSCA section 6(h). What chemicals are covered by this provision?

PBT Chemicals Subject to Section 6(h)

Decabromodiphenyl ethers (DecaBDE) (CASRN 1163-19-5)

Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)- (CASRN 54464-59-4)

Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)- (CASRN 54464-57-2)

Hexachlorobutadiene (CASRN 87-68-3)

Pentachlorothio-phenol (CASRN 133-49-3)

Phenol, isopropylated, phosphate (3:1) (IPTPP) (CASRN 68937-41-7)

2,4,6-Tris(-tert-butyl)phenol (CASRN 732-26-3)

Q37. I am considering submitting a request for a risk evaluation under TSCA section 6(b)(4)(C)(ii) for one of the PBT chemicals subject to TSCA section 6(h) which would exclude the chemical from the expedited action requirement (TSCA section 6(h)). What must I include in a request for a risk evaluation for a PBT substance as contemplated by TSCA sections 6(h)(5) and 6(b)(4)(C)(ii)?

EPA has not yet issued its rule prescribing the form, manner and criteria for submission of manufacturer-requested risk evaluations pursuant to TSCA section 6(b)(4)(C)(ii). This rule must be promulgated no later than 1 year after the date of enactment, or June 22, 2017. However, for chemicals subject to TSCA section 6(h), the law contemplates the opportunity for such requests to be made within 90 days of enactment, or by September 19, 2016.

For the limited purposes of making a request for risk evaluation of a chemical subject to TSCA section 6(h), the request must include the identity of the chemical for which evaluation is requested; the name and headquarters address of the company; and manufacturer contact information including the name, address if different than the headquarters address, email address and telephone number of the company official submitting the request.

Businesses may claim information in requests as confidential business information (CBI). Information claimed as confidential should be clearly marked by bracketing, circling, or underlining. All pages containing such information should also be stamped "CONFIDENTIAL BUSINESS INFORMATION" or with similar designation.

Your requests must be mailed or hand delivered to the address below:

TSCA Confidential Business Information Center (7407M)
WJC East; Room 6428; Attn: "TSCA section 6 PBT Risk Evaluation Request"
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Courier Deliveries:
1201 Constitution Avenue, NW
WJC East; Room 6428 Attn: "TSCA section 6 PBT Risk Evaluation Request"
Washington, DC 20004-3302

Please note that TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, includes new requirements for the submission of materials claimed as TSCA CBI, including:

1. Certification Statement. TSCA now requires that the submitter provide a statement concerning the need for the CBI claim and a certification of the truth and accuracy of the statement of need. EPA has consolidated those requirements into the following general certification:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- i. My company has taken reasonable measures to protect the confidentiality of the information;
- ii. have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- iii. I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- iv. I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

TSCA CBI claims must be accompanied by the above signed certification.

2. Generic Name Requirement if Chemical Name is claimed as CBI. Because the specific chemical identities of the PBT chemical substances at issue are already public, EPA does not expect to receive CBI claims for the chemical identities. Note in general that when a chemical identity is claimed as CBI, a non-CBI structurally descriptive generic name must be provided. Submitters should use the existing guidance to develop these names. See <https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf>. EPA will develop further guidance regarding generic names as required by TSCA.

Note also that TSCA now provides for reviews of CBI Claims for chemical identity. With limited exceptions, all chemical names claimed as CBI in TSCA filings are subject to Agency review. The statute also provides for Agency review of CBI claims of a representative sample of at least 25% of most other types of CBI claims.

Q38. If I request a risk evaluation on a PBT chemical substance subject to TSCA section 6(h), can I specify the narrow use or set of uses for EPA to evaluate?

No. If EPA receives a request for a risk evaluation on a PBT chemical substance subject to TSCA section 6(h), the Agency will evaluate the chemical substance in accordance with TSCA section 6(b).

Q39. If I request a risk evaluation on a PBT chemical substance subject to TSCA section 6(h), will I be required to pay a fee?

Yes. Manufacturers submitting requests for risk evaluations of chemicals subject to TSCA section 6(h) will be required to pay a fee for evaluation of that chemical in accordance with the rule to be issued under TSCA section 26(b)(1) and as described in TSCA section 26(b)(4). EPA intends to issue a final fees rule by June 22, 2017.

Q40. Will I be allowed to later withdraw my request for risk evaluation on a PBT chemical substance subject to TSCA section 6(h)?

No. A manufacturer may not later withdraw a request for risk evaluation on a PBT chemical substance subject to TSCA section 6(h). The request represents a firm commitment on the manufacturer to pay for the risk evaluation in accordance with the rule to be issued under TSCA section 26(b)(1) and as described in TSCA section 26(b)(4). EPA believes that allowing a withdraw under these circumstances would undermine Congress' intent to require EPA to either (1) take expedited action on those chemicals, or (2) conduct a full risk evaluation subsidized by the manufacturer.

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