

EPA Authorities Under TSCA

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Introduction

The mission of the Office of Pollution and Prevention and Toxics (OPPT) is to:

- protect and improve human health and the environment, to achieve risk reduction, sustainability, environmental justice, and enhance the quality of life;
- promote safer designs, wiser use of materials, products, processes, practices and technologies, and disposal methods using pollution prevention as the principle of first choice;
- provide information, education and technical assistance to empower the public to make informed decisions on the risks associated with toxic substances.

In Section 2(b) of the Toxic Substances Control Act (TSCA)¹ the U.S. Congress established the underlying national policy that:

- adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment, and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;
- adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
- authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

Under Section 6602(b) of the Pollution Prevention Act of 1990 (PPA)², Congress established a national policy that:

- pollution should be prevented or reduced at the source whenever feasible;
- pollution that cannot be prevented should be recycled in an environmentally safe manner whenever feasible;
- pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and

- disposal or other release of pollution into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.

OPPT is responsible for administering TSCA and the PPA. To accomplish its work, OPPT has a strategic framework of statutory and regulatory tools as well as voluntary and partnership approaches.

The purpose of this document is to provide: a reader-friendly outline of the tools OPPT has under TSCA to achieve its mission; the situations under which each of these tools may be employed; and the considerations that affect OPPT's determination of which tool is best suited for a given situation. Four questions are answered within the body of each of the tools discussions: 1) How does it work? 2) Who is involved? 3) What does it take? 4) When is it used? Following the discussion of tools available to EPA under TSCA, there is a brief outline of some of the functions the EPA must carry out to achieve its mission. Following each function is a list of tools, both formal and informal that may be used for that purpose.

(This document contains hyperlinks. You can advance from the table of contents to the corresponding section of the document by holding the control button and clicking on the line in the table of contents; in the body of the text you can advance directly to the web address hyperlink at the end of the document by double clicking on the endnote number highlighted in red; in order to view the hyperlink web addresses listed at the end of the document hold the control button and click on the underlined hyperlink. This document was prepared using Microsoft® Word 2002.)

TSCA Section 4 Test Rules

How does it work?

- TSCA §2(b) (1) states: “It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [(defined by the statute to include import)] and those who process such chemical substances and mixtures.” The authority under which EPA requires that such testing be conducted by industry is §4 of TSCA. The implementing regulations for TSCA §4³ test rules are found at 40 CFR Parts 790⁴, 791⁵, and 799⁶.
- In order for EPA to issue a “test rule” under §4, the Agency must make the following statutory “findings”:
 - One or more activities associated with the subject chemical or mixture “may present an unreasonable risk” (“A” hazard/risk finding), **or**
 - The chemical is produced in substantial quantities **and** enters (or may enter) the environment in substantial quantities **or** there is or may be significant or substantial human exposure to the chemical (“B” exposure findings), **and** each of the following:
 - Insufficient data and experience exist upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of the chemical or mixture or of any combination of such activities can reasonably be determined or predicted, **and**
 - Testing is necessary to develop the needed data.
- In making the “A” finding, EPA must also determine that the probability of exposure to the subject chemical is more than just theoretical.
- In making the “B” finding, EPA relies on its “B Policy” which, following public notice and comment, was published on May 14, 1993 (58 FR 28736). It is important to note that EPA is not bound to use this policy if the Agency can adequately develop and support an alternative approach.
- EPA’s “B Policy” contains the following indicative criteria that the Agency uses to make the “B” finding:
 - Substantial production/importation: 1 million pounds or more per year, **and**
 - Substantial environmental release: 1 million pounds or more or 10% of production/importation, **or**
 - Substantial human exposure: 1,000 workers **or** 10,000 consumers **or** 100,000 general population, **or**
 - Significant human exposure: case-by-case basis.

- All test rules must undergo public notice and comment rulemaking procedures prior to finalization and promulgation via publication in the Federal Register.
- All studies conducted under a test rule must adhere to EPA approved test methods/standards and must be performed under the Agency's Good Laboratory Practice Standards (GLPS). The majority of EPA's currently approved TSCA test methods/standards are found at 40 CFR Parts 795⁷, 796⁸, 797⁹, 798¹⁰, and 799¹¹; EPA's TSCA GLPS are found at 40 CFR Part 792¹². EPA often includes "voluntary consensus standards" (e.g., ASTM standards) as the required test methods in test rules. In addition, EPA may also require the use of the internationally accepted the Organization of Economic Cooperation and Development (OECD) test guidelines.
- The cost of performing the required testing is shared among manufacturers and/or processors of each test rule chemical – although cost sharing agreements are typically arranged privately, the testing cost reimbursement procedures are available at 40 CFR Part 791¹³.

Who is affected?

- Chemical producers, importers and processors (including those who intend to produce, import or process) can be required to conduct health effects, environmental effects, environmental fate, and other types of needed studies (e.g., monitoring) under a TSCA §4 test rule. The following approach, although not mandated by TSCA, is one that EPA has utilized in its most recent proposed and final test rules.
- Certain producers and importers of a subject chemical are typically required to comply immediately with the requirements of a promulgated test rule; these producers and importers are categorized by EPA as being in "Tier 1" for the purposes of the test rule.
- Anyone categorized by EPA as being in "Tier 2", while still subject to the test rule (and thus potentially responsible for providing reimbursement to test sponsors), would typically be required by EPA to comply with the test rule only if the Agency issues a Federal Register notice to that effect. Tier 2 includes:
 1. Producers and importers of a subject chemical solely as one or more of the following:
 - As a byproduct,
 - As an impurity,
 - As a naturally occurring substance,
 - As a non-isolated intermediate,
 - As a component of a "Class 2" substance (Class 2 chemical substances are substances that cannot be fully represented by a complete, specific chemical structure diagram),
 - In amounts of less than 1,100 lbs annually,

- For research and development.
 - 2. Processors of the subject chemical.
- In addition to the chemical industry, a large number of groups may be interested in TSCA §4 test rules. These include but are not limited to labor unions (e.g., AFL-CIO), environmental groups (e.g., Environmental Defense), animal welfare groups (e.g., People for the Ethical Treatment of Animals), state and local governments, other federal agencies (e.g., Occupational Safety and Health Administration; Consumer Product Safety Commission), international groups (e.g., OECD) and members of the general public.
 - Finally, TSCA §12(b)¹⁴ “export notification” requirements (implementing regulations found at 40 CFR Part 707¹⁵) are triggered by EPA’s promulgation of a final TSCA §4 test rule.

What does it take?

- In addition to the development of a TSCA §4 “findings” document, each TSCA §4 rulemaking involves the preparation of an Economic Analysis and a Statutory and Executive Order Review.
- There are multiple levels of review within EPA and, in many cases, outside EPA (e.g., Office of Management and Budget).

When is it used?

- The TSCA Interagency Testing Committee (ITC), established under TSCA §4(e), is made up of representatives from numerous federal agencies (e.g., EPA, OSHA, NIOSH, CPSC, FDA, DOE, DOC, and DOI). One of the primary roles of the ITC is to identify TSCA chemicals for which there are suspicions of toxicity or exposure and for which there are few, if any: ecological effects testing data, environmental fate testing data, or health effects testing data.
 - The ITC adds such chemicals to its TSCA §4(e) Priority Testing List and can “designate” them to the EPA Administrator for test rule development consideration in order to meet the data needs of the ITC’s member agencies and departments.
 - For chemicals that are formally designated by the ITC, EPA must (in accordance with the statute) within 1 year issue a proposed test rule or an advance notice of proposed rulemaking or issue a Federal Register notice stating EPA’s rationale for not doing so; this latter action is commonly referred to as a TSCA §4 “Decision-Not-to Test” (or DNT).
- OPPT receives requests for testing action development directly from other EPA Offices (e.g., Office of Air and Radiation) and other federal agencies (e.g., the Agency for Toxic

Substances and Disease Registry). There is no statutory deadline imposed on developing testing actions for these requests.

- OPPT, through its implementation of its TSCA Existing Chemicals Program, is also a source of chemical candidates for TSCA §4 testing action development. There is no statutory deadline imposed on developing testing actions for these requests.

TSCA Section 4 Enforceable Consent Agreements (ECAs)

How does it work?

- Enforceable Consent Agreements (ECAs) are established under TSCA §4 as an alternative to formal rulemaking. ECAs are used where a consensus exists among the Agency and interested parties (including one or more chemical manufacturers or processors, as well as other interested members of the public) about the adequacy of the proposed testing program and other pertinent features of the agreement (See 40 CFR 790.24¹⁶). The procedures for ECA development are described at 40 CFR 790.22(b)¹⁷.
- The usual route to an ECA is through a proposed §4 test rule that also includes an invitation to affected manufacturers and/or processors and the public to enter into ECA negotiations.
- Less often, an ECA is entered into by direct invitation without the issuance of a proposed test rule (for example ECAs for PFOA). This is still a public process with the issuance of a Federal Register notice soliciting the participation of interested parties.
- ECAs, like §4 test rules, are used to develop information on toxicological endpoints for human health and the environment, and can also include chemical fate and transport studies, exposure-related studies, environmental monitoring, and human epidemiology studies.
- ECAs permit more interaction with the test sponsors than the formal rulemaking process allows, and often have the benefit of a more tailored testing approach to answering the toxicological and exposure questions of concern for the chemical substance(s) being examined. For example, tiered testing approaches are common under ECAs.
- The relationship between EPA and industry in developing an ECA is typically less adversarial than in the formal rulemaking context.
- ECAs also permit the use of more “experimental” or “non-routine” testing, for which EPA does not have established guidelines (for example, physiologically based pharmacokinetics (PBPK) modeling, which allows route-to-route extrapolations between different exposure routes).
- ECAs often allow test data to be obtained much more quickly and efficiently than would be the case under final test rule development.
- TSCA §12(b) export notification is required for substances and mixtures covered by ECAs.

Who is involved?

- ECAs typically affect only manufacturers who usually coordinate testing as a formal “testing group” (e.g., the Hazardous Air Pollutants (HAP) Task Force) which becomes the “test sponsor.” An ECA applies only to the signatory companies; therefore, responsibility for the accomplishment of the testing set forth in the ECA is ultimately that of each of the companies signing the final ECA agreement.
- ECAs also involve members of the public, which may include environmental groups (e.g., NRDC) or other companies (e.g., small manufacturers or processors) who will not be signatories to the ECA, but who are interested, for example, in the commercial, legal, or scientific issues presented by the test program. For example, there are close to 200 active Interested Parties involved in the recent developments of PFOA ECAs.

What does it take?

- ECAs require a public process of ECA discussions, which generally occur after EPA requests and receives satisfactory ECA proposals. Having received proposals that EPA believes can form a basis for a successful ECA, EPA issues in the Federal Register a solicitation of interested parties to monitor or participate in these discussions.
- A final ECA requires agreement between EPA and any interested parties on the adequacy of the testing being sought. Agreement between the parties to the ECA is indicated by the signature of a representative of each Company responsible for the testing and conditions set forth in the ECA, and the signature of the Assistant Administrator (AA) for OPPT. The OPPT AA also officially issues a testing consent order incorporating the ECA which sets forth the effective date of the Order (usually the date of publication of the Federal Register notice announcing the issuance of the Order).
- An official public docket is also established for each ECA.

When is it used?

- ECAs are used in lieu of TSCA §4 test rules, when appropriate. In general, proposed §4 test rules have included an invitation to manufacturers, processors, and other interested parties to enter into ECA discussions.
 - ECAs have been used in cases where industry agrees to do some, but not all, of the testing proposed in a test rule under an ECA. EPA may issue a testing consent order for that testing, and then develop a final §4 test rule for the remainder.

- ECAs have also been used in situations where a test sponsor offers to conduct needed testing prior to issuance of a §4 test rule where enforceability is desired as opposed to voluntary testing commitments, which are not enforceable by the Agency.

TSCA Section 5 Manufacture/Processing Notices and Significant New Use Rules (SNURs)

How does it work?

Premanufacture Notices (PMNs):

- §5(a) of TSCA¹⁸ applies to manufacturing and processing notices for new chemicals and for significant new uses of new or existing chemicals.
- Anyone who intends to manufacture or import a new chemical must submit a premanufacture notice to EPA at least 90 days in advance.
 - Chemicals not on the TSCA inventory are considered new chemicals.
 - Certain genetically modified microorganisms are considered new chemicals.
 - PMN regulations are at 40 CFR §720¹⁹.

Significant New Use Notifications (SNUNs):

- Anyone who intends to manufacturer, import or process a chemical for a significant new use is required to submit a "significant new use notice" (SNUN) to EPA at least 90 days in advance.
 - A SNUR is a regulation issued under §5(a) (2) of TSCA.
 - A SNUR is not a ban or restriction on the use of a chemical. It requires that the Agency be notified in advance of manufacture or processing for a significant new use.
 - SNURs are at 40 CFR 721²⁰ and 725²¹ subparts L and M.
- The notice (PMN or SNUN) is reviewed by OPPT to develop information and to determine whether action is needed to prohibit or limit manufacturing, processing, use, distribution in commerce, or disposal of the chemical.
- SNUNs and PMNs undergo the same review process.
 - OPPT experts look at each PMN or SNUN. Using the information in the notice on process, exposure, and production volume, the experts develop a profile of hazards, exposures and releases from manufacture, processing and use, including: occupational exposure/releases, environmental releases, consumer exposure, and ambient or general population exposure.
 - Agency risk managers are provided with an estimate of potential risk by EPA experts who work together to predict the potential risks to humans or the environment from each new chemical or new use of an existing chemical.
 - Decisions are based on information obtained from the notice submitter, consideration of related cases and other relevant factors, and on information and analyses developed by OPPT reviews.

- If the Administrator has not initiated action under §5, §6, or §7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical for which a SNUN was required or for which submission of test data was required under §5(b) of TSCA, the Administrator must publish a Federal Register notice under §5(g) giving reasons for not taking such action.
- Following the 90-day review period, if EPA takes no action, the PMN submitter may begin manufacturing or importing the chemical. The PMN submitter must submit a “Notice of Commencement” (NOC) to EPA within 30 days of first manufacture or importation.
- Following receipt of the NOC, the chemical is added to the Inventory. Once a chemical is listed on the TSCA Inventory, it is considered an existing chemical.
- More information on EPA’s §5 notice review process is available at <http://www.epa.gov/opptintr/newchems>.

Who is affected?

- Anyone who intends to manufacture or import a new chemical, or manufacture, import, or process a chemical for a significant new use in the United States for commercial purposes must submit a notice to EPA unless that person is exempt in accordance with §5(h) of TSCA.
- Only manufacturers, importers, or processors that are incorporated, licensed, or doing business in the United States may submit a PMN or SNUN.

What does it take?

Notice Review Outcomes: A number of considerations are taken into account when deciding whether to regulate a new chemical submission. These considerations include: the magnitude/type of risk; numbers/types of individuals exposed; potential to substitute for a more risky existing chemical; the benefits of the new chemical being considered and the regulatory history associated with the chemistry presented. The outcome following the review of a PMN or SNUN submission may include one or more of the following:

- No action - EPA may review the notice and take no action. This is the most common outcome.
- Voluntary withdrawal of the notice by the submitter, this action is often (but not always) taken in the face of possible EPA action.

- §5(e) Order. EPA may issue a proposed order under TSCA §5(e) to prohibit or limit activities associated with the chemical.
 - EPA must determine that insufficient information exists to evaluate the human health and environmental effects of the chemical, and that: (1) it may present an unreasonable risk (“risk-based finding”) or (2) it is or will be produced in substantial quantities, and there is or will be substantial or significant exposure/release.
 - TSCA §5(e) orders typically include: exposure or release mitigation, testing, labeling and hazard communication, and record keeping.

- TSCA §5(f) actions. If EPA determines that the manufacturing, processing, distribution in commerce or disposal of a chemical that is the subject of a PMN or SNUN requirements presents or will present an unreasonable risk before a TSCA §6 rule can be promulgated, under TSCA §5(f), EPA may:
 - (1) limit the amount or impose other restrictions on the chemical via an immediately effective proposed rule, or
 - (2) prohibit the manufacturing, processing or distribution in commerce of the chemical by issuing a proposed order or applying to a U.S. District Court for an injunction.

- Voluntary Testing Actions. In a limited number of cases, PMN or SNUN submitters voluntarily agree to suspend the notice review period and conduct needed hazard or environmental fate testing in response to a request from EPA.
 - The “voluntary” testing is performed during the 90-day review period with a suspension(s) until the testing is completed.
 - Submitters may also take the option of withdrawing instead of performing the testing.

Significant New Use Rules (SNURs)

- TSCA §5(a)(2) requires the Agency to consider all relevant factors including the following in making a significant new use determination:
 - the projected manufacturing and processing volume,
 - the anticipated extent to which the use changes the type or form of exposure,
 - the magnitude and duration of exposure, and
 - the manner and methods of manufacture, processing, distribution in commerce, and disposal of the chemical substance.

- No risk determination is required to issue a SNUR.

- A SNUR may be issued following review of a PMN, or involve an existing chemical.

- SNURs are generally promulgated following a §5(e) order:
 - §5(e) Orders are only binding on the original PMN submitter that manufactures or imports the chemical.
 - After signing a §5(e) order, EPA generally promulgates a SNUR that mimics the terms of the order.
 - These SNURs are referred to as §5(e) SNURs, or expedited SNURs and are generally promulgated as "direct final" rules.
 - Regulations for expedited SNURs are at 40 CFR 721 Subpart D.
 - The Agency may also issue a SNUR for a new chemical in the absence of a §5(e) order when it identifies potential new uses different from those identified in the PMN which could result in increased exposures to or releases of the chemical, and may result in an unreasonable risk to health or the environment. These SNURs are referred to as "non-5(e) SNURs."

Resources

- Activities involved in issuing a SNUR may include economic analysis, hazard analysis, exposure analysis and notice and comment rulemaking.
- Notice and comment SNURs take anywhere from 1 year to several years to put into effect.
- Typical time frame to issue a SNUR, from start of work until it goes into effect, is two years.
- Cost to a manufacturer, importer, or processor to submit a SNUN is approximately \$7,300.

When is it used?

- A SNUR is used to provide the Agency with an opportunity to review a use before it occurs and if necessary take risk management action. EPA must make the determination that a use is a significant new use, as discussed above. Examples include:
 - Discontinued production - The Agency has issued SNURs in cases where a chemical of concern to the Agency is no longer in production, to ensure that it has an opportunity to consider control measures needed for risk management action if needed before production resumes. The polybrominated biphenyl (PBB) SNUR is an example of a discontinued production SNUR.
 - Discontinued use - The Agency has issued SNURs where certain uses of concern are no longer occurring. For example certain glycol ethers that were once used in consumer products are no longer being produced for that purpose. The Agency has proposed a SNUR for consumer use of those chemicals. Other uses would not be affected.

- Anticipated uses - EPA has issued SNURs where the Agency anticipates that a chemical may be used in a new way that would have a significant impact on exposure or releases to the environment. For example, the Agency is preparing to propose a SNUR for flame retardant chemicals that may be used on residential furniture to meet a flammability standard under development by the Consumer Product Safety Commission.
 - Volume SNUR - SNURs have been issued to require notification before anyone exceeds a specified level of manufacturing or processing where a chemical is manufactured or processed in limited quantities. Volume SNURs are most often used in the New Chemical Program when the Agency wishes to revisit a chemical before production increases significantly beyond what was envisioned at the time of initial review.
 - §5(e) SNUR - After signing a § 5(e) Consent Order, EPA generally promulgates a SNUR that mimics the terms of the Consent Order. The SNUR requires submission of a SNUN by a company not subject to the §5(e) order if that company intends to manufacture or process the chemical substance in a manner that would be inconsistent with the terms and conditions contained in the §5(e) Consent Order (See discussion of manufacturing and processing notices).
- SNURs have also been used to supplement voluntary agreements. For example, the Agency has issued a discontinued production and discontinued use SNUR where all manufacturers voluntarily agreed to stop producing a chemical for a certain use or to stop producing it altogether. The SNUR ensures that no one else engages in that activity without first submitting a notice to the Agency. These SNURs have been important tools in making voluntary agreements workable.

TSCA Section 6(a) Regulation of Hazardous Chemical Substances and Mixtures

How does it work?

- EPA may issue a regulation under TSCA §6²²:
 - **(a)(1)** To prohibit (or limit) the manufacture, processing, or distribution in commerce of a substance/mixture;
 - **(a)(2)** To prohibit (or limit) the manufacture, processing, or distribution in commerce of substance/mixture for a particular use or for a particular use at a particular concentration;
 - **(a)(3)** To require a substance/mixture, or any article containing the substance/mixture, to be labeled or accompanied by warnings and instructions for use, distribution, or disposal;
 - **(a)(4)** To require manufacturers and processors of a substance/mixture to keep records of manufacturing/processing methods and conduct reasonable monitoring or testing necessary to assure regulatory compliance;
 - **(a)(5)** To prohibit or otherwise regulate commercial use of a substance/mixture;
 - **(a)(6)** To prohibit or otherwise regulate disposal of a substance/mixture, or any article containing the substance/mixture, by manufacturers, processors, or anyone who uses it, or disposes of it, for commercial purposes; or
 - **(a)(7)** To require manufacturers or processors to notify distributors, other persons in possession of the substance/mixture, and the general public of the risk of injury and replace or repurchase the substance/mixture.
- Existing regulations promulgated under TSCA §6(a) can be found at 40 CFR part 747 (metalworking fluids)²³, part 749 (hexavalent chromium)²⁴, and part 763 (asbestos Worker Protection Rule and Ban and Phaseout)²⁵.

Who is Involved?

- Regulated parties could include manufacturers, importers, processors, distributors, commercial users, and disposal operators.

What does it take?

- To issue a regulation under TSCA §6(a), EPA must determine that one or more activities involving a substance/mixture presents or will present an unreasonable risk of injury to health or the environment.
- TSCA §6(c) requires EPA to evaluate a number of factors in making this finding, including health and environmental effects, exposure, the benefits of the substance/mixture, the availability of substitutes, and the economic effects of a rule.

- The unreasonable risk finding can be characterized as a judgment that the risk of health or environmental injury from the substance/mixture outweighs the burden to society of potential regulations (59 FR 11122, at 11138 (March 9, 1994).
- Once EPA has made a finding that a substance/mixture presents an unreasonable risk, EPA must use the least burdensome requirements available under TSCA §6(a) that adequately address the risk.
- 40 CFR part 750 subpart A²⁶, sets out procedures for rulemaking under TSCA §6.
- Activities involved in issuing a regulation under TSCA §6(a) include: economic analysis, hazard analysis, exposure analysis, risk assessment, substitutes analysis (more extensive analysis required if regulation will ban or restrict production), evaluation of a number of other factors such as the benefits of the substance/mixture and the consequences of the rule on technological innovation, and notice-and-comment rulemaking.

When is it used?

- As indicated above, to issue a regulation under TSCA §6(a), EPA must determine that one or more activities involving a substance/mixture presents or will present an unreasonable risk of injury to health or the environment.
- Under TSCA §6(c), TSCA §6(a) rulemaking would only be used if no other statutes administered by EPA are available to address an unreasonable risk, unless the Administrator finds that it is in the public interest to use TSCA §6.

TSCA Section 6(b) Quality Control Orders

How does it work?

- If EPA has a reasonable basis to conclude that a particular manufacturer or processor is making or producing a chemical substance in such a way that it presents an unreasonable risk to human health or the environment, EPA may order the manufacturer or processor to submit a description of its relevant quality control procedures.
- If EPA then determines that those quality control procedures are inadequate to prevent an unreasonable risk, EPA may order the manufacturer or processor to modify its quality control procedures to the extent necessary to remedy the inadequacy.
- In addition, if EPA determines that a chemical which presents an unreasonable risk has been distributed, EPA may order the manufacturer or processor to notify its customers and the general public, and to replace or repurchase the chemical as necessary to protect health and the environment.
- These are enforceable orders, failure to comply with an order issued under TSCA §6(b)²⁷ is a violation of TSCA, for which EPA may assess penalties.

Who is Involved?

- Orders may be issued to manufacturers and processors.
- Interested parties include downstream processors and distributors.

What does it take?

- To issue an order under TSCA §6(b), EPA must determine that a manufacturer or processor is producing a chemical that presents an unreasonable risk of injury to health or the environment.
- Orders to revise procedures, to notify customers or the public, or to replace or repurchase chemicals must be issued in accordance with Section 554 of the Administrative Procedures Act²⁸, which requires an adjudication on the record after an opportunity for a hearing. Manufacturers and processors must be offered the option to replace or repurchase, but EPA may prescribe the procedures for doing so in each case.

When is it used?

- By its nature, TSCA §6(b) can only be used in very limited circumstances, where EPA has evidence that a particular manufacturer or processor is not using sufficient quality control procedures.

TSCA Section 7 Imminent Hazards

How does it work?

- §7 of TSCA²⁹ authorizes the Administrator of EPA to commence civil action in a district court:
 - For seizure of an imminently hazardous substance, mixture or any article containing them, and/or
 - For relief³⁰ against any person who manufactures, processes, distributes in commerce, uses, or disposes of an imminently hazardous substance, mixture or article containing them.

- The district court may grant relief to protect health or the environment from the unreasonable risk associated with the chemical, mixture, or article.

- Relief may include issuance of an order requiring:
 - Notification of purchasers of the risk associated with the chemical, mixture, or article,
 - Public notice of such risk,
 - Recall,
 - Replacement or repurchase, or
 - Any combination of the above.

- Where appropriate, the Administrator shall, concurrently with filing of a civil action under §7 or as soon as practicable thereafter, shall initiate proceeding for promulgation of a rule under TSCA §6(a).

- If EPA determines that a chemical is likely to present an unreasonable risk of serious or widespread injury to health or the environment before normal rulemaking procedures can be completed, EPA may declare a proposed rule under TSCA §6 immediately effective upon publication and until the effective date of the final action.

Who is affected?

- Persons who manufacture, process, distribute in commerce, use or dispose of chemicals or articles containing them, may be affected.

What does it take?

- An imminently hazardous chemical substance or mixture is one which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment.

When is it used?

- EPA may initiate action under §7 when manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture is likely to result in widespread or serious injury to health or the environment before a final rule under §6 can protect against such risk.

TSCA Section 8(a) General Information Gathering

How does it work?

- TSCA §8(a)³¹ gives EPA the broad authority to require, by rulemaking, manufacturers (includes importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates.
- §8(a) recordkeeping and reporting requirements are established through rulemaking.
- §8(a) rules are at 40 CFR part 704³², 710³³, 712³⁴ (PMN and SNUR regulations are also partially done under §8(a) as is the §766³⁵ dioxin/furan rule).
- Examples of information that can be required to be reported include:
 - chemical or mixture identity,
 - categories of use,
 - quantity manufactured or processed,
 - by-product description,
 - health and environmental effects information,
 - number of individuals exposed, and
 - method(s) of disposal.
- §8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules) or information can be obtained via use of "model" or standardized reporting rules.
- One example of a model TSCA §8(a) reporting rule is the "Preliminary Assessment Information Reporting" (or PAIR) Rule.
 - Under PAIR, producers and importers of a listed chemical are required to report the following site-specific information on a two page form:
 - Quantity of chemical produced and/or imported;
 - Amount of chemical lost to the environment during production or importation;
 - Quantity of enclosed, controlled and open releases of the chemical;
 - Per release, the number of workers exposed and the number of hours exposed.

Who is Involved?

- Manufacturers (includes importers) and processors of chemical substances may be required to maintain records and/or report such data.
 - Small manufacturers and processors are exempt.
 - Companies whose total annual sales from all sites owned by the domestic or foreign parent company are below \$30 million for the reporting period and who produced or imported less than 45,400 kilograms of the chemical are considered small manufacturers and/or processors.
 - The Administrator may by rule require a small manufacturer or processor to report if the chemical substance or mixture is subject to certain actions under TSCA.

What does it take?

- TSCA authorizes the Administrator to require maintenance and/or submission of records that are necessary for the effective enforcement of TSCA.

When is it used?

- §8(a) rules can be used in a wide variety of circumstances to gather information in support of TSCA activities.
- §8(a) rules have been used:
 - To obtain information to update the TSCA inventory;
 - To obtain use and exposure information necessary to make a decision on whether to take action under §4 or §6;
 - To obtain information on proposed categories of use of a chemical substance or mixture;
 - To obtain information on chemicals that are designated or recommended for testing by the TSCA Interagency Testing Committee (ITC) via immediate final rulemaking. Non-ITC chemicals can be added via notice and comment rulemaking.

TSCA Section 8(c) Allegations of Significant Adverse Reactions

How does it work?

- Under TSCA §8(c)³⁶, EPA can require companies to record, retain and, in some cases, report “allegations of significant adverse reactions” to any substance/mixture that they produce, import, process, or distribute.
- TSCA §8(c) regulations concerning recordkeeping and reporting of allegations of significant adverse reactions are at 40 CFR 717³⁷.
- An “Allegation” is a statement made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.
- Allegations are subject to a recordkeeping requirement and must be made available for inspection or submitted to the Agency by Agency request through letter or FR notice.
- TSCA §8(c) provides a mechanism to identify previously unknown chemical hazards in that it may reveal patterns of adverse effects which otherwise may not be noticed or detected.
- Individuals, employees, communities and others may benefit from this knowledge base.

Who is involved?

- Manufacturers, importers, and processors.
- Any person can make a written or verbal allegation to a company.

What does it take?

- Any person can make an allegation of significant adverse reactions including long-lasting or irreversible damage to human health; partial or complete impairment of bodily functions; impairment of normal activity by all/most persons exposed at one time/each time an individual is exposed; gradual or sudden changes to animal or plant life in a given geographic area; abnormal numbers of deaths/changes in behavior or distribution of organisms; and long-lasting or irreversible contamination of the physical environment.

- Allegations that are "exempt" from the requirements of the TSCA §8(c) rule include those alleging "known human effects"; allegations involving adverse reactions to the environment, if the alleged cause can be directly attributable to an incident of environmental contamination that has already been reported to the U.S. Government under any applicable authority; anonymous allegations.
- Allegations, to be recordable, must implicate a substance that caused the reaction by naming the specific substance, a mixture or article containing the substance, a company process in which substances are involved, or identifying a discharge from a site.
- Allegations made by an employee must be kept by the company for 30 years while all other allegations (e.g., those made by plant site neighbors or customers) must be kept by the company for 5 years.

When is it used?

- TSCA §8(c) records must be kept at a company's headquarters or at a site central to their chemical operations. The record must contain the following information: the original allegation as received; an abstract of the allegation; the results of any self-initiated investigation regarding the allegation; copies of any further required information regarding the allegations (e.g., copies of any reports required to be made to the U.S. Occupational Safety and Health Administration).
- TSCA §8(c) records must be retrievable by the alleged cause of the reaction (i.e., specific chemical identity, mixture, article company process or operation, or site emission, effluent, or discharge).
- A TSCA §8(c) allegation received by a manufacturer or processor may trigger reporting under TSCA §8(e) (substantial risk information).

TSCA Section 8(d) Health and Safety Data Reporting

How does it work?

- Under TSCA §8(d)³⁸, EPA has the authority to promulgate rules to require producers, importers, and processors to submit lists and/or copies of ongoing and completed unpublished health and safety studies.
- Examples of information that can be required to be reported include: epidemiological or clinical studies; studies of occupational exposure; health effects studies; ecological effects studies; and environmental fate studies (including relevant physicochemical properties).
- §8(d) reporting requirements are established through rulemaking.
- §8(d) rules are codified at 40 CFR parts 716³⁹ and 766⁴⁰.

Who is involved?

- Current as well as prospective producers, importers, and (if specified) processors of the subject chemical substance(s) or listed mixture(s).
- Persons who, in the 10 years preceding the effective date that a substance or mixture is added to the rule, either had proposed to produce, import, or (if specified) process, or had produced, imported, or processed (if specified) the chemical substance(s) or listed mixture(s).

What does it take?

- Chemicals that are designated or recommended for testing by the TSCA Interagency Testing Committee (ITC) may be added to the §8(d) rule via immediate final rulemaking. Non-ITC chemicals can be added to the §8(d) rule via notice and comment rulemaking.
- An economic analysis is required.

When is it used?

- EPA's TSCA §8(d) "Health & Safety Data Reporting Rule" (40 CFR 716) was developed to gather health and safety information on chemical substances and mixtures needed by EPA to carry out its TSCA mandates (e.g., to support OPPT's Existing Chemicals Program and Chemical Testing Program and to set priorities for TSCA risk assessment/management activities).
- OPPT has used its TSCA §8(d) authority to gather information needed by other EPA Program Offices and other Federal Agencies.
- As previously noted, chemicals that are designated or recommended for testing by the TSCA Interagency Testing Committee (ITC) may be added to the rule via immediate final rulemaking. Non-ITC chemicals can be added to the §8(d) rule via notice and comment rulemaking.

TSCA Section 8(e) Substantial Risk Reporting Requirement

How does it work?

- §8(e)⁴¹ is a self-implementing reporting provision of TSCA. It states that any person who manufactures, processes or distributes in commerce a chemical substance or mixture in the U.S. and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall inform the EPA Administrator of such information, unless that person has actual knowledge that the Administrator has been adequately informed of such information. [90 Stat. 2029, 15 USC 2607(e)]. §8(e) reporting guidance defines “immediately” to mean within 30 calendar days. An exception is that emergency incidents of environmental contamination must be reported to the Administrator or to the National Response Center immediately.
- Under TSCA §8(e), the term “substantial risk” refers to information that reasonably supports a conclusion that a chemical or chemical mixture presents a substantial risk of injury to health or to the environment. But such information need not establish conclusively that there is a substantial risk.
- There are two “substantial risk” elements: seriousness of adverse effect and extent or likelihood of exposure. The more serious the health or environmental effect, e.g., cancer, birth defects, the less need there is for supporting information on exposure considerations to support a conclusion of substantial risk. However, widespread and previously unsuspected distribution in the environment of a chemical or chemical mixture must be coupled with serious adverse effects as well as significant exposure to humans or environmental species to support a conclusion of substantial risk.
- The types of information subject to TSCA §8(e) reporting include: epidemiological or clinical studies, studies of occupational exposure, health effects studies, ecological effects studies, environmental fate studies, and both emergency and non-emergency reports of environmental contamination.
- §8(e) reporting requirements became effective on January 1, 1977, the effective date of TSCA. Although §8(e) is self-implementing, EPA has issued a number of TSCA §8(e) reporting guidance documents, including the March, 1978 Policy Statement describing the types of information EPA considers reportable under §8(e) and reporting procedures (43FR11110), the 1991 TSCA §8(e) Reporting Guide, and the June, 2003 Policy Clarification and Reporting Guidance (68FR33129). All of these guidance documents are available on the TSCA §8(e) web page at <http://www.epa.gov/oppt/tzca8e/>.

Who is involved?

- Any person who manufactures, imports, processes or distributes in commerce, chemicals or chemical mixtures covered under TSCA is subject to TSCA §8(e) reporting requirements. “Person” is broadly defined, but in most cases TSCA §8(e) submitters are chemical companies and industry trade associations representing them.

What does it take?

- §8(e) notices are always initiated by persons subject to TSCA 8(e) reporting, using their judgment and the reporting guidance issued by EPA to determine what information should be reported. There are no prior rulemaking requirements associated with §8(e). Persons subject to reporting are directed to submit §8(e) notices to the TSCA Document Processing Center at EPA Headquarters.

When is it used?

- EPA screens all §8(e) submissions to determine if any further risk management or risk assessment is warranted. §8(e) submissions are routinely referred to other EPA program offices and regulatory agencies such as OSHA when regulatory controls or other risk management are already in place. The wide range of information submitted under §8(e) is also utilized by TSCA's New Chemicals Program to evaluate premanufacture notices under §5.
- As of June 1, 2005, EPA has received 16,037 initial §8(e) submissions. The Agency has also received approximately 8,000 supplementary §8(e) submissions in which the submitters have provided additional information as it became available or responded to specific requests for information from EPA. These submissions are tracked in the TSCATS data base, available on the web at <http://yosemite.epa.gov/oppts/epatscat8.nsf/ReportSearch?OpenForm>.

TSCA Section 9 Relationship to Other Federal Laws

TSCA §9 addresses EPA’s authority to regulate chemical substances and associated activities that fall under both TSCA and other Federal laws, including laws administered by other Federal agencies and the EPA. It includes procedures under which EPA can refer the regulation of chemicals to other agencies and requirements to coordinate actions taken under activities with other Federal agencies “for the purpose of achieving the maximum enforcement of this Act [TSCA] while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes.”

TSCA Section 11(c) Subpoenas

How does it work?

- In carrying out TSCA, the Administrator may by subpoena require:
 - the attendance and testimony of witnesses, and
 - production of reports, papers, answers to questions and other information the Administrator deems necessary.
- If a person fails to comply with a subpoena, an appropriate district court could order compliance.

Who is affected?

- Persons who possess information that the Administrator may need to administer TSCA may be subject to subpoena under TSCA §11⁴².

What does it take?

- To issue a subpoena, the administrator must determine that the requested information is necessary for carrying out TSCA.

When is it used?

- TSCA subpoenas are used to obtain information necessary for the administration of TSCA when the needed information is not readily available through other means.

TSCA Section 14 Disclosure of Data

Information submitted under specific reporting requirements of TSCA, or in support of TSCA, is subject to the provisions of §14 of TSCA and to EPA's regulations on the confidentiality of business information. The statute provides that information collected under TSCA, but claimed Confidential Business Information (CBI) will only be released under very limited circumstances related at TSCA §14(a)(1)-(4). TSCA §14(a) prohibits EPA disclosing CBI to the general public, including States, Tribes, and local governments. Under TSCA §14(b), health and safety information in a health and safety study submitted to EPA under TSCA is generally subject to public disclosure.

TSCA Section 26(c) Action with Respect to Categories

How does it work?

- Any action authorized to be taken under TSCA with respect to a chemical substance may be taken with respect to a category of chemical substances or mixtures.
- “Category of chemical substances” means a group of chemical substances the members of which are similar in:
 - molecular structure,
 - physical, chemical, or biological properties,
 - use,
 - mode of entrance into the human body or the environment, and
 - some other way suitable for classification for purposes of TSCA.
- “Category of chemical substances” does not mean a group of chemicals grouped solely on the basis of their being new chemicals.

Who is affected?

- Anyone who engages or plans to engage in an activity is affected if that activity involves a chemical substance that is a member of a category subject to an action taken under TSCA, and the activity is covered by that action.

What does it take?

- The Agency may take action with respect to a category if the members of the category are similar in a way that is specified in the definition of category included in TSCA §26 (c)⁴³.

When is it used?

- The Agency may take action with respect to a category if the requirements of TSCA §26 (c) are met.
- Examples of actions taken with respect to categories are:
 - PCB regulations under §6 of TSCA. See the definition of PCB at 40 CFR 761.3⁴⁴.
 - Health and Safety Data Reporting Rules for categories under §8 (d) of TSCA. See 40 CFR 716.120 (c)⁴⁵.

Functional Applications of OPPT Tools

There are a variety of functions that OPPT must carry out to accomplish its mission. The following table identifies some of those functions and the relevant tools available to OPPT.

Obtaining Prior Notice

- Pre-Manufacture Notifications (PMNs)
- Expedited Significant New Use Rules (SNURs)
- Notice and Comment SNURs
- §8(a) rule
- Informal Actions

Obtaining Hazard Data

- §8(c) Records of significant adverse reactions
- §8(d) Health & Safety Studies
- §8(e) Notice of Substantial Risk
- For Your Information submissions (FYIs)
- Voluntary Submissions

Generating Hazard data

- §4 test rules
- §4 Enforceable Consent Agreements
- §5(e) orders
- Voluntary agreement (e.g. High Production Volume Challenge)

Obtaining Exposure, Use, and Production Data

- §8(a) Reports
- §8(a) Inventory Update Reporting
- §8(e) Notice of Substantial Risk
- FYIs
- Informal Actions (e.g. simple request)

Generating Exposure and Exposure-Related Data

- §4 test rule
- §4 Enforceable Consent Agreements
- §5(e) order
- Voluntary agreements (e.g., Voluntary Children's Chemical Evaluation Program, benzidine dyes exposure study)

Assess Risk

- §4(f)
- §5(e/f)

- §6
- Voluntary agreements

Communicate Risk

- §5(e) orders (labels etc)
- §6
- Voluntary

Managing Risk

- §5(e)
- §7 Action to Relieve Imminent Hazard
- §6 Regulation
- §6 Quality Control Order
- Voluntary agreements

Other Actions - formal

- §11 Subpoenas
- Negotiated Rulemaking (e.g., Expedited SNUR)
- §26 - Actions with respect to categories

Other Actions - informal

- Stakeholder Dialogues
- Dissemination of information to stakeholders
- Development of assessment tools for use by stakeholders
- Development of Guidance to assist stakeholders in decision making

Index of Abbreviations

ASTM- Association for Standards and Testing Methodology
CPSC- Consumer Products Safety Commission
DOC- Department of Commerce
DOE- Department of Energy
DOI- Department of the Interior
ECA- Enforceable Consent Agreement
EPA- Environmental Protection Agency
FDA- Food and Drug Administration
FYI- For Your Information
GLPS- Good Laboratory Practice Standards
ITC- Interagency Testing Committee
NIOSH- National Institute of Occupational Safety and Health
NOC- Notice Of Commencement
NRDC- National Resources Defense Council
OECD- Organization of Economic Cooperation and Development
OPPT- Office of Pollution Prevention and Toxics
OSHA- Occupational Safety and Health Agency
PAIR- Preliminary Assessment Information Reporting
PBPK- Physiologically Based Pharmacokinetics
PFOA- Perfluorooctyl acetate
PMN- Premanufacture Notice
SNUN- Significant New Use Notice
SNUR- Significant New Use Rule
TSCA- Toxic Substances Control Act
TSCATS- Toxic Substances Control Act Test Submissions
VCCEP- Voluntary Children's Chemical Evaluation Program

Cross-Walk between TSCA Section Numbers and US Code Numbers

(Please note that the TSCA hyperlinks go to the US Code online. In the US Code TSCA sections are numbered from 2601 through 2629. The following table lists the sections of TSCA by their US Code number. The corresponding TSCA section number appears in parentheses following the US Code number.)

- 2601. (TSCA §2) Findings, policy, and intent.
- 2602. (TSCA §3) Definitions.
- 2603. (TSCA §4) Testing of chemical substances and mixtures.
- 2604. (TSCA §5) Manufacturing and processing notices.
- 2605. (TSCA §6) Regulation of hazardous chemical substances and mixtures
- 2606. (TSCA §7) Imminent hazards.
- 2607. (TSCA §8) Reporting and retention of information.
- 2608. (TSCA §9) Relationship to other Federal laws.
- 2609. (TSCA §10) Research, development, collection, dissemination, and utilization of data.
- 2610. (TSCA §11) Inspections and subpoenas.
- 2611. (TSCA §12) Exports.
- 2612. (TSCA §13) Entry into customs territory of the United States.
- 2613. (TSCA §14) Disclosure of data.
- 2614. (TSCA §15) Prohibited acts.
- 2615. (TSCA §16) Penalties.
- 2616. (TSCA §17) Specific enforcement and seizure.
- 2617. (TSCA §18) Preemption.
- 2618. (TSCA §19) Judicial review.
- 2619. (TSCA §20) Citizens' civil actions.
- 2620. (TSCA §21) Citizens' petitions.
- 2621. (TSCA §22) National defense waiver.
- 2622. (TSCA §23) Employee protection.
- 2623. (TSCA §24) Employment effects.
- 2624. (TSCA §25) Studies.
- 2625. (TSCA §26) Administration.
- 2626. (TSCA §27) Development and evaluation of test methods.
- 2627. (TSCA §28) State programs.
- 2628. (TSCA §29) Authorization of appropriations.
- 2629. (TSCA §30) Annual report.

Hyperlinks to Legal and Regulatory Citations

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- ¹ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2601
 - ² <http://www.epa.gov/opptintr/p2home/p2policy/act1990.htm>
 - ³ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2603
 - ⁴ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=ee497e4176dc96b42ce6a1b684ff97e4&rgn=div5&view=text&node=40:30.0.1.1.1&idno=40>
 - ⁵ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=845f2d0cc0a27ea301407fcd2f7fce0e&rgn=div5&view=text&node=40%3A30.0.1.1.2&idno=40;cc=ecfr>
 - ⁶ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1ac5d6a3dcbbd1e4e8119f8f5a217df1&rgn=div5&view=text&node=40:30.0.1.1.8&idno=40>
 - ⁷ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1ac5d6a3dcbbd1e4e8119f8f5a217df1&rgn=div5&view=text&node=40:30.0.1.1.4&idno=40>
 - ⁸ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=81d0fa6e9189094f97474edf59ee7c81&rgn=div5&view=text&node=40:30.0.1.1.5&idno=40>
 - ⁹ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=81d0fa6e9189094f97474edf59ee7c81&rgn=div5&view=text&node=40:30.0.1.1.6&idno=40>
 - ¹⁰ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=81d0fa6e9189094f97474edf59ee7c81&rgn=div5&view=text&node=40:30.0.1.1.7&idno=40>
 - ¹¹ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=81d0fa6e9189094f97474edf59ee7c81&rgn=div5&view=text&node=40:30.0.1.1.8&idno=40>
 - ¹² <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=4b96dd074196a24dfc66a498a31e8a3b&rgn=div5&view=text&node=40:30.0.1.1.3&idno=40>
 - ¹³ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=39b52799a5b181649a0c4816e81faad4&rgn=div5&view=text&node=40:30.0.1.1.2&idno=40>
 - ¹⁴ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2611
 - ¹⁵ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1c9b69d3d20828d3767eae38ad21e981&rgn=div5&view=text&node=40:29.0.1.1.4&idno=40>
 - ¹⁶ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=ca6f2acaf68e3df5775c51ddc13d85fb&rgn=div5&view=text&node=40:30.0.1.1.1&idno=40#40:30.0.1.1.1.2.1.3>
 - ¹⁷ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=ca6f2acaf68e3df5775c51ddc13d85fb&rgn=div5&view=text&node=40:30.0.1.1.1&idno=40#40:30.0.1.1.1.2.1.2>
 - ¹⁸ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2604

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- ¹⁹ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=4128b15154c858dc7c83feabf542d726&rgn=div5&view=text&node=40:29.0.1.1.9&idno=40>
- ²⁰ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f73c74fee50934d081c24020a19bf911&rgn=div5&view=text&node=40:29.0.1.1.10&idno=40>
- ²¹ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f73c74fee50934d081c24020a19bf911&rgn=div5&view=text&node=40:29.0.1.1.12&idno=40>
- ²² http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2605
- ²³ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=8d515e52ced5d0d4ff700486ccc33fd0&rgn=div5&view=text&node=40:29.0.1.1.14&idno=40>
- ²⁴ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=8d515e52ced5d0d4ff700486ccc33fd0&rgn=div5&view=text&node=40:29.0.1.1.15&idno=40>
- ²⁵ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=8d515e52ced5d0d4ff700486ccc33fd0&rgn=div5&view=text&node=40:29.0.1.1.18&idno=40>
- ²⁶ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=3482e9d0384af88bba17aff55738f9d&rgn=div5&view=text&node=40:29.0.1.1.16&idno=40#40:29.0.1.1.16.1>
- ²⁷ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2605
- ²⁸ <http://www.fda.gov/opacom/laws/adminpro.htm>
- ²⁹ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2606
- ³⁰ <http://dictionary.reference.com/search?db=mwlaw&q=relief>
- ³¹ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2607
- ³² <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=22d8aa3e08d61b0fea2f5493a1829417&rgn=div5&view=text&node=40:29.0.1.1.3&idno=40>
- ³³ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=22d8aa3e08d61b0fea2f5493a1829417&rgn=div5&view=text&node=40:29.0.1.1.5&idno=40>
- ³⁴ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=22d8aa3e08d61b0fea2f5493a1829417&rgn=div5&view=text&node=40:29.0.1.1.6&idno=40>
- ³⁵ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=22d8aa3e08d61b0fea2f5493a1829417&rgn=div5&view=text&node=40:29.0.1.1.19&idno=40>
- ³⁶ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2607
- ³⁷ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=68618b450d6c8d3891ba09a60a07e387&rgn=div5&view=text&node=40:29.0.1.1.8&idno=40>
- ³⁸ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2607
- ³⁹ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=7428149ddc08954de37463cec26e22dd;rgn=div5;view=text;node=40%3A29.0.1.1.7;idno=40;cc=ecfr>

⁴⁰ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=7428149ddc08954de37463cec26e22dd;rgn=div5;view=text;node=40%3A29.0.1.1.19;idno=40;cc=ecfr>

⁴¹ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2607

⁴² http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2610

⁴³ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+15USC2625

⁴⁴ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=68618b450d6c8d3891ba09a60a07e387&rgn=div5&view=text&node=40:29.0.1.1.17&idno=40#40:29.0.1.1.17.1.1.3>

⁴⁵ <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=68618b450d6c8d3891ba09a60a07e387&rgn=div5&view=text&node=40:29.0.1.1.7&idno=40#40:29.0.1.1.7.2.1.2>