# EWG Side-By-Side Comparison of Safe Chemicals Act and Chemical Safety Improvement Act (5/29/13)

| Topic | Safe Chemicals Act (SCA) | Chemical Safety Improvement Act (CSIA) |
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| **Short Title** | The short title reflects the bill's emphasis on ensuring that individual chemicals are safe. Section 1 (p. 1, lines 4-5). | The short title emphasizes the issue of chemical safety generally rather than the importance of ensuring that individual chemicals are in fact safe. Section 1(a) (p. 1, line 6). |
| **Findings** | The SCA acknowledges that people have been "exposed to thousands of chemicals whose safety has not been adequately reviewed" for decades and declares that the EPA must have the authority to act effectively in the field of chemical safety. The findings also acknowledge the increased rate of diseases and disorders linked to exposures to chemical substances; make reference to biomonitoring studies; explain that chemicals persist and accumulate in human bodies; and recognize that children are particularly vulnerable to the effects of chemical exposure. Section 3 (p. 2-4). | The CSIA's findings suggest that "unmanaged risks," instead of individual chemicals themselves, "may pose a danger to human health and the environment." Section 2(b) (p. 3, line 7-9). The findings also state that chemicals "should be safe for the intended use," rather than safe generally. Section 2(b) (p. 3, lines 5-6). The findings make no reference to vulnerable populations, including children; the extent to which chemicals burden our bodies as evidenced by biomonitoring studies; increased incidences of diseases and disorders linked to chemical exposures; or the fact that for years the public has been exposed to chemicals that have not been adequately reviewed and may harm human health and the environment. Section 2(b) (p. 3-4). |

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| **Deadlines** | The SCA sets hard deadlines requiring EPA action. E.g., Section 7 (p. 81) (EPA must categorize a first batch of chemicals no later than 180 days after issuing categorization and prioritization regulations); Section 7 (p. 106) ("Not later than 5 years after [enactment] . . . [EPA] shall complete and publish safety standard determinations for all chemical substances designated as Priority Class 1 substances in the initial batch."). | The CSIA provides few clear deadlines for EPA to complete safety reviews of chemicals, including, but not limited to, EPA's directive to prioritize chemicals and make safety determinations. E.g., Section 4 (p. 18, lines 22-25) (EPA must "make every effort to complete the prioritization of all active substances in a timely manner."); Section 6 (p. 59-60) (stating that the rules EPA develops for conducting safety assessments should include deadlines for completing each assessment and determination, but the deadlines may vary to give EPA flexibility and the rules should allow for reasonable extensions if EPA makes an adequate public justification). |
| **Data Quality** | The SCA directs EPA to use "the best available science," based on recommendations of the National Academy of Sciences, when conducting safety assessments and making safety standard determinations. Section 7 (p. 101, lines 9-19). EPA must also "to the extent practicable, review and incorporate any available scientific information relating to the effect of cumulative exposure relevant to that chemical substance on human health and the environment" when making a safety standard determination. Section 7 (p. 100, lines 16-21). EPA may require epidemiologic studies, biomonitoring or environmental monitoring studies, serial or hierarchical tests, in vitro tests, and any other methodology it deems appropriate for the developing of test data. Section 5 (p. 24, lines 6-13). | The CSIA requires EPA to "establish and publish scientifically sound criteria for evaluating all [ ] data and information" and to "encourage the use of good laboratory practices, peer review, scientifically reliable and relevant test methods, standardized protocols, and other methods to ensure scientific quality" for the development of test data. Section 4(b) (p. 12-13). EPA may consider data that do not meet its scientifically sound criteria, but must explain its decision and use of the data. Section 4(b) (p. 13). |

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| **Minimum Data Sets** | Manufacturers and processors of chemical substances must submit minimum information sets to EPA so that it may evaluate and prioritize chemicals, among other things. Section 5 (p. 16-20). | No comparable provision. |
| **Testing and Development of Information** | The SCA provides EPA with the authority to require testing by rule or order to carry out any provision of the Act. Section 5 (p. 20-21). EPA may require that test information pertaining to bioaccumulation, persistence, or acute, subacute, and chronic toxicity (PBT-related data) be developed. Section 5 (p. 24, lines 6-13). EPA may also require the development of test "information pertaining to carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, or cumulative, synergistic, or any other effect that may be considered in a safety standard determination." Section 5 (p. 23, lines 21-25). EPA may prescribe epidemiological and biomonitoring studies, among other types of studies, but must consider the relative costs of the test protocols or methodologies required by the rule or order. Section 5 (p. 24-25). | The CSIA provides EPA with the authority to require the development of test data by rule, consent decree, or order only if the information is needed to perform a safety assessment, make a safety determination, or to meet testing needs authorized by another federal statute. Section 4(f) (p. 29, lines 17-25 & p. 30, lines 1-4). If EPA decides to issue an order for test data, it must "explain why good cause exists" for issuing an order in place of a rule or consent decree. Section 4(g)(2) (p. 33-34). This would effectively require EPA to show with good cause that the chemical presents an unreasonable risk, which is exactly the question EPA is trying to answer by requesting additional information.<br><br>EPA must develop a two-tiered testing framework for evaluating chemical substances and exposure. Section 4(h) (p. 35-36). While EPA may prescribe guidelines for the development of test data, "including information regarding bioaccumulation, persistence, and the presence of chemical substance or mixture in human blood, fluids, or tissue," and aggregate exposure, Section 4(j) (p. 43-44), EPA must consider "the relative costs of the various test protocols and methodologies," Section 4(f)(4)(C)(i) (p. 32, lines 17-23), and issue a detailed statement of need when promulgating a test rule, order, or consent decree. Section 4(g) (p. 33-34). |

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| **Categorization and Prioritization of Chemicals for Safety Determinations** | To assess the safety of chemicals, EPA must divide portions of its active inventory list into "batches" and then review available use, hazard, and exposure data to categorize and prioritize chemicals in each batch to determine whether further risk management is needed to protect public health and the environment. Section 7 (p. 73-98). EPA may categorize chemicals as follows:<br>• Substances of very high concern (e.g., those that are highly hazardous, toxic, persistent and bioaccumulative, or for which there is evidence of widespread exposure);<br>• Substances of very low concern;<br>• Substances to undergo safety standard determination;<br>• Substances for which there is insufficient information to make an informed categorization.<br><br>Once categories are assigned to chemicals in each batch, EPA must prioritize the chemicals into one of three classes according to prioritization criteria. Section 7 (p. 88-98). Criteria for establishing the priority classes of chemicals include potential impacts on health and the environment, hazard potential, and exposure potential. Section 7 (p. 89). | The CSIA directs EPA to create a screening process for existing chemicals to identify which ones are high priority for a safety assessment and determination and which ones are low priority (only active substances, as opposed to inactive ones, may be prioritized under this framework, unless the inactive substance is already subject to regulation or demonstrates high hazard or exposure). Section 4(e) (p. 17-29). EPA must keep a list of high- and low-priority chemicals. 4(e)(3)(H) (p. 25). While EPA generally determines the order in which to assess chemicals for prioritization, it must expedite its prioritization screening for a chemical if a state actor recommends that the chemical be placed on the high- or low-priority list. Section 4(e)(4) (p. 18).<br><br>EPA is required to make a chemical a high priority if, relative to other chemicals, it has high hazard and high exposure potential. Section 4(e)(3)(E)(i) (p. 24). EPA may make a chemical a high priority if it has the potential for high hazard or high exposure. Section 4(e)(3)(E)(ii) (p. 24). If the chemical is an inactive substance, EPA may make a chemical high priority if it is not subject to a ban or phase-out and shows high hazard and exposure potential. Section 4(e)(3)(E)(iii) (pp. 24-25). (Nothing is explicitly said about requiring chemicals to be made high priorities if data indicate that the chemicals are detected in people through biomonitoring tests or are PBT chemicals.) EPA is required to make a chemical a low priority if it is likely to meet the safety standard under its intended conditions of use. Section 4(e)(3)(F) (p. 25). |

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| | | Criteria EPA should use when prioritizing existing chemicals include: recommendations from state actors; data about hazard and exposure potential; intended conditions of use or significant changes in those conditions; evidence of human or environmental exposure potential; volume information; availability of potential hazard and exposure information needed for a safety assessment or determination (if limited, factor for high priority designation); and extent of federal or state regulation of the substance. Section 4(e)(2)(C) (p. 21-23). If test data for determining a chemical's priority is limited, EPA is required to give interested persons the opportunity to submit such data to the extent that it is reasonably ascertainable, rather than requiring the submission of certain minimum data sets. Section 4(e)(3)(B) (p. 23). |
| **New Chemicals** | The SCA requires companies to submit pre-manufacture notices to the EPA for new chemical substances. Section 6 (p. 36-37). Within 90 days, EPA must assign the chemical to one of the following categories: substances of very high concern, substances likely to meet the safety standard, substances with insufficient information, or substances unlikely to meet the safety standard. Section 6 (p. 40-50).<br>• A substance of very high concern (e.g., a substance that is toxic, persistent, and bioaccumulative, or highly hazardous) may only be manufactured if EPA determines that it qualifies for an exemption (e.g., national security interest and avoiding significant | The CSIA requires companies to submit pre-manufacture notices to EPA for new chemical substances. Section 5 (p. 46-47). Within 90 days, EPA must make one of the following determinations: the substance is not likely to meet the safety standard under the intended conditions of use; the substance is likely to meet the safety standard under the intended conditions of use; or additional information is necessary to determine whether the substance is likely or not likely to meet the safety standard. Section 5 (p. 49-50).<br>• If the substance is not likely to meet the safety standard under the intended conditions of use, EPA must prohibit or place conditions on the manufacture of the chemical. Section 5 (p. 50- |

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| | economic disruption). Section 6 (p. 41-42).<br>• A substance likely to meet the safety standard may be manufactured, but EPA must conduct further safety assessments of the chemical unless it determines it is a substance of very low concern. Section 6 (p. 42-47).<br>• Chemicals categorized as substances without sufficient information may not be manufactured until a minimum information set is submitted and EPA re-categorizes the chemical. Section 6 (p. 47-49).<br>• If EPA determines a substance is unlikely to meet the safety standard, the chemical may not be manufactured unless EPA determines that it qualifies for an exemption (e.g., national security interest and avoiding significant economic disruption). Section 6 (p. 49-50). | 52).<br>• If the substance is likely to meet the safety standard under the intended conditions of use, the new chemical may be manufactured. Section 5 (p. 48, lines 18-24).<br>• If additional information is necessary to make an informed decision, EPA must provide an opportunity for the manufacturer to submit information and may extend the review period "for a reasonable time." Section 5 (p. 52-53). EPA may allow the new chemical to be marketed before the agency receives any additional information or makes a final determination as to whether it will meet the safety standard. Section 5 (p. 53).<br><br>EPA may extend the 90-day review period for good cause for an additional 90 days. Section 5 (p. 48, lines 13-17). |
| **New Uses of Existing Chemicals** | If a safety determination for an existing chemical substance has not yet been made, a person may not manufacture or process the chemical for a use not ongoing as of the date of enactment of the SCA or at a volume significantly higher than the volume manufactured or processed as of the date of enactment of the SCA, unless the person submits a detailed notice and additional data to the EPA and the substance is one that is likely to meet the safety standard. Section 6 (p. 50-51). If EPA has determined that an existing chemical meets the safety standard, no person may manufacture or process that chemical for a new use or at a new | The CSIA requires companies to submit pre-manufacture notices to EPA for significant new uses of chemical substances. Section 5 (p. 46-47). Within 90 days, EPA must make one of the following determinations: the substance is not likely to meet the safety standard under the new intended conditions of use; the substance is likely to meet the safety standard under the new intended conditions of use; or additional information is necessary to determine whether the substance is likely or not likely to meet the safety standard. Section 5 (p. 49-50). |

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| | production volume, unless the person submits a detailed notice to EPA and EPA determines that person has established that the chemical will continue to meet the safety standard if the new use or production volume is authorized. Section 6 (pg. 52-54). | • If the substance is not likely to meet the safety standard under the new intended conditions of use, EPA shall prohibit or place conditions on the manufacture of the new use of the chemical. Section 5 (p. 50-52).<br>• If the substance is likely to meet the safety standard under the new intended conditions of use, the chemical may be manufactured for its new use. Section 5 (p. 48, lines 18-24).<br>• If additional information is necessary, EPA must provide an opportunity for the manufacturer to submit information and may extend the review period "for a reasonable time." Section 5 (p. 52-53). EPA may allow the chemical to be marketed for the new use before the agency receives any additional information or makes a final determination as to whether it will meet the safety standard. Section 5 (p. 53).<br><br>EPA may extend the 90-day review period for good cause for an additional 90 days. Section 5 (p. 48, lines 13-17). |
| **Safety Standard & Safety Assessment** | EPA must conduct safety standard determinations for prioritized chemical substances, beginning with the first priority class. Section 7 (p. 105-07). EPA may conclude that a chemical meets the safety standard only if it finds there is "reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance." Section 7 (p. 100-01). As a health-based safety standard, EPA must base its | EPA must perform safety assessments of high-priority chemicals and determine whether each high-priority chemical meets the safety standard. Section 6 (p. 56, lines 8-12). EPA may not perform safety assessments for low-priority chemicals, unless they are re-designated as high priority.<br><br>The CSIA safety standard is defined as a "standard that ensures that no unreasonable risk of harm to |

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| | safety standard determinations "solely on considerations of human health and the environment." Section 7 (p. 100, lines 8-11). | human health or the environment will result from exposure to a chemical." Section 3 (p. 9, lines 1-5). This is not a strictly health-based standard like the one used in the Safe Chemicals Act, which, as a matter of law, does not allow a cost-benefit analysis when developing a regulation. Rather, the unreasonable risk language — which is used in current law — has been read to require a cost-benefit analysis because the language implies there is such thing as reasonable or acceptable risk.<br><br>Although the CSIA directs EPA to evaluate whether a chemical meets the safety standard "based solely on considerations of risk to human health and the environment," Section 6 (p. 64-65), this does not change the fact that the safety standard, as defined, still involves some consideration of costs and benefits given the way "unreasonable risk" has been interpreted. (This is certainly how the Office of Management and Budget would review any safety determination made by EPA under this provision.) |
| **Risk Management** | EPA may issue a positive safety standard determination without new conditions on the use of the chemical, a positive safety standard determination with new conditions on the use of the chemical, or a negative safety standard determination, which then requires EPA to take risk-managements steps accordingly. Section 7 (p. 108-17). Possible conditions and restrictions range from warnings to bans. Section 7 (p. 120-23).<br><br>Moreover, following a negative safety standard | If EPA determines that a chemical does not meet the safety standard, it must decide which risk-management measures it should take with respect to that chemical. Section 6 (p. 67-72). EPA may pursue a variety of restrictions, including, but not limited to, warnings, use restrictions, production restrictions, phase outs, and bans. Section 6 (p. 67-70). If EPA wants to phase out or ban a chemical, the agency has to conduct and present a careful cost-benefit analysis, including a discussion of technically and economically feasible alternatives, |

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| | determination, "no person shall manufacture, process, or distribute in commerce that chemical substance or any mixture or article containing the chemical substance," unless exceptional circumstances exist. Section 7 (p. 116).<br><br>In addition, for a chemical of "very high concern" (for example, PBT chemicals), EPA must impose use restrictions and other conditions on the manufacturing, processing, use, distribution, and disposal of the chemicals as necessary to achieve the maximum practicable reduction in human or environmental exposure to the chemical. Section 7 (p. 117-20).<br><br>No language appears regarding having to conduct a cost-benefit analysis. | risks posed by each of those alternatives compared to the chemical being considered for regulation, and the economic and social costs and benefits of the proposed restriction compared to potential alternatives, among other things. Section 6 (p. 71-72). Therefore, although the CSIA removes the current law's least-burdensome restriction language, it reads it back into the bill with these requirements to pursue a phase out or ban.<br><br>The CSIA does not explicitly require the same analysis for other types of restrictions, but in practice, it can be expected that EPA will have to perform similar analysis because of the unreasonable risk language in the safety standard. (Once again, this is certainly how the Office of Management and Budget will review any restriction proposed under the CSIA's risk-management provisions.) |
| **Exemptions** | The SCA allows EPA to exempt chemicals from risk management under certain circumstances (e.g., national security interest and avoiding significant economic disruption). However, EPA must justify an exemption decision with "clear and convincing evidence." Section 7 (p. 125-26). | EPA "may exempt the use of a chemical substance from any additional restrictions" under certain circumstances (e.g., national security interest and avoiding significant economic disruption). EPA is not required to justify its exemption decision or meet a specified burden of proof. Section 6 (p. 72, lines 4-24). |
| **Confidential Business Information** | The SCA defines information that is always eligible for protection, information that may be eligible for protection, and information that is never eligible for protection. Section 14 (p. 186-96). Chemical identity information is eligible for CBI protection if | The CSIA defines information that is presumed confidential and information that is not protected from disclosure. Section 13 (p. 97-100). Chemical identity information, including the chemical name and CAS number, is presumed confidential if |

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| | the manufacturer or processor provides up-front documentation and justification for the CBI claim. Section 14 (p. 188-90). CBI protection is not available for chemical identity if the substance is a known or probable reproductive, developmental, neurological, or immunological toxicant, carcinogen or mutagen, or if the substance is persistent, bioaccumulative, and toxic. Section 14 (p. 189, 193). EPA must review all confidentiality claims, or a representative subset of claims, within 90 days of receiving information for which protection is claimed. Section 14 (p. 197-98). | documentation and justification for the confidentiality claim is provided. Section 13 (p. 98, lines 13-24 & p. 100-103). EPA is not required to review CBI claims for information that is presumed confidential, other than confidentiality claims for chemical identity information. Section 13 (p. 108, lines 10-19). CBI claims made before enactment are grandfathered, preventing EPA from requiring re-substantiation of such claims, Section 13 (p.113, lines 1-11), unless the claims covered chemical identities or inventory information for chemicals classified by EPA as high-priority. Section 13 (p. 107-08). |
| **Disclosure of Confidential Information to Medical Personnel in Emergency and Non-Emergency Situations** | The SCA requires EPA to disclose upon request confidential information to "public health or environmental health professionals or medical personnel" if EPA finds disclosure to be in the public interest, finds no conflict of interest or competitive interest on the part of the requester, and obtains a confidentiality agreement from the requester. Section 14 (p. 184-85). | The CSIA requires EPA to follow more detailed procedures before providing confidential information to medical personnel in emergency and non-emergency situations, as compared to the SCA. It also limits disclosure to a more narrowly defined class of "health professional[s] employed by a Federal or State agency or [ ] treating physician[s] or nurse[s]" in a non-emergency situation, and to treating physicians and nurses in emergency situations. Section 13 (p. 104-106). |
| **Penalties** | The SCA increases the penalty amounts authorized under TSCA. Section 16 (p. 107-10). | No provision. |
| **Preemption** | The SCA's preemption provision does not affect the ability of individual states to develop chemical data or further regulate chemicals, unless compliance with both state and federal law would be impossible. Section 18 (p. 214). | No state may require additional development of test data or information on a chemical or chemical class for which companies have to submit similar information to EPA (e.g., for EPA chemical assessments). Section 15 (p. 114, lines 10-22). In |

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| | | addition, no state may create a new, or continue to enforce an existing, restriction on the manufacture, processing, distribution, or use of a chemical after EPA completes a safety determination for that chemical. Section 15 (p. 114, lines 10-25 & 15, lines 1-9). Further, states are prohibited from creating new restrictions on the manufacture, processing, distribution, or use of chemicals EPA classifies as high- or low-priorities. Section 15 (p. 115, lines 10-24).<br><br>States may seek a waiver from EPA to pursue regulations that would otherwise be preempted, Section 15 (p. 116-20), but any waiver granted by EPA would be subject to judicial review and therefore almost certainly challenged in court. Section 15 (p. 119, lines 7-12, 22-25 & p. 120, lines 1-4). |
| **Effect on Tort Cases** | No comparable provision. | The CSIA would make safety determinations admissible in a court of law as determinative of whether a high-priority chemical meets the standard under the conditions of use evaluated by EPA (e.g., whether it is injurious to public health or the environment). Section 15(e) (p. 120, lines 5-13). This provision will have a limiting effect on the ability of private parties to bring tort actions against chemical companies using any other evidence to show injury once EPA has made a safety determination. |

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| **Judicial Review** | The SCA lowers the problematic judicial standard of review found in TSCA. Under the SCA, courts must evaluate rules under a standard reasonableness standard. Section 19 (p. 304-05). Safety determinations made by the EPA are ineligible for judicial review. Section 4 (p. 178). | The CSIA maintains the same problematic judicial standard of review contained in TSCA: if challenged, a court must set aside a rule that "is not supported by substantial evidence in the rulemaking record." Section 16 (p. 122, lines 15-19). Although decisions about prioritization are not subject to judicial review, Section 4(e)(5) (p. 29, lines 11-16), safety determinations are considered "final agency action," subject to judicial review. Section 6 (p. 73, lines 3-5). Waivers granted by EPA allowing sates to regulate chemicals beyond what is allowed by the CSIA's preemption section are also subject to judicial review. Section 15 (p. 119-20). |
| **Citizens' Suits** | The SCA amends the citizens' suit provision in TSCA to allow citizens to bring civil suits for a violation of any rule or order promulgated under TSCA, as amended. Section 20 (p. 216-17). | No comparable provision. |
| **Citizens' Petitions** | The SCA amends the citizens' petition provision in TSCA to allow citizens to petition EPA to issue, amend, or repeal a rule, order, or any other action authorized by TSCA, as amended. Section 21 (p. 217-19). | Includes some changes to the citizens' petition provision of TSCA, but maintains TSCA's limitation on citizens' petitions to certain specified rules and orders. Section 17 (p. 123-26). |
| **Fees & Cost Sharing** | The SCA allows EPA to require by rule "payment of a reasonable fee from any person required to submit data to defray the cost" of administering TSCA, as amended. Section 23 (p. 221-22). | No provision. |
| **Children's Environmental Health Research** | The SCA directs EPA to establish a Children's Environmental Health Research Program within 90 days "to further understanding of the vulnerability | No provision. |

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| **Program** | of children to chemical substances and mixtures." It also directs EPA to establish an Interagency Science Advisory Board on Children's Health Research within 90 days to provide research and advice "with respect to the scientific and technical aspects of issues relating to the implementation of this title with respect to research on protecting children's health." Section 26 (p. 224-29). | |
| **Green Chemistry** | The SCA directs EPA to "establish a program to create market incentives for the development of safer alternatives to existing chemical substances that reduce or avoid the use and generation of hazardous substances" within 1 year. The program must include an expedited review process for safer alternatives to existing chemicals, a research network, research grants, and a workforce education and training program. Section 26 (p. 234-37). | No provision. The CSIA only makes reference to green chemistry once in passing in the findings section, where it states that "innovation in the development of new chemical substances, especially safer chemical substances, should be encouraged to reduce risk, provide improved products, stimulate the economy, create jobs, and protect interstate commerce." Section 2 (p. 4, lines 10-14). |
| **International Cooperation** | The SCA directs EPA to cooperate with international efforts to develop a protocol or database for chemical substances, or to develop safer alternatives for existing chemical substances. Section 26 (p. 237). | No provision. |
| **Hot Spots** | The SCA requires that EPA identify localities that are disproportionately exposed to toxic chemical substances or mixtures, publish and update a list of these localities, and develop plans for each locality identified. Section 26 (p. 238-44). | No provision. |

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| **Implementation of International Agreements and Conventions** | The SCA directs EPA to support the implementation of the Stockholm Convention, Convention on Long-Range Transboundary Air Pollution Persistent Organic Pollutants Protocol, and Rotterdam Convention. Section 26 (p. 248-56). | No provision. |