

Improvements the Udall-Vitter draft makes to the Chemical Safety Improvement Act, by section

Section 3 (Definitions)

- Definition of BEST AVAILABLE SCIENCE deleted
- Definition of POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION added
- Term INTENDED CONDITIONS OF USE changed to INTENDED OR REASONABLY ANTICIPATED CONDITIONS OF USE
- Definition of SAFETY STANDARD:
 - explicitly excludes costs and other non-risk factors, and
 - requires protection of potentially exposed or susceptible populations

Section 3A (Policies, procedures and guidance)

- A 2-year deadline for establishment of all policies, procedures and guidance has been added
- Existing EPA policies are to be retained and built upon, rather than requiring EPA to start from scratch
- Funding sources for submitted information are to be made public
- Biased risk assessment approaches favored by industry have been struck or made neutral
- NAS recommendations on assessing hazard and risk are to be considered
- EPA can forgo strict adherence to tiered testing requirement and require a more advanced test where justified based on available information
- High-priority chemicals are to be promptly scheduled for safety assessments and determinations
- EPA is to clearly delineate the scope of the safety assessment, including:
 - conditions of use
 - potentially exposed or susceptible populations deemed relevant and to be included
 - whether aggregate exposure or a significant subset of exposures is to be assessed, and the basis for the decision

Section 4 (Testing)

- Testing authority has been restored/added for:
 - chemicals produced for export
 - prioritization purposes, but not to establish minimum information requirements
 - new chemicals (section 5)
- The requirement that EPA show “good cause” for issuing a test order has been changed to a requirement to justify why an order is warranted
- The requirement that EPA seek to reduce animal testing is only “to the extent practicable”

Section 4A (Prioritization)

- A 1-year deadline for the rule establishing prioritization screening has been added
- Prior to the rule, and by 6 months after enactment, EPA is to establish an initial list of at least 10 high-priority chemicals, on which it may initiate or continue assessments and determinations

- EPA can draw from an interim list of active substances for purposes of prioritization without having to wait for the inventory reset (in section 8)
- Repopulation of the high-priority list is required as safety assessments/determinations are completed, to ensure a steady flow
- A deadline of 6 months after enactment has been added for EPA to initiate prioritization
- Chemicals for which prioritization is deferred must be identified along with the basis for deferral
- EPA can require testing for deferred chemicals
- Requests for submissions of information must include a deadline

Section 5 (New chemicals and significant new uses)

- Determinations apply to significant new uses as well as new chemicals
- If EPA determines a new chemical or significant new use a) is not likely to meet the safety standard, or b) has insufficient information for the determination, production and use is allowed only under conditions sufficient for EPA to find it is likely to meet the safety standard
- EPA must consider whether to promulgate a SNUR whenever it imposes conditions on a PMN or SNUR submitter, and if it opts not to, provide a public justification
- If EPA finds there is insufficient information for the determination on a new chemical, it can require testing

Section 6 (Safety assessments and determinations)

- Aggressive deadlines for completion of safety assessments, determinations and risk management rules have been added, along with a limited ability for them to be extended
- Deferrals of assessments due to lack of information are subject to deadlines by which the information is to be provided
- Deadlines cannot be extended further due to deferrals
- EPA may initiate, continue and complete assessments and determinations under its current authorities until the new policies and procedures are established
- If EPA finds a chemical does not meet the safety standard, production and use must either be banned or phased out, or allowed only under conditions sufficient for EPA to find that it meets the safety standard
- Compliance dates for risk management rules must be specified and be as soon as feasible
- Risk management options available to EPA now include process quality control measures, and monitoring and testing requirements
- In imposing risk management, costs and benefits are to be considered only “to the extent practicable based on reasonably available information”
- CSIA’s requirement that bans and phase-outs be based on full cost-benefit justification is struck
- Only alternatives deemed relevant by EPA need be considered in deciding on risk management
- EPA can impose any conditions needed on use exemptions from risk management restrictions
- Exemptions from risk management requirements are to be time limited, as well as renewable

- Judicial review is triggered only when EPA takes final action, either a final determination that a chemical meets the safety standard or a final rule where EPA determines a chemical does not meet the safety standard

Section 8 (Information collection and reporting)

- A 1-year deadline for the inventory reset rule and a 6-month deadline for companies to identify their active chemicals have been added
- CBI claims for chemical identity must be asserted at the time of the inventory reset
- All CBI claims for chemical identity for active chemicals identified through the inventory reset must be substantiated or resubstantiated and reviewed by EPA within 5 years (can be extended by 2 years if necessary, with public justification)
- All approved CBI claims for chemical identity for active chemicals are subject to a 10-year sunset, which may only be renewed if reasserted and resubstantiated before expiration and EPA finds the claim is still warranted
- CBI claims for chemical identities are disallowed for chemicals not already on the confidential portion of the inventory, except for new chemicals added to it under section 14
- CBI claims for chemical identities of inactive chemicals must be asserted, substantiated or resubstantiated and reviewed by EPA prior to being moved to active status
- EPA may subject a chemical moving from inactive to active status to prioritization at that time

Section 12 (Exports)

- Testing authority for chemicals produced solely for export has been restored
- Export notification for chemicals subject to testing requirements has been restored
- EPA's obligation to notify recipient countries for exported new or existing chemicals subject to restrictions has been restored

Section 13 (Imports)

- Coverage of imported articles has been restored
- Certification for imported articles is provided for, subject to rules established by EPA
- The requirement for a separate rulemaking by DHS before requiring import notification has been struck

Section 14 (CBI)

- CBI protection can be provided only for information that is a trade secret under FOIA
- Information presumed protected has been narrowed and includes only information specific to a company
- Chemical identity is presumed protected only for chemicals prior to commercial distribution
- Health and safety information is not eligible for CBI protection (current TSCA Section 14(b) is retained verbatim)

- Chemical identities not already on the confidential portion of the inventory cannot be claimed confidential
- All CBI claims are voided and EPA must make the information public for any chemical subject to a ban or phase-out
- All CBI claims must be asserted at the time of information submission
- Assertion of a claim requires a statement that the information meets trade secret requirements (delineated in the text)
- Claims other than for information presumed protected must be substantiated
- Environmental as well as health professionals are eligible to receive CBI
- Responding to an environmental release or exposure is added as basis for needing access to CBI
- Agents of poison control centers, public health or environmental officials of a State or political subdivision of a State, and first responders are added to those eligible to receive CBI in emergency situations, along with physicians and nurses
- Exceptions to protection from disclosure have been added for information already publicly available or required to be disclosed or otherwise made public under any other Federal law
- CBI claims are subject to a 10-year sunset, which may only be renewed if reasserted and resubstantiated before expiration and EPA finds the claim is still warranted
- A clear set of deadlines is established for expiration notification, reassertion and resubstantiation and EPA review of extension requests
- EPA has authority at any time to review a CBI claim and require resubstantiation:
 - for high-priority chemicals
 - for chemicals found not to have sufficient information for a safety determination
 - for inactive chemicals
 - for CBI EPA finds would assist in conducting safety assessments and determinations or promulgating risk management rules, should the information be found not or no longer to warrant protection
- EPA must review a CBI claim and require resubstantiation:
 - if necessary to comply with a FOIA request
 - if EPA has reason to believe the claim is not valid
 - for chemicals found not to meet the safety standard
- EPA must assign a unique identifier to any chemical the identity of which has been approved to be CBI, must tag all information received on that chemical using the identifier, and if/when the chemical identity is made public, identify and provide access to all information received on that chemical
- EPA's review of CBI claims must be done within 90 days (30 days for requests for renewals)
- EPA must review all CBI claims for chemical identity of chemicals in commercial distribution, and at least 25% of all other claims
- No prior notification before release of CBI is required for a broader range of exceptions to protection from disclosure
- Provision requiring removal from office or employment for knowing disclosure of CBI is struck
- EPA's authority is retained to review and require substantiation of CBI claims prior to enactment