or finalized section 6(a) rules to address the risks that were identified. The risk assessments for these chemicals were not conducted across all conditions of use. During the bi-partisan negotiations, EPA expressed the view that, rather than reexamine and perhaps broaden the scope of these assessments, it is better to proceed with proposed and final rules for covered chemicals to avoid any delay in the imposition of important public health protections that are known to be needed. Congress shared these concerns with the House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rule is consistent with the scope of the risk assessments conducted on these substances.

21. SNURS FOR ARTICLES

Section 5(a)(5) addresses the application of significant new use rules (SNURs) to articles or categories of articles containing substances of concern. It provides that in promulgating such SNURs, EPA must make “an affirmative finding . . . that the reasonable potential exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.” This language clarifies that potential exposure in articles is a relevant factor in establishing SNURs to articles. Exposure is a relevant factor in identifying other significant new uses of a chemical substance as well. It is not intended for EPA to conduct an exposure assessment or provide evidence that exposure to the substance through the article or category of articles will in fact occur as a result of potential exposure based on the nature of the substance or the potential uses of the article or category of articles will be sufficient to “warrant notification.” EPA has successfully used the SNUR authority in the existing law to provide for scrutiny of imported articles (many of which are widely used consumer products) that contain unsafe chemicals that have been restricted or discontinued in the U.S. and it’s critical that SNURs continue to perform this important public health function under the amended law.

22. COMPLIANCE DEADLINES

The amended law expands on existing section 6(d) by providing that rules under section 6 must include “mandatory compliance dates.” These dates can vary somewhat with the type of restriction being imposed but, in general, call for compliance deadlines that “shall be as soon as practicable, but not later than 5 years after the promulgation of the rule.” While EPA could in unusual circumstances delay compliance for as long as five years, this should be the exception and not the rule. Exposure to the risk reduction benefits of the rule, it is expected that compliance deadlines will be as soon as practicable after the rule’s effective date as directed in new paragraph 6(d)(1). Senator Barbara Boxer, Ranking Member, Environment and Public Works Committee.


Mr. MERKLEY. I yield the floor.


Mr. VITTER. That response raised an interesting question I would like to start with a question to you on the purpose of the term “conditions of use” and how that term is supposed to be applied by EPA in risk evaluations?

Mr. VITTER. Thank you, Senator INHOFE. There are many important provisions of this law and I think clarifying what Congressional intent was very important to ensure the legislative intent of how this is supposed to be applied by EPA in risk evaluations, it is important to note that many TSCA chemicals have multiple uses—industrial, commercial and consumer uses. EPA has identified subcategories of chemical uses for more specific regulatory reporting requirements, so the Agency is well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled. The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This assures that the Agency’s focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law’s strict deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency’s job would be more difficult.

Mr. INHOFE. Senator VITTER. That response raised an interesting follow up question I would like to
to ask. If EPA’s final Section 6(a) risk management rule includes a restriction or prohibition on some of the conditions of use identified in EPA’s scope of the risk evaluation, but not all of them, is it final agency action as to those forms of use?

Mr. VITTER. That is a very important question and the clear intent of Congress is the answer is yes. This is because, to be legally sufficient according to EPA’s own technical assistance, EPA’s Section 6 rule must require testing at the level that the chemical substance or mixture no longer presents an unreasonable risk. A Section 6(1) order, determining that a chemical substance does not present an unreasonable risk under conditions of use, is similarly final Agency action applicable to all those conditions of use that were identified in the scope of EPA’s risk evaluation on the chemical substance. To be clear, every condition of use identified by the Administrator in the scope of the risk evaluation will either found to present or not present an unreasonable risk.

Mr. INHOFE, this brings me to a question on the testing EPA has the authority to require manufacturers to conduct as a compromise. One of the major flaws in TSCA is the so-called ‘catch 22’ under which EPA cannot require testing of chemicals without first making a finding that the chemical may present an unreasonable risk. In TSCA’s history, EPA has been able to make that finding only for about 200 chemicals. Does the compromise remedy that provision of TSCA?

Mr. INHOFE. It is clear that the compromise directs EPA to systematically evaluate more chemicals than ever before. To help the Agency meet that objective, the compromise does two things. First, EPA can issue a test rule or order if it finds that a chemical substance may present an unreasonable risk to health or the environment. In this case, an EPA order would be a final agency action subject to judicial review. EPA would be well-advised to consider the practice of issuing a ‘statement of need’ similar to that required under section 4(a)(3) when using this authority.

The section also provides EPA discretionary authority to require testing—by rule, order or consent agreement—when EPA determines that new information is necessary to review a pre-manufacture notice under section 5, to conduct a risk evaluation under section 6, or to implement rules or orders under those sections. The compromise also recognizes that EPA may need new information to prioritize a chemical substance for review, to assess certain exports, and at the request of another federal agency. To use this discretion, EPA must issue a ‘statement of need’ that explains the need for testing/exposure information. This would be whether vertebrate animal testing is needed, and why an order is preferred to a rule.

Section 4 of the compromise also requires EPA to use ‘tiered’ screening and testing processes. This means EPA must require less expensive, less complex tests to determine whether higher level testing is required. This is an efficient approach to testing chemicals that is based on EPA experience in other testing programs. Tiered testing will also help assure that EPA is able to prioritize and minimize animal testing that is set out in the compromise.

Finally, section 4 prohibits the creation of a ‘minimum information requirement’ for the prioritization of chemicals. That is a very important provision that should be applied to any and all testing by the Agency regardless of which authority it uses.

Senator VITTER, in addition to new testing authorities the bill also makes changes to the new chemicals program under section 5 which has been largely viewed as one of the major strengths of existing law. It has been credited with spurring innovation in chemistry used for new products and technologies throughout the value chain. The industry we’re regulating in TSCA is highly innovative: 17 percent of all US patents are chemistry or chemistry related. Clearly Congress has an interest in preserving the economic engine that is the business of U.S. chemistry, while ensuring that EPA appropriately reviews new chemical substances and significant new uses. How does the compromise balance these interests?

Mr. VITTER. Protecting innovation and not materially altering the new chemicals process was a critical part of the final compromise. Every effort was made to ensure EPA has the right tools to review new chemical substances but the amendments were intended to conform closely with EPA’s current practice and maintain the Agency’s timely reviews that allow substances to market within the statutory deadlines. First, the compromise retains the 90-day review period for EPA to make a risk-based decision on a new chemical, without consideration of costs or other non-risk factors. Second, when EPA does not have the information sufficient for the evaluation of a new chemical, or when EPA determines that a chemical may present an unreasonable risk, the compromise requires EPA to regulate the new chemical to the extent necessary to protect against unreasonable risk. Once sufficient information is available, of course, EPA must make a decision. These requirements largely reflect EPA’s practice today, under which EPA can allow the new chemical on the market but with limits. Finally, if EPA determines that a new chemical is not likely to present an unreasonable risk, EPA may make a determination to that effect before the end of the 90-day period. This provision ensures that chemicals considered not likely to pose an unreasonable risk are not delayed in getting to market.

Importantly, EPA would not stop reviewing new chemical notices while it develops any policies, procedures and guidance needed to implement these new provisions in Section 5. The compromise is very clear and did not stop or slow its review of new chemicals while it develops any needed new policies, procedures or guidance for Section 5. Also by amending Section 5 to require EPA make an affirmative finding before manufacturing or processing of a substance may commence, Congress did not intend to trigger the requirements of any other environmental laws. This again maintains the consistency with how EPA currently administers the new chemicals program under existing law.

Senator INHOFE, this leads me to another question on a provision that is rather technical and has been misunderstood by many and that is nomenclature. After the TSCA Inventory was established in 1979, questions arose about the appropriate ‘nomenclature’ to be used to list these chemical substances. EPA addressed many of these questions in a series of guidance documents. The compromise includes a provision on nomenclature. What is this provision intended to do?

Mr. INHOFE. Thank you, Senator VITTER. These provision are very important to many major domestic producers including manufacturers of products like glass, steel, cement, along with domestic energy producers across the country. The chemical nomenclature provision in section 8 of the compromise addresses several issues critical to the efficient functioning of the new chemical regulatory framework.

For the purposes of the TSCA Inventory, a single, defined molecule is simple to name. For example, ethanol is a Class 1 chemical on the TSCA Inventory. Its identity does not depend on how it is made. Since one ethanol is chemically the same as another ethanol, a new producer of ethanol can use the existing ethanol chemical listed on the TSCA Inventory. For other substances known as Class 2 chemicals, nomenclature is more complex. For those substances, the name of the substance typically includes either—or both—the source material and the process used to make it. The compromise requires EPA to maintain the Class 2 nomenclature system, as well as certain nomenclature conventions in widespread use since the early days of TSCA.

The compromise also directs EPA to continue to recognize the individual members of categories of chemical substances as being on the TSCA Inventory. The individual members of these categories are defined in inventory definitions developed by EPA. In addition, the compromise permits manufacturers or processors to request that EPA recognize a chemical substance...
currently identified on the TSCA Inventory under multiple nomenclatures as ‘equivalents.’

Importantly, the equivalency provision relates only to chemical substances that are already on the TSCA Inventory. The equivalency provision specifically references substances that have Chemical Abstract Service (CAS) numbers, EPA could usefully apply an equivalency approach to substances on the Inventory that do not have CAS numbers as well, such as for naturally-occurring substances.

Now, Senator VITTER, once a chemical is on the inventory, information about the substance that is provided to EPA often contains sensitive proprietary CBI or trade secrets, and particularly protected. In other cases involving proprietary CBI or trade secret processes is similar to the information that would reveal proprietary CBI or trade secrets—which includes chemical names, formulas and structures. This is clear that when a chemical has undergone a risk evaluation and determined to pose no unreasonable risk, any state chemical management action to restrict or regulate the substance is preempted. This outcome furthers Congress's legislative objective of achieving uniform, risk-based chemical management nation-wide in a manner that supports robust national commerce. Federal determinations reached after the risk evaluation process that a chemical presents no significant risk in a particular use should be viewed as determinative and not subject to different interpretations on a state-by-state or locality-by-locality basis. Further, under the new legislation, EPA will make decisions on preemption that must be made to consider various conditions of use, so there could be circumstances where EPA determines that a chemical does not present an unreasonable risk in certain uses, but does in others. Preemption is intended only with respect to determinations would apply as these determinations are made on a use-by-use basis.

Second, to promote the engagement of all stakeholders in the risk evaluation process—including State governments—this compromise creates a temporary preemption period for identified high priority chemicals moving through EPA's risk evaluation process. The period only runs from the time EPA finishes the evaluation to the time that EPA finishes the evaluation, or the agency deadline runs out. It does not apply to the first 10 TSCA Work Plan chemicals the EPA reviews, and it does not apply to manufacturer-requested risk evaluations. It does apply to any and all other chemical substances EPA chooses to review through a risk evaluation. States with compelling circumstances can request and be granted a waiver by EPA. EPA defines the scope of the evaluation process that a chemical preemption provision as it relates to actions taken prior to enactment of the Frank Lautenberg bill.

Mr. VITTER. Thank you, Senator INHOFE, for those important clarifications. I would like to ask you to help clarify the intent of the preemption provision as it relates to preemption section of this bill. Mr. INHOFE. As we all recognize, the preemption of an agency rule to be supported by substantial evidence. The reluctance was made in this Act is not intended to alter any preemptive effect on common law or state positive law of regulations promulgated or administrative actions taken under preexisting authorities, and is not intended to make any statement regarding legal rights under pre-existing authorities, including TSCA sections 6 and 17 in effect prior to the effective date of this Act. Mr. INHOFE. I appreciate your clarification on the intent of an important aspect of preemption under this act and also wanted to follow up with a question on judicial review. Specifically, what changes to TSCA's judicial review provisions have been made in the compromise?

Mr. VITTER. When TSCA was first enacted in 1976, the Act created a higher level of judicial review for certain types of rulemakings that were required as a result of the TSCA's requirements for chemicals in commerce. Congress took this approach because it wanted to ensure that rulemakings that would directly affect commerce by imposing restrictions on chemicals would be well supported with substantial evidence. The substantial evidence standard requires an agency rule to be supported by substantial evidence in the rulemaking record taken as a whole. The compromise legislation makes no changes to the process for judicial review of regulatory action or the level of review. The compromise now provides EPA with expanded authority to pursue certain administrative actions by order
addition to by rule. This new order authority is intended to allow EPA greater flexibility to move quickly to collect certain information and take certain actions. It is intended that an agency order constitute final agency action on issuance and be subject to judicial review. Sections 5 and 6 of TSCA constitute final agency action on issuance, and continue to be reviewed under the standards established by the Administrative Procedures Act. The intention is that regulatory actions on issuance, and continue to be reviewed, be subject to judicial action on issuance and be subject to judicial review.

Mr. VITTER. Thank you Senator INHOFE. The sound science provisions were a critical part of TSCA reform in my opinion and I hope this bill serves as a model for how to responsibly reform other laws administered by EPA and other Federal Agencies that are based on regulations rooted in science. For far too long Federal agencies have manipulated science to fit predetermined political outcomes, hiding information and underlying data, rather than using open and transparent regulatory processes and justify unreasonable substantive decisions making. This Act seeks to change all of that and ensure that EPA uses the best available science, bases scientific decisions on the weight of the scientific evidence rather than one or two individual cherry-picked studies, and forces a much greater level of transparency that forces EPA to show their work to Congress and the American public.

Congress recognized the need to use available studies, reports and recommendations for purposes of chemical assessments rather than creating them from whole cloth. We do believe, however, that the recommendations in reports of the National Academy of Sciences should not be the exclusive basis of the chemical assessments completed by EPA. Rather, the EPA must conduct chemical assessments consistent with all applicable statutory provisions and agency guidelines, policies and procedures. Where there were other studies and reports unavailable at the time of the NAS recommendations, EPA should take advantage of those studies and reports in order to ensure that the science used for chemical assessments is the best available and most current science.

Mr. INHOFE. Thank you for clarifying the Congressional intent of the important science provisions in this bill. I wanted to ask you one final question. I don't see the language around sound science and other scientific bodies who have raised concerns with the way EPA has been handling things in the past. Could you please discuss the Congressional intent of the bills science provisions?

Mr. VITTER. That is an important question Senator INHOFE and I appreciate your inquiry.

The Lautenberg bill tries to address the concern about forcing paralysis by analysis in several ways. First, the bill establishes that 'unreasonable risk under the conditions of use' as the safety standard to be applied by EPA. 'Unreasonable risk' does not mean no risk; it means that EPA must determine, on a case-by-case basis, whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use. Second, the bill requires EPA to specifically identify the sensitive subpopulations that are relevant to and within the scope of the safety assessment and require that the substance in question. At the same time, EPA should identify the scientific basis for the susceptibility, to ensure transparency for all stakeholders. In this way, the legislation affords EPA the discretion to identify relevant subpopulations but does not require—or expect—that all hypothetical subpopulations be addressed.

While a principle element of this compromise is including protections for potentially susceptible subpopulations to better protect pregnant women and children, a concern I think was first introduced by Senator Lautenberg and I was never to require the national standard to be protective of every identified subpopulation in every instance. If a chemical substance is being regulated in a condition of use that we know has no exposure to a subpopulation, EPA should apply the "unreasonable risk" standard appropriately. In addition, it is clear that the concept of low dose linearity is not firmly established by the science, and the concept is not appropriate to apply as a default in risk evaluations.

Mr. INHOFE. Thank you very much for that explanation, Senator VITTER.

MERCURY-SPECIFIC PROVISIONS IN THE BILL

Mr. WHITEHOUSE. Mr. President, we rise to highlight two mercury-specific provisions—the creation of a mercury inventory and expansion of the export ban to certain mercury compounds—in the Frank R. Lautenberg Chemical Safety for the 21st Century Act that the Senate will approve tonight. These provisions are sections of the Mercury Use Reduction Act that we introduced in the 112th Congress with the late Senator Frank Lautenberg, after whom this legislation is named, and with Senator John Kerry. Senator LEAHY and Senator MERKLEY have been longtime partners in these efforts. Senator LEAHY was a leader in the Senate's consideration of a resolution of disapproval concerning the Bush administration's mercury rule. I yield to Senator LEAHY.

Mr. LEAHY. Mr. President, I thank Senator WHITEHOUSE. His leadership in this area has been paramount.

Under the mercury inventory provision, the EPA will be required to prepare an inventory of mercury supply, use, and trade in the United States every 3 years. Despite an EPA commitment in 2006 to collect this data, there is not yet any good data on mercury inventories for that time period. This bill obligates the EPA to gather this data every 3 years and to make the results available to the public. It also directs the EPA to report on the annual inventory each year when it is completed and provides a mechanism for agencies to request access to the inventory data, which will improve transparency in the management of mercury.