CONGRESSIONAL INTENT BEHIND
SPECIFIC PROVISIONS OF THE BILL
H.R. 2576 -- The Frank R. Lautenberg Chemical Safety for the 21st Century Act

CONGRESSIONAL RECORD -- SENATE
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Mr. INHOFE.
Senator VITTER and I rise today to discuss a few provisions in the bill with the desire of clarifying what the Congressional intent was behind specific provisions of the legislation. Senator VITTER, 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 Congress intended is very important to ensure the legislative intent is understood and followed. To specifically address your first question, the term ''conditions of use'' is specifically defined as 'the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.' The conditions of use of a chemical substance drive the potential for exposure to a chemical. Exposure potential, when integrated with the hazard potential of a chemical, determines a chemical's potential for risk.

So EPA's understanding of a chemical's conditions of use—and importantly it is the circumstances 'the Administrator' determines—will be critical to EPA's final determination of whether a chemical is safe or presents an unreasonable risk that must be controlled.

Finally, to address your question 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 regular chemical 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.
Thank you, Senator VITTER. That response raised an interesting follow up question I would like 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 other conditions 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(a) rule must ensure that the chemical substance or mixture no longer presents an unreasonable risk. A Section 6(i) 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 must, and will be 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 require manufacturers to conduct under this 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 human 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 premanufacture 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 discretionary order authority, EPA must issue a 'statement of need' that explains the need for new testing/exposure information. It must describe how available information has informed the decision to require new information, 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 screening 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 meeting the objective to 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 TSCA in 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 to this section 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 new chemical may present an unreasonable risk, the compromise requires EPA 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 must make a statement 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: EPA should 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 chemical '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 descriptions 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. Although 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 elements that need protecting. There has been a significant debate in recent years regarding the protection from public disclosure of a confidential chemical identity provided in a health and safety study under TSCA section 14(b). Although new section 14(b) is substantially similar to the existing statute, what is the intent behind the additional language related to formulas?

Mr. VITTER.
It was the Congressional intent of the legation to balance the need to ensure public access to health and safety studies with the need to protect from public disclosure valuable confidential business information (CBI) and trade secrets that are already exempt from mandatory disclosure under the Freedom of Information Act. Striking the appropriate balance between public disclosure on the one hand, and the protection of a company's valuable intellectual property rights embodied in CBI and trade secrets on the other hand, is essential to better informing the public regarding decisions by regulatory authorities with respect to chemical, while encouraging innovation and economic competitiveness.

The compromise retains the language of existing section 14(b) to make clear that the Administrator is not prohibited from disclosing health and safety studies, but that certain types of CBI and trade secrets disclosed within health and safety studies must always be protected from disclosure. The new, additional language in this section is intended to clarify that confidential chemical identities—which includes chemical names, formulas and structures—may themselves reveal CBI or trade secret process information. In such cases, the confidential chemical identity must always be protected from disclosure. The new language is not limiting; it makes clear that any other

information that would reveal proprietary or trade secret processes is similarly protected. In other cases involving confidential chemical identities, EPA should continue to strike an appropriate balance between protection of proprietary CBI or trade secrets, and ensuring public access to health and safety information.

In addition to the protection of confidential information, another critically important provision in the deal was preemption. Senator Inhofe could you describe how the compromise address the relationship between State governments and the Federal government?

Mr. INHOFE.
As we all recognize, the preemption section of this bill was the most contentious issue of the negotiations as well as the most important linchpin in the final deal. The compromise includes several notable provisions.

First, it 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, riskbased chemical management nationally 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-bylocality basis.Further, under the new legislation, EPA will make decisions based on conditions of use, and must 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 for no significant risk 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—the 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 defines the scope of 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. These waiver and scope limitations ensure that the pause has its intended effect—to ensure that there is one, comprehensive, nationally-led risk evaluation occurring at a time, allowing EPA and affected manufacturers to focus on and complete the work on a timely basis, and to ensure a uniform and consistent federal approach to risk evaluation and risk management.

Senator VITTER, despite the fact that this law regulates products in commerce and Congress has the authority and Constitutional duty to protect interstate commerce, efforts were made to give States a role in this process, and even to get waivers from preemption where State actions are adequately justified. It should be noted that nothing precludes State action on chemical substances that are not the subject of an EPA risk evaluation or decision. There is also nothing in the compromise that precludes states from offering opinions, advice, or comment during the risk evaluation process. The

risk evaluation process anticipates numerous opportunities for public comment. It is our hope that States with an interest in a particular chemical substance will in fact bring forward relevant scientific information on chemical hazards, uses and exposures to inform an effective federal decision. This will ensure that EPA is making the most informed decisions for the citizens of the United States as a whole, rather than one State affording protection to only a fraction of the country.

Senator VITTER, before we conclude our discussion on preemption, I would to ask you to help clarify the intent of the 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 to preemption and for another question that is very important to clarify in order to capture the full conngressional intent of the bills preemption section. This Act is intended to change the preemption provisions of TSCA only with respect to regulations promulgated and actions taken under this Act after its effective date. 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 preexisting 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 rulemakings that would restrict 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 rulemakings or the standard of review. The compromise now provides EPA with expanded authority to pursue certain administrative actions by order in 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. Orders under Sections 4, 5, and 6 of TSCA constitute final agency action on issuance, and continue to be reviewed under the standards established by the Administrative Procedure Act. The intention is that regulatory actions that result in total or partial bans of chemicals, regardless of whether such action is by rule or order authority, be supported by substantial evidence in the rulemaking record taken as a whole.

Senator INHOFE, before we are done I think there are a few other sections of the bill that have been less discussed that it would be important to touch on. The first is Section 9 of TSCA which discusses the relationship between this and other laws. Could you please speak to what the intent of this bill with regards to Section 9 is?

Mr. INHOFE.
The Senate Report language states that section 9 of TSCA provides EPA with discretionary authority to address unreasonable risks of chemical substances and mixtures under other environmental laws. ''For example, if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information.''

Likewise, the House Report on section 9 of TSCA states: ''For example, if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk.''

This act states in new section 9(a)(5) of TSCA that the Administrator shall not be relieved of any obligation to take appropriate action to address risks from a chemical substance under sections 6(a) and 7, including risks posed by disposal of the chemical substance or mixture. Consistent with the Senate and House reports, this provision means that the Administrator should use authorities under the other laws such as the Solid Waste Disposal Act to prevent or reduce the risks associated with disposal of a chemical substance or mixture.

Senator VITTER, I know another section that is very important to you is the language around sound science and we all know you have worked to ensure that this bill fixes the scientific concerns of the National Academy of Science and other scientific bodies who have raised concerns with the way EPA has reviewed chemicals in the past. Could you please discuss the Congressional intent of the bill's science provisions?

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 tasked to make decisions based on 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 science to justify fair and objective decision 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 sole 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. Further, in instances 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 that is another key element to reforming this outdated law. It should be clear to all that H.R. 2576 attempts to ensure that the Environmental Protection Agency takes the possible exposures to sensitive subpopulations into account when prioritizing, assessing and regulating high priority chemical substances. The goal, of course, is to ensure that factors that may influence exposures or risk are considered as the Agency assesses and determines the safety of chemical substances. A concern, however, could be that the language regarding sensitive subpopulations may be read by some to promote the concept of ''low dose linearity'' or ''no threshold'' for many chemicals, including substances that are not carcinogens. This concept has not been firmly established in the scientific community. Does H.R. 2576 address this concern?

Mr. VITTER.
That is an important question Senator INHOFE and I appreciate the opportunity to clarify. 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 determination on 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 core of the bill since it 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.

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