



GLOBALCHEM

PREPARED REMARKS FOR CAL DOOLEY

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Good morning, everyone. It's my pleasure to welcome you to the 2017 GlobalChem Conference. My name is Cal Dooley, and I am the President and CEO of the American Chemistry Council (ACC).

As I look at this year's program, I can't help but think, "Wow – what a difference a year can make." Thanks to the hard work of many of you in this room, today, we have a brand new federal chemical regulatory regime in the Lautenberg Chemical Safety Act (LCSA). Of course, we also have a new Administration; a new Congress; and a new, promising leader of the U.S. Environmental Protection Agency (EPA) in Scott Pruitt. This year truly marks the beginning of "GlobalChem 2.0."

The work to implement the new Lautenberg Act is well underway, and we've been pleased with the Agency's effort to meet the LCSA's statutory deadlines. As we move forward, we hope that EPA will pay equal attention to interpreting and implementing the new law in the way Congress intended it to – and as stakeholders agreed would work best for our country – as it has to meeting the timeframes the LCSA established.

Before I go on, I'd like to recognize the organizations that help make this event a success, year after year. They are:

Beveridge & Diamond PC, and

Steptoe & Johnson LLP.

I also want to thank Wendy Cleland-Hamnett, Jeff Morris, and their colleagues at EPA for their important contributions to GlobalChem. By their presence and participation, the staff at EPA continues their long-standing commitment to engaging industry in efforts to enhance chemical regulation. We certainly appreciate their commitment to continue that dialogue under the LCSA.

I'd also like to welcome our keynote speaker, Dr. Lynn Goldman. Dr. Goldman brings broad and deep public policy and academic experience to this year's conference. We can look forward to hearing her perspective on the most significant changes under the new LCSA, and her thoughts on the key challenges and opportunities the new law may present.

But first, I hope you'll allow me to reflect on the magnitude of what we achieved together to put our chemical regulatory system on a course that is consistent with the knowledge and know-how of the 21<sup>st</sup> century.

After nearly a decade of hard work and perseverance by many stakeholders, Congress passed and the President signed into law bipartisan reform of the Toxic Substances Control Act (TSCA). TSCA is a word we uttered perhaps hundreds of thousands of times over the years, and certainly on countless occasions at this conference, but now it is a new day thanks to the Lautenberg Chemical Safety Act.

On a personal note, witnessing President Obama sign the LCSA into law last summer was nothing short of extraordinary. Being there with many of the very same people with whom it seemed we might never agree spoke to the bipartisan nature of the legislation. And while we may not always have seen eye-to-eye with the Late Senator Frank Lautenberg, the LCSA was a consensus bill that honored his legacy and spoke to the importance of engaging in give-and-take in order to make progress. Senator Lautenberg's widow, Bonnie Lautenberg, was instrumental to getting this bill across the finish line, and having her there at the signing ceremony made the event even more special.

Since then we have all embarked on a new journey guided by the new chemical regulatory regime. It is a journey that continues to evolve with the beginning of a new Congress; and with new leadership at the EPA.

Administrator Pruitt has committed to making sound science the foundation of all regulation, a principle that ACC, its members and their customers have long supported. His leadership and commitment to science will be instrumental to ensuring that the Lautenberg Chemical Safety Act is implemented in the way that lawmakers intended. It will also help establish LCSA as a model regulatory program that can be adopted and customized by governments around the globe to meet their country's specific needs in a way that is firmly based on risk. The LCSA offers other nations a dynamic solution to chemical management that is more aligned with innovation, safety and well-informed decision-making than the more simplistic, hazard-oriented systems that are in effect in some parts of the globe today.

ACC and our members have worked diligently over the past six months to follow through on the obligations we agreed to under the new law. As I mentioned earlier, we are pleased that EPA has begun to successfully carry out its responsibilities, including meeting some early deadlines, yet there is still so much to do.

Steady and consistent progress will only be possible if EPA, industry and other stakeholders commit to it; view each other as partners with shared goals; and cooperate to reach milestones. There are two areas in particular where industry and EPA can and should work together now to put the program on a solid footing: prioritizing chemicals for review; and conducting efficient risk evaluations.

Prioritization of chemicals for review is a key provision of the LCSA's framework. EPA recently published its proposed rule to establish the prioritization process, but ACC has several concerns with the proposal. Notably EPA suggests that it would be unlikely to designate chemicals as low priorities because the Agency would require that ALL conditions of use meet the low priority criteria. Low-priority designations were intended to be one way EPA could show quick progress in reviewing chemicals, to assure the public about chemical safety, and to conserve resources by focusing its attention on chemicals that pose high risks to human health and the environment. It is critical that EPA get prioritization right.

The foundation of the LSCA is effective and efficient risk assessment of prioritized chemicals and uses. ACC and our members have called for EPA to focus on the particular conditions of use that warrant risk evaluation, including analyzing a substance's hazards and its exposure potential using the best available science and the full weight of the scientific evidence. These principles should apply to the

first ten chemicals from EPA's 2014 TSCA Work Plan list and all chemicals the Agency evaluates in the future.

Unfortunately, the Agency's proposed rule on risk evaluation does not incorporate the key scientific criteria and weight-of-the-evidence provisions that were required by the LCSA. We believe revisions to the rule are necessary so that all stakeholders can understand exactly how EPA will evaluate the quality, reliability, and relevance of the scientific evidence it examines as part of risk evaluations.

Embedded in each of these components of the LCSA is the need for data and information sharing. Industry has a lot to offer in this regard – from our deep knowledge base and expertise both in the U.S. and abroad, to the robust chemical safety information we've developed over the years on chemicals in commerce. That's why it's largely on us to work closely with EPA to provide or identify the information that can help the Agency make quick, accurate risk evaluations.

To that end, ACC recently launched the Center for Chemical Safety Act Implementation to serve as hub for chemical manufacturers, processors, importers and downstream users of chemistry to collaborate and provide input to the EPA.

We will also be relying on our Center for Advancing Risk Assessment Science and Policy (ARASP), which promotes the development and application of up-to-date, scientifically-sound methods for conducting chemical assessments, to serve as an information powerhouse for ensuring chemical safety studies being used by EPA adhere to the highest possible standards, both today and in the future.

The LCSA is a big opportunity, but it is also a big change, and with change, challenges are inevitable. However, it's surprising that we have grown most concerned about EPA's implementation of an area of chemical regulation that underwent only modest changes under the LCSA.

I'm referring, of course, to Section 5, the New Chemicals Program, which governs the review and regulation of chemical substances new to the market. The program was widely considered to be one of TSCA's bright spots, so it survived the TSCA modernization process largely intact.

That said the LCSA did make some important changes to the New Chemicals Program – changes we fully support. These improvements were intended to enhance EPA's ability to analyze new substances before they enter commerce and to ensure that the Agency has sufficient information to make decisions, to codify EPA's mandate to address vulnerable populations, and to ensure transparency in its decisions. Importantly, the legal standard for review of new chemicals did not change.

Some of the new chemical submissions have been identified as having insufficient information, and as I said it's incumbent on our industry to resolve those issues. But in the months since the LCSA was enacted the New Chemicals Program has also been hampered by unnecessary inefficiencies, resulting in a virtual standstill in bringing new chemicals to market. ACC believes the problem stems from EPA's misinterpretation of Section 5 in ways clearly not intended by Congress. This improper reading of the law has already resulted in some serious consequences.

Over the last six months alone, the backlog of new chemical submissions has doubled from 331 to 658. During this time, EPA has completed its review of only

33 of those substances, and little progress has been made toward making final decisions for the remaining submissions. This is stunning for a program that has historically reviewed about 1,000 substances annually.

But here's the real problem: without new chemical building blocks, manufacturers can't innovate. They can't make new or better products that improve people's lives. They can't grow. They can't create new jobs. They can't compete with the rest of the world. That's why ACC and our members stand ready and eager to assist EPA in solving this problem as quickly as possible. With so much is at stake, there is absolutely no time to lose; we must get the new chemicals program back on track.

Right now, governments around the globe are watching how this country is moving forward under the direction of our new government leaders. There are many things that we may not be able to control. But the things that we can control – that we can work together to make successful – should be our top priority.

The Lautenberg Chemical Safety Act is our opportunity to demonstrate how a state-of-the-art, risk-based chemical safety program truly works in practice; how it can protect both public health and the environment without unnecessarily stifling innovation; and how key elements of such a risk-based program can be implemented around the globe today, especially in developing countries where governments and communities could most benefit from the innovation and economic growth that chemistry makes possible. That is why ACC and our members are so committed to implementing the Lautenberg Act successfully.

The LCSEA is also our opportunity to strengthen partnerships with like-minded government agencies around the world that share in our mission. Working together to advance global chemical safety regulations helps advance other social and economic priorities, like international trade. A more harmonized, risk-based framework for ensuring chemical safety could help reduce or eliminate trade barriers that currently stand in the way of much-needed economic growth. Administrator Pruitt's commitment to the best available science under the LCSEA can extend to regulatory cooperation as well, enabling governments and companies around the world to work together to manage chemicals more effectively and more efficiently.

This year's GlobalChem marks the beginning of a new journey in sound chemicals management with ramifications that extend far beyond the walls of this room. So much has changed over the past 12 months that it would be understandable for any of us to feel a little overwhelmed.

Thankfully, some things haven't changed – they are constant – and they are the bedrock of how we can continue to make progress. I'm talking about the value of a shared commitment to both safety and innovation and the importance of cooperation and partnership to progress. Despite tough challenges, collaboration and compromise got us to where we are today. And I have no doubt that they'll help us get to where we want to be tomorrow and in the decades to come.

Thank you.

I now would like to introduce our keynote speaker this morning, Dr. Lynn Goldman.

Dr. Goldman is the Michael and Lori Milken Dean at Milken Institute School of Public Health at the George Washington University. Her responsibilities are informed by her broad and deep public policy and academic experience. Prior to joining GW, she was a professor of environmental health sciences at the Johns Hopkins Bloomberg School of Public Health. She has also served as assistant administrator for toxic substances in the U.S. Environmental Protection Agency.

Please join me in welcoming Dr. Lynn Goldman.