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The Chemicals in Commerce Act

United States House of Representatives
Committee on Energy & Commerce
Subcommittee on Environment and the Economy

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Chairman Shimkus, Ranking Member Tonko, Members of the Subcommittee:

I am Steven J. Goldberg, vice president and associate general counsel for regulatory and government affairs at BASF Corporation.

BASF Corporation supports modernization of the Toxic Substances Control Act (TSCA). We believe substantial progress has been made towards that goal by the most recent draft of the Chemicals in Commerce Act (CICA). We appreciate the subcommittee's focus on this important matter and are grateful for the opportunity to appear before you today.

About BASF

BASF Corporation is the North American affiliate of BASF Group, the world's leading chemical company, which is headquartered in Ludwigshafen, Germany. BASF has nearly 17,000 employees in North America, of which approximately 14,000 are in the U.S. We have facilities in more than 30 states. Our North American headquarters is located in Florham Park, New Jersey. Key U.S. manufacturing locations for BASF include Freeport, Texas; Geismar, Louisiana; and Wyandotte, Michigan. Our major research & development sites in the U.S. include Research Triangle Park, North Carolina; Tarrytown, New York; and Iselin, New Jersey.

As the world's leading chemical company, BASF cares greatly about ensuring that regulatory systems around the world provide assurance to the public that the products of the business of chemistry are safe and ensure that companies can innovate to meet the needs of our customers and society. Our portfolio ranges from chemicals, plastics, performance products and crop protection products to oil and gas. BASF combines economic success with environmental protection and social responsibility. Through science and innovation, we enable our customers in nearly every industry to meet the current and future needs of society. Our products and solutions contribute to conserving resources, ensuring nutrition and improving quality of life. We have summed up this contribution in our corporate purpose: ***We create chemistry for a sustainable future.***

Working With Our Trade Associations

At BASF, one of our pillars is "helping our customers be successful." To this end, we work closely with our basic chemical association, the American Chemistry Council, and key downstream associations including the American Cleaning Institute and the Consumer Specialty Products Association in support of modernizing TSCA. All of these associations and many others have provided a strong voice in favor of reestablishing U.S. and Environmental Protection Agency (EPA) leadership in chemicals management. We at BASF thank them for their work and commend their efforts to members of this subcommittee.

Support for TSCA Modernization and the CICA

BASF strongly supports reform and modernization of TSCA. While the law was groundbreaking when it was adopted in 1976, it has not been successful in recent years in meeting all of the needs of the chemical industry, our customers and consumers. And, although we strongly

believe that the products we manufacture and market are safe, assurance for consumers needs to come from the agency charged with the ultimate goal of assuring safety, *i.e.*, the EPA. In the absence of that assurance, industry has been faced with a multiplicity of efforts from a variety of stakeholders, including state and local governments, which call for regulation of chemicals in different ways. We believe that a consistent approach to chemicals management in the U.S. is required. That approach -- leadership by EPA with modern tools for gathering data and making risk assessment and risk management decisions -- is reflected in the updated discussion draft of the CICA. We believe the updated draft provides a substantial step forward towards reaching sensible chemical management reform. Its provisions are a marked improvement over current law and would provide EPA with the authority to review chemicals, both new and existing, and manage their risks.

The CICA Meets Key Principles for Modernizing TSCA

A number of key principles and concepts for TSCA modernization are the subject of agreement among a wide variety of stakeholders, including the following:

- TSCA should provide for additional authority for EPA to review and manage risks from existing chemicals on the market, as it has successfully done for new chemicals since TSCA's inception;
- A prioritization process is an appropriate way for EPA to commence reviewing existing chemicals in order to ensure its resources are being spent in the most efficient way;
- EPA requires additional authority to call for testing of chemicals where existing data is insufficient to permit reasoned conclusions either as to its priority status or to make risk assessments;
- The appropriate approach for a safety assessment of chemicals is a risk-based standard, *i.e.*, one that takes into account not just hazards but also exposure in leading to safety conclusions;¹
- The safety standard should, at its heart, be one revolving around the concept that the EPA should take action where risks are significant, not when they are insignificant;
- EPA should take into account the needs of identified sensitive subpopulations where appropriate to be able to make a safety assessment;
- EPA requires additional regulatory means, *e.g.*, protective labels or use conditions, to allow it to efficiently manage the risks of chemicals where those risks are more than insignificant;
- Benefit and cost considerations are **NOT** appropriate when making a safety/risk assessment, but **ARE** critical in deciding the appropriateness of risk management measures;

¹ This will require increased authority to gather use information.

- There should be appropriate protections for confidential business information; and
- EPA will require sufficient resources to be able to fulfill its mandate in a timely manner under a modernized TSCA.

While provisions in the proposed bill on exposure data and resource needs require some fleshing out, overall we are pleased that the updated CICA is directed towards meeting these principles and concepts, and thus is a substantial improvement over current law. While all of these subjects are of critical importance, I will focus the remainder of my statement on three key areas.

(1) Risk Assessments and Appropriate Risk Management Measures

A workable, modernized TSCA will only succeed if EPA in fact can do the job it is required to do. This includes requirements that the agency prioritize chemicals for safety review, conduct safety reviews and take appropriate risk management actions. We are pleased that the latest discussion draft of the CICA advances these requirements by setting forth timeframes by which risk assessments and risk management actions must take place once a chemical is designated as high priority. Some stakeholders have noted that one element missing from the current discussion draft is the pace by which this process should take place. In short, it is important to have an understanding of the number of chemicals that must go through the risk assessment process and the timeframe in which EPA must make a prioritization decision. While we share some of this concern, we note that the ability to make an assessment of the appropriate pace of the program depends upon two key elements yet to be assessed: (1) the resources available to the agency and (2) the number of chemicals that are truly active and require prioritization. Without these key facts, we believe it is difficult to legislate an appropriate pace for how many chemicals go into the system.

(2) Risk Assessment Depends Upon the Availability of Use and Exposure Data

As noted earlier, and is reflected in the latest draft of the CICA, the appropriate standard for review of chemical safety is on the basis of risk, not just hazard. This requires the availability of sufficient use and exposure data to allow EPA to make reasoned judgments. While not testifying on their behalf, as a member of the chemical management teams at the American Cleaning Institute and Consumer Specialty Products Association, the leading associations of downstream chemical formulators, I know that the downstream members are committed to an appropriate system of providing adequate use information to help inform chemical safety assessments. That commitment comes with the acknowledgment that TSCA reform must ensure the protection of confidential business information.

(3) Sufficient Resources to Fulfill the Objectives of the Chemicals in Commerce Act

Ultimately, one key to the success of a modernized TSCA is ensuring that EPA has the resources necessary to review new chemicals and prioritize and review active chemical substances under the authority proposed under the CICA. A program that provides EPA the authority, but not the resources, to do its job is a losing proposition for industry, our customers and the public. The

program posited by the CICA clearly will require additional resources in the EPA Office of Pollution Prevention and Toxics to allow the program to work.

While it may be appropriate to consider a “user fee” system for providing some of the resource needs, certain principles are critical in reaching an acceptable fee approach:

- Fees charged must be dedicated to the program itself, not to the general Treasury or other programs within EPA;
- Fees need to supplement, not replace, appropriations for the functions of chemical safety review;
- Fees must be reasonable in amount;
- Fees must not stifle innovation;
- Fees should be focused on activities that provide a direct benefit to the person being charged; and
- A fee system needs to take into account small business considerations.

Having been extensively involved in the development and implementation of the pesticide fee system under the Pesticide Registration Improvement Act (PRIA), which has been in place for the Office of Pesticide Programs (OPP) for 10 years, I can provide some perspective on the possible application of a fees approach as part of increasing the resources for EPA to meet the needs of the program.

Ultimately, PRIA provides some direction for possible approaches towards meeting resource needs in the chemicals area, but it is also a somewhat imperfect model for TSCA fees. This is because the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the pesticide law of which PRIA is a part is a product registration statute. Similar to the Prescription Drug program at the Food and Drug Administration, pesticide applicants receive what amounts to a marketing license that is specific to that applicant. Under FIFRA, each product marketed as a pesticide must be approved. By contrast, TSCA is a substance based system—once a chemical is on the TSCA Inventory, anyone (subject to any patent restrictions) is free to market the same product. And, unlike under FIFRA, each product containing a chemical does not require registration².

Under FIFRA, there are two types of fees that registrants pay. The first is a registration fee. Applicants seeking the approval to market a new active ingredient, new product, new use or even new conditions of use must pay an application fee, which varies in amount depending upon the nature of the application. The second is the annual maintenance fee. All registrants of products must pay a fee per product that they have registered (with a cap on total fees out of any one company).

One can see some similarities in the notion of registration fees for chemicals. Indeed, an application fee for Pre-Manufacturing Notifications already exists. However, those fees go to the Treasury and are not directed specifically to EPA’s chemicals program. Under PRIA,

² One can readily see the impracticality of a product registration system for chemical products. Such a system would result a separate approval for each formulation or even each product/article that contains a chemical.

maintenance fees go to help fund OPP's "Registration Review" program, a program similar to risk assessment program for priority chemicals proposed under the CICA.

While there are things to be learned from the experience with PRIA, ultimately a fee program for chemicals would need to be based on the unique processes and requirements of the chemical management system. BASF stands ready to help inform Congress' consideration of the resource needs of the EPA, including appropriate fee approaches.

Conclusion

Thank you, again, for the opportunity to share BASF's views on the modernization of TSCA and the revised discussion draft of the CICA. BASF supports the approach of the CICA towards reaching bipartisan solutions for the critical issues required to make a modernized TSCA a success. The chemical industry needs, and the public deserves, a predictable, scientifically-based and efficient federal chemical management system that will create greater certainty and promote innovation that will help to create a more sustainable future. BASF looks forward to working with members of the subcommittee to accomplish this task.