





Chemical Industry Principles for Regulatory Cooperation in the Chemicals Sector in NAFTA September 7, 2017

The North American chemical industry¹ supports modernizing the North American Free Trade Agreement (NAFTA) to upgrade the agreement and build upon the economic partnerships and supply chain synergies and efficiencies that have been created through reduced barriers to trade. Addressing regulatory cooperation opportunities holds great promise for better value creation and integration of the Canadian, Mexican, and American economies.

After more than 20 years, modernization of NAFTA is an opportunity to upgrade the agreement to address inefficiencies and reflect procedures adopted or proposed in subsequent negotiations. A comprehensive modernized NAFTA will eliminate remaining tariffs and provide a mechanism to address non-tariff barriers that can arise from discordant regulatory measures. A comprehensive outcome from NAFTA modernization will spur innovation, create jobs, improve industry competitiveness, and ensure long-term growth and prosperity.

Enhanced regulatory cooperation has the potential to maintain high levels of protection for human health and the environment and significantly reduce costs for governments and industry alike. A modernized NAFTA should also codify a process to achieve regulatory coherence and simplification, including an agreement on criteria to identify sound-science approach to promote risk-based assessments, and appropriate recognition of regulatory decisions. This document outlines the essential principles that should guide the renegotiation of NAFTA provisions applicable to the chemical industry. Applying these principles will help assure that NAFTA is as strong, efficient, economically competitive, and effective as possible.

- 1. The revised agreement should include a mechanism to promote stronger North American collaboration by regulators and stakeholders by leveraging relevant international initiatives, such as those aimed at further alignment in chemical regulations, as well as regional initiatives. This will help minimize the potential for imposing additional regulatory barriers when revising, developing, and implementing respective regulations and regulatory activities for chemical substances and products.
- 2. NAFTA should promote a risk-based approach to the regulation of chemical substances and products.
 - All chemical regulations should be science- and risk-based, taking both hazard and exposure into consideration.
- 3. NAFTA should leverage existing and ongoing work and decisions to prioritize, evaluate, and manage chemical substances safely.

¹ Represented by the Chemical Industry Association of Canada (CIAC), the Mexican Chemical Industry National Association (ANIQ), and the American Chemistry Council (ACC)







- Information on chemicals from government databases, inventories and regulations should be used to collect information on the existing chemical substances in commerce in North America, in which to set priorities for assessment.
- Opportunities to appropriately recognize related work and decisions in the three countries, such as:
 - o Identification of chemical substances in commerce:
 - o Prioritization lists of substances for risk assessment; and
 - Risk assessments.
- 4. A mechanism to promote stronger North American scientific cooperation and enhanced coordination on scientific assessments.
 - NAFTA should include an agreement on common scientific criteria to ensure the
 quality and reliability of scientific data underpinning regulatory decisions.

 Among other elements, the agreement should include common principles for data
 quality, including utility, objectivity (which includes reproducibility), weight-ofthe-evidence, and integrity.
 - The right of governmental bodies to make sovereign decisions on the basis of the data and information before them should be explicitly recognized.
 - The U.S., Canada, and Mexico should encourage the use of good laboratory
 practices, peer review, scientifically validated test methods, standardized
 protocols, systematic review and other methods to ensure scientific quality of
 data, in a manner that is non-discriminatory.
- 5. NAFTA should promote transparency in North American cooperative activity to enhance stakeholder confidence and support for regulatory cooperation. Increased transparency by and between the parties should include:
 - Opportunities for meaningful stakeholder notice and comment on the proposed agenda for cooperation.
 - Opportunities for meaningful stakeholder participation in relevant cooperative activities.
 - Access by governments to scientific and technical expertise relevant to assessments under review in the U.S., Canada, and Mexico.
 - A meaningful consultation process on regulatory developments of relevance to the North American relationship, including notification of proposals for new or modified regulations, an opportunity for stakeholder input prior to implementation and a mechanism to respond to stakeholder input in an effective and timely manner.







- 6. To the extent possible, NAFTA should promote alignment in timing of legislative, regulatory, and guidance documents to streamline regulatory implementation, eliminate economic divergences and enhance regulatory alignment.
- 7. NAFTA Parties should share screening-level criteria to prioritize chemicals for further review and evaluation, enabling governments and industry to focus attention and limited resources on those substances of highest concern.
 - The criteria should be science and risk-based, considering both the degree of hazard (hazard identification and characterization) and the extent of exposure potential (risk assessment), based on the weight of scientific evidence.
 - Criteria should be clearly-defined based on common data requirements to facilitate and encourage innovation and engagement by SMEs.
 - The prioritization process should leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
 - The prioritization process should be flexible enough to incorporate relevant scientific advances where there is broad consensus in the scientific community, including alternatives to animal testing.
 - The process should employ a relatively simple and transparent screening method.
 - The process should allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- 8. NAFTA should agree on ways to enhance collaboration to facilitate increased data and information sharing to eliminate duplicative generation, testing and submission of data.
 - Regulatory agencies should share all relevant non-confidential data and information, including relevant data and information analyses.
 - NAFTA should include an agreement that stakeholders relying on data or information owned or controlled by a third party in a relevant regulatory process should demonstrate they have legal authority or permission to access the relevant underlying full study.
 - NAFTA should include adequate safeguards to ensure the protection of commercial and proprietary interests.
 - NAFTA should agree on ways to facilitate sharing of information between governments when requested by the information owner(s), while respecting legal restrictions on access to Confidential Business Information (CBI).







9. NAFTA should promote alignment in the implementation of the U.N. Globally Harmonized System for Classification and Labeling to reduce differences in classification of chemical substances, to promote the consistent communication of information for safe handling, and use and reduce regulatory and transaction costs.