UNITED STATES-MEXICO HIGH-LEVEL REGULATORY COOPERATION COUNCIL WORK PLAN

February 28, 2012

High-Level Regulatory Cooperation Council

United States and Mexico Work Plan

TABLE OF CONTENTS

WORK PLAN FOR THE UNITED STATES AND MEXICO HIGH-LEVEL REGULATORY COOPERATION COUNCIL

BACKGROUND

On May 19, 2010, President Felipe Calderón Hinojosa and President Barack Obama reaffirmed the strategic bilateral partnership between the United States and Mexico, and underscored each country's commitment to significantly enhance the economic competitiveness and the economic well-being of both the United States and Mexico through improved regulatory cooperation.[1] Regulatory cooperation can increase economic growth in each country; lower costs for consumers, businesses, producers, and governments; increase trade in goods and services across our borders; and improve our ability to protect the environment, health and safety of our citizens. President Calderón and President Obama therefore instructed the creation of the High-Level Regulatory Cooperation Council (HLRCC), comprised of senior-level regulatory, trade, and foreign affairs officials from both countries.

On March 3, 2011, Mexico and the United States outlined the mandate for the HLRCC in a Terms of Reference document.[2] Taking into account that bilateral commerce between the United States and Mexico reaches more than a billion dollars daily,[3] the Terms of Reference tasked the HLRCC to create a Work Plan that identified areas of mutual interest for cooperation, taking appropriate account of the goals of the Council, both to facilitate intra-North American commerce and to enhance the competitiveness of North American producers in key export markets, with a special (but not exclusive) emphasis on small and medium-sized enterprises, while enhancing our collective ability to achieve regulatory ends.

In particular, the Terms of Reference instructed the HLRCC to identify sectors for cooperation in line with the following key principles:

1) Making regulations more compatible, increasing simplification, and reducing burdens without compromising public health, public safety, environmental protection, or national security;

2) Increasing regulatory transparency to build national regulatory frameworks designed to achieve higher levels of competitiveness and to promote development;

[1] Joint Statement from President Barack Obama and President Felipe Calderón, May 19, 2010, found at http://www.whitehouse.gov/the-press-office/joint-statement-president-barack-obama-and-president-felipe-calder-n.

[2] Terms of Reference for the High-Level Regulatory Cooperation Council, March 3, 2011, found at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/high-level_regulatory_cooperation_council-terms_of_reference_final.pdf.

[3] Statistic from Ambassador Anthony Wayne, quoted in the article "Comercio México-EU supera los mil mdd diarios: Wayne," published by El Universal.mx, December 1, 2011, found at http://www.eluniversal.com.mx/notas/813182.html.

3) Simplifying regulatory requirements through public involvement;

4) Improving and simplifying regulation by strengthening the analytic basis of regulations;

5) Linking harmonization and regulatory simplification to improvements in border-crossing and custom procedures; and

6) Increasing technical cooperation.

STAKEHOLDER CONSULTATION AND REGULATORY REVIEW OF PUBLIC COMMENTS

Both countries engaged in extensive consultation with stakeholders and the public in the course of development of the Work Plan. The U.S. Department of Commerce published a request for public comment in the *Federal Register* on March 3, 2011, inviting comment on possible areas of regulatory cooperation between the United States and Mexico.[4] The United States received 48 comments from the stakeholder community. Mexico also published a request for public comment on April 14, 2011.[5] Mexico received 252 comments from the stakeholder community. These comments served as a basis for a bilateral discussion within the HLRCC to identify potential sectors and actions for collaboration.

The information gathered through the public consultations was reviewed by the corresponding regulatory bodies of each country. The main regulatory bodies involved from each country included the following:

[4] Request for Public Comments Concerning Regulatory Cooperation Activities That Would Help Eliminate or Reduce Unnecessary Regulatory Divergences in North America That Disrupt U.S. Exports, 76 FR 11760 (published March 3, 2011) (comment period ended April 18, 2011).

[5] Request for proposals related to the subject of regulatory cooperation within the framework of the North American Free Trade Agreement with the purpose of eliminating or reducing unnecessary costs for enhancing external commerce and investment ("CONVOCATORIA para enviar propuestas en materia de cooperación regulatoria en el marco del Tratado de Libre Comercio de América del Norte con el fin de eliminar o reducir costos innecesarios para fomentar el comercio exterior y la inversion," Diario Oficial de la Federación) (published April 14th, 2011) (comment period ended May 16th, 2011).

U.S. Regulators	Mexican Regulators
• Department of Health and Human Services (HHS) • Food and Drug Administration (FDA) • Occupational Safety and Health Administration (OSHA) • Department of Energy (DOE) • Environmental Protection Agency (EPA) • Department of the Interior (DOI), Bureau of Safety and Environmental Enforcement (BSEE) and Bureau of Ocean Energy Management (BOEM) • Department of Agriculture (USDA) • Department of Transportation (DOT) • National Highway Traffic Safety Administration (NHTSA) • Federal Motor Carrier Safety Administration (FMCSA)	• Ministry of Economy (SE) • Federal Commission for the Protection of Sanitary Risks (COFEPRIS) • Ministry of Agriculture, Livestock, Rural Development, Fishing and Food Supply (SAGARPA) • Ministry of the Environment and National Resources (SEMARNAT) • Ministry of Communications and Transports (SCT) • Ministry of Health (SSA) • National Service for Health, Food Safety and Food Quality (SENASICA) • National Metrology Center (CENAM) • National Hydrocarbons Commission (CNH)

Given the time constraints that each government has for implementation of actions in the HLRCC, not all the proposals received during the public comment process could be incorporated in the initial Work Plan. Proposals that were not incorporated in the HLRCC Work Plan and that are trilateral in nature will be considered under the existing NAFTA Committees on Standard Related Measures (CSRM) and Sanitary and Phytosanitary Measures (CSPM), or any other deemed Committee.

THE HLRCC WORK PLAN

The United States-Mexico Work Plan is an outline of the activities to be carried out by the HLRCC for a period of two years. It will be reviewed and modified as appropriate, on an annual basis. This Work Plan includes a balanced set of actions oriented to reduce administrative burdens, align regulations, and create new opportunities for businesses. These actions are ultimately focused on improving the overall economy of our countries, and improving regional competitiveness. Nothing in this Work Plan is intended to give rise to rights or obligations under domestic or international law.

The Work Plan focuses on seven sectoral issues in the following six areas: food, transportation, nanotechnology, e-health, oil and gas, and conformity assessment. Each section of the Work Plan contains a description of the issue, the objective / desired outcome, a list of specific deliverables and timeline, and an explanation of the benefits. In certain cases, deliverables are described as "accomplished." This is because the two countries have been

working together on regulatory cooperation since 2010, and certain of the deliverables were completed in advance of the final publication of the Work Plan.

1) Food

a. Food Safety Modernization

The first item on the HLRCC Work Plan involves food safety modernization. The relevant regulators are FDA and COFEPRIS.

Description: The passage of the Food Safety Modernization Act (FSMA) set in motion sweeping improvements to the security and safety of the food supply in the United States. The legislation directs the U.S. FDA, working with a range of public and private partners, to build a new system of food safety oversight – one focused on applying, more comprehensively than ever, the best available science and good common sense to prevent the problems that can make people sick. Mexico is willing to cooperate with U.S. regulatory authorities with the objective of improving both countries' food safety systems. Given the increasing integration of the agriculture and food sectors of Mexico and the United States, and the close collaboration among regulatory organizations in the two countries, developing common approaches to food safety requirements and policies will benefit consumers and the food industry on both sides of the border.

Objective/Desired Outcome: The Council will intensify the present dialogue between the two countries aimed at implementing FSMA provisions of common interest. Mexico will have the opportunity to comment on U.S. FDA's proposed rules pursuant to timelines set forth in the relevant U.S. Federal Register entries and WTO notifications so that Mexico can learn about and offer its perspectives on the proposed requirements. The Council will facilitate as needed Mexico's participation in rulemaking, highlighting opportunities for involvement in policymaking, such as by meeting with OIRA and FDA to discuss proposed rules.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan include:[6]

- Meeting between regulators to discuss the FSMA, and to consider Mexican views (accomplished in June 2011 with FDA FSMA outreach visit to Mexico);
- Consultation on draft FSMA capacity building plan with foreign government officials, which includes Mexican regulators (by December 2012);
- At least two technical assistance activities for the Mexican private sector (one by June 2012, and one by December 2012); and
- Renew a Food Safety Cooperative Arrangement between FDA and Mexico's Food Safety Agencies that will enhance cooperation on information exchanges and the development of joint safety programs (by December 2012).

[6] Timeline may be adjusted due to the timing of publication of the final implementing rules of the FSMA.

Why Should We Do This?

1. Mexico is a major exporter and supplier of fresh and processed foods to the United States;

2. It is in the best interest of both countries to strengthen mutual collaboration to improve the process of application of FSMA regulations in the areas of production, processing and handling of food that is exported or imported;

3. Timely understanding of FSMA requirements will help both government and industry implement them in a timely and seamless fashion, resulting in improved product safety with minimal or no disruption in supply or trade; and

4. The provision in FSMA for recognition of third parties, such as Mexican regulators, offers the potential for expanding and streamlining trade in agricultural products.

a. E-Certification for Plants and Plant Products

The second item on the HLRCC Work Plan involves e-certification for plants and plant products. Relevant regulators are the U.S. Department of Agriculture/APHIS and SENASICA.

Description: The United States and Mexico will work together to develop compatible electronic certificate programs such that phytosanitary e-certificates for plants and plant products from Mexico will be accepted by APHIS and other relevant authorities at the entry points, and phytosanitary e-certificates for plants and plant products from the United States will be accepted by SENASICA.[7]

Objective/Desired Outcome: The United States and Mexico will work together to develop compatible electronic Export and Import Certificate programs for plants and plant products under the HLRCC, which will involve reciprocal acceptance of e-certificates. For live animals and animal products, USDA continues to work toward implementing an e-certification system in the future. Once the plants and plant products phase is accomplished, both countries will assess next steps related to e-certification of live animals and animal products.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan have estimated deadlines, given that the e-certificate's website will be part of the Mexican Single Window for Foreign Trade (VMDCE) project. Thus, the HLRCC will coordinate the timing of the e-certification initiative with Mexico's Tax Administration Service (Servicio de Administración Tributaria - SAT), which is in charge of the VMDCE. These include:

- System design (from January to March 2012);

[7] While APHIS/Plant can meet the timetable, USDA will need to interface with the Customs and Border Protection (CBP) system before the benefits of e-certification can be fully realized. The CBP interface is under development. In the short term, paper copies of certificates and electronic messaging will be necessary to facilitate trade.

- Integration of business rules and operating the software development (from February to April 2012);
- Computer development of modules (from March to July 2012);
- Tests within the unit (from June to August 2012);
- Acceptance testing (from July to November 2012);
- System operation (by December 2012); and
- Feedback for improvements to the modules (by December 2012).

Why Should We Do This?

1. A compatible electronic certification program will reduce the burden on U.S. and Mexican businesses, reducing and even eliminating certain administrative requirements;
2. A compatible electronic certification program will ensure that we maintain an appropriate protection of plant and plant products for shipments crossing our borders;
3. A compatible electronic certification program will support future development of a single entry point for compliance with customs and other government regulations;
4. E-certificates modernize and streamline processes for trading agricultural products while maintaining safety and reliability; and
5. This initiative will improve the management of procedures related to certification as well as facilitate stakeholder compliance with regulations by reducing compliance time and lowering costs.

2) Transportation: Commercial Motor Vehicle Safety Standards and Procedures

The third item on the HLRCC Work Plan involves commercial motor vehicle safety standards and procedures. The relevant regulators are the U.S. Department of Transportation (DOT)/Federal Motor Carrier Safety Administration (FMCSA) and Ministry of Communications and Transports (SCT).

Description: At the border, there is strong interest in developing consistent and harmonized criteria for the assessment of the safety of trucks. While we currently have North American criteria in place to establish these measures, Mexico is in the process of revising and implementing its relevant safety standard, NOM 068, which governs mechanical and safety conditions for operating trucks on national roads and bridges.

Objective/Desired Outcome: The Council will facilitate a U.S.-Mexico dialogue so that Mexico's revision of NOM 068 is in harmony with existing FMCSA rules, standards, and criteria, in order to minimize costs and eliminate any duplication.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan include:

- DOT-FMCSA will review the updated NOM 068 (trucking safety standards) as soon as it is submitted for public consultation, and provide comments related to ensuring harmonization (by June 2012).

Why Should We Do This?

1. Harmonization of commercial vehicle inspection regulations will improve the safety of our citizens by ensuring that all vehicles are inspected to a consistently high standard, regardless of the vehicle's country of origin;

2. The increased efficiency of commercial vehicle inspections realized as a result of harmonized commercial vehicle inspection regulations will facilitate trade in goods and services across our borders;

3. Ensuring the compatibility of commercial vehicle inspection regulations will lower costs for motor carriers and consumers by simplifying the regulatory burden of compliance with U.S. and Mexican safety requirements; and

4. More than 60% of the value of Mexico's exports to the United States is carried out by land transportation.[8]

3) Nanotechnology

The fourth item on the HLRCC Work Plan involves the potential alignment of U.S. and Mexican policy approaches to oversight of applications of nanotechnology and nanomaterials. The relevant agencies are the Office of Information and Regulatory Affairs (OIRA) and the National Metrology Centre (CENAM).

Description: Mexico and the United States are in the process of developing principles and approaches to inform government oversight and regulation of nanotechnology applications and nanomaterials.

Objective/Desired Outcome: Share information and develop approaches on foundational regulatory elements, including terminology/nomenclature, information-gathering, and approaches to risk assessment and management. Develop initiatives to align regulatory approaches in specific areas, such that consistency exists for consumers and industry in Mexico and the United States.

[8] INEGI, National Accounts, January to August 2011.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan include:

- The United States will share with Mexico the list of regulators that were involved in the development of the general nanotechnology principles (accomplished by September 2011);

- Response of Mexico's relevant regulators to the U.S. Memorandum on "Policy Principles for the U.S. Decision-making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials," of June 9, 2011 (accomplished by October 2011);

- Creation of a mechanism for exchanging information between the United States and Mexico on regulatory matters for nanotechnology applications and nanomaterials (accomplished by February 2012);

- Share the advances of the Mexican side on potential principles on regulations for nanotechnology applications and nanomaterials (accomplished by February 2012); and

- Engage in a dialogue to consider a possible model framework providing key elements and approaches to regulating nanotechnology applications and nanomaterials with respect to potential impacts on the environment, human health, labor, food or agriculture (by February 2013).

Why Should We Do This?

1. Ensuring that the United States and Mexico share information regarding each other's respective regulatory approaches to nanotechnology applications and nanomaterials at an early stage will be critical in reducing risks to environmental and human health while fostering innovation;

2. Considering a joint framework to align regulatory approaches will ensure consistency for consumers and industry within and between both countries; and

3. Consistency in a regulatory approach in this area will facilitate responsible manufacturing and trading of products between the two countries, and will foster the competitiveness of the industry.

4) E-Health

The fifth item on the HLRCC Work Plan involves electronic health record (EHR) certification. Relevant regulators are the U.S. Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) and Mexico's Ministry of Health (SSA).

Description: HHS and its ONC have implemented an EHR certification program for purposes of testing and certifying health information technology (HIT) according to the standards, implementation specifications, and certification criteria adopted by the Secretary of HHS. The goal of this program is to enhance the interoperability, functionality, utility, and security of HIT and to support its meaningful use. In September 2010 in Mexico, the Ministry of Health approved and published the Mexican Official Regulation NOM-024-SSA3-2010, which establishes the objectives and functional features of EHRs to ensure the interoperability, processing, interpretation, confidentiality, security and use of EHR standards and catalogs. DGIS (Health Information General Direction of Health Ministry) started the evaluation process of EHR Systems in May 2011 at the request of any interested vendor. ONC and DGIS wish to further explore the certification rules and processes implemented in each country, as well as approaches to harmonizing common vocabularies and code sets.

Objective/Desired Outcome: First, the countries will share best practices on EHR certification programs. This will entail ONC sharing its EHR certification process lessons learned with Mexico, to help inform and enhance their policymaking as they seek to modify NOM-024-SSA3-2010. Second, both countries will discuss and analyze their interoperability standards portfolios. This work will allow both countries to better understand experiences to date, including best practices and policy challenges, for promoting and establishing interoperability requirements for electronic health information exchange. Both countries will, to the extent practicable, attempt to determine whether and how such standards could be incorporated into regulatory policy. Third, according to existing international standards and the particular needs of each country, the countries will seek to establish a core framework of vocabularies for use in EHR technology. This action aims to support the harmonization of standardized vocabularies in order for translations to be accurately and appropriately mapped to the correct code set. At a later stage, both countries will evaluate the possibility of developing a "Guide of Compatibility" between modified versions of ONC's standards and certification regulations and NOM-024-SSA3-2010 Evaluation in Mexico.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan include:

- Presentation of available Certification Processes, Educational Material inventory and core vocabularies in both countries (by March 2012);
- Communication with staff in both countries regarding education materials related to EHR certification and e-Health workforce curriculum development (by March 2012);
- Solicit formal comment from Mexico on ONC's proposed EHR standards and certification criteria regulation (April/May 2012);
- Define and publish core vocabularies for EHRs in both countries (by October 2012);
- Translation of NOM-024-SSA3-2010 and its modifications to English (by October 2012); and

- Benchmark and develop a gap analysis for EHR standards and certification criteria requirements in both countries (by December 2012).

Why Should We Do This?

1. Increased cooperation between U.S. and Mexican regulators on EHR certification requirements could improve the competitiveness of U.S. health IT companies internationally, and the United States has a more mature EHR certification approach, which positions the United States to share best practices with Mexican officials;

2. Regulatory cooperation regarding harmonized interoperability requirements could benefit the regulated communities in each country and could result in decreased overall development costs for those health IT companies that seek to compete at an international level;

3. Early and proactive efforts between the United States and Mexico to establish regulatory cooperation in these areas would form a foundation on which additional cooperative efforts could be built;

4. The Guide of Compatibility will reduce the cost and time required to implement electronic health record systems developed for the United States or Mexico in the other country, and will therefore increase the number of certified systems available for health institutions;

5. The best practices and educational material shared between agencies, along with a larger number of certified systems, will accelerate the investment, adoption and proper use of health information technology in both countries; and

6. Harmonized vocabularies and similar certification processes will prepare the foundations for international interoperability, which in the future can facilitate the exchange of public health information and achieve faster response to epidemiologic outbreaks.

5) Offshore Oil and Gas Development Standards

The sixth item on the HLRCC Work Plan involves oil and gas drilling standards. Relevant regulators are the U.S. Department of the Interior/Bureau of Safety and Environmental Enforcement (BSEE), the Bureau of Ocean Energy Management (BOEM), and Mexico's National Hydrocarbons Commission (CNH).

Description: Mexico and the United States border the Gulf of Mexico. This means that the exploration and drilling activities that take place in this body of water present risks for both countries, and both countries would benefit from a common set of drilling standards. While different institutional models, regulations and laws bind each country, U.S. and Mexican regulators are open-minded and would like to develop a set of harmonized standards related to the exploration and production of oil resources and well control and containment standards, including requirements for sharing worst-case discharge and spill response plans. Although the harmonization is intended as a long-term goal, there have been short-term successes; the first

product of this common philosophy is that Mexico will incorporate standards according to the American Petroleum Institute Offshore Recommended Practices that apply to operators working in the United States.

On February 19, the two countries signed the Agreement Between the United Mexican States and the United States of America Concerning Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico ("Agreement") to govern transboundary reservoirs underlying the Outer Continental Shelf maritime boundary in the Gulf of Mexico. The Agreement includes a commitment, in Article 19, by both parties to adopt, where appropriate, common health, safety and environmental standards and requirements applicable to activity contemplated under the Agreement within the transboundary area. In addition, there are discussions between the two countries happening now, with both countries working to identify elements of a common approach for the entire Gulf of Mexico.

Objective/Desired Outcome: The Council will build on the current work being done in this area to facilitate strategic approaches to offshore oil and gas development. The long-term goal is to develop, to the extent possible, harmonized standards. The Council will encourage consideration of a range of options, including performance-based standards, to move the agenda forward.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan include:

- Development of a framework document to set a common philosophy, promote harmonization and define the scope of activities (e.g., use of common standards for offshore drilling well control and containment, information sharing expectations for Mexican and U.S. regulators, incorporation and application of industry best practices, and evaluation of whether to include a memorandum of understanding, and if so, the form and content). The framework document will identify both short-term and long-term deliverables (by April 2012); and

- Promoting a dialogue about how to reform existing regulations to harmonize them (by December 2012).

Why Should We Do This?

1. To minimize risks in oil and gas exploration, production activities, and drilling;

2. To ensure coordinated actions of both sides through a common approach to managing contingencies in the whole area of the Gulf of Mexico; and

3. To ensure that both countries have the capacity to respond to an event, utilizing shared knowledge of the most efficient and effective well control and containment procedures.

6) Cross-Sectoral Issue: Accreditation of Conformity Assessment Bodies

The seventh item on the HLRCC Work Plan involves the accreditation of conformity assessment bodies. Relevant regulators are the Occupational Safety and Health Administration

(OSHA) and the Ministry of Economy (SE). Currently, Mexico has accredited three U.S. laboratories for purposes of performing safety testing of certain products that are sold or used in Mexico. These three U.S. laboratories are also recognized as Nationally Recognized Testing Laboratories (NRTLs) by OSHA. However, no Mexican laboratory has been accredited for purposes of performing safety testing of products that are sold or used in the United States, which is a concern for Mexico. OSHA is the agency that accredits laboratories to test products used in U.S. workplaces.

Unlike the other sectors, which consist primarily of bilateral activities intended to align regulatory requirements or to share information, this sector primarily involves submissions by Mexican entities seeking to comply with the U.S. regulator's requirements. The substantive activities in this sector are done individually by the specific entities and not as a workgroup.

Description: OSHA will help Mexican laboratories that are interested in obtaining NRTL recognition understand OSHA's requirements and process for laboratory recognition under the NRTL Program. The Ministry of Economy (i.e., SE) will facilitate this process by coordinating and participating in any necessary meetings or teleconferences between Mexican laboratories and OSHA. Secretaria de Economia will also help U.S. laboratories and agencies understand Mexico's requirements and process for laboratory recognition so that more of them may become recognized.

Objective/Desired Outcome: Interested Mexican laboratories are recognized as NRTLs by OSHA. Interested U.S. laboratories are accredited or otherwise recognized by Mexican authorities to conduct testing, certification and other conformity assessment procedures that are necessary for companies to demonstrate compliance with Mexican requirements.

Specific Deliverables and Timeline: Specific deliverables identified in the Work Plan include:

- OSHA presents its application guidelines to Mexican laboratories with emphasis in (a) problematic areas detected by OSHA in previous authorizations, and (b) independence (accomplished by September 2011);

- OSHA has a call with all of the laboratories, or with each laboratory, to discuss their independence. Before the call, the laboratories provide information that OSHA requests regarding each laboratory's ownership, and governing and control structure. During the call, OSHA discusses the information with the laboratories and notes any serious issues that appear to exist with regard to the laboratory meeting OSHA's NRTL independence requirement. If needed, OSHA may request additional information related to independence and have an additional call with the laboratories to further clarify any issues;

- OSHA has a call with each laboratory to discuss its current technical operations and procedures. Before or during the call, each laboratory provides certain information requested by OSHA. OSHA makes no determination on the adequacy or acceptability of the laboratory's operations or procedures, but will provide informal comments on areas where the laboratory appears to lack procedures and/or technical

capabilities to meet OSHA's NRTL requirements. These comments will not bind OSHA regarding any future determination during its formal NRTL application review process;

- If needed, OSHA has additional calls with any laboratory that has further questions;

- Mexico has a call or meeting with interested U.S. laboratories and agencies to present Mexico's requirements and processes for laboratory recognition and provides those requirements and processes in writing;

- Mexican laboratories determine whether they will apply and formally submit their applications and application fees. Each laboratory must ensure that it submits to OSHA information requested in the guidelines pertaining to the lab's independence;

- OSHA processes NRTL applications in the order that OSHA receives them. Unless delayed due to factors beyond OSHA's control, within 30 days of receiving an application, OSHA performs a limited review of the application to determine if OSHA can proceed with a full review or if OSHA must return the application;

- OSHA has a call with each laboratory to discuss the findings of the limited review. If OSHA finds that any application is substantially incomplete or inadequate, it returns the application within one month after completing the limited review;

- If OSHA finds sufficient information for a full review, it commences a detailed review, beginning with the independence review;

- OSHA completes a detailed review of independence, and contacts each laboratory to discuss OSHA's findings on the laboratory's ability to meet OSHA's independence requirement. OSHA requests additional information, if needed. If a laboratory meets the independence requirement, OSHA informs the laboratory and schedules the technical review of the remainder of the application. If a laboratory does not meet the requirement, OSHA provides written notification to the laboratory and an opportunity to rebut OSHA's determination;

- If any laboratory has independence issues, OSHA and the laboratory communicate to try to resolve the issues;

- Each laboratory formally submits its response to any OSHA notification regarding lack of independence. The laboratory then has one more opportunity to resolve any issues if the first response does not adequately resolve the issue. If the issue cannot be resolved, OSHA rejects the application; and

- If a laboratory has no independence issues, or resolves these issues, OSHA completes the technical review and contacts the laboratory to discuss the findings.

OSHA will complete the remainder of the application process as described in OSHA's current NRTL Program Directive, dated December 2, 1999, beginning at paragraph II.C of Chapter 2 through the end of Chapter 5.

The above deliverables consist of the usual activities that OSHA must perform prior to, and following receipt of, an application by any laboratory seeking recognition under OSHA's NRTL Program. After receiving an application, OSHA periodically provides a report to each NRTL applicant to describe the current status of its application, the upcoming next step of the application process, and the estimated target date for commencing or completing this next step. These target dates for particular OSHA activities are subject to change due to the program's workload and priorities, as well as other factors.

Why Should We Do This?

1. The United States wants to address Mexico's concern, although it makes no guarantee on the outcome of the OSHA process;

2. The United States wants to make Mexico's system more transparent for other U.S. laboratories that may have interest in obtaining accreditation by Mexico; and

3. This initiative increases the Mexican laboratories' and Mexican government's understanding of the OSHA NRTL Program's application process and technical requirements, which may facilitate their decision regarding the elements they must adopt to comply with particular parts of the process and requirements.

MOVING FORWARD

The United States and Mexico will implement the HLRCC Work Plan through bilateral regulatory-agency-led working groups. Initiatives and deliverables outlined in the Work Plan will be carried out by lead departments and relevant agencies in the United States and Mexico.

1) Working Groups

Working groups, either already established or to be established, will be responsible for implementing all HLRCC Work Plan items. Led by senior officials from the primary regulatory departments with representatives from other relevant agencies or groups, the working groups will focus on achieving tangible and practicable deliverables throughout the duration of their work.

Stakeholder engagement will occur in a broad context, in part by seeking input from sectoral stakeholders during select HLRCC meetings. Working groups will be responsible for ensuring appropriate and adequate stakeholder engagement on issues within their purview. In addition, the normal consultative process will be used should any regulation or rule-making occur.

In developing solutions, working groups will be expected to identify mechanisms not only to alleviate current issues, but also to foster ongoing alignment and prevent future unnecessary differences from occurring.

Working groups will provide periodic updates on their progress.

2) HLRCC Activities

Meetings of the HLRCC will be held quarterly to review and discuss progress of the working groups. Stakeholder engagement sessions will be held as part of these meetings twice per year, and results of the HLRCC work will be made public on a regular basis.

The HLRCC will provide a public midterm report one year from publication of this Work Plan on progress to leaders on these initiatives.

The HLRCC will closely monitor the working groups and will undertake to resolve challenges facing the working groups.

The United States and Mexico have an opportunity to take advantage of their highly integrated economies, further strengthening their trade relationship and increasing reliance on each other's regulatory outcomes. Given compatible regulatory objectives and procedures for achieving them, it should not be necessary to do everything twice. Most importantly, this HLRCC Work Plan will provide examples upon which new approaches can be developed on a broader range of sectors and initiatives in the future. Together, we can work towards a better aligned regulatory system that benefits citizens and businesses on both sides of the border.

This HLRCC Work Plan represents an important step along the path to enhanced regulatory cooperation between the United States and Mexico.