

**UNITED STATES - MEXICO
REGULATORY COOPERATION COUNCIL**

PROGRESS REPORT TO LEADERS

[date]

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HIGHLIGHTS

The United States-Mexico High-Level Regulatory Cooperation Council (HLRCC), comprised of senior-level regulatory, trade, and foreign affairs officials from both governments, was created on May 19, 2010,¹ to promote economic growth and job creation through increased regulatory transparency and coordination.

The inaugural HLRCC meeting was held in Washington, D.C. on September 13, 2010, during which both governments agreed that 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. On March 3, 2011, the United States and Mexico agreed to Terms of Reference for the HLRCC,² which called for a Work Plan that outlined cooperative activities for a period of two years.

The HLRCC Work Plan was released on February 28, 2012, identifying areas of mutual interest for cooperation. The Work Plan outlined sectoral initiatives in seven key areas: food safety, E-certification for plants and plant products, trucking safety, nanomaterials, E-health, oil and gas, and conformity assessment.

This report describes the efforts to implement the Work Plan, and summarizes the progress to date in the seven areas. Both Mexico and U.S. hope that the report will help lay the foundation for continued regulatory cooperation between our two countries.

Implementing the Work Plan: Following agreement on the HLRCC Terms of Reference, working groups comprised of regulatory agencies from each country developed detailed implementation plans and set deliverables for each of the seven initiatives. The lists of deliverables were presented in the Work Plan released in February 2012. As working groups continue to meet and move ahead, the Department of Commerce will post on www.trade.gov/hlrcc, while Mexico's Ministry of Economy will do on www.economia.gob.mx/comunidad-negocios/competitividad-normatividad/cooperacion-regulatoria-mexico-eu, information about the Work Plan, including deliverables and status updates.

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.

Early Deliverables: Early deliverables were achieved in advance of the final February 28, 2012, Work Plan since both countries have been working on regulatory cooperation since the HLRCC was created in May 2010. Over the past year, highlights of regulatory cooperation progress include:

- Harmonized commercial vehicle inspection regulations to improve the safety of citizens by ensuring all vehicles are inspected to a consistently high standard, regardless of vehicle's country of origin. Mexico's Ministry of Communication and Transportation updated and published for review its regulation for commercial vehicles: NOM-068-SCT-2-2000 which included system specifications and mechanical components such as Anti Brake-Lock Systems (ABS) and Pneumatic Disc Brakes which will improve the safety conditions of motor vehicles in circulation between the U.S. and Mexico; it also updates the "out of service" criteria currently used by the Commercial Vehicle Safety Alliance, CVSA.)
- A Food Safety Cooperative Agreement was signed by Health and Human Services (HHS) Secretary Kathleen Sebelius, Mexico Secretary of Health Salomón Chertorivski, Secretary of U. S. Department of Agriculture Thomas Vilsak, and Mexico Secretary of Agriculture Francisco Mayorga, on May 22, 2012, that strengthens existing scientific and public health activities related to the regulation of food safety, including products and feed for food-producing animals.
- The U.S. Department of the Interior and Mexico's National Hydrocarbons Commission made progress towards harmonizing common health safety and environmental standards and requirements for the entire Gulf of Mexico through collaboration activities.

Stakeholder Engagement: Both countries engaged in extensive consultation with stakeholders and the public in the course of development of the HLRCC 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 in North America.³ The United States received 48 comments from the stakeholder community. Mexico also published a request for public comment on April 14, 2011. 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.

On April 24, 2012, the Chamber of Commerce hosted a stakeholder engagement session with the HLRCC in Washington, D.C., in which both countries participated. Moving forward, the HLRCC will continue to engage with interested stakeholders to explain what the Council is doing and to solicit input on the implementation of the Work Plan. The HLRCC also developed a mechanism for stakeholders to provide feedback on the High-Level Regulatory Cooperation

³ See <http://www.regulations.gov/#!documentDetail;D=ITA-2011-0003-0002>.

Council process and Work Plan implementation. In the U.S., comments can be sent to HLRCC@trade.gov, and in Mexico to ccroficinamexico@economia.gob.mx.

Executive Order 13609: In May 2012, President Obama issued Executive Order 13609, “Promoting International Regulatory Cooperation,” which strengthened institutional mechanisms for facilitating international regulatory cooperation and reflecting a commitment to regulatory cooperation going forward.⁴ The Executive Order recognized the increasingly global nature of the regulatory playing field, and is meant to provide a general framework for promoting U.S. efforts to eliminate unnecessary regulatory differences and related costs, burdens and delays to market. These efforts include the work underway in the HLRCC.

The Order also recognizes that engaging in international regulatory cooperation not only helps to eliminate or prevent the creation of unnecessary regulatory differences that might impair the ability of American businesses to export and compete internationally, but it helps improve regulatory outcomes. It also notes that while engaging in international regulatory cooperation, we will seek out joint regulatory approaches that are at least as protective as those that would be chosen without such cooperation.

Pact for Mexico: In November 2012, elected President Peña Nieto signed an agreement with the Presidents of the principal political forces of the Congress, the Democratic Revolution Party (PRD), the Institutional Revolution Party (PRI) and the National Action Party (PAN). This document agrees on 95 common compromises that the Government will carry on during the present administration. The Pact emphasizes the importance of regulatory improvement processes in Mexico’s development by including actions such as strengthening the Federal Commission for Competition (CFC), as well as improving regulatory conditions in strategic areas such as the telecommunications and oil sectors.

ESTABLISHING THE HIGH-LEVEL REGULATORY COOPERATION COUNCIL

On May 19, 2010, the Presidents of the United States and Mexico gave the newly created United States-Mexico High Level Regulatory Cooperation Council a mandate to increase economic growth in both nations; lower costs for citizens, businesses, producers, governments, and consumers; increased trade in goods and services across borders; and greater protection of health, safety, and the environment through increased regulatory transparency and coordination.

Mexico and the United States rely on regulation to maintain a high level of health, safety, and environmental standards, while acknowledging that regulation can sometimes impose significant burdens and costs. The Terms of Reference tasked the HLRCC to create a Work Plan that

⁴ Executive Order 13609 (Promoting International Regulatory Cooperation) is available at www.whitehouse.gov/sites/default/files/omb/inforeg/eo_13609/eo13609_05012012.pdf.

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.

The Terms of Reference instruct 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;
- 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.

The Terms of Reference reflect the fact that the HLRCC was not established to create a single regulatory system for both countries, or to allow one country to make regulatory decisions on behalf of the other. Accordingly, the HLRCC Work Plan reflects the goal of strengthening the regulatory relationship between Mexico and the United States, while fully respecting each country's domestic law and policy priorities and prerogatives.

KEY HLRCC MILESTONES

Steady progress has been achieved to date with respect to fostering U.S.-Mexico regulatory cooperation via the HLRCC, as indicated by the following list of key HLRCC milestones and events.

- May 19, 2010 - President Calderón and President Barack Obama announced the creation of the United States-Mexico High-Level Regulatory Cooperation Council (HLRCC)

- September 13, 2010 - The inaugural HLRCC meeting was held in Washington, D.C.
- March 3, 2011 - The United States and Mexico issued the Terms of Reference outlining the mandate, principles, and organization of the work to be performed by the HLRCC.
- February 28, 2012 - The U.S. and Mexico published the HLRCC Work Plan, which identifies seven areas of mutual interest for cooperation and outlines activities to be carried out by the two countries over a period of two years.
- May 1, 2012 - President Obama issued an Executive Order entitled Promoting International Regulatory Cooperation.
- August 22-24, 2012 - The HLRCC organized a series of regulator-to-regulator conference calls to discuss implementation of the Work Plan.
- April 24, 2012 - The U.S. Chamber of Commerce hosted a stakeholder engagement session to coincide with the visit of President Calderón to Washington, D.C., in which both countries participated.
- October 15, 2012 - The 2nd HLRCC government-to-government meeting was held in Washington, D.C.
- December 2, 2012 - Mexican President Enrique Peña Nieto signed the Pact for Mexico, which described his administration's priorities for structural economic reform and competitiveness.

WORK PLAN PROGRESS TO DATE

On February 28, 2012, the HLRCC Work Plan was launched to target existing or emerging misalignments, and focuses on creating systemic mechanisms to secure regulatory alignment into the future in the areas of food, transportation, nanotechnology, e-health, oil and gas, and conformity assessment. The Work Plan deliverables and timelines touch upon a wide array of regulatory cooperation activities and practices, including technical/scientific collaboration, pilot programs, information sharing, mutual recognition, joint standards, and collaborating on common approaches to regulations.

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 were described as “accomplished” if they were completed in advance of the final publication of the Work Plan.

The 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 the Work Plan is intended to give rise to rights or obligations under domestic or international law.

Since the HLRCC Work Plan release on February 28, 2012 much has been accomplished towards meeting the specific deliverables and timelines outlined. To date, all of areas for regulatory cooperation have been worked on by both governments.

In August 2012, regulator to regulator conference calls were held to implement the Work Plan which was followed by a stakeholder engagement meeting as the deliverables in the work plans were discussed and further input was provided. Government-to-government meetings were also held in Washington D.C. in October 2012 to discuss implementation of the outlined deliverables.

The following updates provide, for each area of cooperation in the Work Plan, a brief summary of the goal and the progress made to date.

1. Food

- a. Food Safety Modernization.** The goal is to develop common approaches to food safety in ways that will benefit consumers and the food industry in Mexico and the United States.

Increased Regulatory Collaboration on food safety requirements. The Food Safety Cooperative Agreement (FSCA) signed by Health and Human Services (HHS) Secretary Kathleen Sebelius, Mexico Secretary of Health Salomón Chertorivski, Secretary of U.S. Department of Agriculture Thomas Vilsak, and Mexico Secretary of Agriculture Francisco Mayorga, on May 22, 2012, recommits the two countries to communicate on food safety and to identify areas for coordination and collaboration between several U.S. and Mexican agencies—HHS, through its Food and Drug Administration (FDA), and the U.S. Department of Agriculture; and the Secretariat of Health, through the Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) and the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) in Mexico through its National Service of Health, Food Safety and Agro Food Quality (SENASICA). U.S. and Mexican regulators met to consider Mexican views on the U.S. Food Safety Modernization Act (FSMA) by June 2011. Mexico has also had 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. It is in the best interest of both countries to improve the process of application of FSMA regulations in the areas of production, processing and handling of food that is exported or imported.

Development of Joint Food Safety Outreach Programs. FDA has been working with Mexico's Ministry of Economy and its Federal Delegations, Proméxico and Chambers of Commerce to help educate the food sector in Mexico on new proposed food safety standards and newly implemented requirements under FSMA, and to improve capacity in existing standards and import/export requirements. From July 24 to August 30, 2012, FDA and Economía hosted 16 workshops throughout Mexico to facilitate understanding of FDA's existing rules and regulations on food safety and to update the audience on the latest rules developed under the FSMA. Industry associations were contacted by the FSMA Intersecretarial Working Group in Mexico to engage with stakeholders. Instructions included how to submit comments on proposed regulations during public comment periods and how to receive updated information on forthcoming rules.

Implementation of the U.S. Food Safety Modernization Act. With the leadership of Secretariat of Economy and the participation of COFEPRIS, SENASICA and Secretariat of Economy, the Mexican government introduced an initiative to assist with the effective implementation of the FSMA. The Secretariat of Economy and FDA Latin America Regional Office in Mexico have conducted outreach workshops directed to public, industry, and academic sectors related to the implementation of new FSMA requirements and to provide information on upcoming proposed regulations.

The workshops took place in four regions in Mexico from February 19, 2013, to April 2, 2013. FDA Latin America Regional Office in Mexico conducted outreach activities in March and April 2013 covering the two currently proposal rules: Produce Rule and Preventive Controls for Food for Humans. The outreach activity included guidance on providing comments on proposed rules during the public comment period and how to receive updated information on forthcoming FSMA implementing regulations.

Renewed Statement of Cooperation between FDA and SALUD/COFEPRIS. In June 2012, FDA and SALUD/COFEPRIS renewed their Statement of Cooperation to help assure molluscan shellfish exported from Mexico to the United States are safe for human consumption.

Renewed Memorandum of Understanding between FDA and SAGARPA/SENASICA. In November 2012, FDA and SAGARPA/SENASICA renewed their Memorandum of Understanding to help assure cantaloupe melons exported from Mexico to the United States are safe for human consumption.

Strengthen the Laboratory Capacity Collaboration Program (LCCP). The Laboratory Capacity Collaboration Program (LCCP) between FDA, SENASICA and COFEPRIS, as part of the FSCA is ongoing. The key objectives of this laboratory collaboration program include improving communications and laboratory capacity, consulting with SENASICA and COFEPRIS on the development, validation and implementation of testing methods, and participation in proficiency programs as SENASICA and COFEPRIS pursue efforts for strengthening its laboratory infrastructure for food microbiological testing.

- b. E-Certification for Plants and Plant Products.** The goal is to reduce burdens on U.S. and Mexican businesses, while maintaining the safety and reliability of products, by bringing the two countries together to develop compatible electronic certification programs for plants and plant products.

Agreement on a paperless mechanism. In 2012, Mexico and the United States agreed on the development of an e-certification system to allow the exchange of electronic certificates between governments for plants and plant products. Mexico and the United States also agreed with the E-certification panel of the North American Plant Protection Organization (NAPPO), where both countries took part in the creation of aligned systems in the standard model established by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT). According to the Mexican FIEL Law, Mexican exports sent to the U.S. will be digital and certified by Electronic Signature (FIEL). Utilization of e-certifications will accelerate confirmation and authenticity of documents and will result in less paper for documentation.

Development of an Electronic Certification System. The United States and Mexico have participated in meetings of the North American Plant Protection Organization (NAPPO) and International Plant Protection Convention (IPPC), as they are also working to develop e-certification systems. At the NAPPO meeting in October 2012, the United States shared its developed electronic systems software with Mexico. Mexico's SENASICA and Tax Administration System (SAT) have been working to develop an electronic certification system for importing and exporting plants and plant products which would be part of the Mexican Single Window for Foreign Trade (VUCEM).⁵ From November 20, 2012 to March 13, 2013, 19 Mexican sanitary inspection offices were integrated into the One Stop Shop for Trade Operation Website⁶. After Mexico completes the development of its system, initial pilot tests of e-certification exchanges can be performed with the United States.

⁵ The "Mexican Single Stop Shop" where SENASICA's e-certificates for plants and plant products can be accessed at: <http://www.ventanillaunica.gob.mx/envucem/AboutVU/AboutVU/index.htm>

⁶ Mexican sanitary offices integrated into VUCEM were: Toluca, Progreso, Piedras Negras, Aduana de Carga DF, Matamoros, Coatzacoalcos, Nogales, Guadalajara, Cancún, Lázaro Cárdenas, Mérida, Subteniente López, Cd. Hidalgo, Manzanillo, Tijuana, San Luis Rio Colorado, Ensenada, Tecate y P. Vallarta.

- 2. Transportation: Commercial Motor Vehicle Safety Inspection Standards and Procedures.** Improve the safety of our citizens by ensuring that all trucks in each country are inspected to a consistently high standard, regardless of the vehicle's country of origin.

Align Truck Safety Standards. Mexico's Ministry of Communication and Transportation updated its regulation for inspection of commercial motor vehicles: NOM-068-SCT-2-2000⁷. The main changes are the inclusion of system specifications and mechanical components such as Anti Brake-Lock Systems (ABS) and Pneumatic Disc Brakes, it also updates the "out of service" criteria currently used by the Commercial Vehicle Safety Alliance (CVSA), to improve the safety conditions of motor vehicles in circulation between the U.S. and Mexico. In October 2012, Mexico's Norm Project PROYNOM-068-SCT-2-2012 was approved for unanimity by the *Mexican National Standardization Committee of Land Transport (Comité Consultivo Nacional de Normalización de Transporte Terrestre)* in its 2nd of October 2012 session. On March 2013, the Norm Project PROYNOM-068-SCT-2-2012 was published in Mexico's Official Gazette (*Diario Oficial de la Federación*) for public consultation. The U.S. Department of Transportation's (DOT) Federal Motor Carrier Safety Administration (FMCSA), as agreed to in the February 2012 Work Plan, provided comments related to ensuring harmonization with United States 49 CFR Parts 350-399. The aim is to eliminate duplication in verification costs for vehicles entering either the United States or Mexico.

Develop an Implementation Plan for the Recognition of Mexican Certifications.

Mexico's comment period ended on May 20, 2013 for the Norm Project PROYNOM-068-SCT-2-2012. Mexico is currently in the process of obtaining the final decision from the Federal Commission for Regulatory Improvement. SCT will publish on the Official Gazette a response to every comment. After that, the *Mexican National Standardization Committee of Land Transport* will publish the updated standard, by the end of 2013. Once published, the United States and Mexico will develop an implementation plan for the recognition of Mexican certificates as sufficient to fulfill the requirement for the period inspection of commercial motor vehicles as specified in 49 CFR §396.17.

- 3. Nanotechnology⁸.** Foster innovation while reducing risk to the environment and human health by sharing, at an early stage, information about each nation's regulatory approaches to nanomaterials.

⁷ NOM-068-SCT-2-2000 is known as "Land Vehicles- Passage, tourism, shipping and private federal transportation service- Physical and mechanical conditions and security for federal roads and bridges operations (*Transporte Terrestre-Servicio de Autotransporte Federal de Pasaje, Turismo, Carga y Transporte Privado-Condiciones Físico-Mecánica y de Seguridad para la operación de caminos y puentes de jurisdicción federal*)".

⁸ Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing

Cooperate on developing principles and approaches for government oversight and regulation of nanotechnology applications and nanomaterials. In the United States, the National Economic Council, the Office of Management and Budget, the Office of Science and Technology Policy, and the Office of the U.S. Trade Representative led a multi-agency consensus-based process to develop a set of principles to guide development and implementation of policies for the oversight of nanotechnology applications and nanomaterials. The process led to the publication in June 2011 of the U.S. Memorandum on “Policy Principles for the U.S. Decision-making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.” Under the auspices of the HLRCC, the Memorandum was shared with Mexico’s working group on nanotechnology in September 2011.⁹ Mexico’s workgroup shared its views on the Policy Principles with the U.S.

Establish a mechanism for exchanging nanotechnology applications and nanomaterials. The United States and Mexico are working to establish a mechanism to exchange information on approaches to the regulation of nanotechnology applications and nanomaterials. Through the HLRCC process, Mexican and U.S. regulators have been able to exchange views on Mexico’s development of potential principles on regulations for nanotechnology applications and nanomaterials, beginning with a focus on the potential impacts on the environment, human health, labor, food or agriculture.

Mexican Policy Guidelines Issued for Regulations on Nanotechnologies. Mexico’s “Guidelines on regulations for nanotechnologies to foster competitiveness and protect the environment, the human health and the safety of the consumers” was issued by the Undersecretary for Competitiveness and Standardization of the Secretary of Economy on November 26, 2012. Both the Spanish and English versions are included in Appendix A. The guidelines will become mandatory in Mexico once the corresponding decision is completed in 2013.

Tri- and Multilateral Cooperation. In addition to the bilateral regulatory cooperation initiative, on April 2, 2012, the U.S., Mexico, and Canada, pledged at the North American Leader Summit (NALS) to pursue shared objectives in four sectors: certain vehicle emission standards, railroad safety, the Globally Harmonized System of Classification and Labeling of

nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale. Source: <http://www.nano.gov/nanotech-101/what>

⁹ The working group is comprised of representatives from Centro de Investigación en Materiales Avanzados, Centro Nacional de Metrología, Comisión Federal para la Protección de Riesgos Sanitarios, Red Nacional de Nanociencias y Nanotecnologías of the CONACYT, Instituto Nacional de Ecología y Cambio Climático, Instituto Politécnico Nacional, Dirección General de Normas de la Secretaría de Economía, Secretaría de Medio Ambiente y Recursos Naturales, Secretaría del Trabajo y Previsión Social, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria y Universidad Nacional Autónoma de México.

Workplace Chemicals, and aligning principles of our regulatory approaches to nanomaterials. Mexico and the United States also participate in ISO TC 229 Nanotechnologies, the Working Party for Manufactured Nanomaterials (WPMN) of the Organization for the Economic Cooperation and Development (WPMN-OECD), and within the Versailles Project on Advanced Materials and Standards (VAMAS) in support of responsible nanotechnology development and commercialization.

4. **E-Health.** Decrease costs and reduce the time required to implement electronic health record systems in each country, by increasing cooperation and sharing best practices on the certification of Electronic Health Record technology.

Share Best Regulatory Practices on E-Health Certification Programs. 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) have been actively engaged in rulemaking cycles on Electronic Health Records (EHRs) and agreed to explore opportunities for continued knowledge transfer and potential areas in which to align regulatory approaches. The United States has implemented an EHR certification program for purposes of testing and certifying EHR technology according to the standards, implementation specifications and certification criteria adopted by the United States Department of Health and Human Services (HHS). In September 2010 Mexico's 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 which has been recently updated and described in more detail below. Both countries have reviewed their certification processes and compared education materials related to EHR certification and e-Health workforce curriculum development. The publically available educational material¹⁰ developed by ONC has been referenced on Mexico's Health Information General Direction of Health Ministry (DGIS) Website with an abstract in Spanish to promote its use by Mexican Health Sector. Continuing to understand each other's regulatory frameworks aims to decrease development costs for health IT companies that seek to compete at an international level.

Exchange information on Interoperability Requirements. On October 4, 2012, the 2014 edition Standards and Certification Criteria final rule for EHR technology certification became effective in the United States and sets more rigorous interoperability requirements for EHR technology. Similarly, on January 30, 2013, NOM-024-SSA3-2012 came into force in Mexico, which regulates the Electronic Health Record Systems (including the Electronic Medical Record Systems) and establishes mechanisms to ensure that Health Services Providers of the National Health System to be able to record, exchange, and integrate

¹⁰ <http://www.healthit.gov/policy-researchers-implementers/workforce-development-program>

information. A translation of its modifications into English will allow both countries to discuss and analyze their respective regulatory requirements, interoperability standards portfolios, and to better understand experiences to date, including best practices and policy challenges, for promoting and establishing interoperability requirements for electronic health information exchange. Discussions on how standards could be incorporated into regulatory policy could benefit regulated communities in each country resulting in decreased overall development costs for health IT companies that seek to compete at an international level.

Create a framework for Establishing core Vocabularies. In October 2012, Mexico defined a proposal of core vocabularies for EHRs in order for translations to be accurately and appropriately mapped to the correct code set. The next step is to collaborate on and update the proposal in order to publish it in both countries with the aim of facilitating the exchange of public health information could achieve faster response to epidemiological outbreaks.

Develop a “Guide of Compatibility.” Representatives plan to discuss similarities, differences, experiences, and best practices with their respective regulated communities. DGIS also had an opportunity to comment on ONC's proposed standards and certification criteria for EHR technology (45 CFR Part 170) through the notice and comment rulemaking process. Based on feedback, ONC finalized EHR certification requirements (effective for 2014) last year. This input will facilitate future collaborative work between ONC and DGIS to develop the gap analysis of EHR requirements between the two countries. To further engage stakeholders, ONC will consider issuing a blog post that cites to the HLRCC Work Plan and describes the efforts underway. This blog post could also be used to solicit informal comments and information from multinational EHR companies that may have a significant interest in US/Mexico regulatory alignment. During the next meeting of the HLRCC, the working group will consider a way forward/cooperation framework with the goal of harmonizing regulations for EHRs which would reduce the cost and time required to implement electronic health record systems for both countries and increase the number of certified systems available for health institutions.

- 5. Offshore Oil and Gas Standards.** Minimize risks in oil and gas exploration and production (E&P) activities, by developing a common approach to ensure a set of coordinated actions between the two countries to manage contingencies in the Gulf of Mexico.

Framework to identify critical (E&P) activities in the Gulf of Mexico.

The U.S. Department of Interior's through the Bureau of Safety and Environmental Enforcement (BSEE) and Mexico's National Hydrocarbons Commission (CNH) agreed on a common regulatory philosophy to be used to identify the requirements that both regulators consider as critical for undertaking exploration and development activities in the Gulf of Mexico to minimize risk in oil and gas E&P related activities. The requirements focus on the

following areas 1) Risk Management Systems; 2) Emergency and Oil Spill Response Plans; 3) Containment Capabilities; 4) Auditing and Inspection; and 5) Training.

Sharing Best Practices. Since 2010, BSEE and CNH have worked together to review international practices. Some of these can be observed in the deepwater regulation of both countries, for example, financial and containment requirements are considered to be essential requirements for maintaining safe E&P activities.

Lessons Learned on Inspections and Oil Spill Response. In December 2012, CNH participated as an observer of BSEE's offshore platform inspections in the U.S. territory of the Gulf of Mexico. The inspections included (a) review of information and procedures of the regulator before an unannounced platform inspection; (b) platform inspection including: procedures, observations, and relevant documentation; and (c) evaluation of inspection information, results, and conclusions. Additionally, the participants witnessed a test made on a blow-out preventer (BOP).

In February 2013, BSEE hosted an oil spill preparedness workshop with CNH. The workshop included a discussion of oil spill response regulations, response equipment verification, and a government-initiated unannounced oil spill response exercise and evaluation. As part of the workshop, CNH observed BSEE initiate an unannounced oil spill response deployment exercise. The Bureau of Ocean Energy Management (BOEM), the United States Coast Guard, Louisiana Department of Environmental Quality (LADEQ) and the Louisiana Oil Spill Coordinator's Office (LOSCO) also participated in the exercise.

Collaborate on Harmonizing Existing Regulations. BSEE and BOEM have agreed to collaborate with CNH to focus on harmonizing regulations. As part of that agreement, Mexico is considering implementation of its offshore industrial safety rules¹¹ to include improvements and lessons learned from the prior regulations regarding supervision and monitoring/evaluation.

- 6. Cross-Sectorial Issue: Accreditation of Conformity Assessment Bodies.** Help interested Mexican laboratories achieve recognition under the U.S. Nationally Recognized Testing Laboratory (NRTLs) program carried out by the Occupational and Safety and Health Administration. Assist interested U.S. laboratories become 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.

¹¹ Mexico's regulation dealing with Risk Administration Systems, Emergency and Spill Response Plans, and Contention Capacity to fulfill is entitled: "General Administrative Dispositions that establish procedures, technical requirements and necessary conditions in safety matters that must be observed by PEMEX and subsidiary agencies, for exploring and exploiting hydrocarbons in deep waters activities."

Transparency of Laboratory Accreditation. The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) and Mexico's Ministry of Economy have worked to increase recognition of U.S. and Mexican laboratories in each other's country. By September 2011, OSHA presented its application guidelines to Mexican laboratories with emphasis on problematic areas detected by OSHA in previous authorizations and the independence of the laboratories operating in Mexico, which is problematic for the U.S. recognition process. OSHA, with the assistance of Mexico's Ministry of Economy, has also reached out to Mexican laboratories interested in being recognized through video teleconferences and correspondence exchanges. The United States and Mexico have taken an active role towards increasing Mexican laboratories' understanding of the OSHA NRTL program's application process and technical requirements. Making Mexico's system more transparent for U.S. laboratories seeking Mexican accreditation has also been part of this initiative. To date, there have been no requests for conformity approval from either U.S. or Mexican laboratories.

BENEFITS OF REGULATORY COOPERATION

Although there is limited quantified information on the benefits of regulatory cooperation in general, and the work of the HLRCC more specifically, it is clear that regulatory alignment and ongoing cooperation will ultimately benefit consumers, producers and regulators. For example:

- Working together, Mexican and American regulators can more efficiently and effectively achieve shared goals of ensuring health, safety, and environmental protections.
- Regulators on both sides of the border can avoid duplicating work and save time and money by, for example, sharing work when addressing common regulatory challenges with third countries and combining specialized expertise when approving products, developing regulatory standards, and conducting inspections.
- Products that are approved through more aligned regulatory processes are expected to be available in both markets almost simultaneously.

To better estimate the specific benefits of Mexican-U.S. regulatory cooperation, the HLRCC plans to explore a number of possible new initiatives at its next meeting. They include inviting the participation of academia and experts to study the economic gains of cooperation, and considering examples of specific businesses and consumers receiving gains from the activities in the Work Plan.

CONTINUING WORK

The HLRCC Work Plan represents an important step along the path to enhanced regulatory cooperation between the United States and Mexico. As the second year of the plan is implemented through bilateral, agency-led working groups, initiatives and deliverables will continue to be carried out by lead regulatory agencies in the United States and Mexico.

The HLRCC will work to increase stakeholder engagement, in part by seeking input from stakeholders during select HLRCC meetings and through online updates on their progress. Moreover, working groups will be responsible for ensuring appropriate and adequate stakeholder engagement on issues within their purview. In addition, the normal notice-and-comment procedures will be used in any HLRCC-related rulemaking.

The United States and Mexico plan to continue to explore the opportunities created by their highly integrated economies, to further strengthen their trade relationship, and to increase their reliance on each other's regulatory outcomes. Given their compatible regulatory objectives and procedures for achieving them, Mexico and the U.S. expect to complete the initiatives in the HLRCC Work Plan, and hope that this experience will lead to the development of new initiatives on a broader range of sectors and initiatives in the future.

APPENDIX A

Guidelines on regulations for nanotechnologies to foster competitiveness and protect the environment, the human health and the safety of the consumers.

TAKING INTO CONSIDERATION:

- That the High Level Regulatory Cooperation Council was created by the joint orders of the President of Mexico, Felipe Calderón Hinojosa, and the President of the U.S.A., Barack Obama, on May 19th, 2010;
- That this Council involves high level regulatory, commerce and foreign affairs officers from both countries;
- That the fourth topic in the Council's Work Plan requires the creation of guidelines for establishing a framework for issuing regulations and standards related to nanotechnology and nanomaterials;
- That the realization of those guidelines was allocated to the Working Group on regulations for nanotechnologies, in which several federal regulatory agencies and academic public institutions related to nanotechnologies are represented;
- That on October 30th, 2012, the Working Group announced to have finished its task;

On November 26th, 2012, in Mexico City, with Héctor Nava Jaimes, Director General of the National Center of Metrology and José Antonio Torre Medina, Undersecretary for Competitiveness and Business Regulations, of the Ministry of Economy, and Co-Chair of the High Level Regulatory Cooperation Council, signing as honor witnesses, the Working Group on nanotechnology presented these

Guidelines on regulations for nanotechnologies to foster competitiveness and protect the environment, the human health and the safety of the consumers.

I. Preamble

Nanotechnology uses the properties and the phenomena present in matter at the nanoscale, which encompasses the interval approximately between 1 nm and 100 nm in size ("nm" is the symbol for a nanometer, the measurement unit that characterizes nanotechnology, and is equivalent to one millionth of a millimeter. Those properties and phenomena depend on the chemical nature of substances as well as the way in which they are structured. These substances consist of or contain the so called nanomaterials, which are those that have any of their dimensions, or internal or surface structures, at the nanoscale. They convey their novel features to nanotechnology products.

For some years now, it is possible to find in Mexico cosmetic products, coatings, bactericides, textiles and other products using nanomaterials, advertising their novel properties, . These products are in the country either because they were imported or because they have been manufactured locally. Moreover, for decades Mexico has had infrastructure and world-class human resources that have helped the development of nanoscience and nanotechnology, although in some cases as part of other disciplines. Such developments have not always been reflected in products accessible to the general public.

Even when nanotechnologies are emerging technologies, in full and fast development, and they represent important benefits, the lack of a responsible development could inhibit their use and lead to significant lags in the country's competitiveness, including industrial capacity and the development of innovative approaches, which could cause a negative impact on job creation and economic growth. Furthermore, as an emerging technology, nanotechnology also poses potential risks both to human health and other living beings as well as to the environment during the life cycle of their products. Insufficient attention to these risks could result in adverse effects to society. It should be noted that the identification and assessment of these risks are still in the early stages and only a few cases have had conclusive results.

Mexico has the responsibility to ensure the rights of individuals to health protection and to a safe environment, as stated in Article 4 of the Mexican Constitution. The relevant regulations and laws contain, essentially, provisions along the stages of the life cycle of the products: from their research and development phase, manufacturing, transportation, marketing, use and even

its disposal. In this regard, for example, there are provisions in the Mexican legal framework concerning:

- Sanitary regulations, control and promotion of measures to protect human health, including the assessment of risks to health, in the General Health Law and the corresponding regulations.
- Guarantee the right of every person to an adequate environment and foster sustainable development through prevention of the generation, valuation and integral management of hazardous waste, solid urban wastes and wastes that require special management, in the General Law for Prevention and Integrated Management of Waste, Article 1.
- That work be carried out under safe conditions for the life and health of the employee, according to the Federal Labor Law, Article 3 and in the General Health Law, Chapter V.
- Regulate and promote vegetable health as well as the application, verification and certification of systems for reduction of physical, chemical and microbiological contamination hazards on the primary production of vegetables, in the Federal Law of Vegetable Health, Article 1.
- Regulate chemical, pharmaceutical, biological and food products for its use on animals or their consumption, in the Federal Law of Animal Health, Article 1.
- Regulate the trucking of materials, residues, residual wastes and hazardous wastes circulating along general communication roads, in the Law of Roads, Bridges and Federal Trucking, Article 50.

Particularly, Article 40 of the Federal Law of Metrology and Standardization stipulates that technical regulations (Normas Oficiales Mexicanas, NOM) shall determine:

- a. The characteristics and/or specifications that products and processes must have when they may be a risk for people's safety or damage human, animal or plant health, the environment and the labor environment, or for the preservation of natural resources; and,
- b. The information in labels, containers, packages and advertising products and services for trade, health, ecological, quality, safety and hygiene, in order to provide information to the consumer or user.

Thus, the Mexican legal framework includes a number of regulations that might be useful as a first approximation for nanotechnologies, so these guidelines are intended to complement them regarding these technologies. They are aimed at establishing solid regulations based on scientific data that help to avoid technical barriers to trade, foster the sustainable and better use of these technologies and to give due and appropriate attention to the associated considerations that might be identified, such as:

- a. The fact that the chemical composition of the nanomaterials is not enough to characterize them.
- b. The fast and flexible revision of technical regulations, standards and these guidelines, as often as necessary in order to match the speed of evolution and the generation of information about nanotechnologies, by means of, among others, the exchange of information mechanism established with other countries.
This issue is not of lesser importance taking into account that new information may require immediate action when proof of toxicity levels or environmental impact of nanomaterials does happen.
- c. The contributions from the industry and research and development institutions as sources of reliable information useful as basis for regulations.
- d. The agile and reliable compilation and evaluation of information to be integrated into regulations as appropriate, considering the status of regulations abroad.

II. Objective

To set up general guidelines for federal secretaries and regulatory agencies, within their prescribed scopes of action as appropriate, issue regulations on nanotechnologies in any of its applications, and on the products and services containing or using nanomaterials produced directly or indirectly by humans, in any of the stages along their life cycles.

III. Guidelines

1. To establish new regulations only when the existing regulatory framework does not include them, or does in an insufficient way.
2. To take the decisions aimed at regulatory purposes based on sound technical and scientific evidences. The extent of such information may change according to the scientific and technological advancements, and may vary from almost totally unknown to full determination; nevertheless, in every case the reliability of the information shall be appropriately validated. The means for the validation include the publication in peer-reviewed scientific papers and the findings from a laboratory confirmed by another independent one. In order to get the best possible information, formal statements from the manufacturers and distributors will be pondered as well.
3. To determine the requirements in the regulations avoiding unnecessary limitations for the innovation and the competitiveness of national industry, but keeping them sufficient to preserve and protect the human health and the environment.

4. To take the necessary measures to protect the health of the workers occupationally exposed to nanomaterials, either through the skin or the mucous membranes, ingestion, inhalation or through any other way.
5. To address risk management activities related to nanotechnologies with a multidisciplinary and integral approach, taking into consideration the relevant social, economical and ethical issues, where applicable; and to apply scientific methodologies for risk assessment related to nanotechnologies without excluding nonconventional ones.
6. To request and preserve information from the manufacturers, distributors and traders about nanomaterials located or intended to be located in the country, regarding their toxicology characteristics, and corresponding measures aimed for the mitigation, remediation and relief in the event of exposure, cautions for the safety of its handling, application and use, transportation, storage, and disposal. This information should be updated when changes happen. Incentives, either positive or negative, aimed to enhance the efficacy of these guidelines should be considered.
7. To promote research and development of nanotechnologies in a collaborative way, within the national arena as well as in the international one, especially to reduce the knowledge gap about properties of new nanomaterials or new applications with them, and potential effects on the human health and environment.
8. To keep the society informed, and particularly the consumers, on the contents of nanomaterials in the products accessible to them and its possible effects in the short, medium and long terms, as far as there be reliable information available, under the consideration that the general interest supersedes the particular one. The proper safe handling, monitoring, traceability, accidental release prevention practices and the potential harmful impacts of nanomaterials, as well as disposal and recycling, should be informed in the same way.
9. To promote and consider the opinion from the society on technical, environmental, societal, economical, ethic and legal issues concerning the regulations for development, marketing, use and disposal of products and services based on nanotechnologies, and the attention to potential harmful effects, with the support of diffusion of reliable information on the topic.
10. To foster the coordination among federal secretaries and agencies regulating nanotechnologies, and to promote a common vision on the topic including industry, public and private research and development organizations, and other interested parties.
11. To seek harmonized regulations with those of our trade partners, and to prefer the use of harmonized terminology inside and outside of the country.

12. To keep an open and effective communication on regulatory matters for nanotechnologies with our trade partners.

IV. Review

These guidelines shall be reviewed when relevant modifications become needed, but in no case in periods longer than three years.

This document was prepared by the Working Group on Regulations for Nanotechnology, whose names and signatures are found in the Spanish version, and affiliated to the following organizations:

- Centro de Investigación en Materiales Avanzados (CIMAV)
- Centro Nacional de Metrología (CENAM)
- Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)
- Consejo Nacional de Ciencia y Tecnología (CONACYT) - Red Nacional de Nanociencias y Nanotecnología
- Instituto Nacional de Ecología y Cambio Climático (INE)
- Instituto Politécnico Nacional (IPN) - Centro de Nanociencias y Micro y Nanotecnologías (CNMN)
- Secretaría de Economía (SE)
- Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT)
- Secretaría del Trabajo y Previsión Social (STPS)
- Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)
- Universidad Nacional Autónoma de México (UNAM) - Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades

NOTE: The official version of these Guidelines is the Spanish text *Lineamientos para regulaciones sobre nanotecnologías para Impulsar la Competitividad y proteger al medio ambiente, la salud y la seguridad de los consumidores*. This must be used when there is doubt about the interpretation of the text.