U.S. FDA-MEXICO PRODUCE SAFETY PARTNERSHIP
A DYNAMIC PARTNERSHIP IN ACTION

June 2018

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Message from the Produce Safety Partnership Leadership

We are pleased to present the *U.S. FDA-Mexico Produce Safety Partnership: A Dynamic Partnership in Action* progress report.

The Produce Safety Partnership (PSP) is a groundbreaking collaboration to address the evolving nature of the production and distribution practices facing our respective countries. This report highlights how Mexico and the U.S. are working together to ensure the safety of fresh and minimally processed produce.

Recognizing the importance of safe produce to public health and the economy, Mexico has established a framework for Good Agricultural Practices (GAP). This framework is based on preventive standards, verification, and certification programs for fresh produce and covers the full supply chain from growing through distribution. Mexico has charged its Federal Departments of Agriculture – National Service for Agroalimentary Public Health, Safety, and Quality (SENASICA) – and Health – Federal Commission for the Protection from Sanitary Risks (COFEPRIS) – to work collaboratively to implement its GAP framework and, thus, foster enhanced produce safety.

The U.S. is also strengthening regulatory approaches to food safety. The FDA Food Safety Modernization Act (FSMA) of 2011 empowers the U.S. Food and Drug Administration (U.S. FDA) to better protect public health by implementing requirements that help to ensure the safety and security of the food supply. FSMA embraces preventive controls and strong verification processes as the foundation of a modern food safety system.

We have been working collaboratively on institutionalizing approaches that reinforce preventive practices and rapid response to potential outbreaks. As explained in this report, we have worked together to contain potentially serious outbreaks related to produce and lessen consumer exposure to foodborne disease.

As we move forward, this partnership allows us more flexibility and opportunity to learn about each other's food safety systems and leverage new information to find innovative methods to ensure the safety of produce. We recognize the importance of establishing strong relationships and mutual support among all stakeholders, including industry, government, academia, and consumers working together to ensure food safety.

Dr. Enrique Sánchez Cruz
Director in Chief
SENASICA

Stephen Ostroff, M.D.
Deputy Commissioner of Foods and Veterinary Medicine
U.S. FDA

Lic. Julio Sánchez y Tépoz
Federal Commissioner
COFEPRIS

Safe Produce: A Cross-border Commitment

The PSP is a bilateral partnership that focuses on ensuring the safety of produce traded across our respective borders. Trade in produce between the U.S. and Mexico is vast. Mexico is a major exporter of food products to the U.S., providing U.S. consumers with fresh produce year-round. Mexico supplies a significant percent of the tomatoes, avocados, chilies, berries, cucumbers, lemons, and limes enjoyed in the U.S. The U.S. exports a significant amount of apples, pears, grapes, onions, strawberries, potatoes, and peaches to Mexico.

In 2017, Mexico exported over $11 billion worth of fresh produce to the U.S, and the U.S. exported over $660 million worth to Mexico. Figures 1 and 2 identify each country's top ten fresh produce exports in 2017, by value, and illustrate the variety of fresh fruits and vegetables that cross our borders.

Figure 1: Mexico Exports of Fresh Produce to U.S. (by value), 2017

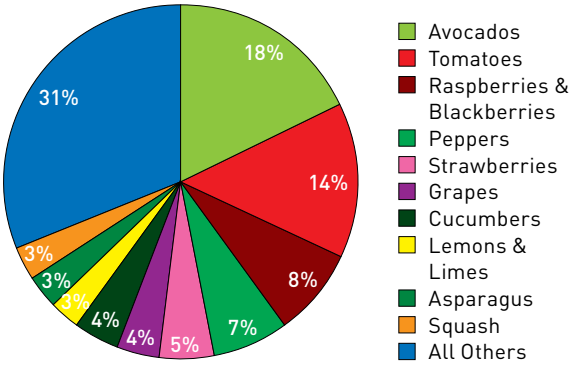
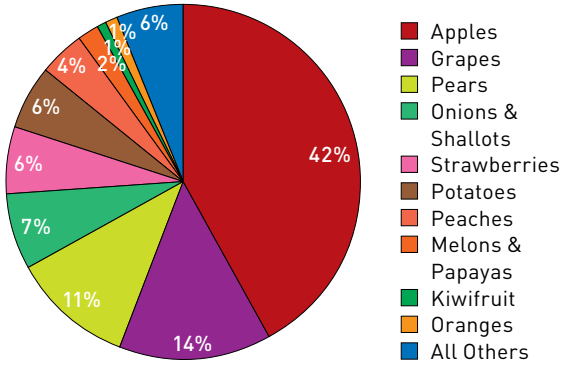


Figure 2: U.S. Exports of Fresh Produce to Mexico (by value), 2017



Interactive Tariff and Trade DataWeb. (2018, March 23). Retrieved from https://dataweb.usitc.gov/, U.S. Department of Commerce, U.S. International Trade Commission.

The Partnership

Foodborne illness outbreaks associated with contaminated produce over the last decade have caused a widespread recognition that we need a new, modern food safety system that focuses on preventing food safety problems, as well as reacting to them. Due to the strong commitment that Mexico and the U.S. share to assure the safety of produce, U.S. FDA, COFEPRIS, and SENASICA signed the PSP Statement of Intent on July 24, 2014.

"Produce is an essential component of a healthy diet, so assuring the safety of fruits and vegetables is a key component of helping consumers achieve healthy diets."

Susan Mayne, Ph.D.
Director, Center for Food Safety and Applied Nutrition, U.S. FDA

The overall goal of the PSP is to work in collaboration to implement preventive practices and verification measures that will support high rates of compliance with produce safety standards, guidelines and best practices and therefore reduce risk of illness or death associated with the consumption of fresh and minimally processed produce. The emphasis of the partnership is to have a governance structure that focuses on joint activities to facilitate an understanding of each other's produce industry oversight systems, coordinated risk communication, and data sharing for fresh and minimally processed produce.

"We've been delighted to share our extensive outreach and education materials on worker health and hygiene with our colleagues from the U.S. FDA. The PSP has provided a framework for sharing creative ideas."

Silvia Rojas
Director of Agri-Food Safety Organic Operation and Pesticides for Agricultural Use, SENASICA

Table 1: Missions of the PSP Organizations: COFEPRIS, SENASICA, and U.S. FDA

COFEPRIS	COFEPRIS is responsible for protecting the population from health risks caused by the use or consumption of goods and services, health products, and the exposure to environmental or occupational factors. COFEPRIS is also responsible for protecting the population from health risks that result from the occurrence of sanitary emergencies and the provision of health services, through regulation, control, and prevention of sanitary risks.
SENASICA	SENASICA's mission is to regulate, manage, and promote the activities of health, food safety, and food quality by reducing the risks inherent in agriculture, livestock, aquaculture, and fisheries in benefit of producers, consumers, and industry. SENASICA is responsible for protecting plants and animals from pests and illnesses of economic and quarantine importance. In addition, SENASICA regulates and promotes the execution and certification of the voluntary System for Risk Reduction from Contamination of fresh fruits and vegetables, for facilitating the local and international trade.
U.S. FDA	The U.S. FDA protects the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that emit radiation. The U.S. FDA also regulates tobacco products to protect public health and reduce use by minors. The U.S. FDA's Center for Food Safety and Applied Nutrition (CFSAN), in conjunction with the Agency's field staff in the Office of Regulatory Affairs, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

Food Safety Modernization in the U.S. and Mexico

The U.S. and Mexico food safety systems are continuously evolving to better protect public health by helping to ensure the safety and security of food supply. The collaboration of the PSP, although not mandated by any legislation, builds upon the cross-border commitment to produce safety that the US and Mexico share.

For example, FSMA aims to ensure the U.S. food supply is safe by shifting the focus from response to preventing contamination and foodborne illness. In enacting FSMA, the U.S. Congress recognized the need to focus on food safety at a global scale to address the wide range of commodities the U.S. imports from more than 200 countries and territories and to assure food is safe regardless of its source. It also recognized that the U.S. FDA cannot succeed on its own, but must work collaboratively with a wide range of food system partners – both public and private all over the world – to achieve established food safety goals.

In November 2015 FDA issued the FSMA Produce Safety Rule, which establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables that are domestically produced or imported for consumption in the U.S.

"U.S. FDA's collaboration with Mexico is a key in the implementation of FSMA and our office in Mexico City has been a linchpin for FSMA and PSP implementation."

Mary Lou Valdez
Associate Commissioner for International Programs Office of Global Regulatory Operations and Policy, U.S. FDA

Mexico has established a set of laws, regulations, and programs, such as the voluntary System for Risk Reduction from Contamination (SRRC), to reduce the risk of physical, chemical, and microbiological contamination in the primary production of fruits and vegetables.

Mexico has also developed strategies to strengthen its National Food Control System through the enforcement of provisions for Good Manufacturing Practices, which are mandatory for all fruit and vegetable growers and packing houses, as applicable. Mexico is also moving toward higher standards through the promotion of Hazard Analysis and Critical Control Point-based certification systems.

"COFEPRIS, as the sanitary authority responsible for the sanitary control and surveillance of food, has the scheme for certification of good manufacturing practices in food processing establishments, which has allowed more than 200 certified companies to export safe products, generating confidence for authorities and consumers in the countries of destination."

Alvaro Pérez Vega
Commissioner of Sanitary Operation and Enforcement, COFEPRIS

Impact: Coordinating and Leveraging Produce Safety Systems to Support Public Health

The PSP is using communications and enforcement tools to enhance knowledge transfer and establish common processes and procedures between the U.S. and Mexico. This collaboration is helping to reduce the impact of foodborne illnesses by reinforcing preventive practices before an outbreak occurs and allowing both countries to respond more rapidly in the event of a potential or actual outbreak.

The following are examples of how Mexico and the U.S. have coordinated and leveraged information to make progress towards PSP goals.

"The examples in this report demonstrate the significant progress that can be achieved when public health authorities work together to implement preventive practices and verification measures to support high rates of compliance. Consumers on both sides of the border are better protected with access to safe fresh produce."

Erik Mettler
Assistant Commissioner for Partnerships and Policy Office of Regulatory Affairs, U.S. FDA

Decline Reported in Cyclospora Outbreaks in 2016

The number of U.S. domestically acquired Cyclospora infections reported in 2016 declined when compared to the three previous years. A variety of activities were conducted by the U.S. FDA and Mexican food safety authorities in response to epidemiologic and traceback information linking *Cyclospora cayetanensis (C. cayetanensis)* foodborne illnesses to fresh cilantro grown in Puebla, Mexico.

From 2013 to 2015, the U.S. FDA and Mexican food safety authorities SENASICA and COFEPRIS performed inspections and environmental assessments at multiple farms and packing houses in the state of Puebla, Mexico, where they found conditions and practices that could cause the contamination of cilantro. U.S. FDA consulted with Mexican food safety authorities in 2015 to implement an annual import alert (Import Alert #24-23) for fresh cilantro from Puebla during the growing season of April 1 through August 31. This import alert allows border officials to detain and refuse admission of cilantro grown in Puebla into the U.S. without physical examination.

Only cilantro producers in the state of Puebla who comply with 11 minimum requirements on good agricultural and food safety practices as part of Mexico's SRRC are placed on a "Green List" and not detained under the import alert. The PSP facilitated the regulatory coordination between the U.S. and Mexico in 2015 prior to the implementation of the import alert. It was agreed that the U.S. FDA would review SENASICA and COFEPRIS certification packages for a farm (supplier) and for the corresponding packing house being supplied by a SENASICA certified farm prior to a firm being added to the Green List.

The first full season that U.S. FDA's import alert for fresh cilantro from Puebla, Mexico was in effect was 2016. As of September 16, 2016, U.S. Centers for Disease Control and Prevention (CDC) reported at least 134 laboratory-confirmed cases of cyclosporiasis in persons who became infected in the U.S. and reported illness onset on or after May 1, 2016. This was a 58-percent

(58%) reduction compared to the same period in 2015, which had 319 confirmed cases. It is worth noting that the CDC reported an increase in the number of laboratory-confirmed cyclosporiasis cases in 2017, but additional data are needed to determine if the increase is due to more frequent testing or to an actual increase in infections.

Prior to the existence of the PSP, this level of joint action was not routine between the countries. This experience also led FDA to implement a testing program for cilantro from Puebla, Mexico and to conduct industry outreach on *C. cayetanensis* control and prevention in partnership with the CDC.

"In just a few short years, we have seen the U.S. FDA-Mexico Produce Safety Partnership grow from concept to reality. We are seeing cooperation on a variety of fronts, from lab procedures to data collection and sharing. As the United States and Mexico have become such strong partners in the food chain, this evolution has been welcomed and we think in the coming years it will yield even greater benefits to consumers, regulators, and industry alike."

Lance Jungmeyer
President, Fresh Produce Association of the Americas

Information Shared During an Outbreak of U.S. Kiwi and Apples

During an outbreak in 2015 for U.S. kiwi and apples, the exchange of information under the PSP led to activities that further prevented contaminated product from entering Mexico.

In August 2015, COFEPRIS informed the U.S. FDA Latin America Office (LAO) in Mexico City about U.S. fresh produce sampled by SENASICA found to be positive for *Listeria monocytogenes*. A week later, COFEPRIS shared the analytical worksheets of the laboratory findings with LAO.

The PSP Laboratory Collaboration work group assisted the U.S. FDA/CFSAN's Office of Regulatory Science and Office of Food Safety in working with the U.S. FDA LAO in Mexico City to submit a request for the *L. monocytogenes* isolates to be shipped from SENASICA's laboratory to U.S. FDA. The isolates were from U.S. kiwi and apple samples collected at the border of Mexico. CFSAN performed Pulse Field Gel Electrophoresis and Whole Genome Sequence analyses on the isolates from SENASICA. Once performed, the U.S. FDA LAO shared the results with PSP Mexican food safety authorities COFEPRIS and SENASICA.

Prior to the existence of the PSP, the ability to share information fluidly between the U.S. and Mexican food safety authorities was not easily done. Due to joint action between the organizations, the ability to conduct an exercise for a *Listeria* isolate transfer allowed the food safety authorities to exchange information and enhance collaboration on laboratory activities, to improve detection and understanding of contamination. This exercise is establishing a two-way protocol for the exchange of strains between Mexico and the U.S.

"SENASICA operates the Good Agricultural Practices program called the SRRC, which is implemented in farms and packinghouses of fresh fruits and vegetables. In addition, the scheme ensures that products certified under the Mexican government program comply with national and international regulations in food safety by reducing physical, chemical, and microbiological contamination. At present, more than 10,000 companies and producers are certified in our scheme, producing more than 80 species of fresh fruits and vegetables in optimal food safety conditions and ready to eat."

Hugo Fragoso Sánchez
General Director for Food Safety, Aquaculture, and Fisheries,
SENASICA

Collaborating to Increase Prevention

Collaboration using mechanisms developed under the PSP led to activities to prevent further contamination in papaya from Mexico.

In the fall of 2017, the U.S. FDA and Mexican food safety authorities, SENASICA and COFEPRIS, used mechanisms established by the PSP in their response to four outbreaks of human infections with *Salmonella* epidemiologically and analytically linked to papaya originating from Mexico. U.S. FDA used the Binational Outbreak Notification Protocol established under the PSP to notify SENASICA and COFEPRIS of the outbreaks.

The Mexican agencies conducted inspections and sampling at various farms and packing houses in several Mexican states, with U.S. FDA joining one. They shared results with U.S. FDA showing several samples matching outbreak strains. Additionally, the Mexican authorities observed conditions and practices that could lead to the contamination of papaya. U.S. FDA used these findings, along with its outbreak investigation, to place four farms on Import Alert 99-35, "Detention Without Physical Examination of Fresh Produce That Appears to Have Been Prepared, Packed or Held Under Insanitary Conditions" and SENASICA likewise implemented a regulatory response.

Additionally, U.S. FDA isolated *Salmonella* in papaya, not matching the outbreak strains, during examination of several entries and placed several Mexican firms on an existing country wide import alert for papaya, Import Alert 21-17, "Countrywide Detention Without Physical Examination of Papaya From Mexico." This alert was put in place in 2011 in response to multiple contamination events including a large outbreak of salmonellosis in which papaya from Mexico was implicated as the vehicle. While outbreaks from consumption of papaya were not identified in 2012-2016, the 2017 outbreaks demonstrate that there are continued challenges in preventing *Salmonella* contamination of papaya.

To further prevention efforts and in response to the papaya outbreaks, SENASICA implemented a program in October 2017, to strengthen the safety of papaya by incorporating minimum food safety requirements through adherence to the SRRC when issuing the International Phytosanitary Certificate, (*Certificado Fitosanitario Internacional*, CFI), to companies exporting papaya to the U.S. SENASICA implemented its program to minimize the potential for contamination of papayas with *Salmonella* in the Mexican papaya industry. Beginning in January 2018, papaya produced by, or exported to the U.S. from, large farms must meet the science-based minimum standards of FDA's Produce Safety Rule.

Partnership Activities

Initially the PSP focused on learning about our respective organizations and deepening the understanding of how our respective food safety systems functioned. Mexico and the U.S. have cooperated on joint inspections and responses to produce-related outbreaks, such as joint traceback investigations and environmental assessments, in addition to enhancing laboratory capacity. Mexican officials from both COFEPRIS and SENASICA routinely accompany U.S. FDA during surveillance inspections at Mexican food firms, including produce firms. Likewise, U.S. FDA accompanies COFEPRIS and SENASICA during inspections of U.S. produce farms and facilities that export to Mexico.

In addition, the PSP conducted the following activities:

- Established a written protocol through a confidentiality agreement to exchange information within the PSP
- Exchanged information on outbreak response, which contributed to the development of a Binational Outbreak Communication Protocol to establish the basis of communication and information exchange between Mexico and the U.S., to respond to outbreaks caused by the consumption of contaminated fresh and minimally processed produce
- Established an information-sharing platform through FoodSHIELD - a web-based system at the University of Minnesota for communication, coordination, education, and training among the U.S.'s food and agriculture sectors - to act as a repository for uploading and reviewing information
- Shared information on laboratory validation methods used by all three agencies
- Shared microbial strain isolates and information on laboratory methodologies to isolate and identify the main foodborne pathogens in produce
- Observed respective inspectional approaches and shared information on training methods for auditors for SENASICA and inspectors for COFEPRIS and U.S. FDA
- Developed a catalogue of web accessible educational materials and an internal glossary for operational and regulatory food safety technical terms for consistency purposes
- Shared information on capacity building and education and outreach materials
- Assisted Mexico with PulseNet certification to implement Pulsed-field Gel Electrophoresis for *Salmonella*
- Held periodic conference calls and in-person meetings in Mexico (September 2014 and September 2016) and the U.S. (April 2017)

What's Ahead for the PSP?

The PSP consists of more than 50 dedicated individuals. Appendix B contains information on the PSP workgroups. Our collective body of work represents an opportunity for further engagement to continue improving the safety of fresh and minimally processed produce.

"There has been extraordinary cooperation on laboratory methods and procedures over the last few years. Mexico and the U.S. have taken giant steps forward in bringing our laboratories closer."

Mario Alanís Garza
General Director of International Affairs, COFEPRIS

Over the next five years, the PSP will explore the following:

- Increasing engagement with key partners in industry, academia, and government to further advance opportunities for the PSP
- Exchanging of information and knowledge, regarding Whole Genome Sequencing methods, practices, and collaborative activities

- Identifying common approaches for auditors and inspectors to improve various tools and procedures for effective compliance and better execute compliance and enforcement activities
- Creating a strategy to conduct joint inspections and a joint pilot on micro-sampling to improve surveillance, detection, and understanding of contamination and to improve decision making for response actions
- Continuing to advance the Binational Communications Outbreak Protocol by evaluating its effectiveness and including specific time frames to enhance its execution
- Enhancing FoodSHIELD features for PSP purposes
- Incorporating other matters of interest, such as food alerts and recalls

The PSP will continue to leverage information and embrace opportunities that arise to implement preventive practices and verification measures to support high rates of compliance with produce safety standards, guidelines, and best practices.

Contact Information for the Produce Safety Partnership

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

To contact COFEPRIS, please send an email to the Executive Directorate of International Operations at deoi@cofepris.gob.mx.

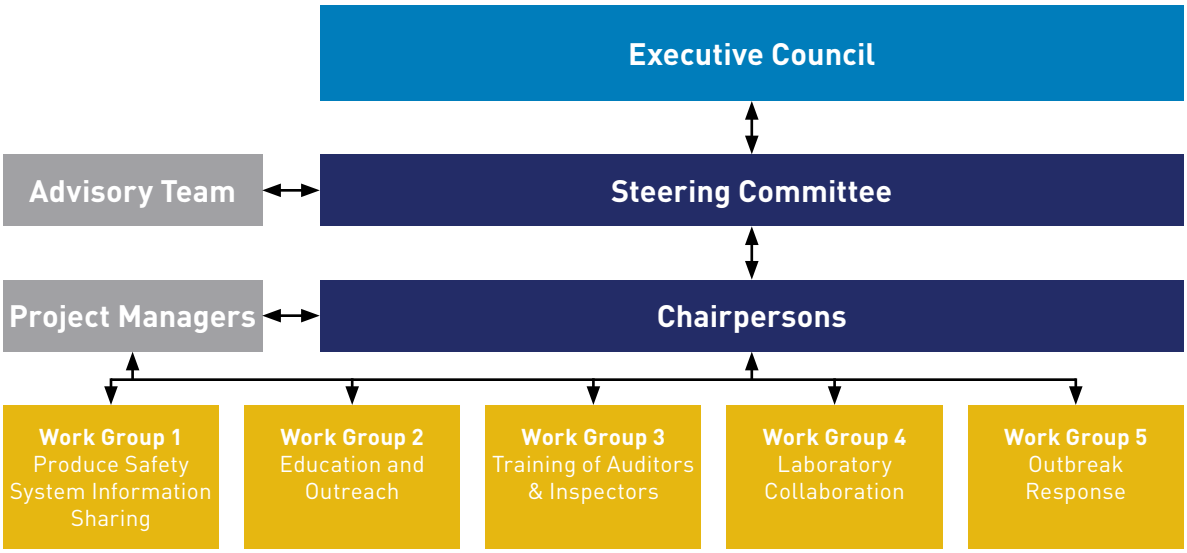
SENASICA
SERVICIO NACIONAL DE SANIDAD, INOCUIDAD Y CALIDAD AGROALIMENTARIA

To contact SENASICA, please send an email to alianzainocuidad.dgiaap@senasica.gob.mx.

FDA U.S. FOOD & DRUG ADMINISTRATION

To contact the U.S. FDA, please send an email to the International Affairs Staff in CFSAN at IAS-ACTION@fda.hhs.gov.

Appendix A
PSP Governance Structure



Executive Council	Consists of senior-level individuals who provide guidance to the PSP Steering Committee when necessary. The Executive Council provides direction or resolution to the PSP Steering Committee when a consensus cannot be reached.
PSP Steering Committee	Consists of director-level individuals who meet periodically to provide direction, address issues, review information, and provide final approval for the work of the PSP. This includes reviewing proposals and designating individuals to work on the PSP and its activities. The Steering Committee meets on a quarterly or as-needed basis by phone and face-to-face.
Chairpersons	Oversee execution of the direction and decisions made by the PSP Steering Committee and Executive Council. They are responsible for disseminating updates and monitoring the progress of the Work Groups. Chairpersons provide regular updates to the PSP Steering Committee or the Work Groups on significant issues that may impact the PSP's mission or scope. They are also responsible for reviewing information and proposals prior to being delivered to the PSP Steering Committee for approval.
Work Groups	The collaboration of the PSP is carried out by specific technical work groups devoted to key areas relating to produce safety. Five work groups conduct activities to develop knowledge of and mutual confidence in the approaches used by the U.S. and Mexican produce safety control systems.

Appendix B
PSP Work Groups

Work Group	Charge	Expected Outcomes	Voice of the Work Groups
1. Information Sharing	Focused on how best to exchange information between organizations about produce safety systems to increase understanding and knowledge, recognize and better target high-risk situations involving produce, and better execute compliance and enforcement activities.	• Better prevention of produce safety problems in the produce supply chain • Increased compliance with regulatory standards • Increased mutual confidence in the way Mexico and the U.S. approach produce safety	"Working together to understand each other's regulatory activities and challenges can only strengthen our relationship." "Sharing information can help identify needs for more targeted approaches and increased regulatory cooperation."
2. Education and Outreach	Dedicated to the development of effective, culturally specific education and outreach materials that support industry compliance with standards for the safety of fresh and minimally processed produce.	• Increased access to and knowledge of information related to improved practices for industry • Better prevention of produce safety problems in the produce supply chain	"A common understanding of the terminology used by each agency has been reinforced." "Through PSP, we can build upon our alliance to decrease risks and ensure a safer food supply."
3. Training of Auditors and Inspectors	Focused on sharing information to identify common approaches for training auditors and inspectors who will verify compliance with standards for the safety of fresh and minimally processed produce.	• Improved tools and procedures for effective compliance • Better execution of compliance and enforcement activities	"PSP gives us an opportunity to learn more about each other's policy-making activities for audits and inspections."

Work Group	Charge	Expected Outcomes	Voice of the Work Groups
4. Laboratory Collaboration	Focused on enhancing the collaboration of ongoing laboratory activities.	• Improved surveillance, detection, and understanding of contamination • Improved decision making for response actions • More effective and efficient response efforts for known hazards	"We have discovered that we share a common theme in the importance of science-based preventive standards." "Through PSP, we have an opportunity to share information on scientific methods such as Whole Genome Sequencing and participate in joint laboratory projects that augment our cross-border commitment to ensure the safety of produce."
5. Outbreak Response	Dedicated to enhancing collaboration during outbreak response and traceback activities, as well as epidemiology and product tracing for Mexico and the U.S.	• Improved surveillance and detection of contamination • Improved epidemiology and product tracing for Mexico and the U.S. • Improved decision making for response actions and more efficient and effective responses to known hazards	"PSP is an example of a true partnership between countries and has opened doors for more communications, especially during critical times in food safety." "Our work together on Whole Genome Sequencing is an example of how we have to work and communicate together to ensure there is understanding across the board."