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Assessment of food safety risk analysis needs in Colombia

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Sanitary/Phytosanitary/Food Safety

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Report Highlights:

The United States is poised to exceed past record levels of food and agricultural exports to Colombia, which in 2015 was the 8th largest market worldwide with \$2.4 billion in sales. The GOC continues to reassess and develop new regulatory standards with detrimental trade implications, including Decree 539 of 2014 and Resolution 719 of 2015. Since December 2015, the joint implementation of these regulations has resulted in approximately \$250,000 worth of consumer-oriented products delayed at ports. This report assesses these new regulatory standards and on how to resolve these issues.

Executive Summary:

In 2015 Colombia was ranked the 8th largest market for U.S. agricultural products, reaching \$2.4 billion in sales. U.S. consumer-oriented product exports were valued at \$505 million in 2015. The Colombian FTA has been a great success for U.S. agriculture; however, sanitary/phytosanitary (SPS) trade irritants remain. Exports of U.S. consumer oriented products to Colombia \$505 million in 2015, representing 21% of total food and agricultural exports. The timely FTA has taken advantage of a rapidly growing middle class in Colombia and significant potential for consumer-oriented product market growth. Unfortunately, the COG has issued a series of regulations that are affecting the flow of U.S. food and agricultural exports to Colombia, particularly Resolution 719 of 2015, which provided a list of food products for human consumption based on their perceived risk to public health.

This regulation established a non-science based criteria listing certain foods has high, medium and low risk. It determines that about 80% of U.S. consumer-oriented products exported to Colombia fall within the “high” or “medium” risk to public health category. For example, fruit juices, ketchup, soda, and canned vegetables are now listed as “high risk”, requiring additional scrutiny and documentation expectations at ports-of-entry (POE). U.S. food safety controls for many high and medium risk products on the Colombian list do not require comparable levels of scrutiny. As a result, the private sector is unable to get the sanitary documentation required for exported products, leading to many delays and additional costs to U.S. agribusinesses at POE. Since December 2015, an estimated \$250,000 worth of consumer-oriented products have been delayed at ports.

The methodology to establish such list has been challenged by the U.S. food and beverage industry, claiming that the list will impact millions of dollars in trade, particularly consumer oriented food exports to Colombia.

Post highly recommends to provide food safety risk analysis training to Colombian regulatory authorities, primarily with the National Food and Drug Surveillance Institute (INVIMA). This training and subsequent follow-up should be aimed at harmonizing U.S. and Colombian food safety regulations, supporting modifications to non-science based trade restrictive regulations recently implemented by the Colombian Ministry of Health. This training should ultimately result in dramatic modifications to the current food risk classifications providing science-based regulations, while streamlining POE bureaucracy.

ASSESSMENT OVERVIEW

1. WHO

Agricultural Counselor, Michael Conlon, led the assessment that sought to determine the current and future problems originated from recently developed regulation in Colombia (Decree 539 and Resolution 719). He was assisted by local staff and private stakeholders with vast experience in international food and rural business systems.

2. HOW

Post conducted a thorough research on the legal and trade consequences of Decree 539 and Resolution 719, issued by the Colombian health authority. This research used qualitative and quantitative data provided by official sources as well as local stakeholders, including importers and exporters. Furthermore, Post contacted the Ministry of Trade, Ministry of Health, trade associations, the Grocery Manufacturing Association (GMA), the U.S. Dairy Export Council (USDEC), as well as individual importers in Colombia and exporters in the United States.

3. WHAT

Market and Regulatory Overview

In 2015, U.S. agricultural product exports to Colombia were valued at \$2.4 billion exports, 1st in South America, and the 8th largest market worldwide. U.S. consumer-oriented product exports were valued at \$505 million in 2015, with a remarkable 5-year growth of 133%.

Colombia recently signed trade agreements with the United States, the European Union and Canada, while also seeking accession to the Organization of Economic Cooperation and Development. Greater economic and trade ambitions are motivating Colombia to adjust and improve food safety regulations. Attempts at regulatory reform have had disastrous results, including trade impacting SPS regulations not being notified to the World Trade Organization (WTO), creating POE delays through increased documentation expectations, impractical food product and manufacturing plant registration requirements, and clumsy development of food safety regulations with unclear approaches to implementation. Some examples:

Decree 539

Decree 539 was issued by the Colombian Ministry of Health in March 2014. Despite its international trade implications, Colombia did not notify the WTO of this new decree. The most significant issue with this regulation stemmed from Chapter 5, which directs INVIMA to inspect all foreign plants that produce animal origin food products (except beef) considered “high risk” in order to obtain the necessary registration to export to Colombia. Post conducted numerous meetings with key stakeholders and high-level officers from INVIMA and the Ministry of Health, which resulted in the suspension of Chapter 5 of Decree 539. Furthermore, Post was informed that a new decree would be notified to the

WTO, which would replace Decree 539.

However, the Colombian government did not change Decree 539's Chapter 4. This chapter is quite problematic as it requires food importers to submit a "sanitary certificate" for all medium and high risk products, in addition to the conventional certificate of free sale. This is not an issue for U.S. exporters of high risk products like meat, poultry, or seafood given that the Food Safety Inspection Service and the U.S. Department of Commerce can satisfy this requirement. However, for processed products, such as carbonated soda beverages, canned fruits and vegetables or prepared foods, there is no U.S. federal authority that issues a sanitary certificate. Post has brought this to the attention of INVIMA and the Ministry of Health, which has resulted in INVIMA's request for additional burdensome documentation from U.S. exporters, including individual shipment and sanitary information on certificates of free sale. Post has contacted several states and many of them have expressed their logistical and legal concerns, as well as the legal inability to make the necessary changes to the standard certificates of free sale normally issued to U.S. food and beverage product exporters.

Resolution 719

In August 2014, the Government of Colombia (GOC) notified a draft regulation to the WTO that classified food products for human consumption based on the risk to public health. Such risks were categorized as "low", "medium", and "high". This regulation was drafted by the Colombian Ministry of Health and the notification did not include the risk assessment criteria applied to develop the list of foods that meet the risk categories. However, Post was advised that this risk categorization was the result of an internal working session by a technical committee that reports to INVIMA. Attempts by Post to meet with this committee have been futile. As part of the WTO notification process and comment period the U.S. government, private sector and others submitted comments against the proposed regulation. Unfortunately, these comments were dismissed by the GOC. Later, in March 2015, the GOC issued Resolution 719, which was based on the ill-conceived draft regulation notified to the WTO.

Under Resolution 719 a large number of products are now considered "high-risk" including dairy, fortified food and beverages, bottled and carbonated beverages, sports/energy drinks, fruit juices, canned vegetables, etc. The U.S. industry, including the U.S. Dairy Export Council (USDEC) and the Grocery Manufacturing Association (GMA), have challenged the criteria used by INVIMA and repeatedly submitted their technical arguments against Resolution 719 and the non-science based criteria for categorizing certain products as "high" and "medium" risk.

Joint Implementation of Decree 539 and Resolution 719

As a result of Decree 539 and Resolution 719, since late 2015 Post has been informed about the detention and delays of numerous U.S. shipments entering Colombia. These shipments have included bottled juices, canned goods, prepared foods from several U.S. exporters such as General Mills, Ocean Spray's, Kraft Foods, etc. The total value of these goods held at port are an estimated \$250,000, with thousands of dollars in demurrage and other costs due to delays getting product to market. The reason behind these detentions revolves around missing documentation that INVIMA now requires for products that they consider "medium" or "high risk." Post has been able to facilitate the release of these detained shipments after onerous case-by-case discussions with INVIMA and numerous state-level health authorities in the United States

Post seeks funds to provide food safety risk analysis training to Colombian regulatory authorities, primarily with INVIMA. This training and subsequent follow-up will harmonize U.S. and Colombian food safety regulations, supporting modifications to non-science based trade restrictive regulations recently implemented by the Colombian Ministry of Health. These regulations established a non-science based criteria listing certain foods has high, medium and low risk. The ultimate objective of this training is to work with the GOC to modify Resolution 719, which currently categorizes 80% of consumer oriented food products as “medium” or “high” risk to public health. U.S. consumer oriented annual exports to Colombia exceed \$500 million and have experienced a remarkable 133% growth in five years. This training will seek to provide Colombian regulators with tools and knowledge for a harmonized, science-based risk analysis methodology. This effort will provide a greater level of influence on the development of Colombian food safety standards to shape trade policies that are more conducive to trade.

Examples of “high-risk” food products under Resolution 719

Fortified Bread

Regulations in force in Colombia require the fortification of certain products, including breads, with enriched wheat flour to address nutrient deficiencies in the population. Wheat flour is identified as a suitable additive to foods to address this deficiency by the Ministry of Health, which raises the question of how the government requires fortification on one hand, while classifying such products as high risk on the other. Furthermore, internationally recognized bodies such as Codex Alimentarius, the World Health Organization and Food and Agricultural Organization and the Institute of Medicine have developed guidelines and principles for the addition of essential nutrients to food. Classifying fortified bread as high risk is inconsistent with these guidelines and principles.

Carbonated Beverages

Variables used to establish the risk of these products relate to microbiological and chemical risk, and to frequency of consumption by sensitive population groups. However, other variables, such as the characteristics of food processing, do not appear to have been considered. In addition, the influence of one variable in relation to another also does not appear to have been considered, which in certain cases could impact the appropriate weight given to the respective variables in mitigating risk. The use of carbon dioxide has a very effective antimicrobial effect in water-based drinks, especially against yeasts and fungi. Carbon dioxide is effective against yeast because it suppresses the production of CO₂ as a byproduct of fermentation of sucrose to ethanol. It also deprives fungi of oxygen for growth, and the sterilization of packages also effectively mitigates risk.

Dairy Products (e.g. Non-Fat Dry Milk Powder)

The initial risk assessment document is not consistent with OIE or Codex, and also omitted the safeguards noted in these groups’ guidance documents in their risk assessment criteria. It is clear that dairy processing, packaging and other intrinsic factors contribute to the safety of the dairy products. In order to be harmonized with international standards, it is critical that the guidance of both these organizations be included as a foundation for any risk categorizations of dairy products. The classification of all dairy products as high risk is scientifically inaccurate given the guidance of international organizations such as Codex and the OIE.

4. OPPORTUNITIES

Since the issuance of Resolution 719, Post has repeatedly offered technical assistance to INVIMA in order to develop and implement a science-based methodology on risk assessment. However, INVIMA has consistently turned it down.

However, this situation has changed and during a recent meeting with INVIMA, its General Director mentioned that they may consider working on a technical proposal to modify Resolution 719, for which they would be open to accept external technical assistance. This proposal would be presented to the Ministry of Health, which ultimately is the only public entity in Colombia with the policy authority to amend Resolution 719. This technical assistance, INVIMA suggested, could come in the form of U.S. risk analysis experts conducting single or multiple workshops in Bogota to work with INVIMA's technical staff.

Clearly, this is a unique opportunity for Post to shape public food policy in Colombia, and provide U.S. exporters with better conditions in this rapidly growing market.

5. RECOMMENDATIONS

While Post is highly concerned about the current detrimental effects that stem from these two regulations, the most worrisome issue is the potential future trade irritants and barriers for U.S. food and agricultural exports to Colombia.

As result, Post strongly advises to seek funding to provide the GOC with technical assistance to revisit the food risk analysis it conducted before issuing Resolution 719. This assistance would seek to harmonize U.S. and Colombian food safety regulations, supporting modifications to non-science based trade restrictive regulations recently implemented by the Colombian Ministry of Health. This training should ultimately result in dramatic modifications to the current food risk classifications providing science-based regulations, while streamlining POE bureaucracy. As it was mentioned, around 80% of the consumer oriented products on the list under Resolution 719 was considered "medium" or "high" risk. The goal would be to reduce this percentage dramatically, with a particular focus on those products primarily originated in the U.S.