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Three Cities in Three Days: Readout Report of the Ecuador GE-Food Product Labeling Workshops

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Report Highlights:
Under the auspices of the U.S. Department of State, the U.S. Department of Agriculture's Foreign Agricultural Service (FAS) office in Ecuador provided support for three workshops on the labeling of genetically engineered (GE) food products held on September 28, 29 and 30, 2015. Ecuadorian government officials (politicians and regulators), members of the food industry, academics, and the public took part in discussions on the impact of GE-food labeling on consumer perception. A key outcome of participant interaction was a discussion of the impact of mandatory GE-food labeling on food sales. This report summarizes the discussions and offers recommendations based on Ecuador's experience with labeling GE-food products.

Executive Summary:

Under the auspices of the U.S. Department of State, the U.S. Department of Agriculture's Foreign Agricultural Service (FAS) office in Ecuador provided support for three workshops on the labeling of genetically engineered (GE) food products held on September 28, 29 and 30, 2015. Ecuadorian government officials (politicians and regulators), members of the food industry, academics, and the public took part in discussions on the impact of GE-food labeling on consumer perception. A key outcome of participant interaction was a discussion of the impact of mandatory GE-food labeling on food sales. This report summarizes the discussions and offers recommendations based on Ecuador's experience with labeling GE-food products. It is based on the Workshops Report produced by rapporteurs Biologist Adriana Castaño H., M.Sc., GMO Biosecurity Adviser, Colombia, and Lawyer María Victoria Córdova Misas, Food Law Expert, Ecuador. This report contains assessments and statements made by the rapporteurs, and such statements are not necessarily those of the institutions, governments or companies mentioned. This report and the discussions contained herein are intended solely for informational purposes. This information has been obtained from sources believed to be reliable, but is in no way guaranteed to be accurate.

Participating in the seminar were Dr. Xavier Sánchez of the Texas Tech University International Center for Food Industry Excellence, who led the discussion; Dr. Richard Goodman, a University of Nebraska expert on allergens and GM foods; Mr. Azmy Azmy, a chemist with Solae Co., a DuPont subsidiary; Mr. David Schmidt, CEO of the International Food Information Council; Ms. Adriana Castaño, Colombian biologist and regional expert in biotechnology regulation and genetically modified organisms (GMOs); and Dr. Victoria Córdova Misas, a local lawyer with extensive experience in Ecuadorian food regulation who specializes in food law.

As a result of working sessions with industry representatives and their questions about the conferences and the application of Ecuadorian regulations, the conclusion was:

- Regulations regarding transgenic-food labeling currently in effect in Ecuador are not clear to the food manufacturers who have to apply and comply with them.

- It is necessary to be clear about what the government means when it applies the 0.9% threshold set forth in GE-food labeling regulations, and how such a threshold will be determined for labeling a processed end product or not.

- Currently, the "CONTAINS TRANSGENICS" statement in the main panel is not fulfilling its purpose. Many manufacturers include it to avoid ending up in an administrative action before the Superintendent of Market Power Control, or being fined or penalized pursuant to the Health Organic Act.

1. BACKGROUND INFORMATION

Under the auspices of the U.S. Department of State, the U.S. Department of Agriculture's Foreign Agricultural Service (FAS) office in Ecuador provided support for three workshops on the labeling of genetically engineered (GE) food products held on September 28, 29 and 30, 2015. This report summarizes the discussions and offers recommendations based on Ecuador's experience with labeling GE-food products. It is based on the Workshops Report produced by rapporteurs Biologist Adriana Castaño H., M.Sc., GMO Biosecurity Adviser, Colombia, and Lawyer María Victoria Córdova Misas, Food Law Expert, Ecuador. This report contains assessments and statements made by the rapporteurs, and such statements are not necessarily those of the institutions, governments or companies mentioned. This report and the discussions contained herein are intended solely for informational purposes. This information has been obtained from sources believed to be reliable, but is in no way guaranteed to be accurate.

Specialists of the highest level were brought together at this event to analyze, on the basis of scientific and technical opinions:

- the need to label genetically modified food products;
- the market impact of mandatory GE-food labeling;
- the effect of such labeling on consumer perceptions; and
- the position of the Ecuadorian food and beverage industry concerning the legal and regulatory requirements.

Against this background, and based on the interrelationship between the Ecuadorian food and beverage industry and authorities responsible for the regulatory measures on genetically modified–food labeling issued as of 2013, three workshops were conducted in Ecuador's major cities: Guayaquil (Ecuadorian coastal region), Cuenca (Ecuadorian southern region), and Quito (capital and metropolitan district).

The workshops were targeted at manufacturers of industrially processed foods and beverages. Officials of the Ecuadorian government, food technologists, and world-renowned professors and scientists were also among the participants.

The workshops sought to encourage discussion on the effects that GE-food labeling has had in Ecuador and contribute to a positive exchange of experiences between Ecuador, the United States, and other countries in the region on current trends and experiences in GE-food labeling. As a final goal, the organizers sought to contribute to the formulation of effective, commercially non-disruptive public policies for food products derived from modern biotechnology.

2. WORKSHOP METHODOLOGY AND TOPICS COVERED

The workshop format consisted of keynote lectures, question-and-answer sessions, and discussions by the food and beverage industry about their experience to date in implementing labeling requirements.

Each workshop included the participation of international experts in the field of genetically modified organisms (GMOs) with extensive experience in biosecurity, risk analysis, GMO research and development, labeling, traceability, public perception, and risk communication. An Ecuadorian expert on food law and its implementation and enforcement in Ecuador and the Andean region also gave a

presentation at each workshop.

The workshops, Q&A sessions, and discussion were moderated by Dr. Marcos Sánchez, associate professor of Food Science and Technology in the Department of Animal and Food Science at Texas Tech University. Dr. Sánchez is an Ecuadorian national who is an expert in the development, coordination, and implementation of international training programs on food safety.

Attendees in the three cities were mainly representatives of the food and beverage industry and government institutions with duties and responsibilities in GMO matters in Ecuador. Officials from the National Health Regulation, Oversight and Control Agency (ARCSA) and the Ecuadorian Agricultural Quality Assurance Agency (AGROCALIDAD) participated in all three cities; the participation of the Secretary General of Production System Coordination [*Secretario General de Relacionamiento del Sistema Productivo*] of the Ministry of Agriculture, Livestock, Aquaculture and Fisheries of Ecuador (MAGAP) was of particular importance during the workshop in Quito.

The workshops in the three cities shared a similar format. Each began with welcoming remarks by Dr. Mariano J. Beillard, Regional Agricultural Attaché at the U.S. Embassy in Lima, Peru. Dr. Beillard noted that U.S. exports to Ecuador in 2014 totaled $430 million, while exports from Ecuador to the United States were $2.3 billion. Dr. Beillard also pointed out that scientific exchange between the United States and the region's countries is important; that mandatory labeling of industrially processed foods and beverages must be based on scientific and risk elements; that commercially viable guidelines, measures and tolerance thresholds must be established; and that consumers should not be given the impression that they are consuming hazardous products. Finally, he reiterated the interest of the U.S. government in supporting training needs regarding the matter as determined by the Ecuadorian government.

Dr. Marcos Sánchez then presented the workshop's objectives, the speakers, and opened the series of conferences in each of the cities where the workshops were held.

The main points of each talk are presented below.

2.1 Challenges in Labeling GMO-derived Foods - Dr. Richard E. Goodman

Dr. Goodman pointed out that the development of a GMO can take from 7 to 12 years of research and an expenditure of around $120 million, of which about $20 million is needed for compliance with regulatory requirements prior to their approval and market introduction. Dr. Goodman referred to food-allergen labeling as a model for GMO post-market control and labeling. He said in this regard that although U.S. food companies must label their products to help consumers avoid a specific allergen or the presence of gluten, to date no GE-food products are labeled as having any allergen presence, and no approved GM crop has caused new allergies.

Dr. Goodman noted that labeling should be validated by detection methods that can gauge the difference between the sampling and the food matrix being analyzed, because a poor analysis can give erroneous results that may endanger people who are allergic to a particular food, and this endangers a company that fails to make the required statements. However, various and sundry opinion leaders without scientific underpinnings and real analyses make unfounded assertions such as: "Food allergies have increased thanks to genetically modified soybeans," "Mice get cancer from eating approved GM corn,"

or “No validated food-assessment methods exist,” leading to information overload and a general lack of trust on the part of consumers.

Dr. Goodman clarified that the objective of GMO labeling based on farm-to-table traceability is difficult and rarely 100 percent accurate. Traceability involves high costs to determine *identity-preserved production* across the agro-commodity supply chain. Errors that occur due to bad sampling or erroneous detection (false positives) in products can cost millions of dollars. Moreover, accurate detection in processed foods is more complicated due to the effects of processing.

2.2 Assessing the Challenges of Labeling Genetically Modified Foods in Ecuador - Azmy Azmy

Mr. Azmy's talk was based on informing the audience as to the implications of establishing *Identity-Preserved* (IP) *Programs* along the agro-commodity supply chain.

Identity-Preserved Programs are implemented throughout the agro-commodity supply chain, from seed production to the end consumer. These programs offer customers non-genetically modified materials that meet countries' market and regulatory labeling standards. Many of these standards are based on setting thresholds for the presence of GM material in consumer end products. Such thresholds determine when labeling is required and may range from 0.9 to 5 percent presence of GM content. Determination of thresholds is not scientifically based, however, and conforms to political or economic circumstances. Such non-science-based decisions can lead to relocation of biotech companies, job losses, scientific brain drain, absence of safe innovation, and the creation of competitive disadvantages.

Mr. Azmy stressed that it is essential to distinguish between an *identity-preserved non-GMO product* and a product represented as *GMO-free*. In countries with zero tolerance, products claiming to be GMO-free cannot contain GMO traces and must prove that they contain no GM DNA. This condition creates doubt, considering the difficulty in constantly and consistently meeting the test criteria for a product to be considered GMO-free. Meanwhile, identity-preserved products are subject to risk and traceability assessments using standardized and controlled processes designed to minimize adventitious mixtures from different sources. Among the practices associated with identity preservation are risk assessment and management based on HACCP (hazard analysis and critical control points); good agricultural practices, delivery and processing throughout the supply chain; handling under established terms and procedures; documentation in accordance with IP procedures; and periodic monitoring to validate the IP system's effectiveness.

A fundamental part of IP programs is GMO detection throughout the supply chain, where sampling is critical to obtaining reliable results. Depending on the sampling amount and site, the percentage of GM material present in a grain shipment may vary, and sometimes false-positive results are obtained. In addition, one needs to bear in mind that the higher the level of food processing, the lower the accuracy of analysis and the possibility of detecting GM DNA.

The most widely used forms of GMO detection are ELISA protein detection and PCR (polymerase chain reaction) DNA detection methods in real time. Mr. Azmy emphasized that quantitative PCR assay of highly processed foods or ingredients will show very high, scarcely repeatable, or even completely unknown quantification limits due to the significant lack of amplifiable DNA. In such cases, laboratories report results as “unquantifiable.” In conclusion, the PCR assay is not necessarily a suitable tool to confirm compliance of refined products like lecithin or soybean oil in a GMO-free program. It is

not feasible to develop analytical methods that can accurately differentiate between GMO-free soy lecithin and refined lecithin that has exceeded the GMO-adventitious-presence threshold. In response, the industry has come up with the alternative of using traceability of lecithin production back to its non-GM source. The market price of IP soy lecithin is significantly higher than the non-IP alternative.

2.3 Labeling of Genetically Modified Food Products in the United States of America - Mr. David Schmidt

Mr. Schmidt presented the results of a 2014 public perception survey of U.S. consumers regarding the use of technology in food production.

The key results of the survey showed that confidence in the safety of the food chain in the United States remains consistently high, among other results. Overall, consumers in the United States have a positive view of modern agriculture and believe that biotechnology can play a role in improving various aspects of sustainability. They consider the three most beneficial uses of biotechnology for this purpose to be: (i) reducing the use of pesticides, (ii) stabilizing food prices, and (iii) feeding the world's undernourished. Mr. Schmidt noted that health organizations and government agencies in the United States remain the most reliable sources of information regarding food biotechnology, animal biotechnology, and sustainability.

Finally, Mr. Schmidt explained that the labeling of GE-foods in the United States applies when changes in product characteristics arise because of genetic modification, and not because of the method through which they were obtained. Labeling is required when there is unexpected presence of allergens in food products, when levels of toxins naturally present in food are increased, or when changes in composition or nutrient profile occur.

2.4 Labeling of GMO-derived Foods - The Latin American Context - Adriana Castaño

Biologist Adriana Castaño explained that there are two models of GMO labeling: 1) a *mandatory* model based on setting thresholds above which foods must be labeled as transgenic or as containing GMOs; and 2) a *voluntary* model based on risk assessment and the principle of substantial equivalence, which seeks to provide information as to any differences due to genetic modification, but not the method of production or the GMO origin. The European Union, Brazil, and Japan are countries where the mandatory model is applied. The voluntary model is applied in the United States, New Zealand, South Africa, and Colombia. Ms. Castaño clarified that neither one should be considered better, although they do have implications and pose difficulties when put into practice; and neither is absolute, in the sense that both have their labeling exceptions and prescribe situations in which labeling is required and in what fashion.

Ms. Castaño explained that a group of Latin American countries comprised of Brazil, Argentina, Colombia, and Paraguay have more than 15 years of solid experience in importing, growing, and exporting GMOs. These countries have set up biosafety systems operating under the control of competent national authorities with well-defined functions and GMO risk-assessment procedures. They also have GMO-detection laboratories functioning under clear regulations and policies. Conversely, countries like Venezuela, Peru, Chile, and Bolivia are in the process of developing and implementing biosafety systems. In these countries, GMO crops are either banned or their introduction is being analyzed. They do not yet have detection laboratories and are currently developing labeling regulations.

In conclusion, Ms. Castaño stressed that GE-food labeling involves related issues such as biosecurity, detection, government control and surveillance, public perception, traceability, and identity preservation. She recommended that such matters be discussed and settled before starting to regulate and implement mandatory GMO labeling, whatever the position taken by a country.

2.5 Ecuadorian Labeling Regulations for Processed Food Products Derived from Genetic Engineering - María Victoria Córdova Misas

Dr. Córdova presented an overview of the regulatory process in Ecuador. She explained that there had been two steps in developing policy on genetically modified–food labeling, one from July 2000 to September 2013, and another from September 2013 to date.

Ecuador has had rules and regulations on GMO-derived-food labeling since 2000, the first such appearing in the Consumer Protection Organic Act. Article 13 of this act states that if consumer products have undergone genetic manipulation, this should be properly stated in boldface type on the product label. Article 14 of the same body of law provides that, at a minimum, labels should specify if a product has been genetically enhanced.

In turn, the regulations of the Consumer Protection Organic Act issued in 2001 establish that suppliers are obligated to provide adequate consumer information and must therefore state on their labels if a product has been genetically enhanced.

In 2006, Article 151 of the Health Organic Act set forth that products containing genetically modified foods, whether domestic or foreign, must include a clear and visible statement to that effect on their labels.

In 2009, Article 26 of the Food Sovereignty Regime Organic Act provided that products made with transgenic organisms must be labeled in accordance with consumer protection legislation.

In line with this, Ecuadorian Technical Standard NTE INEN 1334-1:2011 "LABELING OF CONSUMER FOOD PRODUCTS," Part 1, in force up until October 13, 2013, provided that if consumer products for the market were obtained or enhanced by means of genetic manipulation, that fact was to be stated on the product label in properly bolded text: "**GENETICALLY MODIFIED FOOD.**" In addition, the standard required that when a transgenic or genetically modified food is used as an ingredient in another foodstuff, this fact must be declared in the list of ingredients, which must show the percentage of the transgenic ingredient.

Up to that time, there had been no standard that set out the circumstances and manner of labeling genetically modified foods, even though there were regulations and even organic laws governing the requirement to label such products.

Thus, in 2013, Technical Standard No. SCPM-2013-001, issued by the Superintendent of Market Power Control, set a milestone in the Ecuadorian legal arena with respect to the labeling of genetically modified products. Resolution No. 13353 was issued on October 4, 2013, and published on October 15 of the same year by the Under Secretariat for Quality of the Ministry of Industries and Productivity. This resolution adopts and makes officially mandatory Amendment 2 to Ecuadorian Technical

Regulation RTE INEN 022 "LABELING OF PROCESSED, PACKED AND PACKAGED FOOD PRODUCTS" and mandates its corresponding consistency with the **Regulations for Labeling Processed Consumer Foods**, as well as with a newly amended version of Ecuadorian Technical Standard INEN 1334-1:2014. These regulatory measures establish the obligatory nature of declaring the transgenic content of industrially processed foods. Consequently, it should be noted that the new legal framework refers to "transgenics," not "genetically modified foods."

The standard in question considers any genetically modified organism whose genetic material has been altered using genetic engineering techniques to be transgenic, and it sets the parameters and conditions for labeling, namely:

> (i) Processed food containing transgenic ingredients must so state on the product's main label panel if and when its transgenic content exceeds 0.9%;
> (ii) If a product ingredient contains transgenic material, the name of the ingredient must be stated followed by the word "**TRANSGENIC**;" and
> (iii) For the purposes of traceability, the manufacturer must ask the supplier to state whether the ingredient is transgenic or not.

Technical Standard SCPM-2013-004 of October 17, 2013, provides that labeling must be in accordance with Ecuadorian Technical Standard RTE INEN 022 "LABELING OF PROCESSED, PACKED AND PACKAGED FOOD PRODUCTS." In keeping with this, Article 22 of the **Regulations for Labeling Processed Consumer Foods** (enacted on August 25, 2014, and last amended on December 16, 2014) provides that the labels for all processed foods for human consumption that contain transgenic material must state "CONTAINS TRANSGENICS."

In view of this – and taking into account that the basis for the rules on labeling foods derived from genetically modified organisms is Ecuadorian Technical Regulation RTE INEN 022 "LABELING OF PROCESSED, PACKED AND PACKAGED FOOD PRODUCTS" – the labeling requirement applies only to processed foods. Moreover, since Ecuadorian regulations and technical standards consider additives to be processed foods, they are also covered under the scope of application.

In addition, on December 26, 2013, the Inter-Ministerial Committee on Quality issued Resolution No. 003-2013 CIMC establishing the guidelines for implementation of traceability as a mechanism for determining whether a product contains GMOs. The resolution further provides that in the case of unlabeled products, the statement must be made on their respective invoices.

In turn, the fourth amendment to Article 5.4.10.1 of Technical Standard 1334-1 "LABELING OF CONSUMER FOOD PRODUCTS" provides that the labels of processed foods containing transgenic ingredients must include the "**CONTAINS TRANSGENICS**" statement in properly bolded text in the main panel, in accordance with the provisions in Annex B of NTE INEN 1334-1, if and when the product's transgenic content exceeds 0.9%. This standard defines transgenic foods as foods derived from recombinant nucleic acid techniques used to form new combinations of genetic material from a set of genes taken from a donor. Transgenic foods may contain genetic elements (i.e., coding and regulation sequences) from any organism (eukaryotic or prokaryotic) and new synthesized *de novo* sequences (Article 4.1.4).

It should be mentioned that the term "genetically modified food" or, more precisely, "food derived from

a genetically modified organism or from a genetically modified crop" is used to denote food that is processed using some raw material derived from a GMO, or that is made up of the GMO itself. In other words, a transgenic food can actually be a fruit or seed that comes directly from a transgenic plant or, as in most cases, a conventionally obtained foodstuff produced with a raw material coming from or originating in a transgenic plant (in the technical field, this second component of the scale is called a *commodity).* Accordingly, after the 2013 reform of the various regulations on GMO labeling, Ecuadorian legislation is not explicit as to which foods are to be labeled; that is, whether the requirement refers to GMO-derived foods, GMO foods, or food with GMO content.

Finally, it is noteworthy that although the National Biosecurity Commission was created by presidential decree in 2002, it was not formally enacted until May 2015, and its responsibilities were only recently specified.

3. QUESTIONS FROM WORKSHOP PARTICIPANTS IN THE THREE CITIES

Coincidentally and repeatedly in the three cities visited, the questions from the audience focused on five key issues:

1. Are foods derived from genetic modification or "transgenics" safe? How can consumers be sure how safe they are?
2. Can horizontal transfer occur? Does this mean that when you feed animal feed containing GMOs or derived from GMOs to an animal, the GMOs will be present in the animal and in any product obtained from it (eggs, milk, etc.)?
3. What avenues of communication or effective campaigns should be pursued or implemented to make consumers aware of the presence of GMOs and their safety?
4. Is traceability essential to labeling? What information should raw-material suppliers furnish?
5. Are the laboratory analyses and certification provided by the supplier enough? Are they reliable?

The speakers responded that, to date, after 15 years of uninterrupted global consumption, *there has not been a single case of adverse health effects* in humans; that many international organizations, academics, regulatory authorities, and independent groups have substantiated the harmlessness and safety of GE foods. The speakers expressed the view that there are many pseudo-scientific studies, or studies having no scientific basis, that have attempted to demonstrate the dangers and risks of genetic engineering. Nevertheless, they have not been authenticated by the scientific and international community.

In reference to traceability and detection analysis, the speakers stressed the fact that analyses must be obtained from certified laboratories with accredited techniques, and these laboratories must be clear as to whether they are to detect the presence or absence of GMOs or some specific events. The assays detect initiation and termination sequences (structural sequences of the inserted gene), and the probability of false positives is very high under improper laboratory sample-taking, preparation, and handling conditions (contamination).

Furthermore, identity-preserved (IP) processes are an important support in meeting established thresholds and providing truthful information. These processes, however, must be based on specific

contracts at each stage of the production chain, because farmers tend to rotate between GM and conventional crops.

During the Guayaquil workshop, an ARCSA official spoke briefly to clarify some of the actions being taken by the institution in response to the regulatory requirements issued in Ecuador. The points reported were:

- The lack of a detection laboratory has made monitoring compliance of transgenic-food labeling a challenge for ARCSA.
- ARCSA has responded to this challenge by working with and under the support of the Coastal Advanced Polytechnic School's Biotechnology Research Center of Ecuador (CIBE). The CIBE laboratory is the designated lab for analyzing samples to detect GMO presence and, working in conjunction, they have been able to implement some detection methodologies.
- ARCSA is working with the newly created National Biosecurity Committee to promote communication between the relevant agencies and improve outreach.
- ARCSA is not against GMOs.

4. CLOSED SESSION WITH THE FOOD INDUSTRY

4.1 Guayaquil

The companies that participated in Guayaquil were mostly from the animal feed, aquaculture feed, and primary sectors. The producers said that, so far, they have not felt any large impact from the transgenic-food-labeling regulations in Ecuador and that, in accordance with current regulations, the aquaculture feed industry has not had to implement labeling.

However, it became evident that it is not yet clear to some attendees whether the regulation also applies to animal feed.

Raw material companies and oil manufacturers have been faced with the fact that their customers are requesting certification as to whether their end products contain GMOs or not. These companies have gone back down the chain and asked their suppliers to provide the supporting documents in response, but have not been able to secure certifications, especially in the case of refined oils. They therefore find traceability to be a complex and very expensive proposition in the GMO chain.

4.2 Cuenca

Food industry attendance in Cuenca consisted of cold meat manufacturers, supermarkets, and a cooking school. A few of the companies wanted to know if the reason for labeling has to do with effects on human health or negative experiences that may have occurred with GE-food consumption.

Participants commented that regulations in Ecuador have affected the perception people have of transgenics, and that this is due to a lack of consumer education when the GM-food-labeling rules were issued. Moreover, it has been difficult for the food industry to comply because there is no laboratory in

Ecuador. Therefore, companies go ahead with analyses at private laboratories, but the information contained in the results is not always clear to them.

In order to comply with regulations, companies in the cold meat sector rely on certification provided to them by the supplier as to the presence or absence of GM material. In some cases, cold meat manufacturers have made adjustments to their formulas or simply declared the presence of GM ingredients, even though there may be no GE content. They also commented that substitution of GMO soy protein with the IP non-GMO variety would be very costly.

4.3 Quito

Food industry attendance in Quito was higher than in the other two cities, with the presence of domestic and transnational corporations and private analytical testing laboratories.

To contextualize the food industry's outlook and its experience in implementing the transgenic-food-labeling regulations, Dr. Germán Romo, an industry expert, gave a presentation on the current situation from the food industry's perspective on behalf of the Pichincha Chamber of Industrialists. Dr. Romo mentioned that the customer service center at the company where he works has not received a single inquiry by consumers in relation to GMOs since the regulation came into force. He emphasized that the company has felt no impact on product prices. In addition, he pointed out that Ecuador relies almost 100% on imports of such products as soybean oil, soy protein isolates, emulsifiers (lecithin), milk enzymes (rennet and others), fructose and glucose syrups, amino acids (lysine and others), gelling and thickening agents, cornstarch, vitamins (B2, B12, C, K), maltodextrin, and mannitol, all of which may be GMO derived.

Dr. Romo reported that the National Association of Food and Beverage Manufacturers and ARCSA held a meeting in 2014 to clarify the interpretation of certain points about the labeling rules. From that meeting they concluded that:

- The 0.9% transgenic content refers to the amount in the end product.
- The statement is to be made when one or a combination of ingredients leads to a level higher than the 0.9% threshold.
- Items that lose the transgenic attribute in the refining or industrialization process are not considered transgenic and are therefore not declared as such. Lecithin and maltodextrin are not transgenics.
- In the contents list, it is only necessary to include a legend next to the name of the transgenic ingredient to identify it.

Dr. Romo said that the labeling approach taken by the food industry is based on the “CONTAINS TRANSGENICS” statement (i) when there are GMOs and the inclusion level is greater than 0.9%; (ii) when there are GMOs, regardless of the level of inclusion; and (iii) when the supplier cannot guarantee the item is GMO free, whether there are GMO ingredients or not.

In conclusion, he said that the government needs to conduct communication campaigns on GMOs, have detection laboratories with accredited and standardized methods of protein and DNA analysis, and an institutional framework for implementing and monitoring the requirement. The food industry, in turn, must identify GMO ingredients; make new registries of their foods with ARCSA, indicating transgenic

ingredients; make adjustments to packaging and labels; and replace inventory on the market.

After Dr. Romo's presentation, the floor was opened up to other participants from the food industry for discussion. Representatives of multinational and transnational corporations and a few domestic companies said that the agreements reached with ARCSA at the 2014 meeting provide considerable clarity, but that they carry no legal weight, since the current legislation does not include them. In general, companies said they prefer to avoid interpretations because severe sanctions like fines and temporary or permanent closures might be imposed, or they run the risk of facing an unfair-competition proceeding before the Superintendent of Market Power Control.

Other companies noted that compliance has not been easy because the response from raw materials suppliers, particularly those dealing in corn- or soybean-derived ingredients, has not been clear, complete, and timely or, on occasion, even forthcoming. On the other hand, the determination of the 0.9% threshold on 100% of the total end product formula is not clear when making the calculation, nor is it clear how to calculate and measure this percentage.

Participants from analysis laboratories said that there is no established rule or standard in Ecuador, that there is no reference material for setting up positive and non-positive controls, and that they do not know of any suppliers for the primers required to run detection analyses.

Finally, the participating companies concluded that communication and outreach activities are needed to teach consumers that what is stated on the label is no indication of GMO safety. They also commented that the impression inside the food industry itself is inconsistent, and there is no consensus on interpreting and applying transgenic-food-labeling regulations. They said they are concerned that this lack of consensus is also the case inside the government itself.

5. CONCLUSIONS AND RECOMMENDATIONS

Rules and regulations regarding transgenic-food labeling currently in effect in Ecuador are not clear to the food manufacturers who have to apply and comply with them. There have been various interpretations among national, multinational, and transnational food and beverage companies, as well as differences between sectors (manufacturers of food for human consumption and animal feed manufacturers).

Experts and food industry participants were in agreement that the statement on GM-food labels should not apply to ingredients, raw materials, processing aids, enzymes, and additives because these are not foods and should not be classified as processed foods, but as components thereof. Food items that lose the transgenic attribute in the refining or industrialization process should be considered GMO-derived products or foods and should therefore not have to be declared.

Currently, the "CONTAINS TRANSGENICS" statement in the main panel does not fulfill its purpose, since many manufacturers – out of lack of knowledge, the inability to ensure the supply chain, or failure to obtain certification from the supplier when the product contains GMOs, regardless of the degree of inclusion – declare it to avoid ending up in an administrative action before the Superintendent of Market Power Control, or being fined or penalized pursuant to the Health Organic Act.

The various stakeholders involved (academia, consumers, industry, importers, and researchers, etc.) should be allowed to contribute to the development of a sound and reliable biosafety system and to guide its activities regarding GMOs in the country.