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Report Highlights:

Saudi regulations allow the importation of biotech plant products. However, they are required to be labeled if they contain more than one percent genetically engineered (GE) plant ingredients, and importers of retail food product do not import biotech foods due to concerns that biotech labeling could jeopardize their product image. Saudi Arabia imports large quantities of biotech U.S. corn, soybeans, and their products. In 2003, the Grain Inspection, Packers and Stockyards Administration (GIPSA) issued a certificate that meets Saudi and Gulf Standardization Organization (GSO) requirements. Saudi and GSO regulations prohibit the importation of genetically modified animals, birds, fish and their products. Importation of biotech planting seeds is permitted, but Saudi companies have not done so. Currently, there are no ongoing commercial development activities for GE plants in Saudi Arabia.

EXECUTIVE SUMMARY

The Kingdom of Saudi Arabia (KSA) follows two GSO issued mandatory agricultural biotechnology regulations - GSO 2141/2011 “General Requirements for Genetically Modified Unprocessed Agricultural Products” and GSO 2142/2011 “General Requirements for Genetically Modified Processed Agricultural Products”. The two technical regulations require positive biotech labeling if unprocessed agricultural products, processed food products, feed products or seeds contain more than one percent genetically engineered (GE) plant ingredients. GSO 2141/2011 prohibits the importation of genetically modified animals, birds, fish and their products.

The 2011 GSO regulations superseded the Saudi Ministry of Commerce and Industry’s (MOCI) December 2001 ministerial decree, in which Saudi Arabia became the first GCC country to regulate biotech food imports. (MOCI was renamed the Ministry of Commerce and Investment [MCI] in 2016). The December 2001 MOCI decree required positive biotech labeling if a processed food product or animal feed contained more than 0.9 percent GE vegetable (plant) ingredients.

Since Saudi Arabia’s implementation of MOCI’s ministerial decree on processed biotech food labeling regulations in 2001, no retail packed food products with positive biotech labeling have been imported into the Kingdom. Saudi retail food importers do not import biotech foods due to concerns that biotech labeling could jeopardize their product image and result in their losing market share. On the other hand, Saudi Arabia has imported biotech feed grains such as corn and soybean meal for decades.

Although Saudi Arabia has adopted regulations which allow the importation and planting of biotech seeds under strict conditions, Saudi farmers have not shown an interest in importing and planting biotech seeds. Although the regulations allow the importation of biotech planting seeds, no Saudi companies have imported any.

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PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) Product development:

There is no ongoing development of GE plants in Saudi Arabia.

b) Commercial production:

Although Saudi Arabia has implemented the 2011 GSO biotech regulations, which allow the importation and planting of biotech seeds under strict conditions, so far Saudi farmers have not shown interest in importing and planting biotech seeds.

c) Exports:

Not applicable

d) Imports

According to official trade data, U.S. agricultural and food exports to Saudi Arabia in 2017 reached approximately \$1.50 billion (FOB value), an increase of three percent compared to 2016. U.S. exports of consumer-oriented food products to Saudi Arabia increased by approximately 7 percent from \$507.1 in 2016 to \$540.4 in 2017. Major U.S. exports of bulk and intermediate products to Saudi Arabia included corn, corn oil, rice, soybeans, and soybean meal and valued at approximately \$266.4 million, \$95.8 million, \$88.2 million, \$87.6 and \$81.6 million, respectively. Even though Saudi Arabia began implementing agricultural biotech labeling in 2001, the labeling requirement has not affected imports of biotech agricultural products such as feed grains as all imported corn and soybean/soybean meal are for animal feed. However, no retail packed food products with positive biotech labeling have been imported into the Kingdom to date. In general, Saudi importers of retail-packed food products do not import foods with GE content over 1 percent—as it requires labeling. They are concerned that biotech labeling could jeopardize their product image and result in losing market share, since Saudi consumers have limited knowledge about agricultural biotechnology. Locally produced food products that use imported biotech oil, corn or soybean by-products are not labeled for biotech contents.

Saudi Food and Drug Authority (SFDA) inspects imported high-value food products and processed feed at Saudi ports of entry. Inspections of unprocessed animal feed, planting seeds, fruits, and vegetables are the responsibilities of the Ministry of Environment, Water and Agriculture (MEWA).

e) Food aid:

Saudi Arabia is neither a recipient nor donor of Food Aid.

f) Trade barriers

GE labeling discourages the importation of retail-packed food products due to concerns by importers that biotech labeling could jeopardize their products image and result in losing market share. Saudi consumers have limited knowledge about agricultural biotechnology.

PART B: POLICY

a) Regulatory framework:

In February 2005, the Saudi government established a National Committee for Biotechnology (NCB) that was headed by the Saudi Arabian Standard Organization (SASO) and included members from four ministries (Agriculture, Commerce, Health, and Municipalities) as well as several members from Saudi universities and private sector. This committee, which is now headed by SFDA, is responsible for reviewing government policy concerning biotech activities and standards in the Kingdom.

In June 2011, SFDA assumed the responsibility of setting food and agricultural regulations and standards from the SASO. Since then, the SFDA has represented the country in GSO meetings to help set the GCC food and agricultural regulations and standards. As mentioned earlier, in October 2011, the Saudi biotech decrees were replaced by the GSO agricultural biotech technical regulations (GS 2141 and 2142). It should be noted that the GSO biotech labeling requirements, to a large extent, are very similar to the old Saudi biotech requirements which were replaced effective October 2011.

The regulatory framework of the Saudi NCB is mostly based on the Cartagena Protocol on Biosafety. The NCB has finalized the country's biosafety framework, laws, regulations, guidelines and mechanism of implementation, which are currently waiting for the government approval for implementation.

The NCB has been working with MEWA to ensure that biotech animal feed grain imports are safe for human and animal health and do not have adverse effects on biological diversity.

Until the end of 2011, Saudi Arabia was the only GCC country that regulated imports of processed and unprocessed biotech agricultural products. MCI and MEWA implemented GE decrees on processed foodstuffs and animal feed - issued in January 2001 and December 2004, respectively. The decrees mandated positive biotech labeling if a product contained more than 0.9 percent of biotech vegetable (plant) ingredients.

In October 2011, Saudi Arabia implemented two new GSO agricultural biotech technical regulations GSO 2141/2011 (General Requirements for Genetically Modified Unprocessed Agricultural Products) and GSO 2142/2011 (General Requirements for Genetically Modified Processed Agricultural Products). These technical regulations updated and replaced the old Saudi

agricultural biotech labeling decrees. The GSO regulations increased the biotech threshold level from 0.9 percent to one percent, and rescinded the ban on imports of biotech planting seeds. The GSO biotech regulations stipulate the import requirements for food products produced through agricultural biotechnology if the biotech content is higher than one percent. The regulations allow imports of plant biotech agricultural products as long as they are approved in the country of origin for human or animal consumption or planting.

b) Approvals:

Saudi Arabia does not approve individual biotech events. If imported food, feed, or seed contains more than one percent biotech content, each shipment must be accompanied by a health certificate issued by a competent government agency stating that the GE ingredient (s) used in the foodstuff or grains is/are approved in the country of origin for human or animal consumption or for planting seeds. For U.S. corn, soybeans and soybean meal, the MEWA still accepts the one-time biotech grain certification statement that was issued in 2003 by the USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA). The statement certified that the exported transgenic feed grains and oilseeds (corn, soybean, and soybean meal) are the same as those consumed in the United States. The approved statement eliminates the need for a shipment-by-shipment positive biotech certification for unprocessed agricultural products that is required in section 4.1.5 of the GSO 2141/2011. SFDA accepts health certificates issued by FDA, federal or state departments of agriculture for high value and processed feed products containing more than one percent biotech level. Post has not received any complaints from Saudi food products importers about the ability of U.S. suppliers to provide required biotech certificates. Biotech health certificates issued by exporting companies or other private organizations, including notary public statements, are not recognized.

c) Stacked or pyramided event approvals:

Stacked or pyramided events are not treated separately. They are covered by the product approvals as outlined above.

d) Field testing:

Saudi Arabia allows the importation and planting of GE seeds under strict conditions, however, Saudi farmers have not shown interest in importing and planting GE seeds.

e) Innovative biotechnologies:

Not applicable.

f) Coexistence:

Not applicable

g) Labeling:

If a product contains one or more GE plant ingredients with more than one percent GE content, the words (genetically modified) or (produced from genetically modified [name of the ingredient(s)]) shall appear clearly and easily to read in parentheses immediately following the ingredient(s) concerned, with same font size and different color. The GSO biotech regulations do not allow import of foodstuff that contains GE animal products. According to the SFDA, local food producers must also abide by the biotech labeling requirements.

Labeling and adjoining explanatory statements shall be in Arabic and, where another language is used, it shall be alongside the Arabic. All information that is provided in another language shall be identical with those written in Arabic. The biotech statement must be clearly written in Arabic and English in the same font size and a different color from that of the main product label.

If the GE food product is different from its conventional counterpart, the labeling shall mention any characteristic or property concerning the following:

- Composition
- Mode of storage and packing
- Nutritional value or nutritional effects
- Intended use of product.
- Any health implications on certain group of people, or certain animals or the environment.
- Physical characteristic (color, taste, odor, and the touch).
- Methods for the safe handling, storage, transport and use.

If the food product does not have a conventional counterpart, the labeling shall contain appropriate information about the nature and characteristics of the food product concerned.

If the mode of storage, preparation or cooking of the product is no longer equivalent to or differs significantly from the corresponding conventional food, clear instructions for use must be given on the label of the product.

h) Monitoring and testing:

The GSO has adopted six ISO standards on methods of analysis for the detection of genetically modified organisms and derived products in its original language. The GSO has also adopted three Codex standards for its risk analysis and safety assessment of foods derived from agricultural biotechnology. The Appendix section of this report lists all GSO, ISO and Codex biotech regulations and standards implanted in the seven GSO member countries.

In 2009, SFDA took over the responsibilities of inspecting imported as well as domestically produced processed food, feed and feed concentrates. MEWA is responsible for inspecting imported fruits, vegetables, planting seeds and unprocessed animal feed.

SFDA randomly tests new to market processed foods for biotech contents using the Polymerase Chain Reaction (PCR) Real Time Method for random GE testing in processed food products. Samples for laboratory analysis are taken according to GSO ISO standards numbers 21098, 21569, 21570, 21571, 21572 and 24276. Food product importers are required to declare biotech levels of more than 1 percent and should provide the competent authority an attested certificate indicating the biotech ingredient(s) is used in foods consumed in the country of origin.

i) Low Level Presence (LLP) Policy

KSA does not approve or disapprove biotech vegetable products varieties by event but accepts those approved by supplying countries for human or animal use. This policy therefore prevents potential LLP issues.

j) Additional Regulatory Requirements:

Mandatory Requirements for GE Unprocessed Agricultural Products for Human Consumption:

- If the products are sold in the market by weight, number or volume, the products should be kept in separate places and isolated from the conventional products.
- The product should have a clearly defined and difficult to eliminate label or printed card placed on a suitable place on the specified food stating that “this product is genetically modified using biotechnology”
- It should not be used for agricultural purpose or for any kind of plant propagation.
- It should comply with the GSO traceability and risk assessment requirements.

Mandatory Requirements for GE Unprocessed Agricultural Products for Animal Feed Use:

- It is prohibited to be used in human food.
- It should be placed on the market in a separate location and isolated from conventional product. The product should have a clearly defined and difficult to eliminate label placed in a suitable location on the specified feed stating that “this product is genetically modified using biotechnology”.
- The label should also state that “this product is not for human consumption or for agricultural use.” That means it cannot be used for planting purpose.
- It should not be used for agricultural purpose or for any kind of plant propagation.

Mandatory Requirements for GE Planting Seeds:

- The seed import process should not contradict with regulations of the competent authorities in the importing countries, particularly with regards to plant diseases, harmful weeds, narcotic plants, germination, purity and humidity percentages.
- Written permission should be obtained from competent authorities at least ten days before the arrival of the consignment.
- All chemicals and their concentrations used in the treatment of the seed must be declared.
- The GE planting seed should be treated with different color for easy differentiation from the conventional counterparts.
- The final user adheres to agricultural planting land surveyor rules and guarantees not to mix with the non GE seeds.
- If the GE planting seed does not have a conventional counterpart, the label or the accompanying documents shall contain appropriate information about its nature and characteristics.
- The product must have a clearly written, easy to read and difficult to remove label stating that the product is for agricultural use and not for human and animal consumption.
- Should provide information on the manner of safe handling, storage, transport and use.
- Should comply with the GSO traceability and risk assessment for the GE unprocessed agricultural products for agricultural use according to item 2.16 (GSO 2143/2011).
- Sampling shall be taken according to standards numbers GSO ISO 21098, 21569, 21570, 21571, 21572 and 24276 and sampling stated in the GSO standard for each product.

Mandatory requirements for GE Processed Food and Feed, as specified in the GSO 2142/2011:

- Must be compatible with the ethical regulation applied in the importing country.
- No adverse effects on human health, animal health, plant health or the environment.
- Should not differ from the product which is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for humans or animals.
- The product must be accompanied with a certificate proving that it is allowed to be consumed in the country of production.
- Must declare the presence of any food or food ingredients obtained through certain techniques of genetic modification or genetic engineering of an allergen transferred in any foods or ingredients.

k) Intellectual Property Rights (IPR):

Saudi Arabia does not have IPR regulations that govern agricultural biotechnology products. However, the general Saudi IPR rules are applicable to any violations of IPR including biotech agricultural products. The link provides information on the current Saudi Arabia IPR regulations.

<https://mci.gov.sa/en/ServicesDirectory/Pages/Services.aspx?Category=Trade%20Marks>

i) Cartagena Protocol Ratification:

Saudi Arabia ratified the Cartagena Protocol on Biosafety in August 2007. It is reported that Saudi Arabia is considering signing the Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

j) International Treaties/Fora:

Saudi Arabia is a member of international agricultural products standards setting organizations, such as Codex Alimentarius (Codex), the International Organization for Standardization (ISO), the World Organization for Animal Health (OIE), and the World Trade Organization's (WTO) TBT and SPS Committees. It regularly attends meetings of these organizations and does not often take positions until international consensus are reached. In general, the Saudi and the GSO agricultural biotech regulations and standards are based on Codex and ISO standards.

k) Related Issues:

Not applicable

PART C: MARKETING

a) Public/Private Opinions:

Local newspapers have published articles about agricultural biotechnology that focused mostly on the alleged negative impact of biotech products on human health and the environment. Some articles, taken from European newspapers and mostly written by Greenpeace and other anti-agricultural biotechnologies groups, were re-published in Saudi newspapers. Government agencies and agricultural research centers have not initiated media campaigns to provide unbiased information on biotech food to the public. The SFDA has made it clear on several occasions that the primary reasons for requiring labeling of biotech foods is the consumers' right to know. Consequently, importers have been asking their U.S. suppliers to put the biotech free symbol on product labels to match initiatives taken by many European suppliers. Shoppers in local supermarkets can now find many American and European foodstuffs with biotech free labels as food products with less than 1 percent GE content are considered biotech free.

b) Market Acceptance/studies:

Since the establishment of biotech labeling requirements in Saudi Arabia in 2001, no GE retail packed food products have been imported into the country. Major Saudi food importers do not import food products derived in part from genetic engineering and therefore do not put biotech labels on their products. They are concerned that dealing with biotech products could jeopardize their product image and result in losing market. Saudi consumers have limited knowledge about agricultural biotechnology and, in general, hold negative attitude towards biotech products. On the other hand, some European, Asian and local food producers put the biotech free symbol on their product labels to promote their products.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

There is no ongoing development of GE animals in Saudi Arabia.

b) COMMERCIAL PRODUCTION:

Not applicable

c) EXPORTS:

Not applicable

d) IMPORTS:

Section 4.1.7 of GSO 2141/2011 prohibits imports of any GE animals, birds, fish and their products to all member countries (Saudi Arabia, UAE, Kuwait, Oman, Qatar, Bahrain and Yemen).

e) TRADE BARRIERS:

Saudi Arabia is a member of the GSO – which bans imports of GE animals and animal products.

PART E: POLICY

a) REGULATORY FRAMEWORK:

Section 4.1.7 of GSO 2141/2011 prohibits imports of any GE animals, birds, fish and their products to all member countries (Saudi Arabia, UAE, Kuwait, Oman, Qatar, Bahrain and Yemen).

b) INNOVATIVE BIOTECHNOLOGIES:

Not applicable

c) LABELING AND TRACEABILITY:

Not applicable

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Not applicable

e) INTERNATIONAL TREATIES and FORUMS:

The Kingdom is an active member of OIE

f) RELATED ISSUES:

Not applicable

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Saudi public is opposed to GE animals and animal products for religious reasons.

b) MARKET ACCEPTANCE/STUDIES:

Not applicable

APPENDIX

GSO has issued the following GSO, ISO and Codex technical regulations and standards related to agricultural biotechnology production and trade for implementation in the seven member countries, Saudi Arabia, United Arab Emirates, Kuwait, Qatar, Oman, Bahrain and Yemen. The copyrighted documents can be purchased by logging into the following link:

<https://www.gso.org.sa/store/?lang=en>

- GSO 2141:2011: General Requirements for Genetically Modified Unprocessed Agricultural Products
- GSO 2142 :2011: General Requirements for Genetically Modified Processed Food and Feed
- GSO 2143:2011: General requirements for risk assessment and traceability for genetically modified products
- GSO ISO 21569:2008: Foodstuffs-Methods of analysis for the detection of genetically modified organisms and derived products-Qualitative nucleic acid based methods
- GSO ISO 21570:2009: Foodstuffs-Methods of analysis for the detection of genetically modified organisms and derived products-Quantitative nucleic acid based methods issued by (International Organization for Standardization) in its original language.
- GSO ISO 21571:2008: Foodstuffs-Methods of analysis for the detection of Genetically modified organisms and derived products-Nucleic acid extraction.
- GSO ISO 21572:2008: Foodstuffs-Methods for the detection of genetically modified organisms and derived products-Protein based methods
- GSO ISO 24276:2007: Food stuffs-Methods of analysis for the detection of genetically modified organisms and derived products-General requirements and definitions.
- GSO CAC/GL 44:2009: Principles for the risk analysis of foods derived from modern biotechnology issued by (Codex Alimentarius Commission) in its original language.
- GSO CAC/GL 45:2009 Guideline for the conduct of food safety assessment of foods derived from recombinant-dna plants.
- GSO CAC/GL 46:2009: Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms.
- GSO ISO/TS 21098:2009: Foodstuffs-Nucleic acid based methods of analysis of genetically modified organisms and derived products-Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571 issued by (International Organization for Standardization) in its original language.