USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 6/24/2014
GAIN Report Number: SA1408

Saudi Arabia

Agricultural Biotechnology Annual

2004

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Report Highlights:

There are no significant biotechnology activities reported in Saudi Arabia in 2013/14. In October 2011, Saudi Arabia started the implementation of the Gulf Standardization Organization's (GSO) technical regulations on imported genetically engineered (GE) agricultural products. The GSO technical regulations call for biotech labeling, if the GE contents in the processed or unprocessed agricultural products exceeds one percent. Prior to the adoption of these GSO biotech regulations, Saudi Arabia was implementing its own requirements for labeling food and animal feed products that tested positive for GE contents of more than 0.9 percent. Although the GSO regulations allow for the importation of biotech planting seeds, no Saudi companies have expressed any interest in importing biotech seeds. Saudi Arabia is reportedly ready to sign the Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

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Section I. Executive Summary:

Currently, there are no ongoing GE plant development activities in Saudi Arabia. Although Saudi Arabia has adopted the Gulf Standardization Organization (GSO) biotech regulations which allow the importation and planting of biotech seeds under some strict conditions, Saudi farmers have not shown any interest in importing and planting biotech seeds. Saudi Arabia's government has established a national high-level committee for agricultural biotech which is headed by the Saudi Food and Drug Authority (SFDA) and includes members from four other ministries (Agriculture, Commerce, Health and Municipalities) as well as several members from Saudi universities and the private sector. Saudi Arabia has also established a National Biosafety Committee (NBC) which is located at King Abdul Aziz City for Science and Technology (KACST) and includes members from several Saudi ministries and government agencies. The framework of the NBC is based on the Cartagena Protocol on Biosafety, which was ratified by Saudi Arabia in August, 2007. The NBC has finalized a draft of national biosafety rules which is waiting for the Saudi government review and approval. The NBC has been working with the Saudi Ministry of Agriculture (MOA) to ensure that imports of biotech animal feed products are safe for both human and animal health and do not have adverse impact on the biological diversity. The Saudi government is considering the signing of the Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

The GSO is a regional organization made up of seven national standards bodies of the Arabian Gulf countries that includes the United Arab Emirates, Saudi Arabia, Kuwait, Bahrain, Oman, Qatar and Yemen. On April 12, 2011, the GSO issued two mandatory agricultural biotechnology regulations numbers, GSO 2141/2011 (General Requirements for Genetically Modified Unprocessed Agricultural Products) and the GSO 2142/2011(General Requirements for Genetically Modified Processed Agricultural Products). The GSO 2412/2011 specifies general requirements for genetically modified for processed food and feed products. The two technical regulations require positive biotech labeling if unprocessed agricultural products, processed food product, feed products or seeds contains more than

one percent of GE ingredients.

Saudi Arabia was the leading GCC member in preparing the draft standards for the two GSO biotech regulations and the first country to effectively implement the regulations in October 2011. With more than a decade of experience implementing similar regulations for dealing with both processed food and feed products, it was relatively easy for Saudi Arabia to implement the GSO technical GE regulations. These technical regulations updated and replaced an old Saudi agricultural biotech labeling decree to increase the threshold level for biotech components from 0.9 percent to one percent, and rescinded the ban on imports of biotech planting seeds according to specifications outlined in GSO 2141/2011. However, no biotech planting seeds have been imported thus far into Saudi Arabia. As the case with the Saudi biotech regulations, the GSO 2141/2011 regulation prohibits the importation of any genetically modified animals, birds, fish and their products.

Since Saudi Arabia's implementation of its processed food biotech labeling regulations in 2001, no retail packed food products with positive biotech labeling have been imported into the Kingdom to date. 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 shares, given that Saudi consumers have limited knowledge about agricultural biotechnology. On the other hand, Saudi Arabia has been importing biotech feed grains such as corn and soybean meal from the U.S. and other suppliers for a long time. In 2013, U.S. exported about $1.2 billion worth of food and agricultural products to Saudi Arabia. These imports included soybeans, soybean meal, corn and corn oil that were valued at $113 million, $28 million, $95 million and $115 million, respectively. SFDA inspects imported high value food products and processed feed at the Saudi ports of entry. Inspections of unprocessed animal feed, planting seeds, fruits, and vegetables are the responsibilities of the MOA.

Section II. PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

a. **Product Development:**

There are no GE plant development projects in Saudi Arabia.

Commercial Production:

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

b. **Exports:**

Not applicable.

c. **Imports:**

Saudi Arabia imports GE grain products such as corn, soybeans and soybean meal from the U.S. In 2013, U.S. exported about $1.2 billion worth of food and agricultural products to Saudi Arabia. These imports included corn, soybeans and soybean meal valued at $95 million, $112 million and $27 million, respectively. No retail packed food products with positive biotech labeling have been imported into the Kingdom so far from any country. In general, Saudi importers of retail-packed food products do not import biotech foods. They are concerned that biotech labeling could jeopardize their product image and result in losing market shares, since Saudi consumers have limited knowledge about agricultural biotechnology.

d. **Food Aid recipient Countries:**

Not applicable.

Part B: Policy

a. **Regulatory Framework:**

In February 2005, the Saudi government established a national high-level committee for biotech 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 the SFDA, is responsible for reviewing the government policy concerning biotech activities and standards in the Kingdom.

In June 2011, the SFDA assumed the responsibility of setting food and agricultural regulations and standards from the SASO. Since then, the SFDA represents the country in the 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 NBC is mostly based on the Cartagena Protocol on Biosafety. The NBC 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 NBC, however, has in place a domestic regulatory framework to regulate LMOs until the biosafety framework is approved.

The NBC has been working with the MOA to ensure that biotech animal feed grain imports are safe for human and animal health and do not have adverse effects on biological diversity. It is reported that Saudi Arabia is considering signing the Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

b. **Approvals:**

Until recently, Saudi Arabia was the only GCC country that has been regulating the imports of processed and unprocessed biotech agricultural products. The Ministry of Commerce (MOC) and the MOA implemented their GE decrees on processed foodstuffs and animal feed that were issued in January 2001 and December 2004, respectively. The decrees mandated positive biotech labeling if a product contains 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 have 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 unprocessed and processed food products obtained through agricultural biotechnology if the biotech content is higher than one percent. The regulations allow imports of plant biotech unprocessed and processed agricultural products as long as they are approved in the country of origin for human or animal consumption or planting.

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 MOA 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. Biotech health certificates issued by exporting companies or other private organizations, including notary public statements are not recognized.

c. **Field Testing:**

Not applicable

d. **Stacked Event Approvals:**

Not applicable.

e. **Additional Requirements:**

Mandatory requirements for GE unprocessed agricultural products for human consumption:

- If the products are sold in the market by weight, number or volume, 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 of 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 or other agricultural purpose or for any kind of plant propagation.
- It should be placed on the market in separate places and isolated from the conventional product. The product should have a clearly defined and difficult to eliminate label placed on a suitable place of 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."
- It should not be used for agricultural purpose or for any kind of plant propagation.

Mandatory Requirements for GE Planting Seeds:

- The seeds 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.
- The final user adheres to an autonomic harvesting.
- 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, easily 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 compliance 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 diverse effects on human health, animal health, plant health or the environment.

- Should not be differ from the product, which it 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.

a. **Coexistence:**

- The GE planting seed should be treated with different color for easy differentiation from the conventional counterparts.

- Farmers who plant biotech seed must adhere to agricultural planting land surveyor rules and guarantees not to mix GE seeds with conventional seeds.

- The final user adheres to an autonomic harvesting of biotech crops.

b. **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 ingredients) 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 imports of foodstuffs that contain 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 languages, in the same font size and 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 implication 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, a clear instructions as to how to use must be given on the label of the product.

c. **Trade Barriers:**

Even though Saudi Arabia has been implementing agricultural biotech labeling since 2001, the labeling requirement has not affected its imports of biotech agricultural products.

d. **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. http://www.kacst.edu.sa/en/innovation/patents/pages/regulations.aspx

e. **Cartagena Protocol Ratification:**

Saudi Arabia ratified the Cartagena Protocol on Biosafety in August, 2007.

f. **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 (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 partly based on Codex and ISO standards.

g. **Related Issues:**

Not applicable

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. Appendix section of this report lists all GSO, ISO and Codex biotech regulations and standards implanted in the seven GSO member countries.

The responsibilities of inspecting the processed food and animal feed products was passed to SFDA starting in 2009, when SFDA took over the responsibilities of inspecting imported as well as domestically produced biotech processed food. In 2004, the MOA implemented a similar decree that regulated the importation of feed grains (processed and unprocessed). The MOA has plans to transfer the responsibilities of inspected imported fruits, vegetables, planting seeds and unprocessed feed to SFDA. No exact date has been set to when these responsibilities will be transferred from the MOA to the SFDA. It should be noted the SFDA has already started inspecting processed feed and feed concentrates at the Saudi ports of entry.

Saudi Arabia implements Polymerase Chain Reaction (PCR) Real Time Method for GE testing. Samples for laboratory analysis are taken according to GSO ISO standards numbers 21098, 21569, 21570, 21571, 21572 and 24276.

i. **Low Level Presence Policy:**

Not applicable

Part C: Marketing

a. **Market Acceptance:**

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 biotech food products and 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 shares. 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.

b. **Public/Private Opinions:**

Over the past years, there have been several articles published in local newspapers about agricultural biotechnology that focused mostly on the alleged negative impact of biotech products on human health

as well as on the environment. Some articles published from European newspapers, mostly written by the Green Peace Movement and other anti-agricultural biotech groups, were re-published in Saudi newspapers. No government agencies or agricultural research centers have initiated any favorable media campaign 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 are 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.

c. **Marketing Studies:**

Not applicable

Part D: Capacity Building and Outreach

a. **Activities:**

In June 2008, FAS Riyadh helped recruit several high level GCC food safety officials to visit the United States for a series of biotechnology meetings and informational exchanges with regulatory officials and private industry. In October 2008, FAS Riyadh and the GSO organized the first joint three-day biotech seminar in Dubai, U.A.E. focusing on the importance of science-based protocols to assess risk for agricultural biotechnology. While the USDA provided six biotech experts to speak and pay for their travel costs, the GSO paid for costs related to organizing the seminar. About 100 Gulf food safety and standard officials attended the seminar. The conference created a forum where U.S. and international views on various policy aspects of agricultural biotechnology were heard and discussed. The seminar has helped the GSO biotech committee in reviewing its biotech draft standards and issuing science-based biotech standards that will govern imports of agricultural products to the six GCC member countries.
The SASO and the MOA have participated in many USDA sponsored biotech education trips to U.S. as well as USG or USGC funded regional workshops, in Dubai, Cairo and Tunis.

b. **Strategies and Needs:**

Not applicable

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Not applicable

Part E: Production and Trade

a. **Product Development:**

Not applicable

b. **Commercial Production:**

Not applicable

c. **Exports:**

Not applicable

d. **Imports:**

In December 2001, Saudi Arabia banned the imports of food products that contain any GE animal ingredients. This ban was strengthened by the GSO 2141/2011, which prohibits import of any GE animals, birds, fish and their products. The ban includes cloning and imports of livestock clones or products from cloned animals including genetics (semen and embryos).

E. Capacity Building and Outreach

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:

http://www.gso.org.sa/standards/public/standardsList.seam

- GSO 2141:2011: General Requirements for Genetically Modified Unprocessed Agricultural Products (The Draft Technical regulation has been prepared by Kingdom of Saudi Arabia)
- GSO 2142 :2011: General Requirements for Genetically Modified Processed Food and Feed (The Draft Technical regulation has been prepared by Kingdom of Saudi Arabia)
- 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.