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Report Highlights:

In recent years, Saudi Arabia has published several new announcements, regulations, and standards at an extremely rapid pace. This year, Saudi Arabia issued a plethora of draft regulations to the World Trade Organization (WTO), including registration and recognition requirements for competent authorities of food exporting countries, registration and listing requirements for exporters of various food products, and re-notified the current voluntary Front of Pack Nutritional Labeling (with the aim of converting it to a mandatory regulation). Saudi Arabia also published Guidelines for Marketing Requirements of Food Directed to Children. It is FAS/Riyadh's perspective that more restrictive regulations will follow over the next several years.

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EXECUTIVE SUMMARY

The United States annually exports more than \$1.5 billion (USD) of agricultural and related products directly and indirectly to the Kingdom of Saudi Arabia. Saudi Arabia is reliant on imports to meet up to 75 percent of its food consumption needs, and U.S. retail food exports to Saudi Arabia have grown rapidly over the past several years. In 2021, retail food exports are projected to reach more than \$570 million, which is nearly 47 percent of total U.S. agricultural and related product exports to Saudi Arabia.

The Saudi Food and Drug Authority (SFDA) is the Saudi government entity that sets and enforces regulations and standards related to processed food, seafood, fresh produce, and processed animal feed. In recent years, SFDA has been issuing new announcements, regulations, and standards at an extremely rapid pace. This year SFDA issued several draft regulations to the World Trade Organization (WTO) for public comments including draft regulations on registration and recognition requirements for competent authorities of food exporting countries, registration and listing requirements for exporters of various food products, re-notified the current voluntary Front of Pack Nutritional Labeling (FOPNL) with the aim of converting it to mandatory regulation, and Guidelines for Marketing Requirements of Food Directed to Children.

Some recent regulations have dealt with food additives (additives permitted for use in food Stuffs -SFDA.FD 2500/2021) a comprehensive 373- page technical regulation that lists all allowed food additives, including food coloring. This regulation could be a good reference for U.S. exporters of processed food products suppliers as it lists allowed food coloring. One of the artificial food colorings eliminated from the allowed list is Tartrazine, or E102, which has caused rejections of some U.S. food products at Saudi ports of entry. Another recently updated and broad technical regulation implemented in Saudi Arabia, and other Gulf Cooperation Countries (GCC) as well as Yemen, is the Gulf Standardization Organization (GSO) number 193:2021. This regulation deals with contaminants and toxins in food and feed.

Over the past few years, issues with implementation of existing regulations have closed or threatened to close the market for several U.S. products. At the end of 2018, SFDA abruptly introduced new facility registration and certification requirements for eggs, egg products, and seafood, which immediately stopped shipments of those products from several countries, including the United States. Requirements were loosened for a few months in early 2020 due to the COVID-19 outbreak to help the country's food supply but were instantly reapplied once domestic supplies blossomed. U.S. poultry meat has been absent from the Saudi market since SFDA implemented its ban on electric immobilization in the poultry slaughtering process at the end of May 2018. U.S. seafood is expected to return to the Saudi market early in 2022 due to resolution of a facility registration requirement between USG and SFDA. FDA is the U.S. competent authority for food safety of seafood, honey, and bee products. To facilitate U.S. exports of these products, FDA has updated the Export Listing Module (ELM) allowing U.S. establishments to request FDA certification for inclusion on SFDA's lists of approved establishments. U.S. establishments are eligible for listing if they are in substantial compliance with applicable FDA requirements for the products intended for export. For ease of reference, FDA refers to the Saudi Arabia lists, Saudi Arabia honey and bee products export list and the Saudi Arabia seafood export list, for these products. More information on the requirements may be found at *this link*.

SECTION I. FOOD LAWS

SFDA was formed in 2009 and is the Saudi government agency responsible for establishing regulations and standards concerning food and animal feed. It is also responsible for the inspection of both domestically produced and imported food products. The Saudi Food Act states that "Imported food shall not be released prior to SFDA's approval as laid down by the regulations, policies, and procedure. SFDA shall be responsible for the developing regulatory bylaws for controlling the clearance process of foodstuff intended for importation into the Kingdom of Saudi Arabia. Countries exporting their products to the Kingdom of Saudi Arabia shall comply with the import conditions and requirements issued by SFDA." SFDA determines if imported products meet all the standards and regulations established by Saudi Arabia and the Gulf Standardization Organization (GSO), which is the standards setting agency of the Gulf Cooperation Council (GCC) and Yemen. SFDA is an autonomous entity controlled by a Board of Directors, and its chairman is appointed by Royal Decree. The current Chairman of the Board is the Minister of Health. The Board of Directors reports directly to the King of Saudi Arabia, and SFDA board of directors consists of:

- The Chairman of the Board of Directors
- Governor of the General Authority for Standards, Metrology and Quality
- Executive President of SFDA
- A representative from the Ministry of Interior
- A representative from the Ministry of Health
- A representative from the Ministry of Trade and Investment
- A representative from the Ministry of Finance.
- A representative from the Ministry of Environment, Water and Agriculture
- A representative from the Ministry of Education
- A representative from the Ministry of Municipal and Rural Affairs
- A representative from the Ministry of Economy and Planning
- A representative from the Ministry of Energy, Industry and Mineral Resources
- Four representatives from the Council of Saudi Chambers
- Two technical experts related to SFDA areas of responsibility

SFDA's primary regulations (the Saudi Food and Animal Feed Acts) were issued and implemented in 2016. The Saudi Food Act covers all stages of the food chain to ensure food safety, quality improvement, and the protection of consumer health by minimizing food-related risks. The Saudi Feed Act applies to all stages of the feed chain to guarantee animal feed safety. Its purpose is to safeguard human health from harmful substances resulting from feeding animals' unsafe feed. Both imported and domestically produced food and feed products are subject to the same food safety regulations and labeling requirements.

The SFDA's Operations Sector inspects imported foods and processed feed products at the ports of entry, and mostly conducts tests on imported as well as domestically produced foods, processed feed and animal products at its own laboratories. However, it uses other government agencies' laboratories or accredited domestic private laboratories when needed.

All food, drinks, and edible agricultural products are required to comply with regulations and standards set by the SFDA, or the GSO, and includes food ingredients and processed animal feed. Two SFDA "sectors" (Food and Operations) affect trade in food. The Food Sector is primarily responsible for issuing food and animal feed regulations and standards while the Operations Sector is responsible for inspecting both imported and domestically produced food and animal feed products for compliance with existing SFDA, or GSO, regulations and standards. The SFDA's Food Sector has several departments including risk assessment and food and feed standards. The main duties of the Operations Sector are:

- 1. Evaluate and register imported food and feed on SFDA's E-Service portal,
- 2. Inspect imported food and feed products at Saudi ports of entry,
- 3. Register and inspect foreign facilities that export seafood, livestock, and poultry meat to Saudi Arabia,
- 4. Issue health certificates for food product exports,
- 5. Inspect local food and feed factories

The GSO is made up of the national standards bodies of Yemen and the six GCC countries (the United Arab Emirates, Saudi Arabia, Kuwait, Bahrain, Oman, and Qatar). As a group, the GSO's main role is to create a common set of regulations and standards. The GSO's Food Standards Committee (FSC) is responsible for drafting all new food regulations and standards and updating existing ones. The Chairman of the FSC rotates among member states. All GSO draft standards are submitted for review and approval to the GSO Board of Directors (BOD), which is composed of the ministers responsible for standardization in each member state. They meet twice a year to deliberate on standards and other related issues.

GSO draft regulations and standards are notified to the WTO by the seven member countries, and they are open for public comments for sixty days. Once a new standard is approved by the BOD, it is implemented in each member state, and in most cases after a grace period of six months from the date of approval. In practice, GCC countries differ concerning the timing of implementation and the enforcement of new GSO technical regulations. GSO issues two types of official documents that govern food and agricultural products:

- 1. GSO Technical Regulations: All technical regulations are approved unanimously by all member countries to replace existing national standards. Implementation is mandatory in all member counties.
- 2. GSO Standards: GSO standards are adopted by a majority vote of member states and implementation is voluntary in all member countries.

GSO standards are typically based on Codex Alimentarius regulations and to some extent on European and U.S. standards, but are modified to reflect local religious, cultural, and climatic conditions. The GSO often adopts existing member countries' standards after updating them and making sure that they conform to Codex Alimentarius guidelines and/or International Organization for Standardization (ISO) standards. The GSO Ministerial Board has authorized the GSO to adopt international standards in their original language as a fast-track measure to develop and increase the total number of Gulf standards. As such, the GSO has adopted several ISO and Codex technical regulations and standards.

GSO issued standards are implemented in the seven member countries. Saudi Arabia implements GSO regulations and standards if they are more recently updated compared to existing SFDA regulations. However, originating from the GSO, there are some of SFDA regulations that are not compatible with international standards and U.S. regulations, or are costly to enforce or implement. Examples of this include the ban on animal protein in animal feed, and the ban on poultry stunning/immobilization for religious purposes.

English copies of GSO standards mentioned in this report and other food/agricultural are available and can be purchased from the GSO headquarters in Riyadh by clicking on this link: <u>GSO Standards Store</u>. For a list of SFDA's technical regulations and standards for food, seafood and agricultural products, please use <u>this link</u>. The SFDA technical regulations and standards can be purchased from <u>SFDA online</u> <u>store</u>.

a) Animal Protein Free Feeding

SFDA regulations for livestock and poultry meat products require that health certificates accompany shipments of livestock and poultry meat, and the certificates must clearly indicate that animals slaughtered have not been fed animal protein. In order for the U.S. Food Safety and Inspection Service (FSIS) to issue the required animal protein free certification, U.S. exporters of beef, poultry and related products to the Kingdom must come from slaughter facilities that participate in the Agricultural Marketing Service's (AMS) Export Verification (EV) Programs: the USDA Bovine Export Verification Program for beef or the Animal Protein Free Verification Program for poultry (<u>APFV)</u>.

b) Ban of Poultry Stunning/Immobilization

At the end of May 2018, SFDA implemented part of GSO 993, which was based on a two-decade-old Islamic religious edict that bans poultry stunning/immobilization in the poultry slaughtering process. This prohibition on stunning is based on the concern that the stunning process kills the birds ahead of slaughter, rendering the bird non-halal. This requirement has stopped exports of U.S. poultry meat and products to Saudi Arabia. Through bilateral and multilateral fora, the United States has provided technical information and assurances to SFDA that electrical stunning as practiced in the United States does not kill the birds and that U.S. government regulations require that they are alive and verified after stunning by FSIS inspectors. SFDA is currently studying the issue as the United States continues to push for a resumption of trade.

SFDA strictly enforces Saudi and GSO food import regulations and standards, particularly those related to allowable limits for food additives and labeling requirements. The requirements in the following sections sometimes adversely affect trade.

In September 2017, SFDA began work on a healthy food program aimed at (1) the implementation of a healthy food strategy, (2) developing health food regulations and policy, (3) innovative initiatives to promote healthier lifestyles, and (4) improving the quality of food products.

The Healthy Food Program's goals are to:

- reduce the sugar, salt, and fat (SSF) content of food products;
- encourage a culture of calculating calories to stay healthy;

- promote healthier lifestyles; and
- improve public awareness of healthy diets.

On January 1, 2020, SFDA banned the use of added sugar or its sources (honey, glucose syrup) artificial flavors, color additives and energy drinks in "fresh and mixed juices. The regulation was enforced July 1, 2021on food service outlets operating in the Kingdom.

SECTION II. LABELING REQUIREMENTS

1) General Labeling Requirements

All imported and locally produced prepackaged food products must meet the labeling requirements indicated in GSO 9:2013 (SFDA.FD/GSO 9:2013). Prepackaged food product labels should be in Arabic or include an Arabic language translation on the label. Labels must contain the product name, packer's name, country of origin (COO) of manufacture or production, list of ingredients in descending order of predominance, instructions for the end use of the product (where applicable), and the shelf-life of the product. COO labeling is mandatory for imported and locally produced products in Saudi Arabia. If a food product undergoes processing in a second country, changing its nature, the country in which the processing is performed is the COO of the product. It is prohibited to mention on a product that has been packaged or processed without changing its nature that it is produced in the packing country. However, a phrase can be declared stating that the packaging and processing has been done by the packaging company in the exporting country mentioning the COO of the products. For example, rice imported from the United States, but packed in Saudi Arabia may be labeled as: a "rice" product of the United States packed in Saudi Arabia by ABC company.

SFDA.FD/GSO 2487, which was issued in 2015, discusses general requirements for foodstuff labeling including "stickering." As a member of the GCC countries, Saudi Arabia began implementing Gulf standard GSO 2015 in 2015. Section 7.2.2.1 of the regulation states that if the Arabic labeling information is stated in a supplementary sticker, a single sticker must be provided by the manufacture (designed and printed).

GSO member countries, including Saudi Arabia, require that labels of pre-packaged food products include both production and expiration dates printed on the label prior to export. The following are GSO regulations that govern shelf life for food products:

- SFDA.FD 150-1:2018 "Expiration Dates for Food Products Part 1: Mandatory Expiration Dates" requires mandatory expiration periods for perishable foods, such as fresh or chilled meat and poultry; fresh milk and fresh milk-based products; margarine; fresh fruit juice; table eggs, and baby food.
- SFDA.FD/GSO 150-2:2013 "Expiration Dates for Food Products Part 2: Voluntary Expiration Dates" lists suggested expiry periods for non-perishable food products but allows manufacturers to determine science-based use-by dates.

Shelf life can only be shown by clear and unambiguous production and expiration dates. The use of any of the following statements for expressing expiration date is permissible.

- Expiration Date
- Use by (date)
- Fit for (from the day of production)
- Use Before (date)
- Sell by date (for food products having an expiration period exceeding 3 months).

The production and expiration dates should be declared on the label of the package as follows:

- Day-Month-Year: for foodstuffs with an expiration period less than three months.
- Month-Year: for foodstuffs with expiration exceeding three months.

Dates must be engraved or in relief –and printed by stamp with permanent ink directly on all packages, or on their original label by the producer. Adding stickers for production and expiration dates is not permissible. There may not be more than one date of production or expiration on the same package. The dates may not be deleted, changed or be deceitful. Only the date of production or processing needs to be shown (mm/yy) for products with no specific expiration date. Examples of these products include salt, spices, and milled rice. U.S. exporters should cross check information on the food label, including Production and Expiration dates, with the Saudi buyer before putting together an order.

2) Additional Labeling Requirements

In addition to requirements per SFDA.FD/GSO 9:2013, the following labeling information must be declared for food additives and antioxidants used in food:

- For colorings used in foodstuffs, their mixtures, preparations and diluents, the following additional information must be declared:
 - 1. Common name
 - 2. Color index number
 - 3. Name of solvent or diluent
 - 4. Production and expiration dates in a non-coded manner (day-month-year)
 - 5. Dye purity
 - 6. The statement "Free from alcohol"
 - 7. The statement "Color matter for use in foodstuffs."
- For flavors permitted for use in food, the common name and code number (if found) must be declared on food product containers containing flavors.
- For preservatives permitted for use in food products, the label must identify the common name or European Economic Community (EEC) number and a statement "Preservative for Use in Food Products" on preservative containers.

- For emulsifiers, stabilizers, and thickeners permitted for use in food, the following additional information must be declared:
 - 1. Common name or EEC number.
 - 2. In case of gelatin, lecithin, and mono- and diglycerides, the source shall be mentioned.
- For Sweeteners Permitted for Use in Food Products
 - 1. The name of sweeteners or International Numbering System (INS) numbers as determined by the Codex Alimentarius committee.
 - 2. Food products formulated specifically for use by diabetics or for other special nutritional uses shall contain the statement "Food for special dietary use or food for diabetic" along with the amount of sweetener in mg/liter or in kgs.
 - 3. For combinations of sweeteners, the amount of each in combination shall be declared.

The following warnings must be declared:

- In case of aspartame, "Not to be used by persons who have phenyl ketonuria."
- In case of saccharine, "Use of this product may be hazardous to your health because it contains saccharin, which has, been determined to cause cancer in laboratory animals."
- In the case of sugar alcohol "Excess of consumed quantity may cause diarrhea."

The following additional labeling information must be declared for antioxidants permitted for use in food:

- Common name or EEC number.
- A statement "Antioxidants permitted for use in foodstuffs" in case of antioxidant containers.

3) Other Specific Labeling Requirements

a) Requirements for Nutrition Labeling (Nutrition Fact Panel)

SFDA enforces GSO regulations regarding mandatory disclosure of nutrition information on labels of imported as well as locally produced and prepackaged food products. GSO regulation number 2233 or SFDA.FD 2233 was issued in 2018 (replacing the 2012 version) and requires the mandatory disclosure of nutrition information such as the number of calories, carbohydrates, proteins, fats, and other components that may affect the product's nutrition value or the consumers' health and safety. The following chart was provided by SFDA and is believed to meet the nutritional labeling requirements.

Nutrition Facts

8 servings per container Serving size 2/3 cup (55g) Amount per serving or 100 ml or 100g Calories 230 Daily Need Percentage % [illegible text] Cholesterol 0mg 0% Sodium 160mg 7% Total Carbohydrate 37g 13% Dietary Fiber 4g 14% Total Sugars 4g 5% Includes 10g Added Sugars 20% Protein 3g * Is lower than the daily need percentage for nutrients of one serving based on a nutritional diet including 2000 calories

SFDA requires that food product importers and domestic producers strictly follow pertinent regulations such as SFDA.FD/GSO 9:2013 "Labeling of Prepackaged Food Products" and SFDA.FD 2233:2018 "Requirements of Nutritional Labeling" when disclosing the required nutrition information.

b) Labeling Requirements for Prepackaged Foods for Special Dietary Uses

Definition of Dietary Foods: SFDA standard SFDA.FD 654:2017 defines dietary foods as food products specially prepared or formulated to satisfy dietary requirements and are intended for consumers with physical or physiological conditions and/or specific diseases or disorders. These foods differ significantly in composition from the ordinary products of comparable nature if such ordinary foods exist. The following requirements need to be met by prepackaged foods for special dietary uses:

- The product must be completely free from pork products or their derivatives.
- It must be registered by the Saudi Ministry of Health (MOH).
 - Note that infant formulas and baby foods such as infant formula, ready-made soft and wet foods, breakfast cereals, dry finger foods (including biscuits and snacks) are not considered foods for special dietary uses and there are specific registration requirements for them. All imported baby foods and formulas are inspected by SFDA at Saudi ports of entry and must comply with pertinent GSO or Saudi quality regulations and standards.
- It should not be pharmaceutically packaged in a way suggesting that it is a drug.
- It must be offered for sale in places separated from the ordinary foods in supermarkets. Foods for special dietary uses for infants and children shall be dispensed only by pharmacies, hospitals, and childcare centers.
- Artificial sweeteners are not permitted to be used in any baby and infant foods.

In addition to the general labeling requirements as stated in SFDA.FD/GSO 9:2013, further information must be declared for prepackaged foods for special dietary use and nutrition labelling. Guidelines on permitted and prohibited health and nutrition claims in food labelling must also adhere to the following SFDA regulations and standards:

c) Procedures for Nutrition Labelling of Foods

SFDA.FD 2233:2018: This regulation states the procedures for the nutrition labelling of foods. It applies to the nutrition labelling of all prepackaged food products except for raw products such as fresh fruits, vegetables, meat, and fish.

d) Guidelines on Prohibited and Permitted Health and Nutrition Claims in Food Labelling

SFDA.FD 2333:2018: This 55-page technical regulation contains guidelines on prohibited and permitted health and nutrition claims in food labelling. Below are the lists of claims that are prohibited and those that are allowed on labels of food products sold in Saudi Arabia:

a) The following health and nutrition claims are prohibited on food product labels:

- Claims that refer to the rate or amount of weight loss.
- Claims that refer to recommendations of individual doctors or health professionals cannot be made on food.
- Claims that suggest that health could be affected by not consuming the food.

- Claims that a food can be used in the prevention, alleviation, treatment or cure of a disease, disorder, or physiological condition.
- Claims stating that any given food will provide an adequate source of all essential nutrients.
- Claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients.
- Claims that cannot be substantiated.
- Claims that could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.
- Meaningless claims including incomplete comparatives and superlatives.
- Claims as to good hygienic practice, such as "wholesome", "healthful", "sound".

b) List of permitted health and nutrition claims used on labels of food products:

- Health Claims listed in table no. (1) of SFDA.FD 2333:2018 are permitted to be used on food label and for advertising purposes. The list is currently 49 pages long. These claims should be accompanied with all necessary conditions (including restrictions & warnings) for their use.
- Wording and presentation of claims to be made on food products should be truthful, clear, reliable, and useful to the consumer. Flexibility with the wording of claims (including graphics and symbols) is allowed if it provides the same meaning for consumers as the listed in the tables (1 and 2) and they are not misleading.
- Any health and nutrition claim made on food products label is prohibited unless it fulfills conditions mentioned in SFDA.FD 2333:2018

e) New Labeling Requirements for Horticulture

In July 2019, SFDA announced new labeling and facility registration requirements for fresh imported fruit and vegetables. SFDA did not notify the new produce labeling and exporting facilities registration requirements to the WTO and claimed that they were not TBT changes.

An SFDA letter dated August 14, 2019, gave importers of fresh horticultural products a six-month grace period to adopt the new labeling requirements and commence registering their suppliers. The grace period ended on Feb 25, 2020.

SFDA recently approved a label signaling that it fulfills the fresh horticulture products labeling requirements. The sample label is believed to provide most of the information needed for SFDA facility registration. The label is to be affixed on individual product package.

f) SFDA Healthy Food Program

As part of the Healthy Food Program, SFDA issued several new technical regulations and standards since 2018. Measures one through six below have been identified as the most relevant to U.S. agricultural exports to Saudi Arabia:

- a. In September 2018, SFDA issued SFDA.FD 42/2018 "Front of Pack Nutritional Labeling (FOPNL)", which laid out a traffic light style labeling system (blue, yellow, and red) based on sugar, fat and salt levels found in processed food products, with a format and thresholds unique to Saudi Arabia. Following feedback from local industry and trading partners in 2018, SFDA decided to make this FOPNL scheme voluntary. However, on September 20, 2021, SFDA re-notified to the WTO a revised draft regulation (G/TBT/N/SAU/1212) making the FOPNL requirements mandatory. The comment period ended on November 19, 2021, but date of adoption of the regulation has not been determined. The notification indicated that the regulation will be enforced 18 months from the date of adoption.
- b. On September 20/2021, SFDA notified to WTO a draft regulation number G/TBT/N/SAU/1211 titled Requirements of Food Products with High Nutritional Value and set November 19, 2021, as a deadline to receive comments from interested parties. The draft technical regulation deals with the requirements are based on <u>Nutrient Profiling</u> <u>Model for the Kingdom of Saudi Arabia (</u>Arabic language document). The reported main goal of the regulation is to increase consumer's awareness and empower consumers in selecting healthier food choices.
- c. On June 28, 2021, SFDA notified to WTO a draft regulation number G/TBT/N/SAU/1202 "Guidelines for Marketing Requirements of Food Directed to Children", The guidelines are concerned with controlling the marketing of food directed to children (prepackaged and food meals provided in food establishments) which falls under criteria of low nutritional value based on the Kingdom's nutrients profile adopted from the UK nutrient profile model. The draft regulation bans advertising of such products to children less than 12 years old of foods high in sugar, fat, and sodium contents. The deadline for providing comments was August 27, 2021. A U.S. concerned about this notification because it is not clear what calculation methods are used to classify food products as low nutritional value.
- d. SFDA.FD 59/2018 "Salt Limits Guidelines in Food Products" sets the maximum limit for salt in 22 processed food products such as meat, cereals, snack foods and cheese. The voluntary standard urged local food producers and food products exporters to implement its recommendation by January 1, 2020. Though this standard was announced as voluntary, sometimes, SFDA inspectors at ports of entry enforce voluntary standards as mandatory by mistake. If that occurs, U.S. suppliers should immediately contact FAS Riyadh for assistance.

- e. On January 1, 2020, SFDA implemented its regulation number SFDA.FD 2483 issued in 2018 banning the use of Partially Hydrogenated Oils in all food products imported or locally produced due to health concerns.
- f. On October 1, 2020, SFDA implemented its Technical Regulations number SFDA.FD 2233/2018 or GSO 2233/2018) "Nutritional Data Requirements for Food Products' Card" or the Nutritional Fact Label, also known as the "Back of Pack" nutritional facts panel.
- g. With enforcement beginning on October 1, 2019, SFDA.FD 56/2018 "Declaration of Allergens on Food Establishments Menu's Selling Away-From-Home Foods" requires food establishments to provide allergy warnings on menus of foods they service to customers.
- h. On January 1, 2019, SFDA implemented its SFDA.FD 20:2018, which mandates the food service sector to display caloric information on menus of prepared foods. SFDA says the requirement is needed to increase consumers' awareness of nutritional information of the food they consume so they can make healthier consumption decisions.
- i. SFDA.FD 2362/2018 "Technical Requirements of Bread Production" sets the maximum level of salt in domestically produced bread at 1 gram per 100 grams of produced bread. The regulation was implemented on June 12, 2019. SFDA stated that the new sodium limit in bread aims at harmonizing its legislations with the requirements of the World Health Organization (WHO), which aims to reduce the consumption of salt used in food products.

SFDA collaborates with other Saudi government ministries and agencies to achieve its food safety and healthy food goals. On December 1, 2019, the Saudi General Authority of Zakat and Tax (GAZT) started collecting a 50 percent selective tax on sugary drinks in the local market. GAZT defined sugary drinks as any product in which any source of sugar or other sweeteners is added, to be taken as a drink, whether ready for drinking, or in the form of a liquid concentrate, powder, gel, extract, or any form that can be converted into a drink. In June 2017, the Kingdom started to levy a 100 percent tax on energy drinks and cigarettes and 50 percent tax on carbonated drinks. GAZT is a government agency in Saudi Arabia responsible for the assessment and collection of Zakat and taxes including VAT. Zakat is one of the five pillars of Islam and an obligatory charitable contribution. It is collected from all Muslims who meet certain criteria of wealth to help the needy.

SFDA officials are hopeful that the above measures will help address Saudi Arabia's problems with obesity and diabetes.

4) Labeling of Body Building Foods

SFDA.FD/GSO 2471 was issued in 2015 and provides requirements for the labeling of body building food products. The standard deals with food supplements used for body building that contains nutrients such as amino acids, vitamins, minerals, etc.

5) Labeling of Food Additives when Sold Alone (as Food Additives)

SFDA.FD/GSO CODEX STAN 107:2007: Labeling of food additives when sold as such. This standard is concerned with the labeling of any food additives sold as food additives

to consumers or food manufacturers for use as ingredients in preparing or manufacturing food products.

6) Biotechnology Labeling - General Information

On April 12, 2011, GSO issued two mandatory agricultural biotechnology regulations, GSO 2141:2011 - SFDA.FD/GSO 2141:2011 (General Requirements for Genetically Modified Unprocessed Agricultural Products) and GSO 2142:2011- SFDA.FD/GSO 2142:2011 (General Requirements for Genetically Modified Processed Agricultural Products). GSO 2141:2011 deals with general requirements for genetically modified unprocessed agricultural products, while GSO 2412:2011 specifies the general requirements for genetically modified processed food and feed products. The two technical regulations require positive biotech labeling if unprocessed agricultural products, processed food products, feed products or seed contains more than one percent of genetically engineered (GE) ingredients.

Saudi Arabia, which was the GCC lead country in preparing the draft standards for the two GSO biotech regulations, became the first GSO member country to implement these 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 replaced the old Saudi agricultural biotech labeling decrees by increasing the biotech threshold level 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.

Specifically, the Saudi biotech regulation, GSO 2141:2011, prohibits the importation of any genetically modified animals, birds, fish, and their products. Meanwhile, the SFDA.FD/GSO 2502:2015 and compilation of Codex texts relevant to the labeling of foods derived from modern biotechnology recalls and compiles in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology."

Below is a summary of GSO biotech labeling requirements:

a. Positive 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 easy 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.

b. Bilingual Labeling

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 an easy-to-read font in both Arabic and English (upper case), with a different color from 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, 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 label 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 on use must be given on the label of the product.

c. Health Certificate

Biotech agricultural products exported to Saudi Arabia and GCC countries must have been approved in the country of origin for human or animal consumption, or for use as planting seeds, and meet all relevant Saudi and GSO-approved regulations and standards. Each shipment must be accompanied by an official health certificate issued by a competent government agency stating that the GE ingredient(s) used in the foodstuff, grains or seed exported is approved in the country of origin for human or animal consumption or for planting seeds. The SFDA accepts health certificates issued by the FDA and federal or state departments of agriculture for high value and processed feed products. Health certificates issued by exporting companies or other private organizations, including notary public statements are not recognized.

For U.S. biotech feed grains, the Ministry of Environment, Water, and Agriculture (MEWA) accepts the biotech grains certification statement that was provided in 2003 by the USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA). The statement certifies that the exported transgenic feed grains and oilseeds (corn and 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 by section 4.1.5. of the GSO 2141:2011.

d. Real Time Polymerase Chain Reaction (PCR) Method

Saudi Arabia implements 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.

SECTION III. PACKAGING AND CONTAINER REGULATIONS

1) Packaging Sustainability Measures

The Saudi Arabian Standards Organization (SASO) is responsible for issuing standards for nonfood products including those that come in contact with food products. On February 3, 2020, the organization <u>announced</u> (Arabic text) the suspension of implementation of Phase 2 and Phase 3 of a regulation requiring biodegradable plastic products (M.A-156-16-03-03). Originally issued at the end of 2016, the regulation applies to all disposable products produced from polypropylene and polyethylene plastics. It mandated that all plastic packaging, packing, and wrapping materials be OXO degradable (excluding food contact packaging), and requires the preregistration of plastic products with SASO, the application of SASO's logo, and the use of plastic additives licensed by SASO. For more information SASO's technical regulation for biodegradable plastic products visit <u>www.saso.gov.sa</u> or write <u>r.abdan@saso.gov.sa</u>

2) General food packaging and container requirements

Saudi Arabia has also implemented the following regulations and standards regarding food packaging and container requirements:

- GSO 839:1997 (Food Packages Part 1-General Requirements) is concerned with the general requirements of food packaging. The main requirements are listed below:
 - a. All packaging materials used in fabricating, forming, or treating packages shall be of food grade for contact with foods and in compliance with relevant Saudi standards.
 - b. They shall be clean and in a condition that does not allow any contamination of the contained material.
 - c. They shall maintain the properties of the packaged material and protect it from gaining undesirable odors, flavors, and tastes.

- d. They shall offer protection to the product against contamination with microorganisms, insect, rodents, and dirt in the case the products require it.
- e. They shall be impermeable to moisture in the case of food products.
- f. They shall offer necessary protection against environmental conditions and mechanical hazards such as impacts, vibration, static stresses, and they shall remain intact during handling.
- g. They shall not affect the container because of migration of some of their constituents that may react or be mixed with the food materials.
- h. It shall not be in a pharmaceutical shape.
- GSO 1863:2013 (Food Packages Part 2 Plastic Package) deals with the requirements and specifications for plastic packages used for packaging food materials. Per the standard, the following labeling information should be written on labels of plastic packages used to package foods:
 - a. Type of plastic material
 - b. Weight, capacity, number, or dimensions based on the type of packages
 - c. Statement of food grade
 - d. Purpose and type of application
 - e. Directions for usage
 - a) Warnings if applicable
- Saudi Standard number SASO 2173/2003 (Food Packages Made of Aluminum Foil) deals with the general requirements for food packages made of aluminum foil. Below are the main requirements specified in SASO 2173:
 - a. Purity of aluminum metal shall not be less than 99% aluminum.
 - b. Each package shall be made of one piece of aluminum foil without any connection and free from holes and scratches.
 - c. Shall be made from foil with regular thickness not exceeding 200 micrometers according to the agreement between the user and manufacturer of these packages regarding the strength with relation to the nature of application.
 - d. In case of aluminum foil coated with protection layer, the coating material shall not transfer any health hazard material to the food product or impart the odor or flavor of the food material.
 - e. Shall be impermeable to the water, odors, and gases.
 - f. Shall be impermeable to the light to protect fatty foods from light.
 - g. Shall provide enough protection to the food product from losing or gaining heat.

SECTION IV. FOOD ADDITIVE REGULATIONS

On February 28, 2021, SFDA issued an updated version of SFDA.FD 2500 "Additives Permitted for Use in Food Stuffs." SFDA.FD 2500/2021 a 373 - page comprehensive technical regulation has a list of allowed additives, including allowed food coloring matters (*SFDA regulations store*). This regulation which delisted some artificial food coloring such as Tartrazine or E102 replaces and supersedes SFDA.FD/GSO 2500/2019. The delisting of E102 has caused rejections of some U.S. food products at the Saudi ports of entry. U.S. exporters may purchase the regulation from the *SFDA online store* to refer to allowed artificial colors and in which products they are allowed. SFDA is open to adding other food additives to this regulation under one of the following conditions:

- 1. Food additives that have been allotted an Acceptable Daily Intake (ADI) or calculated on the basis of other criteria, to be safe for human consumption by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- 2. The additives should have a Codex designated International Numbering System (INS) number.

If a food product contains additives that are not listed on SFDA.FD 2500/2021 but meet one of the above-mentioned conditions, the food product supplier should contact SFDA through his/her prospective Saudi importer. The supplier will need to provide information on the new food additives and ask if it is included in the allowable additives list. If an additive does not meet JECFA or INS conditions, the food product will not be cleared by Customs, and it will need to be re-exported to the country of origin or destroyed locally at the importer's expense.

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

Regulation number SFDA-FD 382/2018, "Maximum Limits of Pesticide Residues in Agricultural and Food Products", currently sets maximum limits for pesticide residues. If an existing Saudi or GSO regulation does not provide a pesticide residue limit for a particular food product, Codex Alimentarius regulations are referenced. If Codex Alimentarius does not have an established limit for a particular food product, SFDA references the EU and U.S. regulations and implements the lowest limit from the two sources even if the limit is a default limit. In some cases, Saudi Arabia has adopted an EU default limit, which are established without a risk assessment, instead of a higher U.S. limit that was established based on a scientific assessment. For example:

- 1. SFDA does not have a tolerance for ochratoxin in paprika and is using an EU specification that sets the maximum level of ochratoxin content in paprika at 20 ug/kg. This requirement prevents some U.S. producers from shipping to Saudi Arabia.
- 2. In the summer of 2018, SFDA rejected several containers of U.S. grape leaves for levels of pesticide residue higher than the maximum allowable level of 0.01 PPM. It had not established a Maximum Residue Limits (MRL) for grape leaves and was using the EU

default standard. In March 2020, SFDA determined that the concentrations found were within safe limits and do not pose risk to consumers.

Saudi Arabia and other members of the GSO have developed positive pesticide and other contaminants lists. Per SFDA, the lists were mainly adapted from Codex standards. The following are the major GSO standards enforced in the Kingdom:

- Gulf Standard No. GSO 2481:2015 regulates the MRLs of veterinary drugs in food.
- Gulf Standard No. GSO 2532:2016 regulates the maximum limits of pesticides residues and contaminants in organic food.
- Gulf Standard No. GSO 1016:2015 regulates microbiological criteria for foodstuffs.
- Gulf Standard No. GSO 1995:2015 regulates sweeteners permitted in food.
- Gulf Standard No. GSO 988:1998 is concerned with limits of radioactivity levels (gamma rays, cesium 134, 137) permitted in foodstuffs, drinking water and animal feeding stuffs.
- Gulf Standard No. GSO 2512:2016 is concerned with dairy products with added probiotics.

Procedure for Requesting Addition of New MRL to SFDA/GSO Pesticide Residue Regulations

SFDA regularly updates its MRLs generally referencing levels set by the Codex Alimentarius. Any interested stakeholders can suggest or provide comments on existing or new MRLs limits. To request an additional MRL which has not been established by Codex, the application must be supported by international or national regulations or based on risk assessments. All these document can be submitted for evaluation at *SFDA to ICD@sfda.gov.sa* if it is coming from governmental sector, or to *cec@sfda.gov.sa* if it is companies and private sector.

Contaminants and Toxins in Food and Feed

GSO 193:2021 is a 75-page Gulf Technical Regulation dealing with contaminants and toxins in food and feed.

This regulation which is implemented in the six GCC countries and Yemen contains maximum levels of contaminants and toxicants in food (including tree nuts) and feed. The regulation contains only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

GSO 193:2021 is a comprehensive regulation that supersedes the following GSO technical regulations:

- GSO 1807:2007 "Maximum level for cadmium in food".
- GSO 988:1998 "Limits of radioactivity levels permitted in foodstuffs Part 1".
- GSO 2042:2010 "Maximum levels of Melamine in Foods and Feeds".
- GSO 841:1997 "Maximum limits of mycotoxins permitted in foods and animal feeds Aflatoxins".

SECTION VI. OTHER REGULATIONS AND REGISTRATION MEASURES

a) Imported Food Products

Registration of imported food products is the responsibility of local importers or agents. Each importer or agent is required to open an E-Account and set up an individual user name and password at SFDA's Operations Sector E-Services at <u>E-Account</u>. Once the E-Account is created, importers can upload information about their products, including the harmonized code (HS Code), bar code, item code, listed ingredients in English and Arabic, a picture of each product, and a copy of the product label. The label must contain all information required by the Gulf Standard Organization regulation number GSO 9:2013 "Labeling of Prepackaged Food Stuffs".

The importer is also required to register the address of their warehouses, the names of their staff members authorized to deal with SFDA, including customs brokers contracted in each Saudi port of entry. Individual importers are required to register all food products they intend to import, even if some or all the products they intend to import have been already registered by another importer. The electronic registration is free of charge and there is no expiration date for registration. However, importers are required to re-register their products when there are changes in the product formulations or labels. The registration process seems simple and can quickly be completed if the necessary information is readily available and required documents are uploaded. It is important to note that SFDA does not allow the importation of food products that are not registered in its E-Account database.

b) Electronic Customs Clearance of Food Products and Animal Feed

SFDA maintains a mandatory electronic customs clearance system (E-Clearance) for all food and processed feed products imported into the Kingdom. The mandatory E-Clearance covers all food imports, including packaged products and raw materials for the food processing industry and processed animal feed. SFDA does not process any requests for customs clearance of imported food and processed feed products unless it is submitted through the E-Clearance system. To qualify for E-Clearance, all food and feed product importers, as well as their custom brokers, should create individual E-Accounts with SFDA and complete the online registration process for all imported food and feed products.

c) Animal Feed National Registry (AFNR)

SFDA's Operations Sector uses an electronic Animal Feed National Registry (AFNR) system for registering and licensing domestic feed importers and producers. Each domestic feed importer and producer must open individual E-Account with AFNR and register all imported feed materials including raw feed, compound feeds and non-medicated feed additives in order to obtain an import license and customs clearance of the products electronically upon arrival at Saudi ports of entry. SFDA allows foreign feed producers to voluntarily register the facilities and feed products they intend to export to Saudi Arabia in AFNR.

d) Herbal Preparations Registration

Herbal preparations, health and supplementary foods must be registered with the General Directorate of Medical and Pharmaceutical Licenses of the Ministry of Health (MOH) in order to be marketed in the Kingdom. Registration is done through a local agent by submitting sample products and product brochures, which are studied and tested by the ministry's central laboratory. It takes approximately six months for the ministry to approve and license a product. The ministry charges a onetime fee of approximately \$300 (USD) as a registration fee.

Exporters need to submit the following documents through their local agent to the MOH in order to initiate the product registration and licensing process:

- 1. Table of contents
- 2. An authenticated copy of the agency registration certificate at the Saudi Ministry of Commerce and Investment.

3. When registering for herbal products, a copy of a pharmaceutical wholesale license should be submitted by the local agent.

- 4. Certificate(s) issued by the health authorities in the country of origin clearly stating that:
 - The company is licensed to manufacture the products in the country of origin (state license number and date).
 - The company is permitted to sell the product in the country of origin (certificate of free sale).
 - The company follows good manufacturing practice.
 - Coloring agents, diluents and other substances in the product formula are permitted in the country of origin (if the free sale certificate states such information, it will be sufficient).
 - Package inserts and applicable information stated on the package must be the same as that approved and currently marketed in the country of origin. The package insert must be in Arabic and English languages. The company is obliged to add and/or delete any information required for handling the product in the Kingdom as determined by the registration committee.

5. A certificate issued by the company and authenticated by the relevant authorities in the country of origin must clearly state the following information:

- Registration number and date of marketing in the country of origin.
- Trade and/or generic name.
- Full composition (the scientific name of active and inactive ingredients and their quantities) therapeutic category (if any). The composition of the product to be exported to the kingdom is the same as that marketed in the country of origin.
- Names of countries where the product is currently marketed.
- A certificate of analysis indicating the results of completed analyses for the submitted samples.
- If the product contains ingredients of animal source, the kind of animal must be specified.
- Percentage of alcohol in the finished product, if present, should be indicated with justification of that percentage.

- Full specifications and methods of analyses of the finished product, as well as stability study and data including storage conditions.
- Six samples of the product as well as samples of the outer package and product's label.
- Abstracts of scientific references, brochures, and international scientific periodicals testifying to the efficacy and safety of the product.

e) Foreign Competent Authorities and Establishments Registration Requirements

SFDA has recently issued three important documents that governs the importation of food products to Saudi Arabia including requirements for prior approval of foreign food control agencies of countries that wish to export food products to the Kingdom in addition to the requirements for official registration of foreign establishments that intend to export food products to Saudi Arabia. The documents are discussed below:

1. Process for Approving Foreign Competent Control Authorities and Establishments

Interested in Exporting Food Products of Animal Origin to the Kingdom of Saudi Arabia (KSA). SFDA defines competent authority/authorities as body/bodies responsible for the official food control in the exporting countries. The document that was notified to WTO on October 1, 2014, as G/SPS/N/SAU/93/Add.3, specifies the procedures that should be followed by competent control authorities responsible for food safety in supplying countries of food products of animal origin to KSA need to be recognized by SFDA and it assigns the responsibilities of approving establishments interested in exporting the following nine product categories to the Kingdom:

- Establishments for the export of beef and beef products.
- Establishments for the export of sheep and sheep products.
- Establishments for the export of poultry and poultry products.
- Establishments exporting fishery products and other seafood products of animal origin.
- Establishments for the export of honey and its products.
- Establishments for the export of milk and its products.
- Establishments for the export of breast milk substitutes.
- Establishments for the export of table eggs and its products
- Establishments exporting any other products of animal origin

The process of approving the foreign competent authority starts when a foreign competent authority sends an official request to SFDA through a diplomatic channel. If SFDA accepts the request, it sends a Country Food Safety Evaluation Form (Annex 1) of <u>the Process of Approving Foreign Competent</u> <u>Authority</u>. SFDA evaluates the responses to the questionnaire and provides feedback if needed as well as may request from the competent authority to coordinate SFDA technical visit if required to evaluate the country's Food Safety system. The team will visit the control body and some establishments of food products of animal origin to ascertain that the competent authority in visited country indeed conducts supervision of the facilities per pertinent SFDA/GSO technical regulations and according to health requirements approved in Saudi Arabia. The technical visit will include targeted products facilities such

reference labs, quarantine facilities, animal farms and other control bodies. The responsibilities of SFDA's approved competent authorities are the following:

- a. Send a list of accredited interested exporting establishments to SFDA assuring that the establishments are under its control and meet SFDA approved technical regulations/standard specifications as well as other export requirements. SFDA will publish the list on its website.
- b. If needed coordinate SFDA's technical officials visit to conduct random on site audits of the establishments at any time deemed appropriate by SFDA.
- c. Provide updated establishments list to SFDA when needed including addition or deletion of establishments for revision on SFDA's website.

SFDA implemented the above requirements on livestock and poultry meat and products exporting countries in 2015 while the requirements were enforced on seafood and egg/egg products at the end of 2018 following the enforcement of the Conditions and Requirements for Importing Food to the Kingdom of Saudi Arabia discussed below.

2. <u>Conditions and Requirements for Importing Food to the Kingdom of Saudi Arabia</u>

The conditions (a 42-page document) were notified to WTO on February 1, 2018, as G/SPS/N/SAU/273/Add.1 and was partially enforced at the end of 2018. The document was intended to apply to all food products imported to Saudi Arabia. Its intended objectives are as follows:

- Lay down the conditions and requirements, which must be met by competent authorities in countries intending to export food products to Saudi Arabia.
- Provide assurances from competent authority (s) in exporting countries that the establishments wishing to export their products to Saudi Arabia comply with the regulations approved by Saudi Arabia related to human, animal, and plant health.
- Ensure food safety and facilitate movement of international trade.

In addition to complementing the requirements discussed in document number one above, this document lists in Appendix a new model of SFDA Health Certificates for the following nine product categories and specifies the required certifications by competent authorities of the exporting countries:

- 1. Health Certificate for Export of Red Meat and Meat Products to KSA
- 2. Health Certificate for Export of Poultry Meat and Poultry Meat Products to KSA
- **3.** Health Certificate for Export of Products of Aquatic Animal Origin to the Kingdom of Saudi Arabia
- **4.** Health Certificate for Export of Honey & Bee Products to Kingdom of Saudi Arabia
- 5. Health Certificate for Export of Processed Fruit and Vegetables Products to KSA
- 6. Health Certificate for Export of Table Eggs and Egg Products to KSA
- 7. Health Certificate for Export of Milk, and Milk Products to KSA

- 8. Phytosanitary Certificate for Export to KSA
- 9. Health Certificate for Export of Assorted Food Products to KSA

3. Process for Approving Foreign Competent Control Authorities and Establishments Interested in Exporting Food Products to the Kingdom of Saudi Arabia, notified to the WTO as G/SPS/N/SAU/451 on April 29, 2021.

SFDA puts the purpose of this document is as follows:

To verify the procedures carried out by the official control authorities responsible for the whole food chain within the exporting countries that are interested in exporting their products to the Kingdom of Saudi Araba. These procedures are conducted to assign the authorities the responsibility of approving the establishments interested in exporting the following products:

- Establishments exporting beef and beef products.
- Establishments exporting sheep and sheep products.
- Establishments exporting poultry and poultry products.
- Establishments exporting fishery products and other seafood products of animal origin.
- Establishments exporting honey and its products.
- Establishments exporting milk and its products.
- Establishments exporting breast milk substitutes.
- Establishments exporting table eggs and its products
- Establishments exporting processed vegetables and fruit
- Establishments exporting grain and agricultural crops

This document basically reiterated the need for the competent authority to get approved by SFDA by fulfilling the conditions discussed above in Process for Approving Foreign Competent Control Authorities and the role that the approved competent plays in facilitating trade between the exporting country and Saudi Arabia. A few new things included in the document are the addition of processed vegetables & fruits, grain and agricultural crops and the fee that SFDA charges as the cost of its technical team's visit to exporting countries (if the visit is required) to audit an exporting country's food safety system and inspection of exporting facilities. Inspection fees range between \$4,667 for Arab counties and \$8,800 for North America.

The exporting establishments should comply with the following regulations:

- Food Hygiene Requirements published on the *this link*
- Technical regulation no. GSO 21: Hygienic Regulations for Food and Pants and their Personnel
- GSO 169: General Principles for Food Hygiene
- Technical regulations and specifications relevant to food products
- Hazard Analysis Critical Control Point (HACCP) or any equivalent system
- Best Aquaculture Practices (BAP) (only pertaining to establishments exporting aquaculture products of animal origin)
- Pay SFDA's technical team inspection fee

As discussed earlier the overall contents and requirements of G/SPS/N/SAU/451 are not new and have been implemented on poultry/livestock meat products as well as on fish/seafoods over the past few years and enforced on honey and bee products at the end of October 2021. SFDA has not indicated when it will implement the requirements on dairy and other products.

U.S. Competent Authorities

The Food and Drug Administration (FDA) is the **competent authority that** regulates all foods and food ingredients produced and sold in the United States with the exception of meat, poultry, grains, fresh fruit and vegetables, and fresh eggs that are regulated by the USDA while live fish and other aquatic animals are regulated by The National Oceanic and Atmospheric Administration (NOAA) of the United States Department of Commerce. To address the recent SFDA requirements for seafood and honey and bee products registration requirements, FDA has launched an Update to its Export Listing Module (ELM) to Facilitate U.S. Exports of the aforementioned products to Saudi Arabia. Below is the announcement:

The Saudi Food and Drug Authority (SFDA) has implemented new import requirements for certain food products of animal origin exported to Saudi Arabia. Effective immediately, establishments that export seafood and bee and honey products must appear on SFDA's lists of approved establishments eligible to export such products. SFDA will include foreign establishments on these lists that have been certified to comply with applicable food safety requirements by the competent authority of the exporting country.

FDA is the U.S. competent authority for food safety for seafood and honey and bee products. To facilitate U.S. exports of these products, FDA has updated the Export Listing Module (ELM) to allow U.S. establishments to request FDA certification for inclusion on SFDA's lists of approved establishments. U.S. establishments are eligible for the lists if they are in substantial compliance with applicable FDA requirements for the products intended for export. For ease of reference, FDA refers to the Saudi Arabia lists for these products as the Saudi Arabia honey and bee products export list and the Saudi Arabia seafood export list.

U.S establishments that wish to export seafood or honey and bee products to Saudi Arabia may apply for the initial updates to these lists now through December 10, 2021. FDA expects to send the first version of these lists to SFDA in mid-December 2021. Going forward, FDA will send updates to these lists on a quarterly basis as described on the <u>Food Export Lists</u> webpage.

For more details including step-by-step instructions on how to apply in the ELM, visit <u>Online</u> <u>Applications for Export Lists</u>. Please contact the Export Certification Team at <u>CFSANExportCertification@fda.hhs.gov</u> for any additional questions about the ELM.

SECTION VII. OTHER SPECIFIC STANDARDS

1) Vitamin-Enrichment Requirements

SFDA implements GSO 2539:2017 which has the following general requirements.

- Vitamins and minerals may be added to food products in a form that is bio-available to the human body.
- Vitamins and minerals may not be added to foodstuffs unless these vitamins and minerals are added to the product specification
- Vitamins and minerals may not be added to unprocessed foodstuffs, including fruit, vegetables, meat, poultry, and fish

2) Food for Special Dietary Uses - Low Sodium Iodized

SFDA.FD/GSO 2392:2014: Food for special dietary uses - Low sodium iodized. This standard applies to refined iodized soft edible salt prepared for human consumption.

3) Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses

SFDA.FD/GSO CAC/GL 10:2009 is a standard that contains advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children.

4) General Requirements for Prepackaged Foods for Special Dietary Use (GSO 654:2021)

This technical regulation applies to all prepackaged foods used for special dietary uses, which includes but not limited to foods for special medical purposes, foods for use in weight control diets, gluten-free foods, food supplements, infants and young children's foods, infant formula, follow on formula and formulas for special medical purposes.

5) Halal Food and Certification Requirements

GSO 2055-1/2015 defines Halal food as food and drinks, which are allowed to be consumed according to Islamic rules by eating, drinking, injection or inhaling, and that should comply with requirements mentioned in the regulation.

- Halal Slaughter Certificates: Poultry and livestock slaughtering must take place in an officially licensed slaughterhouse and in accordance with Islamic slaughtering procedures prescribed in GSO number 993:2015 "Animal Slaughtering Requirements According to Islamic Law". Exports of whole meat and parts must be accompanied by halal slaughter certificates attesting that the livestock/poultry slaughtered for export to Saudi Arabia are slaughtered according to the requirements of GSO 993:2015.
- Halal Certificates: Food products containing meat ingredients exported to Saudi Arabia must be accompanied by halal certificates issued by halal certification bodies accredited by SFDA.

At the end of 2020, SFDA began requiring that halal certificates accompanying poultry and livestock meat as well as their products/ingredients exported to Saudi Arabia must be issued exclusively by <u>Halal</u> <u>Certification Bodies (HCB)</u> accredited by its Halal Center (HC). Thus far, the HC has accredited and registered three U.S. HCBs: (1) ISWA Halal Certification Department, (2) Halal Transactions, Inc. and (3) Islamic Food and Nutrition Council of America. A new U.S. company interested in getting approved as HCB could contact SFDA Halal Center at this <u>link</u> to obtain information about registration requirements.

6) Food Sanitation Law/Guidelines

SFDA has issued a 44 page Food Hygiene and Requirements and SFDA summarizes the main objective of the guidelines as achieving a high level of protection for human health and lay down general and specific rules and responsibilities of food business operators on the hygiene of foodstuffs and requirements for food premises and establishments. The guidelines make food business operators responsible primarily for food safety, emphasizes the need to ensure food safety throughout the food chain starting with primary production, requests general implementation of procedures based on the HACCP principles. The guidelines equally apply to all Saudi based food premises and foreign facilities wishing to export food products to the Kingdom.

7) Plant – Based Meat and/or Dairy Alternatives

SFDA implements GSO CODEX STAN 174:2021 Vegetable Protein Products. The requirement applies to vegetable protein products (VPP) intended for use in foods prepared proteins by various separation and extraction processes from vegetable sources other than single cell protein. The VPP are aimed for use in foods requiring further preparation and used by the food processing industry.

8) Soy Protein Products (GSO 1354: 2008)

The regulation deals with soy protein products (SPP) prepared from seeds of soybeans (Glycine Max. L.) by various separation and extraction processes which are intended for use in foods requiring further preparation and in food processing industry.

9) Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods

The following conditions and requirements apply to all consignments of food where the descriptive information on the label, or in the accompanying advertisement materials and commercial documents, indicate the use of organic production methods. The term " organic", "biological", "biodynamic", "ecology" or any other words with similar meanings, including phrases which suggest to the consumer that the product, or any ingredients thereof, has been produced by means of organic production methods. These conditions and requirements cover the following products:

- 1. Unprocessed agricultural and animal products.
- 2. Processed agricultural and animal products.

SFDA.FD/GSO 2374:2014 provides guidelines for the production, processing, labeling, and marketing of organically produced foods. Saudi Arabia requires that food products labeled as organic and exported to the Kingdom must be produced according to the requirements and standards of competent authority of the exporting country and the imported products must be accompanied by official certificate issued by the competent authority that ascertain the organic production claim. SFDA accepts the USDA organic logo if the claim is substantiated by an official certificate issued by a USDA's competent authority. Other pertinent regulations for organic foods are SFDA.FD/GSO 2532:2016 " Maximum Limits of Pesticides Residues and contaminants in Organic Food". The regulation provides maximum residue limits of pesticides and contaminants allowed in organic food. SFDA.FD/GSO 2511 deals with prepackaged organic dates.

In addition to the above regulations importers of organic products must comply with MEWA Organic Agricultural Law and SFDA's requirements for Releasing Organic Food Products discussed below:

- a. The MEWA is the competent authority in the Kingdom to legislate organic agriculture law and its executive regulations.
- b. MEWA's <u>Executive Regulations for Organic Agriculture</u> (in Arabic language) states that any party or individual wishing to engage in any activity (farming, manufacturing, importing, and exporting, etc.) with organic food, must obtain a certificate of authentication from licensing organic certification bodies (OCB). That certificate confirms and documents the organic activity.
- MEWA is the responsible authority for licensing OCB to practice inspection and documentation services in the Kingdom. Any party or individual interested in engaging in organic food production or trade must obtain a license from accredited OCB. MEWA has licensed five OCBs: 1) BCS, Germany, 2) CERES, Germany, 3) TAWTHIQ, Saudi, 4), OneCert, USA, and CCPB, Italy.
- d. The organic authentication certificate and the transaction certificate issued by the OCBs are required to release organic food products imported to Saudi Arabia. In addition, all

organic products imported to the Kingdom are subject to inspection, documentation and tracking by one of the OCBs.

- e. The release of imported organic food products is linked to local importer's commitment to the SFDA <u>conditions of importing and releasing organic food products (</u>in Arabic language). SFDA notified the requirements to WTO on January 7, 2020, as G/TBT/N/SAU/1118 (Clearance Conditions for Organic Food Products). The comment period ended on March 6, 2020, and the regulation was enforced early in 2021.
- f. The authentication authorities in the country of origin that grant transaction certificates are either the official supervisory authority in the country of origin or could be companies licensed by that official authority. The role of MEWA licensed OCBs is to verify the credibility of the issuing authorities and the food production and certification process.
- g. MEWA is a member of the International Organization (IFOAM Organics International), and the certificates issued by MEWA and the national certification bodies for exports of Saudi produced organic products are internationally recognized.

10) Novel Foods

Prior to the importation of novel food items to Saudi Arabia, the following documents must be presented:

- Reliable scientific evidence authenticated by recognized official bodies to confirm the safety of the food for human consumption including Acceptable Daily Intake (ADI), possible warnings in case of intake by a high-risk population and warnings if a food ingredient has exceeded its Recommended Daily Allowance (RDA).
- Ingredient analysis results from accredited labs confirming that the product is fit for human consumption and free from any health hazards.
- A Free Sale Certificate testifying that the product with its components and ingredients is freely sold in one of the countries which apply Codex standards or EU legislations.
- A pledge of full responsibility towards the product after its entry to the market and commitment to follow any relevant circulars, standards, or regulations that SFDA officially publishes in the future.

11) Baby Foods

The GSO standards that establish quality specification for baby foods are GSO 355:2011 and GSO 354:1994.

- GSO 355:2011 (Canned Baby Foods) provides specifications for baby foods that are intended primarily for use during an infant's normal weaning period (from 6 months) and for the progressive adaptation of infants and children to ordinary food. They may be either in ready-to-eat form or in dry form requiring reconstitution with water only.
- GSO 354:1994 (Infant Foods Based on Milk) is concerned with infant foods based on milk in liquid or powdered form intended for use as substitutes for human milk.

12) Requirements for Government Subsidized Baby Food

In addition to the general requirements specified in established GSO standards, Breast Milk Substitutes (BMS) or infant formulas must meet the following specifications:

- Age group: from birth until three years of age
- The percentage of milk protein: (11%)
- Percentage of milk fat: (8%)
- No flavor, only plain

13) Animal Quarantine Regulations

Saudi Arabia has periodically banned cattle, meat, and meat products imports for health reasons. Cattle imports from countries affected by Mad Cow disease, or Bovine Spongiform Encephalopathy (BSE), Foot and Mouth (FMD), and Cattle Plague diseases are banned until the affected countries are declared free of the diseases by OIE. Cattle imports from countries not affected by these diseases are subject to strict quarantine regulations on arrival at Saudi ports of entry. Saudi Arabia also bans meat and meat derivatives from countries affected by BSE and other cattle diseases. It also bans transshipment of livestock meat through countries banned from exporting meat and meat products because of BSE, FMD and other animal diseases.

In addition, Saudi Arabia requests additional statements on the health certificate accompanying livestock and poultry meat shipments indicate that the animals slaughtered for export to the Kingdom were not fed animal protein. Imports of live poultry, poultry meat and hatching eggs are banned from countries affected by avian influenza. Imports of live poultry are also banned from countries with the West Nile Virus epidemic.

For all requirements related to U.S. meat and poultry exports to Saudi Arabia, the FSIS Export Library is regularly updated: Saudi Requirements.

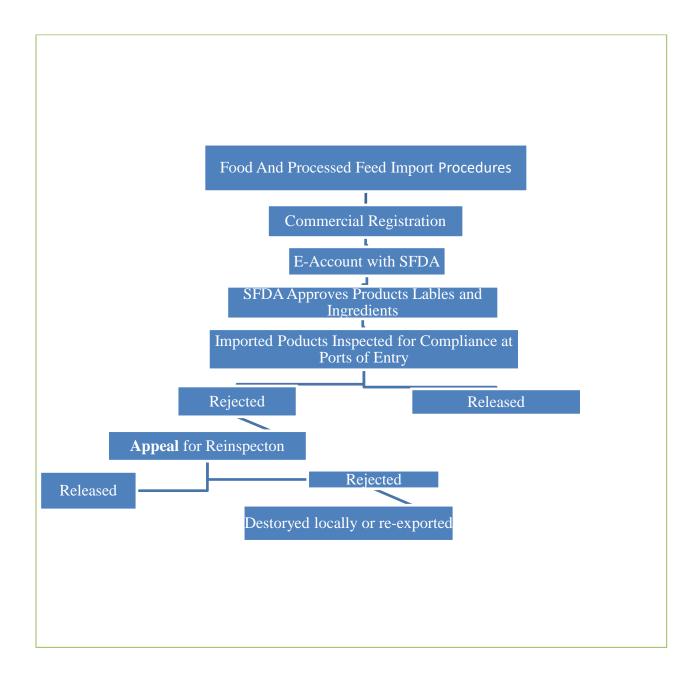
SECTION VIII TRADEMARKS, BRAND NAMES, AND INTELLECTUAL PROPERTY RIGHTS

Royal Decree No. M/5 and Resolution of Council of Ministers No. 75 dated 1984 regulate trademark registration laws in the Kingdom. According to the decree, trademarks are registered with the Trademark Registration Department of the Saudi Ministry of Commerce and Investment (MOCI) through a local agent or lawyer. Once the registration application is received, the Trademark

Registration Department will require one month to study the presented documents to decide on the request.

If an application is approved, the department will publish the trademark in the official government Arabic language newspaper (Uma Al-Qura) with the cost of publication paid by the agent or owner of the trademark. The total registration cost is estimated at approximately \$2,000. Registered trademarks are protected for 10 years and can be renewed for another similar period or periods without any new inspection after republishing it in the official paper.

SECTION IX. IMPORT PROCEDURES



Below are the SFDA's procedures for importing food products into Saudi Arabia:

- Importers must have a Commercial Register, which includes imports and distribution of food products.
- Importers should have already created an E-Account with the SFDA and registered all their imported food products.
- The following required documents must be submitted to the SFDA in order to commence the required product inspections process:
 - Original invoice certified by a chamber of commerce where the exporting company is located.
 - Some of the following certificates (depending on the food item) shall be made available:
 - Certificate of origin (Copy)
 - Halal Certificate (original)
 - Certificate of slaughtering for meat and poultry (original)
 - Any other documents or certificates required by the SFDA
 - In addition to the general requirements listed above, there may be special requirements specified by SFDA according to the nature of imported food products.

1. Inspection Procedures at Border Inspection Posts (BIPs)

With the exception of herbal preparations, health, and supplementary foods (inspected by the Ministry of Health) and live animals, plants, seeds, and grains (inspected by MEWA), all imported foodstuffs, including processed seafood, fruits, and vegetables as well as processed animal feed are inspected by the SFDA's Operations Sector inspectors at Saudi ports of entry or Border Inspection Posts (BIPs).

Imported foods are inspected independently by SFDA Operation Sector inspectors at one of Saudi Arabia's BIPs without any interference from the SFDA headquarters in Riyadh. Laboratory officials pull random samples from full consignments and testing is typically very quick. If an imported consignment is in compliance with pertinent GSO or Saudi regulations and standards, it is cleared. Otherwise, it is rejected.

The domestic importer has no access to SFDA's internal reports during the process. The SFDA informs the importer of its final decision whether to clear the product for sale in Saudi Arabia or reject it due to lack of compliance with established regulations and standards. Rejected products have to be re-exported or destroyed domestically under SFDA's supervision. Importers may appeal the decision to reject a shipment in certain circumstances (see below).

Operations Sector inspectors (Operations inspectors) perform the following mandatory four-stage verification process when food consignments arrive at BIPs:

- **Documentation Check:** All certificates and documents accompanying a consignment are checked and presence of all required documentation is verified.
- <u>Identity Check</u>: The identities of all food items imported in the consignment are verified against information in accompanying documents.
- **<u>Physical Examination</u>**: All food items contained in the consignment are physically verified to ascertain conformity with the technical regulations and standards, and that the labeling requirements are met as specified by the pertinent technical regulations and standards. The inner temperature level of the container is checked to ensure it meets the established pertinent regulations and standards.
- <u>Laboratory Test</u>: If the food inspector has reasons to believe that a laboratory test is needed to take a final decision about the food consignment, he may take random sample and send it for analysis at an authorized laboratory. SFDA does not always include all test details in the test results. FAS/Riyadh has seen several instances where the compound found and/or level was not included.

If the imported food product meets the regulations and standards, it is released by operations inspectors on the same day and referred to Customs for final clearance. Failure to comply with regulations at any of the above stages may result in a rejection of the imported food product and prevent its entry to the Kingdom. Containers can be cleared in less than five working days provided all required documents are in order and imported products meet Saudi Arabian/Gulf specifications. If a product is rejected by one of BIPs inspectors for alleged lack of adherence to established specifications at any of the above four stages, the local importer has the right to appeal the decision in writing to operations inspectors at the SFDA headquarters and ask for reconsideration of the inspection results. In such cases, operations will forward the appeal to a special committee that studies shipment documentation and the BIP's test results to verify compliance with established rules and regulations. If the BIP action was found to be compliant with the rules and regulations pertaining to the rejected product, then the BIP findings and decision is final. If, for any reason, there was a misjudgment by the BIP inspectors, the operations sector must repeal the decision and inform the importer to clear the consignment from Customs.

2. Customs Clearance

As mentioned earlier, shipments of food products must be accompanied by a commercial invoice, health certificate, and other pertinent documents. It should be noted that the Saudi Customs Authority requires that commercial invoices be issued on CIF basis (cost, insurance, and freight). If products are sold on FOB (free on board) basis, the Saudi importers will have to pay for freight and insurance costs and submit the invoices to the Saudi Customs along with commercial invoices when the consignment arrives at the Saudi port of entry. The Saudi Customs requires the CIF information for imported food products to assess and levy import duties. Containers are normally cleared within five working days provided all documents are in order and imported products meet Saudi standards and specifications.

3. E-Commerce

The SFDA allows imports of food products purchased via the internet for personal or commercial purposes without going through the required online pre-registration and import authorization requirements. However, the imported food products will be subject to inspection at the port of entry to ensure that they comply with SFDA's regulations and requirements to ascertain they are fit for human consumption.

4. Imports of Product Samples

Samples destined to potential Saudi buyers or for display in Food Shows are exempt from Saudi labeling and shelf-life regulations but are subject to inspection at ports of entry. A commercial invoice specifying that the product is not for sale and has no commercial value must accompany samples, which are usually sent to Saudi Arabia by D.H.L. and similar carriers.

5. Foodstuff Monitoring

The Environmental Protection Department at the Ministry of Municipality and Rural Affairs is responsible for establishing nationwide food sanitation laws and guidelines. Inspectors at the municipal levels monitor products already in the market. The authorities inspect retailers, wholesalers, restaurants, bakeries, fast food chains, vegetable and meat markets for expiration dates, sanitary and storage conditions as well as product handling. Outlets found selling unhygienic or expired products are exposed to stiff financial fines, temporary closure, or both.

Most Saudi food imports enter the country via the Jeddah port on the Red Sea or Dammam port on the Arabian Gulf. Approximately 70 percent of all food enters through the Jeddah port. Imports from Jordan, Syria, and other nearby countries generally enter the Kingdom by truck.

King Khalid International Airport in Riyadh and King Abdulaziz International Airport in Jeddah also receives significant quantities of food items, particularly fresh fruits, vegetables, and chilled meat. Fresh and chilled products are usually cleared within 24 hours of arrival.

SECTION X. TRADE FACILITATION

Saudi Arabia does not have a pre-clearance import program. Instead, SFDA randomly samples imported products from trusted supplying countries, such as the United States. As such, most imported U.S. food products clear Saudi customs after arriving at ports of entry, without lab testing, in approximately four days. However, if a consignment requires a lab test, results may take up to 15 days, and the importer is responsible for the fee (approximately \$1,333 per tested product). The importer is also responsible for demurrage fees, depending on the location of the customs site. Daily demurrage, or storage, fees for dried and frozen products are \$220 and \$265, respectively. If a product is rejected entry by SFDA for violating import regulations, the importer must re-export the product to the country-of-origin or destroy it locally under SFDA's supervision. If a product is destroyed locally, the importer must also pay the

demurrage fee (a fine of \$4,000 for violating import regulations) and at least \$4,533 (charged by a private company) to destroy the product.

APPENDIX I. GOVERNENT REGULATORY KEY AGENCY CONTACTS

The SFDA sets food and feed products standards. Contact information for the SFDA, and other ministries involved in food and agricultural products safety and inspection, is as follows.

Dr. Sami Al-Sager Vice President for Operations Saudi Food & Drug Authority (Inspects imported food and processed feed products) Tel: 966-11-203-8222 Ext: 5800 Fax: 966-11-275-7238 www.sfda.gov.sa

Dr. Hamad Bin Abdulaziz Al-Batshan Deputy Minister for Animal Resources The Ministry of Environment, Water and Agriculture Tel: 966-11-417-2000 Fax: 966-11-401-1323 www.mewa.gov.sa

In addition to environmental, water, and agricultural production polices, the MEWA is responsible for regulating and inspecting imported feed grains, live birds, hatching eggs, live animals, bovine genetics, and live plants.

APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

Saudi Arabia does not have any relevant import specialists that are not affiliated with the government.

Attachments:

No Attachments