SFDA. FD 513/2020

المتطلبات العامة للأغذية المستحدثة

General Requirements of Novel Foods

Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

Preamble

Saudi Food & Drug Authority is an independent agency mandated, through a panel of experts, to regulate and control locally produced and imported food, drug and medical devices and set their technical regulations and standards. After reviewing relevant technical documents, this draft standard "General Requirements for Novel Foods" was prepared by the SFDA Food Sector and adopted by the SFDA CEO order No (12/7-18-1440) on Nov, 30,2020.

General requirements of Novel foods

1. Domain and scope of application

1.1 This technical regulation is concerned with the general requirements of importing, manufacturing, and placing novel food in the Saudi markets as defined in item (3).

1.2 This technical regulation does not apply to any food ingredients covered by;

- 1.2.1 GSO 2507/2016 "General Standard for Food Enzymes".
- 1.2.2 GSO 2500/2015 "Additives permitted for use in foodstuffs.
- 1.2.3 GSO 2359/2014 "Extraction Solvents and waste limits in food production and food ingredients.
- 1.2.4 GSO 2142/2011 “General Requirements for Genetically Modified Foods and Feed”

2. Supplementary references

2.1 GSO 2055-1 / 2015. "Halal food - Part 1: General Requirements”.

2.2 GSO 9 "Labeling of canned foodstuffs”.

2.3 SFDA. FD 2233 "Requirements for Nutritional data on the labels”.

2.4 SFDA.FD 2333 “Food Requirements for nutrition and health claims".

2.5 SFDA.FD 839 “Food Packs, Part 1, General Requirements”.

2.6 SFDA.FD 1863 “Food packages - Part 2: Plastic packages, requirements General“ .

3. Definitions

3.1 **Novel food**: means any food that was not used for human consumption to a significant degree in the Kingdom of Saudi Arabia before 6 Jumada Al-Awwal 1441 AH (corresponding to 1 January, 2020). Categories of novel foods may include, but are not limited to, the following;

- Food consisting of, isolated from or produced from microorganisms, fungi or algae;
- Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi, or algae;
- Food consisting of, isolated from or produced from material of mineral origin;
- Food consisting of engineering nanomaterials.
- Food consisting of, isolated from or produced from animals or their parts.
- Vitamins, minerals, and other substances which had never been the result of a food production or marketing process within the Kingdom of Saudi Arabia prior to the date indicated above.
- Food of a new or modified molecular composition;
- Foods produced from new sources, or by a production method which has not been applied to foods.
- Traditional foods from countries other than Saudi Arabia.
- Foods exclusively used in food supplements which are not intended to be used as a supplement but rather as a food.

3.2 **Engineered nanomaterials:** means any intentionally produced material that has one or more dimensions of 100 nanometers or less or consisting of separate functional parts, either internally or at the surface, including composition, conglomerates, or aggregates, which may have a size above the order 100 nanometers but retain the properties that are characteristic of the nanoscale.

3.3 **Traditional foods from countries other than the Kingdom of Saudi Arabia:** means novel foods, as defined before, which are derived from primary production with a history of safe consumption in countries other than Saudi Arabia, where the safety of this food is confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people.

4 Requirements

4.1 Foods that fall within the scope of this technical regulation must be subject to post- market monitoring for public health and safety considerations.

4.2 It is strictly prohibited to sell novel food in Saudi Arabia without obtaining an official approval from SFDA (a permit to place a novel food in the market).
4.3 Novel foods must be halal, come from halal sources and satisfy the requirements laid down in item (2.1).
4.4 Novel foods must be packaged in compliance with the standards mentioned in item (2.5) and (2.6) above.
4.5 Novel foods must be safe and fit for human consumption.
4.6 Novel foods must not be composed or used in such a way as to pose risk to consumer's health.
4.7 If an alternative product is used to replace a novel food, it must not be nutritionally incongruent with consumer's consumption.
4.8 Determination of novel food status:
- 4.8.1 Food business operators (FBO)and other interested parties shall be responsible for ensuring that the food intended to be placed on the Saudi Market fits the definition of a novel food.
- 4.8.2 FBOs and other interested parties may seek the opinion of the SFDA to determine whether or not the product destined for the Saudi market is a novel food.

4.9 Requirements for importing, manufacturing and placing novel foods on KSA markets:
- 4.9.1 Applying for an approval to place a novel food on the Saudi market. The application form shall include the following information:
  - 4.9.1.1 Applicant's name and address.
  - 4.9.1.2 Product's name and description.
  - 4.9.1.3 Description of the production process.
  - 4.9.1.4 Product's detailed composition.
  - 4.9.1.5 Methods of analysis
  - 4.9.1.6 Scientific evidence that the product does not pose any risk to human health.
  - 4.9.1.7 Unequivocal, non-misleading explanation of the intended use and labelling requirements.
- 4.9.2 In case of imported traditional foods, the application must include the following:
  - 4.9.2.1 Applicant's name and Address.
  - 4.9.2.2 Product's name and description.
  - 4.9.2.3 Product's detailed composition.
  - 4.9.2.4 Product's country/countries of origin.
  - 4.9.2.5 Documented history of product's safe use in other countries.
  - 4.9.2.6 Unequivocal non-misleading explanation of the intended use and labelling requirements.
- 4.9.3 SFDA may reject any application at any point if there are reasons to believe that it is not justified.
- 4.9.4 Applicants may withdraw their submissions at any time, and thus their applications are considered null and void.
- 4.9.5 SFDA may ask for additional information or scientific evidence in relation to risk assessment studies, product's safety and intended use.

4.10 Applicants shall provide additional information upon request.
4.11 SFDA shall publish its scientific opinion about the effect of the product on public health.
4.12 SFDA shall notify the applicants about its opinion and post it on the public domain.

4.13 For safety reasons, SFDA may require a post-marketing surveillance program applied on a case-by-case basis.

References:

1. The European Commission, the Regulation (EU) 2015/2283 on novel food. Access via: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283
2. Health Canada, Food and Drugs Act (C.R.C., c. 870) - B.28.001 - DIVISION 28 - Novel Foods. Access via: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html
3. Food Standards Australia New Zealand, Australia New Zealand Food Standards Code – Standard 1.5.1 – Novel foods. Access via:https://www.legislation.gov.au/Details/F2017C0032