USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** July 25, 2021

Report Number: EG2021-0013

Report Name: Egypt's National Food Safety Authority Issues New Decision Regulating Microbiological Contaminants

Country: Egypt

Post: Cairo

Report Category: Agricultural Situation, FAIRS Subject Report, Sanitary/Phytosanitary/Food Safety, Country/Regional FTA's, Trade Policy Incident Report, Trade Policy Monitoring, WTO Notifications

Prepared By: Shaza Omar, Senior Agricultural Specialist and Elizabeth Mello, Senior Agricultural Attache

Approved By: Kurt Seifarth

Report Highlights:

The National Food Safety Authority continues to develop standards and procedures regulating food safety in Egypt. On March 18, 2021, NFSA issued a decision of the Board of Directors No. (1) of the Year 2021 on the Technical Regulations of Microbiological Criteria for Food. The decision was published in the national official gazette on March 31, 2021 and entered into force the day after publication.

Decision on the Technical Regulations of Microbiological Contaminants

On March 18, 2021, the National food Safety Authority (NFSA) issued a decision of the Board of Directors No. (1) of the Year 2021 on the Technical Regulations of Microbiological Criteria for Food. The decision stipulates procedures to achieve health and safety objectives when verifying compliance of the relevant microbiological criteria set out in the decisions' s Annexes.

The decision includes two annexes; Annex I, which covers the mandatory technical rules of microbiological standards for food and permissible limits. Annex II stipulates plans for sample withdrawal and testing of some grouped microbiological contaminants

The decision sets out the rules and criteria necessary to determine if food is safe for consumption with regard to their microbiological residues. Such criteria will apply to all foods, both locally produced as well as imported ingredients and industrial input used in food processing. It will be vital for NFSA to continue establishing a comprehensive food safety system.

Post expects that the decision may create barriers to trade, and office sources have commented that the decision is regulating insignificant contaminants. Therefore, these technical regulations may cause disruption to the flow of agricultural products upon implementation.

Please find attached to this report the English version of the decision and the Arabic version of the Annexes. Post will make the annexes available in English as soon as NFSA provides a translated copy.

The National Food Safety Authority

Decision of the Board of Directors No. (1) Of the Year 2021

On

the Technical Regulations of Microbiological Criteria for Foodstuffs

Board of Directors (BOD)

After reviewing the Constitution,

Law No.48 of the Year 1941 on Combating Fraud and Deception,

Law No. 95 of the Year 1945 on Supply Affairs,

Law No. 132 of the Year 1950 on Milk and Milk Products,

Law No. 684 of the Year 1954 Regulating Bread Handling and Transportation,

Law No. 685 of the Year 1954 on Regulating Meat Transportation,

Decree Law of the President of the Republic No. 798 of the Year 1957 on Foodstuff Containers and amendments thereto,

Decree Law of the President of the Republic No. 880 of the Year 1960 on the Requirements of Raw Fish and Ice Transportation in Egypt,

Law No. 10 of the Year 1966 on Food Control and Handling Regulation and Executive Ministerial Decrees related thereto,

Law No. 53 of the Year 1966 on the Enactment of the Law on Agriculture,

Law No. 1 of the Year 2017 on the Enactment of the Law on the National Food Safety Authority (NFSA),

Law No. 154 of the year 2019 on Public Shops,

Decree of the Prime Minister No. 412 of the Year 2019 on the Enactment of the Executive Regulations Implementing Law on NFSA,

Decree of the Prime Minister No. 1296 of the Year 2020 on Re-Formation of the NFSA/BOD,

Decision of the Board of Directors No. (1) Of the year 2018 on Rules Governing the Registration and Handling of Foods for Special Dietary Uses (FSDU), and

Approval of the NFSA/BOD in the meeting held on 17 March, 2021,

Decided the following:

Article (1)

The Scope

Such technical regulations lay down the microbiological criteria for certain microorganisms (bacteria, fungi, viruses, parasites) and the implementing rules to be complied with by food business operators (FBOs) when implementing the general hygiene measures. NFSA shall verify compliance with the rules and criteria laid down in the technical regulations, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other microorganisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of Hazard Analysis and Critical Control Point (HACCP) risk analysis and assessment of food establishment. Such criteria shall apply to all foods whether locally produced or imported as well as ingredients used in food processing.

Article (2)

Definitions

The following definitions shall apply:

NFSA shall mean the National Food Safety Authority.

Food Establishment shall mean any establishment performing any of the activities related to any stage of processing, production, manufacture, storage, preserving, packaging, wrapping, labelling, importation, exportation, transportation, delivery, offering or displaying for sale to the final consumer or to another establishment. The definition also includes fixed, temporary or mobile food business establishments whether profit or non-profit, public or private, permanent or temporary, as well as ruminant and poultry slaughterhouses.

Microorganisms shall mean bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, parasitic helminths of all types whether microscopic or visible to the naked eye and their toxins and metabolites.

Microbiological Criterion shall mean a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the presence or absence of number of microorganisms, and/or based on the quantity of their toxins/metabolites per unit(s) of mass, volume, area or number.

Food safety Criterion shall mean a criterion defining the acceptability of a product, a lot or a batch of foodstuff applicable to products placed on the market during shelf-life.

Process Hygiene Criterion shall mean a criterion indicating the acceptable functioning of the production process in food establishment during preparing and manufacturing. Such criterion is not applicable to products placed on the market unless otherwise specified. The criterion sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with Law on Food.

Batch shall mean a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period.

Shelf-Life shall mean either the period corresponding to the period preceding the ‘use by’ or the maximum durability date.

Ready-to-Eat Foods shall mean foods intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to acceptable level microorganisms of concern.

Food Intended for Infants shall mean food intended specifically for infants.

Food intended for special medical purpose shall mean dietary food for special medical purposes.

Sprouts shall mean seeds germinated for direct consumption by consumers, and sprouts as well as seeds intended for the production of sprouts are subject to traceability.

Colony shall mean a group of cells growing on a solid culture surface (solid medium), each arising from the multiplication of an individual cell. It is used to determine the number of viable microorganisms in a sample per g or ml.

Sample shall mean a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter in question and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced matter in question.

Representative Sample shall mean a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample.

Compliance with Microbiological Criteria shall mean obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through taking samples, performing analyses and implementation of corrective action in accordance with Law on Food and the instructions given by NFSA.

Sampling Plan shall mean a plan showing the microbiological criteria for acceptance or rejection of the sample depending on the examination of a sufficient number of sample units via particular analytical methods (Annexes I and II). The plan comprises the following:

n = Number of sample units to be examined.

m = The acceptable microbial level in the sample unit; which separates the acceptable quality of marginal-quality acceptance. The product shall be acceptable if the value is ≤ (less than or equal to) "m"; if the value is > (greater than) "m" the product is marginally acceptable or rejected.

M = The maximum criterion value that should not be equal to or exceeded in any of "n" units.

c = The maximum number of sample units allowed to have a microbiological criterion value greater than "m" and not to exceed the value of "M".

Sample unit = A sample from the food product examined as one unit from "n". It is either a single or a part of a package or a mixed compound of the product.

Article (3)

General Requirements

1- FBOs shall ensure that foodstuffs at each stage of production, including raw material and input supply, attain the health and safety objectives when verifying compliance with the relevant microbiological criteria set out in Annexes I and II. To this end, FBOs shall at each stage of production, processing, distribution, displaying and handling, including retail, take the required measures as part of the procedures based on Hazard Analysis Critical Control Points (HACCP) principles together with the implementation of Good Hygiene Practices (GHPs) and Good Manufacturing Practices (GMPs), to ensure the following:

(a) that the supply, handling, processing and preserving of raw materials, inputs and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met and according to HACCP,

(b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use, which are pre-determined by food establishment and contained on labels.

2. As necessary, FBOs responsible for the manufacture of the product shall follow up all stages of production in order to verify compliance with the criteria throughout the shelf-life according to the good production practices (GPPs) and under the conditions of distribution, storage and use contained on labels. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes,* and that may pose a risk of *Listeria monocytogenes* and other pathogenic microorganisms for public health and consumer health.

Article (4)

Testing against Criteria

1- FBOs shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are verifying or validating the correct functioning of the procedures based on HACCP principles and GHPs.

2- FBOs shall decide the appropriate sampling frequencies within the establishment, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. FBOs shall make this decision in the context of the procedures based on HACCP principles, GMPs and GHPs, taking into account the instructions for use of the foodstuff.

Article (5)

Specific Rules for Testing and Sampling

1. The analytical methods set out in Annex I shall be applied as reference methods.

2. Samples shall be taken from processing areas, equipment used in food production, food handling areas, storage areas, or from other food areas according to HACCP system, when such sampling is necessary for ensuring that the criteria are met (Annex II). In this case, the international references shall be used with regard to sample taking and handling.

3. FBOs manufacturing ready-to-eat foods, which may pose a risk of *Listeria monocytogenes* for public health, shall take samples from processing areas, equipment, utensils and food contact surfaces for

pathogenic *Listeria monocytogenes* as part of their sampling scheme based on the relevant international references.

4. FBOs manufacturing dried infant formulae and dried foods for special medical purposes intended for infants below six months, which pose a *Cronobacter sakazakii* risk, shall monitor processing areas, equipment, utensils and food contact surfaces for Enterobacteriaceae as part of their sampling scheme based on the relevant international references (Annex II).

5. If the aim of the testing is to specifically assess the acceptability of a certain food product, a batch of foodstuffs or a process, the sampling plans shall be considered as a minimum based on the relevant international references and limits specified in (Annex I).

6. Alternative testing against microorganisms and related microbiological limits may not be allowed. Nevertheless, the use of alternative analytical methods as a reference is acceptable when the methods are validated against the reference methods set out in Annex I, and certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols.

Article (6)

Unsatisfactory Results

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, FBOs shall take the required measures together with other corrective actions defined in their HACCP-based procedures or other actions required to protect consumer health. In addition, FBOs shall take measures to identify the cause(s) of the unsatisfactory results in order to prevent recurrence of unacceptable microbiological contamination. Such measures may include modifications to HACCP-based procedures or to other food hygiene control measures approved and in place.

2. When testing against food safety criteria set out in Annex I provides unsatisfactory results, appropriate procedures shall be taken on a case by case basis, for example withdrawal or recall of the product or batch of foodstuffs from the market or re-exportation, etc. Nevertheless, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. Such treatment may be carried out only by FBOs other than those at retail level, and under the supervision of NFSA.

3. NFSA may take samples from such foods before being placed on the market for performing the required testing in order to verify compliance with the food safety criteria and microbiological criteria specified in Annex I, and to check the fitness for human consumption.

Article (7)
Analyses of Results and Trends

FBOs shall analyze test results. Upon observing a trend towards unsatisfactory results, FBOs shall take standard actions in due course and without undue delay to the correct production process in order to prevent the occurrence of microbiological risks to consumer health.

Article (8)

Review

NFSA shall review the technical regulations taking into account progress in science, technology and methodology, emerging pathogenic microorganisms in foodstuffs, and make use of information from risk analysis and assessment.

Article (9)

All food establishments shall apply the technical regulations. A temporary derogation is granted for a six-month term from date of publication of the technical regulations in respect of compliance with the values specified in Annex I.

Article (10)

The present Decision shall be published in the Supplement of the Official Gazette (Al-Waqae Al-Misriyya), and shall enter into force on the day following the date of publication. Any other provision contrary to what is stated in the present Decision shall hereby be repealed.

http://www.cabinet.gov.eg/englishDated: 18 March, 2021

Chairman of the Board of Directors

Prof. Dr. Hussein Mansour

Attachments:

Microbiological Contaminants Technical Regulation (Published) (002).pdf