**Food and Drug Organization**

**The Office for Monitoring and Evaluation of**

**Food, Cosmetics and Hygiene Products**

# Guideline of the Ministry of Health, Treatment and Medical Education on living modified organism and food-related products

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| **Developed by** | **Confirmed by** | **Approved by** |
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| Biosafety working group of the Ministry of Health, Treatment and Medical Education<br><br>January 28, 2015 | Biosafety working group Secretary<br><br>Dr. Mehrnaz Kheirandish<br><br>January 29, 2015 | Deputy Minister and Head of the Food and Drug Organization<br>Dr. Rassoul Dinarvand<br><br>February 4, 2015 |

## Foreword

The growing number of production units in food and beverage industry, changes in technology and the variety of products has urged the Food and Drug Organization (FDO) to develop new regulations in the light of new scientific food knowledge since 2002. The development of mentioned standards including the minimum standards for establishment and operation of different food factories continued until 2005, but the policy for development of standards changed in June 2006 when it was decided that technical and health standards be developed for the establishment and operation of food production and packaging units as a general standard and details such as production line equipment, laboratory and specific hygienic standards be developed and approved to produce each product in separate standards specific for that product. Furthermore, developing guidelines pertaining to conditions and assessment of functional products (probiotics) was also added to the agenda. According to paragraph (b) of Article 4 and paragraph (c) of Article 5 of Biosafety Act of Islamic Republic of Iran and also given the importance of investigating safety of genetically modified (GM) food, FDO developed and ratified the current guideline. This guideline is the first edition of “the guideline for monitoring and evaluation of raw materials and imports of GM food products” that was ratified by the Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products in 2008.

It should be noted that because of the ever growing nature of global development, the mentioned standards will be revised and updated, when necessary, and recommendations

proposed will be examined by the biosafety working group of the Ministry of Health and the improved guideline will made public after approval.

It is worth noting that all relevant standards including the Cartagena Biosafety Protocol, biological safety law, related regulations and the current guideline are available on the website of the Food and Drug Organization http://fda.behdasht.gov.ir in the biosafety committee secretariat.

This guideline was developed in 2008 by the FDO in collaboration with the following:

The GMO committee, the center of reference laboratories of FDO, Deputy of Health, Deputy of Treatment and Deputy of Research and Technology of Ministry of Health, Pasteur Institute of Iran, National Institute for Genetic Engineering and Biotechnology, Institute of Standard and Industrial Research of Iran, Deputy of Crop Production of Jihad-e-Keshavarzi, Biotechnology Research Center of Jihad-e-Keshavarzi, Faculty of Pharmacy of Tehran University of Medical Sciences, Office of Food Industries at Karaj Faculty of Agriculture, Tarbiat Modares University, and Faculty of Energy Engineering. It was revised in January 2005 by the biosafety working group of Ministry of Health, Treatment and Medical Education.

This guideline was ratified by the President of the FDO on February 4, 2015 and came into force on the date of ratification.

Title



**1. Introduction**

The increasing use of GM products has urged different countries to prepare laws and guidelines related to the safe application, production, exportation, importation, processing and use of these products for human food according to international protocols and treaties.

The safety level of many foods is generally accepted by the community according to the history of their safe consumption. Now special knowledge is required in many cases to identify and manage risks related to food regarding their long-term history of consumption. Foods are generally considered safe, provided that the necessary care is taken during primary production, processing, storage, handling and preparation.

The hazards of foods are developed by the risk analysis process based on the Codex Alimentarius Commission to assess possible risks and, if necessary, to develop methods to manage them.

In general, risk analysis can be used in a variety of foods including foods derived from modern biotechnology. According to the Biosafety Act as well as the mission of the FDO to ensure food safety including foods derived from modern technology, we decided to answer Iran's requirement to issue, renew or cancel health licenses and to monitor LMOs and products of LMOs.

**2. Objectives**

The purpose of this guideline is to determine a framework for issuance, renewal and revocation of health licenses, monitoring and surveying all activities concerning LMOs and products of LOMs related to human-food consumption.

**3. Scope**

This guideline is applied for all LMOs and products of LMOs associated with food products, raw or processed materials, domestically manufactured or imported for human consumption. It should be mentioned that all applicants for any of the above-mentioned issues should observe this guideline, in addition to observing other regulations and guidelines of the FDO pertaining to food.

**4. Definitions**

**4.1 Biosafety**

It is a set of strategies, policies, regulations and procedures to ensure the exploitation of the benefits of modern biotechnology and the prevention of possible adverse effects of this technology on biodiversity, human health, animals, plants and the environment.

**4.2 Modern Biotechnology**

According to the definition in the Cartagena Biosafety Protocol and the Biosafety Act of Iran, modern biotechnology includes:

**A:** Laboratory methods for using nucleic acids such as recombinant deoxyribonucleic acid and the direct injection of nucleic acids into cells or organelles.

**B:** The combination of cells beyond their taxonomic family through overcoming barriers of natural physiological reproduction or recombination techniques used in traditional selection and breeding.

**4.3 Living modified organism: LMO**

It is any living organism produced through recombination of genetic materials using modern biotechnology.

**4.4 Genetically Modified Organism: GMO**

It is any organism whose genetic material is altered in a way that is not possible naturally by mating or natural recombination.

**4.5 Food products**

They are processed, semi-processed or raw materials, which are to feed people including drinks, foods and any other ingredient used in the production, preparation and processing of food, but excluding cosmetics, health products or medications.

**4.6 Genetically Modified foods (GM foods)**

Food derived from genetically modified organisms.

**4.7 Vector**

It is a circular plasmid or DNA in which a gene fragment of interest is inserted and enters the host cell.

**4.8 Event**

It is a line of genetically modified organisms with transgenic structure and unique entry produced through modern biotechnology.

**5. Executive responsibility**

The Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products, Deputy of Food and Drug of medical universities in Iran, reference laboratory for control of food and drug, biosafety committee secretariat at FDO are responsible for the proper performance of this guideline. In addition to investigating all requests related to GMOs and food-related products in the relevant office, they should be sent to the biosafety committee secretariat at FDO to implement appropriate processes.

**6. The process of evaluation**

6.1 All applicants for any activity on LMOs and products of LMOs related to human-food consumption should provide the following documents in addition to all documents mentioned in the rules, regulations and guidelines of the Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products:

- ✓ The purpose of production, import, export and marketing
- ✓ Clear statement to show the shipment is LMO or GMO
- ✓ Date or dates of border and cross-border transfers
- ✓ Name, identification, classification, biological safety level for LMO shipments
- ✓ Description of nucleic acid (gene) or modifications, the technology used and characteristics produced in foodstuff
- ✓ Value or volume of LMO
- ✓ Provision of a valid certificate from the responsible authorities of the country of origin on a clear statement regarding the GMO shipment sealed by Iranian Embassy in the country of origin. If the shipment is announced to be GMO, the certificate should contain event number or specific identification number registered in the biosafety clearing-house site (BCH)[1].
- ✓ Observing regulations regarding labeling if the value of LMO in each shipment is more than the tolerance threshold[2].
- ✓ Providing valid scientific documentation of potential risk assessment of GMO according to paragraph 2-6 of the guideline
- ✓ Records of consumption and previous reports of risk assessment
- ✓ Scientific and practical methods for storage, transport and safe use including: packaging, labeling, in addition to recall and disposal methods, if necessary.
- ✓ Providing a detailed plan for post-marketing surveillance and periodic reports
- ✓ Providing applicable proposal for managing potential risks in the event of unwanted distribution (if the shipment is LMO).

**Note 1.** If the applicant claims that the shipment is not GM, they should complete the pledge form of non-genetically modification (Appendix 1 of this guideline) and provide GMO-free certificate. It should be noted that GMO-free cases will be randomly selected for sampling and sent to authorized laboratories for verification of the authenticity of the applicant's claim.

**Note 2.** Tolerance threshold of GMO is zero in food products without a license from the country of origin, not registered on BCH site (with a special identification code) or without a license from FDO.

**Note 3.** After obtaining a license, the license holder shall immediately notify FDO in case of damage, and shall perform appropriate urgent measures (according to the documents provided by the applicant at the time of obtaining the license).

[1] http://bch.cbd.int/

[2] The guideline of minimum criteria for labeling food and beverage products, certification code SP-Pr-1393-0015, revised on August 25, 2014 and the directive, subject of paragraph B, Article 7 of Biosafety Act

**Note 4.** The Deputy of Food and Drug evaluates GM applications submitted to the Deputy of Food and Drug of universities of medical sciences. If the applicant declares non-GMO, the Deputy of Food and Drug of the relevant university of medical sciences is required to comply with Article 1 of the current guideline. If the product is GMO, applications will be referred to FDO for taking appropriate measures.

6.2 It is mandatory to observe the latest food safety guidelines of Codex pertaining to modern biotechnology products to assess the possible risks to human health, and provide the following information. The office of Monitoring and Evaluation of Food, Cosmetics and Hygiene Products and the Biosafety Committee secretariat are responsible for such evaluation.

- ✓ Description of the recipient organism or the host plant and its use as food
- ✓ Description of the gene donor
- ✓ Description of genetic alteration(s), the inserted gene and its vector
- ✓ Proposed methods for detection and identification of GMO and mentioning the sensitivity, specificity and reliability of the method.
- ✓ Safety assessment, including the following:

1. The expressed materials (non-nucleic acid): (investigating possible allergenicity and toxicity)

2. Analysis of key ingredients

3. Evaluation of metabolites

4. Evaluation of the effects of food processing on metabolites produced by genetic alterations

5. Evaluation of alterations in nutritional properties (or nutritional profile) of GM food.

**Note 1.** The potential risks of LMO should be separately evaluated for each event according to the latest techniques and scientific findings, and be compared to parent organisms (not genetically modified).

**Note 2.** If the shipment is LMO, the applicant is required to observe the provisions of Appendix 3 in the Cartagena Biosafety Protocol (Appendix 2 of this guideline) in addition to observing the items mentioned in 2-6 paragraph of the current guideline to assess the potential risks.

**6.3 Timeline of evaluating the documents**

6-3-1 The Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products should declare receiving documents or possible deficiencies in submitted documents to the applicant within 7 days. If there is a deficiency in the information delivered by the applicant, they are required to complete the information requested within a maximum of 28 days from the date announced and to send them to the mentioned office. If the information requested is not sent within the specified time, the case will be closed through an official announcement.

6-3-2 If the application's subject is LMO, the biosafety working group of the Ministry of Health and if it is GMO, the technical and legal committee should proclaim the final decision within 28 days to the mentioned office as one of the following:

1. The request is approved.

2. The request is rejected. The reasons for rejection should be provided in writing and with documentation.

6-3-3 The final result will be announced to the applicant by the Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products within 7 days.

**Note: 1.** In case of ambiguity or the need for supplemental tests recognized by the relevant working group, a maximum of 28 days will be added to the abovementioned time.

**Note 2.** The applicant is required to cooperate with FDO and biosafety working group during the process of examining the documents of potential risk assessment.

**Note 3.** If an inquiry is needed from other competent authorities, 14 days will be added to the time mentioned in paragraph 6-3-2.

6-3-4 After the final decision of the working group, if the shipment is LMO, the secretariat of the biosafety working group of Ministry of Health will announce the result to the secretariat of the Council and the National Biosafety Chamber House (nBCH) within 15 days for registration and announcement.

Flowchart of evaluating LMO and food-related products

Applicant

Registration in the central secretariat

Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products

Applying usual administrative process

Non-GMO

Initial review of documents by experts on the possibility of genetic modification

Genetically modified

Referring to the Biosafety Committee secretariat

Asking the applicant to complete documents (within 7 days)

Incomplete

Referring to experts at Food Office for documentation

GMO

LMO

Complete

Collecting results in the Biosafety Committee secretariat and raising GMO cases at the meeting of the Technical Legal Committee (within 28 days) and LMO cases in the Biosafety Working Group (within 42 days) and obtaining the final result

Other authorities

Yes

Needs to be reviewed and commented by other competent authorities

No

Announcing the result to the Office for Monitoring and Evaluation of Food, Cosmetics and Hygiene Products (within 7 days)

Informing the applicant

**Appendix 1: The pledge form of non-genetic modification**

Hereby, ..... as the CEO and ..... as the responsible technician of

Institution/Company:

Located in:

Phone:

According to the national Biosafety Act and its directive and also the guideline of the Ministry of Health, Treatment and Medical Education on genetically living modified organisms (LMO) and food-related products approved on ....., we hereby commit ourselves that the foodstuff requested by this company registered as ..... annexed to this letter, has no genetically living modified organism (LMO) or its products (GMO). Obviously, in the case of any violation of the mentioned cases in the relevant regulations or any discrepancy between the shipment and provided specifications, we are committed to returning the shipment and providing a copy of "certificate of return" by the Customs Department to the general office, and also according to the Biosafety Act and Article 1 of Food, Beverage, Cosmetics and Hygiene Act, this company is responsible for all legal consequences and accepts the accountability to the legally competent authorities and obviously we have no right to object.

**Name and last name**

**Signature and date**

**Appendix 3:** Genetically modified foodstuff available in the global market:

| | |
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| 1 | Rice and all of its food products |
| 2 | Soybean and all of its food products such as lecithin |
| 3 | Corn and all of its products such as canned corn, corn oil and corn powder |
| 4 | Canola (rapeseed) and all of its food products |
| 5 | Cottonseed (flax) and all of its food products |
| 6 | Dairy products, fermented products |
| 7 | Potato and all of its food products |
| 8 | Papaya and all of its food products |
| 9 | Zucchini and all of its food products |
| 10 | Tomato and all of its food products |
| 11 | Pea |
| 12 | Sugar beet |
| 13 | Sugarcane |
| 14 | Vitamins (vitamin C produced from corn, vitamin E derived from soybean, B6, B2, A and B12, and vitamins K, D derived from corn) |
| 15 | Yeasts, fungi and bacteria used in food products |