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Report Highlights:

This report outlines production, trade, research, policy, and marketing issues of genetically engineered (GE) plants, animal products, and microbial biotechnology in Italy. Despite the country's general opposition to GE food products, the Italian government and leading Italian agri-food industries and associations have shown support for innovative biotechnologies, such as genome editing. In July 2024, the Italian government extended authorization to conduct innovative biotechnologies field trials for experimental and scientific purposes until December 31, 2025.

EXECUTIVE SUMMARY

Agriculture is an important contributor to Italy's economy, accounting for approximately 2 percent of the country's Gross Domestic Product (GDP). Italy utilizes imported biotech commodities, mainly soybeans (2.5 million metric tons (MMT) imported in 2024) and soybean meal (2 MMT imported in 2024) for feed in its dairy and livestock industries. However, Italian consumer sentiment towards genetically engineered (GE) crops for direct human consumption or domestic cultivation remains unfavorable. Public and private research funding on GE products is minimal and currently no GE field trials are being conducted in Italy.

Conversely, the Italian Minister of Agriculture, Food Sovereignty, and Forests, along with leading farmers' associations (Coldiretti, Confagricoltura, Italian Farmers Confederation), Italy's agri-food industry, and scientists have shown support for innovative biotechnologies, such as genome editing. In July 2024, the Italian government extended authorization to conduct innovative biotechnologies field trials for experimental and scientific purposes until December 31, 2025. Discussions are currently ongoing to extend this deadline to December 31, 2026.

Italy is focused on genomic selection to improve animal breeding. While Italy does not produce cloned animals for commercial purposes, GE animals and clones are researched for medical or pharmaceutical applications. One genetic research center, [Avantea Ltd.¹](https://www.avantea.it/en/), located in Cremona (CR) works on animal cloning for experimental and research purposes only and performs genome editing in pigs for biomedical research.

Italy commercially produces food ingredients derived from microbial biotechnology. Italian companies work on a variety of bacteria, yeasts, fungi, and enzymes for application in food and beverage, pharmaceutical, bio-industrial, and veterinary sectors.

¹ <https://www.avantea.it/en/>

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: Genetic engineering refers to the manipulation of an organism's genes by introducing, eliminating, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques. In Italy, there are no genetically engineered (GE) plants or crops under development.

b) COMMERCIAL PRODUCTION: Italy does not commercially cultivate GE crops or have GE seed production. In 2015, Italy notified the European Commission of its decision to “opt out” of cultivating European Union (EU) authorized GE crops, citing Directive [No. 2015/412²](#). Italy maintains its ban on the cultivation of GE crops despite two European Food Safety Authority (EFSA) rulings stating no new scientific evidence has been presented to support Italy’s use of the safeguard clause. *For more information, see Chapter 1, Part B, sub-paragraph a) Regulatory Framework.*

c) EXPORTS: Italy does not export GE crops.

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32015L0412>

d) IMPORTS: Italy imports approximately 85 percent of its soybean and soybean meal for animal feed. The tables below indicate top exporters of soy products to Italy.

Table 1: Italy's leading soybean imports

Partner Country	Quantity (Metric Tons)			% Market Share			% Change 2024/2023
	2022	2023	2024	2022	2023	2024	
World	2,184,201	2,312,456	2,528,104	100	100	100	9.33
Brazil	1,165,615	1,101,993	1,416,572	53.37	47.66	56.03	28.55
United States	329,706	421,604	683,424	15.1	18.23	27.03	62.1
Canada	394,688	229,890	138,248	18.07	9.94	5.47	-39.86
Slovenia	30,657	87,030	101,273	1.4	3.76	4.01	16.37
Romania	36,238	36,602	51,088	1.66	1.58	2.02	39.58
Ukraine	98,141	145,441	31,636	4.49	6.29	1.25	-78.25
Croatia	23,085	82,771	29,000	1.06	3.58	1.15	-64.96
Austria	16,406	17,119	23,644	0.75	0.74	0.94	38.12
Hungary	10,851	38,457	18,631	0.5	1.66	0.74	-51.55
Togo	20,626	22,722	15,810	0.94	0.98	0.63	-30.42

Source: Trade Data Monitor (TDM), LLC

Table 2: Italy's leading soybean meal imports

Partner Country	Quantity (Metric Tons)			% Market Share			% Change 2024/2023
	2022	2023	2024	2022	2023	2024	
World	1,690,155	1,600,184	1,962,869	100	100	100	22.67
Argentina	1,195,923	925,608	1,284,770	70.76	57.84	65.45	38.8
Brazil	183,295	359,840	352,245	10.85	22.49	17.95	-2.11
Slovenia	208,834	240,617	201,194	12.36	15.04	10.25	-16.38
United States	358	0	61,793	0.02	0	3.15	0
Paraguay	50,463	35,249	25,703	2.99	2.2	1.31	-27.08
Spain	23,841	17,073	10,642	1.41	1.07	0.54	-37.67
Netherlands	10,383	6,958	5,867	0.61	0.44	0.3	-15.68
China	3,237	6,130	3,697	0.19	0.38	0.19	-39.69
Ukraine	138	1,218	3,405	0.01	0.08	0.17	179.56
Benin	0	0	3,011	0	0	0.15	0

Source: TDM, LLC

e) FOOD AID: Italy is not a food aid recipient. However, the Italian government maintains its commitment to food security globally and is a major supporter of the United Nations's Food and

Agriculture Organization (FAO). Italy established the [Directorate General for Development Cooperation](#)³ at the Ministry of Foreign Affairs and International Cooperation in 1979.

f) TRADE BARRIERS:

1. Cultivation Bans

Italy follows EU Directive [No. 2015/412](#)⁴, that allows EU Member States to prohibit in-country cultivation for reasons other than public health or the environment. *For more information, see Chapter 1, Part A, sub-paragraph b) Commercial Production.*

2. Delays in EU Approvals of New Events, Resulting in Asynchronous Approvals

Delays in EU approvals of new events restrict the scope of biotech events present in feed, food, and commercially grown products. Although the legally prescribed review and approval process for GE events is expected to take approximately 12 months, the average time from submission to approval for new products between 2020 and 2024 has been 5.2 years. Asynchronous and lengthy approval times increase risks of trade disruption since the EU applies zero tolerance for the adventitious presence of unapproved GE crops.

PART B: POLICY

a) REGULATORY FRAMEWORK: As a member of the EU, regulations on biotech products apply to Italy (see current *Agricultural Biotechnology Annual European Union* report which can be found at the [FAS GAIN Report Data Base](#)⁵). Italy implemented EU Directive [No. 2001/18/EC](#)⁶ which covers the deliberate release into the environment of genetically modified organisms (“GMOs”) (Italian Legislative Decree [No. 2003/224](#)⁷ in Italian). The Decree transferred oversight of the issue from the Ministry of Health to the Ministry of Environment and Energy Security. It also expanded the number of Italian Ministries responsible for authorizing new GE events: Health; Labor and Social Policies; Agriculture, Food Sovereignty, and Forests; Enterprises and Made in Italy; Education and Merit, as well as the Interministerial Evaluation Committee (created under the lead of the Ministry of Environment and Energy Security and composed of representatives from the above Ministries). Italy defers to the EU definition of “GMO” (“OGM”- Organismi Geneticamente Modificati in Italian). *For more information, see Chapter 1, Part B, sub-paragraph h) Monitoring and Testing.*

³ <https://www.esteri.it/en/ministero/struttura/dgcoopsviluppo/>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32015L0412>

⁵ <https://gain.fas.usda.gov/#/home>

⁶ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0018>

⁷ <https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2003-07-08:224>

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organismi Geneticamente Modificati (OGM)	Genetically Modified Organisms (GMOs)	<ul style="list-style-type: none"> Legislative Decree No. 2003/224 Legislative Decree No. 2016/227 	GMOs are organisms (apart from human beings) whose genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Tecniche di Evoluzione Assistita (TEA)	Assisted Evolution Technologies	<ul style="list-style-type: none"> Law No. 68 of June 13, 2023 Law No. 101 of July 12, 2024 	TEA is an emerging term for new techniques (used with plants, animals, and microorganisms) that include genome editing and cisgenesis.

b) APPROVALS/AUTHORIZATIONS: Approval of GE products in Italy is subject to EU procedures (see current *Agricultural Biotechnology Annual European Union* report which can be found at the [FAS GAIN Report Data Base](#)⁸).

A variety of GE events have been approved for feed and food use at the European level under EU Regulation No. 2003/1829. The list of approved GE products, as well as products with pending is available at: <https://ec.europa.eu/food/food-feed-portal/screen/gmo/search>⁹

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS: Italy implemented EU Regulation No. 2003/1829 and Directive No. 2001/18/EC on GE plants containing stacked transformation events through Legislative Decree No. 2003/224. Stacked events are subject to a risk assessment, following the provisions of EU Regulation [No. 2013/503](#)¹⁰, Annex II.

d) FIELD TESTING: The national media debate on GE crops and plant experimentation has made it difficult for the Italian government to support GE research and cultivation. Public and private research funding on GE products has dwindled and currently no GE field trials are being conducted in Italy. Previously, Italy's Ministerial Decree No. 2005/19 established the requirements to evaluate the risks linked to GE experimental plantings and tasked local regions to find crops and sites where GE field trials could be conducted. In 2008, the regions of Toscana and Marche approved nine crop-site dossiers (citrus, kiwifruit, strawberry, sweet cherry, corn,

⁸ <https://gain.fas.usda.gov/#/home>

⁹ <https://ec.europa.eu/food/food-feed-portal/screen/gmo/search>

¹⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF>

olive, eggplant, tomato, and grape) to carry out GE field trials. However, the Italian Ministry of Agriculture, Food Sovereignty, and Forests (MASAF) never finalized the decree authorizing the work to begin. Concurrently, 16 Italian regions (Valle D'Aosta, Piemonte, Emilia Romagna, Toscana, Lazio, Marche, Umbria, Abruzzo, Campania, Basilicata, Puglia, Sardegna, Alto Adige, Friuli Venezia Giulia, Liguria, and Molise), 41 provinces, and more than 2,350 municipalities declared themselves “GMO-free” which further obstructed the ability for new research and plantings.

e) INNOVATIVE BIOTECHNOLOGIES: On June 13, 2023, the Italian government enacted Law No. 68 to address the country’s severe water crisis. Article 9-bis authorized field trials of innovative biotechnologies for scientific purposes until December 31, 2024. Italy’s first open-field trial of gene-edited rice (“RIS8imo”), planted on May 13, 2024, to test resistance to blast disease, was destroyed by vandals. Despite this setback, some plants in the destroyed field survived and regenerated, allowing the researchers to recover viable seeds which were cultivated at three separate locations. In September 2025, Italy harvested “RIS8ttimo”, marking a major milestone for Italian agricultural research. The Italian government extended the authorization for innovative biotechnologies field trials to December 31, 2025. Discussions are currently ongoing to further extend this deadline to December 31, 2026.

On October 14, 2025, the Italian Council for Agricultural Research and the Analysis of Agrarian Economy (CREA) launched TEA4IT – Assisted Evolution Technologies for Italian Agri-Food Supply Chains, a €9 million (\$10.4 million) initiative funded by MASAF. The project aims to develop resilient, high-quality plant varieties using “Assisted Evolution Technologies” (TEA)—notably genome editing and cisgenesis—to enhance the quality, sustainability, and international competitiveness of Made in Italy agri-food products. Field trials, authorized by the Ministry of the Environment and Energy Security, will focus on key crops such as solanaceous species (tomatoes, eggplants, potatoes, peppers, etc.), fruit trees, cereals, olives, and peaches.

f) COEXISTENCE: In Italy, compliance for rules on coexistence is done on a regional level per Article 117 of the Italian Constitution as amended by Constitutional Law No. 2001/3. Moreover, per Article 26 of Legislative Decree No. 2016/227 notes “the regions and the autonomous provinces of Trento and Bolzano where “GMOs” are cultivated shall take appropriate measures in border areas of their territory, in order to avoid possible cross-border contamination into neighboring Member States, or regions, or autonomous provinces where the cultivation of those “GMOs” is prohibited— in accordance with the principle of coexistence—unless such measures are unnecessary in the light of particular geographical conditions. MASAF shall communicate those measures to the EU Commission.”

g) LABELING AND TRACEABILITY: In April 2004, Italy implemented EU Regulations No. 2003/1829 on genetically modified food and feed and [No. 2003/1830¹¹](#) concerning the traceability and labeling of “GMOs” and the traceability of food and feed products produced from “GMOs.” The EU sets out a framework for guaranteeing the traceability of GE products throughout the food chain, including processed foods in which the production methods have destroyed or altered the genetically modified deoxyribonucleic acid (DNA) (i.e. in oils). These rules apply to GE products used in food as well as those intended to be used in crops (i.e. seeds). Food and feed products containing GE organisms must be labeled. The words “genetically modified” or “produced from genetically modified (name of the organism)” must be clearly visible on the labeling of these products. Only trace amounts of GE content may be exempt from this obligation if it does not exceed a 0.9 percent per ingredient threshold and its presence is adventitious and technically unavoidable.

h) MONITORING AND TESTING: Italy’s Ministry of Health is responsible for food and feed safety—both on the market and at point of entry. MASAF is responsible for testing seeds. Italy conducts random testing of imports and, depending on the product, checks for GE content.

GE Food: The Directorate General for Hygiene and Food Safety at the Italian Ministry of Health is responsible for controls on GE food (including applications for authorization of GE food) and GE food of non-animal origin (both raw materials and processed food). Border Control Posts (PCF) perform controls of GE food and GE food of non-animal origin at the point of entry. Standard controls involve documentary, identity and physical checks, and sampling. Samples are taken from approximately 5 percent of consignments focusing largely on those declared “GMO”-free”. Accredited laboratories upload the analysis’ results directly to the information system of the Experimental Zoo-prophylaxis Institute of Lazio and Tuscany (IZSLT).

The National GE Food Control Plan for 2023-2027 is available at:

https://www.salute.gov.it/imgs/C_17_pubblicazioni_3334_allegato.pdf (in Italian)

GE Feed: The Department One Health - Directorate General for Animal Health at the Italian Ministry of Health is responsible for controls on GE feed, including applications for authorization of GE feed. GE feed controls at the point of entry are performed by the PCF. Standard controls involve documentary, identity and physical checks, and sampling. Accredited laboratories upload the analysis’ results directly to the information system of the IZSLT.

The National GE Feed Control Plan for 2024-2026 is available at:

https://www.salute.gov.it/imgs/C_17_pubblicazioni_3416_allegato.pdf (in Italian)

¹¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF>

GE Seed: MASAF is responsible for controls on GE seed. The Central Inspectorate for Quality Protection and Fraud Repression of Agri-Food Products (ICQRF); CREA-Research, Plant Protection, and Certification Center (CREA-DC); and the Customs Agency perform GE seed controls. MASAF controls registration of seed varieties through the National Register and regulates the tolerances for the adventitious presence of genetically modified seeds in conventional seed lots. Italy applies a “zero tolerance” for adventitious presence of GE seeds in conventional lots. For technical purposes, the tolerance level is 0.049 percent, or the minimum detectable level.

The National GE Seed Control Plan for 2024 is available at:

<https://www.masaf.gov.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/22511>
(in Italian)

Laboratories: The Experimental Zoo-prophylaxis Institute of Lazio and Tuscany ([IZSLT¹²](#)) — a member of the European Network of GE Laboratories— is the National Reference Laboratory (NRL) for GE analysis since 2001. The NRL develops and harmonizes methods and assists the Italian Ministry of Health in collecting and correlating data from the GE laboratories’ official control activities. The NRL has created a scientific-technical group to strengthen the network of GE laboratories and address issues, such as validation methods. In addition to the NRL, 10 IZS laboratories, 6 laboratories of Regional Agencies for Environment Protection (ARPA), and 3 laboratories of ASL (local health units) [undertake GE analyses¹³](#). Second instance analytical services are available to food business operators at the National Health Institute (ISS).

i) **LOW LEVEL PRESENCE (LLP) POLICY:** Italy voted in favor of the “technical solution,” addressing the need to harmonize the EU’s import inspection methodology. In 2011, the European Commission (EC) published a regulation allowing a 0.1 percent limit for yet unapproved biotech events in feed shipments (technical solution that defines zero), as long as the application was submitted to EFSA. At that time, the EC committed to evaluating the need for the introduction of similar limits for shipments of food. In July 2016, the EC’s Standing Committee on Plants, Animals, Food, and Feed failed to establish a technical solution (a threshold that defines zero) for an LLP allowance of biotech events in food.

j) **ADDITIONAL REGULATORY REQUIREMENTS:** N/A

k) **INTELLECTUAL PROPERTY RIGHTS (IPR):** Italy implemented EU Directive [No. 98/44/EC¹⁴](#) on the legal protection of biotechnological inventions through Law Decree No.

¹² <https://www.izslt.it/eng/>

¹³ <https://www.izslt.it/crogm/en/la-rete-italiana-dei-laboratori-del-controllo-ufficiale-ogm/>

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044>

2006/3. In 2010, the law was incorporated in section [IV bis](#) (art. 81-bis – 81-octies)¹⁵ of the Industrial Property Code (IPC).

l) CARTAGENA PROTOCOL RATIFICATION: The Italian Government ratified the Cartagena Protocol on Biosafety to the United Nations' Convention on Biological Diversity (CBP) through Law No. 2004/27. The Ministry of Environment and Energy Security coordinates administrative, technical, and scientific activities relating to Biosafety and manages the [Italian Biosafety Clearing House](#)¹⁶ (BCH). The Italian BCH is designed as an information-sharing platform, in support of the decision-making process on national biosafety issues. The Italian BCH was founded within the international framework set up by the Convention on Biological Diversity; it follows the indications of the Aarhus Convention; reflects the provisions of the European Community; responds to the requirements of the Italian Law on public consultation and access to information; and supports the implementation of legislation by the Italian Regional Authorities. A national [portal](#)¹⁷ linked to the BCH was created in 2005, in order to foster public participation and implement the Protocol's requirements.

m) INTERNATIONAL TREATIES and FORUMS: Italy is a member of the Codex Alimentarius (Codex) and the International Plant Protection Convention (IPPC). Italy's Codex point of contact is MASAF - [Directorate General for European and International Policies](#)¹⁸. Italy's IPPC point of contact is MASAF - [Directorate General for Rural Development](#)¹⁹. Furthermore, sustainable agriculture and food security represent a priority for the Italian Ministry of Foreign Affairs and International Cooperation - Directorate General for Development Cooperation²⁰ ([DGDC](#)).

n) RELATED ISSUES: N/A

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Italian consumers and policymakers are influenced by vocal anti-biotech organizations and consumer associations.

b) MARKET ACCEPTANCE/STUDIES: Italy's general attitude towards GE crops remains hostile. The uncertainty around Italy's national biotech policy and the negative media sharply affects supermarket chain marketing strategies. Several private label brands have consistently marketed their products as "GMO-free." However, most media and even anti-biotech groups recognize many Italian Protected Designation of Origin (PDO) products come from animals fed with GE soybean meal and many processed food items may contain ingredients derived from GE products. Italy's further acceptance of GE crops will require countering misinformation and

¹⁵ <https://www.wipo.int/wipolex/en/text/477643>

¹⁶ <https://bch.cbd.int/en/countries/IT>

¹⁷ <https://bch.cbd.int/en/countries/IT>

¹⁸ <https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/20889>

¹⁹ <https://www.ippc.int/en/countries/italy/>

²⁰ <https://www.esteri.it/en/ministero/struttura/dgcoopsviluppo/>

generating local agricultural community awareness about the costs and limitations of Italy's anti-biotech policies.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: There are no GE animals under development in Italy. Italy utilizes genomic selection to improve agricultural animal populations. Animal genetic engineering in Italy is primarily used for medical or pharmaceutical applications. There is one genetic research center, [Avantea](#)²¹ located in Cremona that uses animal cloning techniques with livestock species; it does not commercially clone food animals. Avantea was the first company to clone a horse and clone descendants are in active sport horse breeding programs elsewhere in the EU. This company uses animal biotechnologies to create biomedical animal models for experimental and research purposes.

b) COMMERCIAL PRODUCTION: Genetically engineered animals and clones are not being developed at this time in Italy for commercial agricultural purposes. Italy is not actively employing the use of GE animals or products derived from GE animals or clones.

c) EXPORTS: It is unknown whether products from offspring of cloned animals are being exported.

d) IMPORTS: It is unknown whether genetic material produced with modern biotechnology techniques are imported. It is also unknown if offspring of cloned animals are imported.

e) TRADE BARRIERS: Major barriers over the use of animal biotechnology to improve animal breeding stem from public resistance and political opposition.

PART E: POLICY

a) REGULATORY FRAMEWORK: Italy implemented EU Regulation No. [2003/1829](#)²² on genetically modified food and feed in April 2004. On January 26, 2012, EFSA published its "Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects." This document provides guidance for the risk assessment of food and feed containing, consisting of, or produced from GE animals, as well as for the health and welfare assessment of these animals, within the framework of EU Regulation No. 2003/1829 on GE food and feed. In 2013, EFSA published its "[Guidance](#) for the Environmental Risk

²¹ <https://www.avantea.it/en/>

²² <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32003R1829>

Assessment (ERA) of Living GE Animals to be Placed on the EU Market.” Additional information on GE animals, relevant documents, and reports can be found on EFSA’s [website](#)²³.

b) APPROVALS/AUTHORIZATIONS: No biotech animals are approved for feed and food use in Italy. Food from clones falls under the scope of the "[Novel Food Regulation](#)²⁴" and is subject to authorization. No such application has been submitted since this Regulation entered into force.

c) INNOVATIVE BIOTECHNOLOGIES: In Italy, there is one genetic research center, Avantea Ltd., located in Cremona performs genome editing in pigs for biomedical research.

d) LABELING AND TRACEABILITY: In April 2004, Italy implemented EU Regulations No. 2003/1829 on genetically modified food and feed and No. 2003/1830 concerning the traceability and labeling of “GMOs” and the traceability of food and feed products produced from “GMOs.” The same labeling rules apply to animals derived from genetic engineering, as do plants derived from genetic engineering (*see Chapter 1, Part B, sub-paragraph g) Labeling and Traceability*).

e) ADDITIONAL REGULATORY REQUIREMENTS: N/A

f) INTELLECTUAL PROPERTY RIGHTS (IPR): Italy implemented EU Directive No. 98/44/EC on the legal protection of biotechnological inventions through Law Decree No. 2006/3. In 2010, the law was incorporated in section [IV bis](#) (art. 81-bis – 81-octies)²⁵ of the Industrial Property Code (IPC).

g) INTERNATIONAL TREATIES and FORUMS: Italy has been a member of the Codex Alimentarius Commission ([CAC](#)²⁶) since 1966 and is also a member of the World Organization for Animal Health ([OIE](#)²⁷).

h) RELATED ISSUES: N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There is no active debate on the marketing of cloned or GE animals in Italy.

b) MARKET ACCEPTANCE/STUDIES: In Italy, animal biotechnology is currently a non-issue since it is focused on animals for medical and pharmaceutical purposes to treat diseases. There are no known studies relating to marketing animal biotechnology products in Italy.

²³ <https://www.efsa.europa.eu/en/topics/topic/genetically-modified-animals>

²⁴ https://food.ec.europa.eu/safety/novel-food/legislation_en

²⁵ <https://www.wipo.int/wipolex/en/text/477643>

²⁶ <https://www.fao.org/fao-who-codexalimentarius/committees/cac/about/en/>

²⁷ <http://www.oie.int/>

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) **COMMERCIAL PRODUCTION:** Italy commercially produces food ingredients derived from microbial biotechnology. Italian companies work on a variety of bacteria, yeasts, fungi, and enzymes for application in food and beverage, pharmaceutical, bio-industrial, and veterinary areas.

b) **EXPORTS:** There are no official statistics on exports of microbial biotechnology products. Italy exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

c) **IMPORTS:** There are no official statistics or estimates on imports of microbial biotechnology products. Italy's imports of microbial biotech-derived food ingredients are mostly enzymes used in alcoholic beverages, dairy products, and processed products. Likewise, Italy imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

d) **TRADE BARRIERS:** The EU classifies a product as non-“GMO” only when the genetically engineered microorganism and its modified genetic material are absent from the final product. If this condition is not met, the product has to be labeled as containing “GMO” and the GE microorganism has to be approved under the EU's “GMO” Directive.

PART H: POLICY

a) **REGULATORY FRAMEWORK:** As a member of the EU, regulations on biotech-derived microbes or microbial biotech-derived food ingredients also apply to Italy.

Contained use of “genetically modified micro-organisms (GMMs)”: The Directorate General for Health Prevention (DGPRES) at the Italian Ministry of Health coordinates administrative, technical, and scientific activities aimed at enforcing Decree [No. 2001/206²⁸](#), in cooperation with the Ministries of Environment and Energy Security; Agriculture, Food Sovereignty, and Forests; Enterprises and Made in Italy; University and Research; Interior; Labor and Social Policies. According to the Decree, when premises are to be used for the first time for contained uses, users

²⁸ https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2001-06-01&atto.codiceRedazionale=001G0260&elenco30giorni=false

shall submit a [notification](#)²⁹ (in Italian) to the DGPRE: dgprev@postacert.sanita.it. Users of “GMMs” shall also carry out an assessment of the contained uses as regards the risks to human health and the environment that those contained uses may pose. The assessment shall result in one of the following classes:

- Class 1: for activities with no or negligible risk;
- Class 2: for activities with low risk;
- Class 3: for activities with moderate risk;
- Class 4: for activities with high risk.

Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless, by agreement with the Ministry of Health, there is sufficient evidence to justify the application of less stringent measures. Following the notification, a class 1 contained use may proceed without the prior consent of the Ministry of Health at the latest 45 days after submission of the notification. A class 2 contained use may not proceed without the prior consent of the Ministry of Health, which shall communicate its decision in writing at the latest 60 days after submission of the notification. Classes 3 and 4 contained use may not proceed without the prior consent of the Ministry of Health, which shall communicate its decision in writing at the latest 90 days after submission of the notification.

A list of plants authorized by the Italian Ministry of Health for the contained use of “GMMs” is available at:

https://www.salute.gov.it/new/sites/default/files/imported/C_17_pagineAree_4243_7_file.pdf
(in Italian).

Food Additives, Flavorings, and Enzymes: The Directorate General for Hygiene and Food Safety at the Italian Ministry of Health is concerned with health aspects related to food additives, food flavorings, and food enzymes. In Italy, production, marketing, and storage of food additives, food flavorings, and food enzymes are regulated by the State-Regions-Provinces [Agreement](#)³⁰ (in Italian) of April 29, 2010, concerning guidelines on the implementation of Regulation No. 2004/852 on the hygiene of foodstuffs. Only authorized food business operators can produce, sell, and store food additives, food flavorings, and food enzymes.

Novel Foods: The Directorate General for Hygiene and Food Safety at the Italian Ministry of Health manages health aspects related to novel foods. EU Regulation [No. 2015/2283](#)³¹ defines a novel food as any food that was not used for human consumption to a significant degree within the EU before May 15, 1997, regardless of when Member States joined the Union, and that falls

²⁹https://www.salute.gov.it/new/sites/default/files/external_data/scheda_informativa/BIOT_NIA_A1_P/moduli/REV%200%20Modulo%20di%20notifica%20di%20impianto%20destinato%20ad%20impieghi%20di%20MOGM.doc

³⁰ http://www.regione.piemonte.it/governo/bollettino/abbonati/2011/01/attach/dgr_01278_830_23122010_a1unico.pdf

³¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&rid=1>

under at least one of the ten categories listed in Article 3 of the legislation. Manufacturers should note that microbial biotech-derived products may be considered novel foods if the production process is entirely new. The European industry group Food Supplements Europe provides practical guidance [on its website](#).

Novel foods require pre-market authorization. Applications must be submitted to the European Commission via an [e-submission system](#)³², which may request a risk assessment from the European Food Safety Authority (EFSA). An [overview](#)³³ of the authorization procedure is available on EFSA's website.

Food business operators are responsible for verifying whether a food they intend to market in the EU qualifies as a novel food. The Novel Food Regulation provides a consultation process when the status of a food or ingredient is unclear. Commission Implementing Regulation [No. 2018/456](#)³⁴ outlines the procedural steps that operators must follow to consult the competent authority of the Member State where the product will first be marketed. In Italy, this authority is the Ministry of Health Directorate General for Hygiene and Food Safety.

The Novel Food Regulation does not apply to GEs falling within the scope of Regulation No. 2003/1829; food enzymes under Regulation [No. 2008/1332](#)³⁵; food additives [No. 2008/1333](#)³⁶; food flavorings [No. 2008/1334](#)³⁷; and extraction solvents used or intended to be used in the production of foodstuffs or food ingredients within Directive No. 2009/32.

b) APPROVALS/AUTHORIZATIONS: Approval of biotech microbes and/or derived food ingredients in Italy follows EU authorization procedures. The EU's "Package on Food Improvement Agents" includes four Regulations: Regulation [No. 2008/1331](#)³⁸ establishing a common authorization procedure for food additives, food enzymes, and food flavorings; Regulation No. 2008/1332 on food enzymes; Regulation No. 2008/1333 on food additives; and Regulation No. 2008/1334 on food flavorings.

The EU maintains Union Lists of authorized food additives and flavorings, included in the annexes to Regulations No. 1333/2008 and No. 1334/2008, respectively. Although Regulation No. 1332/2008 provides for a similar list of food enzymes, it has not been published. Based on applications submitted before March 15, 2015, the Commission compiled a Register of food enzymes, which serves as the basis for the Union List once EFSA has delivered its scientific opinions on each entry.

³² <https://foodsupplementseurope.org/publications-guidelines/>

³³ <https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflownutrinovel2018.pdf>

³⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0456&from=EN>

³⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1332-20121203&rid=1>

³⁶ <https://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=CELEX:02008R1333-20180812&qid=1540307429675>

³⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1507214561524&uri=CELEX:02008R1334-20170713>

³⁸ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1331>

To include a new substance in the Union Lists, applicants must follow the Common Authorization Procedure established by Regulation No. 1331/2008. The implementing rules are provided in Commission Regulation No. 234/2011, and detailed guidance for applicants is available on the European Commission's [website](#).³⁹

Novel Foods: Commission Implementing Regulation [No. 2017/2470](#)⁴⁰ establishes a list of novel foods authorized in the EU. Entries in the list include specifications, conditions of use, additional labeling requirements, and post-monitoring requirements.

c) LABELING AND TRACEABILITY: Labeling and traceability of microbial biotech-derived food ingredients in Italy are subject to EU procedures.

Food Enzymes: Annex VII, Part C of Regulation No. 2011/1169 lists the categories of food enzymes, which must be designated by the name of their category, followed by their specific name or E-number. Articles 10-13 of Regulation No. 2008/1332 set out specific labeling requirements for food enzymes and food enzyme preparations.

Food Additives: Annex VII, Part C of Regulation No. 2011/1169 on the provision of food information to consumers lists the categories of food additives, which must be designated by the name of their category, followed by their specific name or E-number.

Food Flavorings: Annex VII, Part D of Regulation No. 2011/1169 sets out rules for the indication of food flavorings, smoke flavorings, and the use of the term “natural.”

Novel Foods: Annex, Table 1 of Commission Implementing Regulation [No. 2017/2470](#)⁴¹ sets additional labeling requirements for novel foods authorized in the EU.

d) MONITORING AND TESTING: The Directorate General for Hygiene and Food Safety at the Italian Ministry of Health is responsible for controls on food additives, food flavorings, and food enzymes. Border Control Posts (PCF); Veterinary Offices for Compliance with EU Requirements (UVAC); and Maritime, Aviation, and Border Health Offices (USMAF-SASN) perform random controls on food additives, food flavorings, and food enzymes at the point of entry. Standard controls involve documentary, identity and physical checks, and sampling. Second instance analytical services are available to food business operators at the National Health Institute (ISS). Accredited laboratories upload the analysis' results directly to the National Health Information System ([NSIS](#)⁴² – in Italian).

³⁹ https://food.ec.europa.eu/food-safety/food-improvement-agents/common-authorisation-procedure_en

⁴⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538482947249&uri=CELEX:02017R2470-20180903>

⁴¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538482947249&uri=CELEX:02017R2470-20180903>

⁴² <https://www.salute.gov.it/new/it/tema/nuovo-sistema-informativo-sanitario/>

The National Food Additives and Food Flavorings Control Plan for 2025-2027 is available at: <https://www.unionalimentari.com/wp-content/uploads/2025/04/Piano-nazionale-controllo-ufficiale-AA-e-AR-2025-2027.pdf> (in Italian)

The National Control Plan on Food Ingredients treated with Ionizing Radiation for 2023-2027 is available at: <https://www.salute.gov.it/new/sites/default/files/2025-04/Aggiornamento%202025%20del%20Piano%20nazionale%20controllo%20ufficiale%20alimenti%20trattati%20con%20radiazioni%20ionizzanti.pdf> (in Italian)

e) ADDITIONAL REGULATORY REQUIREMENTS: N/A

f) INTELLECTUAL PROPERTY RIGHTS (IPR): Italy implemented EU Directive [No. 98/44/EC](#)⁴³ on the legal protection of biotechnological inventions through Law Decree No. 2006/3. In 2010, the law was incorporated in the Industrial Property Code (IPC). Article 162 of the IPC regulates deposit, access, and re-deposit of a biological material. The law was also incorporated in section [IV bis](#) (art. 81-bis – 81-octies)⁴⁴ of the Industrial Property Code (IPC).

g) RELATED ISSUES: N/A

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Currently, there is no concern on microbial biotechnology in Italy.

b) MARKET ACCEPTANCE/STUDIES: Currently, microbial biotechnology is not an area of focus.

Abbreviations and definitions used in this report:

ARPA: Regional Agencies for Environment Protection

AUSL: Local Health Units

BCH: Biosafety Clearing House

CBP: Convention on Biological Diversity

CIA: Italian Farmers' Confederation

CREA: Council for Agricultural Research and the Analysis of Agrarian Economy

DGDC: Directorate General for Development Cooperation

DGPRES: Directorate General for Health Prevention

EFSA: European Food Safety Authority

EU: European Union

FAO: Food and Agriculture Organization of the United Nations

GDP: Gross Domestic Product

⁴³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044>

⁴⁴ <https://www.wipo.int/wipolex/en/text/477643>

GE: Genetically Engineered
GMO: Genetically Modified Organism
ICQRF: Central Inspectorate for Quality Protection and Fraud Repression of Agri-Food Products
IPC: Industrial Property Code
ISS: National Health Institute
IZSLT: Experimental Zoo-prophylaxis Institute of Lazio and Tuscany
MASAF: Italian Ministry of Agriculture, Food Sovereignty, and Forests
MMT: Million Metric Tons
NRL: National Reference Laboratory
PCF: Border Control Posts
TEA: Assisted Evolution Technologies
USMAF-SASN: Maritime, Aviation, and Border Health Offices
UVAC: Veterinary Offices for Compliance with EU Requirements

Terms used in this report:

The term **agricultural biotechnology** refers to a range of tools, including traditional breeding techniques, that alter living organisms or parts of organisms to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering.

Agricultural microbial biotechnology is defined as using biotechnology, predominately genetic engineering (GE) but also genome editing, to alter one or more characteristics of a microorganism. Microorganisms (microbes for short) are single-celled organisms, such as bacteria, fungi, and microalgae. These organisms are often mass cultured through fermentation to produce food ingredients or are used in other agricultural applications.

Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is often used with high-value animals to further spread high-merit genetics within an animal population. For this reason, genetically engineered or genome edited animals may be cloned—but it is a separate, distinct procedure that does not change the animal's genome. Cloning is included in this report both because it can be regulated in and of itself, or in conjunction with biotechnology regulations. Cloning regulations often cover both cloned animals themselves and their descendants.

Animal genetic engineering and **genome editing** results in the modification of an animal's genome to introduce new traits and change one or more characteristics of the species.

Genetic engineering refers to the manipulation of an organism's genes by introducing, eliminating, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques. Genome editing is considered a subset of genetic engineering under this definition.

Innovative biotechnologies is an emerging term for new techniques (used with plants, animals, and microorganisms) that may include cisgenic or transgenic changes. Terms that are used for these techniques include genome editing, new genomic techniques, new breeding techniques, new plant breeding techniques, precision breeding, plant breeding innovation, and targeted mutagenesis. Multiple technologies may underlie innovative biotechnologies techniques including but not limited to: zinc finger nucleases (ZFN), oligonucleotide-directed mutagenesis (ODM), Transcription Activator-Like Effector Nuclease (TALEN), meganucleases, RNA- dependent DNA methylation, clustered regularly interspaced short palindromic repeats (CRISPR-Cas9), and synthetic genomics.

Attachments:

No Attachments