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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 Minister of Agriculture, Food Sovereignty, and Forests, along with leading farmer associations (Coldiretti, Confagricoltura, and Cia), Italian agri-food industries, and scientific institutions have shown support for innovative biotechnologies, such as genome editing. In July 2024, the Italian government extended authorization to conduct agricultural biotechnology 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 2.2 percent of the country's Gross Domestic Product (GDP). Italy utilizes imported biotech commodities, mainly soybeans (2.3 million metric tons (MMT) imported in 2023) and soybean meal (1.6 MMT imported in 2023) for feed in its dairy and livestock industries. However, Italian consumer sentiment towards genetically engineered (GE) crops remains hostile and politically unpalatable to support GE research and cultivation. Public and private research funding on GE products has gradually been cut and currently no GE field trials are being conducted in Italy.

Despite Italy's general opposition to GE products, 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.

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], 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 any GE crops or have GE seed production. On October 1, 2015, the Italian Ministry of Agriculture, Food Sovereignty, and Forests (MASAF)[2], notified the European Commission of Italy's decision to "opt out" of cultivating European Union (EU) authorized GE crops, citing Directive No. 2015/412[3], which permits Member States (MS) to prohibit in-country cultivation for reasons other than public health or the environment. Since July 2013, Italy has banned the cultivation of GE crops, despite

[2] Please note that the Italian Ministry of Agriculture, Food, and Forestry Policies changed its name to Italian Ministry of Agriculture, Food Sovereignty, and Forests (MASAF) as of October 21, 2022.
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32015L0412

two European Food Safety Authority (EFSA) rulings stating no new scientific evidence has been presented to support Italy using the safeguard clause. *For more information, see Chapter 1, Part B, sub-paragraph a) Regulatory Framework.*

c) EXPORTS: Italy does not export GE crops.

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 2023/2022
	2021	2022	2023	2021	2022	2023	
World	2,413,495	2,184,201	2,320,446	100	100	100	6.24
Brazil	1,403,457	1,165,615	1,101,993	58.15	53.37	47.49	-5.46
United States	378,255	329,706	421,604	15.67	15.1	18.17	27.87
Canada	421,514	394,688	229,890	17.47	18.07	9.91	-41.75
Ukraine	99,292	98,141	145,441	4.11	4.49	6.27	48.2
Uruguay	0	0	99,731	0	0	4.3	0
Slovenia	21,794	30,657	89,791	0.9	1.4	3.87	192.89
Croatia	34,852	23,085	84,967	1.44	1.06	3.66	268.07
Romania	19,261	36,238	40,482	0.8	1.66	1.75	11.71
Hungary	3,050	10,851	34,721	0.13	0.5	1.5	219.99
Togo	7,603	20,626	23,178	0.32	0.94	1	12.38

Source: Trade Data Monitor (TDM), LLC

Table 2: Italy's leading soybean meal imports

Partner Country	Quantity (Metric Tons)			% Market Share			% Change 2023/2022
	2021	2022	2023	2021	2022	2023	
World	1,652,198	1,690,155	1,607,073	100	100	100	-4.92
Argentina	1,053,429	1,195,923	925,608	63.76	70.76	57.6	-22.6
Brazil	364,526	183,295	359,840	22.06	10.85	22.39	96.32
Slovenia	87,712	208,834	246,043	5.31	12.36	15.31	17.82
Paraguay	20,113	50,463	35,249	1.22	2.99	2.19	-30.15
Spain	33,872	23,841	17,708	2.05	1.41	1.1	-25.72
Netherlands	4,966	10,383	7,338	0.3	0.61	0.46	-29.33
China	4,983	3,237	6,116	0.3	0.19	0.38	88.92
Croatia	1	4,119	1,571	0	0.24	0.1	-61.86

Belgium	935	1,297	1,548	0.06	0.08	0.1	19.35
France	1,301	60	1,326	0.08	0	0.08	2096.32

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[4] at the Ministry of Foreign Affairs and International Cooperation in 1979.

f) TRADE BARRIERS:

1. Cultivation Bans

Italy follows EU Directive No. 2015/412[5], 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 should take approximately 12 months, many assessments can take upwards of six years before approvals are given. 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[6]). Italy implemented EU Directive No. 2001/18/EC[7] which covers the deliberate release into the environment of genetically modified organisms ("GMOs") (Italian Legislative Decree No. 2003/224[8] 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

[4] https://www.esteri.it/en/ministero/struttura/dgcoopsviluppo/
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32015L0412
[6] https://gain.fas.usda.gov/#/home
[7] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0018
[8] https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2003-07-08;224

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.*

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)	• 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	• 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[9]).

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 for which an authorization procedure is pending, is available at: https://webgate.ec.europa.eu/dyna2/gm-register/[10]

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 risk assessment, following the provisions of EU Regulation No. 2013/503[11], Annex II.

[9] https://gain.fas.usda.gov/#/home
[10] https://webgate.ec.europa.eu/dyna2/gm-register/
[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF

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, 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 formalized Law No. 68, the to tackle the country's severe water crisis. Specifically, the law provided for urgent provisions on agricultural genetics (art. 9 bis), authorizing field trials of innovative biotechnologies for experimental and scientific purposes until December 31, 2024.
In July 2024, Italy extended the authorization until December 31, 2025, as a swift response to the destruction of Italy's first open field trial of gene-edited rice (named "RIS8imo") by vandals in the northern province of Pavia. The rice field, planted on May 13, 2024 by a research group from the University of Milan aimed at testing gene-edited rice resistance to plant pathogens, including blast disease.

According to Italy's Minister for Agriculture, Italy needs to invest in innovative biotechnologies to develop more productive, climate-resilient, and disease-resistant crops with improved quality and nutritional properties. Italy's farmer associations (Coldiretti, Confagricoltura, and CIA) have stressed the need for innovative biotechnologies to preserve and enhance Italy's biodiversity, while fostering the sustainability and competitiveness of the agricultural sector.

f) COEXISTENCE: In Italy, compliance for rules on coexistence is done on a regional level per Article117 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: Italy implemented EU Regulations No. 2003/1829 on genetically modified food and feed and No. 2003/1830[12] concerning the traceability and labeling of "GMOs" and the traceability of food and feed products produced from "GMOs" in April 2004. 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 not only to GE products used in food, but also to those intended to be used in crops (i.e. seeds). Food and feed products containing GE organisms must be labeled as such. 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 the threshold of 0.9 percent per ingredient and its presence is adventitious and technically unavoidable.

h) MONITORING AND TESTING: Italy's Ministry of Health is responsibility 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, Food Safety, and Nutrition 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 Directorate General for Animal Health and Veterinary Medicine 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.

[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF

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)

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 2023 is available at:
https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/20532
(in Italian)

Laboratories: The Experimental Zoo-prophylaxis Institute of Lazio and Tuscany (IZSLT[13]) — 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 analyses[14]. 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 evaluate 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

[13] https://www.izslt.it/eng/
[14] https://www.izslt.it/crogm/en/la-rete-italiana-dei-laboratori-del-controllo-ufficiale-ogm/

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Italy implemented EU Directive No. 98/44/EC[15] 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)[16] 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[17] (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[18] 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[19]. Italy's IPPC point of contact is MASAF - Directorate General for Rural Development[20]. Furthermore, sustainable agriculture and food security represent a priority for the Italian Ministry of Foreign Affairs and International Cooperation - Directorate General for Development Cooperation[21] (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

[15] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044
[16] https://www.wipo.int/wipolex/en/text/477643
[17] https://bch.cbd.int/en/countries/IT
[18] https://bch.cbd.int/en/countries/IT
[19] https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/20889
[20] https://www.ippc.int/en/countries/italy/
[21] https://www.esteri.it/en/ministero/struttura/dgcoopsviluppo/https://www.esteri.it/en/ministero/struttura/dgcoopsviluppo/

marketed their products as "GMO"-free." However, most media and even anti-biotech groups recognize most typical 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 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[22] 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: N/A

PART E: POLICY

a) REGULATORY FRAMEWORK: Italy implemented EU Regulation No. 2003/1829[23] 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

[22] https://www.avantea.it/en/
[23] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32003R1829

and welfare assessment of these animals, within the framework of EU Regulation No. 2003/1829 on GE food and feed. On May 23, 2013, EFSA published its "Guidance for the Environmental Risk 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[24].

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[25]" 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: 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" in April 2004. The same labeling rules apply to animals derived from genetic engineering, as does 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 leg

al 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)[26] of the Industrial Property Code (IPC).

g) INTERNATIONAL TREATIES and FORUMS: Italy has been a member of the Codex Alimentarius Commission (CAC[27]) since 1966 and is also a member of the World Organization for Animal Health (OIE[28]).

h) RELATED ISSUES: N/A

PART F: MARKETING

[24] https://www.efsa.europa.eu/en/topics/topic/genetically-modified-animals
[25] https://food.ec.europa.eu/safety/novel-food/legislation_en
[26] https://www.wipo.int/wipolex/en/text/477643
[27] https://www.fao.org/fao-who-codexalimentarius/committees/cac/about/en/
[28] http://www.oie.int/

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.

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: Post is not aware of any trade barriers that negatively affect U.S. exports of microbial biotech-derived food ingredients or processed food products containing microbial biotech-derived food ingredients. In general, most biotechnology-related trade barriers in Italy stem from EU regulations.

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 (DGPRE) at the Italian Ministry of Health coordinates administrative,

technical, and scientific activities aimed at enforcing Decree No. 2001/206[29], 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 shall submit a notification[30] (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/imgs/C_17_pagineAree_4243_4_file.pdf (in Italian).

Food Additives, Flavorings, and Enzymes: The Directorate General for Hygiene, Food Safety, and Nutrition 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[31] (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, Food Safety, and Nutrition at the Italian Ministry of Health is concerned with health aspects related to novel foods. EU Regulation No.

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

[30] https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&label=servizionline&idMat=BIOT&idAmb=NIA&idSrv=A1&flag=P

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

2015/2283[32] defines novel food as any food that was not used for human consumption to a significant degree within the Union before May 15, 1997, irrespective of the dates of accession of MS to the Union, and that falls under at least one of ten categories of food mentioned in Article 3 of the 'novel foods' legislation. A guidance document[33] on "human consumption to a significant degree" is available on the European Commission's website. Moreover, the European industry group Food Supplements Europe offers useful guidance[34] on their website in the form of a decision tree.

Novel foods require a pre-market authorization. Applications for authorization must be submitted to the European Commission via an e-submission system[35]. The Commission may request the European Food Safety Authority (EFSA) to carry out a risk assessment. An overview[36] of the different steps of the authorization procedure is available on EFSA's website. Authorizations are generic and no longer applicant-linked as was the case under the previous rules.

Food business operators are responsible for verifying whether the food they intend to market in the EU is novel or not. Novel Food Regulation provides for a consultation process when the status of a food or food ingredient is unsure. Commission Implementing Regulation No. 2018/456[37] lists the procedural steps that food business operators must follow to consult with the competent authority of the Member State (in Italy, the Ministry of Health - Directorate General for Hygiene, Food Safety, and Nutrition) where they first intend to market their product.

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[38]; food additives No. 2008/1333[39]; food flavorings No. 2008/1334[40]; 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 is subject to EU procedures. The EU's "Package on Food Improvement Agents" includes four Regulations: Regulation No. 2008/1331[41] 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.

[32] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&rid=1
[33] https://ec.europa.eu/food/system/files/2016-10/novel-food_guidance_human-consumption_en.pdf
[34] https://ec.europa.eu/food/system/files/2016-10/novel-food_guidance_human-consumption_en.pdf
[35] https://foodsupplementseurope.org/publications-guidelines/
[36] https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflownutrinovel2018.pdf
[37] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0456&from=EN
[38] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1332-20121203&rid=1
[39] https://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=CELEX:02008R1333-20180812&qid=1540307429675
[40] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1507214561524&uri=CELEX:02008R1334-20170713
[41] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1331

Food Enzymes: Regulation No. 1332/2008 on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU. EFSA is currently evaluating industry applications for authorization of existing and new food enzymes. Until the Commission draws up an EU-list of authorized food enzymes, national rules on the marketing and use of food enzymes, and food produced with food enzymes will continue to apply. So far, in Italy, the only two enzymes authorized as food additives are invertase and lysozyme.
For more information, see the European Commission's website:
https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en.

Food Additives: Annex I to Regulation No. 2008/1333 lists the definitions of 26 different categories of food additives. Only additives included in the EU's positive list (annex II to Regulation No. 2008/1333) are authorized for use in food products marketed in the EU. Annex III to Regulation No. 2008/1333 contains a second list of food additives approved for use in food ingredients, such as other food additives, food enzymes, food flavorings, and nutrients. Commission Regulation No. 2012/231 sets out specifications for food additives listed in Annexes II and III.

Inclusion in the EU positive list is based on a risk assessment by EFSA. An important difference from U.S. legislation is that the EU does not allow the use of flour beaching agents, chlorine, bromates, and peroxides. Commission Regulation No. 257/2010[42] sets out a re-evaluation program for EFSA to assess food additives that were approved before Regulation No. 1333/2008 entered into force. Please find a link to the summary table[43] of permitted food additives and status of their re-evaluation by EFSA (as of September 1, 2024). For more information on the re-evaluation of food additives, see:
https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

Food Flavorings: Part I of Annex I of Regulation No. 1334/2008 establishes a list of authorized flavoring substances. Commission Implementing Regulation No. 2013/1321[44] establishes the EU positive list of authorized smoke flavoring primary products for use as such in or on foods, and/or for the production of derived smoke flavorings. Regulation No. 2003/2065[45] establishes a safety assessment and authorization procedure for smoke flavorings intended for use in or on foods.

[42] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:080:0019:0027:EN:PDF
[43] fs_food-improvement-agents_reeval_summary-table.xls (live.com)
[44] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:333:0054:0067:EN:PDF
[45] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32003R2065

Novel Foods: Commission Implementing Regulation No. 2017/2470[46] 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. In 2016, EFSA completed a re-evaluation of EU-approved food colors. As a result, Annex V to Regulation No. 1333/2008 on food additives was amended to introduce mandatory labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122), and Allura Red AC (E129). Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children". Commission Regulation No. 2012/232[47] lowered the limits for food colors Quinoline Yellow (E104), Sunset Yellow (E110), and Ponceau 4R (E124). Food color Red 2G (E 128) was removed from the EU's positive list in 2007.

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." Regulation No. 2008/1334 provides additional rules on the use of the term "natural."

Novel Foods: Annex, Table 1 of Commission Implementing Regulation No. 2017/2470[48] sets additional labeling requirements for novel foods authorized in the EU.

d) MONITORING AND TESTING: The Directorate General for Hygiene, Food Safety, and Nutrition 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

[46] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538482947249&uri=CELEX:02017R2470-20180903
[47] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:078:0001:0012:EN:PDF
[48] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538482947249&uri=CELEX:02017R2470-20180903

National Health Institute (ISS). Accredited laboratories upload the analysis' results directly to the National Health Information System (NSIS[49] – in Italian).

The National Food Additives and Food Flavorings Control Plan for 2020-2024 is available at: https://www.salute.gov.it/imgs/C_17_pubblicazioni_2927_allegato.pdf (in Italian)

The National Control Plan on Food Ingredients treated with Ionizing Radiation for 2023-2027 is available at: https://assets-eu-01.kc-usercontent.com/81954d07-82f8-0181-f3b0-51ccf4d64a1b/ce64f0c5-1609-41d7-a81f-de8280b57a84/piano-nazionale-controllo-ufficiale-2023-2027_aggiornamento-2024.pdf (in Italian)

e) ADDITIONAL REGULATORY REQUIREMENTS: N/A

f) INTELLECTUAL PROPERTY RIGHTS (IPR): Italy implemented EU Directive No. 98/44/EC[50] 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)[51] of the Industrial Property Code (IPC).

g) RELATED ISSUES: N/A

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Currently, there is no debate 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
DGPRE: Directorate General for Health Prevention
EFSA: European Food Safety Authority

[49] https://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&tema=Piani,%20finanziamenti%20e%20monitoraggio%20del%20SSN&area=sistemaInformativo
[50] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044
[51] https://www.wipo.int/wipolex/en/text/477643

EU: European Union
FAO: Food and Agriculture Organization of the United Nations
GDP: Gross Domestic Product
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
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 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** result 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 are 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 figure 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