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Report Highlights:

This report describes production, trade, research, policy, and marketing issues of genetically engineered (GE) plants, animal products, and microbial biotechnology in Italy. Despite Italy's opposition to GE products, the Italian Minister of Agriculture, Food, and Forestry Policies, along with leading farmers' associations (Coldiretti, Confagricoltura, and Cia), agri-food industry players, and scientists have come forward in favor of innovative biotechnologies, such as genome editing.

EXECUTIVE SUMMARY

Agriculture is one of Italy's key economic sectors, accounting for approximately two percent of Gross Domestic Product (GDP). The country depends on imported biotech commodities, mainly soybeans (2.1 million metric tons (MMT) imported in 2020) and soybean meal (1.8 MMT imported in 2020) as feed for its dairy and livestock industries. Nevertheless, the general attitude towards genetically engineered (GE) crops remains hostile. The national media debate on GE crops and plant experimentation has made it politically unpalatable to support GE research and cultivation. Therefore, public and private research funding on GE products has gradually been cut to zero and currently no GE field trials are being conducted in Italy.

Despite Italy's opposition to GE products, the Italian Minister of Agriculture, Food, and Forestry Policies, along with leading farmers' associations (Coldiretti, Confagricoltura, and Cia), agri-food industry players, and scientists have come forward in favor of innovative biotechnologies, such as genome editing.

Italy is focused on genomic selection to improve animal breeding. Italy does not produce cloned animals for commercial purposes. GE animals and clones are primarily used for medical or pharmaceutical applications. There is one genetic research center, Avantea Ltd., located in Cremona (CR) that works on animal cloning for experimental and research purposes only. Avantea also 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 & beverage, pharmaceutical, bio-industrial, and veterinary areas.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Genetic engineering is an approach to agricultural biotechnology that moves genes from one organism to another. In Italy, there are no genetically engineered (GE) plants or crops under development.

b) COMMERCIAL PRODUCTION: Italy does not commercially cultivate any GE crops, even for GE seed production. On October 1, 2015, the Italian Ministry of Agricultural, Food, and Forestry Policies (MIPAAF) notified the European Commission of Italy's decision to "opt out" of cultivating European Union (EU) authorized GE crops as per Directive No. 2015/412, which allows Member States (MS) to prohibit in-country cultivation for reasons other than public health or the environment. Since July 2013, Italy has been banning the cultivation of GE crops, despite 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 a) Regulatory Framework.

c) EXPORTS: Italy does not export GE crops, although Italian animal products are likely derived from animals that were fed feed with GE ingredients and some processed products likely also include GE derived ingredients.

d) IMPORTS: Italy is unable to meet domestic demand for feed inputs and therefore imports approximately 85 percent of its soybean and soybean meal. The tables below indicate the top

exporters of soy products to Italy. Given that GE soybeans represent a significant portion of the global supply, Italy likely is using GE soybean in its feed ingredients.

Table 1: Italy's leading soybean imports

Partner Country	Quantity (Metric Tons)			% Market Share			% Change 2020/2019
	2018	2019	2020	2018	2019	2020	
World	1,513,752	2,001,853	2,159,985	100	100	100	7.9
Brazil	256,024	601,074	931,644	16.91	30.03	43.13	55
United States	379,236	906,694	427,455	25.05	45.29	19.79	-52.86
Canada	374,686	136,244	327,509	24.75	6.81	15.16	140.38
Ukraine	175,779	79,991	209,361	11.61	4	9.69	161.73
Croatia	25,988	107,956	90,063	1.72	5.39	4.17	-16.57
Paraguay	123,434	77,338	62,715	8.15	3.86	2.9	-18.91
Argentina	1	24,952	24,457	0	1.25	1.13	-1.98
Romania	49,376	23,601	21,022	3.26	1.18	0.97	-10.93
Austria	19,003	5,672	19,018	1.26	0.28	0.88	235.29
Uruguay	17,239	10,259	11,539	1.14	0.51	0.53	12.48

Source: Trade Data Monitor (TDM)

Table 2: Italy's leading soybean meal imports

Partner Country	Quantity (Metric Tons)			% Market Share			% Change 2020/2019
	2018	2019	2020	2018	2019	2020	
World	2,161,826	1,937,934	1,817,575	100	100	100	-6.21
Argentina	1,584,110	1,467,213	1,452,971	73.28	75.71	79.94	-0.97
Brazil	155,746	153,476	175,938	7.2	7.92	9.68	14.64
Paraguay	133,806	136,647	76,493	6.19	7.05	4.21	-44.02
Slovenia	28,290	20,031	32,106	1.31	1.03	1.77	60.28
Spain	33,800	9,269	30,142	1.56	0.48	1.66	225.19
China	13,464	22,713	19,849	0.62	1.17	1.09	-12.61
Hungary	15,151	218	15,185	0.7	0.01	0.84	6876.05
Netherlands	5,180	4,024	4,545	0.24	0.21	0.25	12.94
Austria	3,679	1,398	2,268	0.17	0.07	0.13	62.26
Ethiopia	0	0	1,602	0	0	0.09	0

Source: TDM

e) FOOD AID: Italy is not a food aid recipient. However, the Italian government maintains its commitment to food security globally, being one of the Food and Agriculture Organization of the United Nations' (FAO) major supporters. It established the Directorate General for Development

Cooperation at the Ministry of Foreign Affairs in 1979. Since 2002, the Italy/FAO Cooperative Program has sponsored 39 projects in 85 countries, with a total budget of €100 million, in order to address poverty and improve food security by enhancing agricultural productivity. The monies were allocated to the Global Trust Fund's three thematic priority areas:

1. Food Security and Food Safety;
2. Transboundary Animal and Plant Pests;
3. Investments in the Agricultural Sector.

f) TRADE BARRIERS:

1. Cultivation bans

On October 1, 2015, MIPAAF notified the European Commission of Italy's decision to "opt out" of cultivating EU authorized GE crops as per Directive No. 2015/412, which allows MS to prohibit in-country cultivation for reasons other than public health or the environment. For more information, see Chapter 1 Part A 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 approval process should take approximately 12 months, in practice GE events are taking more than six years for approval. Differences in the speed of authorizations continue to lead to situations where products are approved for commercial use outside the EU, but not within the EU. These asynchronous approvals result in severe risks of trade disruption since the EU applies zero tolerance for the adventitious presence of unapproved GE crops, affecting potential imports for Italy.

PART B: POLICY

a) REGULATORY FRAMEWORK: As a member of the EU, generally EU regulations on biotech products also apply to Italy (see current *Agricultural Biotechnology Annual European Union* report which can be found at the FAS GAIN Report Data Base). Italy implemented EU Directive No. 2001/18/EC on the deliberate release into the environment of genetically modified organisms ("GMOs") through Italian Legislative Decree No. 2003/224 (in Italian). The Decree moved the responsibility for the deliberate release of GE material from the Ministry of Health to the Ministry of Environment. It also made numerous Ministries responsible for authorizing new GE events: Health, Labor, Agriculture, Economic Development, and Education, as well as the Interministerial Evaluation Committee (created under the lead of the Ministry of Environment and composed of representatives from the above Ministries). For more information, see Chapter 1 Part B h) Monitoring and Testing.

Italy implemented EU Directive No. 2015/412 of the European Parliament and of the Council amending Directive No. 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms in their territory through Italian Legislative Decree No. 2016/227 (in Italian) (hereafter referred to as The Decree) amending Legislative Decree No. 2003/224.

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). Under EU Regulation No. 2003/1829, EFSA must evaluate all GE products before they can be authorized for use in the EU. Applicants first submit an application for authorization to the national competent authority of one of the MS (in Italy, the Ministry of Health) who then forwards the application to EFSA for its scientific risk assessment. The EFSA's Scientific Panel on "GMOs" carries out a detailed risk assessment to evaluate the safety of the GE products for food or feed. After EFSA has reviewed the application for safety and provided their scientific opinion, the EU Commission and MS review and vote upon the application for market approval.

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/dyna/gm_register/index_en.cfm

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, Annex II.

d) FIELD TESTING: The national media debate on GE crops and plant experimentation has made it politically unpalatable to support GE research and cultivation. Public and private research funding on GE products has gradually been cut to zero and currently no GE field trials are being conducted in Italy. Italy's Ministerial Decree No. 2005/19 established the main requirements to evaluate the risks linked to GE experimental plantings and tasked the 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, MIPAAF never finalized the needed decree to authorize the work, citing the absence of coexistence rules as the reason. At more or less the same time, 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", further hampering the scope for new research and plantings.

e) INNOVATIVE BIOTECHNOLOGIES: Despite Italy's opposition to GE products, the Italian Minister of Agriculture, Food, and Forestry Policies, leading farmers' associations (Coldiretti, Confagricoltura, and Cia), agri-food industry players, and scientists have come forward in favor of innovative biotechnologies, such as genome editing. On April 29, 2021, the European Commission released its much-anticipated study on "New Genomic Techniques (NGTs)" or innovative biotechnologies. The study found that there are strong indications that the current GE legislation needs to be amended to address some NGTs and their products, including the need to be adapted to scientific and technological progress. Furthermore, the study confirmed that NGT products have the potential to contribute to sustainable agri-food systems, in line with the objectives of the European Green Deal and Farm to Fork Strategy. The EU Commission plans to initiate policy action on plants produced by targeted mutagenesis and cisgenesis, which will involve an impact assessment, including public consultation.

Italy's farmers' associations (Coldiretti, Confagricoltura, and CIA) applauded the findings and stressed how innovative biotechnologies might help preserve and enhance Italy's biodiversity, while fostering the sustainability and competitiveness of the agriculture sector. Moreover, they highlighted how genome editing would allow breeders and researchers to develop more productive, nutritious, and climate-resilient crops, simply accelerating modifications that could happen spontaneously in nature. They called for the implementation of science-based policies that support the techniques and the authorization of field trials.

On May 18, 2018, MIPAAF approved the allocation of €6 million in Italy's budget for 'BIOTECH', a three-year sustainable agriculture research plan to be implemented by the Italian Council for Agricultural Research and the Analysis of Agrarian Economy (CREA). The research focuses on genome editing and cisgenesis for grapevine, olive, apple, citrus fruit, apricot, peach, cherry, strawberry, kiwifruit, eggplant, tomato, basil, artichoke, wheat, rice, and poplar trees. Founded in 2015, CREA is Italy's largest agricultural research institute, comprising 12 main research centers, more than 2,000 staff members, and 5,300 hectares of experimental farms.

f) COEXISTENCE: In Italy, the competence for rules on coexistence lies at the regional level per Article117 of the Italian Constitution as amended by Constitutional Law No. 2001/3. Moreover, per Article 26-sexies of Legislative Decree No. 2016/227, *"Beginning April 3, 2017, 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. MIPAAF 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 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 as long as it does not exceed the threshold of 0.9 percent per ingredient and its presence is adventitious and technically unavoidable.

h) MONITORING and TESTING: In Italy, the primary responsibility for food and feed safety—both on the market and at point of entry—rests with the Ministry of Health. MIPAAF is responsible for testing seeds. Italy conducts random testing of imports and, depending on the product, checks for GE content. The increased sensitivity and sophistication of the equipment means that even trace amounts can complicate the clearance process for non-GE grain and soybean shipments.

GE Food: Office VI of the Directorate General for Food Hygiene, Food Safety, and Nutrition (DGSAN) at the Italian Ministry of Health is responsible for controls on GE food, including applications for authorization of GE food. Office II of DGSAN is responsible for controls on 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.

The National GE Food Control Plan for 2020-2022 is available at: http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2939 (in Italian)

GE Feed: Office VII of 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. Standard controls involve documentary, identity and physical checks, and sampling. 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 Feed Control Plan for 2020-2022 is available at: https://www.salute.gov.it/pianoNazionaleIntegrato2020/stampaDettaglioPianoNazionaleIntegrato2020.jsp?id=2591 (in Italian)

GE Seed: MIPAAF is responsible for controls on GE seed. The Central Inspectorate for Quality Control of Foodstuff and Agricultural Products (ICQRF); CREA-Research, Plant Protection, and Certification Center (CREA-DC); and the Customs Agency perform GE seed controls. MIPAAF 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 2020 is available at: https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/15975 (in Italian)

Laboratories: The Experimental Zoo-prophylaxis Institute of Lazio and Tuscany (IZSLT) — 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, 5 laboratories of Regional Agencies for Environment Protection (ARPA), and 3 laboratories of AUSL (local health units) undertake GE analyses. 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 (PAFF) failed to establish a technical solution (a threshold that defines zero) for an LLP allowance of biotech events in food. Thus, an absolute zero tolerance for unapproved biotech events found in shipments of food to the EU continues. This decision makes it difficult to export many food products to the EU market, since it is nearly impossible to guarantee that these products will not contain minute traces of biotech events.

j) ADDITIONAL REGULATORY REQUIREMENTS: N/A

k) 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.

The Italian Law Decree sets out provisions concerning the legal protection of biotechnological inventions and specifies patentability conditions. *"Inventions that are new, involve an inventive step, and are susceptible to industrial application shall be patentable even if they concern a product consisting of, or containing biological material, or a process by means of which biological material is produced, processed, or used."* Further provisions describe the procedure to be followed by the Italian Patent Office to assess the patentability of inventions. As required by Article 6 of the Italian Law Decree, *"Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory license for non-exclusive use of the patent inasmuch as the license is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty."* Similarly in Article 6, *"Where the holder of a patent concerning a biotechnology invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory license for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Applicants must demonstrate that: (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual license; (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety."*

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, Land, and Sea coordinates administrative, technical, and scientific activities relating to Biosafety and manages the Italian Biosafety Clearing House (BCH) – In Italian. 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 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 the Italian Ministry of Agriculture, Food, and Forestry Policies (MIPAAF) - Directorate General for European and International Policies. Italy's IPPC point of contact is MIPAAF - Directorate General for Rural Development. Furthermore, sustainable agriculture and food security represent a priority for the Italian Ministry of Foreign Affairs, Directorate General for Development Cooperation (DGDC).

n) RELATED ISSUES: N/A

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Italy's politicians and consumer opinions are strongly influenced by vocal anti-biotech non-governmental organizations (NGOs) (i.e. Greenpeace and Legambiente), consumers' associations (i.e. Federconsumatori), and lobbying groups that are leading the charge against the development of biotechnology.

b) MARKET ACCEPTANCE/STUDIES: Italy's general attitude towards GE crops remains hostile. To date, Italy has deemed its "Made in Italy" campaign and its role as a leading organic crop producer as limiting it from taking advantage of the gene revolution. The uncertainty around Italy's national biotech policy and the negative media has sharply affected supermarket chain marketing strategies. Several private label brands have indeed consistently marketed their products as "GMO"-free". However, after years of denial, most media and even anti-biotech groups now realize that 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 may center on how to respond to the misinformation circulating about health and environmental risks, in addition to having a candid discussion with the agricultural community about the costs of Italy's anti-biotech policies.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: In Italy, there are no GE animals under development likely to be on the market in the coming year or in the next five years. 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 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 also 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 is being imported. It is also unknown whether products from offspring of cloned animals are being imported.

e) TRADE BARRIERS: N/A

PART E: POLICY

a) REGULATORY FRAMEWORK: Italy implemented EU Regulation No. 2003/1829 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. 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." EFSA has set up a webpage to keep track of the progress of the work on GE animals, as well as providing the relevant documents and reports.

b) APPROVALS/AUTHORIZATIONS: No biotech animals are approved for feed and food use in the EU because no such application has been submitted since the regulations on GE organisms and on novel food entered into force.

Food from clones falls under the scope of the "Novel Food Regulation" 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 that 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 Part B, 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. As stated in Article 3, *"Inventions that concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."* Article 4 considers unpatentable *"processes for modifying the genetic identity of*

animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes."

g) INTERNATIONAL TREATIES and FORUMS: Italy is a member of the Codex Alimentarius Commission (CAC) since 1966. The Secretariat of the Codex Alimentarius Commission is located at FAO headquarters in Rome. Italy is also a member of the World Organization for Animal Health (OIE).

h) RELATED ISSUES: N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Currently, in Italy, there is no active debate on cloning or GE animals.

b) MARKET ACCEPTANCE/STUDIES: In Italy, animal biotechnology is currently a non-issue and is expected to remain as such, as long as genetic engineering is focused on animals for medical and pharmaceutical purposes to treat diseases. We are unaware of any market 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 & beverage, pharmaceutical, bio-industrial, and veterinary areas.

b) EXPORTS: There are neither official statistics nor estimates on exports of microbial biotechnology products. However, Italy exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

c) IMPORTS: There are neither official statistics nor estimates on imports of microbial biotechnology products. Italy imports microbial biotech-derived food ingredients, such as enzymes that are traditionally 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, generally EU regulations on biotech-derived microbes or microbial biotech-derived food ingredients also apply to Italy.

Contained use of genetically modified micro-organisms (GMMs): Through Legislative Decree No. 2001/206 (in Italian), Italy implemented EU Directive No. 98/81/EC amending Directive No. 90/219/EEC, and repealed by EU Directive No. 2009/41/EC on the contained use[1] of genetically modified micro-organisms (GMMs). The Directorate General for Health Prevention (DGPRE – in Italian) at the Italian Ministry of Health coordinates administrative, technical, and scientific activities aimed at enforcing such Decree, in cooperation with the Ministries of Environment, Agriculture, Economic Development, University and Research, Interior, and Labor. According to the Decree, when premises are to be used for the first time for contained uses, users shall submit a notification (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_0_file.pdf (in Italian).

[1] Contained use means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment.

Food Additives, Flavorings, and Enzymes: The Directorate General for Food Hygiene, Food Safety, and Nutrition (DGSAN) 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 (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: Office IV (Special foods, food supplements, and novel foods) of DGSAN at the Italian Ministry of Health is concerned with health aspects related to novel foods. EU Regulation No. 2015/2283 defines novel food as food that has not been consumed to a significant degree in the EU before May 15, 1997, and falling within at least one of the categories listed in Article 3 of the Regulation (e.g. cranberry extract powder). It can be a newly developed, innovative food resulting from new production techniques (e.g. nanotechnology) as well as a traditional - but unknown to EU consumers - food from a non-EU country (e.g. noni juice).

Food consisting of, isolated from, or produced from microorganisms, fungi, or algae shall be subject to EU Regulation No. 2015/2283 on Novel Foods (applicable since January 1, 2018) if it was not used for human consumption to a significant degree within the EU before May 15, 1997. A guidance document on "human consumption to a significant degree" is available on the European Commission's website. Moreover, the European industry group Food Supplements Europe offers guidance for food business operators on "The verification of the status of a new food under the Novel Food Regulation".

Novel foods require a pre-market authorization. Applications for authorization must be submitted to the European Commission via an e-submission system. The Commission may request the European Food Safety Authority (EFSA) to carry out a risk assessment. An overview 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 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 - DGSAN - Office IV) 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 falling within the scope of Regulation No. 2008/1332; food additives falling within the scope of Regulation No. 2008/1333; food flavorings falling within the scope of

Regulation No. 2008/1334; and extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of 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 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.

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 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 of permitted food additives and status of their re-evaluation by EFSA (as of December 17, 2020). 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 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 establishes a

safety assessment and authorization procedure for smoke flavorings intended for use in or on foods.

Novel Foods: Commission Implementing Regulation No. 2017/2470 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 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 lays down additional rules on the use of the term "natural".

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

d) MONITORING AND TESTING: Office VI of the DGSAN 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 – in Italian).

The National Food Additives and Food Flavorings Control Plan for 2020-2024 is available at: http://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 2020-2022 is available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2929_allegato.pdf (in Italian)

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. Articles 5 and 10 of Law Decree No. 2006/3 regulate deposit, access, and re-deposit of a biological material.

g) RELATED ISSUES: N/A

PART I: MARKETING

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

b) MARKET ACCEPTANCE/STUDIES: In Italy, microbial biotechnology is currently a non-issue and is expected to remain as such.

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
DGSAN: Directorate General for Food Hygiene, Food Safety, and Nutrition
EFSA: European Food Safety Authority
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 Control of Foodstuff and Agricultural Products
ISS: National Health Institute
IZSLT: Experimental Zoo-prophylaxis Institute of Lazio and Tuscany
MIPAAF: Italian Ministry of Agriculture, Food, and Forestry Policies
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:

Agricultural biotechnology refers to an evolving continuum of technologies. It is a broadly applied term that may refer to plants, animals, or microorganisms developed through making intentional changes to DNA. This most commonly includes recombinant DNA technologies, induced mutagenesis, genome editing, and other emerging techniques.

Genetic engineering is an approach to agricultural biotechnology that moves genes from one organism to another. Commonly used terms are: biotechnology, biotech, transgenic, cisgenic, bioengineered, and genetically engineered (GE).

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 and fungi. These organisms are mass-cultured through fermentation to produce food ingredients.

Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is, therefore, different from the genetic engineering or genome editing of animals (both in the science and often in the regulation of the technology and/or products derived from it). Researchers and industry may use cloning when creating animals via other animal biotechnologies. For this reason, cloning is included in this report.

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

Innovative biotechnologies are an emerging term for breeding techniques (used with plants, animals, and microorganisms) that, by most common definitions, are not transgenic. Terms that are used for these techniques include New Genomic Techniques (NGT), New Breeding Techniques (NBT), New Plant Breeding Techniques (NPBT), Precision Breeding (PB), Plant Breeding Innovation (PBI), precision breeding, targeted mutagenesis, and genome editing.

Innovative biotechnologies techniques may include (but are 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