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Report Highlights:

This report describes production, trade, research, policy, and marketing issues of genetically engineered (GE) plant and animal products in Italy. The national debate between pro and anti-biotech parties continues without much progress. To date, Italy has deemed its “Made in Italy” campaign and its role as a leading organic crop producer as proscribing it from taking advantage of the gene revolution.

SECTION I: 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, as feed for its dairy and livestock industries. However, 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. 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. The rising cost of feed materials and a greater understanding of just how prevalent consumption is of products that already rely on GE inputs may become a critical factor. The Italian Ministry of Agricultural, Food, and Forestry Policies continues to advocate for innovation involving cisgenesis and genome editing, but not transgenic modification.

On September 13, 2017, the European Court of Justice (CJEU) [ruled](#) in favor of three Italian farmers who were prosecuted for having cultivated the European Union (EU)-approved GE maize MON 810 in breach of a national decree issued July 12, 2013 prohibiting its cultivation in the Italian territory. The CJEU concluded that member states cannot adopt emergency measures concerning genetically modified food and feed “as long as it is not evident that products authorized by Regulation No. 2003/1829 or in accordance with that regulation are likely to constitute a serious risk for human, animal health, and the environment.”

Regarding GE animals and clones, GE in Italy is focused on genomic selection to improve animal breeding and is primarily used for medical or pharmaceutical applications. Italy does not produce cloned animals for commercial purposes. There is, however, 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.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

TABLE OF CONTENTS

Report Highlights

Section I: Executive Summary

Section II: Plant and Animal Biotechnology

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

PART B: Policy

PART C: Marketing

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

PART E: Policy

PART F: Marketing

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Genetic engineering is the genomic selection to improve plant breeding and understanding the metabolic pathways involved in plant architecture, quality determination, and virus resistance. 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.
- 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 85-90 percent of its soybean and soybean meal. In 2016, Italy imported 1.3 MMT (Million Metric Tons) of soybeans, mainly from Brazil (536,524 MT), the United States (272,375 MT), and Canada (172,793 MT). In 2016, Italy imported 2.1 MMT of soybean meal, mainly from Argentina (1,425,603 MT), Paraguay (349,574 MT), and Brazil (142,219 MT). Given GE soybeans represent a significant portion of the global supply, Italy likely is using GE soybean in its feed ingredients.
- 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

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, please see [GAIN Italy Agricultural Biotechnology Annual 2016](#). On October 1, 2015, the Italian Ministry of Agricultural, Food, and Forestry Policies 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. For more information, see Chapter 1 Part B a) regulatory framework.

In November 2015, Giorgio Fidenato, President of the Federated Farmers Association, and others ('the applicants') were prosecuted before the Italian District Court of Udine for having cultivated the EU-approved GE maize MON 810 in breach of a national decree issued July 12, 2013 prohibiting its cultivation in the Italian territory. [The decree was first introduced as an emergency measure based on Article 34 of EU Regulation [No. 2003/1829](#) on genetically modified food or feed, and Article 54 of EU Regulation [No. 2002/178](#)]. A penal order was issued, against which the applicants lodged an opposition, claiming that the national decree was unlawful since it was issued in breach of Article 34 of EU Regulation No. 2003/1829, and Articles 53 and 54 of EU Regulation No. 2002/178.

In this context of criminal proceedings against the applicants, on February 24, 2016, the Italian District Court of Udine asked the European Court of Justice (CJEU) whether emergency measures concerning genetically modified food and feed might be taken on the basis of the precautionary principle for risks that have not been explicitly foreseen by Article 34 of EU Regulation No. 2003/1829. For more information, see [GAIN Italian Farmer Fights for Right to Cultivate GE Maize MON810](#).

On September 13, 2017, the CJEU [ruled](#) in favor of the applicants, concluding that member states cannot adopt emergency measures concerning genetically modified food and feed "as long

as it is not evident that products authorized by Regulation No. 2003/1829 or in accordance with that regulation are likely to constitute a serious risk for human, animal health, and the environment.” Mr. Fidenato expressed satisfaction with the ruling, saying he and the other farmers involved in the trial finally feel as if “justice is on our side”.

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. The EU takes 47 months on average for an import 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 close-to-zero tolerance for the presence of EU unauthorized biotech events in food and feed, 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 EU Agricultural Biotechnology Annual 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).

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.

Per Article 26-ter of The Decree, “During the authorization procedure of a given ‘GMO’ or during the renewal of consent/authorization, the Italian Ministry of Agricultural, Food, and Forestry Policies (MIPAAF), in agreement with the Permanent Conference between State, regions, and the autonomous provinces of Trento and Bolzano may ask the EU Commission that the geographical scope of the written consent or authorization be adjusted, in order to exclude from cultivation all or part of the Italian territory. The request shall be communicated to the EU

Commission at the latest 45 days from the date of circulation of the assessment report under Article 14, paragraph 2 of EU Directive No. 2001/18/EC, or from receiving EFSA opinion under Article 6, paragraph 6, and Article 18, paragraph 6 of EU Regulation No. 2003/1829.” The Commission shall send MIPAAF’s request to the notifier/applicant and other Member States without delay. The notifier/applicant has 30 days to adjust or confirm the scope of its initial application. If the notifier/applicant does not answer, the scope shall be adjusted according to MIPAAF’s request.

Per Article 26-quater of The Decree, “Where no request was made pursuant to the aforementioned Article 26-ter, or where the notifier/applicant confirmed the geographical scope of its initial notification/application, MIPAAF may adopt measures restricting or prohibiting the cultivation in all or part of the national territory of an authorized ‘GMO,’ or of a group of ‘GMOs’ defined by crop or trait, provided that such measures are in conformity with the European law, reasoned, proportional, non-discriminatory, and based on compelling grounds, such as those related to:

- a) environmental policy objectives;*
- b) town and country planning;*
- c) land use;*
- d) socio-economic impacts;*
- e) avoidance of ‘GMO’ presence in other products, without prejudice to Article 26 bis of Directive No. 2001/18/EC;*
- f) agricultural policy objectives;*
- g) public policy.*

Those grounds may be invoked individually or in combination (with the exception of public policy reasons that cannot be used alone), depending on the particular circumstances of the area in which the measures will apply, but shall in no case conflict with the environmental risk assessment carried out pursuant to EU Directive No. 2001/18/EC, Italian Legislative Decree No. 2016/227, and EU Regulation No. 2003/1829.

The measures restricting or prohibiting the cultivation of a ‘GMO’ in all or part of the national territory shall be adopted by MIPAAF after consultation with the Ministries of Environment and Health, and, if based on letter b) after consultation with the Ministry of Infrastructures and Transports; if based on letter d) after consultation with the Ministry of Economic Development, in agreement with the Permanent Conference between State, regions, and the autonomous provinces of Trento and Bolzano; and if based on letter g) after consultation with the Ministry of Interior.

MIPAAF shall send the EU Commission a draft of the measures that intend to adopt and the corresponding grounds invoked. During a period of 75 days starting from the date of such communication, MIPAAF shall refrain from adopting the restrictive measures and operators shall abstain from planting the ‘GMO’ or ‘GMOs’ concerned. On expiry of the 75-day period, the restrictive measures are adopted through MIPAAF’s decree, after consultation with the Ministries of Health and Environment, and, if based on letter b) after consultation with the Ministry of Infrastructures and Transports; if based on letter d) after consultation with the Ministry of Economic Development; if based on letter g) after consultation with the Ministry of Interior, in agreement with the Permanent Conference between State, regions, and the autonomous provinces of Trento and Bolzano. The restrictive measures shall be adopted either in the form originally proposed, or as amended to take account of any non-binding comments received from the EU Commission. MIPAAF shall communicate such measures to the EU Commission, the other Member States, and the ‘GMO’ authorization holder without delay. MIPAAF, the Ministries of Environment and Health, the regions, and the autonomous provinces of Trento and Bolzano shall publish the adopted measures on their official websites.

The restrictive measures shall not apply to the cultivation of any authorized ‘GMO’ seeds and plant propagating materials which were planted lawfully before the adoption of such measures.” Furthermore, “The restrictive measures do not prohibit the free circulation of ‘GMO’ varieties as such, or those contained in other products, or cultivated for experimental purposes.”

Per Article 26-quinquies of The Decree, “Each region and the autonomous provinces of Trento and Bolzano may request MIPAAF that all or part of their territory be reintegrated into the geographical scope of the consent/authorization from which it was previously excluded, or the restrictive measures taken pursuant to Article 26-quater be revoked on their territory.”

Per Article 35 of The Decree, “Without prejudice to the criminal penalties that may be applicable, administrative fines ranging from €25,000 to €75,000 are imposed on those who violate the prohibition of cultivation or introduction of ‘GMOs’ into ‘GMO’-free territories. Additional administrative penalties include the suspension of the right to cultivate ‘GMOs’ granted by a previous commercialization permit for a maximum period of six months. Violators shall destroy, at their own expense, the GM crops involved and implement the required cleanup measures.”

b) APPROVALS: Approval of GE products in Italy is subject to EU procedures (see [EU-28 Annual Biotechnology Report, November 2016](#)). 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 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 full list of GE approved products is available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

c) STACKED or PYRAMIDED EVENT APPROVALS: 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, the Italian Ministry of Agricultural, Food, and Forestry Policies 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: In the last twenty years, Italy has been adopting a cisgenic approach to improve pathogen resistance and quality traits in apple, durum wheat, and poplar trees. On July 19, 2017, the Agriculture Committee of Italy's Chamber of Deputies delivered a favorable [opinion](#) (in Italian) on a draft ministerial decree presented by the Italian Ministry of Agricultural, Food, and Forestry Policies in support of genome editing and cisgenesis. The draft decree provides for the allocation of €21 million in Italy's budget for a three-year sustainable agriculture research plan to be implemented by the Italian Council for Agricultural Research and the Analysis of Agrarian Economy ([CREA](#) – in Italian). The research will focus 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. The Italian Minister of Agriculture Maurizio Martina noted, "these techniques are much different from transgenesis (insertion of a gene from a different gene pool) and will allow Italy to

produce crops resistant to climate change and diseases.” He also stated, “Italy is pushing hard not to include this work under the EU restrictive ‘GMO’ regulation system. It is a mistake to reason on the old transgenic organisms created in the 90’s - this debate has already slowed our country too much. I prefer to concentrate on the most advanced research technologies for agriculture.”

On June 22, 2017, the Italian Society of Agricultural Genetics ([SIGA](#) – in Italian), the Italian Life Sciences Federation ([FISV](#) – in Italian), and CREA launched [guidance](#) (in Italian) in support of innovative biotechnologies. The document intends to promote the use of innovative biotechnologies in Italy by making the technology accessible to farmers, public research facilities, SMEs (small and medium sized enterprises), and startups.

f) COEXISTENCE: In Italy, the competence for rules on coexistence lies at the regional level per Article 117 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. The Italian Ministry of Agricultural, Food, and Forestry Policies shall communicate those measures to the EU Commission.”*

g) LABELING: 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. The Italian Ministry of Agricultural and Forestry Policies 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 (DGFHFSN) at the Italian Ministry of Health is responsible for controls on GE food, including applications for authorization of GE food. Office II of DGFHFSN is responsible for controls on GE food of non-animal origin (both raw materials and processed food). The Port, Airport, and Border Health Offices (USMAFs) 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 5-10 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 2015-2018 is available at:

<http://www.salute.gov.it/pianoNazionaleIntegrato2015/homePianoNazionaleIntegrato2015.jsp>
(in Italian)

GE feed: Office VII of the Directorate General for Animal Health and Veterinary Medicine (DGAHVM) 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 veterinary services of the Border Airports and Ports (BIPs). 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 (PNAA) for 2015-2017 is available at:

http://www.salute.gov.it/imgs/C_17_pubblicazioni_2269_allegato.pdf (in Italian)

GE seed: The Italian Ministry of Agricultural and Forestry Policies (MIPAAF) is responsible for controls on GE seed. The Central Inspectorate for Quality Control of Foodstuff and Agricultural Products (ICQRF) and the Agricultural Research Council-[Center for Seed Testing and Certification](#) (CRA-SCS), in cooperation with customs 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 2015 is available at:

<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/8989> (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 scope of accreditation covers 67 qualitative PCR (Polymerase Chain Reaction) methods and 14 quantitative real-time PCR methods. The NRL regularly participates in GeMMA (Genetically Modified Material Analysis) proficiency test schemes organized by either the EU Reference Laboratory for GE food and feed or the Food and Environment Research Agency (United Kingdom). 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, 4 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 (FBOs) 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 a 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). 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/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 Ministry of Agricultural, Food, and Forestry Policies - [Directorate General for European and International Policies](#). Italy’s IPPC point of contact is the Ministry of Agricultural, Food, and Forestry Policies - [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: Several vocal anti-biotech non-governmental organizations (NGOs) (i.e. Greenpeace and Legambiente) and lobbying groups lead the charge against the development of biotechnology in Italy, strongly influencing politicians’ and consumers’ opinion. The main farmer organizations are divided in their support of biotechnology. While Coldiretti (the largest Italian Farmers’ Union) and CIA (the Italian Farmers' Confederation) maintain strong anti-biotech attitudes, Confagricoltura (the General Confederation of Italian Agriculture) is calling for a more progressive position stressing the need for innovation and biotech research.

Currently, public opinion generally does not favor GE foods, making it politically difficult to allow the planting of EU-approved GE crops.

However, a growing number of Italian farmers and scientists have come forward in favor of the technology. On December 1, 2016, Confagricoltura Brescia organized the conference “Role and achievements of biotechnology research in agriculture.” More than 400 students attended the event whose guest of honor was Senator for Life and scientist Elena Cattaneo. She pointed out the apparent Italian contradiction between the prohibition of GE research and cultivation, and the import of large quantities of GE feed, while stressing the usefulness and safety of GE crops. Senator Cattaneo highlighted the importance of conducting GE field trials and Italy’s missed opportunity with that. She reiterated the role that science and innovation could play in boosting the Italian economy and encouraged the audience “to do more in the name of progress.”

b) MARKET ACCEPTANCE/STUDIES: Italy’s debate between pro and anti-biotech parties continues without much progress. The general attitude towards GE crops in Italy remains hostile. To date, Italy has deemed its “Made in Italy” campaign and its role as a leading organic crop producer as proscribing 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”.

On September 13, 2017, Coldiretti reiterated that approximately 76 percent of Italians are against cultivation of GE crops. Moreover, according to the study “[Global Health and Ingredient-Sentiment](#)” (in Italian) conducted by Nielsen in the first quarter of 2016, 60 percent of Italians voluntarily avoid consuming GEs.

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.

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. Genetic engineering in Italy is focused on genomic selection to improve animal breeding and is primarily used for medical or pharmaceutical applications. There is one genetic research center, [Avantea Ltd.](#), located in Cremona (CR) 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) **INNOVATIVE BIOTECHNOLOGIES:** In Italy, there is one genetic research center, Avantea Ltd., located in Cremona (CR) that works on animal cloning for experimental purposes only. Avantea also performs genome editing in pigs for biomedical research.

c) **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).

d) 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.”*

e) INTERNATIONAL TREATIES/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](#)).

f) 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.

Abbreviations and definitions used in this report

ANBI: National Association of Biotechnologists
ARPA: Regional Agencies for Environment Protection
AUSL: Local Health Units
BCH: Biosafety Clearing House
BIPs: Border Airports and Ports
CBP: Convention on Biological Diversity
CIA: Italian Farmers' Confederation
CNR: National Research Council
CRA: Agricultural Research Council
CRA-SCS: Agricultural Research Council-Center for Seed Testing and Certification
CREA: Council for Agricultural Research and the Analysis of Agrarian Economy
DGAHVM: Directorate General for Animal Health and Veterinary Medicine
DGDC: Directorate General for Development Cooperation
DiSBA: Department of Bio-Agro Food Sciences
EFSA: European Food Safety Authority
EU: European Union
FAO: Food and Agriculture Organization of the United Nations
FBOs: Food Business Operators
FISV: Italian Life Sciences Federation
GDP: Gross Domestic Product
GE: Genetically Engineered
GeMMA: Genetically Modified Material Analysis
GI: Geographical Indications
GMO: Genetically Modified Organism
ICQRF: Central Inspectorate for Quality Control of Foodstuff and Agricultural Products
ISMEA: Italian Institute for Services to the Agro-food Market
ISS: National Health Institute
IZSLT: Experimental Zoo-prophylaxis Institute of Lazio and Tuscany
MIPAAF: Italian Ministry of Agricultural and Forestry Policies
MMT: Million Metric Tons
NRL: National Reference Laboratory
PCR: Polymerase Chain Reaction
SCoFCAH: Standing Committee on the Food Chain and Animal Health
SIA: Italian Society of Agronomy
SIBV: National Society of Plant Biology
SIGA: Italian Society of Agricultural Genetics
SIPAV: Italian Society of Plant Pathology
SOI: Italian Society of Horticulture
UNASA: National Union of Italian Academies for Food Science, Agriculture, and Environment
USMAFs: Port, Airport, and Border Health Offices

Terms used in this report:

The term **agricultural biotechnology** refers to an evolving continuum of technologies. It is a broadly applied term that may or may not refer to crops or animals developed through recombinant DNA technologies. Commonly used terms are: plant (or animal) biotechnology, transgenic, biotech, bioengineered, and genetically engineered (GE).

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 animal.

Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from the genetic engineering of animals (both in the science and often in the regulation of the technology and/or products derived from it). However, since researchers and industry use cloning along with other animal biotechnologies, it is included in this report.

Cisgenesis is genetic modification of plants with cisgenes only. A cisgene is a natural gene, coding for an agricultural trait, from the crop plant itself or from a sexually compatible donor plant that can be used in conventional breeding. The gene belongs to the conventional breeder's gene pool.

Genetic engineering is the genomic selection to improve plant breeding and understanding the metabolic pathways involved in plant architecture, quality determination, and virus resistance.

The polymerase chain reaction (PCR) is a biochemical technology in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.