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Required Report - public distribution

Date: 9/12/2018

GAIN Report Number: IT1830

Italy

Agricultural Biotechnology Annual

2018

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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.

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 soybean meal (2.2 million metric tons (MMT) imported in 2017) and soybeans (1.4 MMT imported in 2017), 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.

Despite Italy's strong opposition to GE products, a growing number of Italian farmers, agri-food industry players, and scientists have come forward in favor of innovative biotechnologies, such as cisgenesis and genome editing.

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.

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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. On October 1, 2015, the Italian Ministry of Agricultural, Food, and Forestry Policies (MIPAAF)¹ 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 85-90 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.

¹ Please note that the Italian Ministry of Agricultural, Food, and Forestry Policies (MIPAAF) changed its name to Italian Ministry of Agricultural, Food, Forestry Policies, and Tourism (MIPAAFT) as of July 13, 2018.

Table 1: Italy's leading soybean meal imports

Partner Country	Unit	Quantity			% Share			% Change
		2015	2016	2017	2015	2016	2017	2017/2016
World	T	2,206,665	2,140,738	2,236,487	100	100	100	4.47
Argentina	T	1,047,041	1,425,603	1,677,051	47.45	66.59	74.99	17.64
Paraguay	T	333,296	349,574	317,520	15.10	16.33	14.20	- 9.17
Brazil	T	285,797	142,219	102,118	12.95	6.64	4.57	- 28.20
Slovenia	T	155,007	97,224	71,893	7.02	4.54	3.21	- 26.05
Spain	T	40,322	27,550	23,215	1.83	1.29	1.04	- 15.73
Croatia	T	3,008	13,566	13,739	0.14	0.63	0.61	1.28
China	T	5,936	16,078	13,097	0.27	0.75	0.59	- 18.54
Romania	T	45	1,638	3,495	0.00	0.08	0.16	113.38
Austria	T	1,704	3,760	3,410	0.08	0.18	0.15	- 9.32
Other	T	334,509	63,524	10,949	15.16	2.97	0.48	-82.76

Source: Global Trade Atlas (GTA)

Table 2: Italy's leading soybean imports

Partner Country	Unit	Quantity			% Share			% Change
		2015	2016	2017	2015	2016	2017	2017/2016
World	T	1,057,853	1,278,038	1,435,829	100	100	100	12.35
Brazil	T	269,542	536,524	411,856	25.48	41.98	28.68	- 23.24
Paraguay	T	149,540	126,290	266,051	14.14	9.88	18.53	110.67
United States	T	149,877	272,375	200,527	14.1	21.3	13.9	- 26.38

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Canada	T	171,129	172,793	171,064	16.1 8	13.5 2	11.9 1	- 1.00
Ukraine	T	123,641	14,424	149,819	11.6 9	1.13	10.4 3	938.69
Slovenia	T	35,675	17,967	47,221	3.37	1.41	3.29	162.82
Uruguay	T	57,274	4,121	34,906	5.41	0.32	2.43	746.93
Croatia	T	18,492	15,202	33,869	1.75	1.19	2.36	122.79
Nigeria	T	-	-	27,310	0.00	0.00	1.90	0.00
Other	T	82,683	118,342	93,206	7.81	9.26	6.50	-21.24

Source: GTA

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.

On April 19, 2018, the Italian District Court of Udine acquitted Giorgio Fidenato, President of the Federated Farmers Association, of the charge of having cultivated GE maize MON810 in 2015 (in breach of a national decree issued July 12, 2013 prohibiting its cultivation in the Italian

territory), “because the act is not provided for by law as a crime”. This was the fourth ruling in a row in favor of Mr. Fidenato since September 13, 2017, when the European Court of Justice (CJEU) [ruled](#) in his favor. 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.” Mr. Fidenato expressed satisfaction with the Court of Udine ruling and is planning to plant again GE maize MON810 in the Friuli region. For more information, see [GAIN Italian Court Rules in Favor of GE Maize MON810 Cultivation](#).

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, for the 11 products approved in 2017, the EU’s risk assessment and review process took an average of 7.5 years.

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 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). 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.

Per Article 26-ter of The Decree, *“During the authorization procedure of a given ‘GMO’ or during the renewal of consent/authorization, 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](#)). 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 full list of approved GE products, as well as products for which an authorization procedure is pending, 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, 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: On July 25, 2018, the European Court of Justice [ruled](#) that organisms created through newer genome-editing techniques are to be regulated as “GMOs” in the EU. This decision subjects such organisms, and food and feed products containing these organisms to expensive and lengthy approval processes as well as traceability, labelling, and

monitoring obligations. Italian reaction to the ruling was mixed, with farmers' association Coldiretti and Slow Food movement warmly welcoming the decision, while farmers' associations Confagricoltura and Cia, and the agri-food industry describing it as a setback for cutting-edge science and innovation with potential economic and environmental consequences. The Italian Ministry of Agricultural, Food, Forestry Policies, and Tourism (MIPAAFT) has yet to release an official statement on the judgment.

On May 18, 2018, MIPAAFT 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](#) – in Italian). 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.

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. MIPAAF 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. MIPAAFT 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 2018-2020 is available at:

http://www.salute.gov.it/imgs/C_17_pubblicazioni_2692_allegato.pdf (in Italian)

GE seed: MIPAAFT 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. MIPAAFT 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 2017-2018 is available at:

<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/12275>

(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 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 MIPAAFT - [Directorate General for European and International Policies](#). Italy’s IPPC point of contact is MIPAAFT - [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), consumers’ associations (i.e. Federconsumatori and Adusbef), and lobbying groups lead the charge against the development of biotechnology in Italy, strongly influencing politicians’ and consumers’ opinions. The main farmer organizations are divided in their support of biotechnology. While Coldiretti (the largest Italian Farmers’ Union) maintains strong anti-biotech attitudes, Confagricoltura (the General Confederation of

Italian Agriculture) and CIA (the Italian Farmers' Confederation) call 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.

Despite Italy's strong opposition to GE products, a growing number of Italian farmers, agri-food industry players, and scientists have come forward in favor of innovative biotechnologies.

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". 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. Published in February 2018, the Italian [study](#) "Impact of GE maize on agronomic, environmental, and toxicological traits: a meta-analysis of 21 years of field data", fits perfectly in this strategy by showing the large-scale benefits of the technology through a rigorous analysis of scientific data. Conducted by Sant'Anna School of Advanced Studies of Pisa and the University of Pisa, Department of Agriculture, Food, and Environment, the study aims to increase the general knowledge about agronomic traits and safety for human health and the environment of GE maize cultivation through a meta-analysis of the peer-reviewed literature (6,006 publications and 11,699 data) on this GE maize in the United States (mainly Iowa, Illinois, and Nebraska), Europe (Germany, Spain, France, Czech Republic, Denmark, Hungary, Italy, Slovakia, and the United Kingdom), South America (Brazil, Argentina, and Chile), Asia, and Africa from 1996 to 2016.

Study results support the cultivation of GE maize compared to the conventional processes, mainly due to higher yields (from 5.6 to 24.5 percent), lower incidence of insect attack, and reduction of human exposure to mycotoxins (-29 percent), fumonisins (-31 percent), and thricothecenes (-37 percent).

In response to the study findings, Massimiliano Giansanti, President of Confagricoltura (the General Confederation of Italian Agriculture) expressed his pride in Italian researchers and

stated “only innovation will make Italy’s agriculture globally competitive. Confagricoltura has always called for a more progressive position on GEs, supporting research and experimentation”. Coldiretti reiterated “approximately 69 percent of Italians consider food containing GEs less healthy than conventional food, and 81 percent of local consumers would never eat meat and drink milk from genetically modified or cloned animals”. Roberto Moncalvo, President of Coldiretti said, “GEs not only pose serious environmental risks, but are the worst enemy of ‘Made in Italy’”.

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) APPROVALS: 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 (CR) 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).

e) 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.*"

f) 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](#)).

g) 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, Food, and Forestry Policies
MIPAAFT: Italian Ministry of Agricultural, Food, Forestry Policies, and Tourism
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:

Agricultural biotechnology: this term 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 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). Researchers and industry frequently use cloning when creating animals via other animal biotechnologies.

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 is an emerging term for breeding techniques (used with both plants and animals) that, in many instances, are not transgenic. In this report, the innovative biotechnologies include techniques such as (but not limited to), zinc finger nucleases (ZFN), oligonucleotide-directed mutagenesis (ODM), transcription activator-like effector nuclease (TALEN), cisgenesis and intragenesis, meganucleases, grafting, agro-infiltration, RNA dependent DNA methylation, clustered regularly interspaced short palindromic repeats (CRISPR-Cas9), reverse breeding, and synthetic genomics.

