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# Italy

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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:**

## *SECTION I: EXECUTIVE SUMMARY*

Agriculture is one of Italy's key economic sectors, accounting for approximately 2 percent of GDP (Gross Domestic Product). 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 agro-biotechnology 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. In February 2016, Italy's Agriculture Minister Maurizio Martina made a distinction between innovative biotechnologies and "GMOs" [genetically modified organisms]. He advocated for innovation involving cisgenesis and gene-editing, but not transgenic modification.

Regarding GE animals and clones, genetic engineering 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***



## *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 Agriculture notified the European Commission of Italy's decision to "opt out" of cultivating EU (European Union) 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. Socioeconomic and public policy concerns could be used, but also town and country planning, coexistence, and land use. These reasons may be invoked individually or in combination, depending on the particular circumstances in the MS, region, or area in which the measures will apply.

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 2015, Italy imported 1.1 MMT (Million Metric Tons) of soybeans, mainly from Brazil (269,542 MT), Canada (171,129 MT), and the United States (149,877 MT). In 2015, Italy imported 2.2 MMT of soybean meal, mainly from Argentina (1,047,041 MT), Paraguay (333,296 MT), the United States (300,119 MT), Brazil (285,797 MT), and Slovenia (154,440 MT). Given GE soybeans represent a significant portion of the global supply, Italy likely is using GE soybean in its feed ingredients. Italy imports most of its corn from other European countries, but the corn would not be GE. In 2015, Italy's corn imports from the Unites States totaled 1,460 MT, valued at $5.6 million. Since approximately 90 percent of U.S. corn is GE, it is highly likely that these corn imports were from GE plants.

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 36 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. Safeguard clause**

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 refute to support Italy using the safeguard clause. For more information, please see GAIN1538. In October 2015, in an open

letter to the Italian newspaper L'Espresso, Italian Agriculture Minister Maurizio Martina reiterated his support of a "GMO [genetically modified organism] cultivation ban" noting "the extensive agriculture models that have been allowing for GMO cultivation have proven to be dependent on very few players. Moreover, the level of constraints, environmental and other, is significant where agriculture is mostly organized as small family businesses." Martina stressed the importance of biodiversity and expressed support for a "GMO-free supply chain for corn and soybeans."

**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 46 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: Italy implemented EU Directive No. 2001/18/EC on the deliberate release into the environment of genetically modified organisms through Italian Legislative Decree No. 2003/224 (hereafter referred to as The Decree). 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). The Decree also gave autonomous competence to the Ministries of Environment, Health, and Agriculture to use the safeguard clause: "With an emergency act, they can temporarily limit or prohibit the release into the market, the use, or sale of GMO products as such or contained in a product if, after the date of authorization—based on new information regarding the assessment of environmental risks, or following a new evaluation of the existing information based on new or supplementary scientific knowledge—they have reasonable grounds to believe that such GMO products represent a risk for human, animal heath, or the environment." More information on Italy's application of the safeguard clause can be found in the TRADE BARRIERS paragraph (f).

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 Panel on Genetically Modified Organisms 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.

Within Italy, per Art. 2 of Legislative Decree No. 2003/224, the Ministry of Environment has the responsibility for the deliberate release of GE material. Per Art. 1 of Legislative Decree No. 2001/212 (implementing Directives 98/95/EC and 98/96/EC on the marketing of seeds and on the common catalogue of varieties of agricultural plant species and related controls), the Ministry of Agriculture has the authority to grant authorizations to cultivate GE seeds.

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 principles provided in EFSA's Guidance Document.

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 agro-biotechnology 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 Agriculture 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. In February 2016, the Italian Minister of Agriculture Maurizio Martina stated his support for genome editing and cisgenesis, by allocating €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 Economics (CREA – in Italian). The research will focus on genome editing and cisgenesis for grapevine, olive, apple, citrus fruit, apricot, peach, cherry, pineapple, tomato, wheat, and poplar. Minister 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."

The President of Confagricoltura (the General Confederation of Italian Agriculture), Mario Guidi expressed appreciation for Minister Martina's support towards innovative biotechnologies, while defining as "incoherent" the Ministry's position on genetic engineering. Guidi stated, "genome-editing and cisgenesis will be crucial for the competitiveness of the Italian agro-food sector and production sustainability. We appreciate Minister Martina's support and hope that this will lead to the authorization of open-field testing for these new techniques and hopefully to a proposal at the European level aimed at distinguishing transgenics themselves from these innovations". Minister Martina's plan

also received pledges of support from the National Research Council (CNR – in Italian), the Italian Society of Agricultural Genetics (SIGA - in Italian), the National Society of Plant Biology (SIBV), the Italian Society of Horticulture (SOI – in Italian) , the National Society of Agronomy (SIA – in Italian), the Italian Society of Plant Pathology (SIPAV – in Italian), the Georgofili Academy (in Italian), the National Union of Italian Academies for Food Science, Agriculture, and Environment (UNASA – in Italian), and the Italian Association of Biotechnologists (ANBI – in Italian).

f) COEXISTENCE: There is not a national coexistence policy in Italy. The competence for rules on coexistence lies at the regional level per Art.117 of the Italian Constitution as amended by Constitutional Law No. 2001/3.

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 genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms 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 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 (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 (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/imgs/C_17_pubblicazioni_2257_allegato.pdf

**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 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. On February 22, 2011, MS on the Standing Committee for Food Chain and Animal Health (SCoFCAH) endorsed a Commission proposal providing for a "technical solution" designed to harmonize the implementation of the zero tolerance policy on non-authorized GE material in feed. The proposal is intended to address the uncertainty faced by EU operators placing feed on the market composed of imported raw materials from non-EU countries. This "technical solution" defines the lowest level of GE presence that is considered by the EU Reference Laboratory when validating detection methods, as 0.1 percent. It is limited to GE feed material authorized for commercialization in a non-EU country and for which a EU authorization request for the biotech event in question has been lodged with EFSA for at least three months or of which the authorization has expired. Feed will be considered non-compliant with EU legislation when the presence of this GE feed material is, after due consideration of the margin of error, above the technical zero of 0.1 percent. The regulation was adopted (Commission Regulation No. 2011/619) and

entered into law July 20, 2011.

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 Art. 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, "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/FORA: 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 Agriculture - Directorate General for European and International Policies. Italy's IPPC point of contact is the Ministry of Agriculture - 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). As specified in the DGDC's Programming Guidelines and Orientations for 2014-2016 (in Italian), Italy will continue to participate in the process of forming a global partnership for food security. Funds will continue to be

directed to the UN Rome-based Agencies (FAO, WFP, and IFAD) on a priority basis through humanitarian and emergency initiatives. The Italian Cooperation will focus on increasing ecological awareness in farming, supporting smallholders and producers' organizations, while also encouraging research and innovation.

n) RELATED ISSUES: N/A

***PART C: MARKETING***

a) PUBLIC/PRIVATE OPINIONS: Several vocal 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. In June 2016, more than 2,400 Italian farmers signed a petition (in Italian), highlighting the role that science and innovative technologies could play in boosting the Italian economy. "Without research and innovation in agriculture, Italy's farming is going to disappear. Italian farms must be able to compete in the global market. However, without product innovation, this is not possible." The petition also pointed out the apparent contradiction between the prohibition of "GMO research and cultivation, and the import of large quantities of GM feed."

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".

In a recent study by Italian supermarket chain Coop, more than 70 percent of Italians are willing to pay more for all-natural foods, 65 percent for "non-GM foods", 62 percent for organic foods, and 60 percent for foods without colorants. Two in three Italians regularly purchase typical food products linked to the places where they live. According to Coldiretti, Italian purchases of gluten-free food rose by 50 percent in 2015, while organic food purchases were up 20 percent during the same year. This growth, which also includes higher demand for "non-GM" and locally produced foods, is due to an increased awareness and interest in well-being, physical fitness and health, as well as a rise in food allergies. 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 works on animal cloning for experimental and research purposes only.

b) COMMERCIAL PRODUCTION: Genetically engineered animals and clones are not being developed at this time in Italy for commercial purposes. Italy is not actively employing the use of genetically engineered animals or products derived from genetically engineered 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. The outcome of the public consultation on the draft Scientific Opinion for this guidance was published February 2012. 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 genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms in April 2004. 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 traces of GEs may be exempt from this obligation if they do not exceed the threshold of 0.9 percent and their presence is adventitious and technically unavoidable.

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 Art. 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." Art. 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/FORA: 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 manages the Italian Biosafety Clearing House (BCH), an information-sharing platform for all those involved in the assessment and management of the risk associated with Living Modified Organisms (any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology). Italy is a member of the Codex Alimentarius Commission (CAC) since 1966. In 2008, the CAC developed the "Guideline for the Conduct for Food Safety Assessment of Foods Derived from Recombinant-DNA Animals." 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
**DGDC**: Directorate General for Development Cooperation

**DGAHVM**: Directorate General for Animal Health and Veterinary Medicine
**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
**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
**MMT**: Million Metric Tons
**MIPAAF**: Italian Ministry of Agricultural and Forestry Policies
**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 developed through recombinant DNA technologies. Commonly used terms are; plant 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.