USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 6/4/2015
GAIN Report Number: IT1538

Italy

Agricultural Biotechnology Annual

2015

Approved By:
Christine Sloop
Prepared By:
Ornella Bettini

Report Highlights:
This report describes the production, trade, research, policy, and marketing issues of genetically engineered (GE) plant and animal products in Italy. 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.

TABLE OF CONTENTS

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: Production and Trade

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT
b) COMMERCIAL PRODUCTION
c) BIOTECHNOLOGY EXPORTS/IMPORTS

PART F: Policy

a) REGULATION
b) LABELING AND TRACEABILITY
c) TRADE BARRIERS
d) INTELLECTUAL PROPERTY RIGHTS (IPR)
e) INTERNATIONAL TREATIES/FORA

PART G: Marketing

a) MARKET ACCEPTANCE
b) PUBLIC/PRIVATE OPINIONS
c) MARKET STUDIES

PART H: Capacity Building and Outreach

a) ACTIVITIES
b) STRATEGIES AND NEEDS

SECTION I: Executive Summary

Italy implemented EU Directive No. 18/2001 on the deliberate release into the environment of genetically modified organisms through Legislative Decree No. 224/2003. Italy does not commercially cultivate any genetically engineered (GE) crops, but it allows imports in the form of processed products and animal feed which are likely to contain GE content. 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.

Italy does not have a coexistence policy, but a January 2015 Inter-ministerial Decree officially bans the planting of GE crops, despite two EFSA rulings saying no new scientific evidence has been presented to refute EFSA's earlier findings or to support Italy using the safeguard clause.
On October 12, 2013, Vice President Silvano Dalla Libera of Futuragra and President Giorgio Fidenato of the Federated Farmers Association harvested a hectare of GE maize MON810 in Vivaro (Friuli Venezia Giulia Region in Northern Italy). On October 18, 2013, Mr. Fidenato appealed the national ban prohibiting the cultivation of GE maize MON810, but on April 24, 2014, the Regional Administrative Court of Lazio (TAR) ruled against his appeal. On February 6, 2015, the Italian Council of State ruled against Fidenato's appeal to TAR's decision.

During Italy's EU Presidency (July 1 – December 31, 2014), it advanced a revision to the EU's regulations to allow Member States to "opt out" of cultivating EU-approved GE crops for reasons other than health or environmental concerns. On March 2, 2015, the EU Council formally adopted European Directive No. 2015/412, amending EU Directive No. 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GEs in their territory. Directive No. 2015/412 allows governments to opt out before an EU authorization through a deal with the applicant company or afterwards by invoking a number of possible grounds (not health or environment risks which remain the domain of the European Food Safety Authority). Socioeconomic and public policy concerns could be used, but also town and country planning, coexistence, and land use. Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region, or area in which those measures apply.

Regarding GE animals and clones, there is no active debate but the work being done is limited. In Italy, genetic engineering is more geared towards genomic selection to improve animal breeding and is mainly 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.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY IN ITALY

CHAPTER 1: PLANT BIOTECHNOLOGY

A) Production and Trade

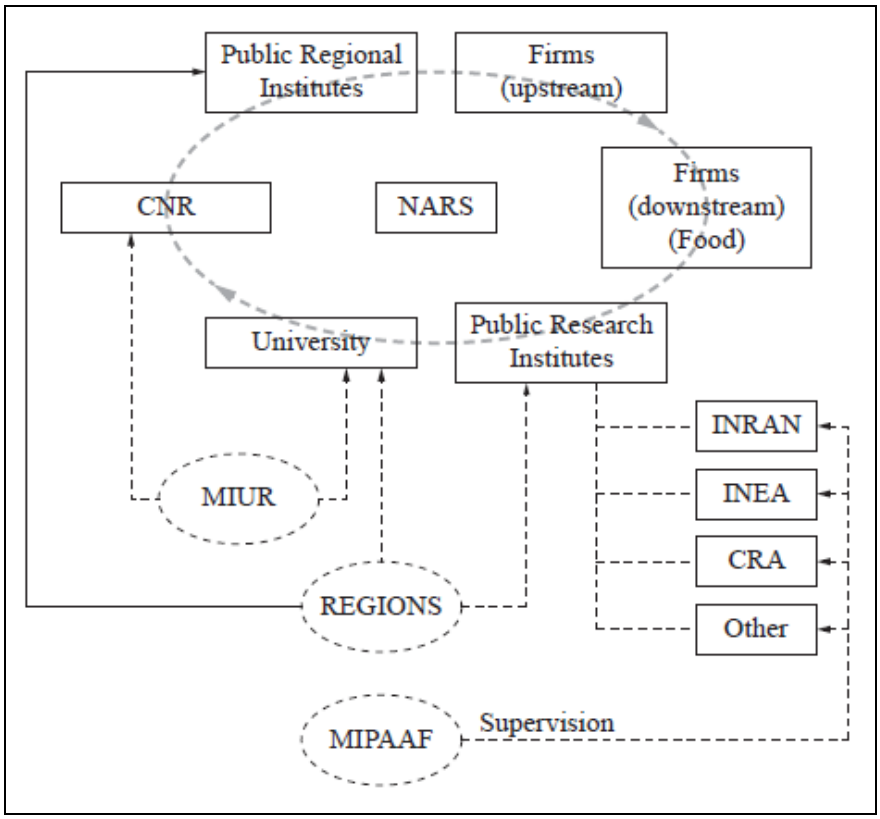
a) PRODUCT DEVELOPMENT: In Italy, there are no GE (Genetically Engineered) plants or crops under development. Genetic engineering is mainly geared towards genomic selection to improve plant breeding and understanding the metabolic pathways involved in plant architecture, quality determination, and virus resistance.

There are three main players involved in the Italian public Agricultural Research System:

1. The Ministry of Agriculture, Food, and Forestry (MIPAAF);
2. The Ministry of Education, University, and Research (MIUR);
3. The Regions and the Autonomous Provinces of Trento and Bolzano

To a lesser extent, the Ministry of Health, the Ministry of Economic Development, and the Ministry of Environment and Land Protection also engage in agricultural research activities. The National Agency for the Evaluation of Universities and Research Institutes (ANVUR) is in charge of evaluating public funding programs aimed at enhancing research and innovation activities.

Table 1: Italy's Agricultural Research System



Source: Studies in Agricultural Economics 114 (2012) 71-78

1. **The Ministry of Agriculture, Food, and Forestry** (MIPAAF)
Research Office (DISR IV) of the Department for European and International Policies and Rural Development at the Ministry of Agriculture, Food, and Forestry funds and supervises agricultural research projects carried out by national public research bodies, universities, and public/private organizations with statutory research purposes. Public research bodies include the National Agricultural Research Council (CRA), the National Institute of Agricultural Economics (INEA), the National Institute for Research on Food and Nutrition (INRAN), the National Rice Institute (ENR), the Italian Institute for Services to the Agro-food Market (ISMEA), and the Institute of Agro-food Development (ISA).

The **National Agricultural Research Council** (CRA) is Italy's largest agricultural research institute, comprising 15 research centers, 32 research units, 1,400 staff members, and 5,300 hectares of experimental farms.

CRA - Genomics Research Centre (CRA-GPG**)**

Located in Fiorenzuola d'Arda (Emilia-Romagna), CRA-GPG conducts crop genetic improvement research activities aimed at increasing food quality, safety, and security, within a general framework of sustainable agriculture and product & process innovation. Research projects are conducted on straw cereals (barley, oat, triticale, durum wheat, soft wheat, and rice), fruits, vegetables, flowers, trees, and industrial plants, in collaboration with CRA-Cereal Research Centre (CRA-CER), CRA-Corn Research Unit (CRA-MAC), CRA-Rice Research Unit (CRA-RIS), CRA-Unit for Cereal Selection in Continental Areas (CRA-SCV), CRA-Fruit Research Unit (CRA-FRF), CRA-Research Centre for Citrus and Mediterranean Crops (CRA-ACM), CRA-Research Centre for Fruit Tree (CRA-FRU), CRA-Research Centre for Horticulture (CRA-ORT), CRA-Research Unit for Vegetable Crops (CRA-ORL), CRA-Research Unit for Vegetable Crops in Central Areas (CRA-ORA). Plant breeding activities are carried out in collaboration with private companies and have led to the registration of successful varieties of barley, oat, and triticale.

CRA-GPG is also a Coordinating member of the International Wheat Genome Sequencing Consortium (IWGSC). Established in 2005 by a group of wheat growers, plant scientists, and public and private breeders, IWGSC "aims at generating a high quality genome sequence of bread wheat publicly available, in order to lay a foundation for basic research that will enable breeders to develop improved varieties". Specifically, CRA-GPG is working on the physical mapping of wheat chromosome 5A. Moreover, Professor Luigi Cattivelli from CRA-GPG and Roberto Tuberosa, Professor of Plant Genetics and Plant Breeding at the Department of Agricultural Sciences, University of Bologna co-chair the Expert Working Group on Durum Wheat Genomics and Breeding within the Wheat Initiative. Created in 2011, following endorsement from the G20 Agriculture Ministries, the Wheat Initiative intends to encourage and support the development of a vibrant global public-private research community sharing resources, capabilities, data, and ideas to improve wheat productivity, quality, and sustainable production around the world. The combination of new varieties and agronomic practices will in turn allow farmers to improve and stabilize wheat yields in diverse production environments.

Professor Tuberosa, University of Bologna also coordinates the Italian Technological Platform "IT-Plants for the Future" aimed at fostering cooperation among industry, university, public, and private research centers, associations, and consortia, in support of the national plant research.

2. The Ministry of Education, Universities, and Research (MIUR)

MIUR finances the agricultural research through the National Research Council (CNR) and Universities - Faculties of Agriculture, Veterinary Medicine, Life Sciences, Economic Sciences, and Medicine.

CNR is Italy's largest public research institute, comprising 7 departments, 109 institutes, and more than 8,000 staff members.

CNR - Department of Bio-Agro Food Sciences (DiSBA)
DiSBA's research activities are grouped into three main projects:

a) "**Plant, Animal, and Microbial Genomics**": research activities focus on genetic characterization of plants and microorganisms; plant development and cellular biology; biochemistry; plant-environment interactions; and animal genomics.

b) **"Food":** research activities focus on developing new diagnostic techniques and technologies to improve food quality and safety.

c) **"Sustainable Agriculture**": research activities focus on the development of new applications fostering sustainability in crop and animal production through innovative and eco-friendly practices.

CNR - Institute of Agricultural Biology and Biotechnology (IBBA)
Headquartered in Milan (Lombardia), IBBA operates through the Units of Lodi (Parco Tecnologico Padano - PTP), Pisa, and Rome.

Parco Tecnologico Padano (PTP)

Founded in Lodi (Lombardia) in 2000, PTP is a center of excellence for the Italian agro-food biotechnology, focusing on quali-quantitative improvement of plant and animal productions and sustainability. PTP manages a bio-incubator, a science park with research laboratories (plant and animal biotechnologies), and a genomics platform ISO9001 certified and SINAL17025 accredited for DNA-based diagnostic analyses applied to agricultural and food sectors, in support of universities, start-ups, spin-offs, and private research centers. PTP set up a Centre for Research and Study in the field of Agro-Food (CeRSA). Within CeRSA, the Plant Science Unit conducts genomics research applied to crops aimed at understanding metabolic pathways involved in plant architecture, quality determination, and virus resistance.

More information on Plant Science Unit's activities can be found at:
http://www.tecnoparco.org/index.php?option=com_content&view=article&id=63%3Agenomica-vegetale&catid=47&Itemid=68&lang=en

3. Regions

The 20 Italian Regions and the Autonomous Provinces of Trento and Bolzano plan and fund agricultural research programs tailored to local needs and contextual factors (Constitutional Law No. 3 of 18/10/2001).

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 a net importer of soybean and soybean meal, which represent the main ingredients in animal feed. In 2014, Italy imported 1.4 MMT (Million Metric Tons) of soybeans, mainly from Brazil (427,365 MT), Ukraine (254,357 MT), and the United States (202,116 MT). In 2014, Italy imported 1.9 MMT of soybean meal, mainly from Argentina (1,028,960 MT), Paraguay (248,768 MT), Slovenia (242,365 MT), Brazil (177,777 MT), and the United States (132,702 MT). Given GE soybeans represent a significant portion of the global supply, Italy likely is using GE soybean in its feed ingredients. In 2014, Italy imported 4.7 MMT of corn, mainly from Ukraine (1.4 MMT), Hungary (1.0 MT), France (421,292 MT), and Romania (354,353 MT). In 2014, Italy's corn imports from the Unites States totaled 1,151 MT, valued at $3.7 million.

e) FOOD AID RECIPIENT COUNTRIES: Italy is not a food aid recipient. However, the Italian Government maintains its commitment to food security globally, being one of FAO's (Food and Agriculture Organization of the United Nations) 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 Mln, 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.

B) Policy

a) REGULATORY FRAMEWORK: Italy implemented EU Directive No. 18/2001 on the deliberate release into the environment of genetically modified organisms through Legislative Decree No. 224/2003 (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 GE 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 GE 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 (h).

b) APPROVALS: Approval of GE products in Italy is subject to EU procedures. Under EU Regulation No. 1829/2003, GE products and derived ones must be evaluated by EFSA before they can be authorized in the EU. Applicants must submit an application for authorization, in line with European legislation and EFSA's guidelines, to the national competent authority of one of the Member States (in Italy, the Ministry of Health) who then forwards the application to EFSA for its scientific risk assessment. EFSA's Panel on Genetically Modified Organisms (GMO) carries out a detailed risk assessment to evaluate the safety of the GMO and derived food or feed. The Panel's independent scientific advice is then used by the Commission and Member States when taking a decision on market approval.

A variety of GE events have been approved for feed and food use at the European level under EU Regulation No. 1829/2003. The full list of GE approved products is available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm. The list of GE products pending renewal authorization under EU Regulation No. 1829/2003 is available on the European Food Safety Agency's (EFSA) website.

Within Italy, per Art.2 of Legislative Decree No. 224/2003 (implementing EU Directive No. 18/2001 on the deliberate release into the environment of genetically modified organisms), the Ministry of Environment has the responsibility for the deliberate release of GE material. Per Art.1 of Legislative Decree No. 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) 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 transposed EU Directive No. 18/2001 on the deliberate release into the environment of genetically modified organisms through Legislative Decree No. 224 of July 8, 2003 and Ministerial Decree of January 19, 2005. Ministerial Decree of January 19, 2005 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, Toscana and Marche approved nine crops-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 'GE-free', further hampering the scope for new research and plantings.

d) STACKED EVENT APPROVALS: Italy implemented EU Regulation No. 1829/2003 and Directive No. 2001/18/EC on GE plants containing stacked transformation events through Legislative Decree No. 224/2003. Stacked events are subject to risk assessment, following the principles provided in EFSA's Guidance Document.

e) ADDITIONAL REQUIREMENTS: N/A

f) COEXISTENCE: Italy does not have a coexistence policy, but a January 2015 Inter-ministerial Decree officially bans the planting of GE crops, despite two EFSA rulings saying no new scientific evidence has been presented to refute EFSA's earlier findings or to support Italy using the safeguard clause. 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. 3 of October 18, 2001. More information on Italy's application of the safeguard clause can be found in the TRADE BARRIERS paragraph (h).

g) LABELING AND TRACEABILITY: Italy implemented EU Regulations No. 1829/2003 on genetically modified food and feed and No.1830/2003 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 European Union 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 traces amounts of GE content may be exempt from this obligation as long as it does not exceed the threshold of 0.9 percent and its presence is adventitious and technically unavoidable.

h) TRADE BARRIERS:

1. Safeguard clause

On January 23, 2015, the Italian Ministers of Agriculture, Health, and Environment signed an Inter-ministerial Decree extending the ban on the cultivation of genetically engineered crops for another 18 months. The initial Decree was first introduced on July 12, 2013, as an emergency measure based on Art. 54 of EC Regulation No. 178/2002 and Art. 34 of EC Regulation No. 1829/2003. On September 24, 2013, the European Food Safety Authority (EFSA) GMO Panel concluded that, based on the documentation submitted by Italy, there was no evidence to invalidate EFSA's previous risk assessments on the genetically modified maize MON810 or to support Italy's request to impose emergency measures under Article 34 of EC Regulation No. 1829/2003. The complete text of the EFSA Scientific Opinion can be viewed at: http://www.efsa.europa.eu/en/efsajournal/pub/3371.htm.

On October 12, 2013, Vice President Silvano Dalla Libera of Futuragra and President Giorgio Fidenato of the Federated Farmers Association's harvested a hectare of GE maize MON810 in Vivaro (Friuli Venezia Giulia Region in Northern Italy). The Minister of Agriculture insisted the regional authorities remove the crop as it contravened the national ban. On October 18, 2013, Mr. Fidenato appealed the national ban prohibiting the cultivation of GE maize MON810, but on April 24, 2014, the Regional Administrative Court of Lazio (TAR) ruled against his appeal. On February 6, 2015, the Italian Council of State ruled against Fidenato's appeal to TAR's decision.

During Italy's EU Presidency (July 1 – December 31, 2014), Italy advanced a revision to the EU regulations to allow Member States (MS) to "opt out" of cultivating EU-approved GE crops for reasons other than health or environmental concerns. On March 2, 2015, the EU Council formally adopted European Directive No. 2015/412, amending EU Directive No. 2001/18/EC. Directive No. 2015/412 allows governments to opt out before an EU authorization through a deal with the applicant company or afterwards based on a wide range of reasons (not health or environmental risks which remain the domain of the European Food Safety Authority). 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.

On April 22, 2015, the European Commission (EC) announced the outcome of its review of the decision-making process for the authorization of GE food and feed, following the Political Guidelines presented to the European Parliament in July 2014. The review confirmed the need for changes that reflect public views by allowing national Governments more authority on the use of EU-authorized GE crops for animal (feed) or human (food) consumption. As a result, the EC proposed to confer upon MS more freedom to restrict or prohibit the use of EU-authorized GE events in food or feed in their territory. MS will have to justify that their opt-out measures comply with the principles of the single market and the EU's WTO obligations. Opt-outs shall be based on legitimate reasons other than those assessed at the EU level, i.e. risk to human or animal health, or the environment. This legislative proposal will be sent to the European Parliament and the Council to run its ordinary legislative course.

Commenting on the EU Commission's proposal, Alessandro Sidoli, President of the Italian Association for the Development of Biotechnology (Assobiotec) stated, "The nationalization of GE imports would sacrifice the fundamental principle of the internal market. GEs are an integral part of our daily lives, as Europe benefits from this key enabling technology through trade. We pay with GE cotton banknotes and wear GE cotton clothes, and we heavily rely on GE commodities to feed our farm animals". According to the Italian Feed Association (Assalzoo), "the nationalization of GE imports would be disastrous for trade as Italy is a net importer of soybean and soybean meal, which represent the main ingredients in animal feed. Any attempt to nationalize the EU decision-making process would lead to serious threats to the EU's single market and would inevitably result in upsetting the balance of EU supply for food and feed uses. This proposal would limit the choice for livestock farmers and threaten their livelihoods, damaging jobs, growth, innovation, and competitiveness".

1. Delays in EU Approvals of New Events, Resulting 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. Italy conducts random testing of imports and depending on the product, checks for genetically engineered 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.

i) INTELLECTUAL PROPERTY RIGHTS (IPR): Italy implemented EU Directive No. 98/44/EC on the legal protection of biotechnological inventions through Law Decree No. 3 of January 10, 2006. Pursuant to the principles laid down in Directive No. 98/44/EC, 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."

j) CARTAGENA PROTOCOL RATIFICATION: The Italian Government ratified the Cartagena Protocol on Biosafety to the United Nations' Convention on Biological Diversity (CBP) through Law No. 27 of February 4, 2004. 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 Cartagena Protocol's Biosafety Clearing House (BCH) was created in 2005, in order to foster public participation and implement the Protocol's requirements.

k) INTERNATIONAL TREATIES/FORA: In line with the EXPO 2015 theme, 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 Directions for 2013-2015, Italy will continue to participate in the process of forming a global partnership for food security, by supporting projects launched within the Aquila Food Security Initiative (AFSI) during the Italian Presidency of the G8 in 2009. 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.

l) RELATED ISSUES: N/A

m) 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 checking seeds.

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 'GE-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

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 2013-2014 is available at:
https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/7967

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 European Union Reference Laboratory for GE food and feed or the Food and Environment Research Agency (UK). 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).

n) LOW LEVEL PRESENCE POLICY: Italy voted in favor of the technical solution, addressing the need to harmonize the EU's import inspection methodology. On February 22, 2011, Member States at the Standing Committee on the 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. This draft regulation was subject to the scrutiny of the European Parliament and of the Council for three months following their formal receipt of the draft and was adopted (Commission Regulation No. 619/2011) and entered into law July 20, 2011.

C) Marketing

a) MARKET ACCEPTANCE: 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 have sharply affected supermarket chain marketing strategies. Several private label brands have consistently marketed their products as 'GE-free'. However, GE food products are being consumed in Italy. After years of denial, most media and even anti-biotech groups are realizing 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.

Many believe Italy's staunchly anti-biotech position does not benefit its farmers or food processing industry. In the long term, Italy's economic interests call for the support of science-based policies that foster innovation, not policies that increase the costs of critical inputs needed to support the country's expanding "Made in Italy" exports or that hamper the adoption of important advances that can benefit producers, consumers, and the environment. Future acceptance of GE products may center on the rising cost of feed materials and greater understanding of just how prevalent consumption is of products that already rely on GE inputs.

On May 25, 2015, Coop Italia, a leading grocery retailer presented at Expo Milan the results of a research project "Today's Food, Tomorrow's Food" conducted with Doxa, a Milan-based market research organization. The survey was carried out on a representative sample of 6,400 individuals between the ages of 18 and 54 in eight countries: Italy, Germany, the United Kingdom, the United States, Russia, China, India, and Brazil. Consumers were asked about their current perceptions of food and how they expect them to change by 2050. According to the study, the majority of Italian respondents associate food with pleasure - such as selecting fresh and tasty foods (57 percent) and enjoyment of meals with family and friends (43 percent). Moreover, 67 percent of Italian respondents

do not rule out the possibility of eating GE food in the near future, while also being willing to try food in pill form (70 percent) or insects (44 percent). Manipulation of food, i.e. adding food additives, such as coloring, sweeteners, etc. (70 percent) and environmental pollution (66 percent) are viewed by the majority of Italians as risks more likely to affect their lives than food shortages (27 percent) or too expensive food (30 percent).

The study is available at:
http://www.ecoop.it/documents/10180/33545280/Coop+_il+Cibo+del+futuro+25+05_def.pdf/8c8f0051-0e02-4d4d-8d75-a2a451e97a25

b) 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 the 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 trade and planting of EU-approved GE crops.

However, a growing number of Italian farmers and scientists have come forward in favor of the technology. On June 11, 2014, 716 Italian farmers wrote a letter to Senator for Life and scientist Elena Cattaneo asking the Government of Italy to "recognize the freedom of scientific research and put a stop to the Italian anti-GE policy". "Without research and innovation in agriculture, Italy's farming is going to disappear. Italian farms must be able to compete in the global market, but, without product innovation, this is not possible". The letter also pointed out the apparent contradiction between the prohibition of GE research and cultivation, and the import of large quantities of GE feed. Senator Cattaneo promptly answered the letter arguing, "GE crops are not more risky than non-GE or organic ones. Moreover, the scientific community has clearly expressed the usefulness and safety of GE crops, calling for further research and testing of these products in field trials in Italy. Therefore, the so-called 'precautionary principle' should be abandoned and Member States should allow the cultivation of approved GE crops". On July 4, 2014, a group of 33 Italian researchers signed a letter in support of Senator Cattaneo's position, highlighting the role that science and innovative technologies could play in boosting the Italian economy.

Furthermore, on the eve of the 10th world conference "The Future of Science" (Venice, September 18-20, 2014), former Minister of Health and Professor of Oncology, Umberto Veronesi stated, "science can

help agriculture develop new plants that are resistant to extreme climate conditions. I'm convinced that biological agriculture and traditional food products can live side by side with GEs. Closing the door to GEs and research makes no sense. We must not be afraid of genetics, because in the end we are all GEs".

c) MARKETING STUDIES: We are unaware of any study in Italy relating to the marketing of GE plants and plant products.

D) Capacity Building and Outreach

a) ACTIVITIES: FAS Rome routinely meets with public authorities, industry, and agricultural associations, facilitating bilateral information flow and mutual understanding between the United States and Italy. FAS Rome outreach activities provide venues for communicating the importance of innovation in addressing such key issues as food security, climate change, and energy and how a science-based regulatory system is critical to global trade and safeguarding the public.

1) FAS Italy Hosts IFIC Foundation Expo 2015 Communications Summit

On May 20, 2015, U.S. Embassy Rome hosted the IFIC (International Food Information Council) Foundation Expo 2015 Communications Summit: "Emerging Market Leaders Workshop on Effective Messaging on Global Food Production Issues." The event, organized by FAS Rome in cooperation with the U.S. Mission to the United Nations in Rome saw the active participation of Ambassadors and FAO representatives from Emerging Market countries as diverse as Indonesia to Somalia. The summit provided expert insights and best practices as part of the EXPO Milan 2015 theme: "Feeding the Planet, Energy for Life."
The event which was live streamed reached an estimated audience of 500,000 and registered 1.5 million social media impressions.

2) FAS Italy Hosts Visiting Biotech Scientist Dr. Fauquet

On December 8-9, 2014, FAS Italy hosted the visit to Rome of Dr. Claude Fauquet (Director of the International Laboratory for Tropical Agricultural Biotechnology) who has developed a genetically engineered cassava, which he hopes to deliver to small farmers in Africa by 2018. Post organized a biotech brown bag, a DVC with African journalists/technical experts, shot a video for placement on the U.S. Embassy website, and hosted a workshop on "The benefits of biotechnology for smallholder farmers and food security: the example of the virus resistant cassava in Africa" to inform FAO

staff/permanent representatives, Italian and Vatican officials, and media about how biotech can be an important tool in responding to humanitarian and developmental needs.

3) FAS Rome Hosts "Innovative Technologies and the Economy" DVC with Jack Bobo

On February 19, 2014, FAS Rome hosted "Innovative Technologies and the Economy" DVC roundtable that involved opinion leaders from key Italian ministries, research institutes, and agro-food organizations, and was moderated by Jack Bobo, State Department's Senior Advisor for Biotechnology and Christine Sloop, Agricultural Counselor, FAS Rome, Italy. The goal was to focus on the role science and innovative technologies can play in boosting the economy.

4) FAS Rome Hosts Biotech Research and Development Roundtable

On March 19, 2014, FAS Rome hosted a Biotech Research & Development roundtable with Jack Bobo, State Department's Senior Advisor for Biotechnology; Michael Schechtman, Biotechnology Coordinator, Agricultural Research Service/USDA; Pesach Lubinsky, Science Advisor, New Technologies and Production Methods Division, Foreign Agricultural Service/USDA; Craig Morris, Director, Western Wheat Quality Lab, Agricultural Research Service/USDA, and a select group of Italian scientists and researchers. The participants discussed agricultural research in Italy, as well as the Italian Government's current biotech policies and how they affect research and research funding.

5) FAS Rome Organizes "Innovative Technologies Salon Dinner" at the Deputy Chief of Mission's Residence

On March 18, 2014, FAS Rome organized an "Innovative Technologies Salon Dinner" at the Deputy Chief of Mission's residence. The event involved key Italian stakeholders, State Department's Senior Biotechnology Advisor, Jack Bobo, and USDA Agricultural Research Service's Senior Biotechnology Advisor, Michael Schechtman. The goal was to provide an open forum to discuss biotechnology research developments and allow Jack Bobo and Michael Schechtman to respond to technical questions.

FAS Rome GAIN reports are available at:
http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx

b) STRATEGIES AND NEEDS:

Plant Biotechnology to Address Agriculture Sustainability and Boost Productivity: While Italy is increasingly sensitive to agricultural sustainability and is taking measures to make its agriculture more sustainable (including good agricultural practices, reduced pesticide use, reduced pollution and greenhouse gas emissions, renewable energies, organic), plant biotechnology is not currently being considered by the Italian Government as another tool to address this issue. Organic agriculture is often considered in Italy as the only way to make agriculture more sustainable. However, fostering organic production, adopting environmentally friendly conventional farming practices, and allowing biotech crops that reduce pesticide use and increase productivity are all ways Italy could address agriculture sustainability.

Plant Biotechnology to Address Food Security: The OECD-FAO Agricultural Outlook 2012-2021 report released in July 2012, considers plant biotechnology in its chapter "Achieving Sustainable Agricultural Productivity Growth" and states "biotech crops can on the one side help farmers reduce the use of other inputs, thereby reduce input costs, and through increased productivity and predictability, improve farmers' output and incomes. On the other side, they can increase the cost of seeds and reduce the seed capital value of farmers. Since plant biotechnology is generally scale-neutral, the benefits may be more accessible to developing countries and smallholders in general."

On May 7-8, 2015, the G20 Agriculture Ministers agreed to draft an Action Plan on Food Security and Sustainable Food Systems to be submitted for consideration at the Antalya G20 Leaders' Summit in November 15-16, 2015. Ministers invited FAO, IFPRI (International Food Policy Research Institute) and other international organizations to establish a platform in measuring and reducing food loss and waste. Agriculture Ministers committed to meeting the challenge of global food security and nutrition for an expected world population of nine billion by 2050. The G20 conclusions of May 2015 should encourage Italy to incorporate agricultural biotechnology as a key research, development, and innovation tool for achieving global food security.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

E) Production and Trade

a) BIOTECHNOLOGY 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 is more geared towards genomic selection to improve animal breeding and is mainly used for medical or pharmaceutical applications. Founded in Rome in 1944, the Italian Livestock Breeders Association (AIA) conducts research programs on genetics/genomics of all livestock, aimed at increasing the competitiveness of the national livestock-breeding sector.
Moreover, Italy's Research Center for Meat Production and Genetic Improvement (CRA-PCM), located in Monterotondo Scalo (Rome) conducts research programs on genetics of all livestock, as well as of microorganisms to improve animal breeding. Also, Italy's Parco Tecnologico Padano set up a Centre for Research and Study in the field of Agro-Food (CeRSA). Within CeRSA, the Animal Science Unit conducts research programs on genetics/genomics of all livestock, aimed at improving animal productivity, meat quality, and cattle health. Furthermore, CNR (National Research Council) Department of Bio-Agro Food Sciences (DiSBA) conducts research activities on animal genomics, while also developing new applications fostering sustainability in animal production through innovative and eco-friendly practices.

b) COMMERCIAL PRODUCTION: Genetically engineered animals and clones are not being developed at this time in Italy for commercial purposes. There is one genetic research center, Avantea Ltd., located in Cremona (CR) that works on animal cloning for experimental and research purposes only. The Italian livestock sector is not actively employing the use of genetically engineered animals or products derived from genetically engineered animals or clones.

c) EXPORT/IMPORTS: Italy is not actively employing the use of genetically engineered animals or products derived from genetically engineered animals or clone. It is unknown whether genetic material produced with modern biotechnology techniques is being imported or whether products from offspring of cloned animals are being exported.

F) Policy

a) REGULATION: Italy implemented EU Regulation No. 1829/2003 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 Regulation (EC) No. 1829/2003 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.

In Italy, the Ministry of Health - Department of Veterinary Public Health, Food Safety, and Collegial Bodies for Health Protection is responsible for animal welfare and animal reproduction. Border Inspection Posts (BIPs) and Veterinary Offices for Compliance with Community Requirements (UVAC) perform inspections and notify infringements to other Member States, third countries, and international bodies. Both Office VI and VIII of the Directorate-General for Animal Health and Veterinary Medicine at the Italian Ministry of Health collect data on animal welfare from BIPs and UVAC. Office VI also undertakes vertical inspections in the Regions.

Official controls on farm: controls on farm are performed by the veterinary services of the Local Health Units (AUSL) and coordinated by the Regional Veterinary Services (RVS) that send the inspection results to the Ministry of Health. Currently, Italian farms are inspected at least once every three years. The AUSL are responsible for taking action in the event of non-compliance, by imposing punitive measures or, when animals are severely maltreated, referring the farm to the judicial authorities.

Official controls during transport: roadside checks to monitor animal welfare during transport are carried out by the AUSL, in cooperation with Forest Guards, Police, and Carabinieri, who have the legal power to stop and inspect vehicles, check documents, assess the welfare of animals, and issue sanctions. Inspections of animals coming from other Member States are normally conducted in cooperation with the UVAC.

b) LABELING AND TRACEABILITY: Italy implemented EU Regulations No. 1829/2003 on genetically modified food and feed and No.1830/2003 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. Depending on whether food from cloned animals is considered different than food from classically bred animals, Novel Foods Regulation No. 258/97 may require specific labeling.

c) TRADE BARRIERS: N/A

d) INTELLECTUAL PROPERTY RIGHTS (IPR): Italy implemented EU Directive No. 98/44/EC on the legal protection of biotechnological inventions through Law Decree No. 3 of January 10, 2006. 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. 27 of February 4, 2004. 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).

G) Marketing

a) MARKET ACCEPTANCE: 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.

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

c) MARKET STUDIES: We are unaware of any market studies relating to marketing animal biotechnology products in Italy.

H) Capacity Building and Outreach

a) ACTIVITIES: There have been no recent activities conducted in Italy on animal biotechnology.

b) STRATEGIES AND NEEDS: N/A

Abbreviations and definitions used in this report

AFSI: Aquila Food Security Initiative
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
CRA: Agricultural Research Council
CRA-GPG: CRA-Genomics Research Centre
CRA-ACM: CRA-Research Centre for Citrus and Mediterranean Crops
CRA-CER: CRA-Cereal Research Centre
CRA-FRF: CRA-Fruit Research Unit
CRA-FRU: CRA-Research Centre for Fruit Tree
CRA-MAC: CRA-Corn Research Unit
CRA-ORA: CRA-Research Unit for Vegetable Crops in Central Areas
CRA-ORL: CRA-Research Unit for Vegetable Crops
CRA-ORT: CRA-Research Centre for Horticulture
CRA-RIS: CRA-Rice Research Unit
CRA-SCV: CRA-Unit for Cereal Selection in Continental Areas
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
ENR: National Rice Institute
ERA: Environmental Risk Assessment
EU: European Union

FAO: Food and Agriculture Organization of the United Nations
FBOs: Food Business Operators
GE: Genetically Engineered
GeMMA: Genetically Modified Material Analysis
GI: Geographical Indications
ICQRF: Central Inspectorate for Quality Control of Foodstuff and Agricultural Products
INEA: National Institute of Agricultural Economics
INRAN: National Institute for Research on Food and Nutrition
ISMEA: Italian Institute for Services to the Agro-food Market
ISA: Institute of Agro-food Development
ISS: National Health Institute
IZSLT: Experimental Zoo-prophylaxis Institute of Lazio and Tuscany
IWGSC: International Wheat Genome Sequencing Consortium
MMT: Million Metric Tons
MIPAAF: Italian Ministry of Agricultural and Forestry Policies
MIUR: Italian Ministry of Education, Universities, and Research
NRL: National Reference Laboratory
PCR: Polymerase Chain Reaction
SCoFCAH: Standing Committee on the Food Chain and Animal Health
USMAFs: Port, Airport, and Border Health Offices

Terms used in this report:

Animal genetic engineering results 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).

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and therefore included in this report.

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.