

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 6/11/2013

GAIN Report Number: IT1326

Italy

Agricultural Biotechnology Annual

2013

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. The general attitude towards GE crops in Italy remains hostile. Italy's 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.

TABLE OF CONTENTS

Report Highlights

Section I: Executive Summary

Section II: AGRICULTURAL BIOTECHNOLOGY IN ITALY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

PART B: Policy

PART C: Marketing

PART D: Capacity Building and Outreach

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: Production and Trade

PART F: Policy

PART G: Marketing

PART H: Capacity Building and Outreach

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. Italy has not approved any products for 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 agrobiotechnology 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 maintains a *de facto* ban on planting GE crops. However, Italy's *de facto* ban was challenged in the European Court of Justice in September 2012. According to the Court findings, "the cultivation of genetically modified organisms such as the MON 810 maize varieties cannot be made subject to a national authorization procedure when the use and marketing of those varieties are authorized pursuant to Article 20 of EC Regulation No. 1829/2003 on genetically modified food and feed, and those varieties have been accepted for inclusion in the common catalogue

provided for in Council Directive No. 2002/53/EC of 13 June 2002”. The Court’s decision also confirmed that coexistence measures do not need to be in place to allow approved GE plants to be cultivated.

Despite the European Court’s findings, the Italian Ministry of Health applied in February 2013 to the EU Commission to implement the safeguard clause based on ‘environmental concerns’. In May 2013, the Italian Senate also voted unanimously in favor of Italy’s application of the safeguard clause and sought to increase monitoring and control of GE seeds by the Italian Forest Service to avoid cross-contamination with conventional crops and the use of GE seeds. 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 controls on GE seeds.

The general attitude towards GE crops in Italy remains hostile. Italy’s debate between pro and anti-biotech parties continues without much progress. 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.

In Italy, genetic engineering is not used in animals, although it is used for medical and pharmaceutical applications. Currently, there is no active debate on cloning and GE animals, nor any cloning taking place.

SECTION II: AGRICULTURAL 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.

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 some GE derived ingredients.

d) **IMPORTS:** Italy is a net importer of soybean and soybean meal, which represent the main ingredients in animal feed. In 2012, Italy imported 2.1 MMT (Million Metric Tons) of soybean meal, mostly from Argentina (1,017,909 MT), Slovenia (549,400 MT), and Brazil (160,117 MT). In 2012, Italy's soybean meal imports from the United States totaled 52,312 MT, valued at \$26.5 million. In 2012, Italy imported 237,903 MT of soybeans, mainly from Ukraine (117,150 MT) and Paraguay (65,288 MT). In 2012, Italy's soybean imports from the United States totaled 957 MT, valued at \$1.1 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 resulted has sponsored more than 50 Italy-funded projects with a total budget of €96.9 Mln. Over the past five years, 40 percent of Italy's aid went to sub-Saharan Africa, 25 percent to the Near East, and 20 percent to Asia. The monies were allocated to the Global Trust Fund's three thematic priority areas:

- 1) Food security;
- 2) Transboundary Animal and Plant Pests;
- 3) Investments in the agricultural sector.

On June 6, 2013, Italy announced it would contribute an additional €6 Mln to support FAO's strategic priorities, including €1 Mln toward the Organization's emergency program.

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 a 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 health, or the environment". More information on Italy's application of the safeguard clause can be found in the TRADE BARRIERS paragraph (g).

b) APPROVALS: Approval of GE products in Italy is subject to EU procedures. Under EU [Regulation No. 1829/2003](#), GE products and derived products 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. However, on April 4, 2013, the Italian government urged the European Commission not to renew Monsanto's ten-year-old MON 810-corn authorization claiming cultivation of the GE seeds presents "environmental risks." Monsanto's MON 810 maize and BASF's Amflora potato are the only two GE products authorized for cultivation in the European Union, but are not

commercially grown in Italy. The original approval—which was valid for ten years—dates to 1998 and Monsanto has since requested a renewal. The original authorization was issued based on an opinion and study by the European Food Safety Authority (EFSA) on the human and animal health risk; however, no environmental review was deemed necessary.

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 Regulation EC 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, Trentino Alto Adige, Friuli Venezia Giulia, Liguria, and Molise), 41 Provinces, and 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 maintains a *de facto* ban on planting GE crops. In April 2012, the Presidents of the 22 regions and autonomous provinces of Italy voted unanimously to ask the Ministry of Agriculture to invoke the safeguard clause to ban the cultivation of GE crops in Italy. The Regions justified their request on the need to protect Italy's organic production and Geographical Indications. However, Italy's *de facto* ban was challenged in September 2012, when the European Court of Justice published its final Decision on the administrative procedure initiated by Pioneer—a leading developer and supplier of advanced plant genetics—to plant GE crops in Italy.

According to the Court, “the cultivation of genetically modified organisms such as the MON 810 maize varieties cannot be made subject to a national authorization procedure when the use and marketing of those varieties are authorized pursuant to Article 20 of EC Regulation No. 1829/2003 on genetically modified food and feed, and those varieties have been accepted for inclusion in the common catalogue provided for in Council Directive No. 2002/53/EC of 13 June 2002”. The Court's decision also confirmed that coexistence measures do not need to be in place to allow approved GE plants to be cultivated.

The Court's decision followed a formal request submitted by Italy's State Council in the frame of a legal case initiated by Pioneer Hi-Bred Italia Srl versus the Italian Ministry of Agriculture, relating to the Ministry's refusal to grant any authorizations to cultivate GE seeds in Italy. The Ministry claimed it rejected the applications because no official national coexistence guidelines existed. DuPont Pioneer is now waiting for the final decision of Italy's State Council on the legal case against the Ministry of Agriculture. DuPont Pioneer hopes for the removal of the current ban on cultivation, per EU legislation (Directive 90/220/EU, in accordance with EU Regulation No. 1829/2003 and Directive 2001/18/EC).

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 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.

h) TRADE BARRIERS:

1. Safeguard clause

On May 21, 2013, the Italian Senate voted unanimously in favor of Italy’s application of the safeguard clause and sought to increase monitoring and control of GE seeds by the Italian Forest Service to avoid cross-contamination with conventional crops and the use of GE seeds.

Specifically the motion was::

1 - To adopt the safeguard clause pursuant to Article 23 of Directive 2001/18/EC and/or to take the precautionary measures provided for in Article 34 of Regulation (EC) No. 1829/2003, in accordance with the procedure provided for in Article 54 of Regulation (EC) No. 178/2002, for the protection of human health, the environment, and the economic and social model of the Italian food industry.

2 - To strengthen the work already being conducted by the Forest Service to monitor and control the use of GE seeds.. Their responsibility is to conduct checks in order to avoid contamination between genetically modified crops and conventional agriculture and to check for the presence of unauthorized GE seeds.

3 - Increase public scientific research on behalf of organic agriculture, and in the case of GE products, contain all research in laboratories.

In February 2013, the Ministry of Health applied to the EU Commission to implement the safeguard clause based on ‘environmental concerns’. This was done regardless of the fact that the European Court of Justice had determined in September 2012 that “the cultivation of genetically modified organisms (MON 810) cannot be made subject to a national authorization procedure when the use and marketing of those varieties are authorized by the European Parliament.” EFSA is currently reviewing Italy’s Safeguard request and determining whether there are any new scientific arguments in the documents provided by the Italian authorities. EFSA has yet to comment or provide any feedback and no completion date has been set.

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 the 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. The national portal is available at: <http://bch.minambiente.it>

k) **INTERNATIONAL TREATIES/FORA:** 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 2011-2013, 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 participates actively within the G20 in developing innovative mechanisms for increasing agricultural productivity, mitigating the negative effects of agricultural price volatility, and reducing the negative effects of 'Land Grabbing'.

Italian Development Cooperation's Programming Guidelines and Directions for 2011-2013 are available at:

http://www.cooperazioneallosviluppo.esteri.it/pdgcs/documentazione/PubblicazioniTrattati/2011-03-22_LineeGuida2011-2013Engl.pdf.

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 at the Italian Ministry of Health is responsible for controls on GE food, including applications for authorization of GE food. The Port, Airport, and Border Health Offices (USMAFs) perform GE food controls 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'. The USMAFs also perform controls of GE foods of non-animal origin (both raw materials and processed food). 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 Food Control Plan for 2012-2014 is available at:

http://www.salute.gov.it/imgs/C_17_pubblicazioni_1666_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 2012-2014 is available at:

http://www.salute.gov.it/imgs/C_17_pubblicazioni_1663_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 National Agency for Seeds (INRAN), 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 actually 0.049 percent, or the minimum detectable level.

The National GE Seed Control Plan for 2011-2012 is available at:

<http://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/5302>

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 26 qualitative PCR (Polymerase Chain Reaction) methods and 2 quantitative real-time PCR methods. The NRL regularly participates in GeMMA (Genetically Modified Material Analysis) proficiency test schemes. 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, 8 laboratories of Regional Agencies for Environment Protection (ARPA), and 6 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:** The general attitude towards GE crops in Italy remains hostile. Italy's 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. The uncertainty around Italy's national biotech policy and the negative media have sharply affect 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..

b) **PUBLIC/PRIVATE OPINIONS:** Several vocal NGOs 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.

Of note, in July 2012, 200 Italian scientists and farmers wrote an appeal to President Napolitano and former Prime Minister Monti. The letter specifically asked that Italy be given the possibility to compete in agriculture —both scientifically and economically—by putting a stop to the anti-GE policy in Italy. “Without research and innovation in agriculture, Italian farming is going to disappear. Italian farms must be able to compete in the global market, and, 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. “Most of the food that Italy imports contains GE products. Without GE feed, the ‘Made in Italy’ would not exist. Italy’s geographic indicators make extensive use of GE feed.” The Italian 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. The petition was signed by more than 200 individuals, many eminent in their fields of expertise.

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.

FAS Rome GAIN reports are available at:

<http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx>

Recent FAS Rome reports on agricultural biotechnology:

IT1224 [Biotechnology in Italy in 2012](#)
IT1223 [Say Yes to GMOs or Italian Agriculture will suffer](#)
IT1213 [European Court Likely to Rule Italy's Biotech Authorization is Not Legal](#)
IT1211 [Regions Want Italy to Invoke the Safeguard Clause](#)
IT1210 [Italian farmer on trial for planting GM corn](#)
IT1137 [Italian Ministry of Agriculture Tests Seeds for GMOs](#)
IT1131 [Agricultural Biotechnology Annual](#)
IT1127 [Italy Intends to Invoke Safeguard Clause](#)

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 green house 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.” The G20 conclusions in 2011, as well as the commitment of the G8 in May 2012 on a “[New Alliance on Food Security and Nutrition](#),” 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 not used in animals in Italy, although it is used for medical or pharmaceutical applications.

b) **COMMERCIAL PRODUCTION:** There are no GE animals commercially produced in Italy.

c) **BIOTECHNOLOGY EXPORTS:** Italy does not export any GE products, clones or products from clones to the United States

d) **BIOTECHNOLOGY IMPORTS:** Italy does not import GE animals, or livestock clones, or products from these animals, including genetics.

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. EFSA is working on a similar guidance document on the risk assessment relating to the safety of releasing GE animals bred for food and feed purposes into the environment. EFSA has set up a webpage on GE animals (<http://www.efsa.europa.eu/en/topics/topic/gmanimals.htm>) to keep track of the progress of the work on GE animals, as well as providing the relevant documents and reports. To date, EFSA has not received any applications for GE animals.

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 the police and Carabinieri (the Italian military police), 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.

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: N/A

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 only focused on animals for medical and pharmaceutical purposes to treat diseases.

b) PUBLIC/PRIVATE OPINIONS: Currently, there is no active debate on cloning and GE animals in Italy, nor any cloning taking place.

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

DGDC: Directorate General for Development Cooperation

DGAHVM: Directorate General for Animal Health and Veterinary Medicine

EFSA: European Food Safety Authority

EU: European Union

FAO: Food and Agriculture Organization of the United Nations

GE: Genetically Engineered

GeMMA: Genetically Modified Material Analysis

FBOs: Food Business Operators

GI: Geographical Indications

ICQRF: Central Inspectorate for Quality Control of Foodstuff and Agricultural Products

INRAN: National Agency for Seeds

ISS: National Health Institute

IZSLT: Experimental Zoo-prophylaxis Institute of Lazio and Tuscany

MIPAAF: Italian Ministry of Agricultural and Forestry Policies

MMT: Million Metric Tons

NRL: National Reference Laboratory

PCR: Polymerase Chain Reaction

SCoFCAH: Standing Committee on the Food Chain and Animal Health

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.