



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - public distribution

Date: 7/18/2005

GAIN Report Number: IT5026

Italy

Biotechnology

Annual

2005

Approved by:

Ann Murphy
U.S. Embassy

Prepared by:

Sandro Perini

Report Highlights: As for any other member state, Italy's biotech regime is subject to EU legislation. In general, Italy follows EU policies on agricultural biotechnology, but in certain areas it has maintained a more restrictive position, as in the case of seeds for planting, coexistence, and the deliberate release of GM (implementation of Directive 18/2001).

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Rome [IT1]
[IT]

Table of Contents

SEEDS FOR PLANTING 3
COEXISTENCE 3
DELIBERATE RELEASE OF GM 4
FIELD TESTING 4
THE "AMATO DECREE" 4
TRACEABILITY AND LABELING..... 5

SEEDS FOR PLANTING

The main authority in Italy is the Ministry of Agriculture (MOA). The MOA controls registration of seed varieties with the National Register and also sets policy when establishing the tolerance level for adventitious presence (AP) of genetically modified seeds in conventional lots. Article 1 of the Legislative Decree of April 24, 2001, formally implementing the EU Directive 98/95, states that seed planting is subject to the authorization of the Ministry of Agriculture, fixing the general principle that all appropriate measures are taken in order to prevent GM seeds from entering in contact with conventional seeds. Regarding the problem of the AP in conventional seed lots, the Italian Ministry of agriculture has always maintained a zero tolerance principle using severe controls in order to prevent any seed lot "contaminated" by AP to be marketed and planted in Italy. For technical purposes, "zero tolerance" is actually a 0.049 percent level, or the minimum detectable value. This policy has created many problems with both seed companies and farmers. In the summer of 2003, in particular, there have been cases of seed seizures, field seizures, and in some instances (especially in Piedmont) crop destructions in fields, where sown seeds tested positive. This heavy situation brought the local authorities and the leading seed companies to draw up an agreement aimed at compensating farmers for their income losses. In the last couple of years, in any case, problems related to AP have been limited because seed companies agreed to import corn seed no longer from the U.S. but from other countries, where the same companies have their seed producing fields. This situation, has led to a major loss in terms of seed exports from the U.S. to Italy.

According to the Italian biotech industry, however, the lack of any EU regulation concerning AP does not justify the zero tolerance fixed by the GOI. The Italian representations of the biotech industry say that AP of GM seeds in conventional lots should be considered as "impurities" (for which an actual tolerance exists), as the EU Directives do not specify that such impurities cannot belong to GM varieties.

COEXISTENCE

As previously reported, in IT4027, IT4031, IT4034, IT5002, IT5003 and IT5032, a coexistence law was finally passed by the Italian Parliament on January 28, 2005. It includes the broad concepts to which regional plans will have to conform when fixing their own regulations on this matter. The final text of the law removed the deadline (initially fixed at the end of 2005) by when each of the 20 Italian regions should approve their coexistence plans. Up to that date (the approval of the regional plans) transgenic crops are not authorized in Italy. This rule therefore establishes an indefinite moratorium over GM cultivation in Italy. In order to mitigate this effect, a following agreement between the Ministry of Agriculture and the regions fixed a new deadline, postponed to July 28, 2006. That agreement stated that the Ministry of Agriculture would have had six months after the approval of the law to issue the ministerial decree fixing the guidelines for the regions. After then, the regions will have one more year to establish their coexistence plans. However, the special committee of experts and scientists appointed by the Ministry of Agriculture in order to delineate the guidelines to be incorporated into the ministerial decree met for the first time only in late May, 2005 and decided to postpone at least to September the possible conclusion of its efforts. Therefore it is likely that the decree will be issued in the fall of 2005, with a further slip in the date (by 12 months) for the regions to fix their plans. Corn is the only biotech crop that currently could be planted in Italy. Plantings take place in March-April, so this new deadline implies that the first biotech seedings in Italy will not likely occur before the spring of 2007.

Furthermore, the same Italian coexistence law says that the regions, in compliance with the EU Commission recommendations 2003/556, can identify one or more "homogeneous" areas.

As neither the Italian or the EU legislation specifies what “homogeneous” area actually means, a broad interpretation of this concept could eventually lead to the declaration of an entire region as GM-free, a possibility upon which the Commission has already expressed a negative opinion. As a matter of fact, some 11 out of the 20 Italian regions have already declared themselves GM-free, likely followed in the near future by two or three more regions. Most of these regions cite that they are applying the precautionary principle, in order to prevent any risk to human health or the environment. The regions that already passed their anti-biotech legislation are: Liguria, Alto Adige, Emilia-Romagna, Tuscany, Marche, Umbria, Latium, Abruzzo, Apulia, Basilicata and Calabria. It is important to note, however, that the most important corn producing regions (Lombardy, Veneto and Friuli-Venezia Giulia) have not passed such legislation, while the local farm organizations in these regions have expressed their basic favorable disposition towards allowing biotech crop plantings.

DELIBERATE RELEASE OF GM

The EU Directive 18/2001 has been implemented in Italy through the Legislative Decree 334/2003. Among among the other measures, the Decree moved the leadership on this matter from the Ministry of Health to the Ministry of Environment. However, the same decree empowered several Ministries with a role in the authorization of new biotech events. These are Health, Labor, Agriculture, Production Activities, Education, as well as the CIV (Interministerial Evaluation Committee), specifically created under the lead of the Ministry of Environment, and composed of representatives from the different ministries. Although the function of the several Ministries, compared to Environment, remains advisory, the decree gives autonomous competence not only to the same Ministry of Environment, but also to other Ministries, such as Health and Agriculture, to use the safeguard clause in that it falls under their jurisdiction. The above Ministries, therefore, can, “with an emergency act, temporarily limit or prohibit the release into the market, the use or sale of a GMO, 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 GM can represent a risk for human, animal health, or the environment”.

The same decree, furthermore, specifies that the Ministry of Environment should pay particular attention to the compatibility of biotech release with typical and high quality products. This clause is considered by the Italian biotech industry to be inconsistent with the EU legislation, that, they state, does not fix any incompatibility between biotech crops and typical productions. This issue is highly sensitive in Italy, whose authorities, especially from the agricultural sector, focus on the need to defend these claimed high quality products from any “contamination” from biotech products.

FIELD TESTING

Regarding the request for authorization for field experimentation, moreover, the above decree fixes a further requirement, the evaluation of the risk for agri-biodiversity. On this purpose the Minister of Agriculture has recently (January 19, 2005) issued a specific decree, imposing particular geographic limits to biotech experiments and giving the regions the authority to fix the areas where these experiments would be possible.

THE “AMATO DECREE”

Please refer to IT4037 for previous details on the Amato Decree. Both the Coexistence law and the Decree on the deliberate release of GMO's make express reference to the safeguard clause, to be applied based on the precautionary principle, when there are concerns related

to human health or environment. This same concern, reportedly, in August 2000 pushed the Italian Government to issue the so called Amato Decree (from the name of the Prime Minister of that time), which banned the commercialization and use of four GM corn varieties already authorized by the EU. This decree substantially relied on Italy's right to use the "precautionary principle", alleging that proper procedures were not followed by the EU Commission to ascertain the absence of any health and environmental risk. The decree claimed also that, since biotech corn was not "substantially equivalent" to conventional corn, it did not receive the appropriate review under the EU regulations.

In November 2000 Assobiotec (the Italian umbrella organization for biotech companies) filed a lawsuit against the Amato decree with the administration court (TAR) of Latium region. A final decision, however, was taken by the TAR four years later (November 2004), when it ruled that the Amato Decree be annulled. The rule quoted a series of scientific recommendations speaking in favor of the four corn products, and that products could be considered substantially equivalent to the conventional products.

TRACEABILITY AND LABELING

T & L regulations have been fully implemented in Italy in April 2004. Reportedly, however, since then there has been no case of GM products sold for food use at retail level in Italy, labeled accordingly. According the Italian Food Industry Association, there has been, on the other hand, only one case of an Italian company selling GM soybean oil and labeled as a GM product for the catering and restaurant sector. Most Italian companies, on the contrary, preferred to be supplied with GM-free raw materials (especially soy and corn products), when selling at retail level, in order to label their products as GM-free products. This was due also to the strict controls implemented by the Italian authorities over food products possibly containing GM, as well as the wish of the food companies not be damaged by any positive testing of their products.