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Report Highlights:

Italy's recent 'yes' and 'abstention' votes to approve EU importation of specific new biotech events, after years of negative votes, represents the most important recent development on biotechnology in Italy. Field-testing of genetically-modified crops could restart, after a long ban, but is still opposed by the Minister of Environment.

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OVERVIEW

Since our Annual report of July 2006, there have been some new developments and changes in the Italian environment toward biotechnology. First, after many years of negative votes as a Member State (MS) in Brussels, Italy has recently started to vote in favor of (or abstain in) approving EU importation of new biotech events. This major development is thanks to increased pragmatism on the part of the Italian Ministries of Health and Agriculture. The opposition, however, to biotech remains very strong, including some leading farmer organizations and political parties. This opposition was shown, in particular, on two recent occasions; the Minister of Environment's maintaining a ban on biotech field tests despite approval given by the Minister of Agriculture, and in outcries against the new EU regulation allowing up to 0.9 percent GM content in organic foods.

On coexistence, virtually no progress has been made in Italy over the past year. The technical body, established by the central government and composed of the regions (recognized by the Constitutional Court as the only government entities competent on this matter) has not yet agreed on the general guidelines that the individuals should follow to articulate their own coexistence regulations. No biotech plantings, therefore, are expected in Italy until 2008 if then. Some regions, such as Lombardy, however, are exhibiting a pro-biotech attitude. This region could finalize its coexistence regulations during the coming fall/winter.

COEXISTENCE

As reported last year, the Italian Constitutional Court in March 2006 ruled against the then Coexistence law, which had passed Parliament in January 2005. Basically, the law was declared unconstitutional because the responsibility for delineating coexistence regulations was a function of regional governments. As a consequence, each of the 20 Italian regions was mandated to develop its own regulations on this issue. The decision has withdrawn the main parts of the law, including the "de facto" moratorium and the penal sanction for liability, while it has maintained only those sections establishing the coexistence principle. At the same time, it recalled the decision of the European Court of Justice, denying the request from an Austrian region to be considered GM free. However, according to a circular issued by the former Minister of Agriculture Alemanno, before the end of his mandate (spring of 2006), the moratorium on planting GM crops has still to be considered effective until each region approves its own coexistence legislation. A special technical working group has been created within the so called State-Regions Conference, that is supposed to elaborate the general guidelines to be followed by the regions when establishing their coexistence rules. These guidelines, that will not be mandatory for the regions, were expected by the end of June, 2007, but, according to Post contacts, have been further postponed by a few more months. At the technical working group's first meeting last January a draft heavily anti-biotech text was introduced, specifying, among the other measures, buffer zones of 1,000 meters. Lombardy and Veneto, the two leading pragmatic regions, rejected this approach, and insisted on lower buffer zones of 150 to 300 meters. On the other hand, some individual anti-biotech regions (Piedmont, Latium and Tuscany, in particular), have taken the initiative to issue regional laws establishing a new moratoria in biotech cultivations, evidently out of fear that in the absence of their coexistence regulations some farmers might decide to plant biotech crops).

To date, the only EU approved-for-planting GM varieties of interest to Italian farmers are corn, and only a few regions in the north of the country produce commercial quantities of this crop. It is likely that next fall/winter Lombardy, the major corn producing region where the local government has shown an understanding of the economic benefits of biotech, could be the first to set coexistence rules. If so, however, biotech planting might not take place before 2009. A regional coexistence law, even if passed this fall, needs to be ratified by the EU, and this process can last up to six months. This would make spring 2008 plantings impossible.

SEEDS FOR PLANTING

As outlined in last year's reports, Italy applies a "zero tolerance" for adventitious presence of genetically modified seeds in conventional lots. 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, makes seed planting subject to the authority of the Ministry of Agriculture, fixing the general principle that all appropriate measures need to be taken to prevent GM seeds from entering in contact with conventional seeds. For technical purposes, the tolerance level is actually 0.049 percent, or the minimum detectable level.

DELIBERATE RELEASE OF GM

EU Directive 18/2001 was implemented in Italy through the Legislative Decree 334/2003. Among other measures, the Decree moved the responsibility for this matter from the Ministry of Health to the Ministry of Environment. However, the same decree made several ministries responsible for authorizing new biotech events. These are Health, Labor, Agriculture, Economic Development, Education, as well as the CIV (Interministerial Evaluation Committee), which was specifically created under the lead of the Ministry of Environment, and composed of representatives from the various ministries. Although the function of the several ministries remains advisory to Environment, the decree also gives autonomous competence not only to Health and Agriculture to use the safeguard clause. 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 does not identify any incompatibility between biotech crops and typical productions. This issue is highly sensitive in Italy, where traditional "high quality" food items are touted as needing protection from any "contamination" from biotech products.

No new developments have occurred in the last year on deliberate release of GMO's. Competence remains with the Ministry of Environment.

APPROVAL OF NEW BIOTECH EVENTS

Dossiers on approving new events for use and importation under the EU Directive 1829/2003 remain under the competence of the Ministry of Health, which generally works in strict cooperation with the Ministry of Agriculture. While Italy had always voted against approval at EU level meetings a major shift occurred in recent months, when the Italian delegation, thanks to the cooperation between the Ministries of Health and Agriculture, voted either in favor of the new biotech events or abstained. Apparently, the Italian authorities have become sensitive to the criticism that their negative votes in Brussels were inconsistent with maintaining human and animal health, with Italy's role as host of the European Food Safety Authority (EFSA), with Italy's responsibilities in the EU, with the EU's commitment in the WTO/SPS agreement to use science, not politics, as a basis for regulating trade, with Italy's dependence on international trade to maintain its food processing industry, and with the interests of Italian farmers.

Of course, political pressures from many anti-biotech groups (including Coldiretti, the leading farmer organization) will try to change the new Italian position on the vote on biotech events, but a swing back to a completely negative attitude seems, at current time, unlikely.

FIELD TESTING

After years of prohibiting experimental field trials of new genetically modified crops, the Italian Minister of Agriculture, Paolo De Castro, in May moved the Italian agricultural research community a big step closer to being able to restart research stalled long ago when such fieldwork was banned. The Minister of Agriculture is, however, being opposed by the Minister of the Environment, Pecoraro Scanio, who is also leader of the Green Party.

The procedure for regulating such GM crop field trials is covered by EU Directive 2001/18, which was implemented in Italy by the Legislative Decree 224 on July 8, 2003, and later by a further implementing Ministerial Decree on January 19, 2005. In accordance with these decrees, the needed technical approvals for each involved GM crop must come from a special inter-ministerial committee consisting of ten members: two appointed by the Ministry of Agriculture, two by the Ministry of Environment and six from the Regions of Italy.

The committee had twenty applications to deal with and decided to divide the research protocols into two groups taking into consideration experimental priorities. The research approved by Minister De Castro includes nine different crops: kiwi, citrus, sweet cherries, strawberries, corn, eggplant, olives, tomatoes and grapes. The second group still awaiting committee action includes sugar beet, chicory, rapeseed, wheat, apples, ornamental plants, potatoes, rice, soybeans, plums and tobacco.

The Minister of Agriculture has drafted a Ministerial Decree authorizing the nine approved protocols, and has passed it to the Ministry of Environment for its advice, as is required by law. Pecoraro Scanio, who has always maintained a very strong anti-biotech political position, publicly opposed the approval of GMO field trials in Italy. As a result of this opposition, field trials are "de facto" suspended, despite the protocols having been approved in an absolutely clear process, agreed to even by the regions and the expert committee, which includes two appointees from the

Ministry of Environment. A solution to this contest between the two ministers can be found only at the political level, and does not seem easy.

TRACEABILITY AND LABELING

Traceability and labeling regulations were fully implemented in Italy in April 2004. Since then, however, virtually no foods have been sold at retail level labeled as GM products, due mainly to the worries of processors and distributors that they will be targeted by so-called consumer groups. This does not necessarily mean that no GM food products are consumed in Italy. Many observers, for example, believe that most of the soybean oil produced in Italy from imported GM soybeans is used by the hotel and restaurant sector, which do not have to label their retailed foods. In the case of animal feeds, the main GM feed ingredient is, of course, soybean meal. After years of denial, most media and even anti-biotech groups are realizing that most typical Italian DOP products, including Parmigiano Reggiano, Grana Padano and Parma ham come from animals intensively fed with GM soybean meal.

In mid June the EU Council passed a regulation fixing a 0.9 tolerance level for organic foods. This action was badly received by many Italian groups (farmer organizations, political parties, environmentalists, etc). As a result the Italian Minister of Agriculture drafted a decree establishing a technical zero tolerance for GM content in organic foods, which would actually mean a 0.1 percent level as the minimum detectable level. The State and Regional Conference has already endorsed this draft legislation. The new decree will supposedly become effective only in January 2009, leaving all the needed time, as the Minister explained, to refine the rules at the national level and notify them to the EU.