



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - public distribution

Date: 8/4/2005

GAIN Report Number: PO5017

Portugal

Biotechnology

Annual

2005

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Report Highlights:

Spain is the only European Union Member with a substantial cultivation area of biotech corn. Portugal began planting biotech corn this year for the first time. Newly elected governments in both countries have meant the evolution of Governmental positions on biotechnology, including new biotechnology-event approvals, and coexistence decrees. Portugal has just announced a coexistence decree, while Spain is currently working to have one in place in early 2006. (LR32CM60SH5).

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Madrid [SP1]
[PO]

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Executive Summary

In Spain, biotech corn planted area during 2005 is expected to drop to 48,000 hectares (ha), down from 58,220 ha in 2004, and in Portugal to increase to 1,000 ha from zero ha in 2004. The Iberian Peninsula drought, which began in the fall of 2004, reduced corn-seeded area, including biotechnology corn plantings this spring from last year's level in Spain and from what would have been planted in Portugal. The reduction is primarily due to a sharp decline in corn seeding in the Ebro Valley region, where the corn borer incidence is particularly high. In Portugal, farmers are just starting to plant biotech seeds, after a 5-year interregnum.

The Governments of Spain (GOS) and Portugal (GOP), socialist in ideology, appear to be experimenting more with the EU "precautionary principle" than their predecessor Governments. This has been evidenced by a more negative approach to voting on biotech approvals in Brussels, and in delays of approvals at home (in the case of Spain at least until July 13, 2005 when Spain approved NK603 for planting). As an example, in the EU Environment Ministers Council meeting on June 24, 2005, the GOS supported a continued ban on planting certain corn and rapeseed biotech seeds imposed in specific EU Member States, in opposition to the EC proposal, and the GOP abstained in the same vote.

The GOP has just finalized a national coexistence decree that will regulate biotechnology production, while Spain is still working on its coexistence decree in time for the 2006 crop. The Portuguese decree sets a minimum distance of 200 meters between biotech and conventional corn plots, and a 300-meter distance between biotech and biological corn plots, and establishes a framework for biotechnology-free regions. This will likely mean the cultivation of biotechnology corn in the mid-to-southern regions of Portugal, where farms are larger and more responsive to technological opportunities.

Biotechnology Trade and Production

Biotechnology Crops

Spain

Spain: Areas Cultivated to Bt Corn

	1998	1999	2000	2001	2002	2003	2004	2005
Areas (1,000 ha)	22.32	24.95	25.82	11.54	23.28	32.16	58.22	48.0

Source: ISAAA and Spanish AGMIN.

- Spain is a feed deficit country, so Spanish corn farmers have tremendous incentive to produce for a reliable local market, which, even with increased yields due to biotechnology seeds, they will not be able to satiate;
- Currently the demand of biotech corn seeds is in *Ebro Valley* regions of Aragón and Cataluña where the corn borer is particularly intense. Industry sources report that in 2004, the Aragón and Cataluña regions represented respectively for 25,000 and 16,000 ha of Bt-corn areas.
- However, an increase in biotechnology seeded acreage in the coming years will depend on: (1) GOS biotech policies, in particular the coexistence decree (see below) and the approval of new biotech seeds resistant to herbicides; and, (2) the success local farmers enjoy when using these products.

- CAP reform will likely lead to a reduction in corn production, but only in the marginal, non-irrigated areas that would not have otherwise embraced biotechnology corn production. As a result, the share of biotech seed planted will likely increase, as farmers will tend to use best production technologies available, and those who can't will opt for alternative production. The GOS approval of NK-603 may mean an increase other important Spanish corn areas, including *Ribera del Duero* and *Andalucia*. With new approvals, Spanish biotech corn areas will easily surpass 60,000 ha.

Portugal

- Portugal did not cultivate biotech crops during the past five years due to AGMIN DISPATCH dated 12/27/99, which suspended sale/use of biotech seeds listed in the National Seed Catalogue (NSC). The same dispatch banned biotech seed trials with commercial purposes.
- The GOP has not invoked any safeguard measures related to the planting of biotech crops, and so all biotechnology varieties approved by in the EC catalog can now be planted in Portugal.

Biotechnology Policy

Regulatory Framework for Agricultural Biotechnology

Spain

Responsible Ministries and Their Role

- Three Ministries oversee biotech issues: Agriculture, Health and Environment.
- The Ministry of Agriculture approves and monitors biotech seeds for planting.
- The Ministry of Health and Consumer Affairs monitors and enforces labeling.
- The Ministry of Environment monitors and enforces evaluation of new GMO events, field trials, and applies penalties set by 2001/18 Directive (transposed to national order by Law 9/2003).
- A Biosafety Committee, with representatives from these Ministries, studies and proposes changes;
- An inter-ministerial council at the Director General level reviews each biotech event. The Council has final word on applications to cultivate biotechnology events.

Political Factors That May Influence Regulatory Decisions Related to Agricultural Biotechnology

- External: (1) Prevailing EU policies towards GMOs; (2) EC motivation to support GMOs; (3) Seemingly weakening integration process within the EU, signaled by the setback in France and the Netherlands. This may lead to “re-nationalization” of GMO policies at the Member State level.
- Internal: (1) GOS’ internal debate to develop a coherent biotechnology policy. (2) Influence of NGOs on the perception of biotech products. Greenpeace has 40,000 affiliates in Spain, and carries out several high-profile activities with considerable media impact. (3) Consumer perceptions of biotechnology.

List of Biotechnology Crops

Maize Varieties Approved in Spain for Cultivation

Event	Strain	Company	Publication Date in Official Journal
Bt - 176 (SYN-EV176-9)	COMPA CB	Syngenta	03-26-98
	JORDI CB	"	03-26-98
	BRAMA	"	03-11-03
	ESCOBAR	"	02-16-04
MON-810 (MON-00810-6)	ALICAN BT	Limagrain	03-11-03
	ARISTIS BT	Nickerson Sur	03-11-03
	DKC 6575	Monsanto	03-11-03
	PR33P67	Pioneer Hi-Bred	03-11-03
	CAMPERO Bt	Advanta	02-16-04
	CUARTAL Bt	Arlesa	02-16-04
	DKC 6550	Monsanto	02-16-04
	GAMBIER BT	Nickerson Sur	02-16-04
	JARAL Bt	Semillas Fitó	02-16-04
	PR 32 P76	Pioneer Hi-Bred	02-16-04
	PORTECT	Koipesol	02-16-04
	ELGINA, OLIMPICA	Pioneer Hi-Bred	EU Catalogue
	BOLSA, LEVINA	Pioneer Hi-Bred	09-17-04
	NOVELIS	Coop de Pau	"
DK 513	Monsanto	"	

- List of approved varieties for cultivation includes the 17 varieties listed in the EU seed catalogue (derived from MON-810), plus four varieties derived from Bt - 176.
- Between 1998 and 2002, COMPA CB was the only variety planted in Spain. Other significant varieties are DKC 6575, PR33P67, JARAL Bt and PR 32 P 76.
- On January 2003, the industry submitted a NK 603 strain for approval by the authorities. Finally on July 13, 2005 NK 603, a glyphosate-resistant event was

approved for planting in Spain. The NK 603 approval will likely be used the *Ribera del Duero* and the *Andalucia* regions.

Field Testing

- Industry sources report there are field trials with NK 603.
- Full list of pending requests can be checked at <http://www.mma.es>.

Coexistence Policy

- Spain does not have a coexistence law in effect, but there is one under development;
- Local authorities plan to have the new coexistence law in place by February 2006.
- Previous GOS coexistence law projects considered a 25 meter minimum distance between biotech and conventional seed plots;
- According to our sources, the distance currently under discussion has been raised to 50 meters. We do not know if this will be final, nor if the authorities will introduce further restrictions, namely buffer zones.

Spain's biotech agenda

- The GOS is still finding its way regarding biotechnology policy;
- The pro-active attitude of the previous GOS is still apparent in the Ministry of Agriculture, but the Ministry of the Environment seems to be finding its way;
- On June 24, the GOS voted against the EC, in support of five EU countries that had banned certain biotech crops, which was and is concerning; and,
- On recent EC proposals regarding biotechnology events, the GOS has abstained.

Technological Fees

- Not charged by the authorities.

Relevant sites

Legislation, Spanish National Safety Commission, trial requests, reports and table of approved products:

http://www.mma.es/calid_amb/seg_bio/index.htm#

Publications by *Fundación Genoma España*:

http://www.gen-es.org/02_cono/02_cono.cfm?pag=0300

Information from the Spanish Agency of Food Safety on Transgenic crops:
<http://www.aesa.msc.es/aesa/web/AESA.jsp>

Portugal

Responsible Government Ministries and Their Role

- The Environment Ministry is the ultimate authority on the national position on events submitted under the 2001/18 EU Directive.
- The Portuguese Environment Ministry (PEM) represents the GOP at EU Environment Ministers Council level. The PEM develops its positions on the basis of the technical recommendations issued from the Environment Institute (IA), and in coordination with the political advice from the Ministry's office of international relations (GRI).
- The IA represents the Ministry at technical level Committee meetings. For preparation of its dossiers on each event, IA follows a procedure of consultation with other GOP agencies: General Directorate of Health (DGS) in the case of products destined for human consumption, and the AGMIN's crop protection directorate (DGPC) for planting seeds.
- The AgMIN is the ultimate body responsible for GM-submittals under the 1829/03 EU Regulation.
- The AGMIN's food monitoring and quality general directorate (DGFCQA) has technical level responsibility for preparing biotech dossiers, issuance of technical-level recommendations to the GOP, and representing Portuguese authorities at technical-level meetings of specialized EU Committees.

Role of Biosafety Committee

- The previous GOP instituted the Biosafety Committee in 2004, through joint decision 174/2004 from GOP Presidency, AGMIN/DGPC and Environment Ministry;
- The Biosafety Committee was intended to provide coordinated technical support to GOP decision-making on new biotechnology seed requests;
- The Biosafety Committee never became operational, and the Health Ministry seat is the only one presently occupied.

Political Factors That May Influence Regulatory Decisions Related to Agricultural Biotechnology

- Political factors that may influence regulatory decisions are basically the same as in the case of Spain (see above).

List of Biotechnology Crops

- The 17 varieties inscribed in the EUSC.

Field Testing

- AGMIN DISPATCH dated 12/27/99 bans the planting of biotech seed experimentation for commercial purposes.
- Testing of seeds for non-commercial purposes remains permitted, but subject to IA approval. Earlier this year, the industry presented IA with a request for carrying out experimentation in northern *Ponte da Barca*, and near-Lisbon *Cadaval* regions.
- Applications refer to field testing with seeds containing modifications not yet approved in the U.S. – E 5846.49.7.12 and E 5846.53.9.4 - and the following seeds with stacked modifications: 1507 x NK 603; 59122 x NK 603; 59122 x NK 603 x 1507.
- IA posted applications for public comment in its site, at <http://www.iambiente.pt>. Concerned Municipalities expressed a negative view.
- The commenting period has just expired, and IA will deliberate shortly.

GM-planting seed experimentation for commercial purposes

Coexistence Policy

- The GOP has just approved the national coexistence law, which will regulate biotech crop production starting in 2006. The coexistence decree will be published shortly.
- Local authorities justify the need for coexistence law on the basis of the precautionary principle, and public concern over GMOs. Coexistence law sets technical cultivation parameters, inter-crop minimum distances, buffer zones, procedural requirements, and facilitates the designation of biotechnology-free zones;
- A 200 meters distance is required between biotech and traditional corn crops and 300 between biotechnology and organic corn production. This distance can be replaced with a buffer zone of 24-rows planted to conventional seeds or may be reduced to 50 meters, with a 28-row buffer zone. In case of insect tolerance strains, producers need to create "refuge" conventional variety zones inside the biotech seed plots, representing at least 20 percent of total crop area.
- The Portuguese AGMIN/DGPC recently concluded a three-year study on the impact of GMOs in agriculture – Project AGRO-17. The conclusions of this study have just been presented in Lisbon, being of favorable in nature. DGPC is now planning to carry out a new multi-year project to study field cross-contamination and other matters directly tied to the regulation of coexistence.

Portugal's biotech agenda

- Above remarks on Spain apply to Portugal, with the difference that the previous GOP was less favorable than the previous GOS;
- In the June 24 EU Environment Ministers Council meetings, Portugal abstained in the EU Commission vote to overthrow five Member State decisions to ban cultivation of biotech seeds;
- Anti biotechnology lobbying is coordinated and led by a movement titled "Transgenic out of the Plate" (TOTP). TOTP integrates a vast spectrum of organizations, from environment NGO Quercus to the Nature Protection League (LPN) and small farmers confederation (CNA). TOTP has been gaining increased visibility with high profile, well-staged events;
- Earlier this year, a well-known attorney filed a well-publicized case in the Portuguese Courts, advocating the banning of biotech seeds due to absence of national coexistence law;
- Over the years, large-scale farmers have supported biotech-free corn production, invoking commercial reasons. CAP changes now should now encourage these farmers to be more interested in biotechnology;
- AGOFFICE contacts report that farmer enthusiasm resulting from the coexistence courses is very high, which suggests considerable farmer interest in biotech seeds. Under the new coexistence decree, attendance at these courses is mandatory for cultivating biotech crops.

Technology fees

- No technology fees are charged in Portugal.

Marketing Issues – Market Acceptance

Spain

- According to the "The Eurobarometer," Spain is one of the EU countries with greater GMO acceptance;
- In 2004, 14 percent of Spaniards expressed concern over GMOs (24 percent in the EU-25), down from 18 percent in 2002 (30 percent in the EU-15).
- Food manufacturers with recognized labels have eliminated potential biotech products from food product composition. This concerns multinationals and national manufacturers with well-asserted brands.
- An extremely small percentage of food products are sold at retail with the "contains GMO" mention, without problems to-date. This mention is carried primarily by certain vegetable oil brands.

- The local feed industry has instructed its members to label all feed by default with “Contains GMO.”

Portugal

- Market acceptance of biotech products is considered reasonable;
- Multinationals and local manufacturers with higher-profile brands have eliminated biotech-derived products;
- The feed association has instructed its members to always label feed with “contains GMO.”

Capacity Building

Outreach Activities

N.A.

Future Actions

N.A.