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"Post-Market Monitoring plans of Bt176 in Spain: 1998 -2005"

by

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ABSTRACT

The first GM maize hybrids were registered in the Commercial Variety Register in Spain on the 26th of March 1998. The registered hybrids, Compa Cb and Jordi Cb, were carrying the genetic modification identified as "Bt-176". This genetic modification expresses the Cry1Ab protein from *Bacillus thuringiensis* for protection against the insect pest of European Corn Borer *Ostrinia nubilalis* and Mediterranean Corn Borer *Sesamia nonagrioides.* Since then, Spanish farmers have planted Bt-176 maize on their farms, approximately 22000 ha annually (5 % of the total acreage).

The placing on the market of this genetically modified maize was approved in the European Union according to Directive 90/220/EEC on February 5, 1997. Following this the authorization at the EU level, the inscription at the Plant Variety Commercial Register of one EU State is required before the commercialization of any maize hybrid seed for plantings in the EU. This registration allows the commercialization of seeds from the registered maize hybrid in this country.

As part of the Spanish hybrid authorization, the Spanish authorities required that a post-marketing monitoring plan be implemented, which addressed the following points:

- An evaluation of the efficacy of the hybrids against target insects;

- An study on the potential development by corn borers of resistance to the CryAI(b) protein, in areas where Bt-176 maize is being grown to a significant degree;
- An evaluation of potential effects on the non-target entomofauna and on soil microorganisms, in fields cultivated with these Bt-176 maize varieties;
- An evaluation of potential effects on the population of bacteria in the gut flora of animal fed with these Bt-176 maize hybrids, in particular regarding the resistance to ampicillin;
- Indication on the area to be cultivated with conventional maize in relationship to the area cultivated with these Bt-maize hybrids, in order to provide refuge for corn borers;
- A program for educating growers on proper use of the technology.

Syngenta has presented a monitoring plan which was further developed, and carried out, in collaboration with public research institutions in Spain. The monitoring plan has been in effect and results are now available. The results indicate that Bt-176 maize does not have any unexpected negative impacts to the environment in Spain, indicating that it is as safe for the environment as its conventionally-bred counterpart.

Some key findings from the post-market monitoring plan have been published in international peer-reviewed scientific journals. These include the following studies and results. A baseline susceptibility survey indicates that there have been no changes in susceptibility after eight years of Bt-maize cultivation in Spain. A 3-year farm-scale study, which assessed the potential impacts of Bt maize on predatory arthropods, has indicated that there are natural variations, but that Bt maize is compatible with naturally occurring predators. A thorough evaluation of the bacterial populations in the soil and guts of animals fed on Bt-176 maize demonstrate that none of the parameters measured were significantly different ($P<0.01$) between Bt-176 maize and controls under the diverse conditions studied.

The results of the post-market monitoring plan and our commitment to stewardship for Bt-176 maize in Spain will be reviewed in more detail and we will describe how these studies reinforce the conclusions from the initial regulatory assessments.

Syngenta, Biotechnology, GMO, Bt176, Post-marketing monitoring, Stewardship, GM Crops,