Report on the implementation of the Insect Resistant Management plan for MON 810 in the European Union

- MON 810 cultivation in Spain in 2003 and 2004 –

Introduction

Monsanto has developed an alternative to traditional insecticides for the control of lepidopteran insect pests, with reduced impact on the environment, by genetically modifying maize plants to produce the insecticidal protein Cry1Ab from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*). These Insect-Protected maize plants, called MON 810, guard against foliage feeding and stalk tunneling from the European corn borer (ECB) (*Ostrinia nubilalis* (Hübner)) and the pink stem borer (*Sesamia nonagrioides*).

In April 1998, after a review of the risk assessment conducted for MON 810 in the notification (C/F/95/12/02, presented by Monsanto Europe SA) by France, acting as *rapporteur* country, by the competent authorities of the member states, and by the Scientific Committee on Plants, the European Union decided, in Commission Decision 98/294/EC, to approve the placing on the market of MON 810 in accordance with Directive 90/220/EC. According to this Decision, Monsanto SA committed to inform the Commission and the competent authorities of the Member States of the results of monitoring for insect resistance.

Decades of experience have taught entomologists that insect populations adapt, sometimes quickly, to even the best insecticides if the use of those insecticides is not managed appropriately. For this reason, as early as 1992 in the USA, Monsanto established an expert advisory panel composed of leading pest and resistance management researchers from academia, USDA-ARS, and university extension services to develop effective insect resistance management strategies for Insect-Protected maize.

Following this example, in the European Union, Monsanto has worked since 2001 to establish, with three other companies (Syngenta, Pioneer, Dow), the "European Union Working Group on Insect Resistant Management" or EUWGIRM. This group developed an IRM plan that enables concrete implementation of the management strategy described in Appendix III of the notification C/F/95/12/02 (Monsanto Company, 1995). This IRM plan (Annex I) is based on the concrete experience acquired in world areas where MON 810 is grown, on results from research performed by scientists world-wide (including the EU) and on the

scientific opinion on insect resistance published by the European Commission's Scientific Committee on Plants (SCP, 1999).

In 2003, MON 810 was fully commercially introduced for the first time in Europe in Spain. In accordance with the Commission Decision on MON 810 (European Commission, 1998), a strategy to delay the development of insect resistance was implemented. The basis for this implementation was the "Harmonised insect resistance management (IRM) plan for cultivation of Bt maize in the EU" developed by the EWGIRM (*see* above). This report describes the components and results of the IRM plan that was implemented.

The acreages planted in Spain in 2003 and 2004 with Bt maize expressing the Cry1Ab protein were 32000 and 58000 ha respectively, and covered the main three geographical areas: Ebro Valley, the center of Spain, and the Extremadura-Andalusia region.

Implementation of the IRM plan

The success of the IRM plan is ensured by the implementation of three key aspects. These are 1) refuge, 2) baseline studies and monitoring of the target pests, and 3) communication and education. These different aspects are reviewed in the following sections.

1) Refuge

According to the "Harmonised insect resistance management (IRM) plan for cultivation of Bt maize in the EU" (EU WG IRM plan, 2003, Annex II), farmers planting more than 5 ha of MON 810 maize must plant a refuge area with maize that does not express Cry1Ab and that corresponds to at least 20% of the surface planted with MON 810.

Many initiatives (reviewed in the section 3 "Communication and education") have been taken to explain to farmers the importance of implementing IRM measures. For cultural reasons, certain farming communities such as some of those in Spain, are reluctant to accept "signed agreements" imposing particular agricultural practices. As a consequence, the seed industry put a particular emphasis on the development of communication tools (*see* below).

The effective implementation of refuges on farms was monitored at the end of each planting season through a survey conducted by ANTAMA (Spanish association supporting the use of new technologies in agriculture) and ABE (Agricultural Biotechnology in Europe). At the same time the survey assessed the effectiveness of IRM communications programmes and the difficulties faced by farmers in implementing refuges. In 2004, the survey was carried out in the Ebro Valley (Huesca, Lerida and Zaragoza), which is where most of the Bt maize that is currently planted in Spain is located. The survey involved 100 farmers who each planted more than 5 ha of [***Bt??] maize, and who collectively planted 3.540 ha of maize, of which 2538 ha was Bt maize.

The result of the survey indicated that 97% of the farmers had received the information that they are required to plant a refuge. It also revealed that 66% of the farmers planted both conventional and Bt maize on their farm, with 58% of the farmers declaring that they had specifically implemented a structured refuge in their fields.

2) Baseline and monitoring studies

a) Baseline studies

Baseline studies with Cry1Ab were first performed in 1998 when Syngenta commercialised the first Bt maize variety in Europe (Bt 176). This initial study was supported by the Ministry of Environment (Gonzalez-Nunez *et al.*, 2000), and it aimed to establish the sensitivity of the target insect populations towards the Cry1Ab protein that also is expressed in MON 810. This served as a baseline against which insect population sensitivity to Cry1Ab (collected as part of the monitoring programme) could be compared once the Bt maize was grown commercially.

The insect species considered were European corn borer (ECB; *Ostrinia nubilalis* (Hübner)) and pink stem borer (*Sesamia nonagrioides*). Those studies were performed by the research group of Dr. [redacted] and Dr. [redacted] (Department of Plant Biology, Centro de Investigaciones Biologicas, CSIC), and covered the three main regions where insect pressure would justify the use of MON 810 maize, i.e. Ebro Valley, the centre of Spain, and the Extremadura-Andalusia region. These published studies revealed no difference in susceptibility among populations of ECB or among populations of *Sesamia* collected in the three regions (Gonzalez-Nunez *et al.*, 2000, Annex III) prior to the introduction of MON 810.

b) Monitoring for insect resistance

The group of Dr. [redacted] and Dr. [redacted] have performed monitoring for ECB and *Sesamia* resistance to Cry1Ab across the three above-mentioned regions since 1999, the date of the commercialization of the Bt maize Bt 176 from Syngenta that also expresses a Cry1Ab protein (Farinos *et al.*, 2004).

Three populations of ECB and three of *Sesamia* were sampled in total from the Ebro Valley, the centre of Spain, and the Extremadura-Andalusia region, each population being collected once every 2 years. The results of analysis of insect susceptibility to Cry1Ab were as follows:

ECB - The monitoring studies performed with ECB collected during the 2004 season did not reveal any significant variation in insect susceptibility among the regions nor were there differences in susceptibility from the earlier baseline studies (Castanera *et al.*, 2004; Ortego, 2005), Annex IV).

Sesamia - The monitoring studies performed in 2004 revealed more variability among populations in susceptibility than was seen in the previous ME-CSIC study (Farinos *et al.*, 2004). This variability can be interpreted as intrinsic variability of the testing protocol or of the

populations across the years, but does not seem to reflect an increased tolerance as a consequence of Bt maize planting because the highest tolerance level observed would not be sufficient to allow survival of *Sesamia* when feeding on MON 810 maize (Ortego, 2005). It is also important to note that other noctuid insect pests (Lepidoptera: Noctuidae) related to *Sesamia* have exhibited relatively high levels of inter-and intra-population variation in susceptibility in previously published studies (for example, *Helicoverpa zea;* Stone and Sims, 1993). Nevertheless, the same population will be sampled and evaluated in 2005 to assess whether these results are indeed due to natural variability.

3) Communication and Education

An extensive grower education program is essential for the successful implementation of the IRM plan.

To this end, each purchaser of Bt maize receives a technical user guide (*see* Annex 2) that contains the latest information on the growers' IRM obligations. The user guide requires farmers to implement IRM measures, including refuge planting (*see* Annex 2).

The grower education programme has been developed and agreed by all seed companies that sell GM maize expressing Cry1Ab proteins in Spain.

In 2004, in order to measure the effectiveness of this education programme, a survey founded by ANTAMA/ABE, was performed in the Ebro Valley (Huesca, Lerida and Zaragoza), which is the main Bt maize area in Spain. The survey involved 100 farmers who each planted more than 5 ha of Bt maize and who collectively planted 3.540 ha of maize. 97% of the farmers answered that they were made aware of the fact that they are required to plant a refuge, whereas 34% recognized that they planted only Bt maize on their farm. A possible explanation for the latter result is that farmers may have relied on their neighbours' maize fields as refuges.

In 2005, additional emphasis was given to refuge implementation by 1) reinforcing the strength of the message (e.g. From "Estrategia de Refugios" [Refuge strategy] to "Para que la protección dure mucho tiempo SIEMBRE REFUGIOS" [For protection that lasts, always plant refuges] and stating that the neighbors´ fields are not valid as refuge), and 2) additional advertisement in the press stressing that the sustainability of MON 810 depends on responsible implementation of refuges by farmers. Further surveys are planned for the 2005 season to assess the effectiveness of these initiatives.

Conclusions

The commercial introduction of MON 810 has been accompanied by a rigorous insect resistance management (IRM) plan in Spain in 2003 and 2004, centred on three major elements: refuge implementation, monitoring, and farmer education.

No major issues related to insect resistance management were experienced in 2003 and 2004. Nevertheless, certain improvements in the IRM plan have been

initiated. One objective for 2005 is to develop a better understanding of the natural variability in susceptibility of *Sesamia* populations from one year to the next. New sampling of populations will, therefore, be undertaken during the 2005 season. A second objective is to increase the percentage of farmers implementing refuges in their fields. For this purpose, the process of educating retailers and farmers has been further reinforced in 2005, and the messages on the necessity of implementing refuges strengthened.

Monsanto and the seed companies marketing maize expressing the Cry1Ab protein have been operating together to establish an IRM programme that is adapted to the EU agricultural landscape, and will continue to work closely together to assess its implementation and subsequently build on those learnings.

References:

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Annex 1

Harmonised insect resistance management (IRM) plan for cultivation of Bt maize in the EU

Annex 2

Technical user guide for MON 810 maize

Annex 3

References cited in the text