Comisario Europeo
Mr Vytenis Andriukaitis
Comisión Europea
Dirección General de Salud y Seguridad Alimentaria
B - 1049 Bruselas
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Por favor, responder a la siguiente dirección: Testbiotech, Christoph Then, Frohschammerstr. 14, D-80807 München, christoph.then@testbiotech.org

22 de abril de 2016

Carta abierta

Estimado Comisario Andriukaitis,

Aparición de teosinte en el Estado español y cultivo de maíz genéticamente modificado MON810

Enviamos esta carta como seguimiento a los datos presentados en una carta conjunta que le fue enviada por varias organizaciones de la sociedad civil en febrero de 2016 (Nota 1). En este documento aportábamos evidencias de que el teosinte, ancestro del maíz cultivado, está presente en Estado español desde 2009.

Se sabe que las poblaciones de teosinte pueden convertirse en receptoras de ADN transgénico procedente del maíz modificado genéticamente MON810, que se cultiva en el Estado español en algunas de las regiones en las que el teosinte se ha convertido en un problema. La información genética transgénica podría incorporarse al teosinte mediante cruzamiento, haciendo que éste comience a producir la toxina Bt y confiriendo una mayor capacidad de supervivencia a los híbridos de maíz y teosinte en comparación con las plantas de teosinte originales. Este escenario supone riesgos graves para los agricultores y para el medio ambiente.

Bajo estas circunstancias, la situación actual exige una reevaluación detallada del análisis de riesgos ambientales realizado por la Autoridad Europea de Seguridad Alimentaria (EFSA) y las autoridades españolas. Como el documento adjunto evidencia, las autoridades españolas autorizaban el cultivo del MON810 presumiendo que no había posibilidad alguna de transferencia genética debido a la inexistencia en Europa de especies silvestres emparentadas con el maíz (Nota 2).

Como mencionábamos en nuestro anterior escrito, el productor del maíz MON810, la empresa estadounidense Monsanto, debería haber incluido esta información en sus informes de seguimiento anuales, tal y como obliga la ley. Sin embargo, nuestro análisis de la opinión publicada por la EFSA en abril 2016 (Nota 3) pone en evidencia que ni Monsanto ni la EFSA mencionan la propagación del teosinte en España ni sus posibles implicaciones para el cultivo del maíz MON810.

Le pedimos, por tanto, que:

- rechace la opinión formulada por la EFSA
- adopte medidas para detener el cultivo de MON810 en España

medio ambiente.

Su decisión debería tener en cuenta asimismo que la evaluación de la EFSA ha señalado varias deficiencias en el informe de seguimiento presentado por Monsanto. Estas deficiencias afectan al plan de gestión de resistencias y a la forma en que se recopila información de los agricultores y de la literatura científica. Esto refuerza nuestra demanda de que se retire la autorización de cultivo del maíz MON810, en concreto, dado que el seguimiento realizado por el solicitante no cumple la normativa de la UE.

Atentamente y en representación de las organizaciones abajo firmantes

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Referencias

Nota 1. Carta previa a Comisario Andriukaitis (24-02-2016): http://www.redsemillas.info/wp-content/uploads/2016/02/160224-Open-NGO-Letter-to-Commission-on-Teosinte-in-Spain-24-February-2016.pdf

Nota 2. Carta de la Comisión Española de Bioseguridad – Opinion on the Environmental Risk Assessment and Monitoring Plan on Application EFSA-GMO-RX-MON810 (06-11-2008): www.testbiotech.org/node/1617

Nota 3. EFSA GMO Panel (2016) Scientific opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014 from Monsanto Europe S.A. EFSA Journal 2016;14(4):4446, 26 pp. doi:10.2903/j.efsa.2016.4446

Esta carta se ha enviado en representación de las siguientes organizaciones:
Amigos de la Tierra (Estado español), Coordinadora de Organizaciones de Agricultores y Ganaderos COAG (Estado español), Ecologistas en Acción (Estado español), GeneWatch UK, Plataforma Andalucía Libre de Transgénicos (Estado español), Red de Semillas “Resembrando e Intercambiando” (Estado español) y Testbiotech (Alemania).

S/001-38603

MINISTERIO
DE MEDIO AMBIENTE, Y
MEDIO RURAL Y MARINO

DIRECCION GENERAL DE CALIDAD Y EVALUACION AMBIENTAL

María Jesús Rodríguez de Sancho

DIRECTORA GENERAL

Ministerio de Medio Ambiente, y Medio Rural y Marino
11 NOV 2008
Dirección General de Calidad y Evaluación Ambiental
Secretaría Particular
SALIDA 271

INCOMING N°. 7595
18 NOV 2008
EFSA

Madrid, 6 November 2008

Mr. Per Bergman
Head of GMO Unit
European Food Safety Authority
Largo N. Palli 5/A
43100 Parma
ITALY

Subject: Spanish Biosafety Commission Opinion on the Environmental Risk Assessment and Monitoring Plan on Application EFSA-GMO-RX-MON810 (20.1a)

Dear Mr. Bergman,

On 23 October 2007 and in accordance with Articles 6.3 (c) and 18.3 (c) of Regulation (EC) No. 1829/2003, EFSA called for expression of interest to the EU Competent Authorities of the Member States under Directive 2001/18/EEC to carry out the Environmental Risk Assessment (ERA) of Application EFSA-GMO-RX-MON810 for the renewal of authorisation of genetically modified MON 810 maize which express insect resistance to be used as seeds or other plant-propagating material, submitted under Article 20.1a of the mentioned Regulation. The Spanish Competent Authority gave its conformity to perform this task on 14 December 2007.

During the assessment process carried out by the Spanish Biosafety Commission *(Comisión Nacional de Bioseguridad*, CNB) it was requested the Monsanto Company to supply additional information regarding some biosafety issues related to this genetically modified plant in two occasions. Finally, on 6 October 2008 the CNB informed EFSA that all additional information requested had been provided and it was considered appropriate.

According with the EFSA mandate and taking into consideration all information received from the Applicant and the scientific comments made by other EU Member States, the Spanish Biosafety Commission has carried out the Environmental Risk Assessment of this dossier.

We are pleased to enclose the Opinion of the Spanish Biosafety Commission on the environmental risk assessment and the monitoring plan of Application EFSA-GMO-RX-MON810 (20.1a) including the Annex I which contains the chronological record of the whole evaluation process carried out by the Spanish Competent Authority for Directive 2001/18/EC.

We hope that this Report will be taken into consideration by the EFSA GMO Panel.

Yours sincerely,

María J Rodríguez de Sancho
President of the National Commission on Biosafety

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MINISTERIO
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SECRETARÍA DE ESTADO DE CAMBIO BLIMÁTICO

DIRECCION GENERAL DE CALIDAD Y EVALUACION AMBIENTAL

APPLICATION EFSA-GMO-RX-MON810 (20.1a) CONCERNING THE RENEWAL OF EXISTING PRODUCTS OF REGULATION (EC) No. 1829/2003, REGARDING THE PLACING ON THE MARKET OF GENETICALLY MODIFIED MON810 MAIZE FOR CULTIVATION FROM MONSANTO EUROPE, S.A.

SPANISH BIOSAFETY COMMISSION OPINION ON THE ENVIRONMENTAL RISK ASSESSMENT AND MONITORING PLAN

1. Background

On 22 April 1998 was published the Commission Decision N° 98/294/EC (EC, 1998) regarding the authorisation for the placing on the European market of the genetically modified maize (*Zea mays* L.) MON 810, pursuant to Council Directive 90/220/EEC. The Competent Authority of the lead Member State, France, gave the final consent.

Before the Decision, the European Commission had sought the opinion of the relevant Scientific Committees on this notification, due to the fact that some competent authorities of Member States raised objections to the MON 810 notification (reference C/F/95/12-02) that had been forwarded to the European Commission with a favourable opinion by the lead Competent Authority (France). The Scientific Committee on Plants on 10 February 1998 delivered an opinion, which concluded that there is no reason to believe that the placing on the market of MON 810 maize would have any adverse effects on human or animal health and the environment (SCP, 1998).

MON 810 maize was authorised in the European Union for all intended uses, with the exception of food, by Commission Decision 98/294/EC on 22 April 1998 (EC, 1998) and final consent was granted by the French competent authority on 3 August 1998. Food and food ingredients produced from MON 810 maize was notified according to Article 5 of Regulation (EC) 258/97 (EC, 1997) on 6 February 1998 (EC, 2004).

The current Application is for the renewal of the authorisation for continued marketing of existing MON 810 maize products that were authorized under Directive 90/220/EEC (Decision 98/294/EC) and subsequently notified in accordance to Article 20(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed, and published in the Community Register according to Article 28 of the same regulation.

2. Mandate

On 23 October 2007, in accordance with Articles 6.3 (c) and 18.3 (c) of Regulation (EC) No. 1829/2003, EFSA called for expression of interest to the EU Competent Authorities of the Member States under Directive 2001/18/EEC to carry out the Environmental Risk Assessment (ERA) of application EFSA-GMO-RX-MON810 for the renewal of authorisation of genetically modified MON 810 maize to be used as seeds or other plant-propagating material, submitted under Article

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20.1a. The Spanish Competent Authority (Spanish CA) gave its conformity to perform this task on 14 December 2007.

During the assessment period, Spanish experts of the Biosafety Commission have requested the Monsanto Company to supply additional information regarding some biosafety issues related to this genetically modified plant. The Spanish CA requested additional information twice to the Applicant through EFSA (13 May 2008 and 18 July 2008). On 6 October 2008 the Spanish CA informed EFSA that all additional information requested had been provided and it was considered appropriate.

The Spanish Biosafety Commission has carried out this Environmental Risk Assessment (ERA) of application EFSA-GMO-RX-MON810 taking into consideration the Application, the received additional information by the applicant and the scientific comments made for the EU Member States. Annex I contains the chronological record of this process.

3. Scope of the notification.

The scope of the current renewal application includes the MON 810 maize for food and feed use, the feed containing or consisting of the GM plants, the import and processing of the GM and its cultivation in Europe. MON 810 maize would continue to be planted, traded and used in the European Union in the same manner as it was done prior to the submission of this renewal application, as equivalent products from current commercial maize and by the same operators currently involved in the planting, trade and use of maize.

The food safety aspects are specifically covered in separate applications, which are not under the scope of this Report:

- Application for renewal of the authorisation for continued marketing of existing food additives, feed materials and feed additives produced from MON 810 maize that were notified according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed;
- Application for renewal of the authorisation for continued marketing of existing food and food ingredients produced from MON 810 maize that were notified according to Article 5 of Regulation (EC) No 258/97 and subsequently notified under Articles 8(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed;

The requested duration of the authorisation for the renewal of existing MON 810 maize products that were authorized under Directive 90/220/EEC (Decision 98/294/EC) and subsequently notified in accordance to Article 20(1)(a) of Regulation (EC) No 1829/2003 is 10 years.

4. Description of the product

MON 810 maize expresses the Cry1Ab insecticidal protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which confers protection against predation by certain lepidopteran insect pests, including the European Corn Borer (ECB) (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp).

The transformation plasmids in the DNA solution used to produce MON 810 were PV-ZMBK07 and PV-ZMGT10. MON 810 was generated using the particle acceleration method, by the integration of sequences from the plasmid vector PV-ZMBK07, containing the cry1Ab coding sequence of interest, which was derived from *Bacillus thuringiensis* subsp. *kurstaki*.

For the DNA characterization of the sequences actually inserted and of the flanks in MON 810, molecular analysis was performed (Scanlon et al., 2007). Genomic DNA was digested using restriction enzymes and subjected to Southern blot analyses to determine: the insert number (number of insertions of the integrated DNA within the maize genome), the copy number (the number of copies of the integrated DNA within one locus), the integrity of the inserted elements from plasmid PV-ZMBK07, the absence of elements from plasmid PV-ZMGT10, and the absence of plasmid backbone sequence. Taking into account this analysis the Monsanto Company states that MON 810 contains a single DNA insert containing a single copy of the introduced DNA fragment, and this at a single locus in the maize genome.

The organisation of the elements within the insert in MON 810 was further confirmed using PCR analysis and sequencing of the insert by amplifying two overlapping regions of DNA that span the entire length of the insert (Rigden et al., 2003). The data show that MON 810 contains the e35S promoter, Hsp70 intron, and the cry1Ab coding sequence at a single integration locus. Additional experiments determined specifically that 307 bp of the 3' portion of the e35S promoter are present (314 bp of the original 5' sequence are missing) as well as 2448 bp of the 5' portion of the cry1Ab coding sequence, which is sufficient to encode a polypeptide encompassing the insecticidal active tryptic core. In addition, MON 810 does not contain the T-nos transcriptional termination sequence. No additional genetic elements from the transformation vector PV-ZMBK07 and no genetic elements from plasmid PV-ZMGT10 were detected in the genome of MON 810.

Data supplied on expression level of the introduced protein measured in grain and forage collected from MON 810 grown in the field shows that the level of Cry1Ab in MON 810 plants is similar when plants are grown in different geographies and when the gene is present in different genetic backgrounds (range for grain: 0.19-0.69 Og/g fwt; range for forage: 4.00-5.56 Og/g fwt). The level of expression remains sufficient to provide season long control of the targeted insect pests.

During the risk assessment process the Spanish Competent Authority asked for more detailed data regarding the possibility of deletions or reorganization in the insertion site and on the chromosomal location of the insert. This request was before reasonable raised by Austria which specifically commented that the Southern blot analysis of the insert copy number by means of *Hind*III digested genomic DNA of MON810 hybridising with probes spanning the whole inserted DNA resulted in two fragments instead of the single expected one. Additionally, both fragments seemed to be of higher molecular weight than that indicated by the notifier.

Neither the response from the company to the Spanish CA nor the response to other requests from the EFSA GMO Panel concerning the molecular characterisation fulfils the requirements made by the Spanish CA. In this regard, the Spanish CA considers that, although in view of the recent published literature and in view of the experience on the agronomic use of the event in different varieties used in Spain do not seem to provide new evidence of any risk on health and

environment, however, it considers that further clarifications can be requested by the EFSA GMO Panel to the notifier in order to provide information on the two aspects raised on this topic.

5. ENVIRONMENTAL RISK ASSESSMENT

Comments were made by other Member States regarding the whole dossier. The main comments raised related to potential impacts for the environment were:

1) Interaction between the GM plant and target organisms (baselines susceptibilities, refuges); 2) interaction of the GM plant with non-target organisms; 3) environmental monitoring plan, specially related to potential indirect long term effects on biodiversity; 4) general surveillance of the impact of the GM plant (questionnaires).

The aspects considered by the Spanish Biosafety Commission for the assessment of potential adverse effects of the release into the environment the MON 810 maize are:

5.1. Persistence and invasiveness, selective advantage or disadvantage.
5.2. Potential for gene transfer.
5.3. Genetic and phenotypic stability.
5.4. Interaction between the GM plant and target organisms.
5.5. Potential interaction of the GM plant with non-target organisms.
5.6. Potential impacts of the specific cultivation, management and harvesting techniques.
5.7. Effects on biogeochemical processes.

5.1. Persistence and invasiveness, selective advantage or disadvantage

Maize is highly domesticated and does not behave as an invasive crop because of the characteristics of this species, such as the dormancy and the limited survival of the seed in the soil, and the frost sensitivity of maize seedlings. In any case, if volunteers were to appear in the cultivated area, they are easily controlled with other, non-selective herbicides and by soil cultivation techniques.

During more than 10 years of cultivation of MON 810 maize all over the world there are no evidences of increasing ability to be persistent or invasive in MON 810 when compared to conventional maize. In the unlikely event of the establishment of MON 810 plant in the environment, the introduced trait would confer only a limited selective advantage (protection from lepidopteran pests) of short duration, narrow spatial context and have negligible consequences for the environment. Hence the risk to the environment from MON 810 through increased persistence and invasiveness of this maize is negligible.

The lepidopteran-protection trait provides a selective advantage to MON 810 maize over untreated conventional maize relevant in agricultural habitats and when lepidopteran pest pressure is very high. The likelihood for the introduced trait in MON 810 to confer any meaningful competitive advantage or disadvantage of relevance to the agronomic or natural environment is considered as negligible.

5.2. Potential for gene transfer

Maize (*Zea mays*) does not have sexually compatible wild relatives in Europe and is able to hybridize with wild species of the genera *Tripsacum* or *Zea,* species which are limited in geographical area to Mexico and Guatemala. Therefore the risk of genetic transfer from MON 810 maize is limited to traditional cultivated maize only, depending on wind, flowering synchrony and distance between the crops. In EU conditions, if outcrossing of an introduced trait to sexually compatible plants would occur the introduced lepidopteran protection trait present in MON 810 could be transferred to a recipient maize crop but the selective advantages are considered of negligible risk to the agronomic and natural environment.

Several studies have demonstrated that maize pollen is relatively heavy and that its outcrossing capacity reduces significantly with increasing distance. Furthermore, the probability of genetic exchange depends on factors such as synchrony of pollination, wind direction and intensity, humidity and temperature (OECD, 2003).

The application of coexistence norms established by any of the Member States, derived from '*Commission Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming*', should ensure that the outcrossing between the said crops is reduced to insignificant levels. In any case, if outcrossing were to occur, this would not lead to effects on human health or the environment, but consequences would be limited to economic and commercial repercussions.

5.3. Genetic and phenotypic stability

The Monsanto Company considers that the characterization of this event has demonstrated a single insert derived from plasmid PV-ZMBK07 in the maize genome (Kania *et al.*, 1995; Scanlon *et al.*, 2007). In this sense the studies would show that the inserted cry1Ab gene is stably integrated into the plant chromosome based on segregation data and Southern analysis. The stability of this insertion has been demonstrated through seven generations of crossing and the Southern blot analysis demonstrates that the insertion event has been stable during maize breeding.

In addition, MON 810 does not contain the T-nos transcriptional termination sequence. No additional genetic elements from the transformation vector PV-ZMBK07 and no genetic elements from plasmid PV-ZMGT10 were detected in the genome of MON 810. Additionally, backbone sequence from both PV-ZMBK07 and PV-ZMGT10 was not detected.

Nevertheless, the Spanish CA considers that the questions reasonably rose by the Austrian CA on the possibility of deletions or reorganization in the insertion site and on the chromosomal location of the insert should be answered satisfactorily by the company at the request of EFSA GMO Panel.

5.4. Interaction between the GM plant and target organisms.

The development of resistance in targeted lepidopteran pests (*O. nubilalis* and *Sesamia* spp.) to the insecticidal Cry1Ab protein expressed in MON 810 maize is a potential concern arising from the widespread cultivation of this GM crop. In those countries where MON 810 has been planted, insect resistance management (IRM) plans have been put in place to minimize the risk of insect resistance evolving to Cry1Ab toxin. This has to be performed wherever MON 810 is grown. These IRM plans routinely include setting aside refuges for the production of susceptible target insects, educating farmers as to the importance of IRM, measuring the susceptibility of target insects prior to widespread product use, and putting in place insect resistance monitoring programs.

The resistance monitoring plans conducted in several EU countries, specially in Spain, during the last years of MON 810 grown, and baseline susceptibility of the primary target pest species studies carried out as well, have shown that, up until now, any significant resistance to MON 810 has evolved (González-Núñez *et al.,* 2000; Farinós *et al.*, 2004; Ortego, 2005; Hernández-Crespo, 2007). Consequently, the Spanish CA agrees with the Applicant that Insect Resistance Management (IRM) plans have to be put in place in those countries where MON 810 is planted to diminish to the minimum level the potential development for insect resistance to Cry1Ab toxin.

We also agree with the considerations made by the applicant in relation to the sporadic nature of secondary pest infestations, and the possibility of recording an unexpected level of resistance of these pests towards the Cry1Ab toxin within the frame of general surveillance. However, we also referred to other Lepidoptera different from *O. nubilalis* and *S. nonagrioides*, which could be primary pests in some European areas, such as *Sesamia cretica* in Southern Europe (Fernández *et al,* 2003; Cifuentes & Alcobendas 2006; Lenniaud *et al*, 2006). In fact, the applicant refers to *Sesamia* spp. throughout the Technical Dossier, but in the IRM presented (Appendix 1: "Harmonised Insect Resistance Management (IRM) plan for the cultivation of Bt maize in the E.U.") only *S. nonagrioides* is considered.

After the suggestion made by the Spanish CA, the applicant has categorized as minimal instead of negligible both the likelihood of occurrence of the adverse effect (insect resistance to Cry1Ab) and the estimation of the risk, indicating that "IRM Plan in cultivation countries is needed". Although it is not exactly what the Spanish CA suggested: "minimal when appropriate IRM plans are implemented", we consider acceptable the modification adopted in the Technical Dossier, since it reflects this inherent risk for insect-resistant plants.

5.5. Potential interaction between the GM plant and non-target organisms.

The applicant has included in the Technical Dossier the studies reported to the Spanish National Competent Authority in relation to the commercial planting of maize MON810 in Spain. Moreover, they have incorporated the most recent papers published in peer-reviewed journals, on the assessment of risks to non-target fauna, including Lepidoptera, updating the list of publications of the previous Technical Dossier.

In the answer the applicant cites the EFSA's opinion on the safeguard clause invoked by Hungary on MON810, concluding that no new scientific evidence was presented that would invalidate the previous risk assessments of genetically modified maize MON810. Likewise, it is cited the EFSA opinion on the safeguard clause invoked by Greece on, among other matters, the adverse effect of MON810 maize on honey-bee colonies, concluding that the planting of this maize is unlikely to result in any adverse effects on bees.

Although it is not mentioned in the answer of the applicant, we have also taken into account the safeguard clause invoked by France, -since it has been repeatedly used by the MS in their comments to this application-, as well as the response of Monsanto concerning the appearance of resistance in target insects and the effects on non-target organisms. In general, we agree with the notifier that the list of references used by the French Committee is scarce if we take in consideration all the publications during the last years about the possible adverse effects of the release of the maize expressing the toxin Cry1Ab. In addition, their choice has been biased, since there have been omitted many of the most relevant publications with results indicating a lack of negative effects on different organisms due to the use of transgenic maize.

The applicant has included the list of references about effects of transgenic maize on non-target fauna in the Technical Dossier, as suggested by the Spanish CA, with information about the results and conclusions of the studies. In addition, they have added a table (Table 1) with groups that are exposed to maize in EU areas, and a new column has been inserted in Table 3 indicating the ecological process in which the organism studied is implicated. However, the applicant does not answer our question asking for studies on non-target Lepidoptera in representative EU maize growing regions, and it is significant to notice that they have not included non-target Lepidoptera in Table 1. They state that a monitoring plan for IRM is being developed, but this will not reveal any effect on non-target Lepidoptera, unless the species is a pest, and we consider that GS, which is mainly based on questionnaires, will neither disclose any adverse effect on non-target fauna.

The Spanish CA considers that these aspects have to be considered more deeply in the environmental monitoring plan.

5.6. Effects on biogeochemical processes

MON 810 maize could interact with a spectrum of non-target organisms that are involved in the biogeochemical processes of decomposition and nutrient recycling in the soil (decomposers, detritivores and soil microbial communities in the receiving environment). Decomposers of plant material and organic substances and primary consumers feeding on organic debris (detritivores). Bacterial and fungal populations are critical to maintaining soil health and quality.

Agricultural practices such as fertilization and cultivation techniques usually have effects on soil microbial populations, species composition, colonization, and associated biochemical processes.

Consequently, significant variation in microbial populations is expected in the agricultural environment when MON810 maize is grown.

The Cry1Ab protein present in decaying MON 810 maize materials is not a novel protein in the soil as far as the *cry1Ab* gene expressed by MON 810 maize was derived from the genome of a common soil bacterium *B. thuringiensis* subsp. *kurstaki*.

A number of studies have reported no negative effects of Cry1Ab expressing maize on other soil organisms (discussed in EFSA 2006a). Considering that the toxic mechanism of Cry1Ab protein is specific to larvae of certain lepidopteran insect pests, the potential for activity of this protein towards microorganisms can be consider as negligible.

In addition, regarding the persistence of the Cry1Ab protein in the soil, the cultivation of Bt maize will result in the respective Bt toxins being incorporated into the soil from root exudates, pollen deposits, decomposing roots, stems and leaves after harvest. Some scientific publications indicate that the Bt toxin may persist in soil during cultivation of Bt maize and may accumulate in sequential crops and that this might affect soil organisms while others have shown that it is degrade rapidly in soil, which confirms the absence of adverse effects on soil microorganisms. Considering the available information on potential effects of Bt plants on the soil environment and in particular on soil non-target organisms due to altered decomposition rates, adverse effects are considered as unlikely.

5.7. Potential impacts of the specific cultivation, management and harvesting techniques

No specific cultivation, new or specific crop management or changes in harvesting techniques are required to grow MON 810 maize different to the traditional crop. But it has to be taken in consideration that there is a risk that target insects develop *Cry1Ab* toxin resistance in a medium/long term and for this reason IRM plans have to be established, setting aside refuges for the production of susceptible target insects, educating farmers as to the importance of IRM, measuring the susceptibility of target insects prior to widespread product use, and putting in place insect resistance monitoring programs.

5.8. Potential interactions with the abiotic environment

Like other plants, cultivated maize is known to interact with the abiotic environment (soil, water and air). Maize production in general is known to have indirect impacts on biophysical and biogeochemical processes in the soil through tillage, fertilizer application, and establishment of a monoculture in a defined area. Taking into account that all the agronomic practices currently used to grow maize in the E.U. remain applicable for growing MON 810 maize and no specific techniques for cultivation, management and harvesting are required, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

No negative interactions between the family of Bt proteins and the abiotic environment are known. Furthermore, as discussed before, most of the studies show that the insecticidal protein Cry1Ab is subjected to rapid degradation in soil and there are therefore not expected to negatively affect soil or water. Consequently, the impact on the abiotic environment from the cultivation of MON 810 maize in the E.U is expected not to result as significant.

6. ENVIRONMENTAL MONITORING PLAN

As the scope of this application includes the use of MON 810 for the cultivation of varieties in the European Union (E.U.), a monitoring plan conforming to Annex VII of Directive 2001/18/EC is included, as required by Articles 5(5) and 17(5) of the Regulation (EC) No 1829/2003.

According to Annex VII of Directive 2001/18/EC, the objective of a monitoring plan is:

- To confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment (ERA) are correct, and
- To identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the ERA.

Analysis of the characteristics of MON 810 and comparison to the experience with cultivation of conventional maize within the E.U. has been assessed by the Spanish Biosafety Commission on the risk for potential adverse effects on human and animal health and the receiving environment, resulting from the use of MON 810 maize in the E.U., including the cultivation of MON 810 varieties, and it has been considered negligible relative to direct effects of the GM plant on:

- Persistence and invasiveness
- Selective advantage or disadvantage
- Potential for gene transfer
- Interactions of the GM plant with non-target organisms
- Effects on biogeochemical processes
- Impacts of the specific cultivation, management and harvesting techniques
- Potential interactions with the abiotic environment

Nevertheless, regarding interactions between the GM plant and target lepidopteran pests, the development of resistance of the corn borers *O. nubilalis* and *Sesamia* spp. to the newly introduced protein Cry1Ab expressed in the plant has been identified as a potential risk for the environment. Specifically, long-term effects due to the resistance evolution in targeted lepidopteran pests continue to be a potential concern arising from the widespread cultivation of MON 810. This implies that insect resistance management (IRM) plans have to be put in place in those countries where MON 810 are going to be planted to minimize the risk of insect resistance evolving to Cry1Ab.

6.1. Case-specific GM plant monitoring

As stated in the section 9.4. of the Technical Dossier, the likelihood of development of resistance to Cry1Ab has been categorized as minimal. Therefore, it is proposed that case-specific post-marketing monitoring actions would be required to confirm that this assumption is correct. The applicant proposes to carry out case-specific post marketing monitoring actions in the form of insect resistance monitoring, as described in the Appendix 1: "Harmonised Insect Resistance Management (IRM) plan for the cultivation of Bt maize in the E.U.", developed in 2003. In this case, the Spanish Biosafety Commission agrees with the Applicant, while stressing the refuges enforcement.

6.2. General Surveillance (GS)

GS should be used to identify any unforeseen adverse effect of the GMO or its use that were not predicted in the risk assessment. Therefore, the type of GS will largely depend on the type of unanticipated effect is being surveyed. As an example, in the Council Decision of 3 October 2002 (2002/811/EC) is mentioned that any unanticipated adverse effect on the cultivated ecosystem such as changes in biodiversity, cumulative environmental impacts from multiple releases and interactions may require a different approach to GS of other effects arising from gene transfer. We consider that the GS presented by Monsanto, mainly based on questionnaires to farmers, does not cover all the aspects mentioned in this guidance, especially those related with changes in the biodiversity and effects on non-target fauna, and it should be improved.

In the strategy to carry out the GS of the impact of the GM plant (section 11.4.2. of the Technical Dossier), the applicant affirms that "where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect) linked to the genetic modification, further evaluation of the consequence of that effect should be science-based and compared with baseline information". However, it is not mentioned which baselines will be used and how they will be established, in particular in view of the different agroecosystems and agricultural practices throughout maize growing regions in the EU.

The questionnaire presented by the applicant is deficient in the main issues related to the potential effects on the environment due to the cultivation of MON810 maize. In general, some of the questions use technical terms that are not appropriate to be asked to most farmers. In the question 3.4, both corn borers are separated, but in realistic terms, farmers do not distinguish larvae of these species. The question 3.7., the occurrence of wildlife (mammals, birds and insects) in MON810 fields is based on the general impression of the farmer about it; we think that this question is absolutely insufficient and inadequate to obtain reliable information, and technicians or specialists would be suitable personnel for assessing it.

The rest of tools that the applicant will use are: individuals and organizations normally involved in agriculture, company stewardship programmes, existing networks and data from other sources. However, it is not described how these resources and information will be integrated into the GS. According to the design of the monitoring plan included in the Annex VII of the Directive 2001/18/EC, this should identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and

carried out appropriately. For example, it should be described information if and how existing networks or established monitoring systems collecting ecological or environmental parameter in different MS will be incorporated into the GS plan.

In short, the use of farmer questionnaires as the only method for GS is not considered suitable for the assessment of unexpected environmental effects of maize MON810. We believe that the proper way to cover environmental effects is to include as part of GS the possibility to carry out specific post release actions and studies upon agreement with the National Competent Authorities. We want to stand out that in its response, the notifier mentions the EFSA's opinion on the Post Market Environmental Monitoring (EFSA, 2006b), which encourages applicants to establish contacts with national CAs at an early stage in the commercialisation planning.

6.3. Reporting the results of monitoring

The Spanish Commission on Biosafety agrees with the applicant that monitoring results will be prepared and sent to the National Competent Authorities on an annual basis, except in the case of adverse findings that need immediate risk mitigation, which will be reported as soon as possible.

7. Conclusion

According to the current state of scientific knowledge and after examining the existing information and the data provided by the Monsanto Company, the Spanish Commission on Biosafety could give a favourable opinion to the renewal of commercialisation in the EU of MON 810 maize if the proposals and conditions established in this ERA report are implemented.

Madrid, 27 October 2008

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MINISTERIO
DE MEDIO AMBIENTE, Y
MEDIO RURAL Y MARINO

SECRETARÍA DE ESTADO DE CAMBIO BLIMÁTICO

DIRECCION GENERAL DE CALIDAD Y EVALUACION AMBIENTAL

ANNEX I

Chronological Record for the Environmental Risk Assessment on the Application EFSA/GMO/RX-MON810 (20.1a)

- 23 October 2007: EFSA called for expression of interest to the EU Competent Authorities of the Member States under Directive 2001/18/EEC to carry out the Environmental Risk Assessment (ERA)
- 14 December 2007: The Spanish Competent Authority (Spanish CA) for Directive 2001/18/EC gave its conformity to perform the ERA
- 25 April 2006: Monsanto response to EFSA with additional information
- 29 January 2008: EFSA Valid application
- 9 May 2008: Spanish CA letter sent to EFSA requesting for additional information
- Consultation period for Member States (3 months) till 11 August 2006
- 13 May 2008: EFSA letter to Monsanto: Stop the Clock
- 5 June 2008: Monsanto sent additional information to EFSA and placed on the GMO EFSAnet
- 30 June 2008: Spanish Biosafety Commission experts meeting
- 18 July 2008: Spanish CA letter sent to EFSA requesting for more additional information
- 19 August 2008: EFSA received additional information
- 6 October 2008: Letter from the Spanish CA to EFSA stating that the information is complete and informing that the clock for this application could be re-started
- 19 September 2008: Spanish Biosafety Commission experts meeting
- 7 October 2008: EFSA letter to Monsanto confirming that the Spanish CA has completed its evaluation
- **29 October 2008: Spanish CA sent to EFSA the Environmental Risk Assessment Report Application EFSA-GMO-RX-MON810 (20.1a)**

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