ANALYSIS BY MONSANTO OF THE OPINION ON THE DISSEMINATION OF MON 810 ON THE FRENCH TERRITORY BY THE COMMITTEE OF PREFIGURATION OF A HIGH AUTHORITY ON GENETICALLY MODIFIED ORGANISMS ON JANUARY 09, 2008

30 JANUARY 2008

TABLE OF CONTENTS

A. GENERAL ANALYSIS

GENERAL OVERVIEW

The opinion[1] from the French Committee of the prefiguration of a high authority on genetically modified organisms shows that extensive public research has been performed since first commercialisation of MON 810 maize[2] in 1998. The list of scientific references considered in the Opinion represents only a small fraction of the total number of papers published since 1998 on various subjects including pollen dissemination (six references cited, more than 50 published), potential for the development of resistance in target insects (two references cited, more than 120 published), effects on non-target organisms (14 references cited, more than 130 published) and effects on human health (one reference cited, more than 60 published). All these studies, of which many were performed in Europe, could also have been considered as "new scientific facts" reported since MON 810 was first commercialised. It is important to note that "new scientific data" is not synonymous with "new risks"; in fact, the large amount of research performed on MON 810 has confirmed the initial conclusion of safety for the environment as well as human health and animal health by demonstrating the absence of new risks.

Risk assessment follows a structured approach that considers both hazard (potential for adverse effects) and the likelihood that this hazard will occur (exposure). This is detailed in the guidance document of the European Food Safety Authority (EFSA, 2006b) that discusses strategies for evaluating risks in accordance with European Community legislation. Neither hazard nor exposure taken individually can support a conclusion of unacceptable risk. Risk emerges only when there is significant likelihood that a potential hazard will occur under typical use conditions of a product, and the magnitude of the risk is judged to be unacceptable or unmanageable.

Appropriate use of the structured approach for evaluating potential risks is essential in order to avoid drawing a conclusion of "unacceptable risk" without sufficient evidence. Although the majority of the papers presented in the Opinion include information relevant to risk assessment (hazard or exposure), the information provided does not demonstrate any new unacceptable risks for the environment or human and animal health. Throughout the document, the "new scientific facts" are focused either on hazard or exposure and are not considered jointly as required for risk assessment, even though the joint information was largely documented in the literature.

Since 1998, the safety of MON 810 has been evaluated by European competent authorities and French regulatory authorities (the most recent published opinion is by the Commission of Biomolecular Engineering (CGB)[3] (Commission du Génie Biomoléculaire, 2007)). Furthermore, Monsanto has submitted monitoring reports to the

1 Referred as "Opinion" in the rest of the document

2 Referred as "MON 810" in the rest of the document

3 The « CGB » was, between 1993 and 2007, the French scientific authority in charge of the risk assessment related to the dissemination of GMO into the environment.

Member States competent authorities, including France (the most recent dates from July 31st, 2007). These safety evaluations and monitoring reports were not taken into account in the Opinion although they considered most of the scientific information presented as "new facts" in the Opinion (*i.e.*, the one available at the time of the reports) and support the conclusion of the absence of new risk.

The analysis of the Opinion was complicated as the references were cited with insufficient details and not according to current practice (no mention of journal or volume). Certain citations had the potential to correspond to several publications, to different authors with the same name, or could not be obtained using common literature search tools. In some cases, the name of the first author was spelled incorrectly. When the correct citation corresponding to the subject being discussed could not be identified and another was found to be more plausible, we incorporated it as well to the analysis.

1. THE COMMITTEE UNDERLINES THE PUBLICATION OF SEVERAL NEW SCIENTIFIC FACTS RELATED TO THE IMPACT OF MON 810 ON THE ENVIRONMENT, HUMAN HEALTH, ECONOMY AND AGRONOMY.

a. Dissemination

In August 1998, the French Ministry of Agriculture and Fisheries authorized the placing on the market of MON 810 in accordance with Directive 90/220/EC on the deliberate release of GMOs. This authorization was issued following a thorough review at the French and European levels of Notification C/F/95/12/02 submitted by Monsanto (Monsanto Company, 1995). This notification included a structured environmental risk assessment which concluded that:

1. The Cry1Ab protein expressed in MON 810 does not represent a risk to organisms other than certain Lepidoptera.
2. The dissemination of MON 810 is not different to that of conventional maize. Therefore, the extensive knowledge on dissemination of conventional maize can *de facto* be applied to MON 810.
3. The exposure of organisms to the Cry1Ab protein outside of MON 810 maize fields is low, taking into account the low expression of MON 810 in pollen and the low amount of pollen disseminated.

In fact, the references cited in the Opinion and the synthesis made of them does not support a conclusion that the parameters used for the initial evaluation of MON 810 have changed.

b. Appearance of resistance in target insects

The development of resistance in insects targeted by Cry1Ab would reduce the value of MON 810 for farmers. Consequently, as the developer, Monsanto is highly motivated to take actions to reduce the likelihood of insect resistance.

To sustain the performance of the product, Monsanto has established and implemented a monitoring plan, in place since MON 810 was first commercialised. This plan is composed of two elements: insect resistance management (IRM) and general surveillance. The IRM part includes tools for early detection of resistance in

target pests, strategies to prevent resistance and a description of measures that would be put into place in the event that resistance is detected. The general surveillance plan is an additional tool that allows the appearance of resistance in primary or secondary target pests to be detected. It includes a questionnaire to farmers and a report on the follow up activities on the product once commercialised. None of the two elements of the monitoring plan have shown to date any evidence of the development of resistance.

Importantly, the results of the monitoring plan are in accordance with the conclusions of the Opinion, which confirms the absence of identified resistance in primary target insects. Moreover, the secondary target insects cited in the Opinion are not present in France or in Europe.

c. Effect on non-target organisms

A large number of studies on the potential effects of MON 810 on non-target organisms exists. This comprehensive weight of evidence provides confidence that the Cry1Ab protein, as expressed in MON 810, presents negligible risk to non-target organisms.

It is important to remember that EU regulatory policies oblige notifiers, as well as Member States, to inform the Competent Authorities or the European Commission of any information which becomes available that modifies the risk evaluation (for environment and health) (Directive 2001/18/EC). The extensive scientific literature published since 1998 confirms the safety of MON 810 and support the opinions published by the Scientific Committee on Plants (Scientific Committee on plants, 1998), EFSA (EFSA, 2004; EFSA, 2005b; EFSA, 2006a; EFSA, 2006c) and the CGB (Commission du Génie Biomoléculaire, 1999; Commission du Génie Biomoléculaire, 2007) in which these regulatory authorities conclude to the absence of environmental and health risks linked to MON 810.

The majority of the studies cited in the Opinion examine the exposure of selected organisms to Cry1Ab protein in MON 810; however the study findings do not establish a risk to any of the non-target organisms studied. There is no evidence demonstrating an adverse effect on organisms other than the targeted Lepidoptera. The two Lepidoptera species cited in the Opinion are *Spodoptera*, a target pest in maize (and therefore exposed to the Cry1Ab protein as it feeds on the plant) and larvae of the Monarch butterfly, for which it has been clearly demonstrated that the exposure (to the protein) is limited in geographies where Monarch is present such as the US but is zero in Europe where it is not present. While the Opinion does not refer to any European butterfly, it is useful to note that the risk to butterfly species in Hungary was considered to be insignificant by EFSA (2005b).

The corresponding section of the Opinion concludes with the publication of Marvier *et al.* (2006), who present a global analysis of the potential impact on non-target organisms. This analysis shows that MON 810 has no effect on the abundance of non-target organisms. If there were effects on some invertebrate families (no proof of direct toxicity exists to date), these would be less important than those associated with insecticide treatments. Moreover, this same study was cited by the CGB in its opinion

of June 2007, which confirmed that the existing safety evaluation of MON 810 was still valid (Commission du Génie Biomoléculaire, 2007).

d. Human health

The only effect of MON 810 on human health or the environment described in the Opinion refers to the positive impact on food safety, also noted by AFSSA[4] (2004). The Opinion concludes that MON 810 has lower levels of fumonisin, a possible carcinogen for humans, than maize not expressing the Cry1Ab protein. The maximum allowable levels in food derived from maize are fixed by Regulation EC N° 1126/2007 of the Commission on September 28th, 2007 (Commission of the European Communities, 2007). Depending on the product, the maximum thresholds are between 200 and 4000 ppb. Importantly, the Opinion concludes that the levels of fumonisin in conventional maize grains regularly exceed 2000 ppb in the Midi-Pyrénées and Aquitaine (large agricultural regions of France); consequently, the lower levels of fumonisin in MON 810 can positively impact health.

2. THE COMMITTEE LISTS THE POINTS WHICH HAVE NOT SUFFICIENTLY BEEN TAKEN INTO ACCOUNT OR ARE NEW, AS HAVING TO BE TAKEN INTO ACCOUNT IN THE EVALUATION OF IMPACT OF ALL GMOS.

The procedures to evaluate GMOs are very detailed, both at the level of the EU (EFSA, 2006b) or more international bodies such as Codex[5] or the OECD[6], in which France participates actively.

Whether considering environmental or human and animal health aspects, the CGB and AFSSA (that have build up experience in the field of GMO evaluation over at least 10 years) have issued a number of positive opinions on GMO products, thus recognising the value of existing approaches.

More specifically for MON 810, the CGB and AFSSA confirmed its safety in their opinions on hybrid maize that contain MON 810 and in the answer to a study presented by Greenpeace (AFSSA, 2003a; AFSSA, 2003b; AFSSA, 2003c; AFSSA, 2003d; AFSSA, 2004; AFSSA, 2007a; AFSSA, 2007b; Commission du Génie Biomoléculaire, 2007).

CONCLUSION

Based on i) the Opinion, ii) assessments carried out by regulatory authorities since 1998 iii) the wealth of scientific publications confirming the safety of MON 810 and finally on iv) the monitoring reports provided by Monsanto Europe S.A. to European authorities, the deliberate release of MON 810 on the French territory does not present any risk.

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4 AFSSA (Agence Française de Sécurité Sanitaire des Aliments) is the French scientific authority in charge of genetically modified food and feed evaluation since 1998.

5 http://www.codexalimentarius.net/web/biotech.jsp

6 http://www.oecd.org/biotrack

B. DETAILED SCIENTIFIC ANALYSIS

1. THE COMMITTEE UNDERLINES THE PUBLICATION OF SEVERAL NEW SCIENTIFIC FACTS RELATED TO THE IMPACT OF MON 810 ON THE ENVIRONMENT, HUMAN HEALTH, ECONOMY AND AGRONOMY.

a. Dissemination

> ***"****The new fact since 1998 concerns the characterisation of pollen dispersal (Klein et al., 2003 ; Rosi-Marshall et al., 2007 ; Brunet 2006) (Kuest ; Chapela 2001) over large distances (kilometers) (A. MESSEAN, 2006) linked mainly to climatic conditions and events and to the environment. These results prove the impossibility of zero cross-pollinisation between GM and non-GM fields at local level (small agricultural region) (A. MESSEAN, 2006). The discussion centered on the importance of these results when it comes to the impact on seed purity, "respect" of adventitious presence thresholds and coexistence rules. The dissemination of Bt toxin and its persistence were proven and are dependent on soil, climatic and environmental factors (Icoz et Stostky; 2007)"*

Response

In August 1998, the French Ministry of Agriculture and Fisheries authorized the placing on the market of MON 810 in accordance with Directive 90/220/EC on the deliberate release of GMOs. This authorization was issued following a thorough review at the French and European levels of Notification C/F/95/12/02 submitted by Monsanto (Monsanto Company, 1995). This notification included a structured environmental risk assessment which concluded that:

1. The Cry1Ab protein expressed in MON 810 does not represent a risk to organisms other than certain Lepidoptera.
2. The dissemination of MON 810 is not different to that of conventional maize. Therefore, the extensive knowledge on dissemination of conventional maize can *de facto* be applied to MON 810.
3. The exposure of organisms to the Cry1Ab protein outside of MON 810 maize fields is low, taking into account the low expression of MON 810 in pollen and the low amount of pollen disseminated.

In fact, the references cited in the Opinion and the synthesis made of them does not support a conclusion that the parameters used for the initial evaluation of MON 810 have changed.

Detailed scientific analysis

Note : Kuest ; Chapela (2001) was replaced by Quist and Chapela (2001).

"The new facts since 1998 concerns the characterisation of pollen dispersal over large distances (kilometres) linked mainly to climatic conditions and events and to the environment"

Maize pollen dispersal over large distances (kilometres) linked to climatic conditions and the environment cannot be classified as new facts since 1998.

In the technical report Messéan *et al.* (2006), it is stated that "*However, up to now, it is difficult to quantify the small amount of pollen disseminated to far away points through convective fluxes and its role in long-distance pollination (Emberlin, ibid.; Brunet et al., 2003, Aylor et al.,2003)*."

We refer to the above referenced report from Emberlin *et al.* (1999) on dispersal of maize pollen, which is a review that compiles evidence available from publications and internet sites. All referenced publications in this report are dated prior to 1998 (and some going back as early as 1938).

- The Emberlin *et al*. (1999) compilation has an entire section reviewing potential long range maize pollen dispersal. The report mentions the importance of particular weather conditions and the viability of pollen as a function of time. The conclusion states in summary that : *"Transport on airflow over longer distances is likely to occur under a range of weather situations including uplift and horizontal movement in convection cells, and uplift and transport in frontal storms. As the pollen maize pollen grains remain viable for about 24 hours in normal weather conditions pollination could occur at sites remote from the source (e.g. 180 km)"*.
- Furthermore, the Emberlin *et al*. (1999) study reviews characteristics of maize pollen including morphology, duration of pollen viability, environmental elements impacting the pollen viability duration. The study puts features of pollination in perspective using data from empirical studies, dispersion theory models and particle deposition theory as to give estimation of deposition rates and concentrations of pollen remaining airborne downwind from a source.
- The article mentions already the importance to make a clear distinction between pollen flow and pollen deposition as compared to cross pollination. The importance of a) synchronisation of maturation of the flowers (both male and female parts), b) relative concentration strengths of the pollen produced by the donor plot and the receptor plot at the point of pollination (pollen competition), c) the amount of self or cross sterility in the variety and d) density of the stands were highlighted as importance for cross pollination levels were highlighted.

Recent studies do confirm the importance of flowering synchronization (Mazzoncini *et al.*, 2007; Palaudelmas *et al.*, 2007) as well as the impact of pollen viability and the observation that non viable pollen is falling more slowly and flying longer distances (Foueillassar & Weber, 2007).

Luna V *et al.* (2001) reported maize pollen viability to be maintained for one to two hours after dehiscence depending on atmospheric water potential. The theoretical distance viable pollen could move was calculated to be 32 km. Cross pollination however occurred at a maximum distance of 200 meters from the source. It further stated that "the results are consistent with the conclusions that maize pollen is desiccation intolerant". Similar results were obtained by Stevens *et al.* (2004).

Pollen dispersal does consequently not predict the level of cross-fertilization. The Committee cited pollen dispersal studies over large distances (Brunet, 2006; Klein *et al.*, 2003; Messéan *et al.*, 2006) have a particular focus on maize pollen flow. The first attempts to measure pollen mediated gene flow over large distances confirm the predictable knowledge of very low levels of cross fertilisation under a normal pollen competition regime.

We do not ignore the fact, as was demonstrated during the recently held "Third International Conference on Coexistence between Genetically Modified (GM) and non—GM based Agricultural Supply Chains" (Seville - Spain, 20th and 21st November 2007) that additional studies (Delage *et al.*, 2007; Viner & Arritt, 2007) have been made as to predict pollen dispersal over large distances**.** There is however no evidence of any critical new facts as compared to the period prior to 1998.

"These results prove the impossibility of zero cross-pollination between GM and non-GM fields at local level (small agricultural region) (A. MESSEAN, 2006). The discussion centered on the importance of these results when it comes to the impact on seed purity, "respect" of adventitious presence thresholds and coexistence rules"

The Community rules provide European citizens with freedom of choice by enforcing labeling of food and feed products when containing traces in excess of 0.9% of deregulated biotech events, such as MON 810. The concept of coexistence refers to the freedom of choice for European farmers to select a conventional, organic or biotech based crop production system. The European Commission adopted a guideline (2003/556/EC, 23rd July 2003) which specifies that farmers introducing a new regional production system need to implement farm management measures (including cleaning of equipment, buffer zones, isolation distances and communication between neighboring farmers) allowing a harvested product meeting the above mentioned 0.9 % threshold. There are currently no European established thresholds for adventitious presence in seed. Member States can develop their own legal binding measures which should be scientific based and economical proportional allowing farmers to retain access to all crop production systems. The labeling and traceability has nothing to do with the product safety as the products have been assessed via an operational European biotech regulatory framework for safety prior to deregulation (Directive 2001/18/C; Regulations (EC) No 1829/2003 and No 1830/2003).

Long distance cross pollination resulting from the "small amount of pollen disseminated via convective flux" as cited in the Committee's referred publication from Messéan (2006) confirms the position that seed and grain thresholds for adventitious presence need to be different from zero (zero threshold is not achievable). The biology of the maize reproduction system does not allow an absolute purity and is neither considered a sustainable objective nor respecting the European guidelines related to coexistence as described above. Low level of gene flow has negligible consequences for the purity of seed and grain. Coexistence practices are intended to maintain gene flow at acceptably low levels to enable farmers to realise the environmental and economic benefits of MON 810, while minimizing impacts on neighbouring conventional or organic maize producers.

European Union legislation has established adventitious presence thresholds for food and feed for approved events (such as MON 810) at 0.9% (including organic food and feed) as to allow for impurities resulting from their cultivation. Pollen flow is recognized as one source of impurities, and isolation distances are implemented as one of the tools to ensure coexistence of GM, conventional and organic crops.

Recent reviews studies and individual reports do support the above.

- The review paper from Devos *et al.* (2005) states in conclusion *"Existing data on pollen dispersal in maize demonstrated that the levels of cross-fertilization drops rapidly over the initial meters around the pollen source. Most of the released pollen deposited within 30 m of the source. At distances farther than 30-50 m from the source, pollen dispersal is very low but not zero."*
- General conclusions in the document from Messéan (2006) and referred to by the Committee confirm the above in the "Executive Summary and conclusions" section on page 15.
    - Seed production is technically feasible for a threshold of 0.5% with few or no changes in current practices.
    - If GM presence in seed does not exceed 0.5%, coexistence in crop production is technically feasible for the target threshold of 0.9%. For maize, additional measures are needed for some specific situations defined by climatic, landscape and agronomic parameters. The report evaluates measures found to be technically simple and effective.
- Under the EU funded SIGMEA project a meta-analyses of more than 20 European studies of gene flow in maize (Husken *et al.*, 2007) were analyzed.

  Their conclusion is that the evaluated datasets indicate that a 20-50 m separation distance is enough to maintain the labeling threshold below 0.9%.
- The recent review study from Sanvido *et al.* (2007) makes similar conclusions based upon more than 30 datasets (20 m for silage maize and 50 m for grain maize is proposed).
- Nine years of real life coexistence experience in Spain was concluded to be satisfactory even with the increased adoption of the event MON 810 (Melé *et al.*, 2006; Messeguer *et al.*, 2006; Messeguer *et al.*, 2007; Novillo *et al.*, 2007; Ortega Molina, 2006; Pla *et al.*, 2007).

- Additional recent individual confirmative studies were communicated during the Third International Conference on Coexistence between Genetically Modified (GM) and non—GM based Agricultural Supply Chains" (Seville (Spain), 20th and 21st November 2007): (Ganz *et al.*, 2007; Kraic *et al.*, 2007; Van de Wiel *et al.*, 2007; Vogler *et al.*, 2007).
- The results of the 2007 real life situations in France confirm that coexistence can be achieved using the implementation of the guideline issued by the French Ministry of Agriculture. This guideline recommends 24 border rows using conventional maize of same maturity class as the MON 810 field in case the isolation distance would be inferior to 50 m (Leprince-Benetrix, 2008).

Specific comments to the Committee's referenced article of Rosi-Marshall et al. (2007)

Pollen dissemination from maize fields as reported by Rosi-Marshall *et al*. (2007) mentions that maize pollen moved a maximum average distance of 41 meters, which is within the expected range of pollen dispersal (40 to 60 meters) cited by other researchers (Devos *et al.*, 2005; Husken *et al.*, 2007; Raynor *et al.*, 1972; Sanvido *et al.*, 2007). The fact that pollen can fall within this range (or further) in headwaters and be disseminated as such is not contested. The study focuses on potential effects of MON 810 pollen in headwaters as related to non-target organisms and is appropriately discussed below in the section identified as "Effect on non-target organisms".

The Committee's selection of Quist & Chapela (2001) (referenced as Kuest ; Chapela 2001 by the Committee) is not supported, based on subsequent scientific criticism of the author's methods and conclusions, leading the journal Nature to state that "Nature has concluded that the evidence available is not sufficient to justify the publication of the original paper" (full statement and reference below). More importantly, subsequent research discussed below confirmed that genes from GM maize were not present in native landraces as claimed in the Quist and Chapela (2001) report, further supporting the conclusion that the inclusion of this report by the Committee was not justified.

- The following is the note from the Nature editor (to be found after the Brief Communication from Quist and Chapela in Nature 416, 602 (11 April 2002)[7]

  "In our 29 November issue, we published the paper "Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico" by David Quist and Ignacio Chapela. Subsequently, we received several criticisms of the paper, to which we obtained responses from the authors and consulted referees over the exchanges. In the meantime, the authors agreed to obtain further data, on a timetable agreed with us that might prove beyond reasonable doubt that transgenes have indeed become integrated into the maize genome. The authors have now obtained some additional data, but there is disagreement between them and a referee as to whether these results significantly bolster their argument.

[7] http://www.nature.com/nature/journal/v416/n6881/full/nature740.html

In light of these discussions and the diverse advice received, Nature has concluded that the evidence available is not sufficient to justify the publication of the original paper. As the authors nevertheless wish to stand by the available evidence for their conclusions, we feel it best simply to make these circumstances clear, to publish the criticisms, the authors' response and new data, and to allow our readers to judge the science for themselves."

- The technical information provided in the original publication was analyzed in detail by experts in the field, including the Editorial Board of Transgenic Research magazine, who stated that the report by Quist and Chapela is a "testimony to technical failure and artifacts" resulting from the PCR methods used. The editors noted: "no evidence is presented to justify any of the conclusions presented in the paper." (Christou, 2002).
- Mexican and U.S. scientists confirmed that genes from GM maize are not present in native landraces of maize in Oaxaca, Mexico (Ortiz-Garcia *et al.*, 2005). The researchers screened for genetic elements that are present in all commercialized biotech maize varieties using highly sensitive PCR-based markers, and analyses were conducted by Genetic ID in the US and GeneScan in Germany. No GM maize gene sequences were found in 125 fields and 18 localities in the State of Oaxaca after analyzing 153,746 seeds during 2003 and 2004. According to the authors, "Our results suggest that many concerns about unwanted or unknown effects of this process [transgene introgression] can be discounted at present, at least within the sampled region."
- The gene detection methods used by Quist and Chapela (2001) also were challenged by scientific experts from several universities (Cleveland *et al.*, 2006). According to the experts, the polymerase chain reaction (PCR) method used was flawed and lacked the proper controls, resulting in detections of artifacts and inaccurate data interpretation.

"The dissemination of Bt toxin and its persistence were proven and are dependent on soil, climatic and environmental factors (Icoz et Stostky; 2007)"

The Committee citation of work by Icoz & Stotzky (2007) is not related to MON 810 nor does it provide any negative new findings. These researchers studied the Cry3Bb1 *Bt* protein produced in MON 863 maize, and they conclude that the Cry3Bb1 protein degrades rapidly and does not persist in soil. There were minor differences in the rate of dissipation of the Cry3Bb1 in different soil mixtures or conditions.

Pertinent data regarding dissemination or persistence of the Cry1Ab protein from MON 810 in multiple environments can be found in a publication that included monitoring of many fields located in several maize-growing regions of the USA. The paper shows that after 3 years of consecutive *Bt*-maize field production the Cry1Ab protein is not present and does not persist in any soil, regardless of soil composition, geographic region or climatic environment (Dubelman *et al.*, 2005).

b. Appearance of resistance in target insects

"*No new facts on the main target insects (no shown resistance) but selection of resistant strains for two Lepidopteran secondary pests (Huang et al, 2007; Van Rensburg, 2007)"*

Response

The development of resistance in insects targeted by Cry1Ab would reduce the value of MON 810 for farmers. Consequently, as the developer, Monsanto is highly motivated to take actions to reduce the likelihood of insect resistance.

To sustain the performance of the product, Monsanto has established and implemented a monitoring plan, in place since MON 810 was first commercialised. This plan is composed of two elements: insect resistance management (IRM) and general surveillance. The IRM part includes tools for early detection of resistance in target pests, strategies to prevent resistance and a description of measures that would be put into place in the event that resistance is detected. The general surveillance plan is an additional tool that allows the appearance of resistance in primary or secondary target pests to be detected. It includes a questionnaire to farmers and a report on the follow up activities on the product once commercialised. None of the two elements of the monitoring plan have shown to date any evidence of the development of resistance.

Importantly, the results of the monitoring plan are in accordance with the conclusions of the Opinion, which confirms the absence of identified resistance in primary target insects. Moreover, the secondary target insects cited in the Opinion are not present in France or in Europe.

Detailed scientific analysis

Independent of the cultivation of MON 810, Cry1Ab-resistant alleles/insects are expected to exist in any natural population and are not evidence of field-level or population-level resistance. The two studies cited by the Committee are reports of finding small numbers of resistant alleles or insects in pest populations (as would be expected) - not of finding resistant populations. Huang *et al.* (2007) reports finding Cry1Ab-resistant alleles (insects) in a population of sugarcane borer. van Rensburg (2007) shows that the small number of African stem borers (*Busseola*) that survive on *Bt* maize tend to be more tolerant to Cry1Ab than insects from areas where *Bt* maize is not used. In both cases, these resistant insects remain rare in the overall population and *Bt* maize remains highly effective (Huang *et al.*, 2006).

Field resistance to any insecticidal product - leading to product failure - requires high frequencies (more than 30%) of resistant insects in a population. Under natural conditions, alleles for resistance are expected to occur at very low frequencies (less than 1 in 100, and usually less than 1 in 1000).

For the specific pests of interest in France (European corn borer (ECB - *Ostrinia nubilalis*) and *Sesamia*), resistance monitoring studies indicate that alleles for Cry1Ab resistance appear to be very rare indeed (probably much less than 1 in 1000). For

example, Bourguet *et al.* (2003) estimated that the frequency of Cry1Ab resistance alleles in ECB populations in the northern US to be less than 0.000423. In another study, Stodola *et al.* (2006) estimated the same frequency in the southern US to be between 0 and 0.0044.

However, the presence of resistant alleles in pest populations is why insect resistance management (IRM) plans are necessary for all *Bt* maize products, wherever they are grown - to keep resistant allele frequencies so low that product performance is not affected such IRM strategies have been implemented in France and other countries where MON 810 is grown. These IRM plans involve the use of strategies like refuge areas and very high insecticidal protein concentrations to manage resistance (Roush, 1994). The proactive implementation of these IRM plans is unique to *Bt* crops and does not occur for conventional insecticidal products.

After more than a decade of use and very high levels of adoption, there are still no confirmed cases of field resistance arising to Cry1Ab-expressing *Bt* maize, indicating that the IRM strategies in place are effective (Tabashnik *et al.*, 2003).

c. Effect on non-target organisms

"New facts confirm possible toxicological adverse effects on earthworms (Zwahlen et al. 2003), isopods, nematods and the monarch butterfly (Rhopalocera) (Harwood et al. 2005; Prasifka et al. 2007; Dutton et al, 2005). The exposure of natural Monarch populations remains very limited (less than 1%), in particular via harmful behavioural effects (Marvier et al., 2007). Publications show the presence of possible Bt toxins in the trophic chain (Obrist et al, 2006) as well as a persistence of the insecticides in water (Douville et al, 2006 ; Rosi-Marshall et al, 2007) or in sediments drained from fields (more than 20 to 40 days) (Icoz, Stotsky, 2007), in contact with roots and soil (Saxena et Stotzky, 2005; Mulder et al. 2006; Castaldini et al, 2005) with an exposure of insect populations (Griffith et al., 2006; Johnson et al, 2006) higher up in the trophic chain. A global analysis of the non target entomofauna (Marvier et al 2007) shows an effect of Bt maize on certain invertebrate families, effects which are however less important than those caused by insecticides. Finally the study by Marvier et al showed no direct toxic effects"

Response

A large number of studies on the potential effects of MON 810 on non-target organisms exists. This comprehensive weight of evidence provides confidence that the Cry1Ab protein, as expressed in MON 810, presents negligible risk to non-target organisms.

It is important to remember that EU regulatory policies oblige notifiers, as well as Member States, to inform the Competent Authorities or the European Commission of any information which becomes available that modifies the risk evaluation (for environment and health) (Directive 2001/18/EC). The extensive scientific literature published since 1998 confirms the safety of MON 810 and support the opinions published by the Scientific Committee on Plants (Scientific Committee on plants, 1998), EFSA (EFSA, 2004; EFSA, 2005b; EFSA, 2006a; EFSA, 2006c) and the CGB

(Commission du Génie Biomoléculaire, 1999; Commission du Génie Biomoléculaire, 2007) in which these regulatory authorities conclude to the absence of environmental and health risks linked to MON 810.

The majority of the studies cited in the Opinion examine the exposure of selected organisms to Cry1Ab protein in MON 810; however the study findings do not establish a risk to any of the non-target organisms studied. There is no evidence demonstrating an adverse effect on organisms other than the targeted Lepidoptera. The two Lepidoptera species cited in the Opinion are *Spodoptera*, a target pest in maize (and therefore exposed to the Cry1Ab protein as it feeds on the plant) and larvae of the Monarch butterfly, for which it has been clearly demonstrated that the exposure (to the protein) is limited in geographies where Monarch is present such as the US but is zero in Europe where it is not present. While the Opinion does not refer to any European butterfly, it is useful to note that the risk to butterfly species in Hungary was considered to be insignificant by EFSA (2005b).

The corresponding section of the Opinion concludes with the publication of Marvier *et al.* (2006), who present a global analysis of the potential impact on non-target organisms. This analysis shows that MON 810 has no effect on the abundance of non-target organisms. If there were effects on some invertebrate families (no proof of direct toxicity exists to date), these would be less important than those associated with insecticide treatments. Moreover, this same study was cited by the CGB in its opinion of June 2007, which confirmed that the existing safety evaluation of MON 810 was still valid (Commission du Génie Biomoléculaire, 2007).

Detailed scientific analysis

Effects of Bt maize and Cry1Ab on NTOs have been widely studied since the mid 1990s. The risk assessment examing the potential for adverse effects of MON 810 and Cry1Ab on NTOs concluded that there is negligible risk based on acute toxicological studies (see Section « Environmental assessment » (US EPA, 2001a)).

Many independent studies conducted globally have confirmed the conclusions of the risk assessment since MON 810 was first commercialized. The publications mentioned by the Committee and evaluated below do not provide any new evidence to change the earlier conclusion that MON 810 presents a negligible risk to non target organisms.

"New facts confirm possible toxicological adverse effects on earthworms (Zwahlen et al. 2003), isopods, nematodes and the monarch butterfly (Rhopalocera) (Harwood et al. 2005; Prasifka et al. 2007; Dutton et al, 2005)"

Zwahlen *et al.* (2003) investigated the effects on the mortality and weight of immature and adult earthworms (*Lubricus terrestris*) in the laboratory and field exposed up to 200 days to *Bt* maize litter (Bt11). No significant effects on adults and immature earthworms were observed on mortality or in relative weight; however, only for adults, a weight loss of 18% was observed between days 180 and 200. The significance of this weight loss in terms of reproduction or population dynamics is not addressed in the paper. Nevertheless, one could speculate that the weight loss could

fall within the natural variation for earthworms if other varieties (transgenic and non-transgenic) were added to the experimental design. For example, Clark & Coats (2006) examined the sub-acute effects on adult earthworms (*Esenia fetida*) of 4 *Bt* varieties (two Bt11 and two MON 810) compared to their isolines. Clark and Coats (2006) found variable results: a significant increase in weight was observed for earthworms in two varieties (Bt11 after 90 days exposure and MON 810 after 108 days exposure), while no differences were observed in the other two comparisons (Bt11 after 108 days exposure and MON 810 after 90 days exposure). Clark and Coats (2006) concluded that there is little direct hazard from *Bt* maize leaf material to earthworms and that differences in the nutritional parameters of the *Bt* lines and isolines may lead to differences in effects on NTOs.

The OECD (2007) have reviewed the research studies prior to 2006 and concluded, "Considering all available studies the predominant weight of evidence gives no indication for harmful effects of *Bt* maize on earthworms." Field studies have been performed and are referenced in the risk section of the OECD report, since they incorporate both hazard (effects) and exposure (*see* paragraphs 72 and 111). In addition, this study has been cited in the opinion of the EFSA GMO panel (EFSA, 2005a) that concluded to the safety of Bt11[8] for human and animal health, and the environment as well as in the opinions of the same group of experts which concluded to the absence of new elements likely to change the evaluation of MON 810 (EFSA, 2004; EFSA, 2005b) following its review of the safeguard clauses invoked by Austria and Hungary.

Harwood *et al.*, (2005) shows that non-target herbivores and higher order arthropod predators ingest Cry1Ab in the field when feeding on *Bt* maize (Bt11), however they do not make any claims concerning adverse effects. In this study, the researchers showed exposure of Cry1Ab to non target organisms but they did not demonstrate any hazard. In another study by the same author (Harwood & Obrycki, 2006) (not referenced by the Committee) the researchers also show that Cry1Ab is ingested by isopods (slugs), however, no claims on toxicity (hazard was not assessed) are mentioned in the paper.

Both of these studies illustrate that the demonstration of exposure is not sufficient to establish risk.

Other papers have been published showing movement of Cry1Ab through the trophic system with no risk to prey and predators due to lack of hazard to these NTOs from the Cry1Ab toxin. For example, Obrist *et al.* (2006c) demonstrated that spider mites fed on *Bt* maize (MON 810) contained large amounts of biologically active Cry1Ab; however, no effects from *Bt* maize were observed on mortality, developmental time, preoviposition time or fecundity of predatory mites fed on spider mites containing Cry1Ab (Obrist *et al.*, 2006c). Also, Dutton *et al.* (2002) showed no effects from *Bt* maize on predatory lacewings fed on spider mites containing high levels of Cry1Ab.

[8] Bt11 expresses Cry1Ab

Prasifka *et al.* (2007) examines the response of Monarch butterfly larvae to *Bt* maize (MON 810) anther tissues. The presence of Cry1Ab maize anthers on milkweed plants represents a very minor exposure to Monarch butterfly larvae and presents a low level of risk in the field. The authors point out earlier studies also established when exposure is considered that the effect on monarch populations is negligible.. Dively and co-workers (2004), concluded "When considered over the entire range of the Corn Belt, which represents only 50% of the (monarch) breeding population, the risk to monarch butterfly larvae associated with long-term exposure to *Bt* maize pollen is 0.6% additional mortality."

The OECD (2007, paragraph 109) concluded that "cultivation of *Bt* maize expressing Cry1Ab poses no great risk to the Monarch butterfly, because only a minor part of the whole population would be exposed to pollen shedding maize fields in the United States." In this addition, this point, also including an European butterfly, was reviewed in the opinions of the EFSA GMO panel which concluded to the absence of new elements likely to change the evaluation of MON 810, following its review of the safeguard clauses invoked by Austria and Hungary (EFSA, 2004; EFSA, 2005b).

Dutton *et al.* (2005) examined the effects of *Bt* maize (Bt11) and *Bt* spray (Dipel) on mortality and developmental time of the Lepidoptera *Spodoptera littoralis*. No further analysis involving NTOs were described in the publication. Activity of the Cry1Ab protein on this species is expected since Cry1Ab is known to be active against certain Lepidoptera. *As opposed* to *what the Opinion mentioned, this article does not refer to Monarch butterflies.*

None of the references (Harwood et al., 2005; Harwood and Obrycki, 2006; Prasifka et al., 2007; Dutton et al., 2005) mentioned nematodes.

"The exposure of natural Monarch populations remains very limited (less than 1%), in particular via harmful behavioural effects (Marvier et al., 2007)"

Marvier *et al.* (2007) conducted a meta-analysis of effects of *Bt* cotton (expressing Cry1Ac) and *Bt* maize (expressing Cry1Ab and Cry3Bb) on NTOs, taking into consideration results from 42 field studies. The results of the meta-analysis showed that MON 810 had no effect on the abundance of NTOs.

The article does not specifically mention Monarchs or behavioural effects.

This study has been cited in support of the CGB opinion (Commission du Génie Biomoléculaire, 2007) that concludes that the evaluation of MON 810 should not be questioned.

"Publications show the presence of possible Bt toxins in the trophic chain (Obrist et al, 2006) as well as a persistence of the insecticides in water (Douville et al, 2006 ; Rosi-Marshall et al, 2007) or in sediments drained from fields (more than 20 to 40 days) (Icoz, Stotsky, 2007), in contact with roots and soil (Saxena et Stotzky, 2005; Mulder et al. 2006; Castaldini et al, 2005) with an exposure of insect populations (Griffith et al., 2006; Johnson et al, 2006) higher up in the trophic chain. A global analysis of the non target entomofauna (Marvier et al 2007) shows an effect of Bt maize on certain invertebrate families, effects which are however less important than those caused by insecticides. Finally the study by Marvier et al showed no direct toxic effects"

Obrist *et al.* (2006a) described a series of laboratory and field experiments conducted with the aim of measuring and understanding exposure of predators to the Cry1Ab protein (from event Bt176). The authors studied the exposure component of risk, but not the hazard component, and therefore do not make any conclusions on risk of *Bt* maize to the species studied. The authors conclude that exposure of predators to Cry1Ab will depend on the feeding ecology of the insect. They studied the exposure to Cry1Ab of different species of prey and predators before, during and after pollen shed. The authors findings showed: *Orius* are exposed to Cry1Ab only during pollination (most likely from feeding on pollen) and this exposure is minor; *Mirids* are exposed before and during pollination since they are considered omnivorous feeding on plant tissue and prey; *Nabis* and the carabid beetle *Demetrias atricapillus* are negligibly exposed to Cry1Ab through the season; Chrysopids, a well-studied species in terms of hazard and exposure in the laboratory but lacking Cry1Ab exposure examination in the field until Obrist *et al.* (2006a) revealed negligible toxin levels before, and during pollen shed, but relatively high toxin levels after pollen shed, coinciding with the presence of predatory mites. None of the species and groups of arthropods studied in these experiments has been shown to be affected by Cry1Ab (de la Poza *et al.*, 2005; Gonzalez-Zamora *et al.*, 2007; Romeis *et al.*, 2004).

A second publication of Obrist and co-workers (Obrist *et al.*, 2006b) reported the investigation on the uptake of Cry1Ab toxin by larvae of the green lacewing after consuming two *Bt* maize-fed herbivores. This study, addressing only the exposure element of the risk, confirms that even if the toxin remains biologically active when ingested by herbivore species, *Chrysoperla carnea* is not susceptible to Cry1Ab (Dutton *et al.*, 2002).

Douville *et al.* (2007 (available online Feb 2006)) examined the persistence of DNA in water and sediments and found that DNA could be detected for up to 21 and 40 days respectively. DNA from *Bacillus thuringiensis* in not new to water streams. For many years *B. thuringiensis* variety *kurstaki* (which expresses Cry1Ab) has been used in organic agriculture and residual sprays are expected in water streams. *B. thuringiensis* variety *israelensis* is directly sprayed on water streams and lakes in many countries, including the US and Canada, for the control of black flies and mosquitoes. A recent EU-funded project (ECIBCO) concluded that *Bt* spray applications in bodies of water are a safe and effective control method for these pests in the EU (ECIBCO, 2007). The unlikelihood of DNA causing adverse effects is acknowledged by the EPA (US EPA, 2001b) which states: "Nucleic acids are

ubiquitous in all forms of life, have always been present in human and domestic animal food and are not known to cause any adverse health effects when consumed as part of food. EPA believes there is a reasonable certainty that no harm will result from aggregate exposure to residues of nucleic acids that are part of a plant-incorporated protectant." Importantly, a recent exhaustive review of literature investigating the impact of GMO crops on ecosystems, as well as human and animal health makes no mention of any adverse effects of DNA (OECD, 2007).

Rosi-Marshall *et al* (2007) examined the input of *Bt* maize by-products in agricultural streams and its potential effects on caddisflies. The presence of *Bt* in water streams should not be a concern (*see* above, commentary for Douville *et al.*, 2006). Regarding the safety of *Bt* plants to caddisflies, the authors analyzed the growth rate and mortality of two species of caddisflies, *Lepidostoma liba* and *Helicopsyche borealis*, exposed to an unspecified *Bt* maize variety(ies) (the event(s) was not specified and therefore the Cry1Ab expression was unknown) and one non-*Bt* maize variety (not the near-isoline of the transgenic variety used). The authors found no effects on mortality of either caddisfly species and only moderate effects on growth on *L. liba.* These effects could have been a result of nutritional or anti-nutritional differences related to the different genetic backgrounds of the two varieties used and not an effect of genetic transformation or expression of Cry1Ab. Other investigators have shown that MON 810 does not pose a risk to caddisflies (in part because Cry proteins degrade rapidly in aquatic environments) and that effects seen on some other aquatic invertebrates are likely due to the hybrid background of the test material and not to Cry proteins (Jensen *et al.*, 2007). Rosi-Marshall *et al.* (2007) argues that the varieties were selected for their similarity related to C/N to standardize nutritional value of the detritus; however, there are many other compounds that could have been essential for the growth of the caddisflies that were not considered when selecting the maize variety to test.

This paper has been reviewed by EFSA (Plenary Meeting of the Scientific Panel on Genetically modified Organisms held on 22-23 November 2007 in Brussels, Belgium (EFSA, 2007a; EFSA, 2007b) which concluded “In summary, the conclusions of the paper Rosi-Marshall *et al.* (2007) are not supported by the data presented in this paper. The GMO Panel is of the opinion that based on the available information such a low level of exposure to *Trichoptera* in aquatic ecosystems is unlikely to cause a toxic effect”. Other scientists have also commented this paper (Beachy, 2008; Parrott, 2008).

Icoz & Stotzky (2007) studied the Cry3Bb1 *Bt* protein produced in MON 863 maize, and they conclude that the Cry3Bb1 protein degrades rapidly and does not persist in soil. Their data showed that the Cry3Bb1 protein was released into soil via root exudation and through decay of plant biomass, but dissipated in less than 21 days under all tested conditions. This paper seams to be irrelevant to the environmental risk assessment of MON 810 since the *Bt* maize considered in the study does not contain Cry1Ab.

In the press release cited in reference, Saxena & Stotzky (2005) do not show any new information. They reviewed data showing that the exudation of Cry1Ab protein is a common phenomenon with other Cry proteins in maize, rice and potato demonstrating that exposure to the Cry proteins in soil is possible, however, exposure alone is not predictive of risk since hazard also needs to be determined (*see* comments for Harwood *et al.*, 2005 and Obrist *et al.*, 2006a). However, that exudation was not detected in canola, cotton and tobacco. These researchers previously demonstrated that the Cry1Ab protein released from root exudates or from biomass of MON 810 *Bt* maize had no apparent effects on earthworms, nematodes, protozoa, bacteria and fungi in soil (Saxena & Stotzky, 2001). They also showed that the Cry1Ab protein was not taken up from soil by subsequent plantings of radish, carrot, turnip and non-*Bt* maize, and did not move far vertically in soil (Saxena & Stotzky, 2002). The exposure of non-target organisms to *Bt* proteins or any toxin is not evidence of risk. A more recent review on effects of *Bt* maize and Cry1Ab on soil organisms and soil processes concluded, "because most studies have generally indicated few or no significant detrimental effects on microbes and other organisms in below-ground soil ecosystems, more studies on the risks associated with *Bt* plants, at least those currently available, to these organisms are probably not indicated" (Icoz & Stotzky, 2008).

Mulder *et al.* (2006) examined the effect of maize straw (*Bt* maize events MON 810 and Bt176, and their respective near-isolines) on respiration and catabolic activities of bacteria communities. The results showed a short term increase in CO_2 production lasting between 1-3 days in soil amended with transgenic or conventional maize tissue. By the 4th day of incubation there did not seem to be any difference in CO_2 production between the various treatments. The variability in CO_2 production between soils would be expected due to differences in chemical and physical factors and would also be influenced by the amendment of the soil by the maize varieties. This is supported by the authors' observations on germplasm differences in sugar content between *Bt* maize and their isolines. Also, the authors found no significant difference in the number of Colony Forming Units (CFU) between the transgenic or conventional tissue treatments. Mulder *et al.* (2006) conclude that "the possibly adaptive radiation of bulk soil bacteria in our microcosms shortly after the addition of *Bt*-maize straw was much more easily detectable in the laboratory than in the field". Other research shows that the microbial communities in soil are more likely to be affected by factors other than the transgene or Cry1Ab protein in the soil such us plant characteristics (cultivar), soil type, plant growth stage, season (Fang *et al.*, 2005; Griffiths *et al.*, 2005; Icoz *et al.*, 2007).

Mulder *et al.* (2006) did not address the presence or persistence of *Bt* protein in field soil. As stated above in the Saxena and Stotzky 2005 news release, a more recent review on effects of *Bt* maize and Cry1Ab on soil organisms and soil processes concluded,"because most studies have generally indicated few or no significant detrimental effects on microbes and other organisms in below-ground soil ecosystems, more studies on the risks associated with *Bt* plants, at least those currently available, to these organisms are probably not indicated"(Icoz & Stotzky, 2008).

Castaldini *et al.* (2005) conducted microscom and green house experiments to assess the effects of two *Bt* maize events (Bt11 and Bt176) and only one near-isogenic line on soil eubacterial and fungal communities, as well as on soil respiration. The authors demonstrated differences in microbial communities and respiration among the three maize treatments. However, the limited experimental design which was aimed at developing the methodology does not allow the evaluation of inherent biological variability and therefore can not assess whether the observed differences are greater than those naturally occurring within any maize agricultural ecosystem. In support, Han *et al.* (2007) demonstrated considerable variation of soil respiration rates occurring within a conventional maize ecosystem where both biotic and abiotic factors play a significant role. Also important, as mentioned above in the comments to Mulder *et al.* (2006), changes in the microbial communities may be related to differences in genetic background. Finally, a recent review of effects of *Bt* maize and Cry proteins on soil organisms and soil processes concluded, "because most studies have generally indicated few or no significant detrimental effects on microbes and other organisms in below-ground soil ecosystems, more studies on the risks associated with *Bt* plants, at least those currently available, to these organisms are probably not indicated" (Icoz and Stotsky, 2008).

Griffiths *et al.* (2006) examined the effects of *Bt* maize (MON 810) and an insecticide on soil microbial and faunal community. The results support and reinforce previous safety assessments of *Bt* maize. The author's conclude, "the results indicate that, although there were statistically significant effects of the *Bt* trait on soil populations, they were small. The *Bt* trait had no greater effect than the insecticide treatment. Results from this glasshouse experiment were in broad agreement with conclusions from field experiments using the same plant material grown in the same soils." *The paper does not address exposure to insect populations since nematodes do not belong to the phylum Arthropoda.*

Johnson et al. (2007 (available online Dec 2006)) discusses risk assessment and does not provide any specific new data on the exposure of non-target insects to Bt proteins.

Also relevant and of major importance, there are recent reviews (Ferry *et al.*, 2006; LFL, 2005; Romeis *et al.*, 2006) and many publications describing research on NTOs conducted in the field and laboratory in Europe which provide a weight of evidence argument further confirming the negligible risk conclusion of the risk assessment conducted for *Bt* maize expressing the Cry1Ab protein (*e.g.* MON 810) (Arpas *et al.*, 2005; Babendreier *et al.*, 2004; Babendreier *et al.*, 2005; Babendreier *et al.*, 2007; Bakonyi *et al.*, 2006; Candolfi *et al.*, 2004; Dutton *et al.*, 2002; Dutton *et al.*, 2003; Eckert *et al.*, 2006; Eizaguirre *et al.*, 2006; Escher *et al.*, 2000; Farinos *et al.*, available online 2007; Felke *et al.*, 2002; Gonzalez-Zamora *et al.*, 2007; Heckmann *et al.*, 2006; Kramarz *et al.*, 2007; Ludy & Lang, 2006; Lumbierres *et al.*, 2004; Meissle & Lang, 2005; Meissle *et al.*, 2005; Obrist *et al.*, 2005; Obrist *et al.*, 2006a; Obrist *et al.*, 2006b; Obrist *et al.*, 2006c; Pons & Stary, 2003; Pons *et al.*, 2004; Pons *et al.*, 2005; Pont & Nentwig, 2005; Raps *et al.*, 2001; Rodrigo-Simon *et al.*, 2006; Romeis *et al.*, 2004; Sanders *et al.*, 2007; Toth *et al.*, 2004; Tounou *et al.*, 2005; Turlings *et al.*, 2005; Vercesi *et al.*, 2006; Vojtech *et al.*, 2005; Wandeler *et al.*, 2002; Weber &

Nentwig, 2006; Zwahlen *et al.*, 2000; Zwahlen *et al.*, 2003; Zwahlen & Andow, 2005).

Icoz & Stotzky (2008) reviewed the fate and effects of insect-resistant *Bt* crops in soil ecosystems and showed that the weight of evidence indicates that neither *Bt* maize nor Cry1Ab have a detrimental effect on earthworms (6 references included Zwahlen *et al.*, 2003); collembola or mites (9 references including Griffith *et al.* 2006); nematodes (8 references including Griffith *et al.* 2006); and other organisms (*see* Table 1 in publication); diversity of microbes (13 references); microbe-mediated processes and functions in the soil (19 references); and that there is low persistence and no accumulation of Cry1Ab in soil (10 references). The review demonstrates that the observable effects on microbes are transient and are a consequence of indirect effects from plant characteristics (cultivar), soil type, season, and environmental factors. The authors conclude that effects on soil and micro-organisms research efforts should shift from *Bt* crops to other transgenic crops such as those designed to express pharmaceutical and industrial products.

The impact of *Bt* toxins on the soil has been reviewed in the opinion of the EFSA GMO panel (EFSA, 2005a) that concluded to the safety of Bt11 for human and animal health, and the environment.

d. Human health

"New facts have shown the impact of Bt maize on mycotoxin levels, which can be reduced by 90% to 95% (AFSSA ; 2004) compared to untreated conventional hybrids. Insecticide treatment does not lead to similar decreases. The levels of fumonisins (classified as possibly carcinogenic for humans, 2B group CIRC), in conventional hybrids regularly exceed 2000 ppb depending on insect attacks in the regions of Midi-Pyrénées and Acquitaine"

Response

The only effect of MON 810 on human health or the environment described in the Opinion refers to the positive impact on food safety, also noted by AFSSA[9] (2004). The Opinion concludes that MON 810 has lower levels of fumonisin, a possible carcinogen for humans, than maize not expressing the Cry1Ab protein. The maximum allowable levels in food derived from maize are fixed by Regulation EC N° 1126/2007 of the Commission on September 28th, 2007 (Commission of the European Communities, 2007). Depending on the product, the maximum thresholds are between 200 and 4000 ppb. Importantly, the Opinion concludes that the levels of fumonisin in conventional maize grains regularly exceed 2000 ppb in the Midi-Pyrénées and Aquitaine (large agricultural regions of France); consequently, the lower levels of fumonisin in MON 810 can positively impact health.

[9] AFSSA (Agence Française de Sécurité Sanitaire des Aliments) is the French scientific authority in charge of genetically modified food and feed evaluation since 1998.

Detailed scientific analysis

There is indeed a substantial database supporting reduced levels of mycotoxins in MON 810 (Bakan *et al.*, 2002; Clements *et al.*, 2003; Crowley, 2007; de la Campa *et al.*, 2005; Dowd, 2000; Dowd, 2001; Hammond *et al.*, 2002a; Hammond *et al.*, 2004; Hammond *et al.*, 2006a; Magg *et al.*, 2002; Munkvold *et al.*, 1999; Munkvold, 2003; Papst *et al.*, 2005; Pietri & Piva, 2000; Schaafsma *et al.*, 2002; Wu, 2006).

MON 810 reduces insect feeding damage that lowers the potential for entry and infection of maize by mycotoxigenic fungi. MON 810 has been shown to consistently have reduced fumonisin levels in the grain of *Bt* varieties grown in France, Germany, Italy, Argentina, United States, and Turkey, where field trials have been carried out. The lowering of fumonisin mycotoxin levels in grain from MON 810 can have beneficial impacts on human and animal health.

2. THE COMMITTEE LISTS THE POINTS WHICH HAVE NOT SUFFICIENTLY BEEN TAKEN INTO ACCOUNT OR ARE NEW, AS HAVING TO BE TAKEN INTO ACCOUNT IN THE EVALUATION OF IMPACT OF ALL GMOS.

The procedures to evaluate GMOs are very detailed, both at the level of the EU (EFSA, 2006b) or more international bodies such as Codex or the OECD, in which France participates actively.

Whether considering environmental or human and animal health aspects, the CGB and AFSSA (that have build up experience in the field of GMO evaluation over at least 10 years) have issued a number of positive opinions on GMO products, thus recognising the value of existing approaches.

More specifically for MON 810, the CGB and AFSSA confirmed its safety in their opinions on hybrid maize that contain MON 810 and in the answer to a study presented by Greenpeace (AFSSA, 2003a; AFSSA, 2003b; AFSSA, 2003c; AFSSA, 2003d; AFSSA, 2004; AFSSA, 2007a; AFSSA, 2007b; Commission du Génie Biomoléculaire, 2007).

a. Toxicological elements

"No new facts other than the toxic impact as described above, but a large majority of members underlined the insufficiency of the 90-day rat study, which has insufficient power. Indeed, the methodology used (validated by the OECD) on rats does not allow to conclude on the absence or presence of significant differences between the test group and the comparator, and on the biological interpretation of the observed differences (Lavielle, 2007). It is necessary to rethink the protocol. The committee considers it necessary to perform long-term studies, on material with appropriate genetic backgrounds, on other varieties and especially on larger samples. The committee underlines the absence of evaluation of endocrine, teratogenics and transgenerational effects"

The safety of MON 810 is established on the basis of extensive compositional analyses and comparative agronomic and phenotypic assessments. These analyses demonstrate that MON 810 is substantially equivalent to conventional maize, except for the introduced lepidopteran-protection trait, which is conferred by the expression of the Cry1Ab protein.

The human and animal safety of the Cry1Ab protein is demonstrated by a) history of safe use, b) lack of homology to known protein toxins and allergens, c) lack of evidence of any acute toxicity in oral gavage studies in rodents, and d) its rapid digestion in simulated gastric and intestinal fluids. The safety of MON 810 and of the Cry1Ab protein is further confirmed by animal feeding studies in the rat and in broiler chickens (Hammond *et al.*, 2002b; Hammond *et al.*, 2006b) using MON 810 containing diets. These studies confirmed the absence of any toxic effects associated with the introduced protein and the absence of any unanticipated or pleiotropic effects linked to the genetic modification.

In particular, the design of 90-day rat feeding study has been derived from the OECD guideline for the testing of chemicals (408 – Repeated dose 90-day oral toxicity study in rodents) (OECD, 1998). Its results were reviewed by EFSA that concluded that *"The results of 90-day sub-chronic rodent studies do not indicate adverse effects from consumption of maize line MON 810, and therefore there are no resultant concerns over its safety."*

Furthermore, in a recently issued draft report, EFSA concluded that "9*0-day rodent feeding studies, when adequately controlled both in terms of nutritional balance and traditional reference plants/whole foods, form a sensitive comparative platform with which toxicologically significant differences as well as nutritional deficiencies/ improvements can be detected between the whole GM plant derived food/feed and the comparator"*. (Draft report for public consultation: Safety and Nutritional Assessment of GM Plant derived Foods/Feed, September12, 2007).

It should also be underlined that in ten years of commercialization, there have been no verified incidents of adverse health or environmental effects linked to the cultivation or use of MON 810.

The Lavielle (2007) reference is an internal advice to the French Ministry of Agriculture and Fishery that discusses the pertinence of the MON 810 90 day rat study but does not point out to any new risk associated with MON 810.

EFSA reviewed the 90-day subchronic rodent study in the context of several MON 810 containing stacks and concluded that "*it does not indicate adverse effects from consumption of MON810 maize and therefore confirm that there are no resultant concerns over its safety*". In addition EFSA mentioned that "*For MON810 maize, there are well-performed toxicological studies with the relevant species of animals and a statistically well-designed approach*" (EFSA, 2005c).

AFSSA, the French competent authority in food/feed safety created in 1999, also reviewed this study in the context of MON 810 containing stacks (*e.g.* LY038 x MON 810 (AFSSA, 2007b)) and concluded that none of the observed parameters are significantly different between the control rats and the rats fed with MON 810.

b. Biological and microbial effects

"The biological and microbiological effects resulting from the dissemination or the persistence of Bt molecules or of the transgene in soil (for over 200 days) are to be examined (Crecchio, Stotzky, 2001)"

The paper by Crecchio *et al.* (2005) reports the adsorption and binding of *Bt* toxins to an organomineral complex as well as the insecticidal activity of the bound toxin and its resistance to degradation. It was found that there was strong binding of the *Bt* toxin to the organomineral complex and that the bound toxin seemed unavailable for degradation by microorganisms and also remained toxic to insect larvae. A later paper (Dubelman *et al.*, 2005) tested the persistence and accumulation of *Bt* toxins in a variety of soil types under field conditions. This study showed that Cry1Ab protein present in maize tissue does not persist or accumulate in soil.

A more recent review on effects of *Bt* maize and Cry1Ab on soil organisms and soil processes by the same research group concluded, "because most studies have generally indicated few or no significant detrimental effects on microbes and other organisms in below-ground soil ecosystems, more studies on the risks associated with *Bt* plants, at least those currently available, to these organisms are probably not indicated" (Icoz & Stotzky, 2008). In addition, the effect of Cry1Ab on microbial populations was not identified as a risk in the opinion of the EFSA GMO panel related to the placing on the market of *Bt*11 (EFSA, 2005a).

CONCLUSION

Based on i) the Opinion, ii) assessments carried out by regulatory authorities since 1998 iii) the wealth of scientific publications confirming the safety of MON 810 and finally on iv) the monitoring reports provided by Monsanto Europe S.A. to European authorities, the deliberate release of MON 810 on the French territory does not present any risk.

REFERENCES

AFSSA. (2003a) Examen des compléments d'information en réponse aux objections des Etats membres relatives à un dossier d'autorisation de mise sur le marché d'un maïs grain génétiquement modifié lignée MON 863 et d'un maïs hybride MON 863 x MON 810 résistants aux insectes en vue de l'importation, la transformation et l'utilisation comme tout autre maïs, à l'exclusion de la culture, sur le territoire de l'Union européenne, au titre de la directive 2001/18/CE, *http://www.afssa.fr/Documents/BIOT2003sa0324.pdf*

AFSSA. (2003b) Avis sur les compléments d'information en réponse aux objections des Etats membres concernant la mise sur le marché de grains et produits dérivés de grains de maïs de la lignée MON 863 et du maïs hybride MON 863 x MON 810 résistants aux insectes au titre du règlement (CE) 258/97 relatif aux nouveaux aliments et aux nouveaux ingrédients alimentaires, *http://www.afssa.fr/Documents/BIOT2003sa0325.pdf*

AFSSA. (2003c) Avis relatif à un dossier d'autorisation de mise sur le marché d'un maïs grain génétiquement modifié lignée MON 863 et d'un maïs hybride MON 863 x MON 810 résistants aux insectes, en vue de l'importation, la transformation et l'utilisation comme tout autre maïs, à l'exclusion de la culture, sur le territoire de l'Union européenne, au titre de la directive 2001/18/CE, *http://www.afssa.fr/Documents/BIOT2003sa0179.pdf*

AFSSA. (2003d) Avis relatif à une demande d'avis sur le rapport d'évaluation initiale établi par les autorités allemandes concernant la mise sur le marché d'un maïs grain génétiquement modifié lignée MON 863 et d'un maïs hybride MON 863 x MON 810 résistants aux insectes au titre du règlement (CE) 258/97 relatif aux nouveaux aliments et aux nouveaux ingrédients alimentaires, *http://www.afssa.fr/Documents/BIOT2003sa0215.pdf*

AFSSA. (2004) Avis relatif à un dossier d'autorisation de mise sur le marché d'un maïs hybride NK 603 x MON 810 résultant du croisement conventionnel des lignées parentales issues de deux maïs portant l'un l'évènement de transformation NK 603, l'autre l'évènement de transformation MON 810 en vue de son importation et de son utilisation, à l'exclusion de la culture, au titre de la directive 2001/18/CE, *http://www.afssa.fr/Documents/BIOT2004sa0154.pdf*

AFSSA. (2007a) Avis relatif à un dossier d'autorisation de mise sur le marché d'un maïs génétiquement modifié MON 88017 x MON 810 tolérant à un herbicide et résistant à des insectes, pour l'importation et l'utilisation en alimentation humaine et animale de grains et de ses produits dérivés, au titre du règlement (CE) n° 1829/2003, *http://www.afssa.fr/Documents/BIOT2007sa0079.pdf*

AFSSA. (2007b) Avis relatif à un dossier d'autorisation de mise sur le marché d'un maïs génétiquement modifié LY038 x MON 810 résistant à des insectes et dont la teneur en lysine a été modifiée pour l'importation et l'utilisation en alimentation humaine et animale de grains et produits dérivés, au titre du règlement (CE) n° 1829/2003, *http://www.afssa.fr/Documents/BIOT2007sa0073.pdf*

Arpas, K., Toth, F. and Kiss, J. (2005) Foliage-dwelling Arthropods in *Bt*-transgenic and Isogenic Maize: A comparison through spider web analysis, *Acta Phytopathologica et Entmologica Hungarica*, **40**, 347-353.

Babendreier, D., Kalberer, N., Romeis, J., Fluri, P. and Bigler, F. (2004) Pollen consumption in honey bee larvae: a step forward in the risk assessment of transgenic plants, *Apidologie*, **35**, 293-300.

Babendreier, D., Kalberer, N. M., Romeis, J., Fluri, P., Mulligan, E. and Bigler, F. (2005) Influence of Bt-transgenic pollen, Bt-toxin and protease inhibitor (SBTI) ingestion on development of the hypopharyngeal glands in honeybees, *Apidologie*, **36**, 585-594.

Babendreier, D., Joller, D., Romeis, J., Bigler, F. and Widmer, F. (2007) Bacterial community structures in honeybee intestines and their response to two insecticidal proteins,

Bakan, B., Mecion, D., Richard-Molard, D. and Cahagnier, B. (2002) Fungal growth and *Fusarium* Mycotoxin content in isogenic traditional maize and genetically modified maize grown in France and Spain, *J. Agric. Food Chem.*, **50**, 728-731.

Bakonyi, G., Szira, F., Kiss, I. and Nagy, P. (2006) The effects of Bt-toxin producing corn on springtails (Collembola), *http://www.mkk.size.hu/dep/zoo/eng/research.htm*

Beachy, R. (2008) The burden of proff: A response to Rosi-Marshall *et al*. In., Vol. 2008, p. Letter.

Bourguet, D., Chaufaux, J., Seguin, M., Buisson, C., Hinton, J. L., Stodola, T. J., Porter, P., Cronholm, G., Buschmann, L. L. and Andow, D. A. (2003) Frequency of alleles conferring resistance to Bt maize in French and US corn belt populations of the european corn borer, *Ostrinia nubilalis*, *Theor Appl Genet*, **106**, 1225-1233.

Brunet, Y. (2006) On maize pollen transport in the atmospheric boundary layer. In *27^th Conference on Agricultural and Forest Meteorology, 17^th Symposium on Boundary Layers and Turbulence, 17^th Conference on Biometeorology and Aerobiology*. San Diego, California, USA

Candolfi, M. P., Brown, K., Grimm, C., Reber, B. and Schmidli, H. (2004) A faunistic approach to assess potential side-effects of genetically modified *Bt*-corn on non-target arthropods under field conditions, *Biocontrol Science and Technology*, **14**, 129-170.

Castaldini, M., Turrini, A., Sbrana, C., Benedetti, A., Marchionni, M., Mocali, S., Fabiani, A., Landi, S., Santomassimo, F., Pietrageli, B., Nuti, M. P., Miclaus, N. and Giovannetti, M. (2005) Impact of *Bt* Corn on Rhizospheric and Soil Eubacterial Communities and on Beneficial Mycorrhizal Symbiosis in Experimental Microcosms, *Applied and Environmental Microbiology*, **71**, 6719-6729.

Christou, P. (2002) No Credible Scientific Evidence is Presented to Support Claims that Transgenic DNA was Introgressed into Traditional Maize Landraces in Oaxaca, Mexico, *Transgenic Research*, **11**, 3-5.

Clark, B. W. and Coats, J. R. (2006) Subacute effects of Cry1Ab corn litter on the earthworm *Eisenia fetida* and the springtail *Folsomia candida*, *Environ. Entomol.*, **35**, 1121-1129.

Clements, M. J., Campbell, K. W., Maragos, C. M., Pilcher, C., Headrick, J. M., Pataky, J. K. and White, D. G. (2003) Influence of Cry1Ab protein and hybrid genotype on fumonisin contamination and fusarium ear rot of corn, *Crop Sci.*, **43**, 1283-1293.

Cleveland, D., Soleri, D., Cuevas, F., Crossa, J. and Gepts, P. (2006) Detecting (trans)gene flow to landraces in centers of crop origin: lessons from the case of maize in Mexico, *Environ. Biosafety Res*, **4**, 197-208.

Commission du Génie Biomoléculaire. (1999) Avis relatif à l'effet du pollen de maïs résistant aux insectes sur le monarque, *http://www.ogm.gouv.fr/experimentations/evaluation_scientifique/cgb/autres_avis/avis_220699.pdf*, 1-4.

Commission du Génie Biomoléculaire. (2007) Avis sur un rapport de Greenpeace relatif à la teneur en protéine Bt du mais MON 810, *http://www.ogm.gouv.fr/experimentations/evaluation_scientifique/cgb/autres_avis/MON_810.pdf*, 1-4.

Commission of the European Communities. (2007) Commission Regulation (EC) No 1126/2007 of 28 September 2007 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards *Fusarium* toxins in maize and maize products (Text with EEA relevance), *Official Journal of the European Union L 255*, 14-17.

Crecchio, C., Ruggiero, P., Curci, M., Colombo, C., Palumbo, G. and Stotzky, G. (2005) Binding of DNA from *Bacillus subtilis* on montmorillonite-humanic acid-aluminium or iron hydroxypolymers: effects on transformation and protection against DNase, *Soil sci. Soc. Am. J.*, **69**, 834-841.

Crowley, L. (2007) Row erupts in Italy over GM study results. In *Food Navigator*. Vol., pp. http://www.foodnavigator.com/news/ng.asp?n=81414-inran-gm-crops-fumonisins-monsanto.

de la Campa, R., Hooker, D. C., Miller, J. D., Schaafsma, A. W. and Hammond, B. G. (2005) Modeling effects of environment, insect damage, and *Bt* genotypes on fumonisin accumulation in maize in Argentina and the Philippines, *Mycopathologia*, **159**, 539-552.

de la Poza, M., Pons, X., Farinos, G. P., Lopez, C., Ortego, F., Eizaguirre, M., Castanera, P. and Albajes, R. (2005) Impact of farm-scale Bt maize on abundance of predatory arthropods in Spain, *Crop Protection*, **24**, 677-684.

Delage, S., Brunet, Y., Dupont, S., Tulet, P., Pinty, J.-P., Lac, C. and Escobar, J. (2007) Atmospheric dispersal of maize pollen over the Aquitaine region. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*. Seville (Spain)

Devos, Y., Reheul, D. and De Schrijver, A. (2005) The co-existence between transgenic and non-transgenic maize in the European Union: a focus on pollen flow and cross fertilization, *Environ. Biosatety Res.*, **4**, 71-87.

Dively, G. P., Rose, R., Sears, M. K., Richard, L., Hellmich, R. L., Stanley-Horn, D. E., Calvin, D. D., Russo, J. M. and Anderson, P. L. (2004) Effects on monarch butterfly lavae (Lepidoptera: Danaidae) after continuous exposure to Cry1Ab-expressing corn during anthesis, *Environ. Entomol.*, **33**, 1116-1125.

Douville, M., Gagne, F., Blaise, C. and Andre, C. (2007 (available online Feb 2006)) Occurrence and persistence of *Bacillus thuringiensis* (*Bt*) and transgenic *Bt* corn C*ry1Ab* gene from an aquatic environment, *Ecotoxicology and Environmental Safety*, **66**, 195-203.

Dowd, P. F. (2000) Indirect reduction of ear molds and associated mycotoxins in *Bacillus thuringiensis* corn under controlled and open field conditions: utility and limitations, *Journal of Economic Entomology*, **93**, 1669-1679.

Dowd, P. F. (2001) Biotic and abiotic factors limiting efficacy of Bt corn in indirectly reducing mycotoxin levels in commercial fields, *J. Econ. Entomol.*, **94**, 1067-1074.

Dubelman, S., Ayden, B. R., Bader, B. M., Brown, C. R., Jiang, C. and Vlachos, D. (2005) Cry1Ab Protein does not persist in soil after 3 years of sustained *Bt* Corn use, *Environm. Entomol.*, **34**, 915-921.

Dutton, A., Klein, H., Romeis, J. and Bigler, F. (2002) Uptake of *Bt*-toxin by herbivores on transgenic maize and consequences for the predator *Chrysoperla carnea*, *Ecol. Entomol.*, **27**, 441-447.

Dutton, A., Klein, H., Romeis, J. and Bigler, F. (2003) Prey-mediated effects of *Bacillus thuringiensis* spray on the predator *Crysoperla carnea* in maize, *Biological Control*, **26**, 209-215.

Dutton, A., Romeis, J. and Bigler, F. (2005) Effects of *Bt* maize expressing Cry1Ab and *Bt* spray on Spodoptera littoralis, *Entomologia Experimentalis et Applicata*, **114**, 161-169.

ECIBCO. (2007) European Consortium for Integrated Biological Control as an environmental solution to the problems caused by mosquitoes of public health and economic importance. Public health, environmental and economic considerations, *http://www.emca.asso.fr/activities/CETWEB/ECIBCO4.html*

Eckert, J., Schuphan, I., Hothorn, L. A. and Gathmann, A. (2006) Arthropods on maize ears for detecting impacts of *Bt* maize on non target organisms, *Environmental Entomology*, **35**, 554-560.

EFSA. (2004) Opinion of the Scientific Panel on genetically modified organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC (Question N° EFSA-Q-2004-062), *The EFSA Journal*, **78**, 1-13.

EFSA. (2005a) Opinion of the Scientific Panel on genetically modified organisms related to the notification for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing, *Question EFSA-Q-2004-012*, **213**, 1-33.

EFSA. (2005b) Opinion of the scientific panel on genetically modified organisms on a request from the Commission related to the safeguard clause invoked by Hungary according to Article 23 of Directive 2001/18/EC, *The EFSA Journal*, **228**, 1-14.

EFSA. (2005c) Opinion of the scientific panel on genetically modified organisms on an application (reference EFSA-GMO-UK-2004-01) for the placing on the market of glyphosate-tolerant and insect resistant genetically modified maize NK603 x MON 810, for food and feed uses under Regulation (EC) No 1829/2003 from Monsanto, *The EFSA Journal*, **Question No EFSA-Q-2004-086**, 1-22.

EFSA. (2006a) Opinion of the Scientific Panel on genetically modified organisms on a request from the Commission related to the safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC, *The EFSA Journal*, **411**, 1-26.

EFSA. (2006b) Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed, *The EFSA Journal*, **99**, 1-100.

EFSA. (2006c) Opinion of the Scientific Panel on genetically modified organisms related to genetically modified crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses invoked according to Article 16 of Directive 90/220/EEC *The EFSA Journal*, **338**, 1-15.

EFSA. (2007a) 38th plenary meeting of the scientific panel on genetically modified organisms(draft agenda), *http://www.efsa.europa.eu/EFSA/Event_Meeting/GMO_Agenda_38thplenmeet.pdf*

EFSA. (2007b) Minutes of the 37th plenary meeting of the scientific panel on genetically modified organisms held on 22-23 November 2007 in Brussels, Belgium (adopted on 18 December 2007), *http://www.efsa.europa.eu/EFSA/Event_Meeting/GMO_Minutes_37th_plenmeet,3.pdf*

Eizaguirre, M., Albajes, R., Lopez, C., Eras, J., Lumbierres, B. and Pons, X. (2006) Six years after the commercial introduction of Bt maize in Spain: field evaluation, impact and future prospects, *Transgenic Research*, **15**, 1-12.

Emberlin, J., Adams-Groom, B. and Tidmarsh, J. (1999) A Report on the Dispersal of Maize Pollen Soil Association, pp. 1-22.

Escher, N., Käch, B. and Nentwig, W. (2000) Decomposition of transgenic *Bacillus thuringiensis* maize by microorganisms and woodlice *Porcellio scaber* (Crustacea: Isopoda), *Basic and Applied Ecology*, **1**, 161-169.

Fang, M., Kremer, R. J., Motavalli, P. P. and Davis, G. (2005) Bacterial diversity in rhizospheres of nontransgenic and transgenic corn, *Applied and environmental microbiology*, **71**, 4132-4136.

Farinos, G. P., de la Poza, M., Hernandez-Crespo, P., Ortego, F. and Castanera, P. (available online 2007) Diversity and seasonal phenology of aboveground arthropods in conventional and transgenic maize crops in Central Spain, *Biological Control*, **In Press, Corrected Proof**

Felke, M., Lorenz, N. and Langenbruch, G.-A. (2002) Laboratory studies on the effects of pollen from Bt-maize on larvae of some butterfly species, *J. Appl. Ent.*, **126**, 320-325.

Ferry, N., Edwards, M. G., Gatehouse, J., Capell, T., Christou, P. and Gatehouse, A. M. R. (2006) Transgenic plants for insect pest control: a forward looking scientific perspective, *Transgenic Research*, **15**, 13-19.

Foueillassar, X. and Weber, M. (2007) Maize pollen viability: an important factor to consider in coexistence studies. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 255-256. Seville (Spain)

Ganz, C., Struzyna-Schulze, C., Eder, J., Holtz, F., Schmidt, K. and Broer, I. (2007) "Erprobungsanbau 2005": Different crops as spacers to minimize cross fertilization between GM and non-GM maize on field scale level. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 267-268. Seville (Spain)

Gonzalez-Zamora, J. E., Camunez, S. and Avilla, C. (2007) Effects of Bacillus thuringiensis Cry Toxins on Developmental and Reproductive Characteristics of the Predator Orius albidipennis (Hemiptera: Anthocoridae) Under Laboratory Conditions, *Environ. Entomology*, **36**, 1246-1253.

Griffiths, B., Caul, S., Thompson, J., Birch, A., Scrimgeour, C., Andersen, M., Cortet, J., Messean, A., Sausse, C., Lacroix, B. and Krogh, P. (2005) A comparison of soil microbial community structure, protozoa and nematodes in field plots of conventional and genetically modified maize expressing the *Bacillus thuringiensis* Cry1Ab toxin, *Plant and Soil*, **275**, 135-146.

Griffiths, B. S., Caul, S., Thompson, J., Birch, A. N., Scrimgeour, C., Cortet, J., Foggo, A., Hacket, C. A. and Krogh, P. H. (2006) Soil microbial and faunal community responses to *Bt* maize and insecticide in two soils, *J. Environ. Qual.*, **35**, 734-741.

Hammond, B. G., Campbell, K., Degooyer, T., Robinson, A., Richard, J., Segueira, J., Rubinstein, C., Cea, J., Plancke, M., Pinson, L., Radu, C., Esin, H., Tatli, F. and Grogna, R. (2002a) Reduction of fumonisin levels in grain from YieldGard corn borer, *Proceedings of the 2nd Fungal Genomics, 3rd Fumonisin Elimination and 15th Aflatoxin Elimination Workshops*

Hammond, B. G., Stanisiewski, E., Fuchs, R., Astwood, J. and Hartnell, G. (2002b) Safety assessment of insect protected crops: testing the feeding value of Bt corn and cotton varieties in poultry, swine and cattle, *Molecular Methods in Plant Analysis*, **22**, 119-137.

Hammond, B. G., Campbell, K. W. and Pilcher, C. D. (2004) Lower fumonisin mycotoxin levels in the grain of Bt corn grown in the United States in 2000-2002, *J. Aric. Food Chem.*, **52**, 1390-1397.

Hammond, B. G., Campbell, K., Cea, J., Esin, H., Pietri, A., Piva, G., Pierre, T., Richard, J., Rubinstein, C., Sequeira, J. and Ttali, F. (2006a) The use of GMOs as a prevention strategy for mycotoxin formation. In: *The Mycotoxin factbook*. Wageningen Academic Publishers, pp. 199-210.

Hammond, B. G., Dudek, R., Lemen, J. K. and Nemeth, M. A. (2006b) Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn, *Food and Chemical Toxicology*, **44**, 1092-1099.

Han, G., Zhou, G., Xu, Z., Yang, Y., Liu, J. and Shi, K. (2007) Biotic and abiotic factors controlling the spatial and temporal variation of soil respiration in an agricultural ecosystem, *Soil Biology and Biochemistry*, **39**, 418-425.

Harwood, J. D., Wallin, W. G. and Obrycki, J. J. (2005) Uptake of *Bt* endotoxins by nontarget herbivores and higher order arthropod predators: molecular evidence from a transgenic corn agroecosystem, *Molecular Ecology*, **14**, 2815-2823.

Harwood, J. D. and Obrycki, J. J. (2006) The detection and decay of Cry1Ab Bt-endotoxins within non-target slugs, *Deroceras reticulatum* (Mollusca: Pulmonata), following consumption of transgenic corn, *Biocontrol Science and Technology*, **16**, 77-88.

Heckmann, L. H., Griffiths, B. S., Caul, S., Thomson, J., Pusztai-Carey, M., Moar, W. J., Andersen, M. N. and Krogh, P. H. (2006) Consequences for *Protaphorura armata* (Collembola: Onychiuridae) following exposure to genetically modified *Bacillus thuringiensis (Bt)* maize and non-Bt maize, *Environmental Pollution*, **142**, 212-216.

Huang, F., Leonard, R. B. and Gable, R. H. (2006) Comparative susceptibility of European Corn Borer, Southwestern Corn Borer, and sugarcane Borer (Lepidoptera: Cambiadae) to Cry1Ab protein in a commercial *Bacillus thuringiensis* corn hybrid, *J. Econ. Entomol.*, **99**, 194-202.

Huang, F., Leonard, B. R. and Wu, X. (2007) Resistance of sugarcane borer to Bacillus thuringiensis Cry1Ab toxin, *Entomologia Experimentalis et Applicata*, **124**, 117-123.

Husken, A., Ammann, K., Messeguer, J., Papa, R., Robson, P., Schiemann, J., Squire, G., Stamp, P., Sweet, J. and Wilhelm, R. (2007) A major European synthesis of data on pollen and seed mediated gene flow in maize in the SIGMEA project. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 53-56. Seville (Spain)

Icoz, I., Saxena, D., Andow, D. A., Zwahlen, C. and Stotzky, G. (2007) Microbial Populations and Enzyme Activities in Soil in situ under Transgenic Corn Expressing Cry Proteins from Bacillus thuringiensis. In 2006.ppt, I. e. a. (ed.) *Powerpoint*. The ASA-CSSA-SSSA International Annual Meetings

Icoz, I. and Stotzky, G. (2007) Cry3Bb1 protein from *Bacillus thuringiensis* in root exudates and biomass of transgenic corn does not persist in soil, *Transgenic Research*, 1-12.

Icoz, I. and Stotzky, G. (2008) Fate and effects of insect-resistant *Bt* crops in soil ecosystems, *Soil Biology and Biochemistry*, **40**, 559-586.

Jensen, P. D., Lamp, W. O., Dively, G. P. and Swan, C. M. (2007) A risk assessment of Bt corn tissue on non-target arthropods in agricultural streams. In *National Meeting of the Entomological Society of America*. San Diego, CA, USA

Johnson, K. L., Raybould, A. F., Hudson, M. D. and Poppy, G. M. (2007 (available online Dec 2006)) How does scientific risk assessment of GM crops fit within the wider risk analysis?, *Trends in Plant Science*, **12**, 1-5.

Klein, E. K., Lavigne, C., Foueillassar, X., Gouyon, P.-H. and Laredo, C. (2003) Corn pollen dispersal: Quasi-mechanistic models and field experiments, *Ecological Monographs*, **73**, 131-150.

Kraic, J., Mihaleic, P., Singer, M. and Plackova, A. (2007) Coexistence of genetically modified and conventional maize: practical experience on-farm in Slovakia. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 251-252. Seville (Spain)

Kramarz, P. E., De Vaufleury, A. and Carey, M. (2007) Studying the effect of exposure of the snail Helix aspersa to the purified Bt toxin, Cry1Ab, *Applied Soil Ecology*, **37**, 169-172.

Lavielle, M. (2007) Remarques sur les analyses statistiques effectuées au sujet du maïs MON 810. 1-2, Unpublished Work.

Leprince-Benetrix, F. (2008) Les premiers résultats de l'observatoire 2007 de la coexistence. In. Yvoir.fre, Vol. 2008

LFL, L. f. L. (2005) Monitoring of the environmental effects of the bt gene, 1-111.

Ludy, C. and Lang, A. (2006) Bt maize pollen exposure and impact on the garden spider, *Araneus diadematus*, *Entomologia Experimentalis et Applicata*, **118**, 145-156.

Lumbierres, B., Albajes, R. and Pons, X. (2004) Transgenic Bt maize and *Rhopalosiphum padi* (Hom., Aphididae) performance, *Ecological Entomology*, **29**, 309-317.

Luna V, S., Figueroa M, J., Baltazar M, B., Gomez L, R., Townsend, R. and Schoper, J. B. (2001) Maize Pollen Longevity and Distance Isolation Requirements for Effective Pollen Control, *Crop Sci*, **41**, 1551-1557.

Magg, T., Melchinger, A. E., Klein, D. and Bohn, M. (2002) Relationship between European corn borer resistance and concentration of mycotoxins produced by *Fusarium* spp. in grains of transgenic Bt maize hybrids, their isogenic counterparts, and commercial varieties, *Plant Breeding*, **121**, 146-154.

Marvier, M., McCreedy, C., Regetz, J. and Kareiva, P. (2007) A meta-analysis of effects of *Bt* cotton and maize on nontarget invertebrates, *Science*, **316**, 1475-1477.

Mazzoncini, M., Balducci, E., Gorelli, S., Russ, R. and Brunori, G. (2007) Coexistence scenarios between GM and GM-free corn in Tuscany region (Italy). In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 295-296. Seville (Spain)

Meissle, M. and Lang, A. (2005) Comparing methods to evaluate the effects of *Bt* maize and insecticide on spider assemblages, *Agriculture, Ecosystems and Environment*, **107**, 359-370.

Meissle, M., Vojtech, E. and Poppy, G. M. (2005) Effects of Bt maize-fed prey on the generalist predator *Poecilus cupreus* L. (Coleoptera: Carabidae), *Transgenic Research*, **14**, 123-132.

Melé, E., Messeguer, J., Palaudelmas, M., Penas, G., Salvia, J. and Serra, J. (2006) Coexistència entre blat de moro Bt i convencional. In *Varietats de Panís*. Barcelona, Spain, Vol., pp. 19-23.

Messéan, A., Angevin, F., Gómez-Barbero, M., Menrad, K. and Rodríguez-Cerezo, E. (2006) New case studies on the coexistence of GM and non-GM crops in European agriculture. JRC, pp. 1-116.

Messeguer, J., Penas, G., Ballester, J., Bas, M., Serra, J., Salvia, J., Palaudelmas, M. and Melé, E. (2006) Pollen-mediated gene flow in maize in real situations of coexistence, *Plant Biotechnology Journal*, **4**, 633-645.

Messeguer, J., Palaudelmas, M., Penas, G., Serra, J., Salva, J., Ballester, J., Bas, M., Pla, M., Nadal, A. and Melé, E. (2007) Three year study of a real situation of coexistence in maize. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 93-96. Seville (Spain)

Monsanto Company. (1995) Submission to the French Commission du Génie Biomoléculaire. Application to place on the market genetically modified higher plants: insect-protected maize (MON810), *Monsanto report*

Mulder, C., Wouterse, M., Raubuch, M., Roelofs, W. and Rutgers, M. (2006) Can Transgenic Maize Affect Soil Microbial Communities?, *PLoS Computational Biology*, **2**, 1165-1172.

Munkvold, G. P., Hellmich, R. L. and Rice, L. G. (1999) Comparison of fumonisin concentrations in kernels of transgenic Bt maize hybrids and non-transgenic hybrids, *Plant disease*, **83**, 130-138.

Munkvold, G. P. (2003) Cultural and genetic approaches to managing mycotoxins in maize, *Annu. Rev. Phytopathol.*, **41**, 99-116.

Novillo, C., Ojembarrena, A., Tribo, F., Alcalde, E., Biosca, D., Aragon, M. and Costa, J. (2007) Nine years of consumer-driven coexistence for GM crops in Spain. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 31-34. Seville (Spain)

Obrist, L. B., Klein, H., Dutton, A. and Bigler, F. (2005) Effects of Bt maize on *Frankliniella tenuicornis* and exposure of thrips predators to prey-mediated Bt toxin, *Entomologia Experimentalis et Applicata*, **115**, 409-416.

Obrist, L. B., Dutton, A., Albajes, R. and Bigler, F. (2006a) Exposure of arthropod predators to Cry1Ab toxin in *Bt* maize fields, *Ecological Entomology*, **31**, 143-154.

Obrist, L. B., Dutton, A., Romeis, J. and Bigler, F. (2006b) Biological activity of Cry1Ab toxin expressed by *Bt* maize following ingestion by herbivorous arthropods and exposure of the predator *Chrysoperla carnea*, *BioControl*, **51**, 31-48.

Obrist, L. B., Klein, H. and Dutton, A. (2006c) Assessing the effects of Bt maize on the predatory mite *Neoseiulus cucumeris*, *Experimental and applied acarology*, **38**, 125-139.

OECD. (1998) OECD guideline for the testing of chemicals. Repeated dose 90-day oral toxicity study in rodents,

OECD. (2007) Consensus document on safety information on transgenic plants expressing *Bacillus thuringiensis* - derived insect control proteins, *OECD*, **ENV/JM/MONO(2007)14**

Ortega Molina, J. (2006) The Spanish experience with co-existence after 8 years of cultivation of GM maize. In *Co-existence of GM, conventional and organic crops, Freedom of Choice Conference*. Vienna, Austria

Ortiz-Garcia, S., Ezcurra, E., Schoel, B., Acevedo, F., Soberon, J. and Snow, A. A. (2005) Absence of detectable transgenes in local landraces of maize in Oaxaca, Mexico (2003-2004), *Proceedings of the National Academy of Sciences*, **102**, 12338-12343.

Palaudelmas, M., Messeguer, J., Penas, G., Serra, J., Salva, J., Pla, M., Nadal, A. and Melé, E. (2007) Effect of sowing and flowering dates on maize gene flow. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 235-236. Seville (Spain)

Papst, C., Utz, H. F., Melchinger, A., Eder, J., Magg, T., Klein, D. and Bohn, M. (2005) Mycotoxins produced by *Fusarium Spp*. in isogenic Bt vs. Non-bt maize hybrids under European corn borer pressure, *Agronomy Journal*, **97**, 219-224.

Parrott, W. (2008) Study of *Bt* impact on caddisflies overstates its conclusions: Response to Rosi-Marshall *et al*. In., Vol. 2008, p. Letter.

Pietri, A. and Piva, G. (2000) Occurrence and control of mycotoxins in maize grown in Italy. In *Proceedings of the 6th International feed production conference*, pp 226-249. Piacenza, Italy

Pla, M., LaPaz, G., Penas, G., Garcia, M., Palaudelmas, M., Esteve, T., Messeguer, J. and Melé, E. (2007) Pollen-mediated gene flow from GM to conventional maize in a field study: assessment of real-time PCR based methods. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 343-344. Seville (Spain)

Pons, X. and Stary, P. (2003) Spring aphid-parasitoid (Hom. Aphididae, Hym. Braconidae) associations and interactions in a Mediterranean arable crop ecosystem, including *Bt* maize, *J. Pest Sci.*, **76**, 133-138.

Pons, X., Lumbierres, B., Lopez, C. and Albajes, R. (2004) No effects of Bt maize on the development of *Orius majusculus*, *GMOs in Integrated Production*, **27**, 131-136.

Pons, X., Lumbierres, B., Lopez, C. and Albajes, R. (2005) Abundance of non-target pests in transgenic Bt-maize: A farm scale study, *Eur. J. Entomol.*, **102**, 73-79.

Pont, B. and Nentwig, W. (2005) Quantification of Bt-protein digestion and excretion by the primary decomposer *Porcellio scaber*, fed with two Bt-corn varieties, *Biocontrol Science and technology*, **15**, 341-352.

Prasifka, P. L., Hellmich, R. L., Prasfika, J. R. and Lewis, L. C. (2007) Effects of Cry1Ab-expressing corn anthers on the movement of monarch butterfly larvae, *Environ. Entomol.*, **36**, 228-233.

Quist, D. and Chapela, I. H. (2001) Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico, *Nature*, **414**, 541-543.

Raps, A., Kehr, J., Gugerli, P., Moar, W. J., Bigler, F. and Hilbeck, A. (2001) Immunological analysis of phloem sap of *Bacillus thuringiensis* corn and of the nontarget herbivore *Rhopalosiphum padi* (Homoptera: Aphididae) for the presence of Cry1Ab, *Molecular Ecology*, **10**, 525-533.

Raynor, G. S., Ogden, E. C. and Hayes, J. V. (1972) Dispersion and deposition of corn pollen from experimental sources, *Agronomy Journal*, **64**, 420-427.

Rodrigo-Simon, A., de Maagd, R. A., Avilla, C., Bakker, P. L., Molthoff, J., Gonzalez-Zamora, J. E. and Ferre, J. (2006) Lack of detrimental effects of *Bacillus thuringiensis* Cry toxins on the insect predator Chrysoperla carnea: a toxicological, histopathological, and biochemical analysis, *Applied and Environmental Microbiology*, **72**, 1595-1603.

Romeis, J., Dutton, A. and Bigler, F. (2004) *Bacillus thuringiensis* toxin (Cry1Ab) has no direct effect on larvae of the green lacewing Chrysoperla carnea, *Journal of Insect Physiology*, **50**, 175-183.

Romeis, J., Bartsch, D., Bigler, F., Candolfi, M., Gielkens, M., Hartley, S., Hellmich, R., Huesing, J., Jepson, P., Layton, R., Quemada, H., Raybould, A., Rose, R., Schiemann, J., Sears, M., Shelton, A., Sweet, J., Vaituzis, Z. and Wolt, J. (2006) Moving through the tiered and methodological framework for non-target arthropod risk assessment of transgenic insecticidal crops, *Proceedings of the 9th International Symposium on the Biosafety of Genetically Modified Organisms*, 62-67.

Rosi-Marshall, E. J., Tank, J. L., Royer, T. V., Whiles, M. R., Evans-White, M., Chambers, C., Griffiths, N. A., Pokelsek, J. and Stephen, M. L. (2007) Toxins in transgenic crop byproducts may affect headwater stream ecosystems, *Proceedings of the National Academy of Sciences*, **104**, 16204-16208.

Roush, R. T. (1994) Managing pests and their resistance to *Bacillus thuringiensis*: can transgenic crops be better than sprays?, *Biocontrol Sci. and Technol.*, **4**, 501-516.

Sanders, C. J., Pell, J. K., Poppy, G. M., Raybould, A., Garcia-Alonso, M. and Schuler, T. H. (2007) Host-plant mediated effects of transgenic maize on the insect parasitoid *Campoletis sonorensis* (Hymenoptera: Ichneumonidae), *Biological Control*, **40**, 362-369.

Sanvido, O., Widmer, F., Winzeler, M. and Bigler, F. (2007) Scientific criteria for the evaluation of cross-fertilisation data to define isolation distances for transgenic maize cultivation. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 97-100. Seville (Spain)

Saxena, D. and Stotzky, G. (2001) *Bacillus thuringiensis* (Bt) toxin released from root exudates and biomass of Bt corn has no apparent effect on earthworms, nematodes, protozoa, bacteria, and fungi in soil, *Soil Biol. and Biochem.*, **33**, 1225-1230.

Saxena, D. and Stotzky, G. (2002) Bt toxin is not taken up from soil or hydroponic culture by corn, carrot, radish or turnip, *Plant and soil*, **239**, 165-172.

Saxena, D. and Stotzky, G. (2005) Release Of Larvicidal Cry Proteins In Root Exudates Transgenic *Bt* Plants. ISB News Report, pp. 1-3.

Schaafsma, A. W., Hooker, D. C., Baute, T. S. and Illincic-Tamburic, L. (2002) Effect of *Bt*-corn Hybrids on Deoxynivalenol content in grain harvest, *Plant Dis.*, **86**, 1123-1126.

Scientific Committee on plants. (1998) Opinion of the Scientific Committee on plants regarding the genetically modified, insect resistant maize lines notified by the Monsanto Company,

Stevens, W. E., Berberich, S. A., Sheckell, P. A., Wiltse, C. C., Halsey, M. E., Horak, M. J. and Dunn, D. J. (2004) Optimizing Pollen Confinement in Maize Grown for Regulated Products, *Crop Sci*, **44**, 2146-2153.

Stodola, T. J., Andow, D. A., Hyden, A. R., Hinton, J. L., Roark, J. J., Buschman, L. L., Porter, P. and Cronholm, G. B. (2006) Frequency of resistance to *Bacillus thuringiensis* toxin Cry1Ab in Southern United States corn belt population of european corn borer (Lepidoptera: Crambidae), *J. Econ. Entomol.*, **99**, 502-507.

Tabashnik, B. E., Carrière, Y., Dennehy, T. J., Morin, S., Sisterson, M. S., Roush, R. T., Shelton, A. M. and Zhao, J.-Z. (2003) Insect resistance to transgenic *Bt* crops: lessons from the laboratory and field, *J. Econ. Entomol.*, **96**, 1031-1038.

Toth, F., Arpas, K., Szekeres, D., Kadar, F., Szentkiralyi, Szenasi, A. and Kiss, J. (2004) Spider web survey or whole plant visual sampling? Impact assessment of *Bt* corn on non-target predatory insects with two concurrent methods, *Environ. Biosafety Res.*, **3**, 225-231.

Tounou, A. K., Gounou, S., Borgemeister, C., Goumedzoe, Y. M. D. and Schulthess, F. (2005) Susceptibility of *Eldana saccharina* (Lepidoptera: Pyralidae), *Busseola fusca* and *Sesamia calamistis* (Lepidoptera: Noctuidae) to *Bacillus thuringiensis* Cry toxins and potential side effects of the larval parasitoid *Cotesia sesamiae* (Hymenoptera: Braconidae), *Biocontrol Science and Technology*, **15**, 127-137.

Turlings, T. C. J., Jeanbourquin, P. M., Held, M. and Degen, T. (2005) Evaluating the induced-odour emission of a Bt maize and its attractiveness to parasitic wasps, *Transgenic research*, **14**, 807-816.

US EPA. (2001a) *Bacillus thuringiensis (Bt)* plant-incorporated protectants October 15, 2001. Biopesticides Registration Action Document, *http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/1-overview.pdf*

US EPA. (2001b) Exemption from the requirement of a tolerance under the federal food, drug, and cosmetic act for residues of nucleic acids that are part of plant-incorporated protectants (formely plant-pesticides), *Federal Register*, **66 (139)**, 37817-37830.

Van de Wiel, C. C. M., Dolstra, O., Thissen, J. T. N. M., Groeneveld, R. M. W., Kok, E. J., Scholtens, I. M. J., Smulders, M. J. M. and Lotz, L. A. P. (2007) Pollen-mediated gene flow in maize under agronomical conditions representative for The Netherlands. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 269-207. Seville (Spain)

van Rensburg, J. B. J. (2007) First report of field resistance by the stem borer, *Busseola fusca* (Fuller) to *Bt*-transgenic maize., *South African Journal of Plant and Soil*, **24**, 147-151.

Vercesi, M. L., Krogh, P. H. and Holmstrup, M. (2006) Can *Bacillus thuringiensis (Bt)* corn residues and Bt-corn plants affect life-history traits in the earthworm *Aporrectodea caliginosa*?, *Applied Soil Ecology*, **32**, 180-187.

Viner, B. and Arritt, R. (2007) Predicting dispersion and viability of maize pollen using a fluid dynamic model of atmospheric turbulence. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, p 297. Seville (Spain)

Vogler, A., Bannert, M. and Stamp, P. (2007) Short and long distance pollen dispersal in maize under Swiss alpine conditions. In *Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains*, Vol. Book of Abstracts, pp 227-228. Seville (Spain)

Vojtech, E., Meissle, M. and Poppy, G. M. (2005) Effects of Bt Maize on the herbivore *Spodoptera littoralis* (Lepidoptera: Noctuidae) and the parasitoid *Cotesia marginiventris* (Hymenoptera: Braconidae), *Transgenic Research*, **14**, 133-144.

Wandeler, H., Bahylova, J. and Nentwig, W. (2002) Consumption of two *Bt* and six non-*Bt* corn varieties by the woodlouse *Porcellio scaber*, *Basic and Applied Ecology*, **3**, 357-365.

Weber, M. and Nentwig, W. (2006) Impact of Bt corn on the diplopod *Allajulus latestriatus*, *Pedobiologia*, **50**, 357-368.

Wu, F. (2006) Mycotoxin reduction in Bt corn: potential economic, health, and regulatory impacts, *Transgenic Research*, **15**, 277-289.

Zwahlen, C., Nentwig, W., Bigler, F. and Hilbeck, A. (2000) Tritrophic Interactions of Transgenic *Bacillus thuringiensis* Corn, *Anaphothrips obscurus* (Thysanoptera: Thripidae), and the Predator *Orius majusculus* (Heteroptera: Anthocoriadae), *Environ. Entomol.*, **29**, 846-850.

Zwahlen, C., Hilbeck, A., Howland, R. and Nentwig, W. (2003) Effects of transgenic *Bt* corn litter on the earthworm *Lumbricus terrestris*, *Molecular Ecology*, **12**, 1077-1086.

Zwahlen, C. and Andow, D. A. (2005) Field evidence for the exposure of ground beetles to Cry1Ab from transgenic corn, *Environ. Biosafety Res*, **4**, 113-117.