Application for authorization to place on the market MON 810 pollen in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part VII

Summary

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

EFSA-GMO-NL-2012-107

(c) Name of the product (commercial and other names)

MON 810 maize, YieldGard® Corn Borer

(d) Date of acknowledgement of valid application

Not known at time of submission

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

(b) Address of applicant

Monsanto Europe S.A. Avenue de Tervueren 270-272 B-1150 Brussels BELGIUM	Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 U.S.A.

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Not applicable

1.3. Scope of the application

(a) GM food

- ☐ Food containing or consisting of GM plants
- ☑ Food produced from GM plants or containing ingredients produced from GM plants

(b) GM feed

- ☐ Feed containing or consisting of GM plants
- ☐ Feed produced from GM plants

(c) GM plants for food or feed use

- ☐ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
- ☐ Seeds and plant propagating material for cultivation in the EU

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?

No ☑

Yes ☐

1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☑ (MON 810 was approved for deliberate release into the environment under Directive 90/220/EEC, which was before Directive 2001/18/EC came into force)

1.6. Has the GM plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?

No ☑ (derived products were, however, notified under Regulation (EC) No 258/97.

Yes ☐ (in that case, specify)

On 22 April 1998 the import and cultivation of MON 810 in the EU was granted by the European Commission under Directive 90/220/EEC.

Based on the opinion of the UK Competent Authority, in 1997 Monsanto notified foods and food ingredients derived from the progeny of maize line MON 810 to the European Commission, according to Article 5 of Regulation (EC) No 258/97 on novel foods and novel food ingredients.

In addition, applications for renewal of the authorization for continued marketing of existing products produced from MON 810 have been submitted in April 2007 (*food additives, feed materials and feed additives* produced from MON 810 notified according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed; *food and food ingredients produced from MON 810* notified pursuant to Article 5 of Regulation (EC) No 258/97 and subsequently notified according to Article 8(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed). In May 2007, an application was submitted for renewal of the authorization for continued marketing of existing MON 810 maize products that were authorized under Directive 90/220/EEC (Decision 98/294/EC) and subsequently notified in 2004, in accordance to Article 20(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed.

1.7. Has the product been notified/authorised in a third country either previously or simultaneously?

No ☐

Yes ☑

Cultivation of MON 810 is lawful in several countries across the world, including the U.S.A., Canada, Argentina, South Africa, Uruguay, the Philippines, the EU, Colombia and Honduras, while importation of derived foods and feeds is lawful in Australia, China, Japan, Korea, Mexico, New Zealand, Russian Federation, Switzerland and Taiwan.

1.8. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification

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

The use of MON 810 would enable farmers to effectively control ECB, providing protection of potential maize yield and a reduction in the use of chemical insecticides for this insect pest. MON 810 would provide benefits to growers, the general public, and the environment, including: (1) a more reliable, economical, and less labour intensive means to control ECB, (2) insect control without harming non target species, (3) a means for growers to significantly reduce the amount of chemical insecticides now applied to the crop thereby achieving ECB control in a more environmentally compatible manner than is currently available, (4) a reduction in the manufacturing, shipment , and storage of chemical insecticides used in maize, (5) a reduction in the exposure of workers to the pesticide and pesticide spray solution, (6) a reduction in the number of empty pesticide containers and amount of spray solution that must be disposed of according to applicable environmental regulations, (7) a fit with integrated pest management (IPM) and sustainable agricultural systems, and (8) both large and small growers will benefit from the planting of MON 810 as no additional labour, planning, or machinery is required.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

The scope of the current application complements the scopes of previous MON 810 renewal applications, and includes the use of MON 810 pollen as or in food. The range of uses of MON 810 will continue to be identical to the full range of equivalent uses of current commercial maize.

(c) Intended use of the product and types of users

MON 810-derived food and food ingredients will continue to be traded and used in the European Union in the same manner as equivalent products from current commercial maize and by the same operators currently involved in the trade and use of maize.

(d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

MON 810 is substantially equivalent to conventional maize except for its introduced trait: protection against certain lepidopteran insect pests, which is a trait of agronomic interest. This maize was shown to be as safe and as nutritious as conventional maize. Therefore, MON 810-derived food and food ingredients will be stored, packaged, transported, handled and used in the same manner as products derived from current commercial maize. No specific conditions are warranted or required for the food and food ingredients produced from MON 810.

(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for

MON 810 food and food ingredients are suitable for use throughout the EU.

(f) Any type of environment to which the product is unsuited

MON 810 food and food ingredients are suitable for use throughout the EU.

(g) Any proposed packaging requirements

MON 810 is substantially equivalent to conventional maize (except for the introduced lepidopteran-protection trait). Therefore, MON 810-derived food and food ingredients will continue to be used in the same manner as other equivalent maize derived products and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(2)(c), (d) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMO plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC.

Operators shall be required to label foods and feeds derived from MON 810 with the words "produced from genetically modified maize". In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 810-derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the EU Register, operators in the food/feed chain will be fully aware of the traceability and labeling requirements for MON 810. Therefore, no further specific measures are to be taken by the notifier.

(i) Estimated potential demand

(i) In the Union

The EU is a big producer of maize. In 2010, the EU-27 produced about 85.6 MMT of maize seed and planted approximately 14.1 Mha[1]. The largest maize producers in the EU are France, Romania, Italy and Hungary. The EU also imports maize from markets such as Ukraine and other Eastern European countries, Argentina and Brazil.

(ii) In export markets for EU supplies

In 2009, a total of 16.4 MMT of grain was exported from EU-27 countries of which 15.1 MMT was intra-EU trade. A total of 1.2 MMT of maize grain was exported to non-EU countries such as Korea, Syria, Algeria and Turkey[1].

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

MON-ØØ81Ø-6

1.9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

Misuse of food and food ingredients produced from MON 810 is unlikely, as the proposed uses for this maize are included in the current food uses of conventional maize. MON 810 is substantially equivalent to other maize except for the introduced trait: protection against certain lepidopteran insect pests, which is a trait of agronomic interest. This maize is shown to be as safe and as nutritious as conventional maize. Therefore, all measures for waste disposal and treatment of MON 810-derived products are the same as those for conventional maize. No specific conditions are warranted or required for the continued marketing of MON 810-derived food and food ingredients.

[1] http://faostat.fao.org - Accessed May 2012

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

2.1. Complete name

(a) Family name

Poaceae

(b) Genus

Zea

(c) Species

mays (2n=20)

(d) Subspecies

Not applicable

(e) Cultivar/breeding line or strain

MON 810

(f) Common name

Maize, corn

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

Because of its many divergent types, maize is grown over a wide range of climatic conditions. The bulk of the maize is produced between latitudes 30° and 55°, with relatively little grown at latitudes higher than 47° latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21° and 27° C and the freeze-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation with no upper limit of rainfall for growing maize, although excess rainfall will decrease yields.

There are no wild relatives of maize in Europe.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Maize (*Zea mays* L.) is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers. Self- and cross-pollination are generally possible, with frequencies of each normally determined by proximity and other physical influences on pollen transfer.

(b) Specific factors affecting reproduction

Tasselling, silking, and pollination are the most critical stages of maize development and, consequently, grain yield may ultimately be greatly impacted by moisture and fertility stress.

(c) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

Out-crossing with cultivated *Zea* varieties

The scope of this application does not include consent for the environmental release of MON 810 according to Directive 2001/18/EC, Part C. Outcrossing with cultivated *Zea* varieties is therefore not expected in the context of this application.

Out-crossing with wild *Zea* species

Wild relatives of maize do not exist in Europe.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

(b) Specific factors affecting survivability

Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. Volunteer maize is not found growing in fencerows, ditches or roadsides as a weed. Although maize seed from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed. The appearance of "volunteer" maize in fields following a maize crop from the previous year is rare under European conditions. Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices including cultivation and the use of selective herbicides.

Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Freezing temperatures have an adverse effect on maize seed germination and have been identified as being a major risk in seed maize production. Temperatures above 45 °C have also been reported as injurious to maize seed viability.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

In general, dissemination of maize may occur by means of seed dispersal and pollen dispersal. Dispersal of the maize grain is highly restricted in domesticated maize due to the ear structure including husk enclosure. For maize pollen, the vast majority is deposited in the same field due to its large size (90 to 100 µm) with smaller amounts of pollen deposited usually in a downwind direction. However, the current application does not include the deliberate release of MON 810 in the EU but only the use of MON 810 pollen as or in food.

(b) Specific factors affecting dissemination

Dispersal of maize seeds does not occur naturally because of the structure of the ears of maize. Dissemination of isolated seeds may result from mechanical harvesting and transport as well as insect or wind damage, but this form of dissemination is highly infrequent. Genetic material can be disseminated by pollen dispersal, which is influenced by wind and weather conditions. Maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation. Dispersal of maize pollen is limited by its large size and rapid settling rate.

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

The sexually compatible species in the EU, as mentioned in Section 2.4 of this document, can be found across the EU, in areas where natural conditions would allow the growth and reproduction of maize plants.

2.8. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

Not applicable, as maize is grown in the EU.

2.9. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

Maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and nematode, insect and mite pests. Maize has a history of safe use for human food and animal feed.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

The particle acceleration transformation method was used in the development of MON 810.

(b) Nature and source of the vector used

MON 810 was generated using the particle acceleration method, by the integration of sequences from the plasmid vector PV-ZMBK07, containing the *cry1Ab* coding sequence of interest, which was derived from *Bacillus thuringiensis* subsp. *kurstaki*.

(c) Source of donor DNA used for transformation, size and intended function of each constituent fragment of the region intended for insertion

The individual components of MON 810 insert and the function of these DNA sequences are given in Table 1.

Table 1. Genetic elements inserted in MON 810

Genetic Element	Source	Size (kb)	Function
P-*e35S*$^{MON\ 810}$	Cauliflower mosaic virus	0.3	Promoter
I-*Hsp70*	*Zea mays* L.	0.8	Stabilizes level of gene transcription.
CS-*cry1Ab*$^{MON\ 810}$	*Bacillus thuringiensis*	2.5	Encodes a variant of Cry1Ab1 protein, which targets specific lepidopteran insect pests

3.2. Information relating to the GM plant

3.2.1. *Description of the trait(s) and characteristics which have been introduced or modified*

MON 810 expresses the Cry1Ab protein derived from *Bacillus thuringiensis* subsp. *kurstaki*, which provides protection from certain lepidopteran insect pests, including European corn borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp).

3.2.2. *Information on the sequences actually inserted or deleted*

(a) The copy number of all detectable inserts, both complete and partial

MON 810 contains a single DNA insert containing a single copy of the introduced DNA fragment, and this at a single locus in the maize genome.

(b) In case of deletion(s), size and function of the deleted region(s)

Not applicable

(c) Sub-cellular location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

The Chi square analysis of the segregation pattern, according to Mendelian genetics, was consistent with a single site of insertion into the maize nuclear DNA.

(d) The organisation of the inserted genetic material at the insertion site

Genomic DNA from MON 810 was analyzed by Southern blotting to determine the intactness of the genetic elements within the insert, and the presence or absence of plasmids backbone sequences. The organisation of the elements within the insert in MON 810 was further confirmed using PCR analysis and sequencing of the insert.

(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modification

Not applicable

3.2.3. *Information on the expression of the insert*

(a) Information on developmental expression of the insert during the life cycle of the plant

Expression level of the introduced protein was measured in grain and forage collected from MON 810 grown in the field.

The level of Cry1Ab in MON 810 plants is similar when plants are grown in different geographies and when the gene is present in different genetic backgrounds (range for grain: 0.19-0.69 µg/g fwt; range for forage: 4.00-5.56 µg/g fwt). The level of expression remains sufficient to provide season long control of the targeted insect pests.

In addition, Cry1Ab protein levels in pollen were collected from MON 810 plants grown in 2002 in U.S. fields. The level of the Cry1Ab protein in pollen collected from all sites was below the Limit of Detection (LOD), which was 0.090 µg/g fwt.

(b) Parts of the plant where the insert is expressed

Cry1Ab protein was determined in forage and grain, which are the most relevant tissues in terms of food and feed safety. Additional information was provided on pollen in the frame of the current risk assessment.

3.2.4. *Genetic stability of the insert and phenotypic stability of the GM plant*

The inserted *cry1Ab* gene has been shown to be stably integrated into the plant chromosome based on segregation data and Southern analysis.

3.2.5. *Information (for environmental safety aspects) on how the GM plant differs from the recipient plant in:*

(a) Mode(s) and/or rate of reproduction

Comparative assessments of the phenotypic and agronomic characteristics of MON 810 and conventional maize have been conducted at multiple sites in the field. MON 810 has been produced as a commercial product since 1997 in the U.S.A. and is also currently commercially produced in multiple other countries.

The experience gathered from these plantings demonstrates that, except for the protection against target lepidopteran pests, there are no biologically significant differences in the reproductive capability, dissemination or survivability of MON 810 when compared to conventional maize. The agronomic equivalence between MON 810 and conventional maize (except for the introduced lepidopteran-protection trait) is further supported by the data demonstrating that MON 810 is compositionally equivalent to conventional maize.

It is concluded that MON 810 does not differ from conventional maize with regard to reproduction, dissemination, survivability or other agronomic and phenotypic traits. Regardless, it should be noted that the scope of the current application does not include the cultivation of MON 810 varieties in the EU but only the authorisation for the use of MON 810 pollen as or in food.

(b) Dissemination

The introduced lepidopteran-protection trait has no influence on maize reproductive morphology and hence no changes in seed dissemination are to be expected.

(c) Survivability

Maize is known to be a weak competitor in the wild, which cannot survive in Europe outside cultivation without the aid of human intervention. Field observations have demonstrated that MON 810 has not been altered in its survivability when compared to conventional maize

(d) Other differences

Comparative observations of the phenotypic and agronomic characteristics did not reveal biologically significant differences between MON 810 and conventional maize, except for the introduced trait.

3.2.6. *Any change to the ability of the GM plant to transfer genetic material to other organisms (for environmental safety aspects)*

(a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 810 has a genetic transfer function. Therefore, no changes are expected in the ability of these maize lines to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 810 is unchanged compared to conventional maize and that pollen production and pollen viability were unaffected by the genetic modification, the out-crossing frequency to other maize varieties or to wild relatives (which are not present in the EU) would be unlikely to be different for MON 810, when compared to conventional maize varieties.

However, it should be noted that the scope of this current application does not include the cultivation of MON 810 varieties in the EU but only the authorisation for the use of MON 810 pollen as or in food.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

These studies compared MON 810 to conventional controls that are similar in pedigree but are not an isogenic control because of the variability in the parental High-Type II.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

1994 U.S. field season

MON 810 and the conventional control maize were grown at six field sites in major maize-growing areas of the U.S.A (Illinois, Iowa, Indiana and Nebraska) during the 1994 field season. Each maize line was grown in a single replicate plot at all sites. All the plants were grown under normal agronomic field conditions for their respective geographic regions.

1995 European field season

Grain and forage from MON 810

MON 810 and the conventional control maize were grown at three field sites in major maize-growing areas of France during the 1995 field season.

Grain and forage of progeny of MON 810

MON 810 hybrids and the conventional control maize were grown in France and Italy during the 1995 field season.

4.3. Selection of material and compounds for analysis

Forage samples were analyzed for proximates (protein, fat, ash, and dry matter), ADF, NDF, and carbohydrates by calculation. Compositional analyses of the grain samples included proximates (protein, fat, ash, and moisture), ADF, NDF, amino acids, fatty acids, fiber, anti-nutrient, minerals and carbohydrates by calculation.

The results of these compositional analyses conducted for MON 810, compared to conventional maize hybrids, and the subsequent compositional analyses performed for MON 810 containing stacks (MON 863 × MON 810 × NK603; MON 863 × MON 810, NK603 × MON 810 and MON 88017 × MON 810) do not indicate a need for further analysis of selected compounds in this maize.

4.4. Comparative analysis of agronomic and phenotypic characteristics

The scope of this application is limited to the authorisation of the use of MON 810 pollen as or in food, and does not include the cultivation of MON 810 varieties in the EU. Agronomic observations performed during field trials with MON 810 support a conclusion that from an agronomic and phenotypic (morphological) point of view, MON 810 is equivalent to conventional maize, except for the introduced lepidopteran-protection trait.

This is also confirmed by the extensive commercial experience with MON 810, since 1997 and MON 810 containing stacks (MON 863 × MON 810 × NK603; MON 863 × MON 810, NK603 × MON 810 and MON 88017 × MON 810).

4.5. Effect of processing

Using both wet and dry milling processes, maize is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As MON 810 is substantially equivalent and as safe and as nutritious as conventional maize, the use of MON 810 for the production of foods and feeds is not different from that of conventional maize. Consequently, any effects of the production and processing of MON 810 foods and feeds are not expected to be different from the production and processing of the equivalent foods and feeds, originating from conventional maize.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

The Cry1Ab protein expressed in MON 810, present at low levels in the plant, has been reviewed and considered safe by the Scientific Committee on Plants and by EFSA. The Cry1Ab protein has negligible potential to cause adverse effects to animal or human health. It has a highly specific, insecticidal mode of action in the gut of target insects that is based on binding to specific receptors for *Bt* proteins. The long history of safe use of this protein in microbial *Bt* products and its history of safe use in previously approved GM products, such as products derived from MON 810, further support its safety to humans and animals.

In addition to its long history of safe use, the acute toxicity of this protein was directly assessed in an acute oral gavage study. There were no indications of acute toxicity when administered by gavage to laboratory mice at doses which are orders of magnitude higher than expected consumption levels from food or feed products containing or consisting of MON 810. This lack of toxicity was expected based on the absence of a toxic mechanism in animals, the history of exposure, and the rapid degradation of this protein in simulated human gastric fluids. In addition, Cry1Ab is not homologous to any known toxins (except for the expected homology of Cry1Ab to other *Bt* proteins) or other biologically active proteins. Compared to other proteins, Cry1Ab is present at very low levels in MON 810.

(b) Testing of new constituents other than proteins

Since maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world, and as MON 810 was shown to be substantially equivalent to conventional maize, testing of any constituents other than the introduced proteins is not indicated.

(c) Information on natural food and feed constituents

Maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world. No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment.

(d) Testing of the whole GM food/feed

The compositional and nutritional equivalence of grain and forage from MON 810 and conventional maize have been established by compositional analysis. In addition, the dietary safety of the Cry1Ab protein within the maize matrix was further confirmed by animal feeding studies using rats and broiler chickens.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The Cry1Ab protein was assessed for its potential allergenicity by a variety of tests, including a) whether the genes came from allergenic or non-allergenic sources, b) sequence similarity to known allergens, and c) pepsin stability of the protein in an *in vitro* digestion assay. In all cases, the protein did not exhibit properties characteristic of allergens.

(b) Assessment of allergenicity of the whole GM plant

As the introduced protein does not have any allergenic potential, it was concluded that the use of MON 810-derived food and food ingredients does not lead to an increased risk for allergenic reactions compared to the equivalent range of food uses of conventional maize.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

The introduced trait of lepidopteran-protection is of agronomic interest, and does not change the nutritional aspects of this maize. Hence, this maize is not more or less attractive for the production of food and food ingredients. Therefore, anticipated dietary intake of maize-derived products is not expected to be altered upon the authorization of MON 810, and no nutritional imbalances are expected as a result of the use of MON 810-derived food and food ingredients.

(b) Nutritional assessment of GM feed

A confirmatory feeding study in broiler chickens was conducted to compare the nutritional value of MON 810 and non-transgenic control grain, as well as commercial reference hybrids, and to provide additional confirmation of the safety of this maize. The results of this study show that there were no biologically relevant differences in the parameters tested between broilers fed the MON 810-containing diet and the non-transgenic control diet. The MON 810-diet was as wholesome as its corresponding non-transgenic control diet and commercially available reference diets regarding its ability to support the rapid growth of broiler chickens. This conclusion was consistent with the evaluation of the composition of MON 810, which showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference maize hybrids. These data confirm the conclusion that MON 810 and its derived products are as safe and nutritious as conventional maize.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

MON 810-derived food and food ingredients replace a portion of current commercial maize products. Anticipated dietary intake and/or extent of use of current commercial maize products is not expected to be altered upon authorisation of the use of MON 810 pollen as or in food.

Further, no evidence of toxicity was observed when mice were dosed acutely with 4000 mg/kg Cry1Ab protein. Using highly conservative estimates of potential intake of pollen , high margins of exposure (MOE) were calculated for this protein for children and adults, ranging from 6.2×10^7 to 6.9×10^7. Therefore, there is a reasonable certainty that consumption of pollen from MON 810 maize, would not adversely affect the health of adults or children in the EU.

9. RISK CHARACTERISATION FOR THE SAFETY ASSESSMENT OF GM FOOD AND FEED

Based on the molecular characterization and the comparative analysis of compositional, agronomic and phenotypic characteristics of MON 810 compared to its conventional counterpart, no unanticipated adverse effects could be identified. Further, the integrity of the insert over several generations was demonstrated in the stability analysis, meaning that the same *cry1Ab* gene and translated Cry1Ab protein is produced in all plant tissues, including pollen. The safety of the newly expressed Cry1Ab protein has been demonstrated and included in earlier applications.

The Cry1Ab expression in pollen as well as pollen production and viability were unaffected by the genetic modification, hence the present assessment shows that conclusions would apply for pollen as well. Additionally, the human dietary risk assessment for MON 810 pollen concluded on negligible risk for the health of humans. Therefore, the present application concludes that MON 810 pollen is as safe as conventional pollen for use as or in food.

10. POST-MARKET MONITORING ON GM FOOD/FEED

There are no intrinsic hazards related to MON 810 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterisation for food and feed use of MON 810 demonstrates that the risks of consumption of MON 810 and its derived products are consistently negligible and not different from the risks associated with the consumption of conventional maize and maize-derived products. As a consequence and as stipulated in the EU Register of GM food and feed, no specific risk management measures are indicated, and post-market monitoring of the use of food and food ingredients produced from this maize is not appropriate.

11. ENVIRONMENTAL ASSESSMENT

Not applicable as this application under Regulation (EC) No 1829/2003 includes food and food ingredients derived from MON 810 for uses equivalent to any other maize and does not include deliberate release of the GMO into the environment.

12. ENVIRONMENTAL MONITORING PLAN

Not applicable as this application under Regulation (EC) No 1829/2003 includes food and food ingredients derived from MON 810 for uses equivalent to any other maize and does not include deliberate release of the GMO into the environment.

13. DETECTION AND EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GM PLANT

An event-specific PCR-assay allowing the detection and the quantification of MON 810 has been validated in a collaborative trial by the American Association of Cereal Chemist (AACC) in collaboration with the German Federal Institute of Risk Assessment (BfR), GeneScan and the Joint Research Center from the European Commission. This method has been included as Annex D2 in the current CEN draft standard pr ISO 21570 “Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Quantitative nucleic acid

based methods" and published by the Joint Research Centre (JRC) on their website[2], who is acting as the European Union Reference Laboratory for GM Food and Feed (EU-RL-GMFF).

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

14.1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

(a) Notification number

B/FR/94.02.11; B/FR/94.02.16; B/FR/94.03.02; B/FR/95.03.06; B/FR/95.03.08; B/FR/95.03.09; B/FR/95.03.10; B/FR/95.03.11; B/FR/95.03.12; B/IT/95-38; B/IT/95-23

(b) Conclusions of post-release monitoring

Post-release surveillance of trials performed in the EU provided no significant evidence that this maize would likely cause any adverse effects to human or animal health or to the environment.

(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

Post-release surveillance from environments inside and outside the EU provided no significant evidence that MON 810 would pose any risk of adverse effects to human or animal health or to the environment.

14.2. History of previous releases of the GM plant carried out outside the Union by the same notifier

(a) Release country

MON 810 was first commercialized in the U.S. in 1997 and approved for cultivation in the EU in 1998. It has been grown ever since in multiple countries around the world.

(b) Authority overseeing the release

Agencies in charge of commercial field release

(c) Release site

Major maize growing regions within the different countries

(d) Aim of the release

Commercial release for all uses as conventional maize.

(e) Duration of the release

See section 14.2(a)

(f) Aim of post-releases monitoring

Extensive pre-market risk assessment did not provide evidence of adverse effects potentially associated with the cultivation, handling or use of MON 810, indicating that a requirement for post-release monitoring would not be appropriate.

In addition, MON 810 is commercialized alongside stewardship programmes such as insect resistance management programmes, involving downstream stakeholders in the use of this maize, in order to ensure the implementation of good agricultural practice in its cultivation

[2] http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm - Accessed May 2012

and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur.

However, no such unanticipated effects have been observed since the commercialization of MON 810.

(g) Duration of post-releases monitoring

See section 14.2(f)

(h) Conclusions of post-release monitoring

See section 14.2(f). Those conclusions were recently confirmed by EFSA (2011[3]; 2012[4]).

(i) Results of the release in respect to any risk to human health and the environment

Field-testing and post-marketing experience provided no significant evidence that grain or derived products from MON 810 are likely to cause any adverse effects to human or animal health, or to the environment. Those conclusion were recently confirmed by EFSA (2011[3]; 2012[4]).

[3] http://www.efsa.europa.eu/en/efsajournal/pub/2376.htm - Accessed May 2012
[4] http://www.efsa.europa.eu/en/efsajournal/pub/2610.htm - Accessed May 2012