# Application for renewal of the authorisation for continued marketing of existing food and food ingredients produced from MON 810 maize that were 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

**Part II**

Summary

**April 2007**

## A. GENERAL INFORMATION

### 1. Details of application

**a) Member State of application**

Not applicable.

**b) Notification number**

Not known at the time of application

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

The Monsanto development code for this genetically modified maize is: MON 810. In countries where MON 810 varieties are being cultivated, packages of seed of this maize are marketed under the name of the hybrid variety, in association with the trademark YieldGard® Corn Borer, indicating clearly to growers that this maize is protected from specific lepidopteran insect pests.

**d) Date of acknowledgement of notification**

Not known at the time of application

### 2. Applicant

**a) Name of applicant**

Monsanto Company, represented by Monsanto Europe S.A.

**b) Address of applicant**

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B-1150 Brussels
BELGIUM

Monsanto Company
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St. Louis, Missouri 63167
U.S.A

**c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))**

MON 810 maize[1] will continue to be traded and used in the European Union in the same manner as current commercial maize and by the same operators currently involved in the trade and use of maize.

[1] Hereafter referred to as MON 810

**3. Scope of the application**

**( ) GM plants for food use**
**( ) Food containing or consisting of GM plants**
**(x) Food produced from GM plants or containing ingredients produced from GM plants**
**( ) GM plants for feed use**
**( ) Feed containing or consisting of GM plants**
**( ) Feed produced from GM plants**
**( ) Import and processing (Part C of Directive 2001/18/EC)**
**( ) Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)**

**4. Is the product being simultaneously notified within the framework of another regulation (e.g. Seed legislation)?**

| | |
|---|---|
| **Yes ( )** | **No ( x )** |
| **If *ye*s, specify** | |

**5. Has the GM plant been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?**

| | |
|---|---|
| **Yes ( x )** | **No ( )** |
| **If *n*o, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC** | |

**6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?**

| | |
|---|---|
| **Yes ( x )** | **No ( )** |
| **If *ye*s, specify**<br>On 22 April 1998 the import and cultivation of MON 810 in the E.U. was granted by the E.U. Commission under Directive 90/220/EEC.<br>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. | |

## 7. Has the product been notified in a third country either previously or simultaneously?

| Yes ( x ) | No ( ) |
|---|---|

**If *yes*, specify**

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

## 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 (*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 reduct ion 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 a s 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

The scope of the current renewal application includes food and food ingredients produced from MON 810 which are lawfully placed on the market in the E.U., as listed in the Community Register of GM Food and Feed[2]. The range of uses of these MON 810-derived products will be identical to the full range of equivalent uses of current commercial

[2] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

maize derived products.

**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) 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) 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 (for the labelling, *see* question 8.(f)).

**f) A proposal for labelling in accordance with Articles 13 and 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing, consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC.**

In accordance with Regulations (EC) N° 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 810 grain and derived products.

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 E.U. 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

Community 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.

**g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)**

MON-ØØ81Ø-6

**h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited**

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

## 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.

## B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

### 1. Complete name

| | |
|---|---|
| **a)** | **Family name**<br>Poaceae (formerly Gramineae) |
| **b)** | **Genus**<br>*Zea* |
| **c)** | **Species**<br>*mays* (2n=20) |
| **d)** | **Subspecies**<br>N/A |
| **e)** | **Cultivar/breeding line**<br>MON 810 |
| **f)** | **ComMON name**<br>Maize; Corn |

### 2. a) Information concerning reproduction

| | |
|---|---|
| ***(i)*** | ***Mode(s) of reproduction***<br>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. |
| ***(ii)*** | ***Specific factors affecting reproduction***<br>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. |
| ***(iii)*** | ***Generation time***<br>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 b) Sexual compatibility with other cultivated or wild plant species

Out-crossing with cultivated *Zea* varieties

The scope of this renewal 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.

## 3. Survivability

### 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.

## 4. Dissemination

### 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 renewal application does not include the deliberate release of MON 810 in the E.U. but only the continued use of existing food and food

ingredients produced from MON 810.

**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.

## 5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

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.

## 6. 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

Maize is widely grown in the European Union. The most important areas of maize production in Europe include the Danube Basin, from southwest Germany to the Black Sea, along with southern France through the Po Valley of northern Italy.

## 7. 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

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.

## C. INFORMATION RELATING TO THE GENETIC MODIFICATION

### 1. Description of the methods used for the genetic modification

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

### 2. 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*.

### 3. Source of donor DNA, 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*$^{\text{MON 810}}$ | Cauliflower mosaic virus | 0.3 | Promoter |
| I-*Hsp70* | *Zea mays* L. | 0.8 | Stabilizes level of gene transcription. |
| CS-*cry1Ab*$^{\text{MON 810}}$ | *Bacillus thuringiensis* | 2.5 | Encodes a variant of Cry1Ab1 protein, which targets specific lepidopteran insect pests |

## D. INFORMATION RELATING TO THE GM PLANT

### 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).

### 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) Chromosomal 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.

### 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.

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

Cry1Ab protein was estimated in forage and grain, which are the most relevant tissues in terms of food and feed safety.

## 4. Information on how the GM plant differs from the recipient plant in

**a) 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 Canada, Argentina, South Africa, Uruguay, the E.U. and the Philippines.

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 renewal application does not include the cultivation of MON 810 varieties in the E.U. but only the renewal of the authorisation for the continued marketing of existing MON 810-derived food and food ingredients, entered in the Community Register of GM Food and Feed, in the E.U.

**b) Dissemination**

The introduced lepidopteran-protection 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.

## 5. 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.

## 6. Any change to the ability of the GM plant to transfer genetic material to other organisms

**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 E.U.) 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 renewal application does not include the cultivation of MON 810 varieties in the E.U. but only the renewal of the authorisation for continued marketing of existing MON 810-derived food and food ingredients, entered in the Community Register of GM Food and Feed, in the E.U.

## 7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

### *7.1 Comparative assessment*

**Choice of the comparator**

Compositional analyses were performed on forage and grain samples from MON 810, grown under representative field conditions in the U.S.A. and in the E.U., respectively in 2004 and 2005. The study also included compositional analyses of forage and grain collected from a control. The analytical results have shown that MON 810 is compositionally equivalent to the control comparator used in the study and is within the published and reported literature ranges for commercial hybrids.

### *7.2 Production of material for comparative assessment*

**a) number of locations, growing seasons, geographical spread and replicates**

**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.

**b) the baseline used for consideration of natural variations**

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

### *7.3 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 x MON 810 x NK603; MON 863 x MON 810 and NK603 x MON 810) do not indicate a need for further analysis of selected compounds in this maize.

### *7.4 Agronomic traits*

The scope of this application is limited to the renewal of the authorisation for continued marketing of existing MON 810-derived food and food ingredients in the E.U., but does not include the cultivation of MON 810 varieties in the E.U. Agronomic observations performed during field trials with MON 810 supports 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 (NK603 x MON 810 since 2002; MON 863 x MON 810 since 2003 and MON 863 x MON 810 x NK603 since 2005).

### *7.5 Product specification*

MON 810-derived food and food ingredients are currently imported into the E.U. in mixed shipments of maize products, produced in other world areas. These products are handled by operators that have traditionally been involved in the commerce, processing and use of maize and maize derived products in the European Union.

The presence of MON 810 in maize grain or in maize derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequences, while specific ELISA has been developed to detect the presence of Cry1Ab protein in individual plants or in specific tissues. 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 D 2 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"

### *7.6 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.

### *7.7 Anticipated intake/extent of use*

Food and food ingredients produced from MON 810 were first placed on the E.U. market in 1997. In July 2004 these products were notified to the European Commission, following Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003, in order to allow for their continued marketing in the E.U. given that they had been lawfully placed on the market before Regulation (EC) No 1829/2003 came into force, on 18 April 2004.

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 renewal of the authorisation of existing MON 810-derived

products.

## *7.8 Toxicology*

### *7.8.1 Safety assessment 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.

### *7.8.2 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.

### *7.8.3 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.

### *7.8.4 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 Cry1Ab protein within the maize matrix was further confirmed by animal feeding studies in the rat and in broiler chickens.

## *7.9 Allergenicity*

### *7.9.1 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 proteins did not exhibit properties characteristic of allergens.

### *7.9.2 Assessment of allergenicity of the whole GM plant or crop*

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.

## *7.10 Nutritional assessment of GM food/feed*

### *7.10.1 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 renewal of MON 810, and no nutritional imbalances are expected as a result of the use of MON 810-derived food and food ingredients.

### *7.10.2 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.

## *7.11 Post-market monitoring of 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 previously stipulated in the Community 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.

## 8. Mechanism of interaction between the GM plant and target organisms (if applicable)

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

## 9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

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

## 10. Potential interactions with the abiotic environment

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

## 11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants and if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment)

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

### 12. 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 D 2 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"

## E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

### 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 E.U. 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 E.U. provided no significant evidence that MON 810 would pose any risk of adverse effects to human or animal health or to the environment.

### 2. History of previous releases of the GM plant carried out outside the Community by the same notifier

**a) Release country**

MON 810 was first commercialized in the U.S. in 1997 and approved for cultivation in the E.U. in 1998. In 2006, MON 810 was grown in the U.S.A., Canada, Argentina, South Africa, Uruguay, the Philippines, and the E.U. (Spain, France, Germany, Czech Republic, Portugal and Slovakia).

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|---|---|
| **b)** | **Authority overseeing the release**<br>Agencies in charge of field release |
| **c)** | **Release site**<br>Major maize growing regions within the different countries |
| **d)** | **Aim of the release**<br>Commercial release for all uses as conventional maize. |
| **e)** | **Duration of the release**<br>Please see Section E.2.(a) |
| **f)** | **Aim of post-releases monitoring**<br>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.<br>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 and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur.<br>However, no such unanticipated effects have been observed since the commercialization of MON 810. |
| **g)** | **Duration of post-releases monitoring**<br>Please see Section E.2.(f) |
| **h)** | **Conclusions of post-release monitoring**<br>Please see Section E.2.(f) |
| **i)** | **Results of the release in respect to any risk to human health and the environment**<br>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. |

**3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):**

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|---|---|
| **a)** | **Status/process of approval**<br>The JRC websites http://gmoinfo.jrc.it/gmc_browse.aspx?DossClass=0 and http://gmo-crl.jrc.it/statusofdoss.htm and the EFSA website http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and applications under Regulation (EC) No 1829/2003. |
| **b)** | **Assessment Report of the Competent Authority (Directive 2001/18/EC)**<br>Not applicable in the context of the scope of this renewal application. |
| **c)** | **EFSA opinion**<br>EFSA has issued opinions on MON 810 containing stacks (NK603 x MON 810, MON 863 x MON 810, MON 863 x MON 810 x NK603) (http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html) . |
| **d)** | **Commission Register (Commission Decision 2004/204/EC)**<br>http://ec.europa.eu/food/dyna/gm_register/index_en.cfm |
| **e)** | **Molecular Register of the Community Reference Laboratory/Joint Research Centre**<br>Information on detection protocols is posted at http://gmo-crl.jrc.it/ |
| **f)** | **Biosafety Clearing-House (Council Decision 2002/628/EC)**<br>The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.biodiv.org/ |
| **g)** | **Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)**<br>EFSA provides a link to the publicly accessible summary of this renewal application (http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html). |