Application for authorization of MON 88017 maize for cultivation in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II
Summary

Data protection.
This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

Czech Republic

b) Notification number

Not available 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 88017. In countries where MON 88017 is being cultivated, packages of this maize are marketed under the name of the hybrid variety, in association with the trademark YieldGard VT Rootworm/RR2™ [1], indicating clearly to growers that the hybrid is protected against specific coleopteran insect pests and tolerant to glyphosate[2].

d) Date of acknowledgement of notification

Not available at the time of application.

2. Applicant

a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

b) Address of applicant

Monsanto Europe S.A.
Avenue de Tervuren 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 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 88017 will be cultivated, traded and used in the European Union in the same manner as commercial maize and by the same growers and operators currently involved in the production, storage, transport, processing and use of maize.

[1] YieldGard VT Rootworm/RR2 is a trademark application by Monsanto Technology LLC.
[2] Active ingredient of Monsanto's Roundup family of agricultural herbicides. Roundup® is a registered trademark of Monsanto Technology LLC.

3. Scope of the application

( ) GM plants for food use ( ) Food containing or consisting of GM plants ( ) 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 or containing ingredients produced from GM plants ( ) Import and processing (Part C of Directive 2001/18/EC) (X) 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 *yes*, 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 *no*, 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 *yes*, specify An application pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed (EFSA-GMO-CZ-2005-27) was submitted in October 2005, which covers the use of MON 88017 for food, feed, import and processing as any other maize in the E.U.	

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

Yes (x)	No ( )

If *yes*, specify

MON 88017 has been notified to and evaluated by numerous international regulatory authorities. Approval for cultivation was granted in the U.S.A. and Canada. Other countries around the world, such as Australia, Korea, Mexico, Japan, Russia, Singapore, Taiwan and the Philippines approved MON 88017 for import, food and feed uses.

The status of other pending regulatory reviews, which are currently in progress in numerous countries around the world, depends on the country and its local regulatory framework.

8. General description of the product

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

MON 88017 has been developed to produce the Cry3Bb1[7] and the CP4 EPSPS proteins that confer protection against certain coleopteran pests (*Diabrotica* spp.) and tolerance to glyphosate, respectively. MON 88017 was produced by *Agrobacterium*-mediated transformation of maize cells with plasmid vector PV-ZMIR39.

The use of MON 88017 enables the farmer to effectively control the targeted coleopteran insect pests in maize, ensuring maximum realization of yield potential, while removing the environmental burden of the production, packaging and transport of insecticides, previously used to control *Diabrotica* spp. In addition, growers will have the possibility to apply glyphosate over the top of maize for broad-spectrum weed control.

b) Types of products planned to be placed on the market according to the authorisation applied for

The scope of the current application is for cultivation of MON 88017 in the E.U., which complements the scope of Monsanto's pending application EFSA-GMO-CZ-2005-27. The range of uses of this maize will be identical to the full range of equivalent uses of conventional maize.

c) Intended use of the product and types of users

MON 88017 will be cultivated, traded and used in the E.U. in the same manner as current commercial maize and by the same growers and operators currently involved in the production, storage, transport, processing and use of maize.

[7] Cry3Bb1 protein expressed in MON 88017

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

MON 88017 is substantially equivalent to conventional maize except for its protection against target coleopteran pests and its tolerance to glyphosate, which are traits of agronomic interest. This maize was shown to be as safe and as nutritious as conventional maize. Therefore, MON 88017 and derived products will be stored, packaged, transported, handled and used in the same manner as the commercial maize products. No specific instructions and recommendations for use, storage and handling are therefore warranted or required.

e) Any proposed packaging requirements

MON 88017 is substantially equivalent to conventional maize (except for its protection against targeted coleopteran insect pests and its tolerance to glyphosate). Therefore, MON 88017 and derived products will be used in the same manner as other maize and no specific packaging is foreseen. (For the labelling, *see* question A.8.(f)).

f) Any proposed labelling requirements in addition to those required by Community law (Annex IV of Directive 2001/18/EC; Regulation 1829/2003 art. 13 and 25)

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 88017 and derived products.

The applicant and his licensees will sell certified MON 88017 seed for planting in the E.U. Seed vendors shall be required to label seed bags containing MON 88017 varieties with the words "genetically modified maize" or "contains genetically modified maize" as well as the product's unique identifier MON-88Ø17-3.

Operators shall be required to label products containing or consisting of MON 88017 with the words "genetically modified maize" or "contains genetically modified maize", and shall be required to declare the unique identifier MON-88Ø17-3 in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 88017 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.

Growers and operators handling or using MON 88017 grain and 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, growers and operators in the food/feed chain will be fully aware of the traceability and labelling

requirements for MON 88017.

Therefore, no further specific measures are to be taken by the applicant.

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-88Ø17-3

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 88017 is suitable for cultivation in all maize production regions in 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

The scope of this application is for cultivation of varieties of MON 88017 in the E.U.

MON 88017 is substantially equivalent to conventional maize except for the introduced coleopteran-protection and glyphosate-tolerance traits which are traits of agronomic interest. Moreover, the information presented in this application established that MON 88017 is as safe and as nutritious as conventional maize and unlikely to pose any threat to the environment or to require special measures for its containment. Therefore, any measures for waste disposal and treatment of MON 88017 products are the same as those for conventional maize and no specific conditions are warranted or required for the placing on the market of MON 88017.

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

1. Complete name

a)	**Family name** Poaceae (formerly Gramineae)
b)	**Genus** *Zea*
c)	**Species** *mays* (2n=20)
d)	**Subspecies** *mays*
e)	**Cultivar/breeding line** A x Hi-II
f)	**Common name** Maize; Corn

2. a) Information concerning reproduction

(i)	***Mode(s) of reproduction*** Maize (*Zea mays*) reproduces sexually. It is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, which encourages the natural outcrossing between maize plants. 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*** 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*** 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

In Europe, the potential for genetic transfer and exchange with other organisms is limited to other maize plants. Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. All maize will inter-pollinate, except for certain popcorn varieties and hybrids that have one of the gametophyte factors (*GaS*, *Ga*, and *ga* allelic series) on chromosome 4. Maize pollen, therefore, moves freely within an area, lands on silks of the same variety or different varieties, germinates almost immediately after pollination, and within 24 hours completes fertilisation.

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 domestication. 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, due to its relatively large mass and size (90 – 100 µm), the vast majority does not move more than a few

meters from the crop in significant quantities. Most maize pollen falls within five meters of the field edge with smaller amounts of pollen deposited usually in a downwind direction.

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 and increase the chance of fungal infection.

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 E.U. and represents a significant portion of global maize production. 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

Like other plants, cultivated 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 and the toxic and allergenic risk posed from consumption of maize and derived products is likely to be very low.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 88017 was produced by *Agrobacterium*-mediated transformation of immature embryos of A x Hi-II maize tissue.

2. Nature and source of the vector used

The plasmid vector PV-ZMIR39 was used for the transformation of maize cells to produce MON 88017. It was constructed using standard molecular biology techniques. It is a disarmed, binary *Agrobacterium tumefaciens* transformation vector that contains both left and right transfer-DNA (T-DNA) border sequences to facilitate transformation. The T-DNA region contains the *cp4 epsps* and *cry3Bb1* gene expression cassettes, and is the portion of plasmid PV-ZMIR39 that is integrated into the maize genome during the transformation process.

3. Source of donor DNA, size and intended function of each constituent fragment of the region intended for insertion

Starting from the left border, the region intended for insertion contains: 1) the *cp4 epsps* coding sequence (CS-*cp4 epsps*) joined to a DNA targeting sequence coding for the chloroplast transit peptide 2 (TS-*CTP2*), regulated by the 5' untranslated end of the rice actin 1 sequence containing the promoter (P-*Ract1*) and first intron (I-R*act1*), and the nopaline synthase 3' transcript termination sequence (T-*nos*); and 2) the *cry3Bb1* coding sequence (CS-*cry3Bb1)* regulated by the enhanced 35S plant promoter (P-*e35S*), a 5' untranslated leader of the wheat chlorophyll a/b/-binding protein (L-*Cab*), the I-*Ract1*, and the 3' transcript termination sequence for wheat heat shock protein 17.3 (T-*Hsp17*).

A detailed description of all elements is presented in Table 1.

D. INFORMATION RELATING TO THE GM PLANT

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

MON 88017 expresses:

1. the modified Cry3Bb1 protein, derived from *Bacillus thuringiensis* subsp. *kumamotoensis*, which provides protection against certain coleopteran pests (*Diabrotica* spp.),
2. the CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4 which provides tolerance to glyphosate.

By using MON 88017, growers will have the possibility to control corn rootworm larvae, an insect pest that is spreading through the Danube basin and already established in some European countries (*see* CRW distribution maps for 2007[8]), and to apply glyphosate herbicides over the top of MON 88017 maize for broad-spectrum weed control with a minimal risk of crop injury.

2. Information on the sequences actually inserted or deleted

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

MON 88017 has 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)

No deletion was intended in the development of MON 88017. Nonetheless, results of the molecular analysis at the insertion site demonstrated that 25-27 base pairs were deleted, likely when the T-DNA in MON 88017 was inserted into the maize genome.

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

The presence of the MON 88017 insert in the nuclear genome is demonstrated by the Chi square analysis of the segregation results. The Chi square analysis of the segregation pattern, according to Mendelian genetics, was consistent with a single site of insertion into the maize nuclear.

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

MON 88017 contains one copy of the T-DNA at a single integration locus on an approximately 13 kb *Sca* I restriction fragment. No additional elements from the transformation vector PV-ZMIR39, linked

[8] http://www.entm.purdue.edu/wcr/

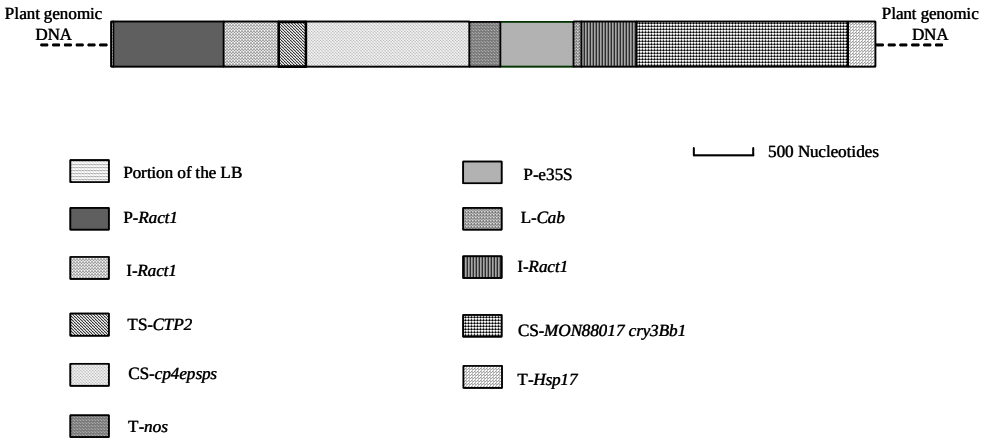
or unlinked to intact cassettes, were detected in the genome of MON 88017. Additionally, MON 88017 does not contain any detectable plasmid backbone sequence. Finally, PCR and DNA sequence analyses allowed to determine the 5' and 3' insert-to-plant junctions and confirmed the organisation of the elements within MON 88017 insert (*see* Table 1). These data support the conclusion that only the two expected full-length proteins, Cry3Bb1 and CP4 EPSPS, are encoded by the DNA insert present in MON 88017. A schematic representation of the MON 88017 insert is given in Figure 1.

Table 1. Summary of the genetic elements inserted in MON 88017

Genetic Element	Size (~kb)	Function (Reference)
B-Left Border	0.02	Portion of the left border sequence from *Agrobacterium tumefaciens* involved in transfer of T-DNA
P-*Ract1*	0.93	Promoter from the rice actin gene
I-*Ract1*	0.48	Intron from the rice actin gene
TS-*CTP2*	0.23	DNA sequence coding for the N-teminal chloroplast transit peptide
CS-*cp4 epsps*	1.37	DNA sequence coding for the native CP4 EPSPS protein
T-*nos*	0.25	3' transcript termination sequence of the nopaline synthase (nos) coding sequence from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation
P-*e35S*	0.61	Promoter and leader for the cauliflower mosaic virus (CaMV) *35S* RNA containing the duplicated enhancer region
L-*Cab*	0.06	5' untranslated leader of the wheat chlorophyll a/b-binding protein
I-*Ract1*	0.48	Intron from the rice actin gene
CS-*cry3Bb1*	1.96	DNA sequence coding for a synthetic variant of Cry3Bb1 protein from *Bacillus thuringiensis*
T-*Hsp17*	0.21	3' transcript termination sequence for wheat heat-shock protein 17.3, which ends transcription and directs polyadenylation

B - Border region.
P - Promoter
I - Intron
TS - Targeting sequence
CS - Coding sequence
T - Transcript termination sequence
L - Leader
Cry3Bb1 refers to the protein expressed by MON 88017, unless otherwise stated

Figure 1. Schematic representation of the MON 88017 insert



3. Information on the expression of the insert

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

The levels of the Cry3Bb1 and CP4 EPSPS proteins in various tissues of MON 88017 produced from 2002 in the U.S. and 2006 in the E.U., were measured using enzyme-linked immunosorbent assay (ELISA).

In 2002, MON 88017 and conventional maize were planted at three field locations, situated in the major maize-growing region of the U.S.A. A randomized complete block design with three replications was used at all sites. The following tissues were collected: overseason leaf samples (OSL 1-4), overseason whole plant (OSWP 1-4), and overseason root (OSR 1-4), young leaf, pollen, silk, forage, forage root, scenecent root, grain and stover tissues.

In 2006, trials were conducted in seven locations, situated in Germany and Spain, which are representative of maize producing regions suitable for commercial production. A randomized complete block design containing MON 88017, as well as the control, with three replications was used at each site. Over season leaf (OSL 1-4), over season root (OSR 1-4), over season whole plant (OSWP 1-2), forage root, senescent root, pollen, silk, and grain tissues collected from each plot at all field sites, were analysed.

Results of these analyses confirm expression of the Cry3Bb1 and CP4 EPSPS proteins throughout key developmental stages of MON 88017 and in all parts of the plant. The range of Cry3Bb1 and CP4 EPSPS protein levels from MON 88017 grown in the E.U. are similar to the corresponding range of expression levels obtained from data collected from other field trials where Cry3Bb1 and CP4 EPSPS protein expression levels in MON 88017 were assessed. Generally, levels of the Cry3Bb1 and CP4 EPSPS proteins declined over the growing season.

b) Parts of the plant where the insert is expressed

Cry3Bb1 and CP4 EPSPS proteins were found to be expressed in leaf, root, pollen, silk, forage, forage root, grain, stover and senescent root at appropriate times of plant development. Grain and forage are the most relevant tissues for the food and feed safety assessment of MON 88017, while leaf, root, pollen, silk and stover are relevant tissues in terms of environmental risk assessment.

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

a) Reproduction

Agronomic data collected from trials performed with MON 88017 in the U.S.A. in 2002 and in the E.U. in 2006 demonstrated that MON 88017 has not been altered in survival, multiplication or dissemination characteristics when compared to conventional maize varieties. The introduced traits for coleopteran-protection and glyphosate-tolerance have no influence on maize reproductive morphology and hence no changes in seed dissemination would be expected.

Observational data from comparative assessments in the field using MON 88017 and experience from commercial plantings in the U.S.A. show that no biologically relevant differences exist between MON 88017 and conventional maize.

b) Dissemination

The introduced traits have 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 outside cultivation without human intervention. Field observations have demonstrated that MON 88017 has not been altered in its survivability when compared to conventional maize.

d) Other differences

Comparative assessments in the field did not reveal any biologically significant differences between MON 88017 and conventional maize hybrids, except for the introduced traits that are of agronomic interest.

5. Genetic stability of the insert and phenotypic stability of the GM plant

MON 88017 contains one insert with a single copy of the transformed DNA, which is stably integrated into the nuclear maize genome. The insert is inherited in a Mendelian fashion. This has been confirmed by Southern blot analyses.

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 88017 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 88017 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.) is unlikely to be different for MON 88017, when compared to conventional maize varieties.

Further, as no intrinsic hazard is related to the potential outcrossing of the inserted traits, the environmental risk assessment for this maize concluded that the risk of harm arising from plant to plant gene transfer from MON 88017 is negligible

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

MON 88017 was compared with a conventional control maize with similar genetic background, as well as with other commercially available maize hybrids.

7.2 Production of material for comparative assessment

a) number of locations, growing seasons, geographical spreading and replicates

2002 U.S. field season
MON 88017 and the conventional control maize were grown at three replicated field sites in major maize-growing areas of the U.S.A. (Iowa, Illinois and Nebraska) during the 2002 field season.

2003-2004 Argentinean field season
MON 88017 and the conventional control maize were grown at four replicated field sites across Argentina during the 2003-2004 field season.

2006 E.U. field season
MON 88017 and the conventional control maize were grown at seven replicated field sites across the E.U. during the 2006 field season.

b) the baseline used for consideration of natural variations

The three studies compared MON 88017 to control maize. Reference hybrids were grown under similar conditions as the test and control. Where statistical differences occurred between MON 88017 and the control maize, the measured analyte was compared to a confidence interval developed from the reference hybrids. Differences were also compared to historical ranges and ranges reported in literature.

7.3 Selection of material and compounds for analysis

The compounds that were selected for analysis in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD.

Based on the positive results of these extensive compositional analyses conducted for MON 88017 compared to conventional maize, there is no indication to further analyze other selected compounds in this maize.

7.4 Agronomic traits

Field trials with MON 88017 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, MON 88017 is equivalent to conventional maize, except for the introduced insect-protection and glyphosate tolerance traits.

7.5 Product specification

MON 88017 will be used in the E.U. by growers and operators that have traditionally been involved in the production, commerce, processing and use of maize and maize-derived products in the European Union.

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 88017 is substantially equivalent and as safe and as nutritious as conventional maize, the use of MON 88017 for the production of foods and feeds is no different from that of conventional maize. Consequently, any effects of the production and processing of MON 88017 are not expected to be any different from the production and processing of the equivalent foods and feeds originating from conventional maize.

7.7 Anticipated intake/extent of use

There are no anticipated changes in the intake and/or extent of use of maize or derived products for use as or in food or feed as a result of the addition of MON 88017 to the conventional maize supply. MON 88017 is expected to replace a portion of current maize hybrids such that its intake or use will represent some fraction of the total products derived from maize.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

MON 88017 expresses the Cry3Bb1 and CP4 EPSPS proteins in the same plant. An assessment of their human and animal safety was conducted based upon the extensive characterization of these two proteins.

An assessment of safety of the Cry3Bb1 leads to the following conclusions, which are similar to the conclusions reached for the MON 863 Cry3Bb1[9] protein that was considered as safe by EFSA:

a) A history of safe use of Cry3Bb1 protein can be established based on similarity to the wild type Cry3Bb1 protein present in Raven (Ecogen, Inc.) bioinsecticide and to the Cry3Bb1 protein produced in MON 863. The safety and nutritional assessment of MON 863 has been previously reviewed by EFSA and a positive scientific opinion was adopted. MON 863 was planted commercially for the first time in 2003 in the U.S.A. In 2007, over 8 million hectares of this crop, alone or in combination with other traits, was grown worldwide.

b) No biologically relevant structural similarities were observed between the Cry3Bb1 protein expressed in MON 88017 and pharmacologically active proteins that are known to cause adverse health effects in humans or animals.

c) Results from the acute oral toxicity study demonstrated that the Cry3Bb1 protein is not toxic and does not cause any adverse effects.

d) Digestibility studies demonstrate that the Cry3Bb1 protein is rapidly degraded in simulated digestive fluids and would be unlikely to elicit potential toxic effects.

e) Acceptable margins of exposure for the Cry3Bb1 protein expressed in MON 88017 indicate that there is no health risk associated with dietary exposure to this introduced protein in MON 88017.

The analysis of the CP4 EPSPS protein leads to the following conclusions, which are similar to the conclusions reached for the CP4 EPSPS protein produced in a number of glyphosate tolerant crops, such as NK603 that was considered as safe by EFSA:

a) A history of the safe use of CP4 EPSPS protein has been demonstrated based on the similarity of the CP4 EPSPS protein in MON 88017 to EPSPSs naturally present in food crops (*e.g.*, soybean and maize) and in microbial food sources such as Baker's yeast (*Saccharomyces cerevisiae*), and to the CP4 EPSPS protein produced in a number of other glyphosate-tolerant crops that have already completed the regulatory process, including soybean, NK603 maize, cotton

[9] Cry3Bb1 protein expressed in MON 863

and canola. CP4 EPSPS-expressing crops have been cultivated since 1996 on an aggregate area of more than 100 million hectares worldwide.

b) No biologically relevant structural similarities were observed between the CP4 EPSPS protein and toxic or pharmacologically active proteins that are known to cause adverse health effects in humans or animals.

c) Results from the acute oral toxicity study demonstrate that the CP4 EPSPS protein is not toxic and does not cause any adverse effects.

d) Digestibility studies demonstrate that the CP4 EPSPS protein is rapidly degraded in simulated digestive fluids and would be unlikely to elicit potential toxic effects.

e) Acceptable margins of exposure for the CP4 EPSPS protein indicate that there is no health risk associated with dietary exposure to this introduced protein in MON 88017.

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 88017 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the introduced proteins is 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.

MON 88017 was shown to be substantially equivalent to conventional maize, except for the introduced coleopteran-protection and glyphosate-tolerance traits, and as safe and as nutritious as any other, commercially available maize.

7.8.4 Testing of the whole GM food/feed

The compositional and nutritional equivalence of grain and forage from MON 88017 and conventional maize have been established by compositional analysis. Additionally, the wholesomeness of MON 88017 grain has been confirmed by repeat-dose animal feeding studies in rat and in broiler chickens using MON 88017-containing diets. These studies confirm the absence of any toxic effects associated to the introduced proteins and the absence of any unanticipated or pleiotropic effects linked to the genetic modification. There was no evidence of any adverse effects on human or animal health.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

Cry3Bb1 and CP4 EPSPS have already been evaluated for allergenicity in the context of MON 863 and NK603 maize applications (2001/18/EC Directive and Regulation (EC) N° 258/97) that received EFSA positive scientific opinions.

These proteins were assessed for their potential allergenicity by a variety of tests, including a) whether the proteins came from allergenic or non-allergenic sources, b) absence of structural similarity of the protein to known allergens, and c) pepsin stability of the protein in an *in vitro* digestion assay, d) calculation of the proportion of Cry3Bb1 and CP4 EPSPS proteins to the total protein in MON 88017 grain. 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

Maize is not considered a common allergenic food. Food allergies to maize are of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to maize dust have been reported.

As MON 88017 is substantially equivalent and as safe as conventional maize, there is no reason to expect that the use of MON 88017 will increase the potential for allergenicity. Further, as the introduced proteins in MON 88017 do not have any allergenic potential, it was concluded that the use of MON 88017 for food or feed does not lead to an increased risk for allergenic reactions compared to the equivalent range of food and feed uses of conventional maize.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in MON 88017 are of agronomic interest, and are not intended to change any nutritional aspects of this maize. Hence this maize is not expected to be more or less attractive for use as food (or feed), for processing, or as a food (or feed) ingredient. Therefore, anticipated dietary intake of maize-derived foods and feeds is not expected to be altered upon commercialisation of MON 88017, and no nutritional imbalances are expected as a result of the use of MON 88017.

7.10.2 Nutritional assessment of GM feed

A confirmatory feeding study in broiler chicken was conducted to compare the nutritional value of MON 88017 grain and conventional control grain as well as commercial maize hybrids, and to provide 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 broiler chickens fed the MON 88017 diet and the conventional control diet. The MON 88017 diet was as wholesome as its

corresponding conventional control diet and commercially available reference diets regarding its ability to support the growth of broiler chickens. This conclusion was consistent with the evaluation of the composition of the MON 88017, which showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference maize hybrids. These data confirm and support the conclusion that the MON 88017 is as safe and nutritious as conventional maize.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of MON 88017 was conducted on the basis of its substantial equivalence to conventional maize (except for the introduced traits) and by extensive characterisation of the introduced traits, which are of agronomic interest, resulting in the expression of the Cry3Bb1 and CP4 EPSPS proteins.

There are no intrinsic hazards related to MON 88017 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 88017 demonstrates that the risks of consumption of MON 88017 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional maize and maize-derived products.

As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this maize for food, feed or processing is neither warranted, nor appropriate.

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

MON 88017 carries two introduced proteins, the Cry3Bb1 and the CP4 EPSPS, which confer protection against damage from certain coleopteran insect pests and tolerance to glyphosate herbicide, respectively. Since the CP4 EPSPS protein confers glyphosate-tolerance to the maize plant and does not have any target organism, target organisms for MON 88017 will be limited to those of the Cry3Bb1 protein.

The Cry3Bb1 protein present in MON 88017 confers protection against certain economically damaging coleopteran insect pests, in particular the larvae of *Diabrotica* spp (corn rootworm). This species may be considered the target organism which interacts with MON 88017.

The Cry3Bb1 protein must be ingested by a susceptible insect to produce an insecticidal effect. Following ingestion, Cry3 proteins are solubilized and the released Cry protein is proteolytically processed by digestive enzymes, to activate the toxin. The activated form of the Cry3 protein must traverse the insect midgut peritrophic membrane and selectively bind to specific receptors to exert its insecticidal activity. In susceptible organisms, cation-selective pores are formed by the Cry3Bb1 protein disrupting cell homeostasis and ultimately leading to the death of the insect.

The rootworms are economically important pests of maize spreading in E.U. maize-growing regions. By using MON 88017, growers will have the possibility to control corn rootworm larvae through a rational strategy which reduces the environmental costs associated with the use of traditional insecticides

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

9.1 Persistence and invasiveness

Like for conventional maize, the likelihood of this maize to spread within cultivated fields or beyond the agricultural environment where it is grown is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in MON 88017 when compared to conventional maize. In the unlikely event of the establishment of MON 88017 plants in the environment, the introduced traits would confer only a limited selective advantage (protection against coleopteran pest, tolerance to glyphosate) of short duration, narrow spatial context and with negligible consequences for the environment. Hence the risk of establishment and spreading of MON 88017 in the environment is negligible.

9.2 Selective advantage or disadvantage

Compared with conventional maize, the presence of the introduced traits in MON 88017 would only confer a meaningful advantage under specific conditions, *i.e.* where target coleopteran pest species would be present in sufficiently high numbers or where plants would be treated with glyphosate herbicide and if no other more important factors limiting its survival in the environment were present. This introduced "advantage" is only relevant in agricultural habitats (*i.e.* in maize fields) and is short in duration. The risk of the coleopteran pest-protection and the glyphosate-tolerance traits in MON 88017 to be the cause of any adverse effects resulting from a competitive advantage or disadvantage is negligible, as maize is unlikely to establish outside cultivation under European conditions (*see* Section D.9.1). When viewed in the context of today's baseline agronomic practices for the production of maize, these advantages present negligible risk to the agricultural environment.

9.3 Potential for gene transfer

There is no potential for gene transfer from MON 88017 to wild plant species in the E.U., while the likelihood for gene transfer to other maize crops, depends mainly on wind, flowering synchrony and distance between the crops. In the event that an introduced gene outcrossed to other maize, its transfer would only confer a selective advantage under specific conditions (*i.e.* upon attack by the target insect and /or applications of glyphosate- containing herbicide), as discussed in Section 9.2. Therefore, gene transfer from MON 88017 to other maize crops is not considered to constitute an adverse environmental effect in itself and the environmental risk posed by this potential transfer to other maize crops, and hence by MON 88017, is negligible.

9.4 Interactions between the GM plant and target organisms

Since the CP4 EPSPS protein in MON 88017 confers glyphosate-tolerance to the maize plant and does not have any target organism, target organisms for MON 88017 will be limited to those of Cry3Bb1 protein, *i.e.* corn rootworm species.

Control of pest species is not considered adverse to the environment in an agro-ecosystem. The theoretical adverse effects of MON 88017 on non-target organisms (through indirect interactions) cannot be considered different from the effects produced by other coleopteran pest control measures, such as insecticide applications in conventional maize. Therefore, MON 88017 poses no increased risk to these organisms, compared to conventional maize.

The only identified potential consequence from interactions between MON 88017 and its target coleopteran pests, if it occurs, would be the development of resistance in the target pests to the insecticidal Cry3Bb1 protein expressed in MON 88017. However, since an Insect Resistance Management (IRM) plan will be put in place in those countries where MON 88017 will be commercially planted, the risk for insect resistance to Cry3Bb1 to occur will be negligible.

9.5 Interactions of the GM plant with non-target organisms

As MON 88017 and conventional maize are not different with respect to their phenotypic, agronomic characteristics and ecological interactions (except for the introduced coleopteran-protection and glyphosate-tolerance traits), it was concluded that the impact of MON 88017 on NTOs in the environment is not different from that of conventional maize. Furthermore, the potential exposure of NTOs to the introduced Cry3Bb1 and CP4 EPSPS proteins presents no conceivable mechanism for causing adverse effects because of their specificity and properties.

A conclusion of negligible hazard for the Cry3Bb1 protein expressed in MON 88017 on NTOs is supported by the history of safe use of *Bt* microbial pesticides, the mode of action of Cry3 proteins and their spectrum of activity. As well, based on the natural occurrence and history of exposure of NTOs to the CP4 EPSPS and related EPSPS proteins, which are known as a class of proteins without any conceivable mechanism for biological activity toward other organisms, there is no *a priori* reason to suspect that the CP4 EPSPS proteins could be harmful to NTOs. The non-hazardous nature of the Cry3Bb1 and the CP4 EPSPS proteins to NTOs was further confirmed in first tier NTO studies. Therefore, the risk for any adverse effects to NTOs, through their ecological interactions with MON 88017 or through contact with the produced Cry3Bb1 or CP4 EPSPS proteins, is negligible.

9.6 Effects on human health

The likelihood for any adverse effects, occurring in humans as a result of their contact with this maize, is no different from that for conventional maize, as MON 88017 contains the Cry3Bb1 and CP4 EPSPS proteins, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

9.7 Effects on animal health

The likelihood of potential adverse effects in animals fed on MON 88017 and in humans, consuming those animals, is negligible (*see* Sections D.7.8, D.7.9, D.7.10). Therefore, the risk of MON 88017 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

There is no evidence that MON 88017 plants would be any different from conventional maize regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as MON 88017 is compositionally equivalent and has equivalent growth and development, morphology, yield, plant health and survival characteristics to conventional maize (*see* Sections D.4, D.7.1 and D.7.4). The Cry3Bbl protein is subjected to rapid degradation in soil and the CP4 EPSPS proteins belong to the safe class of EPSP synthases that are ubiquitous in the environment.

9.9 Impacts of the specific cultivation, management and harvesting techniques

As MON 88017 is equivalent to conventional maize, except for the introduced coleopteran-protection and glyphosate-tolerance traits, all the agronomic practices currently used to grow maize in the E.U. remain applicable for growing MON 88017. Additionally, the possibility of using glyphosate herbicides for weed control in crop is added to the farmer's weeding options, which already include the use of glyphosate in inter-row treatments in some countries.

Pest and weed control is an established baseline management technique in maize. The introduced coleopteran-protection and glyphosate-tolerance traits in maize merely provide the farmer with an additional option or tool to control coleopteran pests and remove competing weeds from the crop. Therefore, cultivation of MON 88017 instead of conventional maize does not change any basic management technique in maize as such, but gives growers more flexibility to apply the existing tools for management, while creating at the same time new opportunities to grow maize in a more sustainable way (*e.g.* reduced tillage, reduced insecticide applications, or integrated pest management). It should be noted that the importance and aim of the basic management technique of removal of harmful insect pests and weeds from the MON 88017 field in order to achieve optimal yield of the crop, is neither new nor different compared to conventional maize. In order to secure the valuable agronomic and other benefits of coleopteran-protected maize on a longer term, an IRM plan was developed, as described in Section D.9.4.

In conclusion, in comparison to any other maize, no typical characteristics of the genetically modified plant could be identified, which may cause adverse effects on the environment through a need to change management practices. Therefore, the environmental impact of farming practices to grow MON 88017 in the E.U. is considered no different from any other maize.

10. Potential interactions with the abiotic environment

Like other plants, cultivated maize is known to interact with the abiotic environment (soil, water and air), *e.g.* establishment of roots in the soil, nutrient and water uptake and gas exchange. Maize production in general is known to have indirect impacts on biophysical and biogeochemical processes in the soil through tillage, fertilizer application, and establishment of a monoculture in a defined area. All the agronomic practices currently used to grow maize in the E.U. remain applicable for growing MON 88017 and no specific techniques for cultivation, management and harvesting are required.

As MON 88017 was shown to be substantially equivalent to conventional maize (except for the introduced coleopteran-protection and glyphosate-tolerance traits) with respect to its composition, phenotypic and agronomic characteristics, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

11.1 General (risk assessment, background information)

As the scope of this application under Regulation (EC) No 1829/2003 includes the use of MON 88017 for the cultivation of varieties in the E.U., a monitoring plan in accordance with Annex VII of Directive 2001/18/EC was included, as required by Articles 5(5) and 17(5) of the said Regulation.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) for MON 88017 was conducted as required by Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003. Analysis of the characteristics of MON 88017 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of MON 88017 in the E.U. is consistently negligible.

The e.r.a. describes, however, that specific strategies for risk management are required with regards to the interaction between the GM plant and target organisms. Insect Resistance Management (IRM) measures will be put in place in MON 88017 cultivating countries to pro-actively avoid and in any case delay insect resistance development. Therefore, the applicant proposes to set up case-specific post marketing monitoring (CSM) actions, in the form of Insect Resistance Monitoring.

The monitoring will further concentrate on general surveillance (GS) to allow the identification of adverse effects of MON 88017 or its use on human health or the environment, which were not anticipated in the e.r.a.

11.3 Case-specific GM plant monitoring (approach, strategy, method and analysis)

The conclusions of the e.r.a. (described in Section D.9) consistently show that the placing on the market of MON 88017 poses negligible risk to human and animal health and the environment. Specific strategies for risk management are however required with regard to the interactions between the GM plant and target organisms. Insect resistance management measures will be put in place in MON 88017 cultivating countries to proactively avoid and in any case delay insect resistance development. The party placing the GM plant on the market will therefore set up CSM actions in the form of insect resistance monitoring, as described in the IRM plan presented by the applicant.

11.4 General surveillance of the impact of the GM plant (approach, strategy, method and analysis)

Any potential adverse effects of MON 88017 on human health and the environment, which were not anticipated in the environmental risk assessment, are addressed by the general surveillance plan.

General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

For general surveillance of MON 88017, the party placing MON 88017 on the market will use several tools. The central tool is an annual farm questionnaire addressed to a subset of farmers cultivating MON 88017. Additionally, information from other sources (company stewardship programmes, scientific literature, official websites and existing observation networks) will be incorporated, where appropriate

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of MON 88017 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

11.5 Reporting the results of monitoring

Any recorded observations of adverse findings that are linked to the cultivation and/or use of this maize, which come to the attention of the party placing the GM plant on the market, will receive careful analysis in real time and remediating action, where applicable. Adverse reports will be discussed in the mandatory general surveillance report. The general surveillance reports will be sent to the European Commission,

which will distribute to all Competent Authorities in the E.U. General Surveillance reports will be prepared on an annual basis, except in case of adverse findings that need immediate risk mitigation, which will be reported as soon as possible.

Since monitoring of GM plants is a new topic and a creative process, the monitoring plan and especially the questionnaires can be improved based on experience from year to year.

12. Detection and event-specific identification techniques for the GM plant

MON 88017 will be detectable using the insert-specific PCR method for detecting the introduced DNA present in MON 88017. The proteins present in MON 88017 may also be detected by an appropriate ELISA method.

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

Monsanto notifications under Part B of the Directive 2001/18/EC: B/FR/06/12/10, B/FR/06/12/11, B/FR/06/01/02, B/FR/05/04.01, B/ES/06/02, B/ES/07/04, B/DE/05/169, B/DE/06/185.

b) Conclusions of post-release monitoring

The E.U. field trials with MON 88017 conducted to date aimed at collecting data for regulatory purposes and for variety registration. Post-release monitoring provided no significant evidence that MON 88017 is likely to pose any risk of 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 monitoring provided no significant evidence that MON 88017 is likely to 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

First commercialization of MON 88017 took place on approximately 1600 hectares in the U.S.A. in 2007. Prior to its commercialization, MON 88017 has been extensively tested at multiple locations in the field in the U.S.A. since 2000, in Japan in 2002, Argentina in 2003-2004

	and Canada in 2003.
b)	**Authority overseeing the release** U.S.A.: United States Department of Agriculture and Environmental Protection Agency; Japan: Ministry of Agriculture Fisheries and Forestry; Argentina: Secretary of Agriculture (SAGPyA) – CONABIA; Canada: Canadian Food Inspection Agency.
c)	**Release site** U.S.A.: mainly in the states of the corn belt and in Hawaii and Puerto Rico; Japan: Kawasaki prefecture; Argentina: Buenos Aires, Cordoba and Santa Fe; Canada: Ontario (Vienna, Branchton, Exter, Ingersoll, Ayr), Quebec (St. Huques).
d)	**Aim of the release** Commercial release in U.S.A.: All uses as conventional maize Field release in U.S.A./Argentina: assess the performances: efficacy, yield, breeding, … ; in Japan: stage III environmental assessment; in Canada: agronomic evaluation.
e)	**Duration of the release** Commercial release in U.S.A.: 2007 growing season Field release in U.S.A./Argentina: 12 months; in Japan/Canada: 6 months.
f)	**Aim of post-releases monitoring** Field release in U.S.A./Argentina: assess for volunteers.
g)	**Duration of post-releases monitoring** Field release in U.S.A./Argentina: 12 months.
h)	**Conclusions of post-release monitoring** Field release in U.S.A.: volunteers have been eliminated to prevent persistence in the environment; Argentina: nothing to report.
i)	**Results of the release in respect to any risk to human health and the environment** All countries: no evidence that MON 88017 is likely to cause any adverse effects to human or animal health and 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):

a)	**Status/process of approval** The EFSA website[10] provides information related to the applications submitted under Regulation (EC) No 1829/2003 on genetically modified food and feed.
b)	**Assessment Report of the Competent Authority (Directive 2001/18/EC)** A notification for MON 88017 according to Directive 2001/18/EC has not been submitted by Monsanto.
c)	**EFSA opinion** An EFSA opinion, specifically for MON 88017, was not available at the time of submission of this application. Favourable EFSA opinions have been issued, however, for MON 863 and NK603, expressing similar proteins and were posted on the EFSA website[11].
d)	**Commission Register (Commission Decision 2004/204/EC)** The authorised food and feed are entered in the Community Register of GM food and feed[12].
e)	**Molecular Register of the Community Reference Laboratory/Joint Research Centre** Information on detection methods can be found on the JRC website[13].
f)	**Biosafety Clearing-House (Council Decision 2002/628/EC)** 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)** A notification and SNIF according to Directives 2001/18/EC and 2002/812/EC, respectively, have not been submitted for MON 88017. The EFSA website[14] does provide a link to this summary of the application for MON 88017 under Regulation (EC) No 1829/2003.

[10] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html
[11] http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html
[12] http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm
[13] http://gmo-crl.jrc.it/statusofdoss.htm
[14] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html