Part VII

Summary of Application

Application for the Authorization in the European Union of the Glyphosate tolerant **VCO-Ø1981-5** maize and its uses as food and feed (containing, consisting of and produced from) and other products containing or consisting of **VCO-Ø1981-5** maize with the exception of cultivation, in accordance with Regulation (EC) No 1829/2003 on genetically modified Food and Feed.

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1. General Information

1.1. Details of application

(a) Member State of application

Germany

(b) Application number

EFSA-GMO-DE-2016-130

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

VCO-Ø1981-5 maize

(d) Date of acknowledgement of valid application

1.2. Applicant

(a) Name of applicant

GENECTIVE S.A.

(b) Address of applicant

Rue de Limagrain F-63720 Chappes France

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

Not applicable.

1.3. Scope of the application

(a) Genetically modified food

X Food containing or consisting of genetically modified plants
X Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

X Feed containing or consisting of genetically modified plants
X Feed produced from genetically modified plants

(c) Genetically modified plants for food and feed use

X Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
☐ Seeds and other plant propagating material for cultivation in the Union

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

No	X	
Yes	☐	(in that case, specify)

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

Yes	X	
No	☐	(in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

Table 1. List of previous notifications under Part B of Directive 2001/18/EC

Year	Country	Notification Number / Company
2009	Spain	B/ES/09/01 / Limagrain Iberica
2010	Czech Republic	B/CZ/09/04 / Limagrain Central Europe
2010	Slovak Republic	B/SK/10/03 / Limagrain Central Europe
2010	Spain	B/ES/10/47 / Limagrain Iberica
2011	Romania	B/RO/10/04 / Limagrain Romania
2011	Czech Republic	B/CZ/09/04 / Limagrain Central Europe
2011	Slovak Republic	B/SK/10/03 / Limagrain Central Europe
2011	Spain	B/ES/11/16 / Limagrain Iberica
2012	Spain	B/ES/12/31 / Limagrain Iberica
2012	Czech Republic	B/CZ/09/04 / Limagrain Central Europe
2012	Romania	B/RO/10/04 / Limagrain Romania
2012	Slovak Republic	B/SK/10/03 / Limagrain Central Europe
2013	Spain	B/ES/13/10 / Limagrain Iberica
2014	Spain	B/ES/14/02 / Limagrain Iberica

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

No	X	
Yes	☐	(in that case, specify)

1.7. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No	☐	
Yes	X	In that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application.

USA

FDA **For use in human food and animal feed**

Submitted March 5, 2012 Completed May 7, 2013

"Based on the safety and nutritional assessment Genective has conducted, it is our understanding that Genective has concluded that food and feed derived from corn event VCO-Ø1981-5 are not materially different in composition, safety, and other relevant parameters from corn-derived food and feed currently on the market, and that genetically engineered corn event VCO-Ø1981-5 does not raise issues that would require premarket review or approval by FDA."

USDA **Determination of Nonregulated Status**

Submitted December 7, 2011 Approved September 25, 2013

"In addition to our finding that Event VCO-Ø1981-5 maize is not likely to pose a plant pest risk, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status of Event VCO-Ø1981-5 maize and its progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed habitats."

Canada

CFIA **Approval for unconfined release into the environment**

Submitted July 18, 2012 Approved February 14, 2014

Approval for use as a livestock feed

Submitted July 18, 2012 Approved February 14, 2014

"The feed safety assessment of Maize Event VCO-Ø1981-5 was completed on the basis of information in these documents by the AFD. Taking into account this assessment, the AFD has determined that Maize Event VCO-Ø1981-5 is as safe and nutritious as traditional maize varieties; therefore, Maize Event VCO-Ø1981-5 and its products are considered to meet the present ingredient definitions and are approved for use of lifestock feed ingredients in Canada."

Health Canada **Food Safety Approval**

Submitted July 18, 2012 Approved February 12, 2014

"Based on our evaluation of the submitted information, we have no objection to the sale of food derived from herbicide tolerant maize event VCO-Ø1981-5 for human food use in Canada."

Argentina

SENASA **Food**

Submitted September 04, 2015

CONABIA **Cultivation**

Submitted September 04, 2015

Japan

MHLW **Food**

Submitted April 27, 2015

MAFF **Feed**

Submitted April 27, 2015

South Korea

MFDS **Food**

Submitted August 28, 2014

RDA **Feed**

Submitted August 27, 2014

Taiwan

TFDA **Food/Feed**

Submitted January 19, 2015

China

MOA **Food/Feed**

Submitted October 30, 2013

1.8. General description of the product

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

The maize (*Zea mays* L.) parental plant used for transformation is the maize line Hi-II. VCO-Ø1981-5 maize contains a gene cassette encoding the protein, EPSPS ACE5, which confers tolerance to the herbicide glyphosate.

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

The scope of this application includes viable grain as well as processed products of glyphosate tolerant VCO-Ø1981-5 maize, produced outside of the EU, imported into the EU for processing and their uses as food and feed (containing, consisting of and produced from) (see section 1.3). The range of uses in the EU of VCO-Ø1981-5 maize will be identical to the full range of uses of conventional maize with the exception of cultivation.

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

The only difference between VCO-Ø1981-5 maize and conventional maize is the tolerance to glyphosate. This additional agronomic trait has no effect on the downstream handling of the harvested material and the processed product thereof.

Therefore the intended uses and the type of users for VCO-Ø1981-5 maize are identical to those for conventional maize.

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

No specific use, storage or handling recommendations or instructions are anticipated for food and feed and other products produced from VCO-Ø1981-5 maize.

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

Not applicable.

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

Not applicable.

(g) Any proposed packaging requirements

The packaging of foods and feeds produced from VCO-Ø1981-5 maize will be the same as for conventional maize products.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than Regulation (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003

In accordance with Articles 12(2) and 24(2) of Regulation (EC) No 1829/2003 on genetically modified food and feed, Article 21(2) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Article 7(2) of the Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and food and feed products produced from genetically modified organisms, it is proposed that the current labelling threshold of 0.9 % continues to be applied to the marketing of VCO-Ø1981-5 maize and derived products.

Labelling of foods and feeds consisting of or containing VCO-Ø1981-5 maize:

In accordance with Article 13(2)f and point A(8) of Annex IV of Directive 2001/18/EC, Articles 12-14 and 24-26 of Regulation (EC) No 1829/2003, and

Article 4 of Regulation (EC) No 1830/2003, operators are required to label products containing or consisting of VCO-Ø1981-5 maize with the words “genetically modified maize” or “contains genetically modified maize”, and operators are required to declare the unique identifier VCO-Ø1981-5 in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Labelling of foods and feeds produced from VCO-Ø1981-5 maize:

For food and feed products produced from VCO-Ø1981-5 maize that are not exempted according to Article 5(4) of Regulation (EC) No 1830/2003, operators are required to label foods and feeds derived from VCO-Ø1981-5 maize with the words “produced from genetically modified maize”, in accordance with Articles 12-14 and 24-26 of Regulation (EC) No 1829/2003 and the requirements of Article 5 of Regulation (EC) No 1830/2003. 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 this GM plant is transmitted in writing to the operator receiving the product.

In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

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 No 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food and feed chain will be fully aware of the traceability and labelling requirements for VCO-Ø1981-5 maize.

In the case of products other than food and feed containing or consisting of VCO-Ø1981-5 maize, no further labelling proposal and no specific measures are proposed by the applicant.

(i) Estimated potential demand

(i) In the EU

The potential demand is not quantifiable at present. VCO-Ø1981-5 maize will be used for the same purposes as conventional maize. The agronomic trait does not in itself create additional demands in the downstream food and feed uses. The demand is therefore determined by the demand in the EU for maize products and

by the proportion of conventional as well as other genetically modified maize that will be replaced by VCO-Ø1981-5 maize in the cultivation areas located outside of the EU.

(ii) In EU export markets

Not predictable.

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

The unique identifier for VCO-Ø1981-5 maize is VCO-Ø1981-5.

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

The scope of this application covers the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize in the EU. Therefore, no deliberate release of viable material into the EU environment is expected. However, following the recommendations of the EFSA ERA Guidance (EFSA, 2010) the following environmental exposure routes have to be considered:

Environmental exposure due to accidental spillage of viable plant material from VCO-Ø1981-5 maize during import, transportation, storage, handling or processing,

Exposure through faeces of animals fed with VCO-Ø1981-5 maize,

Exposure through organic plant matter (including pollen) either imported or derived from by-products of industrial processes that used VCO-Ø1981-5 maize.

It is assessed as highly unlikely that vital VCO-Ø1981-5 plants reaching the generative phase and cross-fertilizing conventional maize plants will be established from spilled maize grains outside agro-ecosystems.

In the highly unlikely event of establishment of VCO-Ø1981-5 maize in the receiving environment, volunteer plants could be easily controlled by currently available selective herbicides or by mechanical means. Therefore, no specific measures are recommended in the case of unintended release (spillage or other means) of VCO-Ø1981-5 maize.

EFSA, 2010. EFSA Panel on Genetically Modified Organisms (GMO). Guidance on the environmental risk assessment of genetically modified plants. The EFSA Journal 2010, 8(11), 1879, 111 pp.

2. Information relating to the recipient or (where appropriate) parental plants

2.1. Complete name

(a)	**Family name** Subfamily	***Poaceae*** *Panicoideae*
(b)	**Genus**	***Zea***
(c)	**Species**	***Zea mays* L. (maize)**
(d)	**Subspecies**	***Zea mays subsp. mays* (L.) Iltis (maize, 2n = 20)**
(e)	**Cultivar/breeding line**	**Hi-II**
(f)	**Common name**	**maize, corn**

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

Global

Maize is one of the world's leading cereal crops with rice and wheat. It is grown as a commercial crop in more than 25 countries. Worldwide harvested surfaces of grain maize in Marketing Year (MY) 2012/2013 was of 175 Million Hectares (Mha), with USA and China accounting both 20 % of it followed by Brazil with 9 %. Europe is at the fourth place with 5.4 % of global grain maize harvested area, which corresponds to 9.4 Million Hectares.

Worldwide production of grain maize was about 856 Million Tons (Mt) in MY 2012/2013. The major producers, the USA and China account for 32 % and 24 % respectively, followed by Brazil and Europe with 9 % and 7 % respectively, Argentine with 3 %, Mexico and India both with 2.5 %.

Europe – Grain maize

European harvested surface of grain maize in 2012 was approx. 9.4 Million Hectares (Mha), with Romania representing 29 % and France 18 % of the total surface.

Grain maize European production in 2012 was about 56.5 Mt with France being the main producer with 28 % (16 Mt) followed by Italy with 15 % (8.2 Mt). Romania and Germany produced 11 % (6 Mt) and 10 % (5.5 Mt) of the total European grain maize production respectively.

Europe – Silage maize

A further major maize product is silage maize (or green maize), produced on about 5.3 Mha in the EU in 2009. Silage maize is mainly cultivated for feed use or as substrate for the bio-energy production in biogas plants.

France and Germany (accounting for 28 % of the EU average production area in 2004-2008 each) are the two main producers of silage maize in the EU. Whereas in France the area cultivated for silage maize is similar in size to the area cultivated for grain maize, in Germany silage maize is the predominant maize cultivated.

The largest maize producers (grain and silage) in the EU are Romania, France, Germany, Hungary and Italy, where maize is grown on more than 1 Mha each. Even within a Member State, important regional differences may exist in relation to cultivation of maize.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Maize is a monoecious plant with generative reproduction through seed. There is no vegetative reproduction in maize.

(b) Specific factors affecting reproduction

Pollination occurs mainly through cross-pollination (> 95 %). The pollen is viable for about 30 minutes, under wet and cold conditions longer. It is spread within 25 metres of the originating plant.

(c) Generation time

Maize is an annual crop with a generation time between 5 to 8 months.

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

Maize is only sexually compatible to other *Zea* species. There are neither other cultivated nor wild *Zea* species in Europe.

2.5. Survivability (for environmental safety aspects)

The only known mode of reproduction of maize is via grain/seed.

(a) Ability to form structures for survival or dormancy

The viability of maize grains is very limited in temperate climates. Maize is not known to be persistent or invasive in Europe. Maize seeds do not manifest any dormancy.

(b) Specific factors affecting survivability

Through many years of domestication and selective breeding, maize has lost the ability to survive in the wild and requires human intervention to disseminate its seeds.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Maize grain is disseminated exclusively by sowing on agricultural acreage.

(b) Specific factors affecting dissemination

Pollen is viable only for about 30 minutes. Seed does not exhibit dormancy.

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

No sexually compatible wild relatives of maize are present in the EU.

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

Not applicable.

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

It has to be considered that the scope of this application covers the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize in the EU. Cultivation of VCO-Ø1981-5 maize in the EU is not included in the scope of this application. Accordingly, potential interactions of the GM plant with organisms in EU ecosystems where the plant is potentially or usually grown are not relevant in view of the scope of this application.

Following the recommendations of the EFSA ERA Guidance (EFSA, 2010) environmental exposure due to accidental spillage of viable plant material from VCO-Ø1981-5 maize during import, transportation, storage, handling or processing must be considered. Based on the available information, it is expected that VCO-Ø1981-5 maize will behave identically to conventional maize, apart from its tolerance to glyphosate.

It is assessed as highly unlikely that vital VCO-Ø1981-5 plants reaching the generative phase and cross-fertilizing conventional maize plants will be established from spilled maize grains outside agro-ecosystems.

In the highly unlikely event of establishment of VCO-Ø1981-5 maize in the receiving environment, volunteer plants could be easily controlled by currently available selective herbicides or by mechanical means. Based on the available information, it is expected that VCO-Ø1981-5 maize will behave identically to conventional maize, apart from its tolerance to glyphosate.

EFSA, 2010. EFSA Panel on Genetically Modified Organisms (GMO). Guidance on the environmental risk assessment of genetically modified plants. The EFSA Journal 2010, 8(11), 1879, 111 pp.

3. Molecular characterization

3.1. Information relating to the genetic modification

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

The *Agrobacterium tumefaciens* strain LBA4404 containing plasmid pAG3541 (with the gene of tolerance to glyphosate, *epsps grg23ace5*) was used to produce VCO-Ø1981-5 maize. Only the T-DNA existing between the right and left border (RB and LB) sequences was integrated into the genome of VCO-Ø1981-5 maize.

(b) Nature and source of the vector used

The plasmid pAG3541 contains bacterial antibiotic resistant marker genes, required for the preparation of the transformation vector, and *vir* genes, required for the production of the T-DNA transfer complex. Only the T-DNA existing between the right and left border (RB and LB) sequences is integrated into the genome of VCO-Ø1981-5 maize. The DNA regions outside of the T-DNA borders such as the bacterial antibiotic resistant marker genes and *vir* genes were not transferred.

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

Table 2. Genetic elements of plasmid pAG3541 and their description

Genetic element	Size (bp)	Gene Bank Access number	Vector Nucleotide Location	Description and origin
virC	1306	NC_010929.1	1065-2370	virC operon of pTiBo542 of *Agrobacterium tumefaciens* (Komari *et al*., 1996)
virG	804	NC_010929.1	2481-3284	virG gene of pTiBo542 of *Agrobacterium tumefaciens* (Komari *et al*., 1996)
virB	9463	NC_010929.1	3416-12851	virB operon of pTiBo542 of *Agrobacterium tumefaciens* (Komari *et al*., 1996)
Right border	25	AB027254.1	18084-18108	DNA sequence of right border sequence of nopaline type T-DNA derived from plasmid pTiT37. Used as the initiation point of T-DNA transfer from *Agrobacterium tumefaciens* to the plant genome (Zambryski *et al.,* 1980; Komari *et al.,* 1996).
Intervening sequence	73	NA	18109-18181	Sequences used in DNA cloning.

Genetic element	Size (bp)	Gene Bank Access number	Vector Nucleotide Location	Description and origin
ScUbi4 promoter (Promoter from sugarcane ubiquitin-4 gene)	364	NA	18182-18545	Promoter region of the ubiquitin-4 gene from *Saccharum officinarum* L. (sugarcane) (Albert and Wei, 2003).
ScUbi4 5´UTR (5' untranslated region)	79	NA	18546-18624	5' untranslated region of the ubiquitin-4 gene from *Saccharum officinarum* L. (sugarcane) (Albert and Wei, 2003).
ScUbi4 intron (Intron from sugarcane ubiquitin-4 gene)	1358	NA	18625-19982	Intron region of the ubiquitin-4 gene from *Saccharum officinarum* L. (sugarcane) (Albert and Wei, 2003 and Wei *et al*., 2003).
Intervening sequence	9	NA	19983-19991	Sequences used in DNA cloning.
M(aize)AHAS Chloroplast Transit Peptide	198	X63553.1	19992-20189	N-terminal chloroplast transit peptide sequence derived from the *Zea mays* L. (maize) acetohydoxyacid synthase (*ahas*) gene (Fang *et al.*, 1992). The chloroplast transit peptide allows the expressed protein to be transported to the chloroplast.
Intervening sequence	9	NA	20190-20198	Sequences used in DNA cloning.
epsps grg23ace 5 gene	1242	NA	20199-21440	Coding sequence of the modified 5-enolpyruvylshikimate-3-phosphate synthase from *Arthrobacter globiformis* (Schouten *et al*., 2010)
Intervening sequence	8	NA	21441-21448	Sequences used in DNA cloning.
35S CaMV terminator	270	V00140	21449-21718	Terminator region of the 35S transcript of the cauliflower mosaic virus, which terminates mRNA transcription and induces polyadenylation (Gardner *et al.*, 1981).
Intervening sequence	70	NA	21719-21788	Sequences used in DNA cloning.
Left border	25	AB027254.1	21789-21813	DNA sequence of left border sequence from Ti plasmid pTiA6. Defines the termination point of T-DNA transfer from *Agrobacterium tumefaciens* to the plant genome (Thomashow *et al.,* 1980; Komari *et al.,* 1996).
aadA	789	NA	22989 - 23777	aminoglycoside adenyltransferase gene of *Escherichia coli* (Fling *et al*., 1985).
*tet*R	640	X61367.1	28080 - 28719	tetracycline resistance repressor gene of Tn1721 of *Escherichia coli* (Allmeier *et al*., 1992)
t*et*A	1200	X61367.1	28825 - 30024	tetracyclin resistance gene of transposin Tn1721 of *Escherichia coli* (Allmeier *et al*., 1992)

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3.2. Information relating to the genetically modified plant

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

Certain bacteria are tolerant to glyphosate and it has been found that the EPSPS enzymes isolated from these bacteria often have a high tolerance to glyphosate. The *epsps grg23ace5* gene is an optimized form of the native *epsps grg23* gene sourced from the common soil bacterium *Arthrobacter globiformis* (*A. globiformis*). It confers tolerance to glyphosate.

3.2.2. Information on the nucleic acid(s) sequences actually inserted or deleted

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

The results of the molecular characterization of VCO-Ø1981-5 maize indicate that the event contains a single insert containing the *epsps grg23ace5* gene expression cassette. The results further indicate that the T-DNA segment that contains the *epsps grg23ace5* expression cassette is intact and functional.

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

The insertion process created some short deletions at the extremities of the T-DNA borders – 22 bp and 16 bp on the right and left borders, respectively which resulted in the insert being 3692 bp in size (T-DNA fragment originating from vector plasmid pAG3541 is 3730 bp).

A comparison of the sequences from VCO-Ø1981-5 maize with the Hi-II original sequence also showed that a short deletion (21 bp) in the maize genome was created by the insertion in VCO-Ø1981-5.

However, all regulatory sequences and the *epsps grg23ace5* gene were found to be inserted intact and in the expected order in VCO-Ø1981-5 maize, which was also confirmed by Southern blot analysis.

In further agronomic performance trials and phenotypic observations, VCO-Ø1981-5 maize showed no substantial differences as compared with the conventional counterpart and conventional references. Accordingly it can be concluded that the deletions observed are of negligible relevance.

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

Extensive bioinformatic analysis demonstrates that the insert is located on chromosome 1 in the nucleus of VCO-Ø1981-5 maize plant cell. The laws of segregating in a Mendelian manner are linked to genes on chromosomes in the nucleus.

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

The insertion site was mapped using a BLAST search against the Maize Genetics and Genomics Database and it was determined that the insertion site is located on chromosome 1 of the VCO-Ø1981-5 maize genome.

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

Not applicable.

3.2.3. Information on the expression of the insert

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

The expression of the EPSPS ACE5 protein was detected at five growth stages (V4, V8, R1, R4 & R6) in leaf, root, pollen and grain tissues of VCO-Ø1981-5 maize plants.

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

Expression was detected in all tissues of the VCO-Ø1981-5 plants tested (leaf, root, pollen and grain tissues).

3.2.4. Genetic stability of the insert and phenotypic stability of the genetically modified plant

The stability of the inserted T-DNA segment that contains the *epsps grg23ace5* expression cassette and the phenotypic stability of the introduced glyphosate tolerance trait of VCO-Ø1981-5 maize were confirmed by molecular analyses and glyphosate spray over five consecutive generations. The results supported the presence of a single insertion, segregating in a Mendelian manner.

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

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

VCO-Ø1981-5 maize does not differ from conventional maize in mode nor rate of reproduction.

(b) Dissemination

VCO-Ø1981-5 maize does not differ from conventional maize in dissemination characteristics.

(c) Survivability

VCO-Ø1981-5 maize does not differ from conventional maize in survivability.

(d) Other differences

Not applicable.

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

(a) Plant to bacteria gene transfer

The possibility of horizontal gene transfer (HGT) between VCO-Ø1981-5 maize and prokaryotes has been investigated through homology searches in relevant databases with known microbial genomes.

No region showing significant homology necessary to promote HGT has been detected. The possibility of HGT between VCO-Ø1981-5 maize and microbes has thus been assessed as highly unlikely.

The conclusion from this assessment is that it is very unlikely that the genes present in VCO-Ø1981-5 maize would become established in the genome of micro-organisms in the environment or human and animal digestive tract.

(b) Plant to plant gene transfer

No wild relatives of maize are present in Europe; accordingly a potential gene transfer is limited to other maize varieties planted in the field. Additionally it has to be considered that cultivation of VCO-Ø1981-5 maize is not in the scope of this application and environmental exposure to viable plant material is mainly limited to accidental spillage of maize grains from VCO-Ø1981-5 during import, transportation, storage and handling or processing.

It is further assessed as highly unlikely that vital VCO-Ø1981-5 plants reaching the generative phase and cross-fertilizing conventional maize plants will be established from these spilled maize grains outside agro-ecosystems.

Therefore, the likelihood of this gene transfer to conventional maize plants is evaluated as highly unlikely, the consequence for the health of people and the environment is assessed as marginal and the risk is estimated as negligible.

4. Comparative analysis

4.1. Choice of the conventional counterpart and additional comparators

The comparative analysis of agronomic and phenotypic characteristics as well as the compositional analysis was conducted with genetically modified VCO-Ø1981-5 maize, the conventional counterpart (CCP) and six commercial, non-genetically modified (non-GM) reference maize hybrids.

As the genetic modification introduces an herbicide tolerance trait, the comparison further included treatment with glyphosate (VCO-Ø1981-5) and a conventional herbicide regime (all entries). 'Conventional herbicide regime' means a set of herbicide treatments that are typical for maize grown in the region of each field trial, often known as selective herbicide treatment that would cause minimal damage to the maize crop.

The conventional counterpart (CCP) was produced from a cross of the AAX1 inbred line with the CH02 private inbred. Seeds of VCO-Ø1981-5 maize and the CCP had the same genetic background and differ only by the presence of the transgene.

Six commercial reference hybrids (Agrister, DKC5783, LG3475, LG3490, PR35F38 and PR36K67) were selected representing a wide range of European commercial maize varieties, having FAO indexes bracketing VCO-Ø1981-5 maize and being suitable for cultivation (grain or silage) in the areas where samples were produced.

The commercial reference hybrids are listed varieties in the EU catalog[1], obtained by different maize breeding companies, with a history of safe use as grown across Europe. Coming from different maize breeding companies, these hybrids cover a wide range of germplasm, matched to different FAO units and different European locations. The choice was made on their origin, use (commonly known and grown) and with an attempt to bracket the average maturity of the CCP and VCO-Ø1981-5 maize. However, the germplasm of these reference hybrids is considerably different than the CCP and VCO-Ø1981-5 and not a usual comparison utilized by breeders to develop a new maize variety.

Data from the reference hybrids were used to determine equivalence of the measured parameters.

[1] http://ec.europa.eu/food/plant/propagation/catalogues/database/public/index.cfm?event=homepage

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

The field trials for agronomic performance and for compositional analysis were conducted in the EU in 2010 and 2011; both approaches were only partially conducted at the same locations.

Table 3 provides an overview about the locations of the European field trials for the agronomic performance assessment and the compositional analysis.

For each of both experimental approaches, data from 9 sites were collected and assessed.

Table 3. European field trials

Field Trial Site	2010	2011	2010	2011
	"Composition" locations		"Agronomic" locations	
Muruzábal de Andión, Spain	X			
Ejea de los Caballeros, Spain	X			
Murillo el Cuende, Spain	X			
Borovce, Slovak Republic	X	X	X	X
Gabčíkovo, Slovak Republic	X		X	X
Troubsko, Czech Republic	X	X	X	
Tamarite de Litera, Spain		X		
Caracal, Romania				X
Caslav, Czech Republic				X
Ivanovice, Czech Republic				X
Sal'a, Slovak Republic				X

4.2.1. Compositional analysis

Locations

Material for the compositional analysis of both forage and grain from VCO-Ø1981-5 maize was produced at six field locations across the EU maize growing area in 2010 and three locations in 2011.

The nine field trials were located in seven different locations (Table 3), two of which were planted in both years 2010 and 2011. The trial locations in Spain, the Slovak Republic and the Czech Republic are representative of most of the maize growing areas in Europe, both for grain and silage.

The field sites were planted in a randomized block design with five replications per entry/treatment. The plot size for each location was from 20.8 to 28 m^2, according to locations, with four rows per replicate. The planting population and all agronomic practices were representative of those used for maize production in

each study location.

In order to produce grain, hand pollinations were conducted within each replicate. Local field staff made five separate pollinations for each entry in one row per replicate. Plants were crossed within the row (sib mating), but were not selfed in order to mimic the pollination occurring in a maize field cultivated with one unique variety. Standard breeders' procedures for hand pollination of regulated material were followed.

Sampling

For forage samples, one whole plant without root was collected at the dough stage (R4) by replicate.

For grain samples, ears obtained by sib mating were harvested at physiological maturity (R6) by replicate.

Treatments

There were two treatments for VCO-Ø1981-5 maize: conventional maize weed control or glyphosate treated VCO-Ø1981-5 maize. All other entries (CCP and reference hybrids) received the conventional maize weed control regime applicable for the region where the trial was conducted.

4.2.2. Agronomic performance and phenotypic characteristics

Locations

The nine agronomic field trials were located in seven different locations across the following three EU countries: the Slovak Republic, the Czech Republic and Romania (Table 3). Two field trial locations were planted in both years 2010 and 2011. The trial locations are representative of most of the maize growing areas in Europe, both for grain and silage.

The field sites were planted in a randomized block design with five replications per entry/treatment. The plot size for each location was from 13.9 to 28 m^2, according to locations, with four rows per replicate. The planting population and all agronomic practices were representative of those used for maize production in each study location.

Evaluation parameters

Typical agronomic evaluations used for maize were conducted throughout the 2010 and 2011 growing seasons in Europe at the nine trial locations, *e.g.* plant population density, plant stand count, plant vigor, plant height, ear height, flowering characteristic, grain yield and further.

Treatments

Herbicide treatments were conducted in the same way as indicated for the "compositional trials".

There were two treatments for VCO-Ø1981-5 maize: conventional maize weed control or glyphosate treated VCO-Ø1981-5 maize. All other entries (CCP and reference hybrids) received the conventional maize weed control regime applicable for the region where the trial was conducted.

4.2.3. Statistical analysis

A statistical analysis using difference and equivalence testing was conducted with the compositional data and likewise with the agronomic and phenotypic data.

The primary objective for an average difference/equivalence approach is to estimate overall confidence limits, allowing statements on overall (for all sites, plots, years) differences and equivalences. A linear mixed model was used for the statistical analysis of the data set as described in van der Voet *et al.* (2011).

Statistical calculations were made with the newly developed, publicly available software tool provided by EFSA in October 2014 (for download see http://www.efsa.europa.eu/en/gmo/gmoanalysissoftware.htm) developed with R version 3.1.1.

This comparative assessment evaluates data from the GM maize (glyphosate-treated or conventionally-treated) as compared to the CCP and the six commercial, non-GM reference hybrids, to obtain both difference and equivalence testing results, respectively. In practice, the application of difference testing should detect any unintended effects of the genetic modification, comparing the GM crop to the CCP. Equivalence testing includes the comparisons of the ratio of GM crop:CCP directly to the reference hybrids. Evaluating results in this way allows for a more detailed interpretation with classification into four different equivalence categories.

The results, means and confidence intervals of the GMO and the CCP as compared to the six reference hybrids, are further classified into seven or more different outcome types for the difference test while there are four different equivalence categories linked to the equivalence test.

Van der Voet H, Perry JN, Amzal B and Paoletti C, 2011. A statistical assessment of differences and equivalences between genetically modified and reference plant varieties. BMC Biotechnology 11, 15. 20 pp. (Online, available at http://www.biomedcentral.com/1472-6750/11/15).

4.3. Selection of material and compounds for analysis

The compositional analyses were conducted with forage and grain samples. For the forage samples, one whole plant, without the root, from each plot and by replicate was collected at the dough (R4) stage. Each plant was placed individually in a large plastic bag and shipped directly from the field to the Limagrain Research facilities (Limagrain Europe, Domaine de Mons, 63260 Aubiat, France) where the plants were immediately frozen and stored separately in plastic bags at -20 °C, then ground at dry ice temperature and shipped on dry ice to the laboratory for analysis (Eurofins Analytics, Nantes).

For the grain samples, the ears obtained by sib mating from each replicate were harvested at physiological maturity (R6). The ears harvested on the same row were bulked; ears from different repetitions were kept separately. The ears were transported or shipped to the Limagrain Research facilities (Limagrain Europe, Domaine de Mons, 63260 Aubiat, France) then dried at room temperature. About 150 grams of grain were collected from the center part of the ears for analysis. Sampled grain was shipped at ambient temperature to the laboratory for analysis (Eurofins Analytics, Nantes).

Detailed compositional analysis was conducted in accordance with the OECD Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*). Compositional analysis of forage samples was done on dry material and the results expressed on the dry weight basis. The analytes included protein, acid detergent lignin (ADL), acid detergent fiber (ADF), neutral detergent fiber (NDF), phosphorus, calcium, hemicellulose (NDF minus ADF), energy as expressed in total calories, fat, ash, crude fiber and moisture rate. The moisture rate was determined on fresh material and the results expressed as a percentage of dry weight.

Compositional analysis of grain samples was realized on dry material and the results expressed on dry weight basis. The analytes included protein, fat, acid detergent fiber (ADF), neutral detergent fiber (NDF), crude fiber, ash, carbohydrates, fatty acids (FA), amino acids, vitamins, minerals, key anti-nutrients, and secondary metabolites.

In summary detailed compositional analysis was conducted on 12 analytes for forage and on 68 analytes for grain samples of VCO-Ø1981-5 maize (glyphosate treated and conventional herbicide treated), a conventional counterpart (CCP) and six commercial non-genetically modified reference hybrid varieties. Another 58 analytes were also tested, but the values were below the LOQ and no statistical analysis could be conducted.

Analysis of the forage parameters showed that all analytes (conventional herbicide

treated GM and glyphosate-treated GM) were equivalent or likely to be equivalent (outcome type 1i, 2i, 3ii and 4ii).

The grain comparison results for VCO-Ø1981-5 maize, treated with conventional herbicides, for most analytes (52 of 65 comparisons) were equivalent (outcome type 1i, 2i). No significant differences were found for omega 6 / omega 3 ratio, lysine, methionine, glycine, vitamin E (alpha + total), and cysteine+cystine, and equivalence was more likely than not (outcome type 3ii). Arachidic acid, vitamin B1 and potassium were found to be significantly different and equivalence was more likely than not for arachidic acid and vitamin B1 (outcome type 4ii). Tryptophan, arginine and vitamin B6 were categorized as 5iii, no significant difference but non-equivalence was more likely than not. Finally, potassium was categorized showing significant difference and non-equivalence more likely than not (outcome type 6iii).

The comparison results for the glyphosate-treated VCO-Ø1981-5 maize, CCP and the reference hybrids for 61 of the 68 analytes were equivalent or more likely to be equivalent (outcome type 1i, 2i, and 3ii). Of those 61, 21 were categorized as 2i and 8 were listed as 3ii. Five analytes (vitamin B6, cysteine+cystine, tryptophan, arginine, glycine) of the grain comparisons fell into the outcome types of 5-7. Glycine and vitamin B6 were identified as outcome types 5iii, where there were no significant differences but non-equivalence was more likely than not. Cysteine+cysteine was found to be significantly different but non-equivalence was more likely than not (outcome type 6iii). Tryptophan and arginine were found to be significantly different and non-equivalent (outcome type 7iv).

As recommended by EFSA, further analysis should be conducted for outcomes of 5, 6 (iii) and 7 (iv). For these endpoints, comparisons using data from the ILSI Compositional Database were done for both conventional and glyphosate treatments of VCO-Ø1981-5 maize. The mean values for the GM crop (glyphosate or conventionally treated), CCP and reference hybrids were within the range of values in the ILSI database and therefore not of biological significance.

In conclusion, the comparison assessment of compositional analytes for VCO-Ø1981-5 maize, regardless of the treatment, is equivalent to the CCP, the six reference hybrids and the published ranges. VCO-Ø1981-5 maize is nutritionally equivalent to conventional maize hybrids and there were no indications of unintended effects related to the genetic modification based on these data.

4.4. Comparative analysis of agronomic and phenotypic characteristics

Typical agronomic evaluations used for maize were conducted throughout the 2010 and 2011 growing seasons in Europe at the nine trial locations in the Czech

Republic, the Slovak Republic and Romania.

The following parameters were comparatively evaluated:

- Plant population density
- Plant stand count
- Plant vigor
- Plant height
- Ear height
- Male flowering (pollen shed)
- Female flowering (silking)
- Delay between female and male flowering
- Harvest moisture
- Grain yield

Furthermore the occurrence of biotic stressors (*i.e.* pests and diseases) was characterized. The following was assessed:

- The damage of two common insect pests present on the field locations was scored near harvest: European corn borer (*Ostrinia nubilalis*) and corn rootworm (*Diabrotica virgifera virgifera*).
- Diseases were rated through their symptoms. *Fusarium* spp. and common smut damages were scored near maturity. Plants affected by Fusarium disease were scored on the ears and also through plant lodging at harvest. Plants attacked by common smut were counted in each plot.

Detailed comparative analysis of the agronomic performance of VCO-Ø1981-5 maize treated with glyphosate, VCO-Ø1981-5 maize grown under conventional techniques, the CCP and 6 reference hybrids were compared to each other for each location. Data generated was statistically evaluated to obtain both difference and equivalence testing results.

VCO-Ø1981-5 maize, conventionally treated or treated with glyphosate, and the CCP showed no significant difference for agronomic endpoints. Outcome type 1i (no significant difference and equivalence) was observed for the comparison of VCO-Ø1981-5 (treated or untreated) to the 6 commercial hybrids, showing consistent results for most parameters. Non-equivalence was observed for reproductive characteristics and harvest weights. These non-equivalences/variances observed, such as earliness and grain yield, reflect the natural variability in commercially grown maize and would be expected to show differences.

While flowering dates vary, VCO-Ø1981-5 maize showed no significant difference and equivalence (outcome type 1i) for number of days between silking and pollen shed. Additionally, assessment of harvest measurements in the individual sites reports compared between the GMO and its convential counterpart showed no statistical differences.

These data overall indicate that VCO-Ø1981-5 maize is comparable in agronomic performance to conventional maize hybrids in many parameters, and non-equivalent to some of the specific maturity growth parameters that are unique to the specific maize variety. In conclusion, the agronomic performance data indicates no biologically meaningful differences between the VCO-Ø1981-5 maize (treated or untreated with glyphosate) and the CCP, which indicates no unexpected or adverse effects from the introduced trait.

Plant pest and disease observations were noted on an individual site basis. No differences between the VCO-Ø1981-5 entries and the comparators (CCP and reference hybrids) were identified.

4.5. Effect of processing

VCO-Ø1981-5 maize will be grown for the same uses as currently commercialized maize. There is no indication that processed products from VCO-Ø1981-5 maize would behave differently to those from conventional maize.

5. Toxicology

(a) Toxicological testing of newly expressed proteins

The only novel protein expressed in VCO-Ø1981-5 maize is the modifed EPSP synthase designated as EPSPS ACE5. As the level of expression did not allow sufficient plant-produced protein to be extracted for much of the testing, the protein was expressed in an *E. coli* expression system. The equivalency of the EPSPS ACE5 protein from *E. coli*- and plant-produced sources was confirmed in biochemical tests. The EPSPS ACE5 exhibited decreased enzymatic activity with increasing temperature treatments. After heating at 55 °C, the specific activity decreased significantly. Similarly, the EPSPS ACE5 protein was degraded very rapidly in human simulated gastric fluid, within 30 seconds of incubation.

A 14-day single dose acute oral toxicity study was conducted in mice. No mortality or evidence of toxicity were observed post dosing or during the 14-day observation period in any of the animals. In a 90-day feeding study, no relevant changes were observed in rats fed diets containing up to 33 % (w/w) of milled VCO-Ø1981-5 maize regarding survival, clinical signs, body weight parameters, feed consumption, hematology, clinical chemistry, urinalysis, macroscopic and microscopic pathology when compared to rats fed the corresponding CCP maize.

Following 42 days of daily exposure to diets containing VCO-Ø1981-5 maize (dietary content of approximately 53 % to 65 %), ROSS 708 broiler chickens demonstrated health and growth characteristics comparable to broiler chickens exposed to non-transgenic maize diets.

(b) Testing of new constituents other than proteins

New constituents with the exception of the newly expressed EPSPS ACE5 protein have not been found in VCO-Ø1981-5 maize and are not anticipated to be expressed; accordingly an assessment of new constituents other than proteins is not required.

(c) Information on natural food or feed constituents

No altered levels of food and feed constituents with the exception of the newly expressed EPSPS ACE5 protein have been found in VCO-Ø1981-5 maize. No altered nutritional effects to humans or animals are expected from the introduction of VCO-Ø1981-5 maize into food and feeds in Europe compared to the introduction of any other new hybrid of maize.

(d) Testing of the whole genetically modified food and feed

There are no indications that food and/or feed comprising of or containing maize products derived from VCO-Ø1981-5 would be substantially different as compared to the respective products derived from conventional maize.

In the animal studies conducted (*i.e.* 14-day oral toxicity with protein in mice, 90-day feeding study with whole food/feed in rats, and additional broiler chicken feeding study) no effects on the test animals could be observed.

Dose-response relationships between the amounts of protein or whole feed administered to the test animals and the parameters observed were not determined.

Considering the fact that no effects were observed in these animal test systems, it can be concluded that it is highly unlikely that the consumption of food and feed products derived from VCO-Ø1981-5 maize might have a negative impact on animal or human health.

6. Allergenicity

(a) Assessment of allergenicity of the newly expressed protein

The EPSPS ACE5 protein has no significant sequence homology to known allergens. It is readily digestible when subjected to human simulated gastric (SGF) and human simulated intestinal fluid (SIF). The EPSPS ACE5 protein was rapidly degraded within 30 seconds of incubation in SGF and more than 90 % was degraded within 5 minutes of incubation in SIF. Considering this rapid digestion, it is unlikely that the EPSPS ACE5 protein could have any adverse effects on humans or animals that consume food or feed from VCO-Ø1981-5 maize.

The lack of any similarity to known allergens, lack of any properties associated with known allergens and the very low levels of the protein identified in all tissues in the plant provide a significant weight of evidence that EPSPS ACE5 will not provoke an allergenic response in humans.

(b) Assessment of allergenicity of the whole genetically modified plant

Maize is not considered to be a source of dietary allergens and the widespread use of maize in a number of processed foods has been associated with very few reports of allergic reactions. This is further emphasized by the fact that labelling of products containing maize or maize products is not required. However, two

proteins have been reported as allergens in maize, a 9-kDa lipid transfer protein (LTP) and a 16-kDa trypsin inhibitor (OECD, 2002).

There are no indications that the levels of either of these endogenous allergens have been increased in VCO-Ø1981-5 maize as the single insertion has been characterized and not found to involve DNA sequences encoding these two proteins.

In an additional comparative study the expression level of the 9-kDa lipid transfer protein (LTP) was measured in grains of VCO-Ø1981-5 maize, the conventional counterpart (CCP) and six commercial non-transgenic reference maize varieties. The data obtained on the non-transgenic commercial reference varieties suggest that the level of expression of the lipid transfer protein (LTP) observed in VCO-Ø1981-5 maize is within the biological range of expression of this protein. This quantitative analysis of the LTP allergen further showed no significant differences of VCO-Ø1981-5 maize to the corresponding CCP. It can be concluded that the level of expression of the endogenous allergen (*i.e.* LTP) in VCO-Ø1981-5 maize is not increased and is within the range of expression in conventional maize.

The results of the assessment of VCO-Ø1981-5 maize provided no indications for an increased allergenic potential of this maize as compared to conventional maize considering the whole genetically modified plant as well as food and feed products derived from VCO-Ø1981-5 maize.

OECD, 2002. Consensus document on compositional considerations for new varieties of maize (*Zea mays*): Key food and feed nutrients, anti-nutrients and secondary plant metabolites. Series on the Safety of Novel Foods and Feeds, No. 6. ENV/JM/MONO (2002) 25. Organization for Economic Co-operation and Development (OECD) Paris. 42 pp.

7. Nutritional assessment

(a) Nutritional assessment of the genetically modified food

The comparative assessment of compositional analytes has demonstrated that VCO-Ø1981-5 maize is nutritionally equivalent as regards to the levels of nutrients and anti-nutrients to conventional maize. The bioavilability and biological efficacy of nutrients in food products from VCO-Ø1981-5 maize, also taking into account the potential influences of transport, storage and expected treatment of the foods, is considered to be the same as for the respective products from conventional maize.

(b) Nutritional assessment of the genetically modified feed

As no compositional characteristics were substantially modified in VCO-Ø1981-5 maize, no altered nutritional effects to animals are expected from the introduction of VCO-Ø1981-5 maize into feeds in Europe as compared to the introduction of any other new hybrid of maize.

8. Exposure assessment – Anticipated intake/extent of use

The predicted daily dietary intake calculation was done on the basis of the consumption of maize and maize products as part of the European and other regional human diets. The average EPSPS ACE5 protein intake in Europe is between 4.4 and 41.5 µg/person/day for adolescents and between 2.6 and 22.8 µg/person/day for adults depending on the type of regional diet, with some extreme outliers up to 928 µg/person/day. These calculations are based on the "Chronic consumption data for maize (and derived products)" provided by EFSA (for download see http://www.efsa.europa.eu/en/datexfooddb/datexfooddbspecificdata.htm).

When considering the WHO consumption data, the EPSPS ACE5 protein intake via maize flour for the European diets is calculated to be 20.4 µg/person/day at a maximum.

The contribution of VCO-Ø1981-5 maize to animal feed was also evaluated. The highest exposure for the EPSPS ACE5 protein is estimated for 7 day old broilers with 285 µg/kg bodyweight/day, whereas the lowest exposure is estimated for bred heifers with 34 µg/kg bodyweight/day.

However, all calculations are based on the very conservative scenario that 100 % of commercial maize grain used to produce food or animal feed would be VCO-Ø1981-5 maize, which will not be the case in practice. In addition, an acute toxicity study has been conducted in mice; this toxicity study was conducted using the maximum allowable total dose (*i.e.*, 2000 mg protein/kg animal) of the purified protein and indicated no evidence of toxicity. The maximum consumption by humans and farm animals as calculated above is well below this maximum tested dose. Thereby, we conclude that there is no risk from VCO-Ø1981-5 maize by dietary exposure.

Furthermore, based on the expression levels calculated previously, it is possible to calculate the amounts of maize that would need to be consumed to approach this level (of no effect). With respect to expression in grain, the EPSPS ACE5 could be detected in the range of 1.50 - 3.99 ng/mg dry weight. Using the maximum of this range as the maximum level that could theoretically be consumed, approximately 250 g of maize grain would contain 1 mg of EPSPS ACE5. Allowing for a safety margin of 1000 (a dose level of 2 mg/kg body weight), an individual would need to consume 500 g of maize grain per kg of body weight in a single day to reach this level of exposure. The rapid digestion of this protein in gastric fluid provides additional assurance that it will not exert any toxicity in the human intestine.

9. Risk characterization

Considering the results of the molecular characterization, the compositional analysis, the agronomic and phenotypic analysis together with the toxicological assessment, the allergenicity assessment and the exposure assessment of VCO-Ø1981-5 maize, the following can be concluded:

(a) The consumption of food and feed derived from VCO-Ø1981-5 maize is as safe as food and feed from conventional maize. Adverse effects on human and animal health are estimated as highly unlikely.

(b) The food derived from VCO-Ø1981-5 maize is not nutritionally disadvantageous for the consumer compared to the food which is intended to be replaced.

(c) The food derived from VCO-Ø1981-5 maize does not mislead the consumer concerning its composition and properties.

(d) The feed derived from VCO-Ø1981-5 maize does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

(e) The feed derived from VCO-Ø1981-5 maize is not nutritionally disadvantageous for animals compared to the feed which is intended to be replaced.

In conclusion, there are no intrinsic hazards and specific risks related to VCO-Ø1981-5 maize and food and feed derived from VCO-Ø1981-5 maize as no adverse and / or unanticipated effects have been observed in the programme of safety studies. No indications of risks associated with the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize on human and animal health could be identified. Accordingly a specific labelling of food and feed and other products from VCO-Ø1981-5 maize is not required.

10. Post-market monitoring on genetically modified food or feed

There are no intrinsic hazards related to VCO-Ø1981-5 maize as no signs of adverse or unanticipated effects have been observed in the programme safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterization for food and feed use of VCO-Ø1981-5 maize demonstrates that the risks of consumption of VCO-Ø1981-5 maize or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional maize. As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this maize event for food and feed is not considered appropriate.

11. Environmental assessment

11.1. Mechanism of interaction between the genetically modified plant and target organisms

In this area of assessment, the main environmental concern, according to the EFSA ERA Guidance, is that target organisms develop resistance to the insect or pathogen tolerance traits expressed by the GM plant.

VCO-Ø1981-5 maize has been developed to confer tolerance to the glyphosate herbicide, no target organisms are associated with this product, and therefore an assessment of the potential resistance development in target organisms resulting from the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize is not relevant for this application.

11.2. Potential changes in the interactions of the genetically modified plant with the biotic environment resulting from the genetic modification

(a) Persistence and invasiveness

Maize is very domesticated and cannot survive without human intervention. It does not display weedy characteristics, is not frost tolerant, does not survive normal winter conditions, and there are no sexually compatible wild relatives of maize in the EU, therefore no cross-hybridization or introgression will occur.

Since VCO-Ø1981-5 maize does not differ from conventional maize apart from glyphosate tolerance, it can be concluded that the persistence and invasiveness

potential of VCO-Ø1981-5 maize is no different from conventional maize.

(b) Selective advantage or disadvantage

The potential that the introduced trait confers a selective advantage or disadvantage to the GM crop or to sexually compatible wild relatives has also been assessed. The main limiting factors preventing the spread of the crop outside agro-ecosystems are dependence on humans and lack of frost tolerance; therefore the herbicide-tolerance is unlikely to confer selective advantage or disadvantage to the maize crop.

The herbicide tolerance trait in VCO-Ø1981-5 maize confers a selective advantage as compared with conventional maize only when the plants will be sprayed with glyphosate. This effect is temporally and spatially limited. However, considering the scope of this application, which does not cover the deliberate release and cultivation of VCO-Ø1981-5 maize in the environment, the before mentioned advantage is not relevant here.

Since no sexually compatible wild relatives of maize are found in the EU, cross-hybridization and introgression is highly unlikely.

(c) Potential for gene transfer

It is very unlikely that the new genes present in VCO-Ø1981-5 maize would become established in the genome of micro-organisms in the environment or human and animal digestive tract, and the risk is negligible. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health or the environment are expected.

(d) Interactions between the genetically modified plant and target organisms

The scope of this application covers the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize in the EU. No deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this maize. Therefore an assessment of the potential resistance development in target organisms resulting from the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize is not relevant for this application.

(e) Interactions of the genetically modified plant with non-target organisms

The risk that the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize could harm sustainable agricultural production or biodiversity due to direct or indirect interactions between VCO-Ø1981-5 maize and NTO populations is negligible. Given the scope of this application and considering the low levels of exposure (and hazard) and absence of identified unintended differences, the uncertainty associated with this risk characterization can be considered low and the probability of long-term environmental effects occurring is also low.

(f) Effects on human health

No effects on human health are anticipated (see sections 4, 5, 6, 7 and 8).

(g) Effects on animal health

No effects on animal health are anticipated (see sections 4, 5, 6, 7 and 8).

(h) Effects on biogeochemical processes

Cultivation of VCO-Ø1981-5 maize in the EU is not included in the scope of this application. An assessment of the impacts of VCO-Ø1981-5 maize on biogeochemical processes is not relevant given the scope of this application.

(i) Impacts of the specific cultivation, management and harvesting techniques

Cultivation of VCO-Ø1981-5 maize in the EU is not included in the scope of this application. An assessment of the impacts of VCO-Ø1981-5 maize on the specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

11.3. Potential interactions with the abiotic environment

Not applicable.

11.4. Risk characterisation

A comparative safety assessment has been conducted using a weight-of-evidence approach, considering molecular characterization data as well as compositional and agronomic comparisons between the product and its conventional counterpart. This assessment has been used to establish whether unintended changes in the GM plant have occurred as a result of the genetic modification. The results of this comparative safety assessment demonstrated that the only difference of biological relevance identified between VCO-Ø1981-5 maize and the conventional counterpart is the expression of the intended EPSPS ACE5 protein. Despite the large number of parameters compared, no unintended differences of biological relevance were found.

Potential risks associated with the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize in the EU on human and animal health have been assessed. The conclusion from this assessment was that food and feed derived from VCO-Ø1981-5 maize is as safe for humans and animal consumption as food and feed derived from conventional maize.

In summary the import of viable grain and processed products, processing and all downstream uses including food and feed of VCO-Ø1981-5 maize in the EU will pose negligible risk to human and animal health or the environment. The uncertainties associated with this risk characterization are very low and no long-term adverse environmental effects are expected.

12. Environmental monitoring plan

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for VCO-Ø1981-5 maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM plan also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants provided by EFSA.

It has to be considered that the scientific evaluation of the characteristics of VCO-Ø1981-5 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of VCO-Ø1981-5 maize.

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorization of VCO-Ø1981-5 maize for import as viable grain and processed products, processing and all downstream uses including food and feed use in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorization for the cultivation of VCO-Ø1981-5 maize seed products in the EU.

An environmental risk assessment (ERA) was carried out for VCO-Ø1981-5 maize according to the principles laid down in Annex II to Directive 2001/18/EC, Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the EFSA guidance document on the environmental risk assessment of genetically modified plants. The scientific evaluation of the characteristics of VCO-Ø1981-5 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of VCO-Ø1981-5 maize relative to:

- Persistence and invasiveness
- Selective advantage or disadvantage
- Potential for gene transfer
- Interactions between the GM plant and target organisms
- Interactions of the GM plant with non-target organisms
- Effects on human health

- Effects on animal health
- Effects on biogeochemical processes
- Impacts of the specific cultivation, management and harvesting techniques
- Potential interactions with the abiotic environment.

(c) Case-specific genetically modified plant monitoring (approach, strategy, method and analysis)

As discussed in the previous sections, the scientific evaluation of the characteristics of VCO-Ø1981-5 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of VCO-Ø1981-5 maize. It is therefore considered that there is no need for case-specific monitoring.

(d) General surveillance of the impact of the genetically modified plant (approach, strategy, method and analysis)

(i) Approach

General surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the ERA.

The scope of this application is the authorization of VCO-Ø1981-5 maize for import as viable grain and processed products, processing and all downstream uses including food and feed use. The scope of the application does not include authorization for the cultivation of VCO-Ø1981-5 maize seed products.

Therefore, exposure to the environment will be limited to unintended release of VCO-Ø1981-5 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including VCO-Ø1981-5 maize destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides (with the exception of glyphosate herbicide).

However, in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, general surveillance on VCO-Ø1981-5 maize will be undertaken for the duration of the

authorization. The general surveillance will take into consideration, and be proportionate to, the extent of imports of VCO-Ø1981-5 maize and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorization holder and operators handling and using viable VCO-Ø1981-5 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable VCO-Ø1981-5 maize.

(ii) Strategy and sources of information

The authorization holder is responsible for ensuring that the PMEM plan is put in place and properly implemented in accordance with the conditions of the authorization.

Third parties involved in the general surveillance will report any potential unanticipated adverse effects to the authorization holder, who will immediately investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003.

It has to be considered that the authorization holder is not involved in commodity trade with VCO-Ø1981-5 maize. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable VCO-Ø1981-5 maize. They are exposed to the imported viable VCO-Ø1981-5 maize and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles (Harzard Analysis Critical Control Point system, see website of the Food and Agriculture Organization of the United Nations (FAO)[2]).

Since traders may commingle VCO-Ø1981-5 maize with other commercial maize, including authorised GM maize, the authorization holder is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio, see http://www.europabio.org/) and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology. The following networks are currently involved:

[2] http://www.fao.org/docrep/004/y1579e/y1579e03.htm - Accessed 27 November 2013.

- Importers / Traders

  COCERAL is the European association representing the cereals, rice, feedstuffs, oilseeds, oils and fats and agro-supply trade in the European Union. Its members are the national trade organizations that represent collectors, distributors, exporters, importers and agribulk storers of the above mentioned commodities in the majority of Member States. The main importers of cereals and feedstuffs into the EU are members of COCERAL.

  Also see: http://www.coceral.com/

- Silo Operators

  UNISTOCK is the European association representing professional storekeepers for agribulk commodities within the EU. It regroups representatives from 11 Member States and is itself a member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

  Also see: http://www.unistock.be/

- Processors

  FEDIOL, the federation of the EU Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds meals producers and vegetable oils producers/processors. Its members represent 80% of the EU industry and hold 147 oilseeds processing and vegetable oils and fats production facilities across Europe.

  Also see: http://www.fediol.eu/

These associations represent the majority of European operators importing, handling and processing viable maize commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003, and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable VCO-Ø1981-5 maize, because they focus on processed, non-viable material.

(iii) Method and analysis

The authorization holder, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM maize, including VCO-Ø1981-5 maize, with the help of the selected networks described above.

The different parties agreed on a general framework for monitoring of GMOs, including VCO-Ø1981-5 maize, as follows:

- The authorization holder represented by EuropaBio will:
  - Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed PMEM plan.
  - Inform operators concerning the authorization, safety and general characteristics of VCO-Ø1981-5 maize and of the conditions as to general surveillance.
  - Set up and maintain a website dedicated to operators including detailed information on VCO-Ø1981-5 maize. The website, hosted on the EuropaBio website under www.europabio.org/information-operators contains the following information:
    - An introduction to the purpose of the website
    - A table giving an overview of all currently approved GM plant products subject to general surveillance
    - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU
    - A contact point at EuropaBio for information exchange on any of the GM plant products

    The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.
  - Contact the selected networks of operators annually reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).
- The selected networks of operators (European trade associations) will:
  - Inform and remind their member organizations and companies on an annual basis:

- to monitor for potential unanticipated adverse effects
- that, in the framework of their management or safety standards (ISO, HACCP, …), procedures must be in place and implemented to limit losses and spillage of viable VCO-Ø1981-5 maize and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects
- to inform and remind their own member companies of this requirement
- to report back any adverse effect reported to them to the European trade associations

- Report to the authorization holders directly or via EuropaBio
  - at least annually, regardless whether an adverse effect was observed or not
  - immediately any adverse effects reported to them.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL will notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio will forward this report to the respective authorization holders for inclusion in their annual report to the European Commission.

The general surveillance information reported to and collected by the authorization holder from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorization holder will immediately investigate to determine and confirm whether a significant correlation between the effect and VCO-Ø1981-5 maize can be established. If the investigation establishes that VCO-Ø1981-5 maize was present when the adverse effect was identified, and confirms that VCO-Ø1981-5 maize is the cause of the adverse effect, the authorization holder will immediately inform the European Commission.

(e) Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorization holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of VCO-Ø1981-5 maize and that alters the existing risk assessment becomes available, the authorization holder will immediately investigate and inform the European Commission. The authorization holder, in collaboration with the European Commission and based on a scientific

evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorization holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorization. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable VCO-Ø1981-5 maize.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of VCO-Ø1981-5 maize and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

13. Detection and identification techniques for the genetically modified plant

Southern blot or PCR techniques can be employed for the detection and identification of the inserted nucleotide sequences. Specific ELISAs have been developed and can be used to detect the EPSPS ACE5 protein in individual plants. An event-specific PCR-based assay allowing the detection and quantification of VCO-Ø1981-5 maize has been provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory.

14. Information relating to previous releases of the genetically modified plant (for environmental risk assessment aspects)

14.1. History of previous releases of the genetically modified plant notified under Part B of Directive 2001/18/EC or under Part B of Council Directive 90/220/EEC by the same notifier

(a) Notification number

Please refer to section 1.5. Table 1 for a list of prior notifications in Czech Republic, Slovak Republic, Spain and Romania under Part B of Directive 2001/18/EC.

(b) Conclusions of post-release monitoring

Experimental field trials were performed with VCO-Ø1981-5 maize to assess the degree of glyphosate tolerance, to produce seeds and for breeding purposes, to establish the technical recommendations for the seed and herbicide uses under a range of climatic conditions, to assess the agronomic performance such as yield and to evaluate the phenotypic and compositional characteristics. The aim of the post-release monitoring of VCO-Ø1981-5 maize plants was to check for the presence of volunteers during the next growing season.

(c) Results of the release with respect to any risk to human health and the environment, submitted to the competent authority in accordance with Article 10 of Directive 2001/18/EC

Post-release general surveillance provided no significant evidence that VCO-Ø1981-5 maize is likely to pose any risk of adverse effects to human or animal health or to the environment.

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

(a) Release country

Experimental field trials in the USA, Canada and Japan were performed with VCO-Ø1981-5 maize in collaboration with Athenix Corp. (now an affiliate of Bayer CropScience). Experimental field trials were also conducted in Argentina.

(b) Authority overseeing the release

USA:	USDA
Canada:	CFIA
Japan	MAFF (Ministry of Agriculture Forestry and Fisheries) and MOE (Ministry of Environment)
Argentina:	Ministry of Agriculture, Livestock and Fisheries

(c) Release site

Release sites were located in those regions where maize is traditionally cultivated.

(d) Aim of the release

Experimental field trials were performed to assess the degree of glyphosate tolerance, to produce seeds and for other breeding purposes, to establish the technical recommendations for the seed and herbicide uses under a range of climatic conditions, to assess the agronomic performances such as yield and to evaluate the phenotypic and compositional characteristics.

(e) Duration of the release

The duration of the maize field release is one growing season and one volunteer monitoring season. For the continental USA and Canada, the release ranges from April to November, whereas for maize grown in Puerto Rico, the release can occur any time during the year. In Japan the release ranges from May to November. In Argentina the release ranges from January to July.

(f) Aim of post-releases monitoring

The aim of the post-release monitoring of VCO-Ø1981-5 maize plants was to check for the presence of volunteer plants during the next growing season.

(g) Duration of post-releases monitoring

The post-release monitoring was usually performed for one year; however if

compliance issues were identified during volunteer monitoring, an extention of monitoring was initiated.

(h) Conclusions of post-release monitoring

No unexpected effects have been observed in VCO-Ø1981-5 maize compared to conventional maize.

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

Post-release, general surveillance provided no significant evidence that VCO-Ø1981-5 maize is likely to pose any risk of adverse effects to human or animal health or to the environment when compared with conventional maize.