Application for authorization of H7-1 sugar beet for cultivation and associated uses in the European Union according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II

Summary

SUMMARY OF APPLICATIONS FOR GENETICALLY MODIFIED PLANTS AND/OR DERIVED FOOD AND FEED

H7-1 Roundup Ready Sugar Beet

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

Germany

b) Notification number

Not available at the time of application.

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

The product is H7-1 Roundup Ready® sugar beet.
H7-1 Roundup Ready sugar beet[1] is tolerant to glyphosate, the active ingredient in Roundup® herbicide.

d) Date of acknowledgement of notification

Not available at the time of application.

2. Applicant

a) Name of applicant(s)

(i) KWS SAAT AG

(ii) Monsanto Company represented by Monsanto Europe S.A.

b) Address of applicant(s)

KWS SAAT AG
Grimsehlstrasse-31
D-37574 Einbeck
Germany

Monsanto Europe S.A.
Avenue de Tervuren, 270-272
B-1150 Brussels
Belgium

on behalf of:

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
U.S.A.

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

[1] Hereafter referred to as H7-1 or H7-1 sugar beet.

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))

Not applicable.

3. Scope of the application

(x) GM plants for food use
(x) Food containing or consisting of GM plants
( ) Food produced from GM plants or containing ingredients produced from GM plants[2]
(x) GM plants for feed use
(x) Feed containing or consisting of GM plants
( ) Feed produced from GM plants[3]
(x) 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	

[2] The scope "Food produced from GM plants or containing ingredients produced from GM plants" is already covered by the authorization for placing on the market of food and feed produced from H7-1 sugar beet from 24 October 2007 (see Commission Decision 2007/692/EC).

[3] The scope "Feed produced from GM plants" is already covered by the authorization for placing on the market of food and feed produced from H7-1 sugar beet from 24 October 2007 (see Commission Decision 2007/692/EC).

Table A.5: List of previous notifications under Part B of Directive 90/220/EEC and 2001/18/EC

Year	Country	Notification Number
1995	Belgium	B/BE/95/WSP4 (Monsanto)
1996	Belgium	B/BE/95/WSP4 (Monsanto)
	United Kingdom	B/GB/96/R22/7 (96/R 22/7) (Monsanto)
1997	Belgium	B/BE/95/WSP4 (Monsanto)
	Italy	B/IT/97/18 (Monsanto)
	The Netherlands	B/NL/96/22 (BGGO 96/22) (Monsanto)
1998	Belgium	B/BE/95/WSP4 (Monsanto)
	Italy	B/IT/97/18 (Monsanto)
	France	B/FR/97/10/11 (Monsanto)
	The Netherlands	B/NL/96/22 (BGGO 96/22) (Monsanto)
	United Kingdom	B/GB/98/R22/11 (B/UK/98/R22/11) (Monsanto)
1999	Belgium	B/BE/95/WSP4 (Monsanto)
	France	B/FR/99/01/07 (Monsanto/KWS)
	France	B/FR/99/11/02 (KWS)
	Germany	B/DE/99/94 (ZG2 6786-01-0094) (Monsanto)
	Italy	B/IT/97/18 (Monsanto)
	Italy	B/IT/99/03 (KWS)
	Italy	B/IT/99/27 (KWS)
	Italy	B/IT/99/36 (KWS)
	Spain	B/ES/99/03 (Monsanto)
	The Netherlands	B/NL/96/22-EXT1 (BGGO 96/22-01) (Monsanto)
	United Kingdom	B/GB/98/R22/11 (B/UK/98/R22/11) (Monsanto)
2000	Belgium	B/BE/95/WSP4 (Monsanto)
	Belgium	B/BE/00/VSP2 (KWS)
	France	B/FR/99/01/07 (Monsanto/KWS)
	France	B/FR/00/07/01 (KWS)
	Germany	B/DE/99/94 (ZG2 6786-01-0094) (Monsanto)
	Spain	B/ES/00/08 (Monsanto)
	The Netherlands	B/NL/96/22-EXT1 (BGGO 96/22-01) (Monsanto)
2001	Belgium	B/BE/95/WSP4 (Monsanto)
	France	B/FR/99/01/07 (Monsanto/KWS)
	Germany	B/DE/99/94 (ZG2 6786-01-0094) (Monsanto)
	The Netherlands	B/NL/96/22-EXT1 (BGGO 96/22-01) (Monsanto)
2002	Germany	B/DE/99/94 (ZG2 6786-01-0094) (Monsanto)
2005	Sweden	B/SE/04/7951 (Syngenta Seeds)
2006	Spain	B/ES/06/01 (Monsanto)
2008	Germany	B/DE/07/192 (Planta KWS)
	Spain	B/ES/08/01 (Monsanto)
	Spain	B/ES/08/35 (Syngenta Seeds)

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 H7-1 sugar beet has been notified under part C of Directive 2001/18/EC for cultivation. The notification number is C/DE/00/8.	

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

Yes (X)	No ( )
If *yes*, specify The product has been previously notified in the U.S., Canada, Japan, Russia, Australia, New Zealand, Mexico, Colombia, EU, South Korea, China, Singapore, Taiwan, and Philippines.	

8. General description of the product

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

The sugar beet (*B. vulgaris*) parental plant used for transformation was a proprietary, multigerm sugar beet line designated 3S0057 from KWS SAAT AG. The selected H7-1 sugar beet plant contains a gene cassette encoding one protein, CP4 EPSPS, which confers tolerance to glyphosate.

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

The scope of this authorization is to place on the market H7-1 sugar beet for cultivation and associated uses in the European Union. The range of uses of this sugar beet will be identical to the full range of equivalent uses of conventional sugar beet.

c) Intended use of the product and types of users

There are no specific differences when H7-1 sugar beet is compared to conventional sugar beet, except for its tolerance to glyphosate. Therefore the intended uses and the type of users for H7-1 sugar beet are identical to those for conventional sugar beet.

d) Specific instructions and/or 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 seeds and / or food and feed products produced from H7-1 sugar beet.

e) Any proposed packaging requirements

The packaging of seeds and / or foods and feeds produced from H7-1 sugar beet will be the same as that used for conventional sugar beet.

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

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of H7-1 sugar beet and derived products.

H7-1 sugar beet seeds will be marketed by KWS and its licensees under the name of the variety, in association with the trademark Roundup Ready® sugar beet. Seed bags and packages will be clearly marked with the following words "This product contains genetically modified organisms" or "This product contains genetically modified sugar beet" as well as the product's unique identifier KM-ØØØH71-4.

Operators are currently required to label products containing or consisting of H7-1 sugar beet with the words "genetically modified sugar beet" or "contains genetically modified sugar beet" and shall continue to declare the unique identifier KM-ØØØH71-4 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators are currently required to label foods and feeds derived from H7-1 sugar beet with the words "produced from genetically modified sugar beet". In the case of products for which no list of ingredients exists, operators shall continue to 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 H7-1 sugar beet and derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully

aware of the traceability and labelling requirements for H7-1 sugar beet. Therefore, no further specific measures are to be taken by the applicants.

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)

KM-ØØØH71-4

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

H7-1 sugar beet is intended for cultivation in all sugar beet production regions in the EU as conventional sugar beet.

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

This application is for cultivation and associated uses of H7-1 sugar beet in the EU.

Cultivated beet varieties are neither persistent nor invasive and are rarely observed in other crops or in natural habitats. Cultivated beet is not considered a significant weed problem in agricultural habitats and only occasionally survives in natural habitats, when competition from other species is minimal. H7-1 sugar beet is shown not to be substantially different from conventional sugar beet, except for the introduced tolerance to glyphosate and, therefore, is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, sugar beet volunteers can be easily controlled using currently available selective herbicides or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

1. Complete name

a) Family name

Chenopodiaceae

b) Genus

Beta

c) Species

vulgaris (2n=18, 3n=27, 4n=36)

d) Subspecies

vulgaris

e) Cultivar/breeding line

3S0057

f) Common name

Sugar beet

2. a) Information concerning reproduction

(i) Mode(s) of reproduction

Sugar beet is a biennial plant that develops a large succulent root in the first year and a seed stalk in the second year of its life cycle. Sugar beet roots used for food and feed production are harvested in the first year. Therefore, the sugar beet life cycle is limited to the vegetative stage in agricultural production. Sugar beet reproduces primarily through seed and is a highly self-incompatible pollinator. For seed production, stecklings (vernalized sugar beet plantlets) are produced in the first season. The following season they are transplanted into the field where the seed multiplication will take place.

Reproduction may also occur from vegetative tissue, crowns or portions of roots left in the field ("groundkeepers"), after harvest. It is possible that some regrowth in the following season may produce fertile seed. However, dissemination by these means is rare, since such crop remains are incorporated into the soil by the farmer, preventing their survival.

(ii) Specific factors affecting reproduction

To induce the reproductive stage, sugar beet requires a period of low temperature (vernalization). The length of thermal induction is genetically determined, which typically leads to seed production in the second year of its life cycle. Seed stalk development and flowering may, in some instances, be induced by low spring temperatures in the first year. This is an unwanted phenomenon referred to as "bolting". As day length is also important for flower induction, the term "photo-thermal flower induction" is used, especially when biennial genotypes are induced to flower and set seed in the first year by choosing the appropriate temperature and day length.

(iii) Generation time

Cultivated sugar beet is normally biennial, with seed multiplication occurring in the second growing season. The reproduction cycle for beet ranges from nine to 16 months from seedling emergence to seed maturity.

2 b) Sexual compatibility with other cultivated or wild plant species

Hybridisation with cultivated *Beta* varieties

Sugar beet *(Beta vulgaris)* comprises several cultivated forms of *Beta vulgaris* ssp. *vulgaris*. Those subspecies are interfertile although individually self-incompatible. However, hybridization is a limited occurrence since the sugar beet life cycle is limited to the vegetative stage in agriculture production.

Hybridisation with wild *Beta* species

Hybridisation between *Beta vulgaris* and specific members within the *Beta* section can occur; hybrids are normally vigorous and fertile and do not show incompatibility. Nonetheless, hybrids between *Beta vulgaris* and *Beta macrocarpa* are rare due to different flowering time of the two parental species and often result in partial pollen sterility and embryo abortion. There is no evidence that *B. vulgaris* naturally intercrosses with members of the Chenopodiaceae family other than the *Beta* section.

Artificial hybrids can be produced although with difficulty, with species in the section *Corollinae*. However, such hybrids are highly sterile and set only few seeds when backcrossed to sugar beet. Artificial hybrids between sugar beet and members of the section *Procumbens* normally die at the seedling stage. No hybrids between cultivated sugar beet and *B. nana* of section *Nanae* have been reported. It is concluded that within the Chenopodiaceae family, all crosses between cultivated sugar beet and species from sections other than *Beta*, are highly improbable.

3. Survivability

a) Ability to form structures for survival or dormancy

Seed is the only survival structure. Most seed left in the upper five centimetres of soil will germinate if the conditions are favourable. Seed that is ploughed deeper may remain dormant until the conditions are optimal for germination. It is known that seed may remain dormant for up to 10 years or longer and still retain part of its germination capacity.

After sugar beet production, volunteer sugar beet is very rarely observed in other crops, ditches or on road sides. If volunteer sugar beet were to occur in the following crop, it could be controlled by

broadleaf herbicides or by other agricultural practices, such as tillage during seed bed preparation.

b) Specific factors affecting survivability

Sugar beet plants rarely survive in subsequent crops and are not considered a weed problem in crops planted after sugar beet production. Numerous factors affect the limited ability of sugar beet to survive in rotational crops or outside of cultivation. Sugar beet is a biennial plant that is highly sensitive to frost and poorly competitive with other plants. Prolonged temperatures below -5°C will result in sugar beet plant death. Importantly, if a sugar beet plant were to survive in a cultivated field, it could be controlled by tillage or by most broadleaf herbicides commonly used in rotational crops.

4. Dissemination

a) Ways and extent of dissemination

Dissemination can happen at three stages: seed, pollen and vegetative plant structure.

Seed dispersal

In root production fields, seed dispersal is limited because the sugar beet crop is harvested at the end of the first growing season before flowering and seed production.

In seed production fields, sugar beet plants do not shatter seed as easily as some wild *Beta* species, which drop their seeds as they ripen. However, some loss of seed will occur through shattering. Seeds may be released during harvesting and transport, or disseminated by animals such as birds and mice.

Pollen dispersal

Sugar beet is cross-pollinated. Pollen grains are dispersed mainly by wind, but also by insects. Pollen dispersal is influenced by wind force, humidity and temperature. Although the sugar beet pollen can be carried by the wind over long distances, its concentration is rapidly reduced upon dispersal in the air and settling on the ground where it decomposes. Pollen is very sensitive to moisture and its viability under field condition is no longer than 24 hours.

Pollen dispersal occurs mainly in seed production areas. In root production fields, pollen dispersal is limited because sugar beet is harvested before flowering.

Dispersal of vegetative plant structures

In root production fields, beet crowns and tops are routinely cut off from the beets at harvest and incorporated into the soil to biodegrade. Buried crowns or portions of roots may develop into plants, but rarely do so as sugar beet is sensitive to low temperatures.

b) Specific factors affecting dissemination

See a).

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

The wild relatives of sugar beet originated in Asia Minor, but some forms are widely distributed throughout the Mediterranean area.

Sugar beet is the sole or main crop for sugar production in the temperate zones of the northern hemisphere. Since the mid 1940's, sugar beet has also been grown as a winter crop in countries with hotter climates such as Turkey, Morocco, Algeria, Tunisia, Egypt, Syria, Iraq and Iran.

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

Not applicable.

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

Sugar beet is known to interact with other organisms in the environment. Insects and mammals feed on leaves and roots of plants growing in fields. Sugar beet is also susceptible to several fungal and viral diseases, as well as competition from surrounding weeds.

Sugar beet is not pathogenic or harmful to humans. Sugar beet has been extensively cultivated over the past 200 years and has a long history of safe use.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

A disarmed binary *Agrobacterium tumefaciens* plant transformation vector, designated PV-BVGT08, was used to produce H7-1 sugar beet. *Agrobacterium*-mediated transformation is a well documented process for the transfer and integration of exogenous DNA into a plant's nuclear chromosome. The original transformation was conducted using a sugar beet KWS SAAT AG proprietary multigerm line designated 3S0057.

2. Nature and source of the vector used

PV-BVGT08 is a disarmed *Agrobacterium tumefaciens* double border plant transformation vector. PV-BVGT08 contains a region of DNA (T-DNA) delineated by the right and left border sequences, which hosts the *cp4 epsps* expression cassette conferring glyphosate tolerance. The *cp4 epsps* gene cassette comprises the 35S promoter from a modified figwort mosaic virus (P-FMV), a chloroplast targeting sequence from *Arabidopsis thaliana (ctp2)*, the *epsps* coding sequence from *Agrobacterium* sp. strain CP4 (*cp4 epsps*) and the E9 3' polyadenylation signal from the pea *rbc*S E9 gene (*Pisum sativum*).

In addition, PV-BVGT08 contains the bacterial selectable marker gene *aad*, providing resistance to spectinomycin and streptomycin, as well as DNA origins of replication (*ori-V* and *ori-322*), necessary for replication and maintenance of the plasmid PV-BVGT08 in bacteria. All of these genetic elements are located outside of the T-DNA and, as expected, have not been introduced into H7-1 sugar beet.

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

Table C.3 summarizes the different genetic elements intended for insertion.

Table C.3: Summary of the genetic elements intended for insertion

Genetic Elements	Size (Kb)	Function
Right Border	0.025	A 21-25 bp nucleotide sequence that acts as the initial point of DNA transfer into plant cells originally isolated from *A. tumefaciens* pTiT37.
P-FMV	0.672	The 35S promoter from a modified figwort mosaic virus (FMV).
ctp2	0.31	The N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana epsps* gene.
cp4 epsps	1363	The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) coding sequence from *Agrobacterium* sp. strain CP4.
E9 3'	0.63	The 3' end of the *Pisum sativum rbc*S E9 gene, containing polyadenylation sites that direct mRNA processing and polyadenylation.
Left Border	0.025	A 21-25 bp nucleotide sequence that delimits the T-DNA transfer into plant cells, originally isolated from *A. tumefaciens* plasmid pTi15955, a derivative of the octopine type plasmid pTiA6.
ori-V	0.393	A vegetative origin of DNA replication, originally isolated from plasmid RK2.
ori-322	0.629	A plasmid origin of DNA replication that permits maintenance of the plasmid in bacterial hosts such as *E. coli.*
rop	0.191	A segment of plasmid pBR322 that represses the formation of RNA primer critical to maintenance of the plasmid in bacterial hosts such as *E. coli*.
aad	0.789	The bacterial gene encoding the Tn7 AAD 3' adenyltransferase conferring spectinomycin and streptomycin resistance.

D. INFORMATION RELATING TO THE GM PLANT

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

H7-1 sugar beet contains a fully functional and intact gene encoding the CP4 EPSPS protein, which confers tolerance to glyphosate.

The nature and objective of the product, through its genetic modification, is to improve weed management practices in sugar beet production. Weed management is an expensive, labour intensive, and in many cases a complicated operation necessary for optimal production efficiency of sugar beet. No single currently-registered herbicide offers the broad spectrum weed control afforded by glyphosate. Instead, farmers today must apply several herbicides on multiple occasions.

The use of the Roundup Ready system for sugar beet production would enable farmers to use glyphosate-containing herbicides for effective control of weed pests, while benefiting from the favourable environmental safety characteristics of glyphosate.

2. Information on the sequences actually inserted or deleted

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

An extensive molecular characterization has been completed to determine the copy number of the insert present in the genome of H7-1 sugar beet. The molecular data, as well as Mendelian inheritance data, support the conclusion that a single insert is present in H7-1 sugar beet and that this insert contains one copy of the *cp4 epsps* gene cassette.

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

Not applicable.

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

Based on the inheritance patterns following self-pollination or hybridisation with other sugar beet plants, it has been assessed that the glyphosate tolerance trait segregates in a normal Mendelian manner. This indicates that the insert is stably integrated in the nuclear genome and is located neither in the mitochondria nor the chloroplasts.

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

Southern blot and sequence analyses were conducted to characterise the inserted DNA. Only the DNA required to confer the glyphosate-tolerance phenotype was transferred and inserted at a single *locus*. The only plasmid-derived genetic elements introduced in H7-1 sugar beet are the P-FMV promoter, the chloroplast targeting sequence *ctp*2, the *cp4 epsps* coding sequence and the E9 3' polyadenylation signal. No genetic elements from outside of the right and left borders of the plasmid were transferred into the genomic DNA of H7-1 sugar beet.

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 introduced *cp4 epsps* coding sequence is driven by the constitutive P-FMV promoter. CP4 EPSPS expression levels were determined using a validated ELISA. On average, the expression level of the CP4 EPSPS protein in the top tissue of H7-1 sugar beet was 0.172 and 0.161 µg/mg fresh weight in 1998 and 1999, respectively. In the brei, the CP4 EPSPS expression level was 0.053 and 0.181 µg/mg fresh weight in 1998 and 1999, respectively.

b) Parts of the plant where the insert is expressed

The expression of the *cp4 epsps* coding sequence is regulated by the 35S promoter derived from a modified figwort mosaic virus (FMV), which is constitutively active in plants. Therefore, the CP4 EPSPS protein is produced in all plant tissues.

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

a) Reproduction

Morphological, developmental and inflorescence traits were accurately measured and monitored in field and in greenhouse assessments. It was concluded that there are no biologically meaningful differences between H7-1 sugar beet and conventional sugar beet varieties in morphological, developmental and inflorescence characteristics. Based on those observations, no differences are anticipated in the reproductive capability of H7-1 sugar beet when compared to conventional sugar beet.

b) Dissemination

The mode of reproduction of H7-1 sugar beet is equivalent to conventional sugar beet and, thus, its dissemination capabilities are

also concluded to be equivalent.

c) Survivability

Seed dormancy has been closely monitored. No change in dormancy has been observed in the seed lots tested when comparing H7-1 sugar beet and commonly used, diploid, multicarp and monocarp conventional sugar beet varieties. It can be concluded that there are no biologically meaningful differences between H7-1 sugar beet and conventional sugar beet with regard to survivability.

d) Other differences

No other differences observed.

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

The stability of the insert across generations was studied using Southern hybridisations, which demonstrated that the insert is stably integrated in the sugar beet genome over at least three generations.

Additionally, the stability of the glyphosate tolerance trait has been tested over multiple generations in several European field trials conducted over four years, confirming that the trait is stably integrated and the CP4 EPSPS protein is produced at sufficient levels to provide consistent glyphosate tolerance across multiple locations and over several generations.

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

a) Plant to bacteria gene transfer

No elements known to be involved in DNA mobility have been inserted in H7-1 sugar beet. Therefore, in comparison to conventional sugar beet, no changes are expected in the ability of H7-1 sugar beet to exchange genetic material with bacteria.

b) Plant to plant gene transfer

It is well known that natural hybridisation occurs among cultivated forms of *Beta vulgaris* and between *Beta vulgaris* and some wild or weedy forms of the section *Beta*. H7-1 sugar beet has the same characteristics as conventional sugar beet, except for its tolerance to glyphosate, including its potential for possible outcrossing. However, outcrossing is a limited occurrence, since sugar beet is mainly grown for its roots and the lifecycle is limited to the vegetative stage in agricultural production. When sugar beet is grown for the purpose of multiplying seed, mitigating practices are commonly used in fields to minimize the potential for plant-to-plant gene transfer.

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

H7-1 sugar beet has been shown to be safe as and nutritious as conventional sugar beet in relation to human and animal health. No specific hazards have been identified for H7-1 sugar beet, or its progeny. Finally, the compositional equivalence of H7-1 sugar beet to conventional sugar beet has been established by comparison of the compositional analyses of key sugar beet constituents.

7.1 Comparative assessment

Choice of the comparator

H7-1 sugar beet was compared to a conventional sugar beet with a near-equivalent genetic background.

7.2 Production of material for comparative assessment

a) Number of locations, growing seasons, geographical spread and replicates

Multiple field trials have been conducted in Europe over two growing seasons, with 11 trials established in 1998 and five in 1999. The trials were performed in different geographies representative of conventional sugar beet cultivation areas (for more details *see* table A.4). In 1998, one sample was supplied from each location, while in 1999 three replicate samples were provided from each of the field locations.

b) The baseline used for consideration of natural variations

Several conventional sugar beet varieties available on the market were grown at the same field sites and analyzed concurrently as H7-1 sugar beet and its near-equivalent comparator for key compositional constituents. Additionally, literature data, when reported, were also considered to further define the natural variation in sugar beet.

7.3 Selection of material and compounds for analysis

Extensive compositional analyses have been conducted on samples of root and top tissue of H7-1 sugar beet. Proximate values, total carbohydrates, quality parameters, amino acids, saponins, which are the principal anti-nutrients in sugar beet, and selected plant metabolites were measured in H7-1 sugar beet, its near-equivalent comparator and commercial sugar beet varieties.

7.4 Agronomic traits

Morphological, developmental and inflorescence traits were accurately measured and monitored in field and greenhouse assessments. It was concluded that there are no biologically significant differences between H7-1 sugar beet and conventional sugar beet varieties in morphological, developmental and

inflorescence characteristics.

7.5 Product specification

H7-1 sugar beet contains a fully functional and intact gene cassette encoding the CP4 EPSPS protein, which confers tolerance to glyphosate.

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 CP4 EPSPS protein in individual plants. An event-specific PCR-based assay allowing the detection and the quantification of H7-1 sugar beet has also been developed.

7.6 Effect of processing

Processing of sugar beet is a complicated, multi-step procedure involving heat treatment, high pH and evaporation of water. Existing literature indicates that processing to produce sugar and molasses significantly depletes the DNA and protein content found in the sugar beet roots to levels that are not detectable by a PCR-based method with very sensitive limits of detection.

7.7 Anticipated intake/extent of use

The major food ingredient derived from the sugar beet root is sugar, which is used as a food or as a food ingredient in a variety of foods, including soft drinks, chocolates and confectionery, yoghurts and other milk-based foods, pastries and biscuits, syrups, jams and preserved fruits, breakfast and children foods, ice-creams and sorbets.

The other two by-products from sugar beet root processing, molasses and pulp, are mainly used in animal feeds. A small fraction of these two products are processed and transformed into pure compounds, food additives or fibres, which have very limited application in the food industry. Industrial users are mainly bread manufactures and the pharmaceutical industry. Food uses represent a very minor proportion of the total use of pulp and molasses.

The anticipated uses of sugar, molasses and pulp as food and feed are not expected to change upon the authorization of H7-1 sugar beet varieties for cultivation and associated uses in the EU.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The safety of the CP4 EPSPS protein has been established based upon the following considerations: (1) lack of biologically relevant structural similarities to pharmacologically active proteins known to cause adverse health effects, based on a bioinformatics search of amino acid sequence databases, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered the CP4 EPSPS protein by oral gavage

and (4) a history of safe use. Furthermore, due to the processing of the sugar beet roots to produce sugar, the primary ingredient derived from sugar beet, the human exposure to the CP4 EPSPS protein expressed in H7-1 sugar beet will be negligible.

7.8.2 Testing of new constituents other than proteins

Sugar beet has a history of safe use and consumption around the world. Based on the compositional analysis, H7-1 sugar beet has been shown to be equivalent to conventional sugar beet. Therefore, it is concluded that no testing of any constituent, other than the introduced CP4 EPSPS protein, is necessary.

7.8.3 Information on natural food and feed constituents

Sugar beet has a history of safe use and consumption around the world. No natural constituent of sugar beet is considered to be of significant concern to require additional information or further risk assessment.

H7-1 sugar beet has been shown to be substantially equivalent to conventional sugar beet, except for the introduced glyphosate-tolerance trait, which is of agronomic interest. Therefore, through compositional analyses and animal feeding studies, H7-1 sugar beet has been concluded to be as safe as and nutritious as conventional sugar beet.

7.8.4 Testing of the whole GM food/feed

The CP4 EPSPS protein has been shown to be safe for consumption by humans and animals. Likewise, compositional analyses and comparative phenotypic assessments have demonstrated that H7-1 sugar beet is substantially equivalent to conventional sugar beet, with the exception of the introduced glyphosate-tolerance trait conferred by the production of the CP4 EPSPS protein. Additionally, the food and feed safety of H7-1 sugar beet has been confirmed through a 90-day rat feeding study conducted with H7-1 sugar beet pulp.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The *cp4 epsps* coding sequence isolated from the naturally occurring soil-borne and plant-symbiotic bacterium *Agrobacterium* sp. strain CP4, is not obtained from a source known to be allergenic. To date, no reports of allergy to *Agrobacterium* sp. have been reported.

The CP4 EPSPS protein expressed in H7-1 sugar beet is similar to EPSPS proteins prevalent in foods and feeds derived from plant and microbial sources, and shows no biologically relevant amino acid sequence similarity to any known protein allergens. The CP4 EPSPS protein is extremely labile in simulated gastric and intestinal fluids. Therefore, the probability of the CP4 EPSPS protein remaining intact to be absorbed via the intestinal mucosa during consumption is very

low.

The endogenous protein level in sugar beet roots is very low, of which the CP4 EPSPS protein represent a very minor component. Furthermore, it has been demonstrated that in the sugar derived from H7-1 sugar beet, which is the prevalent human food, the CP4 EPSPS protein is not detectable using a PCR based method with very sensitive limits of detection.

Thus, using the best methodology available today, it can be concluded that the potential of triggering production of antibodies, including IgE antibodies responsible for allergenicity, is negligible.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Sugar beet has been extensively cultivated for at least 200 years, resulting in a long history of safe use. Additionally, the sugar beet plant is not known to be an allergenic source of food and feed. H7-1 sugar beet has been demonstrated to be substantially equivalent to conventional sugar beet, except for the presence of the CP4 EPSPS protein, which has been demonstrated to lack the characteristics of an allergen. Therefore, H7-1 sugar beet is considered not to have allergenic potential.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The extensive compositional analyses conducted on H7-1 sugar beet have demonstrated its equivalence to conventional sugar beet. In addition, the introduced glyphosate tolerance trait is of agronomic interest, and is not intended to change any nutritional aspects of this sugar beet. Hence, this sugar beet is not expected to be less acceptable as a food ingredient. Therefore, anticipated dietary intake of sugar beet-derived foods is not expected to be altered upon commercialization of H7-1 sugar beet, since the food derived from H7-1 sugar beet has been concluded to be as safe as and nutritious as food derived from conventional sugar beet.

7.10.2 Nutritional assessment of GM feed

The extensive compositional analyses conducted on H7-1 sugar beet have demonstrated its equivalence to conventional sugar beet. In addition, the introduced glyphosate tolerance trait is of agronomic interest, and is not intended to change any nutritional aspects of this sugar beet.

A feed performance/digestibility study conducted in sheep has confirmed the nutritional equivalence of H7-1 sugar beet to conventional sugar beet and has demonstrated the absence of any pleiotropic or unanticipated effects from the introduced trait. Hence, this sugar beet is not expected to be less acceptable as a feed or feed ingredient. Therefore, anticipated dietary intake of sugar beet-derived

feed is not expected to be altered upon commercialization of H7-1 sugar beet, since the feed derived from H7-1 sugar beet has been concluded to be as safe as and nutritious as feed derived from conventional sugar beet.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of H7-1 sugar beet was conducted on the basis of its substantial equivalence to conventional sugar beet and by extensive characterization of the glyphosate tolerance trait, imparted by the presence of the CP4 EPSPS protein. The CP4 EPSPS protein has been demonstrated to have negligible potential to cause adverse effects to animal or human health.

The absence of any pleiotropic or unintended effects due to the introduction of the Roundup Ready trait into the sugar beet genome was indicated by the results of a 90 day rat feeding study and confirmed by a sheep digestibility study, which also assessed the nutritional equivalence of H7-1 sugar beet for use as feed. It is concluded that H7-1 sugar beet is as safe and as nutritious as conventional sugar beet and that food and feed products produced from H7-1 sugar beet are as safe and nutritious as their conventional counterparts.

To conclude, there are no intrinsic hazards related to H7-1 sugar beet 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 characterization for food and feed use of H7-1 sugar beet demonstrates that the risks from consumption of H7-1 sugar beet or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional sugar beet. As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this sugar beet for food and feed is not considered appropriate.

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

H7-1 sugar beet is herbicide tolerant and, as such, has no target organisms with which to interact, either directly or indirectly.

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

9.1 Persistence and invasiveness

Sugar beet has been intensively grown in Europe for almost 200 years. Cultivated beet varieties are neither persistent nor invasive and are rarely observed in other crops or in natural

habitats. Cultivated beet is not considered a significant weed problem in agricultural habitats and only occasionally survives in natural habitats, when competition from other species is minimal.

H7-1 sugar beet is not substantially different from conventional sugar beet, except for the introduced glyphosate-tolerance trait. Field trial data have demonstrated that H7-1 sugar beet has not been altered in its phenotypic, agronomic, reproductive, survival and dispersal characteristics when compared to conventional sugar beet cultivars. Therefore, the likelihood of this sugar beet to spread within or beyond the agricultural environment where it is grown is negligible.

9.2 Selective advantage or disadvantage

Within commercially grown H7-1 sugar beet fields, H7-1 sugar beet plants theoretically have a selective advantage over the glyphosate-susceptible weeds under specific conditions in the field (*i.e.* following treatment with glyphosate containing herbicides). However, these conditions are predictable, spatially limited and short in duration. This 'selective advantage' is limited to the agricultural field and to the growing season of the H7-1 sugar beet crop, and is considered of negligible risk to the environment. In addition, the risk of the glyphosate-tolerance trait in H7-1 sugar beet to be the cause of any adverse effects resulting from a competitive advantage or disadvantage in natural environments is negligible.

Therefore the only selective advantage of H7-1 sugar beet, which is associated with the introduced glyphosate-tolerance trait, is considered to be of negligible risk to the environment.

9.3 Potential for gene transfer

Hybridisation between cultivated beet and related *Beta* species has been ongoing for the last 200 years. Beet varieties may hybridise freely with all the members of the *Beta* section if conditions are suitable. H7-1 sugar beet may therefore hybridise with members of the section *Beta,* including *Beta vulgaris,* and give fertile offspring.

The potential for gene transfer from H7-1 sugar beet to conventional sugar beet, weed or wild beets, primarily exists in seed production areas. However, in the event that the glyphosate-tolerance trait would out-cross to a conventional sugar beet plant, its transfer would have negligible consequences for the environment. The environmental risk posed by this transfer, and hence by the cultivation of H7-1 sugar beet in the EU is negligible.

9.4 Interactions between the GM plant and target organisms

No characteristics could be identified which may cause an adverse environmental effect. H7-1 sugar beet is tolerant to glyphosate and, as such, has no target organisms with which to interact, either directly or indirectly.

9.5 Interactions of the GM plant with non-target organisms

As H7-1 sugar beet and conventional sugar beet are not different with respect to their phenotypic and agronomic characteristics and ecological interactions (except for the introduced trait), it was concluded that the impact of H7-1 sugar beet on non-target organisms in the environment are not different from conventional sugar beet. Furthermore, the potential exposure of non-target organisms to the introduced CP4 EPSPS protein expressed in H7-1 sugar beet presents no conceivable mechanism for causing adverse effects because of its properties.

Based on the natural occurrence and history of exposure of NTO's 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 protein could be harmful to NTO's. Further, the non-hazardous nature of the CP4 EPSPS protein was confirmed in laboratory studies using pure CP4 EPSPS protein and in field studies conducted in the EU assessing the susceptibility of H7-1 sugar beet plants to diseases and insects attack compared to conventional sugar beet. In conclusion, the risk for any adverse effects to NTO's, through their ecological interactions with H7-1 sugar beet or through contact with the produced CP4 EPSPS protein, is negligible.

9.6 Effects on human health

H7-1 sugar beet was shown to be substantially equivalent to conventional sugar beet, except for its introduced glyphosate-tolerance trait, imparted by production of the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects. The safety of H7-1 sugar beet was further confirmed by feeding studies in vertebrate animals using H7-1 sugar beet containing diets. In conclusion, the likelihood of potential adverse effects to humans coming into contact with H7-1 sugar beet is no different from to conventional sugar beet. The introduced glyphosate-tolerance trait is imparted by the production of the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects. Therefore, the risk of any change in the occupational health aspects of this sugar beet is negligible.

9.7 Effects on animal health

Based on experience with conventional sugar beet in Europe, there is no potential for sugar beet to cause any adverse health effects in livestock animals. H7-1 sugar beet was shown to be substantially equivalent to to conventional sugar beet, except for the introduced glyphosate-tolerance trait, imparted by production of the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects. The safety of H7-1 sugar beet was further confirmed by feeding studies in different vertebrate animals using H7-1-containing diets. In conclusion, the likelihood of potential adverse effects in animals fed on CP4 EPSPS-containing H7-1 sugar beet and in humans, consuming those animals, is negligible. Therefore, the risk of H7-1 sugar beet for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

Sugar beet production in general is known to have indirect impacts on biogeochemical processes through tillage and fertilizer application. As H7-1 sugar beet was shown to be equivalent to conventional sugar beet with respect to composition, morphology, development, yield, dispersal, stress susceptibility, plant health and survival characteristics, there is no evidence that this sugar beet would be any different from conventional sugar beet varieties regarding its direct influence on nutrient levels in the soil.

It is highly unlikely that there would be meaningful differences between H7-1 sugar beet and conventional sugar beet in their direct influence on soil nutrient levels, and it is highly unlikely that the direct or indirect interaction between CP4 EPSPS-producing H7-1 sugar beet and decomposers or detritivores in the receiving environment would cause any immediate or delayed adverse effects on the decomposition and nutrient recycling functions in the soil. The negligible potential to cause adverse effects on non-target organisms, involved in these biogeochemical processes, was confirmed by analysis of a range of laboratory and field data generated for various CP4 EPSPS-containing crops.

In conclusion, the environmental risk of adverse effects on biogeochemical processes, caused by the interaction of H7-1 sugar beet and non-target organisms in the soil, is negligible.

9.9 Impacts of the specific cultivation, management and harvesting techniques

As H7-1 sugar beet is equivalent to conventional sugar beet (except for the introduced glyphosate-tolerance trait), all the agronomic practices currently used to grow sugar beet in the EU remain applicable for growing H7-1 sugar beet. Additionally, the possibility of using glyphosate herbicides for weed control in-crop is added to the farmer's weeding options, which currently include

the use of glyphosate in existing selective treatments, a range of other selective herbicides and mechanical methods.

It should be noted that the aim of weed management in H7-1 sugar beet is neither new nor different compared to any other sugar beet, and that the glyphosate-tolerance introduced in H7-1 sugar beet merely provides farmers with an additional herbicide option for efficacious weed control in the crop.

There is negligible potential for any adverse environmental effects from the recommended use of glyphosate in H7-1 sugar beet compared to baseline weed control practices. In considering the potential effects of the use of plant protection products in crop management, such as the afore-mentioned usage of glyphosate in sugar beet or the use of any other plant protection product in H7-1 sugar beet, it is appropriate to refer to the prevailing regulatory framework of Council Directive 91/414/EEC of 15 July 1991, concerning the placing on the market of plant protection products.

In conclusion, in comparison to any other sugar beet, 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 risks of the farming practices applied to grow H7-1 sugar beet in the EU are considered no different from conventional sugar beet.

10. Potential interactions with the abiotic environment

H7-1 sugar beet was shown to be substantially equivalent to conventional sugar beet, except for the introduced glyphosate-tolerance trait, imparted by the production of the CP4 EPSPS protein. Although CP4 EPSPS is an introduced protein in sugar beet, it has a history of safe use and has no known negative interactions with the abiotic environment. The CP4 EPSPS protein in H7-1 sugar beet is innocuous and belongs to a large class of EPSPS proteins that are ubiquitous in nature. The family of EPSPS proteins has no known negative interactions with the abiotic environment.

To conclude, no deleterious impact of H7-1 sugar beet on the abiotic environment is expected to result from the cultivation of H7-1 sugar beet in the EU.

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

11.1 General (risk assessment, background information)

As part of the scope of this application under Regulation (EC) No 1829/2003 is for cultivation of H7-1 sugar beet in the EU, a general surveillance plan in accordance with Annex VII of Directive 2001/18/EC was provided, 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.) of H7-1 sugar beet was undertaken as required by Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003 and concluded that the risk for potential adverse effects on human and animal health and the receiving environment is consistently negligible. Since the conclusions of this e.r.a. are derived from the results of scientific studies rather than major assumptions, it is proposed that no case-specific post-marketing monitoring (CSM) actions, typically aimed at testing assumptions made in this assessment, would be warranted or required. Instead, the monitoring will concentrate on general surveillance (GS) to allow the identification of adverse effects of H7-1 sugar beet 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)

Since the conclusions of the e.r.a. consistently show that the placing on the market of H7-1 sugar beet poses negligible risk to human and animal health and the environment and since the conclusions of this e.r.a. are derived from the results of scientific studies rather than major assumptions, it is proposed that no case-specific post-marketing monitoring actions, typically aimed at testing assumptions made in this assessment, would be warranted or required.

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

The objective of general surveillance is to identify the occurrence of adverse effects of the GM crop or its use on human health or the environment, which were not anticipated in the e.r.a.

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 might have been caused by the placing on the market of a GM plant in its receiving agricultural or non-agricultural environment. By nature, the prediction of unanticipated effects does not lend itself to the formulation of clear scientific hypotheses, and therefore it will need adapted scientific methodology.

For general surveillance of H7-1 sugar beet, the party placing H7-1 sugar beet on the market will use several tools. The central tool is an annual farm questionnaire addressed to a subset of farmers cultivating H7-1 sugar beet. Additionally, information from other sources (company stewardship programmes, scientific literature, official websites and existing observation networks) will be incorporated, where appropriate.

Farmers are the closest observers of the cultivation of the GM plants and they already collect information on the cultivation and management of their crops at farm level. Therefore, they can give details on GM plant-based parameters (referring to species/ecosystem biodiversity, soil functionality, sustainable agriculture, or plant health) and on background and baseline environmental data (*e.g.* soil parameters, climatic conditions, general crop management data such as fertilisers, crop protection, crop rotations and previous crop history). Additionally, farmers may give empirical assessments which can be useful within general surveillance to reveal unanticipated deviations from baseline variation for the crop and cultivation area in question, based on their historical knowledge and experience and parallel non-GM cultivation.

The use of existing networks to provide surveillance information is seen as a key aspect for ensuring that sufficient observers are available to identify and report possible unanticipated adverse effects, as well as ensuring methodological consistency and optimising the expenditure of resources. Although it should not be their task, the applicants plan to work, at the appropriate time prior to commercialization, with the Competent Authorities for GM crop cultivation of the different Member States where H7-1 sugar beet will be grown, to review the existing monitoring networks. The annual reports of the selected networks undertaking these surveillance activities might in certain instances be appropriate for inclusion in the GS programme of the applicants.

It has to be noted that established routine surveillance networks might provide useful data on background or baseline characters on a landscape or national level (*e.g.* climatic conditions, cultivation practices) or on monitoring characters (plant diseases or pests, invasiveness, weeds). The party placing the GM plant on the market may therefore consider to use information from this type of networks on an *ad hoc* basis (*e.g.* if a potential adverse

effect is reported in a subset of questionnaires in a certain region) to assess whether this effect is associated with the GM plant or with another influencing factor. Networks for the agricultural and the non-agricultural environment as well as for human and livestock health might be consulted, as appropriate.

A continuous supply and distribution network extends from the technology provider, via intermediate distribution, to the end-user. Through their sales and technical organisations, key participants, especially those companies involved in farm sales, would be regular visitors to fields where GM plants would be cultivated. Experience has shown that this network ensures a continuous and efficient communication link from the grower to the technology provider, especially in relation to complaints about product performance, and thus would provide a key surveillance network for possible adverse effects.

In addition to the above-mentioned general surveillance actions directed to H7-1 sugar beet growers and other stakeholders, the party placing H7-1 sugar beet on the market will actively monitor existing information sources such as official websites, scientific publications and expert reports on GM crops in order to identify, collate and follow-up on potentially adverse observations made for this sugar beet or any other relevant information, in particular with respect to occupational health, animal feed safety or putative ecological effects of the release of this sugar beet.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect) linked to the genetic modification, further evaluation of the consequence of that effect should be science-based and compared with baseline information. Relevant baseline information will reflect prevalent agricultural practice and the associated impact of these practices on the environment.

11.5 Reporting the results of monitoring

Any recorded observations of adverse findings that are linked to the cultivation and/or use of this sugar beet, which come to the attention of the party placing the GM plant on the market, will receive careful analysis in real time and re-mediating 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

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 CP4 EPSPS protein in individual plants. An event-specific PCR-based assay allowing the detection and quantification of H7-1 sugar beet has been provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory. The H7-1 sugar beet method validation report was published on 31 January 2006[4].

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

Please refer to A.5 for a list of prior notifications in Belgium, United Kingdom, Italy, the Netherlands, France, Sweden, Germany and Spain under Part B of Directive 90/220/EEC and Directive 2001/18/EC.

b) Conclusions of post-release monitoring

Experimental field trials were performed with H7-1 sugar beet 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 characteristics. The aim of the post-release monitoring was to find out if H7-1 sugar beet plants might establish from dormant seed or sugar beet debris. As a result of these field trials, no unexpected effects have been observed in the H7-1 sugar beet trials compared to conventional sugar beet.

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 general surveillance provided no significant evidence that H7-1 sugar beet is likely to pose any risk of adverse effects to human or animal health or to the environment.

[4] http://gmo-crl.jrc.ec.europa.eu/summaries/H7-1-validation%20report%20-%20corrected%20version%201.pdf

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

a) Release country

US, Canada, Russia, Chile, Czech Republic, Poland and Japan.

b) Authority overseeing the release

US:	USDA
Canada:	CFIA
Russia:	Ministry of Science and Education
Chile:	Servicio Agricola y Ganadero
Czech Republic:	Ministry of Environment, Environmental Risk Department
Poland:	Ministry of Environment, Plant Protection Institute and Research Center for Cultivar Testing
Japan	MAFF (Ministry of Agriculture Forestry and Fisheries) and MOE (Ministry of Environment)

c) Release site

Release sites were located in those regions where sugar beet 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 characteristics.

e) Duration of the release

The duration of the sugar beet field release is one growing season. For vegetatively grown sugar beet the release was from March to October in the Northern Hemisphere, whereas for sugar beet grown for seed production, the release was from February to August. In Chile the release for vegetatively grown sugar beet was from September to March, and for sugar beet grown for seed production, the release was from August to February.

f) Aim of post-releases monitoring

The aim of the post-release monitoring was to find out if the sugar beet plant might establish from dormant seed or sugar beet debris.

g) Duration of post-releases monitoring

For vegetatively grown sugar beet, the post-release monitoring was usually performed for one year, and for sugar beet grown for seed production, the average was two to three years.

h) Conclusions of post-release monitoring

No unexpected effects have been observed in H7-1 sugar beet compared to conventional sugar beet.

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

Post-release, general surveillance provided no significant evidence that H7-1 sugar beet is likely to pose any risk of adverse effects to human or animal health or to the environment when compared with conventional sugar beet.

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

H7-1 sugar beet was approved for food and feed use in the European Community on 24 October 2007 (*see* Commission Decision 2007/692/EC).

The JRC websites http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx and http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm and the EFSA website http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and Regulation (EC) No 1829/2003.

b) Assessment Report of the Competent Authority (Directive 2001/18/EC)

Not applicable.

c) EFSA opinion

A favorable scientific opinion by EFSA regarding the safety of food and feed produced from H7-1 sugar beet is posted at http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm .

d)	**Commission Register (Commission Decision 2004/204/EC)** http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=27
e)	**Molecular Register of the Community Reference Laboratory/Joint Research Centre** Information on H7-1 sugar beet detection methods is posted at http://gmo-crl.jrc.ec.europa.eu/default.htm
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)** The JRC website http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx provides a link to the SNIF of notifications under Directive 2001/18/EC. EFSA provides a link to the summary of this application for H7-1 sugar beet cultivation under Regulation (EC) No 1829/2003 at http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm