SUMMARY NOTIFICATION INFORMATION FORMAT (SNIF) FOR PRODUCTS CONTAINING GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)

ROUNDUP READY® SUGAR BEET (*BETA VULGARIS*) DERIVED FROM EVENT H7-1

by

KWS SAAT AG

and

Monsanto Company represented by Monsanto Europe S.A.

SUMMARY NOTIFICATION INFORMATION FORMAT (SNIF) FOR PRODUCTS CONTAINING GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)

ROUNDUP READY® SUGAR BEET (*BETA VULGARIS*) DERIVED FROM EVENT H7-1

A. GENERAL INFORMATION

1. Details of notification

a) Member State of notification Germany

b) Notification number C/DE/00/8

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

The product consists of seeds and beet of Roundup Ready® sugar beet, identified as event H7-1, tolerant to glyphosate, the active ingredient in Roundup® herbicide, and seeds and beet of any progeny derived therefrom by conventional breeding methods. This application includes the production of RR sugar beet in the European Union (EU) as well as handling for processing of food[1] and processing and use of feed products.

d) Date of acknowledgement of notification 24 October 2000

2. Notifier

a) Name of notifier

(i) KWS SAAT AG

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

® Roundup Ready is a registered trademark of Monsanto technology LLC

® Roundup is a registered trademark of Monsanto technology LLC

[1] The safety evaluation of foods and food ingredients derived from RR sugar beet event H7-1 will be assessed pursuant to Regulation (EC) N° 258/97 of 27 January 1997.

b) Address of notifier

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.

c) Is the notifier: domestic manufacturer **[X]**
importer [ ]

d) In the case of an import the name and address of the manufacturer shall be given

Not applicable.

3. 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 RR sugar beet event H7-1 contains a gene cassette encoding one protein, CP4 EPSPS, which confers tolerance to the herbicide Roundup.

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

RR sugar beet event H7-1 has been demonstrated to be equivalent to other sugar beet, apart from its tolerance to glyphosate, and therefore will be used in the same manner as any other sugar beet.
The application for consent under Directive 2001/18/EC is for cultivation and use in the EU of event H7-1. The proposed uses of event H7-1 are the same as for any other sugar beet.

c) Intended use of the product and types of users

RR sugar beet event H7-1 has been demonstrated to be equivalent to other sugar beet, apart from its tolerance to glyphosate and therefore the intended

use and the type of users for RR sugar beet are identical to those for traditional sugar beet. RR sugar beet will be used by plant breeders to incorporate the RR trait into sugar beet varieties. Other users will be farmers who want to realise the benefits of using Roundup for in-crop weed control in the production of sugar beet. A third type of user of RR sugar beet will be the sugar factories who purchase sugar beet roots from farmers for production of sugar (sucrose) and other processed products. These users will notice no differences processing RR sugar beet, since they are substantially equivalent to other sugar beet in their quality and processing characteristics.

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

RR sugar beet have been shown to be substantially equivalent to other sugar beet except for their tolerance to glyphosate.

Sugar beet seed, roots, tops and by-products will be handled in the same manner as for any other sugar beet in terms of planting, production, harvesting, and processing. Hence, no specific storage or handling recommendations or instructions is envisaged. Seed and harvested products, roots and tops, will be stored and handled as other sugar beet varieties.

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

Most of EU countries grow sugar beet. RR sugar beet is intended to the areas where sugar beet is normally cultivated.

The import/export of the product is mainly based on refined sugar because the beets are routinely processed in the vicinity of the cultivation areas. Molasses and pulp are traded to a certain extent between countries. In some cases short distance trade of the harvested beet is possible between neighbouring countries but the absolute volume is negligible.

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

Sugar beet are adapted to temperate maritime agricultural areas. Every country in the European Union produces some acreage of sugar beet. RR sugar beet is unsuited in environments where traditional sugar beet varieties are unsuited.

g) Any proposed packaging requirements

RR sugar beet have been shown to be substantially equivalent to other sugar beet in growth, yield, survival, compositional and other characteristics. Hence, packaging will be similar to that used for other sugar beet varieties.

h) Any proposed labelling requirements in addition to those required by law

In accordance with the requirements of Annex IV of Directive 2001/18, packages and bags containing the seeds will be labelled with the following words "*This product contains genetically modified organisms*". Packages and bags containing the seeds of Roundup Ready branded varieties will be imprinted with the Roundup Ready® trademark to allow farmers to know they are purchasing a RR sugar beet variety. As for any other variety, all the usual pieces of information including variety name, seed quality, seed treatment, manufacturer's name and full address, will be given on the seed package.

i) Estimated potential demand

(i) in the Community

The European Union currently produces 1.848 Kha of sugar beet, representing roughly 15.5 million tons of sugar. It is assumed that RR sugar beet will cover part of the European beet production depending on the market demand.

(ii) in export markets for EC supplies

Beets are usually processed in the vicinity of the cultivation area. Consequently, sugar beets are practically not traded between countries. Refined sugar and to a certain extent molasses and pulp are imported or exported.

j) Unique identification code(s) of the GMO(s)

The unique identification code for H7-1, KM-ØØØH71-4, has been attributed based on the guidance for the designation of a unique identifier for transgenic plants developed by the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology.

4. Has the GMHP referred to in this product been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes **[X]** No **[ ]**

Table A.4.: List of previous notifications under Part B of Directive 90/220/EEC

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)

If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

Not applicable.

5. Is the product being simultaneously notified to another Member State?

Yes **[ ]** No **[X]**

(i) If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

Please see following sections.

Or

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

The product has been previously notified in the US and Japan.

6. Has the same GMHP been previously notified for marketing in the Community?

Yes **[ ]** No **[X]**

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

RR sugar beet have been shown to be substantially equivalent to other sugar beet except for their tolerance to glyphosate. Cultivated *B. vulgaris* varieties are not invasive, are weakly competitive outside cultivated areas, and possess few weedy characteristics. Furthermore, volunteers or bolting beet plants are readily managed using current agricultural practices including herbicides (other than glyphosate), hand weeding, and cultivation. Therefore, no specific measures are foreseen to be needed in the event of unintended release or misuse.
The measures to be taken for waste disposal and treatment will be equivalent to those for any other commercial sugar beet variety.

B. NATURE OF THE GMHP CONTAINED IN THE PRODUCT INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

8. Complete name

a) Family name	Chenopodiaceae
b) Genus	*Beta*
c) Species	*vulgaris* (2n=18)
d) Subspecies	*vulgaris*
e) Cultivar/breeding line	R01/H7-1
f) Common name	sugar beet

9. a) Information concerning reproduction

(i) Mode(s) of reproduction

Sugar beet is normally biennial and develops a large succulent root the first year and a seed stalk the second year. Beet reproduces through seed and is highly self incompatible. The multiplication rate ranges from 350 in seed production fields to 10.000 for a single plant under optimal conditions.
Reproduction may also occur from vegetative tissue, crowns or portions of roots left in the field after harvest. It is possible that some regrowth in the following season may produce fertile seed. Dissemination by this means is rather rare since such crop remnants are incorporated into the soil by farmers.

(ii) Specific factors affecting reproduction, if any

To induce the reproductive stage sugar beet require a period of low temperature (vernalization). The length of thermal induction is genetically determined. If seed stalk development in some instances has been induced by low spring temperatures in the first year, an unwanted phenomenon referred to as bolting occurs. 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 beet is normally biennial. The reproduction cycle for beet ranges from 9 to 16 months from seedling emergence to seed maturity.

9. b) Sexual compatibility with other cultivated or wild plant species

Hybridisation with cultivated *Beta* varieties

Sugar beet (*Beta vulgaris*) is predominantly wind pollinated and the distance pollen can travel depends on the wind force, humidity and temperature. There are no substantial genetic barriers within the genus Beta and the subspecies *vulgaris* and sugar beet can hybridise freely.

Hybridisation with wild *Beta* species

Sugar beet (*Beta vulgaris*) hybridises freely with all wild members of the section *Beta (B. maritima, B. macrocarpa* and *B. atriplicifolia)* and hybrids are normally fertile. There is no evidence that *B. vulgaris* intercrosses with members of the Chenopodiaceae family other than the Beta section.

Artificial hybrids can be produced with difficulty with the 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 family Chenopodiaceae, all crosses between cultivated sugar beet and species from sections other than *Beta*, are highly improbable.

10. Survivability

a) Ability to form structures for survival or dormancy

Seed is the only survival structure, and most seed left in the upper 5 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 as long as 10 years or longer and still retain part of its germination capacity.
Volunteer sugar beet are very rarely observed in other crops, ditches or on road sides. If volunteer sugar beet occur in the following crop they will normally be controlled by the broadleaf herbicides used for weed control or other agricultural practices.

b) Specific factors affecting survivability, if any

Beet plants rarely survive in subsequent crops, and are not considered as a weed problem. Numerous factors affect the ability of beet to survive. Beet is biennial, highly sensitive to frost and poorly competitive. Prolonged temperatures below -5° C will deteriorate the plants. Importantly, beet is

sensitive to tillage and to most broadleaf herbicides commonly used in rotational crops.

11. Dissemination

a) Ways and extent of dissemination

The plant dissemination may occur at 3 stages: seed, pollen and plant crowns.

Seed dispersal
Beet seed have no special, morphological characteristics that facilitate dissemination. Beet seed will spread over short distances by several means such as threshing, mechanical soil preparation, heavy rainfall, and animal intervention. The only significant means of dissemination of beet seed is in seed production process where large quantities are harvested, processed, and distributed. In seed production fields, sugar beet plants do not shatter seed as easily as some wild Beta species, which will drop their seeds as they ripen.

Pollen dispersal
Sugar beet is cross-pollinated. Pollen are dispersed mainly by wind but also by insects. However, pollen are very sensitive to moisture and the viability is under field condition not longer than 24 hours.

Dispersal of vegetative plant structures
Routinely in root production fields, leaves are chopped off from the beets at harvest and incorporated into the soil to biodegrade. Remaining crowns or portions of roots may develop into plants. Dissemination by this means is rather unusual since such crop remnants are destroyed and incorporated into soil by the farmer.

b) Specific factors affecting dissemination, if any see a)

12. Geographical distribution of the plant

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 Second World War, 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.

13. 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.

14. Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms

Sugar beet are known to interact with other organisms in the environment. Insects and mammals feed on leaves and roots of plants growing in fields. Sugar beet are 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 is extensively cultivated since 200 years and has a long history of safe use.

15. Phenotypic and genetic traits

Except for the introduced trait, RR sugar beet is the same as traditional sugar beet.

INFORMATION RELATING TO THE GENETIC MODIFICATION

16. Description of the methods used for the genetic modification

A disarmed *Agrobacterium tumefaciens* plant transformation system was used to produce event H7-1. This delivery system is well documented to transfer and stably integrate transferred DNA (T-DNA) into the plant nuclear chromosome. The vector used is PV-BVGT08 (also coded pMON17227). The original transformation was conducting using a diploide fertile sugar beet line.

17. Nature and source of the vector used

PV-BVGT08 is a disarmed *Agrobacterium tumefaciens* double border plant transformation vector containing the *cp4 epsps* gene cassette between the right and left borders, and a bacterial selectable marker gene *(aad*) located outside the borders.

18. Size, source [name of donor organism(s)] and intended function of each constituent fragment of the region intended for insertion

Table B.18. summarizes the different genetic elements intended for insertion.

Table B.18.: Summary of the genetic elements intended for insertion

Genetic Elements	Size (Kb)	Function
Right Border	0.025	A 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 35 S promoter from a modified figwort mosaic virus (FMV) used to drive expression of *cp4 epsps* gene
CTP2	0.31	The N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene
CP4 syn.	1.363	The 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) gene from *Agrobacterium sp*. strain CP4
E9 3'	0.63	The 3' end of the *Pisum sativum* rbcS E9 gene which provides the polyadenylation sites for the CP4 EPSPS gene
Left Border	0.025	A 25 bp nucleotide sequence that delimits the T-DNA transfer into plant cells. It was originally isolated from *A. tumefaciens* pTiA6

INFORMATION RELATING TO THE GMHP

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

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

The nature of the product and the objective of the genetic modification is to improve weed management practices in sugar beet. Weed management is an expensive, labour intensive, and in some cases complicated operation necessary for optimal production efficiency of sugar beet. No single currently-registered herbicide offers the broad spectrum weed control afforded by Roundup. Instead, farmers today must resort to using several applications of multiple herbicides with high input of the respective chemicals.

The use of RR sugar beet for sugar beet production would enable farmers to use Roundup herbicide for effective control of weed pests while receiving the benefits of Roundup's environmental safety characteristics. This new RR sugar beet can positively impact current agronomic practices

20. Information on the sequences actually inserted/deleted/modified

a) Size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP

Southern blot analyses and polymerase chain reaction (PCR) were conducted to characterise the inserted T-DNA. Only the DNA required to confer the glyphosate-tolerance phenotype was transferred and inserted at a single locus. The T-DNA is limited by the right and left borders as expected. Thus, the only introduced plasmid-derived genetic elements present in the transformation event H7-1 are the *P-FMV* promoter, the *cp4 epsps* gene (including the chloroplast transit peptide *CTP2*) and the *E9 3'* polyadenilation sites. No genetic elements from outside of the right and left borders of the plasmid were transferred into the genomic DNA of RR sugar beet event H7-1. A single chromosomal copy of the inserted DNA is present in each line.

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

Not applicable.

c) Location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion, or maintained in a non-integrated form), and methods for its determination

Based of 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 neither located in the mitochondria nor the chloroplasts.

d) Copy number and genetic stability of the insert

An extensive molecular characterization has been completed to determine the copy number of the insert present in the genome of RR sugar beet event H7-1. The molecular data as well as Mendelian inheritance data support the conclusion that a single insertion is present in RR sugar beet event H7-1 and that this insertion contains one copy of the *cp4 epsps* gene cassette. The stability of the insert across generations was studied using Southern hybridisations, which showed that the insert is stable over three generations.

Additionally, the stability of the herbicide tolerance trait has been tested over multiple generations in several European field trials conducted for 4 years, confirming that the trait is stably inserted and the levels of glyphosate tolerance are consistent between locations and generations.

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

Not applicable.

21. Information on the expression of the insert

a) Information on the expression of the insert and methods used for its Characterisation

The expression of the introduced *cp4 epsps* gene is driven by the constitutive *P-FMV* promoter. Expression levels of the introduced protein, CP4 EPSPS, were determined using a validated ELISA. On average, the expression of CP4 EPSPS in leaf tissue was 0.123 and 0.172 µg/mg fresh weight for untreated and Roundup treated material, respectively. The expression of CP4 EPSPS in the root tissue was 0.048 and 0.053 µg/mg fresh weight for untreated and Roundup treated material, respectively.

b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.)

The *P-FMV* promotor controlling the expression of the *cp4-epsps* gene is constitutive and therefore the insert will be expressed in all parts of the plant.

22. Information on how the GMHP differs from the recipient plant

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

Morphological, developmental and inflorescence traits were accurately measured and monitored in the field and in greenhouse. It was concluded that there are no morphological, developmental and inflorescence differences between event H7-1 and the non-transgenic reference lines. Based on those observations, no differences are anticipated in the reproductive capability of RR sugar beet when compared to traditional sugar beet.

b) Dissemination

The mode of reproduction of H7-1 is equivalent to traditional sugar beet and thus its dissemination capabilities will also be equivalent.

c) Survivability

Seed dormancy has been closely monitored. No change in dormancy could be observed in the used seed lots comparing H7-1 and common used, diploid, multicarp and monocarp sugar beet breeding lines.

It can be concluded that there are no meaningful differences between H7-1 and the non-transgenic counterparts in regards to survivability.

d) Other differences

No other differences observed.

23. Potential for transfer of genetic material from the GMHP to other organisms

Event H7-1 has the same characteristics as traditional sugar beet, except for the tolerance to Roundup, and including its potential for possible outcrossing. However, outcrossing is a limited occurrence since sugar beets are mainly grown for their roots and the lifecycle is limited to the vegetative stage in agricultural practice.

It is conceivable that RR bolters will produce pollen in sugar beet production fields. This pollen could fertilise other bolters in the same field and in nearby fields, and produce fertile hybrids. The progeny would be volunteer beet containing the glyphosate tolerance trait in a subsequent rotation. These volunteers would be readily controlled using currently approved methods.

24. Information on any harmful effects on human health and the environment, arising from the genetic modification

RR sugar beet are equivalent to other sugar beet regarding human and animal health. No specific hazards have been identified in RR sugar beet event H7-1, or its progeny, as a result of expressing the CP4 EPSPS protein.

The human safety of the CP4 EPSPS protein has been established based upon the following considerations: (1) no amino acid sequence similarity to known toxins and no immunologically relevant sequence similarity with known allergens, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered CP4 EPSPS protein by oral gavage, (4) very low dietary exposure, and (5) a history of safe use.

Finally, the nutritional equivalence of RR sugar beet event H7-1 to traditional sugar beet has been established by compositional analysis.

25. Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)

RR sugar beet are equivalent to other sugar beet regarding animal health.

26. Mechanism of interaction between the GMHP and target organisms (if applicable) , if different from that of the recipient/parental organism(s)

The glyphosate tolerance trait is intended to provide protection to the crop when Roundup herbicide is applied to control competing weeds. There is therefore no target organism.

27. Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)

On the basis of the characterisation of the introduced protein and the compositional analyses, no specific interactions of event H7-1 with non-target organism are to be expected, beyond those that occur with other sugar beet varieties. Observations in the field have also confirmed that there are no differences between commercial sugar beet and event H7-1 in their phenotype and susceptibility to diseases, indicating that there is no alteration in the interactions with non-target organisms.

28. Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)

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. A PCR-assay allowing the detection and positive identification of RR sugar beet event H7-1 has been developed.

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

29. Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)

Analyses of the characteristics of sugar beet event H7-1 have shown that the likelihood of potential adverse effects on human health and the environment in the European Union, resulting from its cultivation and use as any other sugar beet is negligible. Therefore, the overall environmental risk posed by event H7-1 is also negligible, and strategies for risk management would be the same as for conventional sugar beet.

30. Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)

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

31. Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)

a) Effects on biodiversity in the area of cultivation

Sugar beet have been intensively grown in Europe for almost 200 years. Cultivated beet varieties are neither persistent nor invasive and beet crop is not considered a weed problem in agricultural habitats. It has been demonstrated that H7-1 is equivalent to traditional sugar beet. It can be concluded that the growing of H7-1 represents a no greater risk to biodiversity in the area of cultivation than does the parental variety or any other sugar beet. Some recent publications indicate that RR sugar beet technology allows a flexible management approach to weed control, permitting higher in-field biodiversity early in the season compared with traditional systems.

b) Effects on biodiversity in other habitats

The environmental risk assessment concluded that, like for traditional sugar beet, the likelihood of unintended spreading of RR sugar beet into the environment is negligible as its persistence in agricultural habitats and its invasiveness into natural habitats are unaltered compared to traditional sugar beet varieties. Hence the risk of unintended spreading of RR sugar beet through increased weediness of this sugar beet is negligible. It has also been demonstrated that H7-1 is equivalent to traditional sugar beet. Considering this, the effects of the GMHP on biodiversity in other habitats is no different than from any other sugar beet.

c) Effects on pollinators

Sugar beet is an allogamous species, pollinated by wind and occasionally by insects. H7-1 is equivalent to traditional sugar beet in its biological and

agronomic characteristics. It can be concluded that H7-1 has no other effect on pollinators than the parental variety or any other sugar beet.

d) Effects on endangered species

Traditional sugar beet is not known to have effects on endangered species. The only new trait conferred to H7-1 is the tolerance to glyphosate, due to the expression of the CP4 EPSPS protein, whose safety for humans, animals and the environment has been assessed. In conclusion, the risk of any adverse effects to endangered species, through their ecological interactions with RR sugar beet or with the expressed CP4 EPSPS protein, is negligible.

C. INFORMATION RELATING TO PREVIOUS RELEASES

32. History of previous releases 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.4 for a list of prior notifications in Belgium, United Kingdom, Italy, the Netherlands, France, Germany and Spain under Part B of Directive 90/220/EEC.

b) Conclusions of post-release monitoring

Experimental field trials were performed to assess the degree of glyphosate tolerance, to reproduce 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 performances such as yield and the phenotypic characteristics. The aim of the post release monitoring was to find out if beet plant might establish from dormant seed or beet debris. As a result of these field trials with H7-1 no unexpected effects have been observed in the RR 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 is likely to pose any risk of adverse effects to human or animal health or to the environment.

33. History of previous releases carried out inside or outside the Community by the same notifier

a) Release country

USA, Chile, Czech Republic, Poland.

b) Authority overseeing the release

USA:	USDA
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

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 reproduce 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 performances such as yield and the phenotypic characteristics.

e) Duration of the release

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

f) Aim of post-releases monitoring

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

g) Duration of post-releases monitoring

For vegetatively grown beet the post release monitoring was usually performed for one year, for generatively grown beet in average for 2-3 years.

h) Conclusions of post-release monitoring

No unexpected effects have been observed in RR sugar beet compared to traditional 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 is likely to pose any risk of adverse effects to human or animal health or to the environment.

D INFORMATION RELATING TO THE MONITORING PLAN - IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENT THAT SHOULD BE ADDRESSED IN THE POST COMMERCIALISATION MONITORING PLAN

1. Confirmation that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in E.R.A. are correct

The results of the environmental risk assessment (e.r.a.) of RR sugar beet event H7-1 show that the overall risk to the environment arising from the placing on the market of this sugar beet is negligible, relative to:

- Persistence or invasiveness
- Selective advantage
- Potential for gene transfer
- Impact on non-target organisms
- Effects on biogeochemical processes due to direct or indirect interactions with target and non-target organisms
- Changes in agricultural practice

Moreover, the environmental risk assessment has demonstrated that RR sugar beet event H7-1 presents negligible risk to human and animal health, relative to:

- Persons in proximity or contact with the release
- The consumption of products derived from RR sugar beet

These conclusions have been reached on the basis of scientific data and analysis, rather than on major assumptions, therefore case-specific monitoring of RR sugar beet is not relevant.

2. Identification of the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the E.R.A

As no specific adverse effects were identified, the objective of the monitoring plan should be general surveillance, which seeks to identify and record any unanticipated adverse effects that have not been identified in the risk assessment.