# SUMMARY NOTIFICATION INFORMATION FORMAT FOR GENETICALLY MODIFIED HIGHER PLANTS (GMHP´s)

## ROUNDUP READY ® FODDER BEET DERIVED FROM LINE A5/15

**By**

**DLF-Trifolium A/S**

**and**

**Monsanto Company represented by Monsanto Europe S.A.**

**and**

**DANISCO Seed**

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

## A. GENERAL INFORMATION

### Introduction

In Western and Eastern Europe, fodder beet is used to feed cattle. The major Western European market is Denmark.

Fodder beet is an important component of animal diets because it replaces part of the concentrate ration normally fed to cattle. Therefore, at farm level, fodder beet may contribute to reduce feed inputs. Feeding cows with fodder beet improves the digestibility of nitrogenous compounds in the diet, reducing the soluble nitrogen contents in urine and feces, and thereby contributing to less nitrogen leaching into soils. Furthermore, beet is a spring crop growing actively between August and October and its deep root system efficiently utilizes any excessive nitrogen. Thus fodder beet represents an important factor in achieving compliance with sustainable agriculture requirements.

DLF-Trifolium is a major breeder and marketer of fodder beet varieties. The company has always put emphasis on the quality of the environment and one of its objectives is to breed environmentally friendly crops such as grasses, clover and lucerne. Fodder beet is a part of this effort. The introduction of glyphosate tolerant fodder beet will simplify and improve weed management practices in fodder beet cultivation and will contribute to reduce significantly the quantity of herbicide used to achieve an effective weed control. Moreover, glyphosate has a favorable environmental profile.

For all these reasons, fodder beet varieties tolerant to glyphosate have been developed since 1989, as a result of the cooperation between DLF-Trifolium, Monsanto Company and Danisco Seed. Monsanto has provided the glyphosate tolerant gene, while DLF-Trifolium and Danisco were responsible for developing and breeding glyphosate tolerant varieties in Denmark.

### 1. Details of notification

**a) Member state of the notification**: Denmark.

**b) Notification number**: C/DK/97/01.

**c) Name of the product (commercial and other names):**
The product consists of seeds and plants of Roundup Ready[?] fodder beet (abbreviated RR fodder beet) derived from the transformed line A5/15 by traditional breeding methods. RR fodder beet is tolerant to glyphosate, the active ingredient of Roundup[?] herbicide. The commercial products are RR fodder beet varieties. Like other fodder beet varieties, each will have a different commercial name.

[?] Roundup Ready is a registered trademark of Monsanto Technology LLC
[?] Roundup is a registered trademark of Monsanto Technology LLC

**d) Date of acknowledgment of the notification:** 24 March 1997

## 2. Notifier/Manufacturer/Importer

**a) Name of the notifiers**: i) DLF Trifolium A/S
ii) Monsanto Company represented by Monsanto Europe S.A
iii) DANISCO Seed

**b) Address of the notifiers**: i) Hojrupvej 31, DK-4660 Store Heddinge, Denmark.
ii) Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.
iii) Hojbygardvej 31, DK-4960 Holeby, Denmark.

**c) The notifiers are**: i) DLF-Trifolium is the developer of the genetically modified fodder beet line A5/15 and the breeder and seed producer of beet varieties.
ii) Monsanto Company is the developer of the *cp4 epsps* gene technology in Roundup Ready crops, including beet.
iii) DANISCO Seed is breeder and seed producer of beet varieties.
Danisco Seed is in charge of the seed processing and pelleting.

**d) In case of import: (name and address of the manufacturer)**
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 recipient plant is a diploid yellow fodder beet (*Beta vulgaris var crassae*). The genetic modification confers the glyphosate tolerant trait to traditional fodder beet varieties.

**(b) Any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed conditions for the authorization applied for**
RR fodder beet has been demonstrated to be equivalent to traditional fodder beet, apart from its tolerance to glyphosate, and will be used in the same manner as any other fodder beet.

**(c) Intended use of the product and types of users**
This application includes the production of RR fodder beet in the European Union (EU) as well for feed use. There are no specific differences when RR fodder beet is compared to traditional fodder beet except for its tolerance to glyphosate. RR fodder beet has been shown to be equivalent, with exception of the introduced trait, to fodder beet currently in commerce and therefore, the proposed uses and the types of users for RR fodder beet are identical to those for traditional fodder beet. Fodder beet will be used to feed livestock, principally dairy cattle. The users will be plant breeders and farmers.

**(d) Any specific instruction and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorization applied for**
RR fodder beet has been demonstrated to be equivalent to traditional fodder beet, apart from its tolerance to glyphosate. No specific instructions or recommendations for storage of seeds, plants, or products derived from RR fodder beet are envisaged.

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

Beet is a common crop in arable agricultural systems in Europe, adapted to cool and moist growing conditions. The main production areas are Denmark (20 Kha), France (40 Kha) and Germany (27 Kha). RR fodder beet is intended for any area where beet is currently produced.

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

RR fodder beet is unsuited in environments where traditional fodder beet varieties are unsuited.

**(g) Any proposed packing requirements**

RR fodder beet has been shown to be substantially equivalent to other beet in growth, yield, survival, composition and other characteristics. Hence, packaging of seed and processed products will be similar to that used for other 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 Roundup Ready® fodder beet derived from line A5/15*". Packages and bags containing the seeds will be identified as Roundup Ready to allow farmers to know they are purchasing a RR fodder beet variety tolerant to Roundup. 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 about 3 M tons of fodder beet for feed use.

**(ii) In export markets for EC supplies**

The current market for fodder beet outside EU is estimated to be 600 kha.
No fodder beet is currently exported from the EU.

**(j) Unique identification code(s) for the GMO(s)**

The unique identification code for A5/15, DLF-0A515-7, 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 the Directive 2001/18/EC and/or Directive 90/220/EEC?**

Yes **X** No

**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 the Directive 2001/18/EC.**

**Or**

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

Yes No **X**

**If yes, specify.**

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

Yes No **X**

**If yes, Give notifications number and Member State.**

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

RR fodder beet varieties have been shown to be equivalent to other 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, volunteer 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 anticipated if there is unintended release or misuse. The measures for waste disposal and treatment for RR beet are identical to those for other beet.

## 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** | Chenepodiaceae |
| **b.** | **Genus** | *Beta* |
| c. | **Species** | *vulgaris* (2n=18) |
| **d.** | **Sub species** | *vulgaris* |
| **e.** | **Cultivar/breeding line** | crassa |
| **f.** | **Common name** | beet |

**9(a). Information concerning reproduction**

**(i) Mode(s) of reproduction**

Beet reproduces through seed only and is highly self-incompatible. The multiplication rate ranges from 350 seeds to 10.000 seeds per plant in commercial seed production fields under optimal conditions.

**(ii) Specific factors affecting reproduction, if any**

To afford maximum seed yield beet requires: a good establishment of the plantlet, a vernalisation period of minimum 8 weeks with temperatures below 12 ?C, relative long day during the bolting period, sufficient nutrients and water supply during flowering, sufficient pollen concentration during flowering and warm and dry conditions during ripening period and harvest. A deficiency of one of these factors may affect the reproduction.

**(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

*Beta vulgaris* can be crossed under natural conditions with species in the section *Beta*. *B. maritima*, *B. macrocarpa* and *B. atriplicifolia* can hybridise with *B. vulgaris*. There is no evidence that *B. vulgaris* intercrosses with members of the Chenopodiaceae family other than the *Beta* section.

## 10. Survivability

**(a) Ability to form structures for survival or dormancy**

Seed is the only survival structure and most seeds left in the upper 5 centimeters of soil will germinate if the conditions are favorable. The seeds ploughed deeper may remain dormant until the conditions are optimal for germination. It is known that seeds may remain dormant for 10 years or longer.

**(b) Specific factors affecting survivability, if any**

Beet plants rarely survive in subsequent crops and are not considered a weed problem. Numerous factors affect the ability of beet to survive. Beet is a biennial, highly sensitive to frost and poorly competitive. Importantly, beet is sensitive to tillage and to most broadleaf herbicides commonly used in rotational crops.

## 11. Dissemination

**(a) Ways and extent of dissemination**

Beet seed will spread over short distances by several means such as threshing, mechanical soil preparation, heavy rainfall, and animal activity. The only significant means of dissemination of beet seed is in the seed production process where large quantities are harvested, processed and distributed.

**(b) Specific factors affecting dissemination, if any**

Beet seed have no special, morphological characteristics that facilitate dissemination.

## 12. Geographical distribution of the plant

Cultivated beet is believed to have originated in the near Orient. It is now grown in temperate and Mediterranean climate zones.

## 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 symbiont

Beet has a long history as an agricultural crop in the Member States.

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

Interactions between beet and other organisms in the environment are known. Insects, nematodes and mammals feed on the leaves and roots. Beet is also susceptible to several fungal and viral diseases. Finally, beet competes poorly with weeds for light, nutrients and water. The presence of weeds in beet production fields is known to reduce the yield of beet significantly. Beet has no toxic effects on animals or humans.

## 15. Phenotypic and genetic traits

Beet (*Beta vulgaris*) forms a rosette of leaves and a swollen root in the first year. Beet root phenotypes cover a large range of color (pink, red, orange, yellow and white) and shape. Cultivated beet is a biennial crop. The biennial nature of cultivated beet can be disturbed by a cold period of a minimum of 8 weeks (5-10° C), which may induce the reproductive phase with flowering and fructification in the first year. Fodder beet is diploid and has 18 chromosomes. Most of the commercial beet varieties are diploid or triploid hybrids. Beet is generally highly self-incompatible. It is largely wind-pollinated, with insects playing a minor role. Fodder beet, especially varieties with low dry matter content, is very sensitive to frost.

# INFORMATION RELATED TO THE GENETIC MODIFICATION

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

A disarmed *Agrobacterium tumefaciens* plant transformation system was used to produce line A5/15. This delivery system is well documented to transfer and stably integrate transferred DNA (T-DNA) into plant nuclear chromosome. The particular vector used is pMON17204. The original transformation event was developed by DLF-Trifolium using a proprietary line, DP15, a yellow diploid multigerm fodder beet pollinator.

## 17. Nature and source of the vector used

The plant transformation vector pMON17204 is a disarmed *A. tumefaciens* vector containing four genes (*cp4 epsps, uidA, gox, nptII*) 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 the intended function of each of the constituent fragment of the region intended for insertion

| Genetic Element | Size[1] (Kb) | Function |
|---|---|---|
| Right Border | 0.025 | A 25 nucleotide sequence that acts as the initial point of DNA transfer into plant cells originally isolated from pTiT37. |
| P-FMV | 0.672 | The 35S promoter from a modified figwort mosaic virus (CoMVb) used to drive expression of CP4 EPSPS and *gox* genes. |
| AEPSPS/CTP2 | 0.310 | The N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene. |
| *cp4 epsps* | 1.363 | The 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*) gene from *Agrobacterium* sp. strain CP4. |
| E9 3' | 0.630 | The 3' end of the pea rbcS E9 gene which provides the polyadenylation sites for the CP4 EPSPS and GUS genes. |

| | | |
|---|---|---|
| P-e35S | 0.615 | The cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region used to drive expression of the GUS and *nptII* genes. |
| *UidA* | 1.809 | The *uidA* gene from *E. coli* encoding a ß-D-glucuronidase (GUS) protein. |
| CTP1 | 0.165 | The N-terminus encoding the chloroplast transit peptide of the small subunit 1A of rubisco from *A. thaliana*. |
| GOXsyn | 1.295 | The coding sequence of the glyphosate oxidoreductase (*gox*) gene isolated from *Ochronobactrum anthropi*. |
| NOS 3' | 0.256 | The 3' nontranslated region of the nopaline synthase gene which terminates transcription and directs polyadenylation. |
| *NptII* | 0.795 | The *nptII* gene encoding the enzyme neomycin phosphotransferase II. |
| Left Border | 0.025 | A 25 nucleotide sequence that delimits the T-DNA transfer and acts as the endpoint of DNA transfer into plant cells. It was originally isolated from pTiA6. |

## INFORMATION RELATING TO THE GMHP

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

RR fodder beet plants are tolerant to glyphosate. The tissues of RR fodder beet contain the *cp4 epsps* gene, which encodes for the CP4 EPSPS protein conferring tolerance to glyphosate.

The objective of the genetic modification is to improve weed management techniques in fodder beet, a critical step for optimizing production efficiency. The use of RR fodder beet would enable farmers to utilize Roundup herbicide for effective control of weed pests and to take advantage of the herbicide's environmental and safety characteristics.

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

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

Southern blot and PCR analyses were conducted to characterize the inserted T-DNA. Only the DNA required to confer the glyphosate-tolerance phenotype was transferred and inserted at a single locus. The DNA fragment inserted into the A5/15 genome contains the *cp4-epsps* gene and its regulatory elements. Thus, the only introduced plasmid-derived genetic elements present in RR fodder beet are the P-FMV promoter, the *cp4 epsps* gene (including the chloroplast transit peptide CTP2) and the E9 3' termination signals. No genetic elements from outside of the right and left borders of the plasmid were transferred into the genomic DNA.

**(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 chromosomes, chloroplast, mitochondrion, or maintained in a non-integrated form), and he methods for its determination**

The insert is stably integrated into the plant nuclear genome. This was determined by evaluating the segregation of the Roundup tolerance trait in the offspring deriving from crosses between RR and traditional fodder beet plants, using RR plants as the female parent (seed producer) and the traditional fodder beet plant as the male (pollen donor) parent.

**(d) Copy number and stability of the insert**

Southern blot analyses demonstrate that one copy of T-DNA is inserted into the A5/15 transformation event. The stability of the insert was determined by the following analyses:

Tolerance to Roundup

Testing of multiple generations of RR hybrids for tolerance to glyphosate in field trials has confirmed that the levels of tolerance are consistent across generations.

Physical stability of the insert

Southern blot analyses and PCR walking experiments were performed on the original transformation event and on plants from each of the subsequent 3 generations. No differences in the banding pattern were observed among the generations.

**(e) In case of modification 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 result of the modification**

Not relevant.

## 21. Information on the expression of the insert

**(a) Information on the expression of the insert and methods used for its characterization**

Field trials were conducted in 1995 and 1996 across Europe in the major fodder beet production areas. Expression levels of the protein CP4 EPSPS were measured in young leaf, tops and brei (root tissue processed using standard methods of the beet industry for analysis of roots) using ELISA assays. In 1995, the mean levels of expression were found to be: early leaf, 0.133 µg/mg tissue fresh weight; top, 0.208 µg/mg tissue fresh weight; and brei, 0.058 µg/mg tissue fresh weight. In 1996, the mean levels of expression were found to be: top, 0.236 µg/mg tissue fresh weight; and brei, 0.072 µg/mg tissue fresh weight. No meaningful differences between the ranges and mean levels of CP4 EPSPS in line A5/15 were observed over the two years.

**(b) Parts of the plant where the insert is expressed (e.g root, stems, pollen etc.)**

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

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

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

RR fodder beet is no different than other beet in mode or rate of reproduction.

**(b) Dissemination**

The genetic modification did not influence the dissemination characteristics of RR fodder beet compared with traditional beet.

**(c) Survivability**

Based on the results from field test programs, it has been shown that the biological features affecting survival, including germination, establishment, susceptibility to disease and frost of RR fodder beet are not different from other beet.

**(d) Other differences**

The only new trait introduced in A5/15 is the tolerance to glyphosate.

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

No gene transfer from beet to other organism is documented except for gene transfer by sexual means as described in item 9(b).

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

Beet is extensively cultivated and has a long history of safe use as fodder. RR fodder beet is equivalent to traditional beet in terms of nutrient and naturally occurring antinutrients, and the safety of the introduced protein – CP4 EPSPS – has been demonstrated. No unintended effect of the inserted trait on the composition of RR fodder beet was identified. There will be little, if any, human exposure to the CP4 EPSPS protein and no adverse effects on human health have been observed from handling of RR fodder beet. Based on these information it is concluded that RR fodder beet is equivalent to other fodder beet regarding human health.

The results of several studies on compositional analysis, invasiveness and persistency as well as on the interaction with beet pathogens and herbivores have concluded that the environmental impact of RR fodder beet is not different from any other fodder beet.

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

Based on the extensive compositional analysis, the safety evaluation of the CP4-EPSPS protein and feeding studies, it is concluded that RR fodder beet is as safe and nutritious as commercially grown fodder beet varieties.

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

The inserted gene – *cp4-epsps* – has no intended target organism.

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

CP4 EPSPS is a member of a family of proteins (EPSPSs), which are ubiquitous in plants, fungi and bacteria. EPSPS is an enzyme of the shikimate pathway for aromatic amino acid biosynthesis. There is no known toxicity associated with this class of proteins. CP4 EPSPS and native EPSPS enzymes are functionally equivalent except for their affinity to glyphosate. Thus the interactions of RR fodder beet with non-target organisms is not different from the current situation with traditional fodder beet

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

Southern blot and PCR techniques were employed for the detection and identification of the inserted nucleotide sequences. A specific ELISA has been developed and was be used to detect the CP4 EPSPS protein in seed or plants.

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

**29. Potential environmental impact from the release or the placing on the market of the GMO (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)**

The overall risk assessment have highlighted that the risk posed by the commercialization of RR fodder beet to the environment and to livestock and human health are negligible and RR fodder beets are not different

from traditional beet marketed for the same purpose. However the use of Roundup as in-crop-herbicide will provide farmers with a flexible and efficient alternative compared to traditional herbicide treatment. The environmentally sound profile of Roundup and the overall reduced herbicide input in the crop rotation are additional benefits.

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

RR fodder beet varieties have no target organisms.

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

**(a) Effect on biodiversity in the area of cultivation**

Observations during field-testing showed no effect of RR beet on the biodiversity in the area of cultivation.

**(b) Effect on biodiversity in other habitats**

RR fodder beet has not become more invasive or persistent than traditional beet, and will therefore affect biodiversity like traditional fodder beet.

**(c) Effect on pollinators**

Traditional fodder beet is not known to have effect on pollinators. In the risk assessment it is concluded that RR fodder beet have similar effects on non-target organisms as traditional beet.

**(d) Effect on endangered species**

Traditional fodder beet is not known to have effect on endangered species. The only new trait conferred to A5/15 is the tolerance to glyphosate, due to the insertion of the *cp4-epsps* gene. In the risk assessment it is concluded that RR fodder beet have similar effects on non-target organisms as traditional beet.

# C. Information related to previous releases

## 32. History of previous release notified under Part B of the Directive 2001/18/EEC, by the same notifier

**(a) Notification number**

| Year | Country | Notification Number |
|---|---|---|
| 1993 | Denmark | B/DK/93/2 |
| 1994 | Belgium<br>Denmark | B/B/93W20<br>B/DK/93/2/ |
| 1995 | Belgium<br>France<br>Italy<br>Denmark<br>Spain<br>United Kingdom<br>United Kingdom | B/B/95/WSP4<br>B/F/95/01/07<br>B/IT/94/18<br>B/DK/93/2<br>B/ES/95/2<br>B/UK/95/R22/1<br>B/UK/95/R22/2 |
| 1996 | Belgium<br>Denmark<br>France<br>United Kingdom<br>United Kingdom | B/B/95/WSP4<br>B/DK/93/2<br>B/F/96/01/04<br>B/UK/95/R22/1<br>B/UK/95/R22/2 |
| 1997 | France<br>United Kingdom<br>Belgium<br>Poland<br>Denmark | B/F/96/04/01<br>B/UK/96/R22/8<br>B/B/95/WSP4<br>preo-0830.8/97<br>B/DK/93/02 |
| 1998 | France<br>United Kingdom<br>Belgium<br>Denmark | B/F/96/04/01 + B/FR/97/01/06<br>B/UK/98/R22/12<br>B/B/95/WSP4<br>B/DK793/02 |
| 1999 | France<br>United Kingdom<br>Denmark<br>Belgium | CTPS<br>B/UK/98/R22/12<br>B/DK/99/02<br>B/B/95/WSP4 |
| 2000 | Denmark<br>United Kingdom | B/DK/99/02<br>B/UK/98/R22/17 |
| 2001 | Denmark<br>United Kingdom | B/DK/99/02<br>B/UK/98/R22/17 |
| 2002 | Denmark<br>United Kingdom | B/DK/99/02<br>B/UK/98/R22/17 |

**(a) Conclusions from post-release monitoring**

During post release monitoring characters like re-growth from root debris after harvest, survival in the following crop, and re-growth from shattered seed was observed. Compared to other beet fields, no unexpected events have been observed in the RR fodder beet fields. It is concluded that the implemented post-release measures were efficient, and that A5/15 performs similarly to traditional beets.

**(b) Results of the release in respect to any risk to human health and the environment (submitted to the competent authority in according to Article 10 of the directive 2001/18/EC)**
Field trials have been conducted for 10 years under a wide range of climatic conditions. None of the results indicate that cultivation of RR fodder beet could potentially pose a risk to human health or the environment.

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

| **a) Release country** | **Lituania 1998-2002** | **USA-Oregon 1997-2000** | **Poland 1997-1999** |
|---|---|---|---|
| **b) Authority overseeing the release** | Lietuvos Respublikos Aplinkos Apsaugos Ministerija 1-29-832 | USDA (99-219 XC) 97-190-03N<br><br>(99-664 XC) 99-239-09N | Ministerstowo Rolnictwa Iigospodarkizywnosciowej podsekretarz stanu |
| **c) Release site** | Lituania Kaunas plant variety testing Station | Oregon | Screm Radostowo |
| **d) Aim of the release** | Variety testing | Asses seed production | Variety testing |
| **e) Duration of the release** | 3 years | 2 x 12 months | 3 years |
| **g) Aim on the post-release monitoring** | Register and remove volunteers | Register and remove volunteers | Register and remove volunteers |
| **h) Duration of the post release monitoring** | 1 year | 1 year | 2 years |
| **i) Conclusions of the post-release monitoring** | No atypical event was observed | No atypical event was observed | No atypical event was observed |
| **j) Results of the release in respect to any risk to human health and the environment** | No risk was identified | No risk was identified | No risk was identified |

# D. Information related to the monitoring plan – identified trait, characteristics and uncertainties related to the GMO or its interaction with the environment that should be addressed in the post-commercialization monitoring plan

On the basis of the environmental risk assessment, the Scientific Committee on Plants, concluded that "there is no evidence indicating that the use of the fodder beet tolerant to glyphosate with the purpose to be used as any other fodder beet is likely to cause any adverse effects on the human health and the environment."
As no specific adverse effects or uncertainties - which should require case-specific monitoring- were identified, the objective of the monitoring plan should be general surveillance which seek to identify and record any indirect, delayed and/or cumulative adverse effects which have not been anticipated in the risk assessment.