

Notification C/GB/04/M5/4

Glufosinate Tolerant oilseed rape T45

Summary Information Format

March 2004

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

A. GENERAL INFORMATION

1. Details of notification

a) <i>Member State of notification</i> : United Kingdom
b) <i>Notification number</i> : C/GB/04/M5/4
c) <i>Name of the product (commercial and other names)</i> : The product covered by notification includes: The seeds derived from traditional crossings with the line containing event T45.
d) <i>Date of acknowledgement of notification</i> :

2. Notifier

a) <i>Name of notifier</i> : Bayer CropScience Ltd.
b) <i>Address of notifier</i> : Hauxton, Cambridge CB2 5HU, UK
c) <i>Is the notifier</i> : <i>domestic manufacturer</i> : No <i>importer</i> : Yes
d) <i>In the case of an import the name and address of the manufacturer shall be given.</i> Bayer CropScience, #100, 3131-114 Avenue S.E., Calgary, Alberta, Canada T2Z 3X2

3. General description of the product

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

The recipient organism is a commercial spring variety of oilseed rape commonly grown in Canada, which has been genetically modified to introduce a herbicide tolerant trait.

Herbicide tolerance:

The LibertyLink[®] trait of tolerance to Liberty[®] herbicide (active ingredient glufosinate-ammonium), through the PAT protein (produced by the *pat* gene) that degrades the herbicide Liberty[®], enables farmers to use an effective post-emergent herbicide and to avoid the precautionary pre-emergence herbicide treatments. It allows for postponing weed control operations and herbicide use until really necessary, contributing an important tool in Integrated Crop Management. In addition it has eliminated the dependence of growers on the use of soil incorporated herbicides allowing for conservation tillage practices to be more widely adopted in the culture of canola in western Canada.

a) 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

None

b) Intended use of the product and types of users

Import in the EU for all uses as any other oilseed rape (food, feed and industrial uses) and not for cultivation.

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

No mandatory restrictions for use, storage and handling are proposed as a condition of the authorisation. All standard practices applicable to oilseed rape today remain adequate.

If genetically modified oilseed rape is co-mingled with non-genetically modified oilseed rape during use, storage and handling, the corresponding batch will have to be labelled with the statement "This product contains genetically modified organisms".

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

Not applicable.

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

None

f) Any proposed packaging requirements

Like any other oilseed rape

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

Not applicable

h) Estimated potential demand

Clearance is for import of raw commodities only.

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

T45 ACS-BN008-2

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<p><i>If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC</i></p> <p>Please refer to the risk analysis for the similar event Liberator L62 as this product contains the same gene and promoter that is associated with T45. The safety assessment for this event has been completed and has received a positive opinion from the SCP. The risks associated with the approval requested for the event T45 are further reduced as compared to the previously assessed event L62 due to the fact that the specific request is for import and processing only and does not request clearance for cultivation of T45 in the EU.</p>	

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

Yes : <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<p><i>(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC</i></p>	

Or

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

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>If yes, please specify:</p> <ul style="list-style-type: none">- Cultivation in Canada, USA & Australia- Import in Japan, China, Singapore & Mexico	

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

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p><i>If yes, give notification number and Member State: C/GB/99/M5/2 UK</i></p>	

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

<p>No additional specific measures are suggested to take in case of unintended release or misuse and no specific measures for disposal and treatment.</p>

B. NATURE OF THE GMHP CONTAINED IN THE PRODUCT

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

8. Complete name

a) <i>Family name</i> : Brassicaceae
b) <i>Genus</i> : Brassica
c) <i>Species</i> : napus
d) <i>Subspecies</i> : oleifera
e) <i>Cultivar/breeding line</i> : various
f) <i>Common name</i> : oilseed rape

9. a) Information concerning reproduction

(i) <i>Mode(s) of reproduction</i> Autogamous and allogamous reproduction: oilseed rape is a crop capable of both self-pollination (approx. 70%) and cross-pollination (approx. 30%). The pollen, which is heavy and sticky, can be transferred from plant to plant through physical contact between neighbouring plants and by wind and insects.
(ii) <i>Specific factors affecting reproduction, if any</i> Temperature (insect visits), humidity (pollen viability) and wind. Pollinating insects, in particular honeybees (<i>Apis mellifera</i>) and bumblebees (<i>Bombus sp.</i>) play a major role in <i>B. napus</i> pollination. The spring-type <i>B. napus</i> is not very drought tolerant. Air and soil temperatures influence plant growth and productivity.
(iii) <i>Generation time</i> Between 5-7 months.

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

Successful hybrid formation depends not only on the sexual compatibility of the recipient species (whether the same or related species) but the two species must flower simultaneously, share the same insect pollinator (if insect pollinated) and be sufficiently nearby for the transfer of viable pollen. The consequences of successful transfer will depend on the sexual fertility of the hybrid progeny, vigour and the fertility of subsequent generations or their ability to propagate vegetatively.

The possibility of gene flow from oilseed rape (*Brassica napus*) to wild relatives under natural conditions has been reported, mostly under optimal conditions, on four species: *Brassica rapa* (synonym *Brassica campestris*), *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*.

The frequency of gene flow from oilseed rape to wild relatives under natural conditions is considered very low, the fitness of the interspecific hybrids is generally reduced compared to the parents and the stable introgression of a new trait in the weed species genome is confirmed to be extremely difficult.

10. Survivability

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

Oilseed rape is an annual plant. Seeds are formed as structures enhancing survival. They can persist in soil through dormancy for several years if they were ploughed in deeper soil. Cultivation of the soil usually terminates this dormancy.

b) *Specific factors affecting survivability, if any*

The survival ability of the seeds is affected by soil conditions such as temperature and moisture content.

11. Dissemination

a) *Ways and extent of dissemination*

Two development stages are relevant for dissemination: pollen and seeds.

Pollen: oilseed rape pollen, which is heavy and sticky, can be transferred from plant to plant through physical contact between neighbouring plants and by wind and insects. Although pollen can be blown by wind or carried away by insect pollinators over large distances, the bulk of cross-pollination has been observed to occur over very short distances. Successful pollination declines exponentially with increasing distance between the pollen source and the nearest recipient plant. Pollen dispersal is not entirely relevant to the assessment as this file is for importation of seeds only and presence of flowering plants will be limited to accidentally displaced seeds.

Seeds: oilseed rapeseeds are small and may be left in and near the field (essentially seeds that shattered or leaked from the transport equipment) or may be carried away (essentially seeds that leaked from the transport carriers).

b) Specific factors affecting dissemination, if any

Pollen dissemination is mainly affected by wind and insects. Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus sp.*) play a major role in *B. napus* pollination. The dynamics of bee-mediated pollen movement depend on the quantity of pollen available (size and density of donor population) and the size and location of the receiving populations, as well as environmental conditions and insect activity. There is no specific factor affecting seed dissemination (oilseed rapeseeds have no special adaptations to encourage transport).

12. Geographical distribution of the plant

Since the second world war, rapeseed production in Europe and Canada has increased dramatically as a result of improved oil and meal quality. China, India, Europe and Canada are now the top producers. Today two species of *Brassica* (*B. napus* and *B. rapa*) have commercialised varieties with double low characteristics (low erucic acid content in the oil and very low glucosinolate content in the meal), characteristics desirable for high-quality vegetable oil and high quality animal feed. *B. napus* is grown as a winter annual in regions where winter conditions do not result in very low temperatures. In North America and Northern Europe, a spring biotype of *B. napus* that requires no vernalisation prior to flowering is grown. Oilseed rape is now one of the major global sources of vegetable oil and the major crop grown in Europe for the production of vegetable oil. The total cultivation area of rapeseed in the world is approx. 24 million hectares, with approx. 14 million hectares in Asia (particularly India and China), 7 million hectares in North America (mainly Canada), 3 million hectares in the EU and 0.7 million hectares in Australia. The total cultivation area of rapeseed in the EU in 2000 was 3.035 million hectares with 1.2 million hectares in France, 1.1 million hectares in Germany and 0.4 million hectares in the UK.

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, as the crop is grown normally 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 toxic effects on humans, animals and other organisms

Oilseed rape is not pathogenic or harmful. There are no major interactions with the ecosystem except for being a crop.
Oilseed rape serves as an abundant supply of nectar for foraging insects such as honeybees.
Oilseed rape plants or seeds may be occasionally consumed by flea beetles, animal browsers (e.g. rabbits) and birds.
A number of diseases (e.g. *Sclerotinia sclerotiorum*) may infest the crop.
Oilseed rape oil is used for human food consumption.
Oilseed rape meal is used as high protein feed supplement for livestock and poultry.
Concerns about the nutritional safety of erucic acid in oilseed rape oil and of glucosinolates in oilseed rape meal led to the development of varieties of oilseed rape which have combined low levels of both glucosinolates and erucic acid (also known as "double low" varieties), characteristics desirable for high-quality vegetable oil and high quality animal feed.

15. Phenotypic and genetic traits

Herbicide tolerance

The recipient oilseed rape is a commercial spring oilseed rape variety with no specific phenotypic or genetic trait.

INFORMATION RELATING TO THE GENETIC MODIFICATION

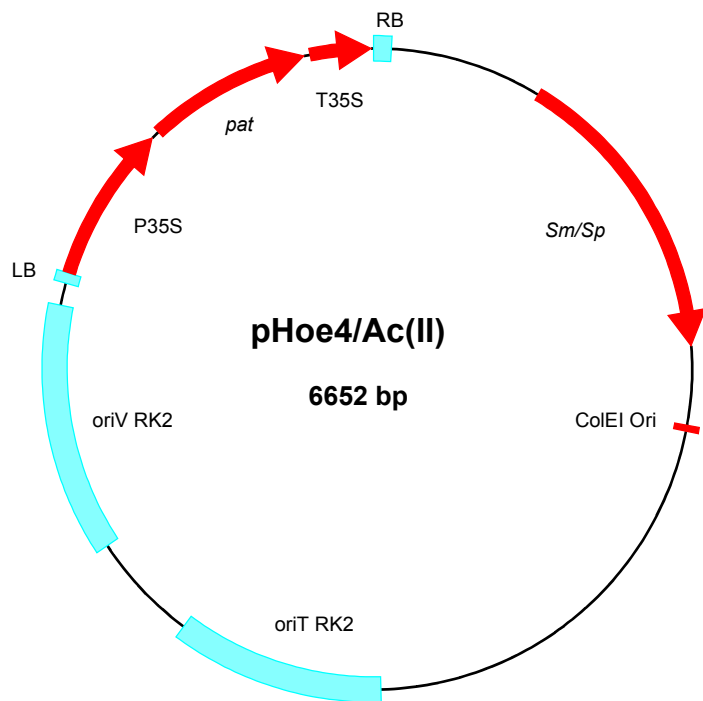
16. Description of the methods used for the genetic modification

Insertion of genetic material by *Agrobacterium tumefaciens* mediated transformation

17. Nature and source of the vector used

Line T45 was produced with plasmid **pHOE4Ac(II)**. This vector has essentially been derived from the vector pPCV002 which has been derived from *E. coli*.

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



Nucleotide number	Genetic element
1 – 60	Synthetic DNA containing the Right Border sequence from the <i>Agrobacterium tumefaciens</i> Ti plasmid pTiT37
61 – 1841	Derived from <i>E. coli</i> plasmid RS38-1 containing the streptomycin / spectinomycin adenylyltransferase gene
1842 – 2692	Derived from synthetic <i>E. coli</i> vector PiAN7 including ori ColE1
2693 – 3164	Derived from <i>Agrobacterium tumefaciens</i> Ti plasmid T37 (adjacent to Apal site at pos. 60)
3165 – 5274	OriV and oriT regions from <i>E. coli</i> RK2 plasmid
5275 – 5310	Synthetic Left Border from the <i>Agrobacterium tumefaciens</i> Ti plasmid pTiAch5
5311 – 5840	35S promoter from Cauliflower Mosaic Virus from the vector pDH51
5841 – 5868	Synthetic polylinker sequences
5869 – 6420	Synthetic <i>pat</i> gene (amino acid sequence from <i>Streptomyces viridochromogenes</i>)
6421 – 6440	Synthetic polylinker sequences
6441 – 6645	35S terminator from Cauliflower Mosaic Virus from the vector pDH51
6646 – 6652	Synthetic polylinker sequences

INFORMATION RELATING TO THE GMHP

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

Herbicide tolerance

The T45 derived lines contain a *pat* gene (bialaphos resistance, origin *Streptomyces viridochromogenes*) coding for phosphinotricin acetyl transferase conferring tolerance to herbicides based on glufosinate ammonium. The *pat* gene is driven by a plant promoter that is active in all green tissues of the plant.

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*

The size and structure of the inserts have been characterised in detail using Southern Blot analysis. PCR analysis has shown that the integrated DNA is restricted to the DNA between the T-DNA border repeats.

In line T45 the inserted DNA has been shown to consist of a single copy of T-DNA insert.

Sequences outside the T-DNA borders of the vector are not present. Based on Southern blots as well as detailed PCR analyses it is confirmed that no sequences of the backbone of plasmid pHOE4Ac(II) are present in the plant.

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*

For the event T45 based on Southern and segregation analyses, it was demonstrated that the DNA has integrated in a single genetic locus in the oilseed rape nuclear genome (chromosomes).

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

Based on Southern blot and PCR analyses, in line T45 the inserted DNA has been shown to consist of a single copy of T-DNA insert.

Based on phenotypic and molecular techniques it was shown that the insert is stable.

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

Linked to the promoter 35S, the expression of the *pat* gene is mainly targeted to green tissue of the plant. Expression level was measured by PAT protein specific ELISA. The PAT protein is detected at low levels in leaf and seed material at a level of approximately 500 and 700 ng/g of total extractable protein.

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

Linked to the plant promoter 35S, the expression of the *pat* gene is mainly targeted to green tissue of the plant (e.g. leaves). The PAT protein can also be detected in very low amounts in dry seed (approx. 0.7 µg/g seed). Only seed will be imported into the EU.

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

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

Reproduction occurs through seed production.

- the shape and size of the seeds is identical to that of the original non-genetically modified variety; there is no development of structures facilitating transport (such as hairs or needles);
- with the exception of tolerance to the herbicide glufosinate ammonium there are no observed phenotypic differences between T45 and conventional canola cultivars.

b) Dissemination

Dissemination of the plants happens through the seed stage. The trait may also be conveyed via the pollen stage. No differences in dissemination capacity have been observed between genetically modified and non-genetically modified plants.

Studies show that the genetic modification did not modify the characteristics of the plants that could have an impact on seed dispersal.

c) Survivability

Survival is essentially determined at the seed stage. There is no indication of any change in seed characteristics as a result of the genetic modification. No difference in survival was recorded at the vegetative stage.

Although non-genetically modified oilseed rape as well as genetically modified oilseed rape can be volunteers and following crops, current agricultural practices (including cultivation, rotation, selective herbicides) are able to control both modified and unmodified volunteer rape plants.

d) Other differences

The GM oilseed rape has been made to be tolerant to Liberty[®] herbicide (active ingredient glufosinate ammonium) and can therefore survive treatment with glufosinate ammonium.

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

There is no evidence of genetic transfer and exchange under natural conditions with organisms other than those with which oilseed rape is able to produce fertile crosses through sexual reproduction. There are no indications that the potential for successful exchange has changed due to the genetic modification. The possibility of gene flow to wild relatives under natural conditions has been reported, mostly under optimal conditions, on four species *Brassica rapa*, *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*.

Should transfer of genetic material to wild relatives occur, no adverse effect on the environment is expected.

When gene flow occurs, the consequences first depend on the sexual fertility of the hybrid progeny and the vigour and fertility of subsequent generations. Successful hybrid formation depends not only on the sexual compatibility of the recipient species (whether the same or related species) but the two species must flower simultaneously, share the same insect pollinator (if insect pollinated) and be sufficiently nearby for the transfer of viable pollen. The consequences of successful transfer will depend on the sexual fertility of the hybrid progeny, vigour and the fertility of subsequent generations or their ability to propagate vegetatively.

In addition, specific studies conducted during the environmental risk assessment of oilseed rape have shown that:

- Any viable progeny of a hybrid oilseed rape-wild relative carrying the herbicide tolerance gene will have no competitive advantage in the absence of selective pressure by herbicide containing glufosinate ammonium.
- Any viable progeny of a hybrid oilseed rape-wild relative carrying the herbicide tolerance gene can be controlled by current agronomic practices, either mechanically by cultivation in the rotation cycle, or chemically by many other active ingredients than glufosinate ammonium.

In order for any horizontal gene transfer to lead to a new type of micro-organism and therefore to introduce a significant impact, some of the following conditions will have to be fulfilled:

- the uptake should result in the incorporation of complete undegraded DNA
- the plant targeted genes should result in significant expression in a prokaryotic background
- the expression should represent a significant increase over the background level
- the traits should convey a competitive advantage to the strain in which they are incorporated.

In the very unlikely case where both horizontal gene transfer from genetically modified plants to bacteria would occur, and where due to genetic recombination the genes would be expressed in micro-organisms (the bar gene is under the control of the 35S promoter, which is not functional in bacteria), this would have no impact since the transgene would not provide a selective advantage (the substrates for PAT protein is the herbicide glufosinate ammonium).

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

No harmful effects on human health arising from the genetic modification are expected.

The PAT protein is not toxic for mammals and does not possess any of the characteristics associated with food allergens. Findings to support this conclusion include:

- The coding sequence of the *bar* gene is derived from a common soil microbe not known to be a pathogen.
- The PAT protein has no homology with any known allergens, toxins or antinutrients.
- The PAT protein has no glycosylation sites present on certain food allergens.
- The PAT protein is quickly degraded and denatured in gastric and intestinal fluids of domestic animals and humans.
- The PAT enzyme is highly substrate specific. It acts on its target, glufosinate but it does not act on glutamate, the closest structural analogue of L-glufosinate.

There were no adverse effects found in mice, even at a high dose level of the PAT protein, after intravenous administration.

Oilseed rape seed of T45 has the same nutritional quality as oilseed rape in commerce. Safe consumption of the oil by humans is supported by the following comparisons:

- Nutritional composition of the oil was not different from the standards of oilseed rape oil in commerce and for most parameters found to meet the standard of statistical equivalence.

The amount of PAT protein present in T45 oilseed rape varieties is small. Refined canola oil contains essentially no protein. Consequently the PAT protein is not detectable in refined canola oil.

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)

The safety of the GMHP to animal health is not different from that of non-genetically modified oilseed rape. No adverse effects on animal health are expected since:

- There are no indications that the PAT protein would alter feed safety of the genetically modified oilseed rape.
- The amounts of PAT present in seed-meal fed to animals would be too low to cause even theoretical concern.
- The low levels of PAT protein and the weight of evidence available concerning the PAT protein lead to the conclusion that there is no risk to livestock following ingestion of the gene product.
- The nutritional quality of feed products derived from the genetically modified oilseed rape is not different from the nutritional quality of feed products derived from non-genetically modified oilseed rape.
- Feeding studies already submitted show no differences between animals fed with genetically modified and non-genetically modified oilseed rape.

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

Not applicable since there are no target organisms.

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

There are no non-target organisms specific to the GMHP compared to non-genetically modified oilseed rape. There are no observed effects of the herbicide tolerant oilseed rape on non-target organisms:

In the very unlikely case where both horizontal gene transfer from genetically modified plants to bacteria would occur and where due to genetic recombination the genes would be expressed in micro-organisms, this would have no impact since the transgenes involved would not provide a selective advantage (the only known substrate of the PAT protein is the herbicide glufosinate ammonium).

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

DNA-based methods:

DNA-based methods available include PCR and Southern-Blot methodology. They allow detection and identification of the event T45 through detection of nucleotide sequences that are specific to these events.

Protein-based methods:

Protein-based methods available include quantitative methods (e.g. specific PAT protein ELISA test) or qualitative methods (e.g. Trait LL Leaf Test kit) based on the specific interaction between antibodies and the PAT protein produced by the introduced gene. They allow detection and identification of glufosinate-ammonium herbicide tolerance trait through detection of the PAT protein in the product.

Protein-based methodology offers an easier-to-use alternative to DNA-based methodology.

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)

While there is no intention to release T45 the following conclusion are applicable to the accidental release of T45 during transport and handling en route to storage and processing in the EU.

The following conclusions were drawn (see items listed Annex II D2 of Directive 2001/18/EC):

- 1) The herbicide-tolerant oilseed rape neither becomes more persistent than the recipient plant in agricultural habitats, nor shows any changed behaviour with respect to invasiveness in natural habitats.
- 2) A selective advantage to the herbicide-tolerant oilseed rape could only be identified upon treatment with glufosinate ammonium.
- 3) Potential for gene transfer to oilseed rape and/or wild relatives is the same as with non-genetically modified oilseed rape: gene transfer to other oilseed rape can occur while gene transfer to wild relatives is very difficult. The same selective advantage, tolerance to treatment with glufosinate ammonium, would be conferred to those plants.
- 4) There are no target organisms.
- 5) No impact could be identified on non-target organisms.
- 6) No adverse effects on human health from contact or handling have been identified.
- 7) No adverse effects on animal health or the feed/food chain following animal feed use have been identified.
- 8) No effect or alteration on biogeochemical processes was observed.
- 9) Adaptations of cultivation and management techniques for the genetically modified oilseed rape are limited to changes in herbicide use, without any adverse environmental impact.

The overall conclusion is that:

- The potential adverse effect identified is establishment of transgenic herbicide tolerance, be it through herbicide-tolerant oilseed rape volunteers or through transfer of the herbicide tolerance gene to wild *Brassica* relatives.
- Standard Good Agricultural Practices allow adequate management of both herbicide-tolerant oilseed rape volunteers and herbicide-tolerant wild *Brassica* relatives i.e. allow adequate risk management of the identified adverse effects.
- The overall risk of herbicide-tolerant oilseed rape T45, taking into account the risk of import, is therefore nil.

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)

Not applicable: there are no target organisms.

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

Presence of volunteer plants will be limited to areas of accidental spillage of seed in transport or storage.

No adverse effects on biodiversity are anticipated as a consequence of import of seed into Europe.

- The herbicide tolerant oilseed rape will not create additional volunteer problems compared to non-genetically modified oilseed rape;
- Standard Good Agricultural Practices provide adequate control of genetically modified oilseed rape volunteers.

b) Effects on biodiversity in other habitats

Presence of volunteer plants will be limited to areas of accidental spillage of seed in transport or storage.

No adverse effects on biodiversity in other habitats are expected (no adverse effects on non-target organisms).

No selective advantage has been conferred to the GMHP.

In natural habitats (absence of selective pressure), the herbicide tolerant hybrid oilseed rape is not likely to become more invasive since there is no selective advantage conferred to the herbicide tolerant hybrid oilseed rape in the absence of selective pressure through herbicide treatment.

In absence of treatment with glufosinate ammonium the presence of the *pat* gene does not confer any selective advantage to herbicide tolerant hybrid oilseed rape. As a consequence, the herbicide tolerance gene is not providing a selective advantage (or disadvantage) in natural habitats or habitats that are not exposed to glufosinate ammonium treatment.

c) Effects on pollinators

In oilseed rape, honeybees (*Apis mellifera*) are considered to be the principal pollinators searching for nectar and pollen, though other insects such as several bumble-bees, some solitary honeybees and some dipteran, lepidopteran, hemipteran and coleopteran insects may have a pollinator role as well.

Presence of volunteer plants will be limited to areas of accidental spillage of seed in transport or storage. No effect on pollinators is anticipated.

d) Effects on endangered species

No adverse effects are expected on endangered species since no adverse effects have been observed on non-target organisms including birds and small mammals.

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

UK: Notification numbers 95/R19/7 and 96/R19/11

Sweden: Notification number: 22/070/98

b) Conclusions of post-release monitoring

Volunteers managed by current agricultural practices.

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)

No human health or environmental risks were observed.

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

a) Inside the Community:

No releases

b) Outside the Community:

Canada (commercial releases since 1997)

Authority overseeing the releases :Canadian Food Inspection Agency

Information on the releases at www.cfia-acia.agr.ca

USA (commercial releases since 1999)

Authority overseeing the releases : USDA-APHIS

Information on the releases at www.aphis.usda.gov

Japan:

Authority overseeing the releases : Ministry of Health Labor and Welfare

Information on the releases at www.mhlw.go.jp/english/index/html

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

The environmental risk assessment identifies no risk for the import of T45 oilseed rape.

T45 oilseed rape will be imported for direct use as food and feed or for processing. No seeds will be imported for cultivation into Europe.

The environmental risk for Europe is no greater than the risks associated with the import and processing of oilseed rape in commerce today.

A plan according to Annex VII for the import of genetically modified oilseed rape T45 has been prepared. This plan will provide for the general surveillance of unanticipated occurrence of adverse effects of the GMHP or its use on human health or the environment, which were not anticipated in the environmental risk assessment.