Notification C/GB/99/M5/2

Glufosinate Tolerant oilseed rape T45

Summary Information Format

February 2003

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

A. GENERAL INFORMATION

1. Details of notification

a) Member State of notification : United Kingdom
*b) Notification number: C/GB/*99/M5/2
c) Name of the product (commercial and other names): The product covered by notification includes: *1. The seeds derived from traditional crossings with the line containing event T45 . The original notification 99/M5/2 also included progeny of a cross between the previously approved oilseed rape event Topas 19/2 and the event T45. The progeny of the cross of the two events is no longer included in the scope of the notification due to the fact that the cultivars derived from the cross of the two events have been replaced in the market with other products and are no longer commercially relevant.*
d) Date of acknowledgement of notification: February 4th 1999

2. Notifier

a) Name of notifier: Bayer CropScience Ltd.
b) Address of notifier:Hauxton, Cambridge CB2 5HU, UK
c) Is the notifier : domestic manufacturer : N importer : Yes
d) In the case of an import the name and address of the manufacturer shall be given. *Bayer Crop Science, #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 a less toxic 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. Farmers are thus given the flexibility to tolerate flora and fauna in their fields that do not pose a threat to either the quality or the yield of their crop.

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).

The imported oilseed rapeseeds will be used for oil extraction primarily.

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 ☐	*No X*
If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC Please refer to the risk analysis for the similar event Liberator L62. 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. ***T45: please refer to application for Part C consent ref. 99/M5/2 dated 28 January 1999.***	

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*	

Or

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

Yes X	*No ☐*
If *yes*, please specify: - Canada (commercial uses) - USA (commercial uses) - Australia - Japan (import to crush for food and feed uses) - China - Singapore	

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

Yes ☐	*No X*
If yes*, give notification 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

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

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

9. a) Information concerning reproduction

(i) Mode(s) of reproduction 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) Specific factors affecting reproduction, if any Temperature (insect visits), humidity (pollen viability) and wind. Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus sp.)* play a major role in *B. napus* pollination. The spring-type *B. napus* is not very drought tolerant. Air and soil temperatures influence plant growth and productivity.
(iii) Generation time Between 6 and 12 months.

9. b) <u>Sexual compatibility with other cultivated or wild plant species</u>

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 five species: *Brassica rapa* (synonym *Brassica Campestris*), *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum* and *Sinapis arvensis*.

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

10. <u>Survivability</u>

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 during 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. <u>Dissemination</u>

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.

Seeds: oilseed rape seeds 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 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)**

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

Line T45 - plasmid **pHOE4Ac(II)** contained between the left and right borders:

1. T45 **pHOE4Ac(II)**

- 35S - *pat* - 35S promoter 35S from couliflower mosaic virus
- the *pat* gene from *Streptomyces viridochromogenes*
- the 35S termination sequences from cauliflower mosaic virus

Table 1 Genetic Elements of T-DNA Component of pHOE4Ac(II)

Abbreviation	**Definition**	**Source**	**Size (bp)**	**Function**
LB	Left border sequence	*A. tumefaciens*	25	T-DNA integration
PLS	Polylinker sequence	Synthetic	27	Plasmid cloning
pat	Glufosinate tolerance gene	*S.viridochromogenes*	551	Herbicide tolerance
PLS	Synthetic Poly Linker Sequence		19	Plasmid Cloning
35S	Termination signal in pat gene	*CcMV*	204	Stop Signal
PLS	Polylinker sequence	Synthetic	6	Plasmid cloning
RB	Right border sequence	*A. tumefaciens*	25	T-DNA integration

INFORMATION RELATING TO THE GMHP

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

Herbicide tolerance

Both the lines (and the resulting hybrid) 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(11) are present in the plant. No *Agrobacterium* DNA containing the Ti-plasmid remains present in the genetically modified 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).

There is no indication of insertion of T-DNA in a functional gene.

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 genes are stable and follow standard mendelian inheritance.

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 activity was assessed by enzymatic assays.

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. 0.5 µg/g seed).

22. <u>Information on how the GMHP differs from the recipient plant in</u>

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

Reproduction occurs through seed production. No differences in seed shattering ability have been observed between the genetically modified oilseed rape plants and non-genetically modified oilseed rape.

- 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);

the germination ability (a key-parameter to test seed dormancy) and evolution of germination ability of the seeds of the genetically modified oilseed rape did not differ from their non-genetically modified counterpart (cf. field trials and germination tests);

no differences in regrowth ability have been observed between the genetically modified and non-genetically modified oilseed rape under greenhouse and field conditions.

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 (shape, size of the seeds, germination ability, regrowth ability, etc.).

c) Survivability

Survival is essentially determined at the seed stage. There is no indication on 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 the Liberty® herbicide (active ingredient glufosinate ammonium) and can therefore survive treatment with glufosinate ammonium.

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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 five species *Brassica rapa, Brassica juncea, Hirschfeldia incana, Raphanus raphanistrum,* and *Sinapis arvensis*.

The frequency of gene flow 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 the herbicide tolerance trait in the weed species genome is confirmed to be extremely difficult.

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.

Environmental studies have demonstrated that the genetic stability, fertility and vigour of the offspring from inter-specific crosses are generally reduced. Potential transgenic exchange is therefore unlikely to lead to establishment as a result of reduced viability of any hybrid plants and competition.

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

- The number of fertile hybrids resulting from pollination between oilseed rape and wild *Brassicaceae* relatives will be very limited.
- 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 an 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.

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 since:

- There are no indications that the PAT, proteins would cause allergenic reactions.

There are no indications that growing the genetically modified oilseed rape would induce or change the intensity of an allergic reaction towards oilseed rape pollen in occupationally or daily exposed personnel.

- The only known substrate of the PAT protein is the herbicide glufosinate ammonium and there is evidence available concerning the safety of PAT.
- The PAT protein is detected in very low amounts in seeds. In addition virtually no protein is present in the refined oil extracted from the plants.
- The nutritional quality of food products derived from the genetically modified oilseed rape is not different from the nutritional quality of food product derived from non-genetically modified oilseed rape. Compositional analyses carried out on oil content, glucosinolate levels, fatty acid profiles including erucic acid content, vitamin E and mineral content showed that the ranges for genetically modified oilseed rape fell within the range for non-modified oilseed rape.

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, proteins 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 non-target organisms specific to the GMHP compared to non-genetically modified oilseed rape. There are no observed effects of the herbicide tolerant (hybrid) 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).
The different studies conducted confirm that the GMHP has no effect on honeybees (attractiveness, behaviour, pollination activity, mortality, etc.) and predatory arthropods of oilseed rape.
No effect could be observed on birds and small mammals.

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.

In addition to these methods, control samples of the product genetic material are available.

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 enroute 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 such as honeybees, birds and small mammals.
6) No adverse effects on human health from contact or handling have been identified.
7) No adverse effect 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

No adverse effects on biodiversity are expected in the area of cultivation (no adverse effects on non-target organisms).

The herbicide tolerance gene provides a selective advantage in cultivated habitats (fields) if the glufosinate ammonium is used as a herbicide for weed control.

In agricultural habitats (fields and field borders, with potential selective pressure through herbicide treatment), the herbicide tolerant (hybrid) oilseed rape is not likely to become more persistent:

- The herbicide tolerant (hybrid) 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

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.

Experimentation was performed on the plants themselves, floral morphology, pollen characteristics and morphology, nectar production and total sugar and glucose content. These data show that there are no pleiotropic effects of the genetic modification on the attractiveness of the herbicide tolerant (hybrid) oilseed rape for the pollinators.

Furthermore, a large number of studies have been conducted over the last years to study the impact of the genetic modification and herbicide spray on bee behaviour: foraging activities, hive activities, life cycle, and development of the populations: no difference could ever be detected in the bee behaviour that could be due to an effect of the genetic modification. No adverse effect on honeybee colonies and their brood has ever been observed.

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

There were no releases under part B in the EU

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 :Canadan 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

E 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

NOT APPLICABLE FOR PRODUCTS FOR IMPORTATION ONLY.