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

## ROUNDUP READY OILSEED RAPE (*BRASSICA NAPUS*) DERIVED FROM EVENT GT73

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## *A. GENERAL INFORMATION*

### *1. Details of notification*

**(a) Member State of notification:** The Netherlands.

**(b) Notification number:** C/NL/98/11.

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

The name of the product is Roundup Ready oilseed rape derived from transformation event GT73. Also defined as glyphosate-tolerant oilseed rape event GT73.

**(d) Date of acknowledgement of notification:** 7 July 1998**.**

### *2. Notifier*

**(a) Name of notifier:** Monsanto Company represented by Monsanto Europe S.A.

**(b) Address of notifier:**

| | |
|---|---|
| Monsanto Europe S.A. | Monsanto |
| 270-272 Avenue de Tervuren | 800 N. Lindbergh Boulevard |
| B-1150 Brussels | St. Louis, Missouri 63167 |
| BELGIUM | USA |

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

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

Not applicable.

### *3. General description of the product*

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

Oilseed rape (OSR). The genetic modification confers the glyphosate tolerance trait to conventional oilseed rape varieties.

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

GT73 has been demonstrated to be equivalent to other oilseed rape, apart from its tolerance to glyphosate, and therefore will be used in the same manner as any other oilseed rape.

The application for consent under Directive 2001/18/EC is for import and use in the EU of GT73. The proposed uses of GT73 are the same as for any other oilseed rape, but do not include the cultivation in the EU of varieties derived from transformation event GT73.

**(c) Intended use of the product and types of users**

There are no specific differences when GT73 is compared to conventional oilseed rape except for its tolerance to glyphosate. GT73 has been shown to be substantially equivalent, with exception of the introduced trait, to oilseed rape currently in commerce and therefore, the proposed uses and the types of users for GT73 are identical to those for conventional oilseed rape.

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

GT73 has been demonstrated to be substantially equivalent to conventional oilseed rape, apart from its tolerance to glyphosate. No specific instructions or recommendations for storage of seeds, plants, or products derived from GT73 are envisaged.

**(e) If applicable, geographical areas within the E.U. to which the product is intended to be confined under the terms of the authorisation applied for**

Grain and derived products of GT73 are intended for import and use throughout the E.U., for the purposes specified in the application.

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

GT73 will be used were conventional oilseed rape is currently used.

**(g) Any proposed packaging requirements**

GT73 has been shown to be substantially equivalent to other oilseed rape. Therefore, GT73 will be used in the same manner as other oilseed rape and no specific packaging is foreseen.

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

In accordance with the requirements of Directive 2001/18/EC, repealing Directive 90/220 on 17 October, 2002, Monsanto will:

a) inform European and International traders of the approval for import into the European Union of GT73,

b) provide all traders with the commercial name of the product and the agreed European and/or international unique identifier (please see section 3j),

c) advise all traders, and other operators using the products, that GT73 is subject to the traceability and labelling requirements of Directive 2001/18/EC, and to the requirements of any Community legislation adopted to regulate the traceability and labelling of GM organisms.

**(i) Estimated potential demand**

*(i) in the Community*

The European Community is an oilseed rape producer and the annual OSR production is almost sufficient to satisfy its internal demand. In 1999-2000 the import of OSR grain from North America was 5000 T.

*(ii) in export markets for EC supplies*

Not applicable, since no GT73 varieties will be planted in Europe.

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

The unique identifier for GT73, MON-00073-7, 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 Harmonisation of Regulatory Oversight in Biotechnology.

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

**Yes [X] No [ ]**

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

Not applicable.

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

**Yes [ ] No [X]**

Please see section 6.

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

Please see following sections.

OR

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

**Yes [X] No [ ]**

**If yes, please specify**

The product has previously been notified in Canada, US, Japan, Australia, Mexico, China, Taiwan and Korea.

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

**Yes [X] No [ ]**

**I f yes, give notification number and Member State**

C/FR/95-06-01 France

A dossier was submitted to the Ministry of Agriculture in May 1995. Due to the lack of official reply (and/or data requirement) from the French Competent Authority, the present application was submitted in the Netherlands in 1998.

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

This application is for consent for import and use in the EU of GT73 as any other OSR, but do not include the cultivation of varieties in the E.U. Therefore an unintended release would be more likely to occur during import, processing and transportation of GT73 grain. However, most OSR grain imported into the E.U. via European sea ports is immediately crushed in nearby crushing facilities and modern methods of transportation and grain handling minimize losses of grain. Therefore, there is little chance of germination of grain resulting in the development of mature plants of GT73 in the E.U. environment.

GT73 is intended for use by oilseed producers, in the same manner as other oilseed rape varieties. The measures for waste disposal and treatment for GT73 products are the same as those for other oilseed rape products.

## *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:** Westar

**(f) Common name**: oilseed rape

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

*(i) Mode(s) of reproduction*

*Brassica napus*, oilseed rape (OSR), reproduces sexually. It is predominantly self-pollinated, although out-crossing occurs to a significant extent, depending upon weather conditions and pollinator activity. OSR is insect pollinated, mainly by bees, but wind pollination is also of importance. Flowering of OSR is indeterminate and the stigma is usually receptive to pollination up to three days after opening of the flowers. Following pollination and fertilisation, the ovary elongates and forms pods (siliques) containing 25 or more seeds. As seeds mature they turn from green to black or reddish brown.

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

The optimum temperature for vegetative growth is about 20°C. Reproduction is favoured by dry weather conditions, which favours the activity of insect pollinators. Water availability is also of particular importance, particularly during the period of seed ripening.

*(iii) Generation time*

The generation time (seed to seed) ranges from about 6 months for spring sown OSR to 11 months for autumn sown (winter) OSR.

### (b) Sexual compatibility with other cultivated or wild plant species

Studies have demonstrated that crosses between *B. napus* and other cultivated or wild plant species occur with varying degrees of difficulty. Out-crossing from *B. napus* to other *B. napus* plants, *B. rapa* (syn. *B. campestris*) and *B. juncea* has been demonstrated to occur naturally under field conditions. Under artificial conditions, including manual crosses, ovary culture techniques, and high foreign pollen pressure, interspecific hybrids may be produced with other species, but these have often been shown to be low in fitness and often sterile. The interspecific crosses are more successful when *B. napus* is used as the female parent and when the species have at least one genome in common.

*i) Crosses between <u>Brassica napus</u> plants*

*B. napus* is principally a self-pollinating crop which is also able to cross with other plants of the same species. Pollen movement is by means of wind and insects, mainly bees. The frequency of intraspecific outcrossing is variable, which reflects the fact that pollinator activity, planting density, genotype, weather, timing of flowering and distance have an impact on outcrossing. Values have been reported as high as 30%.

*ii) Crosses with other Brassica species*

1. *Brassica rapa* (syn. *campestris*)

   *B. napus* and *B. rapa* are known to be sexually compatible under open pollination conditions. This sexual compatibility has been exploited by breeders to transfer useful traits into *B. rapa*, which is a cultivated crop in Canada and Scandinavia.

   While gene transfer from *B. napus* to *B. rapa* is known to occur under controlled conditions, the likelihood of natural introgression of genes from *B. napus* is less certain.

2. *Brassica oleracea*

   *B. oleracea* is the other progenitor of *B. napus*. Natural hybridisation with *B. oleracea*, however, has not been reported. Even with artificial techniques, hybridisations are very difficult to achieve.

3. *Brassica juncea*

   Successful hybridisation has been reported under experimental field conditions using mixed stands of *B. napus* and *B. juncea*. The hybrids showed a low degree of fertility.

4. *Brassica nigra*

   The production of hybrids between *B. napus* and *B. nigra* under field conditions has been unsuccessful. With manual crosses interspecific hybrids were able to be produced, but the hybrid seed and backcrossed progeny exhibited low fertility or sterility and reduced survival characteristics.

5. *Brassica carinata*

   Hybrid seeds have been produced by manual crosses with *B. napus*. Fertility and seed production were generally low.

*iii) Crosses between B. napus and other genera in the Brassicaceae*

These genera include *Diplotaxis*, *Erucastrum*, *Hirschfeldia*, *Raphanus*, and *Sinapis*.

1. *Diplotaxis* species

   Many hybridisations with *B. napus* have been attempted but only *D. erucoides*, *D. muralis*, and *D. tenufolia* have been successful in producing hybrid seed under artificial conditions. The likelihood of producing hybrids with *Diplotaxis* species under natural conditions appears to be low.

2. *Erucastrum gallicum*

   The potential for generation of fertile hybrids between *E. gallicum* and *B. napus* will be lower in frequency than for viable hybrid generation from *R. raphanistrum* and *B. napus*. Further studies have been conducted to define the potential for gene flow between *B. napus* and *E. gallicum*. Although crosses have been successful in the laboratory, these have resulted in less competitive offspring with low viability and this has not been observed under field conditions. Also, *E. gallicum* is not highly competitive and is highly self-fertile and therefore under field conditions would be unlikely to have opportunity to cross with *B. napus*.

3. *Hirschfeldia incana* (synonym *B. adpressa*)

   Hybrid seeds have been produced under field conditions, although the experiments favoured hybrid seed production by interplanting male sterile *B. napus* and fully fertile *H. incana*.

4. *Raphanus* species

   Manual hybridisations with *Raphanus* species have generally been unsuccessful.

5. *Sinapis* species

   No hybrids between *B. napus* and *Sinapis* species have been produced under field conditions, and interspecific hybrid production under artificial conditions has also proven to be extremely difficult.

6. Others

   No reports of other weedy relatives of *Brassica napus*, such as; *Capsella bursa-pastoris* (shepherd's purse), *Thlaspi arvense* (field penny-cress), *Lepidium* sp., *Cardaria draba* (hoary cress), *Neslia paniculata* (ball-mustard), *Sisymbrium officinale* (hedge mustard), and *Erysimum cheiranthoides* (treacle mustard) successfully hybridizing with OSR have been reported.

*iv) Crosses between sexually compatible relatives of B. napus and other genera in the Brassicaceae*

Crosses between *B. rapa* and the cultivated *Brassica* species *B. juncea* and *B. oleracea*, although unlikely, have been successful in producing viable seed so indirect gene transfer to these species cannot be excluded. There are no reports of hybrid seed production between *B. rapa* and the weedy species *B. nigra* when *B. rapa* is used as pollinator. The reverse cross under controlled conditions produced seed at very low frequency (1 per 2000 pollinations) and the F1 plants were much easier to backcross to *B. rapa*. Therefore gene flow is more likely from *B. nigra* to *B. rapa* than the reverse, which is considered unlikely. Gene flow from *B. rapa* to the weedy species *S. arvensis* has

been shown to be very unlikely, since reciprocal crosses under controlled conditions failed to produce any seed.

Crosses between *B. juncea* and *B. nigra* have been successful at low frequency, particularly if *B. juncea* is used as the seed (female) parent. Open pollination of the F1 progeny and backcrossing to *B. juncea* produced plants with low fertility. Backcrossing was easier with *B. juncea* than with *B. nigra*, and the high chromosome numbers of the hybrid progeny suggest that the offspring of this interspecific cross are likely to revert to the cultivated amphidiploid species. Hybrids between *B. juncea* and *S. arvensis* were also only successful when *B. juncea* was used as the seed parent (see Appendix II) and the progeny were poorly fertile. Gene flow from *B. juncea* to *S. arvensis* is considered to be highly unlikely.

## *10. Survivability*

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

OSR is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

Re-growth from OSR seed (volunteers) is often observed in crops grown in rotation with OSR, since dormancy of surviving seeds is usually broken by cultivation. In most cases volunteers are easily controlled by current agronomic practices.

OSR volunteers may also be present in non-cropped disturbed ecosystems, such as field margins, roadsides and railways lines. OSR is not considered an environmentally hazardous colonizing species and volunteers are easily displaced by other weeds, unless those habitats are disturbed on a regular basis. Moreover, these OSR roadside populations are often prevented from reaching maturity by mowing or by chemical treatment.

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

Survival is favoured by the late harvesting of the OSR crop, when pods are mature and more susceptible to natural shattering. Immediate and deep cultivation also favours seed dormancy and survival in the soil. In undisturbed habitats OSR plants show poor survival characteristics; regular disturbance is needed for the establishment of OSR plants from seeds in natural habitats.

### *11. Dissemination*

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

Dissemination may occur by means of seeds or pollen.

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

Seeds have no special features to facilitate widespread dispersal, but they may be disseminated by machinery or fauna. Pollen dissemination occurs by wind and insects (mainly bees). It is mainly short distance dispersal, although dispersal may occur over greater distances at a very low frequency.

### *12. Geographical distribution of the plant*

Oilseed rape is believed to have originated in the Mediterranean area. It is now grown principally in China, Canada and northern Europe.

### *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*

In the E.U., oilseed rape is commercially grown in northern Europe.

### *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 known to interact with other organisms in the environment, particularly with bees (during pollination), birds (eating seeds) and rabbits (eating leaves). It is also susceptible to a range of fungal diseases and insect predators, as well as competition from surrounding weeds. It is not considered harmful or pathogenic to humans.

### *15. Phenotypic and genetic traits*

Except for the introduced trait, GT73 is the same as traditional oilseed rape.

## INFORMATION RELATING TO THE GENETIC MODIFICATION

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

GT73 was modified by incorporation of a DNA fragment derived from plasmid vector PV-BNGT04 into the oilseed rape genome using an *Agrobacterium tumefaciens* mediated transformation.

### *17. Nature and source of the vector used*

The *Agrobacterium tumefaciens* plant transformation vector used to produce the transformation event GT73 was PV-BNGT04. It is a double border vector encoding two genes which confer tolerance to glyphosate: *cp4 epsps* and *goxv247*.

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

Table 18.1 summarizes the different genetic elements intended for insertion into the conventional variety Westar to produce GT73.

**Table 18.1. : Summary of the genetic elements intended for insertion in GT73**

| Sequence | Size (Kb) | Source | Function |
|---|---|---|---|
| Right border | 0.025 | pTiT37 | Initial point of DNA transfer into plant cells |
| *P-CmoVb* | 0.572 | Modified figwort mosaic virus | Promoter |
| *Arab-SSU1A/CTP1* | 0.165 | *Arabidopsis* | N-terminal chloroplast peptide sequence |
| *Goxv247* | 1.296 | *Ochrobactrum anthropi* | Open reading frame encoding the glyphosate degrading protein GOX variant 247 |
| *E9 3'* | 0.632 | *Pisum sativum* | Polyadenylation site |
| *P-CmoVb* | 0.572 | Modified figwort mosaic virus | Promoter |
| *AEPSPS/CTP2* | 0.309 | *Arabidopsis* | N-terminal chloroplast transit peptide sequence |
| *cp4 epsps* | 1.363 | *Agrobacterium* sp. strain CP4 | Open reading frame encoding the glyphosate tolerant CP4 EPSPS protein |
| Left border | 0.024 | pTiA6 | Delimits the T-DNA transfer |

## INFORMATION RELATING THE GMHP

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

GT73 plants are tolerant to glyphosate. The tissues of GT73 contain *cp4 epsps* and *goxv247* genes, which encode the CP4 EPSP and GOX proteins conferring tolerance to glyphosate.

The objective of the genetic modification is to improve weed management techniques in OSR, a critical step for optimising production efficiency, and ensuring a high-quality harvest free of weed seeds.

The use of GT73 for oilseed rape production would enable the farmer to utilize Roundup® herbicide for effective control of weed pests and to take advantage of this herbicide's environmental and safety characteristics. GT73 can positively impact current agronomic practices in OSR by:

1. offering the farmer a new wide-spectrum weed control option;
2. allowing the use of an environmentally acceptable herbicide;
3. increasing flexibility to treat weeds on an "as needed" basis;
4. offering less dependence on herbicides used before planting;
5. providing cost-effective weed control, not only because Roundup herbicide may be less expensive than most current options, but because the total number of herbicides used may be reduced compared to the farmer's current weed management program.

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

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

Southern blot analyses and polymerase chain reaction (PCR) were conducted to characterise the inserted T-DNA. Only the DNA required to confer the glyphosate-tolerance phenotype was transferred and inserted at a single locus. The T-DNA is limited by the right and left borders as expected. Thus, the only introduced plasmid-derived genetic elements present in the transformation event GT73 were the *CMoVb* promoter, the *cp4 epsps* gene (including the chloroplast transit peptide *CTP2*), the gene encoding GOXv247 (including the chloroplast transit peptide *CTP1*), 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 of the glyphosate-tolerant OSR lines. A single chromosomal copy of the inserted DNA is present in each line.

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**(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, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination**

On the basis of the inheritance patterns following self-pollination or hybridisation with other OSR plants, it has been confirmed that the sequence has been stably introduced into the nuclear chromosome.

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

Southern blot and PCR analyses demonstrate that a single copy of plasmid DNA was inserted at the single locus in line GT73.

The *cp4 epsps* and *gox* genes have been shown to be stably integrated into the plant chromosome based on Southern blot analysis, expression data and segregation patterns.

**(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**

Expression of the introduced genes is driven by the constitutive CMoVb promoter. Expression levels were measured in leaf and seed tissues from multiple sites, using ELISA assays. The mean expression levels in seed were in the range of 0.02 to 0.05 µg/mg fresh weight and 0.15 to 0.19 µg/mg fresh weight for the CP4 EPSPS and GOX proteins respectively. Analysis of CP4 EPSPS and GOX proteins in leaf tissue gave mean expression levels of 0.03 and 0.11 µ/mg fresh weight respectively.

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

The mean expression levels in seed were in the range of 0.02 to 0.05 µg/mg fresh weight and 0.15 to 0.19 µg/mg fresh weight for the CP4 EPSPS and GOX proteins respectively. Analysis of CP4 EPSPS and GOX proteins in leaf tissue gave mean expression levels of 0.03 and 0.11 µ/mg fresh weight respectively.

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

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

Data and information collected from field trials conducted in Canada and northern Europe demonstrated no significant morphological, growth or developmental differences between GT73 and conventional oilseed rape. The flowering period, pollen production and viability, self-compatibility, time from seedling to maturity, seed production were observed.

Based on those observations, no differences are anticipated in the reproductive capability of GT73 when compared to the conventional oilseed rape.

**(b) Dissemination**

This application is restricted to import of GT73, therefore the dissemination of oilseed rape pollen or seed produced by GT73 plants is likely to be negligible in Europe.

The mode of reproduction of GT73 is equivalent to that of conventional oilseed rape (see section 22a) and thus its dissemination capabilities (by seed or pollen) will also be equivalent.

**(c) Survivability**

Laboratory and field studies have been conducted to determine whether GT73 the survival and/or over-wintering characteristics of GT73 had been improved, which could increase the potential of GT73 to become a weed.

Based on results obtained in various agricultural environments, it is concluded that there is no difference in survivability between GT73 and conventional oilseed rape.

**(d) Other differences**

No other differences observed.

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

In all respects, with the exception of tolerance to glyphosate, GT73 has been shown to be equivalent to *Brassica napus* L. oilseed rape currently marketed today. On the basis of this conclusion it is anticipated that the potential for gene transfer from GT73 to other organisms is equivalent to that of other *B. napus* plants.

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

An assessment of the human safety of the CP4 EPSPS and GOX proteins was conducted based upon the extensive characterization of those proteins.

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

Finally, the nutritional equivalence of GT73 to traditional oilseed rape has been established by compositional analysis.

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

There is no difference between GT73 and the recipient organism in terms of safety to animals (See question 24).

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

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

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

On the basis of the characterisation of the introduced proteins and the compositional analyses, no specific interactions of GT73 with non-target organisms are to be expected, beyond those that occur with other OSR varieties. Extensive observations in the field have also confirmed that there are no differences between Westar and GT73 in their phenotype, susceptibility to diseases and predators, and yield, indicating that there is no alteration in the interactions with predatory or beneficial non-target organisms.

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

Southern blot or PCR techniques may be employed for the detection and identification of the inserted nucleotide sequences and ELISA for detection of the expressed CP4 EPSPS and GOX proteins.

A detection method has been provided to the Dutch Competent Authority, National Institute of Public Health and the Environment, in charge of the evaluation of this application.

## 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)***

Analysis of the characteristics of GT73 has shown that the likelihood of potential adverse effects on human health and the environment in the European Union, resulting from its *import* and *use* as any other oilseed rape, including use in animal feed but not including the cultivation, is consistently negligible. Therefore, the overall environmental risk posed by the GMHP is also negligible, and strategies for risk management for GT73 would be the same as for traditional oilseed rape.

***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)***

GT73 is herbicide tolerant and, as such, has no target organisms with which to interact, either directly or indirectly.

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

This application is for import and use in the European Union of GT73, and does not include the cultivation of varieties in the E.U. No adverse effects on non-target organisms or the environment are expected.

**Effects on biodiversity in the area of cultivation**

Not applicable.

**Effects on biodiversity in other habitats**

This application is for import and use in the European Union of GT73, and does not include the cultivation of varieties in the E.U. No adverse effects on biodiversity are therefore expected.

**Effects on pollinators**

Please see sections *31.*(a) and *31.*(b).

**Effects on endangered species**

Please see sections 31.(a) and 31.(b).

## *C. INFORMATION RELATED 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**

Notifications under Part B of Directive 90/220/EEC have been made in Belgium, France, Germany and the UK between 1990 and 1996.

**(b) Conclusions of post-release monitoring**

The results of field trials with GT73, undertaken to assess agronomic performance, efficacy and selectivity, yield potential, residues determination, compositional analysis and breeding, showed no significant evidence that GT73 is likely to cause any adverse effects to human or animal health or to the environment.

**(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)**

Post-release general surveillance provided no significant evidence that GT73 is likely to pose any risk of adverse effects to human or animal health or to the environment.

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

**(a) Release country**

**Table 33.1. : First year of experiment and commercialisation**

| Country | First year of experiment | First year of commercialisation |
|---|---|---|
| **Australia** | 1996 | Import 2000 |
| **Belgium** | 1990 | - |
| **Canada** | 1988 | Production 1996 |
| **Chile** | 1994 | - |
| **France** | 1991 | - |
| **Germany** | 1996 | - |
| **Japan** | 1995 | Import 1996 |
| **UK** | 1994 | - |
| **US** | 1995 | Production 1999 |
| **China** | 2002 | - |

**(b) Authority overseeing the release**

**Australia:** Office of Gene Technology Regulator

**Belgium:** Ministry of Agriculture

**Canada:** Canadian Food Inspection Agency (CFIA)

**Chile:** Servicio Agricola y Ganadero

**France:** Ministry of Agriculture

**Germany:** Robert Koch Institute

**Japan:** Ministry of Agriculture, Forestry and Fisheries (MAFF)

**UK:** Department of the Environment

**US:** USDA

**China:** Ministry of Agriculture – GMO office

**(c) Release site**

Realese sites were located in those regions where OSR is traditionally cultivated. Depending on the country, different regions have been identified.

**Australia:** Western Australia, Tasmania, Victoria, South Australia, Queensland, New South Wales.

**Belgium:** region Franc-Waret (South - East Belgium)

**Canada:** Saskatchewan, Manitoba, Alberta.

**Chile:** Temuco, IX Region of Chile.

**France:** Lorraine, Haute-Normandie, Champagne-Ardenne, Picardie, Provence Alpe Cote d'Azur, Rhone Alpes, Bourgogne, Poitou-Charentes, Bretagne, Nord-Pas-de-Calais, Centre.

**Germany:** Bayern, Brandenburgh, Sachsen-Anhalt, Mecklenburg-Vorpommern, Sachsen, Schleswig-Holstein, Niedersachsen, Nordrhein-Westfalen, Thuringen, Baden-Wurttemberg.

**Japan:** 1 isolated field at the National Institute for Agro-Environmental Sciences (Tsukuba city).

**UK:** Lincolnshire, Shropshire, North Yorkshire, Cambridgeshire, Aberdeenshire, Suffolk, Oxfordshire, Essex, Kent, Derbyshire, Warwickshire, Staffordshire, Leicestershire, Lothian, Hampshire, Nottinghamshire, Cheshire, Derbyshire, Tyneside.

**US**: Northern plains.

**(d) Aim of the release**

GT73 has been released for field-testing of agronomic performance (efficacy, selectivity, yield assessment), breeding purposes, residues determination, testing of agronomic equivalence and for compositional analysis. In addition to the above-mentioned purposes, field tests were also carried out to generate the necessary material to establish protein expression. Since 1996 and 1999, GT73 has been commercially released for cultivation respectively in Canada and the US.

**(e) Duration of the release**

The duration of the OSR field releases is one growing season. Since 1996 and 1999, GT73 has been commercially released for cultivation respectively in Canada and the US.

**(f) Aim of post-releases monitoring**

In the case of the field testing performed in Canada and the US, the fields were monitored for volunteers during a period of two years and volunteers were chemically removed.

Since no adverse effects of GT73 have been identified (see section ***29***), no requirement for case-specific post-release monitoring is indicated, which is consistent with approvals granted in other world areas.

GT73 has been commercialized alongside stewardship programmes involving downstream stakeholders in the use of this oilseed rape, in order to ensure the implementation of good agricultural practice in its cultivation and a channel of communication in the unlikely event that unanticipated adverse effects might occur.

**(g) Duration of post-releases monitoring**

In the case of the field testing performed in Canada and the US, the fields were monitored for volunteers during a period of two years.

**(h) Conclusions of post-release monitoring**

The monitoring conducted after the Canadian and US field releases showed no differences in volunteer numbers between GT73 and conventional OSR varieties in the number of volunteers, and confirmed that GT73 volunteers can be effectively controlled. No unanticipated effects have been observed since the commercialization of GT73 in other world areas, nor during the many years of field-testing inside and outside the E.U.

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

Multi-year field-testing and post-marketing experience provided no significant evidence that grain and derived products from GT73 and its progeny are likely to cause any adverse effects to human or animal health and the environment.

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

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

The results of the environmental risk assessment (E.R.A.) of GT73 (Annex II) show effectively zero overall risk arising from the placing on the market of this oilseed rape relating to:

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

Moreover, the risk assessment has demonstrated that GT73 presents effectively zero risk to human and animal health relating to:

- Persons in proximity or contact with the release
- The consumption of products derived from GT73

These conclusions have been reached on the basis of scientific data and analysis, rather than on major assumptions, therefore case-specific monitoring of GT73 is not relevant.

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

The environmental and human health safety assessment for GT73 did not identify any specific risks related to its placing on the market during storage, processing and other uses. Therefore the monitoring plan for GT73 is focused on general surveillance for unanticipated, adverse effects.