Aventis CropScience

Public Information Sheet

AVENTIS CROPSCIENCE N.V.

B. napus hybrids and hybrid parental lines
5-year Program
Spring 2002

European Notification number **B/BE/00/VWSP9**

The release of genetically modified organisms (GMOs) in the environment is at the European level regulated by directive 90/220/EC (recently replaced by directive 2001/18/EC of 12 March, 2001) and at the Belgian level by the Royal Decree of 18 December 1998 on the "regulations for the deliberate release into the environment or marketing of GMOs or products containing GMOs". To ensure the safe use of GMOs both legislations indicate that the release of GMOs for experimental purposes is prohibited without prior written authorisation of the competent minister. The decision whether or not to grant the consent is based upon a thorough biosafety evaluation of the planned release (risk assessment) conducted by the Biosafety Council.

In order to obtain the necessary authorisation from the competent minister, Aventis CropScience N.V. has submitted an application file to the Inspectorate general of Raw Materials and Processed Products of the competent authority. Following the positive advice of the Biosafety Council the competent minster has granted a consent for the company Aventis CropScience N.V. to carry out trials with transgenic spring oilseed rape in the year 2002 in accordance with their application B/BE/00/VWSP9.

In 2002 the release is to be carried out on several trial locations in Flanders and Wallonia on the territory of the municipalities of Nazareth, Maldegem, Bassevelde, Wortegem-Petegem, Kaprijke, Dentergem, Olsene, Oostrozebeke, Vaudignies, Ellezelles, Maffle, Flobecq, Saint Sauveur, Russignies, Orroir, Salles and Saint-Aubin and will follow the normal growing period for spring oilseed rape from April till October.

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0. Table of Contents

1. Description of the genetically modified plants

Scientific and English name:

(a) family :	***Brassicaceae***
(b) genus :	***Brassica***
(c) species :	***napus***
(d) subspecies :	oleifera
(e) cultivar/breeding line :	various
(f) common name :	oiseed rape

Nature of the newly introduced characteristics:

Pollination control system (male sterility and restored fertility) combined with herbicide tolerance.

Function of the new characteristics:

Improve and ease development of new oilseed rape varieties.
Reduce the sensitivity for certain herbicides (glufosinate ammonium herbicides)

Mode of action:

The pollination control system consists of two components; a male sterile plant and a fertility restorer, which in combination will lead to fertile progeny.

The production of pollen in flowering plants occurs in the anthers. The outer cell layer (tapetum) of the anthers is responsible for the development of the pollen. The newly introduced transgenic material initiates the production of an enzyme that eliminates this tapetum layer and thereby prevents pollen development. The activity of this enzyme is limited to the tapetum, in other plant parts the enzyme can not be traced. As a result a male sterile plant is obtained which can efficiently be used for cross-pollinations with other varieties with interesting characteristics.
In the progeny of the male sterile plants, the fertility has to be restored completely in order to gain an optimal harvest. Therefore the so-called “fertility-restorer”-lines have been developed. These lines produce a protein that neutralises the enzyme responsible for the destruction of the tapetum cell layer (Hartley, 1989[1,2]; Mariani ***et al***., 1990[3]; De Block ***et al***., 1993[4]).

In order to reduce the sensitivity for certain herbicides, new genetic material was inserted for the production of enzymes that are able to degrade the active component of certain herbicides. As a result only the GMO plants survive the treatment of the herbicide.

2. Purpose of the experiment

The aim of these field trials can differ according to the type of trial:
- Evaluation of agronomic performance
- Monitoring of large scale introduction (Degrieck ***et al***, 2000[5])
- Development of hybrid parental lines and hybrids

3. Overview of foregoing and future activities

The genetically modified plants were made in a laboratory, scientifically described and increased in greenhouses where interaction with the environment was avoided (according to the relevant legislation[6]). Following the a positive assessment of different characteristics applications for conducting small and later large scale field trials were submitted.
These trials are to be conducted within the framework of a 5-year program that was initiated in 2000.

1990
- Confirmation that the hybridisation system meets the scientific expectations

1991
- Absence of secondary effects
- Stability of the male sterility and the fertility restoration in different
  - genetic backgrounds
  - environmental conditions
- Efficiency of the selection based on a herbicide resistance marker

1992 & 1993
- Feasibility of the system for the agriculture practice and breeding
- Confirmation of the results of 1991 (stability of the trait, herbicide tolerance, etc.).

1994 tot 1999
- Expansion of the field trial program: evaluation of hybrid material in several locations all over the world

During this 11-year period no adverse effects on the environment or public health have been observed.

4. Benefits for the environment, the farmer and the consumer

This product has been used in several countries and the benefits have been confirmed:

Benefits of the use of the pollination control system:
- Higher yield
- Easy yield as a result of uniform growth and seed ripening

Benefits of the specific herbicide tolerance:
Higher yield
Better integrated crop protection activities (In conventional agriculture herbicides are often used preventively to avoid weed emergence. Using a broad-spectrum herbicide in

combination with a non-sensitive crop, this preventive use can be excluded. This kind of herbicide application is beneficial for both the farmer and the environment.)

5. Biology and life cycle of the plant

5.1. General Biology of the used plant

Oilseed rape is the most important oil production crop in Europe. The use of oilseed rape oil was observed since the 16th century. In the 20th century breeders succeeded in the development of varieties with low levels of two components (erucic acid and glucosinolates), thought to have possible detrimental effects on human an animal health. Based on these varieties ("double zero" varieties) oilseed rape became an important agricultural crop.

Oilseed rape is grown is the agricultural ecosystem. Oilseed rape is known to be found in semi-managed areas such as hedgerows, wastelands, and industrial grounds. Volunteer plants can be found in subsequent cropping.

Oilseed rape is a dicotyledonous herbaceous plant. Out of the rosette-stage a branched plant with a smooth, upright stem is formed. Flowers appear in single racemes. Flowering starts on the main stem: buds develop upwards and give typical ***crucifer*** flowers of 1 to 2 cm, with 4 petals and sepals. Flowers begin to open early in the morning and, as the petals completely unfold, pollen is shed and dispersed by both wind and insects. Out of a fertilised flower a cylindrical pod with a length of 5 to 10 cm is formed, which contains 30 to 40 small, round seeds.

5.2. Reproductive biology of the plant

5.2.1. Sexual reproduction

Oilseed rape is mainly pollinated by wind and by pollinating 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 (Mesquida et al. 1982). The theory that succesful pollination declines exponentially with increasing distance between the pollen source and the nearest recipient plant, has been confirmed by different pollen dispersal studies carried out on transgenic and non-transgenic plants (e.g. executed under the BAP, BRIDGE and PROSAMO projects) (Dale, 1991; Scheffler et al., 1993) and indepently confirmed by Kareiva et al., 1990).

Survival of oilseed rape is limited to the seed phase. Seeds can remain dormant for several years under optimal conditions (Crawley et al., 200110). However, oilseed rape seeds also tend to be readily germinating when conditions are favourable, e.g. shallow cultivation, irrigation or rain fall, etc.. Dissemination can occur at the seed stage. Oilseed rape seeds are small and round, and although they have no special adaptations such as hairs for passive transport, loses may be anticipated when handling the material. Such handling is limited to the packaging of seeds, the seeding of the trial, harvesting and further handling of the seed. In view of the small quantities that will be handled, no important losses or dissemination are anticipated.

5.2.2. Vegetative propagation
Seeds are the only means of survival, propagation of green plant parts or surviving plant organs has never been observed.

6. Environmental effects or risks

6.1. OUTCROSSING CAPABILITY AND ESTABLISHMENTS IN NATURAL ECOSYSTEMS

6.1.1. Pollen dispersal
Taking in account the biology of oilseed rape (as discussed above), there is a possibility that genetically modified oilseed rape is found outside the trial area. Hence, crossings with wild relatives are possible. The newly introduced traits are not expected to have an impact on the characteristics of the oilseed rape pollen.

The probability of interspecific crossings with wild relatives of oilseed rape was examined by, amongst others, the OECD (199711). Only four species can hybridise with Brassica napus by open pollination; B. rapa and B. juncea using fully fertile parents; and B. adpressa and R. raphanistrum using a male sterile B napus parent. Ohter species are reported to form hybrids (including the 4 species above) with B. napus when pollination is carried out manually. Most of them were unable to produce fertile progeny.

Many factors will influence the success of hybridisation under field conditions, including: distance between parents, synchrony of flowering, method of pollen spread, specific parental genotypes used, directions of the cross and environmental conditions. Even where there is a possibility of hybridisation between B. napus and a related species growing in the vicinity of a release, poor vigour and high sterility in the hybrids will generally mean that hybrids and their progeny will not survive in either an agricultural or natural habitat.

6.1.2. Seed dispersal
Oilseed rape seeds can be found outside the trial area. Scientific analysis of the seeds from the genetically modified (GM) plants do not reveal any differences in behaviour in respect of non GM-seeds. Moreover, “good agricultural practices are applied in order to minimise seed dispersal.

6.1.3. Selective advantage
Except for the newly introduced traits, there are no indications of a changed biology of the genetically modified plant in respect of its non GM counterpart. The transformed plants will only get a selective advantage when standing in a field treated with a herbicide containing glufosinate ammonium as active ingredient. The non-existing selective advantage of the glufosinate ammonium trait has been demonstrated in numerous field trials with oilseed rape varieties and during post commercialisation monitoring in Canada since the first launch in 1995 (Downey, R.K., 199912).

6.1.4. Volunteers
After termination of the trial small quantities of seed will remain on the trial location. In favourable climatic conditions the seeds will germinate and give rise to new plants, so called “volunteers”. Since the volunteers do not possess any selective advantage (see

above) the normal agricultural practices for oilseed rape can be applied for the management of the volunteers.

6.2. INTERACTIONS WITH TARGET ORGANISMS

There are no target organisms.

6.3. INTERACTIONS WITH NON-TARGET ORGANISMS

There are no non-target organisms.

The pollination-control system combined with herbicide tolerance has extensively been studied by several institutes, universities and regulatory bodies. No harmful interactions with non-target organisms have been demonstrated. We refer to the conclusions of the Scientific Committee of Plants[13] who studied de scientific data and confirmed the safety in this respect. Moreover, the described combination has already been approved in several countries (e.g. US, Canada).

6.4. IMPACT OF LARGE SCALE AND LONG TERM USE

The pollination-control system combined with herbicide tolerance has extensively been evaluated for its impact on the environment and public health. [13] This was done on large scale and long term since the product was already commercialised in other areas outside Europe.

7. Measures for containment, control and follow-up

Aventis CropScience N.V. will perform the trials in accordance with the conditions and recommendations set out in the protocol for field trials with genetically modified oilseed rape, developed by the ministry of agriculture.

8. Destruction of the transgenic material

After termination of the trial the remaining vegetative plants parts will be destroyed. It is foreseeable that a small quantity of seeds is released and will fall in the field at harvest time. These seeds will be left on the field for a couple of weeks to encourage germination. The germinated plants will be destroyed by a herbicide treatment or light soil cultivation.

9. Emergency situations

As soon as any contra-indication on the level of health and/or environment occurs - and this will in the first instance be observed by the people involved in the trial design and execution - the trial will be stopped. The proper authorities will be informed in order to carry out additional inspections.

10. Inspections

The Inspectorate General of Raw Materials and Processed Products of the Belgian Ministry of Agriculture is in charge of the supervision of field trials involving transgenic material. In order to plan their inspections, the notifier has to inform the competent body about the sowing and harvest dates. Inspectors will watch over the execution of sowing and harvesting activities in the field, being in accordance with the ministerial approval en the protocols. In addition the inspector will sample plant material for analysis in an official laboratory.

11. Activity Report

At the end of the growing season the notifier shall submit an activity report to the competent service, the Inspectorate General of Raw Materials and Processed Products, not later than 31/12/2002.
This report will at least contain the following information:

- a copy of the logbook
- the location and period of the release
- the nature of the introduced transformants
- the actual surface of the trial site
- the purpose of the trial(s)
- the frequency and the nature of observations
- the measures that have been observed in order to avoid the spread of transgenic material outside the trial area
- the applied method for the destruction of the harvest and the effectiveness of this method
- the results obtained from the trial
- an overview of the follow-up of the trial area.

12. Socio-economic aspects

An agronomic and economic evaluation of the product was conducted in Canada[14]. A full socio-economic study for one sole biotechnology product will depend on a lot of external data and information. In some cases, this information might not be accessible for a company (e.g. direct and indirect impact on the employment, the ultimate added value, surveys on public concerns and uncertainties) and thus demands for a collaboration with the government and specialised bodies. Moreover, the distinction between the product and other likewise products in hard to make. In this respect however, one could point to the benefits throughout the production of the crop (see previous) and make reference to a general evaluation of genetically modified crops already on the market today (ISAAA[15]).

13. References

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[13] http://europa.eu.int/comm/food/fs/scp

[14] Canola Council of Canada (2001). **An Agronomic and Economic Assessment of Transgenic Canola**, by Serecon Management Consulting, Inc. and Koch Paul Associates. [http://www.canola-council.org/manual/GMO/gmo_main.htm]

[15] http://www.isaaa.org/

14. Glossary

A glossary of biotechnology terminology can be consulted on the VIB web site in collaboration with Agrinfo/Fevia and OIVO. http://www.vib.be