

Information for the public

AVENTIS CROPSCIENCE N.V.

Field evaluation with genetically modified pod shatter resistant oilseed rape

European Notification number B/BE/02/VW4

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 decision 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 of Raw Materials and Processed Products of the competent authority. Regardless the advice (with conditions) of the Biosafety council, the competent minister did not grant a consent for the company Aventis CropScience N.V. to carry out trials with transgenic oilseed rape in the year 2002 in accordance with their application B/BE/02/VW4.

The release was planned to be carried out on several trial locations in Flanders and Wallonia on the territory of the municipalities of Massemen, Deinze, Chimay and Macon and will follow the normal growing period for oilseed rape from April till October.

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2. 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:

Pod Shatter Resistance

The introduced characteristic aims at a higher resistance against the premature opening of the pods during crop ripening. This feature is intended to prevent seed loss just before and during harvest time.

Herbicide tolerance

The plants are tolerant for agricultural applications of the herbicide glufosinate ammonium (Liberty[™]). As a result these plants can be identified and selected in an efficient manner.

Mode of action:

The newly introduced genetic material codes for the production of an enzyme, which alters the composition of the dehiscence zone of the pod to keep it closed longer and thus prevents seeds from dropping. The enzyme is under the control of a genetic element that limits its production to this particular place (dehiscence zone).

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.

3. Purpose of the experiment

The trial aims at evaluating the effectiveness of the newly introduced traits under natural conditions.

4. 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 legislation⁶). Following the a positive assessment of different characteristics applications for conducting small and later large scale field trials were submitted.

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

The potential benefits can not be fully assessed in this stage of the research project. The first step is to conclude on the scientific evidence of the efficacy of the new traits.

Possible benefits of an increased pod shatter tolerance:

- A reduction of seed loss and higher yield as a consequence
- reduced production cost
- Improved oil quality (longer maturation of the seeds)
- Less volunteers

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.)

6. Biology and life cycle of the plant

6.1. 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.

6.2. REPRODUCTIVE BIOLOGY OF THE PLANT

6.2.1. 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.

6.2.2. Vegetative propagation

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

7.	Environmental effects or risks

7.1. OUTCROSSING CAPABILITY AND ESTABLISHMENTS IN NATURAL ECOSYSTEMS

7.1.1. 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.

7.1.2. 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.

If the new trait turns out to be fully functional, an decrease in seed loss and dispersal can be expected.

7.1.3. 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).

7.1.4. 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.

7.2. INTERACTIONS WITH TARGET ORGANISMS

There are no target organisms.

7.3. INTERACTIONS WITH NON-TARGET ORGANISMS

There are no non-target organisms.

The pod shatter tolerance trait is still in an early stage of the research phase. As long as the effectiveness of trait has not been demonstrated, an evaluation of interactions with non-target organisms is irrelevant. A change is behavior is not expected from these plants in respect of the non-GM counterpart.

7.4. IMPACT VAN GROOTSCHALIG EN LANGETERMIJN GEBRUIK

Herbicide tolerant plants have extensively been evaluated for its impact on the environment and public health¹³. This was done on large scale and long term since the product was already commercialized in other areas outside Europe.

The impact of the altered pod shatter resistance cannot be evaluated in this phase of the research since the efficacy has not been confirmed yet.

8. 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.

9. 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.

10. Noodsituaties

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.

11. 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.

12. 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.

13. Socio-economic aspects

An impact is not to be expected as a result of this field trial. Concerning the general desirability of the product, a possible alteration of the agricultural practices to be applied and the impact on the employment can not be evaluated today. 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 (ISAAA¹⁵).

14. References

¹ <u>http://biosafety.ihe.be/CU/CUMenu.html</u>

² Ingram, J. (2000). Report on the separation distances required to ensure crosspollination is below specified limits in non-seed crops of sugar beet, maize and oilseed rape. Review of the use of separation distances between genetically modified and other crops. Published by the Ministry of Agriculture Fisheries and Food. http://www.maff.gov.uk/planth/pvs/pvsd.htm

³ Scheffler, J.A., Parkinson, R., Dale, P.J. (1993). **Frequency and distance of pollen dispersal from transgenic oilseed rape** (*Brassica napus*). *Transgenic Research*, 2, 356-364.

⁴ Kareiva, P., Manasse, R., Morris, W. (1990). **Using models to integrate data from field trials and estimate risks of gene escape and gene spread**. *In : International symposium on the biosafety results of field tests of genetically modified plants and microorganisms*. November 27-30, 1990. Kiawah Island, South Carolina, 31-42.

⁵ Crawley, M.J., Brown, S.L., Hails, R.S., Kohn, D.D., Rees, m. (2001). **Transgenic crops in natural habitats.** *Nature,* Vol. 409, 682-683.

⁶ OECD (1997). **Consensus Document on the Biology of Brassica napus L. (Oilseed Rape).** OECD Environmental Health and Safety Publications. Series on Harmonization of Regulatory Oversight of Biotechnology, No. 7.

⁷ Downey, R.K. (1999). **Gene flow and rape – the Canadian experience**. *BCPC Symposium Proceedings No.* 72 : Gene Flow and Agriculture : Relevance for Transgenic *Crops*, 109-116.

⁸ <u>http://europa.eu.int/comm/food/fs/scp</u>

⁹ <u>http://www.isaaa.org/</u>

15. Glossary

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