Bayer CropScience

Seedlink® Oilseed Rape

Notification C/BE/96/01

Oilseed Rape Ms8 x Rf3

PROPOSED INFORMATION TO THE PUBLIC

July 2002

A new oilseed rape

The distinctive yellow flowers of oilseed rape stand out in the countryside. The crop not only provides ingredients for food but is also a constituent of animal feeds, a lubricant for use in environmentally sensitive areas, and a petroleum substitute in diesel-driven vehicles. This leaflet is about a new type of oilseed rape - SeedLink - which has been developed in part using modern genetic techniques (genetic engineering).

The oilseed rape described here has two distinguishing properties. Firstly, it produces high yields of vegetable oil, a result of it being a cross between two different pure breeds of plant. Secondly, it is tolerant to a herbicide that goes under the tradename, Liberty®. This means that farmers can use Liberty® to control weeds without affecting the crop.

The new type of oilseed rape and the Liberty® herbicide are produced by Bayer CropScience.

Consumers have the right to detailed non-commercial information about crops and food products that employ genetic engineering in their production. This leaflet describes how oilseed rape is grown in Europe, how it is processed and used, and the reasons why genetic engineering methods were used in developing these crops.

It aims to provide information that is balanced and to help people who are interested to make their choices based on an understanding of the facts.

If you have any comments on this leaflet or on the crops it describes, please contact Bayer CropScience at the following address:

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About oilseed rape

Oilseed rape is the major crop grown in Europe for the production of vegetable oils. It is a member of the cabbage family, a sort of turnip. As "rapeseed oil", its traditional forms have been used in kitchens since the 16th century. Its popularity surged again in the 20th century when breeders produced a strain of the plant with lower levels of erucic acid (a fat thought to be bad for the heart) and glucosinolate (a component which limits the value of oilseed rape meal for feeding to livestock).

As with other oil crops such as olives and sunflowers, oilseed rape has to be processed after harvest. The oil-bearing seeds are crushed, leaving a residual meal after the oil is released. Around 40% of the harvested seed is oil and the rest is meal.

The oil is used as a salad dressing and for frying. Rapeseed oil has the lowest saturated fat level of any common vegetable oil, only 7-8% compared with 12% for sunflower and 15% for olive oil. It is also an ingredient in margarine, mayonnaise, spreads and many pre-cooked and processed foods.

Rape methyl ester, a processed form of rapeseed oil is widely used as a diesel substitute in countries such as France and Germany. Standard engines can burn up to 30 - 40% of biodiesel mixed in ordinary mineral diesel. This biofuel is already used on large scale in France and Germany. Biodiesel offers a renewable energy source and helps to reduce the greenhouse gas effect.

Rapeseed oil is also used widely as a biodegradable lubricant, especially in sensitive environments. Rapeseed oil lubricants in chainsaws and outboard motors, for instance, cut down pollution in forests and waterways. The food industry also uses oilseed rape lubricants to prevent hydrocarbon contaminants from getting into food. Rapeseed oil is a raw material for paints, glues, toothpaste, and make-up products such as lipstick.

Oilseed rape meal is used as a protein-rich component of animal feed, supplying a significant proportion of Europe's animal feed needs.

Growing oilseed rape

Oilseed rape is a particularly important crop for Europe. It covers 3.8 million hectares of land in the EU and yields around 3.5 million tonnes of oil. Oilseed rape accounts for over a quarter of all vegetable oil used in Europe. The EU is not completely self-sufficient in vegetable oil, importing around 10% of its needs, largely from North America, South America, and Asia. An increasing number of European farmers are growing oilseed rape, spurred on by the continued demand for vegetable oil. There are, therefore, economic and political incentives for increasing production of oil crops such as oilseed rape, either by extending the areas cultivated or by increasing yields.

There are many different varieties of oilseed rape across Europe, each tailored to suit local climates, soils, growing seasons, and disease resistance requirements.

Oilseed rape is only grown in about one year in four on the same piece of land. This is partly to maintain a balance of nutrients in the soil, and partly to avoid encouraging pests and weeds. Farmers have a wide choice of ways of controlling both weeds and pests and so can use different ones each season to avoid the build-up of resistance.

In Europe, winter oilseed rape is generally planted in August. To preserve the humus content of soils and their water-holding capacity, 'no-till' or 'zero-cultivation' practices are becoming common. The seeds are drilled through the stubble of the previous crop. Standard soil preparation through ploughing requires high-energy consumption for heavy tractor operation. Also normally, herbicides against broad-leaved plants would be sprayed as a precautionary measure before the oilseed rape emerged from the soil. A different herbicide would be used after the crop appeared to keep back grassy weeds. This second herbicide might be used several times in a growing season.

How does SeedLink oilseed rape differ?

SeedLink oilseed rape is almost exactly like the oilseed rape that is already grown in Europe. It differs in just two respects. Firstly it is a high-yielding hybrid crop and secondly it is tolerant of a particular herbicide. Depending on where it is grown, it can produce 10-20% more oil per hectare with roughly the same inputs of fertiliser and the same or less other chemicals. The additional production is due to the phenomenon of hybrid vigour. SeedLink is a hybrid system: two different parental strains are interbred, producing seeds that have higher yields than either. Hybrid seeds and hybrid vigour is common in farmed plants (including organic crops) such as sugar beet, maize, and rye and in horticulture for vegetables and flowers.

Although around 15-20% of European oilseed rape comes from hybrid seeds, hybrid oilseed rape was unusual until recently. This is because oilseed rape and its cabbage-like relatives are bisexuals - self-fertilising plants, containing both male and female organs. Since the organs occur close together, it is difficult to cross-fertilise oilseed rape on the scale needed to produce hybrid seed. A few years ago, however, several different ways of making hybrid oilseed rape seeds were developed. One of these, the SeedLink system, uses a genetic switch to turn off pollen production in one of the parental strains. The hybrid seed arises after that plant is fertilised with pollen from another strain of plant. A second genetic tweak ensures that the resultant hybrid oilseed rape is fully fertile in the farmer's field.

SeedLink oilseed rape is tolerant of the herbicide Liberty®. The tolerance is based on a single enzyme that degrades the herbicide. Other plants, including weedy relatives of oilseed rape, do not have this enzyme and, consequently, are sensitive to the Liberty® herbicide. Liberty® controls most weeds. However, it is readily broken down into organic compounds by bacteria dwelling in the soil. The gene that allows SeedLink oilseed rape to tolerate Liberty® was acquired originally from these natural soil organisms.

The characteristics of the Seedlink® system were conferred on the plant through genetic engineering. The hybrid varieties that farmers will plant are produced conventionally using parental plants derived from these genetically engineered ancestors.

Seedlink® hybrids have higher yields than conventional varieties, while their consistent growth and even ripening make harvesting easier. Liberty® enables farmers to use a less toxic herbicide, but equally important in many production fields growers can avoid the precautionary pre-emergence herbicide treatments. Liberty® used in a Liberty® tolerant crop 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 of the yield of their crop.

How SeedLink® oilseed rape reaches the market

Government controls on genetically engineered products in Europe are stringent and searching. From its earliest phase of research, SeedLink® oilseed rape has been strictly regulated at every turn. As a crop, it has been subject to greenhouse tests, and to many field trials that examine both its growing characteristics and its environmental impact. In parallel, the quality and safety of the crop in human food or in animal feed have been analysed. Before the crop can be sold, all these aspects have to be assessed by independent experts and endorsed by European governments.

Environmental tests

The environmental safety testing of SeedLink® oilseed rape during field trials has taken many forms. In every case it goes far beyond tests performed on non-genetically modified crops; these usually only concern how the crop behaves under farm conditions. In essence, the tests on SeedLink® oilseed rape explore three main dimensions of possible environmental effects.

Firstly, they examine whether its specific genetic modifications have any direct effects on the behaviour of the crop itself. The question most people are interested in is "Is it weedy?" and the answer appears to be "no". In tests over the past decade, genetically modified and conventional oilseed rape have the same appearance and grow in the same way in all environments and field settings. In addition, in field trials designed specifically to test ecological competitiveness, genetically modified oilseed rape crops - like conventional oilseed rape - do not compete well with other plants. By definition, this indicates that they are not weedy.

Secondly, the tests explore whether genetic modification affects how genetically modified oilseed rape interacts with other organisms. The answer appears to be that it has no effect. The birds, insects, and animals that inhabit or eat oilseed rape continue to do so normally whether the crop is genetically modified or not. Rabbits eat the leaves and bees take the pollen, for instance, all with no ill effects.

This raises the third, more complex, question: if the specific genetic modification were transferred to another organism, would there be any harmful environmental effects? Pollen from genetically modified oilseed rape acts perfectly naturally: it disperses on the wind and insects carry it. Just like the pollen of non-genetically modified oilseed rape crops, therefore, it will be transferred to closely related wild relatives of oilseed rape. This could make the wild relatives herbicide-tolerant, leading back to the question, "Does the genetic modification have any direct effects on the behaviour of the wild relatives, making them more weedy, for instance?" The results from tests like those conducted on the crop itself indicate that the answer again is "no".

Environmental impact is monitored long after the initial testing and development is complete and the crops have been approved for sale. To this end, Bayer CropScience has put forward a monitoring scheme and agricultural guidelines. Under these, the company works with farmers and scientific experts to gather more information. Farmers and the company will carefully monitor the behaviour of crop varieties in the field. They will look particularly for any weedy tendencies in the crop and for the spread of the genetically modified characteristic to related plants. They will also keep detailed records of herbicide use.

Crops similar to SeedLink oilseed rape have already been approved and grown for several years in countries such as Canada and the United States. This experience at large scale will serve as a reference for implementing the European monitoring program.

Food and Feed tests

The tests on the safety of genetically modified human food (or animal feed) aim to show whether a genetically modified product is equivalent to existing non-genetically modified products. The composition of the rapeseed oil from SeedLink oilseed rape is unaffected by the genetic modifications that have been made; the oil has the same balance of fatty components. In cooking, pouring, and mixing the product behaves in precisely the same way as oil from non-genetically modified oilseed rape. Regulators have concluded therefore that the oil from SeedLink oilseed rape is "substantially equivalent" to oil from non-genetically modified plants. In every aspect that matters, it is the same.

The nutritional quality of the animal feed product – oilseed rape meal - is also unchanged with the same balance of protein and glucosinolate content. Rabbits or chickens fed either on genetically modified or conventional oilseed rape meal are indistinguishable. In Canada or USA where SeedLink® varieties have been used as component of commercial feed for several years, no effects on animals have been reported. Naturally, regulators have concluded that oilseed rape meal is oilseed rape meal, with or without genetic modification.

Variety testing and seed certification

Every country of the European Union has its own system for testing and registering plant varieties, the specific cultivars of a crop that are thoroughly adapted to local conditions. Only varieties that have some superior characteristic useful to farmers - higher yields or a disease resistance, for instance - will be registered. The variety tests also indicate whether the crop performs consistently and reproducibly: farmers want to know that they will be able to buy the same seed next year as this. Variety registration and listing entails a further 2-3 years of field trials. Farmers are only allowed to buy seeds certified by national authorities after thorough independent testing for seed quality and genetic purity. The quality assurance system, which is based on European law, ensures that, wherever produced, the seeds for sowing the new crop meet the highest quality and purity requirements. In addition, new European legislation is being developed that guarantees separate labelling of genetically engineered varieties and all produce thereof

For all commercially available varieties, whether genetically engineered or not, the original breeders use proven purification and testing methods that ensure the highest genetic purity of the propagation material, forming the basis of the production of commercial seeds for sowing.

European choices

Many Europeans want to do more than be able to choose what food they eat. Some may be concerned about the environmental impact that agriculture has. Others want to be able to trace the origin of their food "from farm to fork". Many people, especially in an enlarged European Union, will continue to see productivity increases and cost reduction as priorities. Others may have no particular concerns. European regulatory authorities have to respond to this breadth of consumer interests and also to the needs of European farmers. In Europe today, agriculture must not only be highly productive but also compatible with environmental protection, rural development and food safety.

Europe has been largely self-sufficient in agricultural produce for the past two decades thanks both to improvements in farming methods and to a programme of farming subsidies that forms part of the European Union's Common Agriculture Policy. Globalisation of trade in agriculture commodities and reform of the Common Agriculture Policy means that those subsidies cannot last forever. Farmers in Europe will have to become still more efficient in order to compete in global markets.

Europe is densely populated and its farmers have adopted intensive, mechanical methods of agriculture. Farmland is not a wilderness, but an environment built by humans over the past 5-8,000 years. Farms support a good deal of wildlife, although their primary purpose is food production for people. Europe has three main forms of farming: organic agriculture, farming based on Integrated Crop Management, and conventional farming. Each of them has its place in addressing different consumer and farming needs.

Many people expect that genetically modification of crops will contribute significantly to improvements both in agricultural production and environmental compatibility. The large increases in yields seen in genetic modified oilseed rape such as SeedLink® may mean that more land can be set aside for environmental purposes. If herbicide use is reduced, this could bring additional environmental benefits. Some genetically modified crops under development have been designed to provide environmental advantages.

The European Union is drawing up legislation to allow the tracking of food from all sources through the food chain. Although the legislation would apply to crops grown outside the EU, tracing foods back to farms on which they were produced would be more difficult if those farms are outside Europe's boundaries. High-yielding oilseed crops similar to SeedLink® are already being grown in Canada and in the United States.

Europe's regulatory systems are adapting in order to allow the various farming methods to co-exist. The need to ensure human safety, environmental safety, and traceability, apply equally to food grown by conventional intensive methods, integrated farming, and organic production. In this way, Europe's regulatory bodies are promoting true choice for consumers and farmers.

Technical Annex - Product Description

SeedLink® oilseed rape has been genetically modified to introduce a pollination control system, linked to a herbicide tolerance trait.

The SeedLink hybridisation system ensures pollination control through:

- A female line obtained by the unique combination of a natural catabolic activity, a ribonuclease (Barnase protein produced by the *barnase* gene), and a DNA sequence limiting its expression to a specific stage and time during the development of the anthers. This female line prevents self-pollination and thereby enables the production of hybrids.

- A fertility restoration line (male line) harbouring a highly specific inhibitor (Barstar protein produced by the *barstar* gene) of the introduced ribonuclease (Barnase protein). Full fertility restoration is obtained after a cross between the female line and the fertility restoration line. Fertility restoration ensures that all the hybrid plants in the farmer's field are fully fertile.

The SeedLink® hybridisation system is combined with the LibertyLink® trait of tolerance to Liberty® herbicide (active ingredient glufosinate-ammonium), through the PAT protein produced by the *bar* gene.

In the European Union, two notifications under Directive 90/220/EEC for placing on the market of SeedLink® oilseed rape were approved in June 1997 (Commission Decision COM/97/392/EC on events Ms1 and Rf1 and Commission Decision COM/97/393/EC on events Ms1 and Rf2).

A third notification under Directive 90/220/EEC for placing on the market of SeedLink® oilseed rape is pending (notification C/BE/96/01 on events Ms8 and Rf3). The European Scientific Committee on Plants expressed a positive opinion on notification C/BE/96/01 on 19 May 1998 (see http://www.europa.eu.int/comm/food/fs/sc/scp/out09_en.html).

The product covered by notification C/BE/96/01 includes:
1. The female line containing event Ms8 and all progeny derived through traditional breeding crosses with non-transgenic oilseed rape
2. The fertility restoration line containing event Rf3 and all progeny derived through traditional breeding crosses with non-transgenic oilseed rape.
3. The hybrid seeds from traditional crossings between parental lines containing events Ms8 and Rf3.

The scope of notification C/BE/96/01 covers all uses as any other oilseed rape and includes both imports and growing of oilseed rape Ms8 and Rf3 in the EU, for food, feed or industrial uses.

Oilseed rape varieties derived from transformation events Ms8 and Rf3 will be labelled with the SeedLink® and LibertyLink® logos.

SeedLink™ Pollination Control

LibertyLink® Herbicide Tolerance