



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on an application for deliberate release of a GMO for research and development purposes

Applicant: Bayer CropScience Limited

Application: For a three year programme of work to release winter oilseed rape genetically modified for pollen infertility, fertility restoration and herbicide tolerance.

Ref: ¹03/R38/1

Date: 8th September 2003

Advice of the Advisory Committee on Releases to the Environment to the Secretary of State under section 124 of the Environmental Protection Act 1990

ACRE is satisfied that all appropriate measures have been taken to avoid adverse effects on human health and the environment from the proposed release and sees no reason for the release not to proceed on the following conditions. The holder of the consent shall:

1. in line with Good Agricultural Practice exercise good volunteer control by cultivating the site post release to reduce the viability and dormancy of freshly shed rape seed².
2. notify the following information at the times shown:

The effects of the release as authorised by the consent, for the assessment of any risks there are of damage to human health and the environment from the genetically modified organisms concerned. This should be in the form of reports submitted:

- either one month after the date of termination³ of each release in the programme of work or by 31 October in the year each trial was terminated whichever is the sooner;
- by one year after the date of the termination of each release or by 31 October whichever is the sooner to cover post-trial monitoring for;

¹ Application reference 03/R38/1 dated 27 June 2003 taking into account all information and amendments as in the applicant's letters dated 17 July 2003, 24 July 2003 and 11 August 2003.

² One way of achieving this is following harvest to refrain from cultivation of the soil in the trial area until a period of 10 days has elapsed after a heavy downpour of rain or in the absence of such an event for at least a month after harvest.

³ For the purposes of this consent 'termination' occurs when the plants that germinated from the seed sown are harvested or otherwise removed from the environment. The latter may include, but is not limited to, destruction of plants in situ with herbicide following poor establishment, or the removal of plant material following vandalism.

1. assessment of the effectiveness of measures to control volunteers, and
2. the re-evaluation of the post trial monitoring requirements
3. ensure that during the first and second cropping year post-termination that a cereal is cultivated on the release site to allow for good volunteer control.
4. any oilseed rape cultivated and harvested from the release site in subsequent years must comply with the current legislation regarding traceability and labelling of GM products and measures must be taken to ensure that unauthorised GM oilseed rape is not placed on the market as a result of Part B releases under this consent.

Comment

ACRE considered the risks to human health and the environment posed by the proposed release of autumn sown herbicide tolerant GM winter oilseed rape for the purpose of national list trials. ACRE have considered the risk assessment for deliberate release trials of this particular GM oilseed rape on several occasions previously. In reaching its view on the current application ACRE considered this previous advice in addition to any new information and expertise available.

In summary the Committee considered the capacity for the modified rape to be more invasive or persistent than conventional varieties and concluded that the herbicide tolerance trait is very unlikely to confer a competitive advantage outside the agricultural ecosystem. Further any transfer of herbicide tolerance to wild relatives is very unlikely to confer a selective advantage. ACRE is content that the risk is very low and for the releases to proceed as described. This is consistent with ACRE's previous advice.

ACRE considered isolation of the GM oilseed rape. The Committee was content with the use of a 6-metre(m) border of non-transgenic oilseed rape to act as a pollen trap. A second option for segregation of the GM oilseed rape from non-GM oilseed rape proposed by Bayer is a 50m separation zone. The Committee was content that a distance of 50m from conventional oilseed rape was in some cases sufficient to minimise cross pollination to neighbouring crops, however the Committee requested that this be increased to a 100m separation distance in the case of varietal associations which are more susceptible to cross pollination. In addition the Committee requested clarification that all oilseed rape harvested from the 6m border will be destroyed in the same manner as material from the release site.

Regarding monitoring of the site the Committee considered that the border or the separation zone (as appropriate) should be monitored post-termination of the trial. Monitoring of previous releases over several years in the UK and in other Members states has revealed no adverse effects on human health or the environment at large. However ACRE is aware of new information suggesting that oilseed rape seeds may persist in greater quantities in the ground than had previously been found. In the agricultural environment, any GM oilseed rape plants that emerge in following crops (volunteers) will be susceptible to normal agricultural practice of weed control. ACRE recommends that each release site be monitored for volunteers in the year following the release. The Committee will assess the effectiveness of measures taken to control volunteers and if necessary re-evaluate the post-trial monitoring requirements.

No commercial oilseed rape will be grown at each release site for two years following each release. In addition ACRE commented that the consent holder be reminded of

their obligation to ensure that any material marketed from the release sites meets the current legislative requirements.

Finally ACRE requested that Bayer provide a statement detailing the source of the release material and provide evidence to verify that only MS8 x RF3 GM material will be released.

Items arising from public representations

ACRE considered the representation received from a member of the public regarding this application in which a number of issues were raised. The Committee considered the comments relating to separation distances and cross pollination. Taking into account the small size of national list trial plots ACRE is content that the proposed use of a 6m non-GM oilseed rape border or a 50m separation zone from neighbouring oilseed rape (100m in the case of varietal associations) is sufficient to eliminate any risk and to maintain commercial oilseed rape harvests below labelling thresholds.

The representation also recommends that oilseed rape should not be grown on the release site for 5-8 years. ACRE considered the possibility of oilseed rape seed remaining dormant in the soil and advised that a cereal should be grown on the release site for 2 years post-termination to allow for the clear identification of volunteers, in addition monitoring will be extended should volunteers become a problem. In subsequent years oilseed rape may be grown but will be subject to condition 4 above (see following comment).

Concern was raised regarding the potential for marketing of unauthorised GMOs as a result of this release. ACRE agree that any oilseed rape cultivated and harvested from the release sites must comply with labelling requirements for authorised GM crops and that unauthorised GM crops should not be placed on the market, this is reflected in condition 4 above. The final substantive point raised in the representation is in relation to the potential for gene stacking as a result of previous GM plantings at the release site. Any previous plantings will have been carried out under a Part B consent which will have included restrictions regarding follow on crops in light of this and the small plot size gene stacking is not expected to be an issue.

ACRE was content that all issues raised had been considered thoroughly during the Committee's assessment of the dossier. ACRE was satisfied that no new issues had been raised from the public with respect to this application.