



## ***ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT***

### ***Advice on notification of locations of GM crop releases for a Part B application (03/R38/1) for the purpose of National List trials***

**19 September 2003**

#### **Background**

Bayer CropScience Limited have applied for a Part B consent under the First Simplified Procedure for the release of herbicide tolerant winter oilseed rape (MS8 x RF3) for the purpose of National List trials (ref: 03/R38/1). ACRE advice on this application has been provided separately and concludes that within the context of the proposed programme of work that all appropriate measures have been taken to avoid adverse effects on human health and the environment.

Under the First Simplified Procedure the first intended release site is specified in the application and the location of further release sites notified prior to sowing. ACRE issued advice regarding the level of detail required for GM crop release sites in September 2000. In summary, the Committee agreed that where well characterised GMOs are being released, for example for the purpose of National List trials, it was acceptable for locations to be specified as parish name initially, with a more precise location (6-figure grid reference) being notified before harvest.

Within the context of the current application (03/R38/1) to release GM oilseed rape (MS8 x RF3) for National List trial purposes, Bayer have notified the location of release sites at the level of county initially, with the intention of providing 6-figure grid references immediately prior to harvest. ACRE was asked to reconsider its advice of 2000 and specifically whether the proposal from Bayer is acceptable in terms of risk assessment. The following advice is provided with respect to this specific case alone.

#### **ACRE's advice:**

For this particular application for small-scale National List trials of herbicide tolerant oilseed rape from Bayer CropScience Limited (03/R38/1), ACRE is satisfied that the notification of sites at county level prior to sowing is acceptable in terms of risk assessment, providing that the GM material does not occupy an area of greater than 500m<sup>2</sup> per release site. However, for the purpose of post-release monitoring, the exact location by means of a 6-figure grid reference must be provided to the authorities before harvest. In addition the consent holder must ensure that sufficient information regarding site location is available to enable an effective inspection regime.

ACRE would like Ministers to note that this advice is provided entirely in terms of evidence-based risk assessment. The Committee has concerns over this application with respect to openness and transparency. The Committee will provide more detailed advice regarding site notifications later this year.

## Consideration

The locations of sites for releases of GM crop plants are required to enable the authorities to assess the risk that might arise from the growing of GM crops and to allow inspections of sites to be carried out by the GM inspectorate. Many Part B consents are issued for the purpose of small scale releases of GM crops to test their performance in an agricultural environment. However some releases are carried out at an advanced stage of development for the purpose of statutory National List trials, often just prior to marketing authorisation being granted. Usually in these circumstances the First Simplified Procedure is used.

ACRE considered the details of this particular application from Bayer (03/R38/1) and the specifics of the GMO in question in relation to level of detail required for site notifications. The Committee is very familiar with MS8 x RF3 oilseed rape which has been the subject of numerous Part B releases and was included in the Farm Scale Evaluations, consequently more than 500 hectares of this particular crop have been grown in trials in the UK. In addition the Committee acknowledge that this GMO is currently being assessed for Part C marketing consent. The Committee is content that this GMO is well characterised and does not pose a risk to human health or the environment.

In the context of National List trials the release sites are small, up to 500m<sup>2</sup> per release site. The consent stipulates that the release plots must either be surrounded by a 6m border of non-GM oilseed rape alternatively a separation zone of 50m (100m in the case of varietal associations) applies, this is sufficient to prevent cross-pollination from the GM trial to neighbouring crops. Additionally a cereal must be grown on the release sites in the two years following harvest and the consent holder must exercise good volunteer control.

With this in mind, and in terms of risk assessment alone, the Committee sees no reason why, in this particular case notification at county level should not be accepted providing that all sites fulfil the following criteria:

- Are limited to arable farmland on which oilseed rape would normally be grown.
- The release sites are subject to restrictions on proximity to neighbouring oilseed rape crops as detailed in the consent.
- Sites are managed according to Good Agricultural Practise and within the conditions of the consent.

However ACRE is of the opinion that exact location of release sites is required for the purpose of post-release monitoring, in order to achieve this a 6-figure grid reference for each release site must be provided to the regulatory authorities prior to the crop being harvested or the plants being removed from the site. In addition ACRE considers it important that site inspections can be carried out during the release. While this does not necessarily require notification of precise grid reference, it is important to ensure that appropriate measures are in place to allow inspectors to locate the site during the trials and post trial monitoring period.

ACRE have provided this specific advice for this particular case because of the particular circumstances involved and only in terms of risk assessment. ACRE is clear that this advice refers to this specific consent for national list trials of MS8 x RF3 oilseed rape (03/R38/1) and that this advice does not set a precedent for all First Simplified Procedure applications. Although the Committee is content that the notification of additional sites at county level does not compromise its risk

assessment, the Committee would like to express its concerns to Ministers regarding openness and transparency. In particular, we continue to support the principle of informing local interested parties of the presence of a GM crop. The Committee would like to reiterate its neutrality in GM issues and stresses the need for the public to be able to make an informed choice regarding GM.

The Committee has made a commitment to discuss the issue of site notifications in relation to regulation 12 (3) of the deliberate release regulations, including the wider range of circumstances beyond National List trials in depth at a subsequent meeting. ACRE will provide further detailed advice to Ministers later this year.