



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

### ***Advice on an application for deliberate release of a GMO for research purposes***

**Applicant:** Natural Environment Research Council, Centre of Ecology and Hydrology Oxford.

**Application:** To release a genetically modified soil bacteria (*Pseudomonas fluorescens*) containing genes that encode for enzymes that synthesise phenazine-1-carboxylic acid (a fungal suppressant) and a marker gene conferring resistance to neomycin and kanamycin.

**Ref:** 04/R39/1

**Date:** 29<sup>th</sup> April 2004

#### **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 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 termination of the release or by 30 November 2004 whichever is the sooner and;
- annually on the anniversary of the date of the termination of the release or by 30 November, whichever is the sooner to cover post-trial monitoring for:
  - (a) the level of GM bacteria present in soil samples from within the trial site and from the area immediately adjacent to it.
  - (b) the re-evaluation of the post trial monitoring requirements.

#### **Comment**

Whilst ACRE acknowledges that all Part B releases generate information relevant to the risk assessment of subsequent related applications, it welcomes the initiation of

studies such as this one, which are designed to inform risk assessments of genetically modified organisms (GMOs) with traits that have not been considered by the Committee previously. This application is for the release of a genetically modified (GM) bacteria containing transgenes conferring bio-control properties against a fungus that causes damping off disease in crops such as wheat, peas and beet. The GMO will be released in association with non-GM wheat plants, which will be destroyed at the end of the trial.

ACRE considered the risks to human health and the environment posed by the release of this GM soil bacterium (*Pseudomonas fluorescens* variant 23.10) containing genes coding for enzymes required for the biosynthesis of phenazine-1-carboxylic acid (PCA; a fungal-suppressant) and neomycin phosphotransferase (*nptI*; that confers resistance to neomycin and kanamycin). The Committee has addressed a number of points in its risk assessment including scientific issues raised in public representations.

Key characteristics of this release from the point of view of risk assessment are that (i) the transgenic traits expressed by the GMO are already present in soil microbes, (ii) the scale of release is very small (totalling 12 square metres) and (iii) the untransformed wild type strain of *P. fluorescens* (SBW25) from which this GMO is derived does not cause disease in animals or plants.

The GMO used in this release (23.10) has been studied in detail by the applicant under contained conditions (in microcosms, growth rooms and glasshouses) in association with three different crops. There is no evidence from studies of bacterial and fungal diversity, community structure and succession that the GMO had an adverse effect.

The Committee has previously assessed the release of a variant<sup>1</sup> of this GMO, which was released by the same applicant in 1993 and 1994. The trials proceeded according to plan and there were no detectable adverse effects on the local habitat and loss or transfer of the transgenes was not detected. Similarly there were no adverse effects observed when a different pseudomonad (*P. putida*) containing PCA and *nptI* genes was released in the USA and the Netherlands.

The Committee consider that there is no reason to expect that the effects of PCA or NPTI synthesis on the metabolism of the GMO would have environmental consequences that are any different from those of non-GM soil bacteria that produce PCA or NPTI naturally.

ACRE assessed the molecular characterisation of the GMO and noted that the construction of the inserted DNA had been carried out in a series of laboratories (documented in peer-reviewed journals). The Committee asked the applicant for clarification about one of the steps involved in introducing the transgenic DNA into the bacterium and is content with the response. ACRE also notes that the genome of the wild type strain (*Pseudomonas fluorescens* variant SBW25) has been sequenced but consider that information from studies comparing the physical characteristics of the GM variant and its non-GM counterpart in the soil under contained conditions are more useful in this case than making predictions about the characteristics/behaviour of the GMO from its genomic sequence.

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<sup>1</sup> The GM pseudomonad released in these earlier trials contained the *nptI* gene but not the PCA operon encoding phenazine-1-carboxylic acid biosynthesis that is present in 23.10. An operon consists of a number of structural genes that are controlled together.

Using a precautionary approach, the Committee assumed that dispersal of the GMO beyond the release site would occur and considered the potential consequences of this happening. As the transgenes (*npt I* and *PCA*) in the GM bacterium are derived from soil micro-organisms and consequently the GM traits are already present in soils, ACRE concludes that the GM bacterium does not pose a risk if dispersed into the wider environment. However, the Committee felt that a possible route for dispersal and persistence of this GM bacterium through soil invertebrates (e.g. earthworms and springtails) could be usefully studied during this trial and this would increase the value of this research in informing future risk assessments.

ACRE notes that the applicant does not propose to monitor for this GMO in soil samples from outside of the trial site, except under exceptional conditions (e.g. vandalism of the site). The Committee advises that soil from outside of the trial site should be sampled for 23.10 as part of the post-release monitoring programme as this would increase the value of this research in informing future risk assessments. The Committee is content with all other aspects of trial site management and post-release monitoring.

### **Public Representations**

Dispersal of the GMO into the wider environment was raised in two of the three public representations received about this application. One of these included an additional concern with regard to the birds and insects that might disperse this GM bacterium; this was that transgenes from the GMO could transfer to the gut microflora of these animals by horizontal gene transfer (HGT). The Committee concluded that the likelihood of HGT from this GMO to bacteria in animal guts is no greater than that from other soil bacteria in which versions of these genes are already present.

Two representations included concerns about the insertion of the *nptI* gene into the soil bacterium as it confers resistance to the antibiotics kanamycin and neomycin. However, genes encoding resistance to these antibiotics are already widespread in naturally occurring bacterial populations. The Committee takes into account the clinical significance of any antibiotic resistance gene inserted into a GMO when advising on its risk. The clinical significance of kanamycin and neomycin is limited and other antibiotics can be used in their place. This advice is consistent with regulation 27 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002.