



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

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

Applicant: Advanced Technologies(Cambridge) Limited

Application: To release genetically modified potatoes with altered carbohydrate metabolism and a marker gene conferring resistance to neomycin and kanamycin.

Ref: 02/R4/12¹

Date: 3rd March 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 condition.

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 31 December 2003 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;
 1. assessment of the effectiveness of measures to control volunteers, and
 2. the re-evaluation of the post trial monitoring requirements until a period of two years when no volunteers are observed.

Comment

ACRE considered the risks to human health and the environment posed by the release of genetically modified potatoes that have altered carbohydrate metabolism and a marker gene conferring resistance to neomycin and kanamycin. The

¹Application reference 02/R4/12 dated 13 December 2002 taking into account all information and amendments as in the applicant's letters dated 11 February 2003 and 21 February 2003.

Committee has addressed a number of points in its safety assessment including scientific issues raised in public representations.

The risks of potatoes genetically modified for altered carbohydrate metabolism have been assessed by ACRE in previous applications (96/R4/6 and 01/R4/10). As with these applications, 02/R4/12 is for a small-scale experimental trial, it consists of a maximum of 4500 GM plants growing in an area of less than 1000 square metres.

Cultivated potatoes are a low risk crop for pollen-mediated gene flow because they are highly self-compatible and they cannot cross with other UK wild species to produce viable offspring. In this trial, non-GM potato plants growing around the GM plants will act as further barrier against pollen-mediated gene flow. As any neighbouring potato crops will be at least 20m from the trial site ACRE consider that the probability of cross-pollination occurring is minimal. As potatoes compete very poorly with other plant species (and there is no evidence to indicate that these GM potato lines are any different), the Committee consider that it is very unlikely that these GM potatoes will persist in uncultivated environments outside of the trial site.

ACRE considered the post harvest monitoring plans proposed by the applicant. In light of the fact that the potato plants will be allowed to flower and that true seed may set, the Committee requested more stringent post harvest monitoring. In particular ACRE requested that the site remain uncultivated in 2004 to allow tubers and true seed to remain near the soil surface and requested that monitoring of the site for the occurrence of volunteers be carried out until a period of two years when no volunteers are observed. In addition the Committee requested that, as true seed can survive in soil for a number of years, that potatoes are not grown on the site for the following seven year period.

The GM potatoes produced as a result of this release will not be put in the human food chain or fed to livestock. ACRE concluded that the proposed trial poses a very low risk to human health and the environment.

Items arising from public representations

ACRE considered the 7 representations received from members of the public with respect to science issues raised regarding this application.

One of the concerns raised was that the persistence of GM potato seed and regenerative material had not been adequately accounted for in the post release management plan proposed by the applicant. ACRE considered in detail best practice for controlling GM potato volunteers that could grow from true seed or tubers. ACRE advised that the trial site and buffer area should be left uncultivated for a year so that tubers and true seed are left near the soil surface. This promotes the growth of volunteers which can then be controlled and also limits the amount of GM potato seed that remains dormant in the seed bank. After this first year the site and buffer zone should be treated with a systemic herbicide so that volunteers are killed before they set tubers. The site and buffer zone can be cropped after a year of bare-ground management although ACRE advised that the land is shallowly cultivated and not ploughed. ACRE advise that the trial site and buffer zone are monitored annually until a period of two years when volunteers are not observed. Potatoes may not be grown on the release site for the following 7 years.

ACRE noted the concern expressed in public representations that the GM potato lines contain a gene (*nptII*) that confers resistance to the antibiotics kanamycin and neomycin. ACRE have assessed the risk associated with GM plants containing this marker gene on a number of previous occasions and have advised that genes

encoding resistance to kanamycin and neomycin are already widespread in naturally occurring bacterial populations. The scientific literature available suggests that horizontal transfer of genes from plants to bacteria in the soil or in animal guts will occur very rarely, if at all. It is far more likely that the *nptII* genes already present in microbe populations will transfer between bacteria rather than between plants and bacteria. The Committee also takes into account the importance of the antibiotics in human and animal medicine, and in the case of kanamycin and neomycin they are only of limited clinical significance and there are readily available alternatives. This advice is consistent with regulation 27 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002.