

Advisory Committee on Releases to the Environment Advice

Advice on the precision bred status of organisms described within a precision breeding marketing notice

Precision Breeding Marketing Notice Reference: PBM/25/SOTU/002

Date: December 2025

Notice summary: A precision breeding marketing notice describing two gene edited potato plants (*Solanum tuberosum*) where six cisgenes have been introduced to the plants' genomes via Agrobacterium-mediated transformation. The genes introduced confer resistance to late blight, potato virus Y and potato leafroll virus, with one, an acetolactate synthase gene, acting as a selection marker *in vitro*.

Advice of the Advisory Committee on Releases to the Environment (ACRE) under section 7 of the Genetic Technology (Precision Breeding) Act 2023 to the Secretary of State for Environment, Food and Rural Affairs.

ACRE considers the organisms described within the referenced marketing notice **to be precision bred**, based on the definition of a precision bred organism outlined in Section 1.2 of the Genetic Technology (Precision Breeding) Act 2023.

Overview

ACRE has assessed the information provided in this marketing notice against the definition of a precision bred organism outlined in Section 1.2 of the Genetic Technology (Precision Breeding) Act (the Act). ACRE's advice is as follows:

'(a) Any feature of its genome results from the application of modern biotechnology'

The potato plants have had an insertion of a T-DNA sequence comprising six cisgenes (*Rpi.vnt1.1*, *Rpi-amr3*, *Rpi-amr1*, *Ry_{sto}*, *RI_{adg}* and an acetolactate synthase (*ALS*) gene) with short linker sequences into their genomes via Agrobacterium mediated transformation. This is a technique of modern biotechnology as defined by the Act.

'(b) Every feature of its genome that results from the application of modern biotechnology is stable'

The plant material described within this marketing notice is exclusively vegetatively propagated. Vegetative propagation has been repeatedly proven to maintain the stability of introduced DNA sequences and prevent loss of trait efficacy in potato¹. Additionally, the

¹ Pence MG, Koch M, DeMond J, Rudgers G. Applying knowledge and experience from potato (*Solanum tuberosum*) to update genetic stability data requirements in the risk assessment for vegetatively propagated biotech crops. *Frontiers in Bioengineering and Biotechnology*. 2024 Apr 4;12:1376634.

cisgenes introduced in these plants have been stably maintained in developed potato lines for several years.

‘(c) Every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone’

The insertion of the cisgenes *Rpi.vnt1.1*, *Ry_{sto}*, *RI_{adg}* and the *ALS* gene to the potato plants were accepted by ACRE as being genetic changes that could have resulted from traditional processes as defined in the Act. ACRE issued an information notice to the notifier requesting they provide additional evidence to support the claim that the introduction of the *Rpi-amr3* and *Rpi-amr1* genes to the plants could have occurred through traditional processes as defined in the Act and therefore could also be considered cisgenes.

Specifically, ACRE asked the notifier to provide evidence that genetic material from *Solanum americanum* or *Solanum nigrum*, the organisms from which the *Rpi-amr3* and *Rpi-amr1* genes originated, could be exchanged with *Solanum tuberosum* by one or more of the traditional processes described in Section 1.6.a(i)-(vii) of the Act, along with a step-by-step description of how this exchange could occur.

The notifier responded to the information notice providing additional evidence² that *Solanum tuberosum* could be crossed with emasculated *Solanum nigrum* to produce plants whose offspring (F1 plants) can produce sterile plants via embryo rescue, a traditional process as defined by the Act. The reported sterility of these plants (F2s) is to be expected owing to the pentaploid nature of their F1 parents, and fertility is expected to be restored in the F2s by doubling their chromosome number, for example by applying the antimitotic agent colchicine to the F1 parents. Ploidy manipulation is a well-established approach in crop-breeding, often allowing for successful removal of fertilisation barriers and endosperm failure of crosses within the genus *Solanum*³ and is a traditional process as defined in the Act.

The applicant also provided detailed information on a number of strategies and the step-by-step process through which genetic material from *Solanum americanum* or *Solanum nigrum* could be exchanged with *Solanum tuberosum* via traditional processes as defined in the Act with relevant intermediates described.

Upon receipt of the additional information provided ACRE accept that *Rpi-amr3* and *Rpi-amr1* genes are cisgenes that could have been introduced from *Solanum americanum* and *Solanum nigrum* to *Solanum tuberosum* via traditional processes as defined in the Act.

‘(d) Its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology’

The potato plants do not contain any feature within their genome made by artificial modification techniques, other than modern biotechnology. The presence of the introduced cisgenes was confirmed by the notifier performing diagnostic PCRs across the unique junctions between genes in the T-DNA. The notifier also confirmed the absence of any

² Eijlander, R., Stiekema, W.J. Biological containment of potato (*Solanum tuberosum*): outcrossing to the related wild species black nightshade (*Solanum nigrum*) and bittersweet (*Solanum dulcamara*). Sexual Plant Reproduction 7, 29–40 (1994).

³ Jansky S (2006) Overcoming hybridization barriers in potato. Plant Breeding 125:1-12.

binary vector backbone was verified by whole genome short read sequencing followed by kmer analysis and PCR.

Therefore, based on the information provided within the referenced marketing notice, ACRE considers these plants to be precision bred.