## Introduction

Australia's gene technology regulatory systems need to be modern, appropriate, consistent, and flexible to respond to scientific advances in a timely manner. Undue regulatory burden in premarket regulation of products developed using new breeding techniques, disproportionate regulation of certain gene editing approaches; and lack of clarity and clear path to market needs to be removed to truly harness the benefits these technologies pose.

Biotechnology offers innovative technologies and applications in many key sectors including agriculture and environmental protection, human health, and food and nutritional security. Crop biotechnology specifically provides technically and commercially viable solutions to mitigate the challenges of food and nutritional security. With a burgeoning population which is expected to increase to 8.6 billion by 2030, biotechnology innovations will contribute significantly towards achieving the 2030 Sustainable Development Goals (SDGs).

## Case study – Gene editing: The last hope for bananas, worldwide

There are more than 1,000 banana varieties globally. Cavendish bananas make up around 97 per cent of the domestic banana market in Australia and about 50 per cent of all global banana production.

What makes the Cavendish banana so special is that it is a genetic outlier among crops because it has three sets of chromosomes, rather than two. This renders the Cavendish banana sterile and only able reproduce from new shoots that grow into little plants (genetically identical to the parent plant) that are removed and propagated<sup>1</sup>.

Since all Cavendish bananas are essentially identical in terms of genetics, this makes it the ideal variety to grow at scale due to predictability in agronomic management, consistent yield and fruit quality, ripening and shelf life. As well as being a highly nutritious fruit, these qualities also allow the bananas to be sold at low cost, making them even more favourable among consumers.

This socially and economically important food crop is facing unprecedented challenges due to its susceptibility to the soil-borne fungus Fusarium wilt tropical race 4 (TR4), also known as Panama disease. TR4 affects nearly all banana varieties. It can remain in the soil for over 40 years and there is no effective control for it. Due to the low fertility and long generation times of conventional breeding with bananas, exploitation of resistance genes that have been identified in banana species with two sets of chromosomes<sup>2</sup> has been slow. Gene editing offers a very promising alternative strategy for the improvement of commercial TR4 banana varieties.



<sup>&</sup>lt;sup>1</sup> Triploid bananas have three sets of chromosomes and therefore cannot pair up into even numbered groups – this makes them sterile and most sterile plants produce no seeds. Banana fruit from triploid varieties, like Cavendish, is therefore seedless.

<sup>&</sup>lt;sup>2</sup> Diploid bananas have two sets of chromosomes, one from each parent (like humans).

Panama disease has devastated Cavendish plantations in many parts of the world and is spreading rapidly across Asia. The disease poses a serious threat to global banana production, including in Australia where Far North Queensland grows 95 per cent of all of Australia's bananas. In communities like these, the banana industry is crucial to jobs, income and quality of life.

In 2017, Distinguished Professor James Dale and the team at Queensland University of Technology (QUT) revealed they had developed and grown genetically modified (GM) Cavendish bananas resistant to TR4. The development of the TR4 resistant line then led to a partnership with US-based international fresh fruit and vegetable leader, Fresh Del Monte, which has enabled the researchers to use the gene editing tool CRISPR to develop a non-genetically modified variety of Cavendish that will also be resistant to TR4. The crop is currently in the sixth year of field trials in the Northern Territory.

Professor James Dale has also pioneered GM biofortified bananas, enriching East African bananas in Uganda with pro-vitamin A. This enriched banana can significantly improve nutrition and prevent vitamin deficiency which leads to an estimated 670,000 deaths of children in developing countries and blindness in another 400,000 every year. The bananas are currently in field trials in Uganda, where the fruit is the major staple food in daily diet. The bananas were expected to be released for use for farmers in 2021, but unfortunately the impacts of COVID-19 will likely delay their release.

Professor James Dale said that major banana producers of the world have already decided that the future of bananas is gene editing. Further to enhanced nutrition and disease resistance, gene editing will also allow producers to focus on consumer traits (think things like the <a href="Pinkglow™">Pinkglow™</a> Pineapple), boutique varieties and improved fruit quality. Rather than focusing on developing new varieties, gene editing will allow us to improve the 1000 plus other great banana varieties that currently don't make it to market because they suffer from low yield, poor fruit quality and disease susceptibility.

Professor Dale believes Australia has the opportunity to be a leader in banana development. Banana breeding in Australia has been ongoing for around 50 years and yet there has still not been a successfully bred variety. While conventional programs are getting better, they are time and highly resource intensive. On a global scale Australia is only a small market and so we need modern and appropriate regulations to keep pace. Without that there is a risk producers will take this technology to countries like Canada and the US where gene technology regulations are risk-based, proportionate and provide a clear path from conception to consumer.