Food Standards Australia and New Zealand 7th July 2020

Re: Application A1199: Food derived from Innate potato lines V11 and Z6

It is imperative that you reject application A1199 submitted by SPS International Inc. to enable the importation of food products derived from the genetically modified Innate Potato lines v11 and Z6. This application prioritises financial considerations and expediency undeterred by the absence of independent human or animal feeding studies demonstrating safety for human consumption. This priority matrix has been authorised as an acceptable standard by FSANZ in its adjudication of the lines v11 and Z6 'as safe for human consumption as food derived from conventional potato varieties'[1] as assessed by the "Safety Assessment of Genetically Modified Foods"[2].

Nonequivalence with conventional varieties

In the Safety Assessment Report – Application A1199 Chapter 5 [1] the report states "the data indicate that tubers from V11 and Z6 are compositionally equivalent to tubers from conventional potato varieties", and therefore claims that feeding studies are not warranted.

The FSANZ has already determined that there are no potential public health and safety concerns with these potato lines. "No potential public health and safety concerns have been identified in the food safety assessment of lines V11 and Z6. On the basis of the data provided in the present application, and other available information, food derived from potato lines V11 and Z6 is considered to be as safe for human consumption as food derived from conventional potato varieties."

However the safety assessment report [1] clearly demonstrates that the Innate Potato lines v11 and Z6 are **NOT** equivalent to conventional potato varieties in the following attributes:

- Introduction of a novel protein VNT1
- Introduction of double stranded RNA (dsRNA)
- Statistically significant **increased levels** of the 14 amino acids alanine, arginine, cysteine, glycine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tyrosine and valine
- Statistically significant **decreased levels** of aspartic acid and asparagine
- Statistically significant **increased levels** of glutamic acid and glutamate
- Reduced indication of potato bacterial or fungal spoilage
- Reduced levels of acrylamide – an intended effect

These alterations demonstrate potatoes produced with these mutational lines are clearly not equivalent to regular potatoes. Accordingly, there must be independent scientific evidence proving short and long-term consumption safety, in line with the introduction of new medicines to the animal or human population.

Genetic Engineer's renouncement due to health risks

It is concerning that the original product development genetic engineer of the Innate potato lines at J.R Simplot (Dr Caius Rommens) has now renounced these potato lines in his publication *Pandora's Potatoes: The Worst GMOs.* He believes that the Innate potato lines are likely to pose significant health risks as follows.

As the now unrecognisable bruising will be retained in the product to reduce wastage and increase consumption, the bruised potato sections can accumulate toxins that could compromise the food safely and nutritional quality of the product. The bruises can accumulate tyramine among other toxins which in humans can play a role in brain activity, blood pressure, immune function, and cell growth [3, 4].

Other now invisible bacterial and fungal potato infections will also be retained in the product and consumed, and health effects resulting from eating these spoiled potatoes have not been studied. Consumers will now not have an option to decline to buy damaged potato product as they cannot be discerned from healthy potatoes.

Unintended consequences of RNA(i) technology

RNA interference RNA(i) may have the unintended consequences of off-target effects of the RNA(i) technology, insertional mutations from the foreign gene cassettes as well as tissue culture-induced mutations. The altered biochemistry resulting from the gene-silencing techniques could result in disrupted plant biochemistry and unintended side-effects [3]. Due to the absence of any feeding studies the unintended side-effects have not been assessed in animals or humans.

Antibiotic Drug Resistance

The application describes the growth of the GM potato lines in a medium containing the antibiotic Timentin. This antibiotic which is listed for use in humans is derived from penicillin.

The prescribing information on the FDA (Food and Drug Administration agency of the USA) website[5] indicates their concern of antibody resistance to Timentin and other antibacterial drugs, which would

ultimately lead to their ineffectiveness. The FDA therefore instructs that Timentin must only be prescribed in limited circumstances.

The widespread introduction of Timentin into the food supply via the Innate potato lines could have devastating effects on human health should general antibody resistance to the penicillin group of antibiotics arise from Timentin-resistant microbes resulting from these modifications.

Requirement for Animal and Human Feeding studies

It is only prudent that given the following:

a) the Innate potato lines V11 and Z6 have been demonstrated by the applicant to **not be equivalent** to conventional potato lines
b) there are potential **unintended biochemical consequences** arising from the RNA(i)/gene silencing technology used in the potato lines
c) the risk of human and animal **antibiotic resistance to the penicillin family** of antibiotics
d) the concerns of health risks expressed by the original subject matter expert on the GM Innate potato lines

that these potato lines must be properly tested independently in animal feeding studies in the first instance. If proven safe in animals, independent human feeding studies should be performed before widespread testing of these novel products on Australian and New Zealand populations without consent.

The illegal testing of these products on unsuspecting Australians and New Zealanders would not have an interim analysis or any other form of surveillance to retrospectively assess the health effects; convenient for

the vendor and government body authorising the potatoes to escape accountability for consequences of their actions.

GM labelling of product

If proven to be safe to consume based on rigorous scientific testing evidence, the products must then be clearly labelled as “GM Product” to enable our populations the choice of consuming genetically altered material created by humans.

I urge you to reject this application and insist on independently performed and proven animal and human feeding studies before accepting such novel products for human consumption in Australia and New Zealand, and to uphold this standard for any new applications for GMO products described ‘as safe as conventional’ products despite their clear genetic deviations from non GMO foods.

References

[1]

https://www.foodstandards.gov.au/code/applications/Documents/A1199_SD1.pdf?csf=1&e=TgmLte

[2]

https://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20FINAL%20Sept%2007L%20_2_.pdf

[3] https://www.gmoscience.org/genetic-engineer-renounces-his-gmo-potatoes/ (2018, updated 2020)

[4] Interview - Rethinking Pandora's potatoes
https://drlwilson.com/Articles/PANDORA.pdf

[5]
https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/050658s022lbl.pdf