

## Comments from the Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources

The Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to provide comments on Application A1128 – Food derived from reduced Acrylamide Potential & Browning Potato Line E12 (the Application).

The Application seeks permission for the sale and use of food derived from the genetically modified potato line E12. This potato line has been modified to produce less acrylamide under certain conditions, such as high temperature cooking. Health concerns have been raised about consumption of acrylamide, and Food Standards Australia New Zealand (FSANZ) considers it is prudent for consumers to limit their dietary exposure. E12 has also been developed to show reduced black spot, which is an enzymatic discolouration of potatoes following damage from cutting and handling that results in wastage of food.

The E12 potato line was produced by transforming the *Solanum tuberosum*, variety Russet Burbank, via an *Agrobacterium* vector, with two RNA interference cassettes. These cassettes were designed to down-regulate the expression of four potato genes, namely

- i) *Asn1* (encoding asparagine synthetase-1) to reduce levels of free asparagine, thus reducing acrylamide potential
- ii) *Ppo5* (encoding polyphenol oxidase-5) to reduce black spot bruising
- iii) *PhL* (encoding phosphorylase-L) to reduce levels of reducing sugars, thus reducing acrylamide potential
- iv) *R1* (encoding water dikinase R1) to reduce levels of reducing sugars, thus reducing acrylamide potential.

The genetic elements to down-regulate *Asn1* and *Ppo5* are encoded by the first cassette, while the genetic elements to down-regulate *PhL* and *R1* are encoded in the second cassette. The Application claims '*The resulting event (E12) has reduced expression of four potato enzymes (asparagine synthetase, polyphenol oxidase, water dikinase and phosphorylase).*'

In terms of the FSANZ safety assessment report, the departments note that:

- Molecular characterisation confirmed: i) the gene fragments used in the interference cassettes are derived from the closely related *Solanum tuberosum*, variety Ranger Russet, and *Solanum verrucosum*, an edible wild potato variety; ii) the single insertion of the interference cassettes into the potato genome; iii) that no plasmid backbone or antibiotic resistance markers were unintentionally incorporated; iv) the insertion of the interference cassettes does not generate new open reading frames (ORFs) at the junctions with homology to known allergens or toxins; and
-

- v) the stability of the inserted cassettes up to a fourth generation of the clonally propagated line.
- E12 potatoes contain novel DNA but no new proteins. If food produced from E12 potatoes contains novel DNA it will be subjected to the labelling of food produced using gene technology provisions of the Food Standards Code.
  - Using nutritional analysis, FSANZ has determined that food produced from these potatoes is as safe as food made from conventional potatoes (compared with the parental Russet Burbank variety).
  - FSANZ has previously approved potato lines with resistance to insects and viruses that were produced using gene technology. This is the first potato variety produced using gene technology for 'quality' traits to be approved.
  - E12 potatoes have not been considered or approved by the Office of the Gene Technology Regulator (OGTR) for cultivation in Australia; the application to FSANZ is intended to secure approval for imported, processed food containing E12 potatoes.
  - FSANZ approval ensures that if the E12 potato was detected in imported food products, there would be no potential for trade disruption on regulatory grounds.
  - To assist the enforcement of any labelling or testing of this novel DNA, the applicant has submitted sufficient data to ensure there is the capability to develop a test method.
  - E12 potatoes have been approved for cultivation and use in food in the USA and Canada.

The departments are of the view that this potato line has the benefits of reduced acrylamide potential and potential reduced black spot formation. No public health or safety concerns regarding toxicity, allergenicity, or nutrient composition concerns were raised by FSANZ in the safety assessment.

Moreover, the safety of the E12 potato line is not affected by whether the second interference cassette is functioning as intended or not. However, we are concerned that claims made within the Application are not supported by the data presented. While the data in the application provides strong evidence of down-regulation of *Ppo5* and *Asn1*, with Northern blot analysis demonstrating a reduction in mRNA specific to these two genes, the data presented in the Application for the down-regulation of *PhL* and *R1* is less robust. Northern blot analysis does not show any reduction in mRNA specific to these genes.

In addition, further evidence of reduced sugars in the E12 potatoes presented in the Application is insufficient to claim down-regulation of these genes for three reasons. Firstly, sugar levels (specifically fructose and glucose) are only statistically significantly reduced in E12 potatoes compared with the wild type Russet Burbank at one month of storage. There is no statistically significant reduction in fresh E12 potatoes or potatoes stored for three or five months. Secondly, even if reduced sugars were demonstrated in the E12 potatoes, this

---

would not provide direct evidence of down-regulation of the *PhL* and *R1* genes. A number of factors can affect the sugar levels in potato tubers, such as size of the tuber<sup>1</sup>. This is not addressed in the Application. Thirdly, the reduced acrylamide in E12 potatoes is also not direct evidence of down-regulation of *PhL* and *R1*. The reduced acrylamide may be a combined result of the down-regulation of *PhL*, *R1* and *Asn1*. However, it may be equally likely to be the result of down-regulation of *Asn1* alone.

The departments recommend that the issues outlined above regarding claims of down-regulation of *PhL* and *R1* be addressed. This may include reference to additional data that provides direct evidence of the down-regulation of these genes. Alternatively, it may include the removal of any claims that these two genes have been down-regulated by the interference cassette.

Subject to adequately addressing these concerns, the departments support the progression of Application A1128.

---

<sup>1</sup> Lisinska and Leszczynski (1989) Potato Science and Technology. Elsevier Applied Science. London and New York

---