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

Submission due: 7 July 2017

The Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to provide comments on Application A1139 – Food derived from potato lines F10, J3, W8, X17 & Y9 (the Application).

The Application seeks permission for the sale and use of food derived from the genetically modified potato lines F10, J3, W8, X17 & Y9. The departments understand that:

- The applicant has used a two-step process whereby 3 primary transformant lines are generated in 3 potato varieties by transformation of each with the same plasmid. This is followed by the generation of 3 secondary transformant lines by transformation of each of the primary lines with a second plasmid.
- Potato lines F10 (derived from potato variety Ranger Russet) and J3 (derived from potato variety Atlantic) are primary transformant lines that are engineered to have reduced blackspot bruising and reduced acrylamide potential under conditions of higher temperature cooking, through the activity of RNA interference (RNAi).
- Potato lines W8, X17, and Y9 are secondary transformant lines derived from E56 (an additional primary transformant line derived from potato variety Russet Burbank, but withdrawn from this application, also with reduced acrylamide potential and reduced blackspot bruising), F10 and J3, respectively.
- These secondary transformant lines have an additional RNAi cassette to further reduce acrylamide potential, and are also engineered to be resistant to foliar late blight, an important fungal disease of potatoes.

In addition, the departments note the following:

- FSANZ has previously approved a similar application for potato line E12 (Application A1128). E12 was transformed with the same plasmid used to generate the primary transformant lines in the current application and contains the same RNA interference cassettes targeting 3 of the 4 genes for reduced acrylamide potential in the current application, and the same RNA interference cassette that targets the gene for blackspot bruising. The main difference between E12, and F10 and J3 is the host potato variety.
- The application provides appropriate information regarding the genetic modification in each of the potato lines, including a detailed description of all transferred genetic elements, and rearrangements that occurred during the transformation process. The application demonstrates that in each case a single insertion occurred, the expression cassettes were adequately intact to function, no plasmid backbone was inserted into the potato, and the inserted DNA was stable.
- The application demonstrated somewhat reduced acrylamide potential in the primary transformant lines F10 and J3.
- Acrylamide production was reduced to a greater extent in the second round transformant lines, W8, X17 and Y9. These lines showed RNA silencing in 2 (X17) or 3 (W8 and Y9) of 4 genes associated with reduced acrylamide potential in the potato tubers. These 3 lines also showed RNA silencing in the gene associated with blackspot bruising. In addition, these lines were found

to be resistant to 3 of 4 strains of foliar late blight, despite the difficulty in detecting the VNT1 protein.

- Bioinformatic analysis showed that the newly introduced VNT1 protein, which is responsible for the resistance to foliar late blight, is unlikely to be allergenic or toxic and would be as susceptible to digestion as many other dietary proteins.
- Compositional analysis of the 5 potato lines showed that the tubers of the genetically modified potatoes are as safe and nutritionally adequate as potatoes currently in the market. Potato line E56 was excluded from the application as no compositional data for this line was included.
- The potato lines contain novel DNA and W8, X17 and Y9 also contain a novel protein that confers resistance to late blight. Therefore, food produced from these potatoes would be subject to the labelling provisions outlined in Standard 1.5.2.

In light of the departments' understanding of the application, the following issues are raised:

(i) The FSANZ Safety Assessment Report states that while approval was initially sought for 6 genetically modified potato lines, the lack of compositional data for the E56 line resulted in this line being removed from the approval process, leaving 5 genetically modified potato lines in the application.

(ii) The departments query the inclusion of the remaining 2 primary transformant lines, namely F10 and J3 in the application. While these 2 lines have compositional data reported, they lack data relating to the levels of RNAi in those lines. This lack of data seems inconsistent with the requirements outlined in the FSANZ Application Handbook, as follows:

> **A.3** (g) "*an analysis of the expressed RNA transcripts, where RNA interference has been used*"
>
> **B.3** (d) "*where RNA interference has been used:… (ii) the expression levels of the RNA transcript…*"

An assumption is made that RNAi levels in the primary transformants F10 and J3 will be equivalent to the levels in the respective secondary transformants X17 and Y9. It is likely that the level of interference in the primary transformant lines is equivalent to that in the subsequent transformants derived from these, however, this data should be included in the application so it can be appropriately scrutinised.

On this basis, the departments support the approval of the 3 secondary transformant potato lines, namely W8, X17 and Y9. However, the departments query whether sufficient RNAi data for the primary transformant lines F10 and J3 have been provided to justify progression through the application process.