



Supporting Document 2

Safety assessment supplement – Application A1216

Food derived from Herbicide-tolerant Canola Line MON94100

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1. History of use of host organism in Australia and New Zealand

Rapeseed is grown worldwide, with the major rapeseed producing countries in 2018 being Canada (20.3 MT¹), China (13.3 MT) and India (8.4 MT)². Australia is ranked 5th at 3.9 MT and New Zealand production was minor in 2018 at 2,785 tonnes. In the case of China and India, a significant amount of non-canola quality rapeseed, is included in the term 'rapeseed'. All of Australia's production is canola.

In 2018, Canada was the largest exporter of canola seed (10.2 MT), while Australia was the third largest exporter at 2.3 MT. Australia's major export destination includes Europe and Asia, and represents around 15-20% of the world's canola export trade³.

In Australia, canola is the third largest broad acre crop behind wheat and barley and the growing area extends from south-western Western Australia to south-eastern Australia and northern New South Wales. Growing certain GM canola varieties has been authorised by the Gene Technology Regulator in Australia. These GM canola varieties account for approximately 20% of the total canola grown in Australia⁴.

2. Phenotypic stability

Data on phenotypic stability was provided to FSANZ by Bayer CropScience Proprietary Limited.

Western blot analysis with a DMO-specific antibody was performed on seed tissue samples collected from five breeding generations of MON94100: R3, R3F1, R4, R5 and R6. Seed tissue of the conventional control was used as a negative control and the *E.coli*-produced DMO+27 protein was used as a positive control.

The DMO protein in all MON94100 samples showed similar migration patterns compared to the *E.coli*-produced positive control. DMO protein was not present in the negative control. As expected, band intensity for the R3F1 was weaker compared to the other generations, due to it being hemizygous for the *dmo* gene. The Western blot showed that the DMO protein has been maintained in five breeding generations and supports the conclusion that the DMO protein in MON94100 is stable.

¹ Million Tonnes

² Data from the Food and Agricultural Organization: <http://www.fao.org/faostat/en/>

³ For further information please see the Australian Oilseed Federation Inc. website: http://www.australianoilseeds.com/oilseeds_industry

⁴ For further information please see 'Fact Sheet – Genetically modified Canola in Australia' from Office of the Gene Technology Regulator: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/factsheets>

3. Novel herbicide metabolites in GM herbicide-tolerant plants

The metabolic profiles resulting from the novel protein (DMO) x herbicide (dicamba) interaction have been established through a significant history of use. On this basis it is not expected that any novel metabolites would be generated in canola event MON94100.

Information was also provided to FSANZ by Bayer CropScience Proprietary Limited regarding the dicamba metabolites present in MON94100. For example, the dicamba-tolerance trait is present in four lines from previous applications to FSANZ. These include applications A1063 (MON87708 soybean), A1080 (MON88701 cotton), A1118 (MON87419 corn) and A1192 (MON87429 corn). Food derived from these lines have been approved by FSANZ and authorised by numerous regulatory agencies worldwide⁵.

There are no concerns that the spraying of MON94100 with dicamba would result in the production of metabolites that are not also produced in non-GM crops sprayed with the same herbicide and already used in the food supply.

⁵ For further information please see the Food and Agricultural Organization webpage listing lines with the dicamba tolerance trait: <http://www.fao.org/food/food-safety-quality/gm-foods-platform/browse-information-by/trait/trait-details/en/?com=39340>