

EXECUTIVE SUMMARY

Purpose of the application

The purpose of this application is to amend [Schedule 25–2 to clause 3 \(a\) of Australia New Zealand Food Standards Code \(the Code\) Standard 1.5.1 Novel Foods](#), to permit the introduction of rapeseed protein, known commercially as CanolaPRO™, as novel food in Australia and New Zealand. The rapeseed protein is intended to be used as protein source in a wide range of food applications, similar to the use of for instance animal, soy or pea proteins.

Throughout this dossier, the substance to be registered can be referred to as “CanolaPRO™”, “rapeseed protein” or “rapeseed protein isolate”. These terms are used interchangeably. The nomenclature “rapeseed” and “canola” refers to the same substance.

The world’s population is projected to increase within the next few decades from 6 billion to 9 billion by 2050¹. Consequentially, demand for high quality proteins will increase. There will not be enough land available for the livestock to meet the increasing demand for animal proteins. At the same time, the carbon footprint needs to be lowered to mitigate the impact on global warming due to our agricultural output. Common belief is that plant-based rather than animal-based proteins will be more sustainable and therefore favorable for human consumption. Rapeseed protein is one of the promising protein sources. This was also recognized by the Australian Grain Research and Development Corporation² who funded a project at the Charles Sturt University, Wagga Wagga NSW, on improving food functionality of canola proteins. This resulted amongst others in a scientific review by Tan et al. (2011) on Canola Proteins for Human Consumption. It can be extracted from rapeseed cake, a by-product from rapeseed oil production. Globally, consumer demand in plant-based proteins is growing significantly. The Australia Institute of Food Science and Technology³ similarly identified these trends on “flexitarianism and alternate protein sources” in an article “Top Four Trends for 2018”. This is coupled with a strong consumer demand for protein across a broad age and demographics. New protein sources are becoming increasingly important as more consumers make a conscious decision to eat less meat. There is a market gap in finding sources of sustainable plant proteins that have the nutritional value and functionality of dairy proteins.

Given these trends and growing demand, CanolaPRO™ meets these market needs by providing a sustainable source of high nutritional value, a good taste profile and desirable functional properties enabling its inclusion in a broad range of food products. The benefits of offering CanolaPRO™ are further elaborated in the main application section “D.1.1 Costs and benefits

¹ UN DESA report, “World Population Prospects: The 2015 Revision”,
https://esa.un.org/unpd/wpp/publications/files/key_findings_wpp_2015.pdf

² <https://grdc.com.au/research/projects/project?id=1943>

³ Food Files: Top Four Trends For 2018 <https://www.aifst.asn.au/food-files-top-four-trends-2018>

of the application”.

No exclusive capturable commercial benefit (ECCB) conferred with this application

For this Application, DSM is not seeking exclusive use of this novel food nor deems that it confers an exclusive capturable commercial benefit with respect to rapeseed protein. There are several industrial players active in the field of plant protein production for use in food, including rapeseed protein. This is substantiated by two US GRAS dossiers submitted by two distinctive companies (GRN000327, US FDA, 2010 and GRN000386, US FDA, 2017) and the EU novel food dossier that was submitted by another company than DSM.

It is expected that, in future, more companies active in plant protein will start producing rapeseed protein.

Characteristics

CanolaPRO rapeseed protein has a protein content of $\geq 90\%$ with negligible amounts of carbohydrates or fat. Typical levels are given in Table 7 in Section C.1.1 of the NOVEL FOODS part of this dossier. It is derived from rapeseed press cake from classical or conventional rapeseeds sources, a byproduct of edible rapeseed oil production. The rapeseed used for the rapeseed protein production is from the *Brassica* varieties (*Brassica napus*, *Brassica rapa* and *Brassica juncea*) that are low in anti-nutrients including erucic acid and glucosinolates.

The protein consists of two major protein fractions: cruciferins and napins. Cruciferins are globulins and are the major storage protein in the seed. They are composed of 6 subunits with a total molecular weight of approximately 300 kDa. Napins are albumins, low-molecular-weight storage proteins (14 kDa) composed of two disulfide-linked polypeptides (Tan, S.H. *et al.*, 2011). CanolaPRO™ rapeseed protein isolate contains approximately 40-65% cruciferins and 35-60% napins. An amino acid profile of rapeseed protein isolate presented in Section “B.3 *Information on the physical and chemical properties of the novel food or novel food ingredient*” of the application confirms the presence of all 9 essential amino acids in appreciable amounts.

Regulatory status

CanolaPRO or Rapeseed Protein Isolate has been evaluated and permitted for use in humans by various Regulatory Authorities and Scientific Bodies (RASBs).

- CODEX

The rapeseed protein as described in this application is within the scope of the VPP, the General Guidelines for the Utilization of Vegetable Protein Products in Foods, as described by Codex Alimentarius (ALIMENTARIUS, C., 1989).



The rapeseed protein is isolated from press cake that remains after pressing oil from the conventional (non-GM) rapeseed cultivars *Brassica napus* or *Brassica rapa* for low erucic acid rapeseed oil as defined in Codex Standard 210-1999 on Vegetable Oils (Alimentarius, C., 1999).

- USA

DSM notified US FDA of the GRAS status of their rapeseed protein (GRN 000683) and received a No Questions letter from the FDA Center for Food Safety and Nutrition in the USA (US FDA, 2017). Rapeseed protein isolate produced by other manufacturers, was the subject of two prior GRAS Notices, GRN000327 in 2010 and GRN000386 in 2011. Both Notices received no questions letters (US FDA 2010, US FDA 2011).

- European Union

The EU authorized the use of rapeseed protein isolate from a competitor as a novel food ingredient in 2014 (EU/424/2014) (EC, 2014). And since March 8, 2017 the use of DSM's CanolaPRO™ is also approved in the EU as being substantial equivalent to EU/424/2014 (EC, 2017).

Intended use of CanolaPRO Rapeseed Protein

DSM intends to market CanolaPRO™ rapeseed (canola) protein isolate to food product manufacturers as a direct protein replacement of animal- or vegetable-based protein such as soy, whey, and pea protein. CanolaPRO™ has broad functionality and can be used in a wide range of food applications, as a protein source, thickener, water binder, emulsifier, gelling agent, foaming agent, or texturizer.

CanolaPRO™ will be used in a variety of food products for the general population. Examples of the intended foods and the proposed maximum levels of use are provided in Table 9, NOVEL FOOD Section "D.1 A list of the foods or food groups proposed to or which might contain the novel food ingredient or substance" of this Application. Due to potential unpalatability (bitterness) and/or technological limitations associated with its water-binding capacity, use levels are not expected to exceed 30% in any one food.

All information provided in this application, to the best of our abilities, has been obtained, described and referenced as indicated in "Section E.1 Data Requirements of the FSANZ Application Handbook ([FSANZ, 1-3-2016](#))" and in accordance with the items provided in Checklist For General Requirements (3.1.1) and Checklist for applications for New Foods, Novel Foods (3.5.2) provided in the Application Handbook aforementioned.

-End of Executive Summary-