SUBMISSION – APPLICATION A1175 Rapeseed Protein as a Novel Food

DSM Food Specialties B.V.
Global Regulatory Affairs Nutrition Cluster

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Attention: [redacted]
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Date
3 September 2020

Contact person
[redacted]

Your reference
A1175 Rapeseed
protein as novel food

Our reference
[redacted]

Submission - Feedback on FSANZ Public Consultation of 31 July 2020 regarding Application A1175 Rapeseed Protein as a Novel Food

Dear [redacted],

We would like to comment on the "Call for Submissions" and "Supporting document 1" that FSANZ published for public consultation on July 31 2020.

DSM, as a global company, is fully committed to ensuring that all our raw materials and products are safe for their intended use and in compliance with global legislations. All necessary measures are taken to ensure that the consumption of CanolaPRO™ does not bring safety risks. Therefore, we were surprised by your concern regarding the risk on *Salmonella*. As we presume that there is some misunderstanding regarding the way DSM controls the risk of *Salmonella* in CanolaPRO™, we would like to use this opportunity to address all aspects of our production process ensuring a microbial safe production process and product. We hope this will take away your concerns regarding *Salmonella* and give you sufficient arguments to conclude that *Salmonella* does not pose a microbiological risk in CanolaPRO™

[redacted]

General:

- DSM operates under Good Manufacturing Practices and performed a Hazard Analysis of Critical Control Points (HACCP) on the manufacturing process of CanolaPRO™ to identify and mitigate any possible microbial safety risk.
- The manufacturing sites have been certified by an external auditor with a FSSC22000 certificate. The FSSC22000 certificates of the production plants have been provided during the evaluation process (30-4-2020).
- The HACCP contains several Prerequisites and Critical Control Points related to the control of (pathogenic) microorganisms. These are explained in the following text.

According to FSANZ in SD1 Section 3.4, '*The acknowledgement from the applicant that the manufacturing process does not have a control point for microorganisms, including Salmonella spp., raises concerns about the scope of the requested permissions*'.
As is described in this document, this does not correctly reflect the position of DSM.

Activities before start of production:

- Equipment cleaning [redacted]
  - After every batch [redacted] the whole wet-processing installation is cleaned via CIP (Cleaning In Place) two times with [redacted] and after the last batch of the week, the installation is cleaned with [redacted]
    - Efficacy of cleaning is tested afterwards by confirming absence of microbial activity by analysing TPC in the flushing water.
- Microbial check of environment
  The environment of the production equipment is checked daily on TPC (total place count) and *Enterobacteriaceae*, which act as indicators for microbial contamination.

Raw materials:

- The raw materials used need to be of acceptable (microbial) quality, amongst others by demonstrating absence of *Salmonella* in each batch of rapeseed press cake. Raw material batches are not accepted when the specifications are not met.
- [redacted]

[redacted]

Process:

- By carefully controlling the temperature, throughput time and other process conditions, the process is managed in such a way that microbes, including *Salmonella,* cannot grow out during production.
- [redacted] The process temperature in the wet-processing line is [redacted]. At this temperature, *Salmonella* is not able to grow[1]. Moreover, *Salmonella* will be inactivated when subjected to this temperature[2]. Multiple references and more data are available through Combase (see also footnote **Error! Bookmark not defined.**), a relevant example is given in Annex 1.
- In-process checks are carried out after each unit operation to check for possible outgrowth of microorganisms during production. Check is done by Total Plate Count analysis.
- Furthermore, the separation step in the production process results in a log3 to log4 reduction of possible microbial contaminations.
- There is no need for further specific microbial reduction steps, such as germ filtration or pasteurisation, in the process, because with the current way of working the microbial levels are well controlled and CanolaPRO™ meets the strict microbial specifications as mentioned in the table below.

Product:

- End-product specifications:
  The final product needs to meet the following microbial specifications:

Parameter	Specification	Unit
Total Plate Count (TPC)	≤ 10e4	CFU/g
Enterobacteriaceae	≤10	CFU/g
E. Coli	absent (in 10 g)	/10 g
Bacillus Cereus	≤ 100	CFU/g
Salmonella	absent (in 25 g)	/25 g
Coagulase-positive-Staphylococci (Staphylococcus aureus and other species)	≤ 10	CFU/g
Yeast + Moulds	≤ 100	CFU/g
Spores of sulfite-reducing bacteria growing under anaerobic conditions	≤ 100	CFU/g
Thermophilic aerobic bacteria	≤ 10e4	CFU/g

- CanolaPRO™ batches that does not meet these specifications are rejected and will not be released.

The combined result of all these measures to prevent microbial contamination of CanolaPRO™ is that CanolaPRO™ is microbiologically safe for use in all intended applications, and no additional microbial reduction steps are needed to still guarantee a microbiologically safe product.

[1] Elliott and Heiniger, 1965, Improved temperature-gradient incubator and the maximal growth temperature and heat resistance of *Salmonella*, Applied Microbiology, Vol.13, No.1, p73-76. https://aem.asm.org/content/aem/13/1/73.full.pdf

[2] Combase - A Web Resource for Quantitative and Predictive Food Microbiology, Accessed 27-8-2020, https://www.combase.cc/index.php/en/
E.g. USDA Agricultural Research Service; [redacted]

We hope we have been able to allay your concerns about the risks for *Salmonella.* We would welcome a phone call where our microbiology experts can explain any more questions your experts might have and take away any remaining concerns. Please do not hesitate to contact us. Please let us know if and when this would suit you.

Kind regards,

Global Regulatory Affairs team
DSM Food Specialties B.V.

Annex 1 Inactivation of *Salmonella spp* at [redacted]
Source: Combase - accessed 27-8-2020 at https://www.combase.cc/index.php/en/
USDA Agricultural Research Service; [redacted]

Salmonella spp in broth

Food category	Culture medium
Food name	Broth
Temperature (°C)	[redacted]
Aw | NaCl	
pH	

Source
USDA-Agricultural Research Service

Conditions
Not specified

Properties
Not specified

Further specifications
Species: S.typhimurium, Strain(s):DT104(H3380)

Details
Salmonella Typhimurium (strain designation H3380), a human clinical isolate, originally obtained from CDC. Prep: vials were partially thawed at room temperature and 1.0 ml of the culture was transferred to 10 ml of BHI in 50-ml tubes and incubated for 24 h at 37 C. This culture was not used in growth studies as it contained freeze-damaged cells. A working culture for use in growth and heating studies was prepared by transferring 0.1 ml of each culture to 10 ml tubes of BHI and incubating aerobically for 24 h at 37 C. These cultures were maintained in BHI for 2 weeks at 4 C. A new series of cultures was initiated from the frozen stock on a biweekly basis. A day before the experiment, the inocula for conducting the growth and heating studies were prepared by transferring 0.1 ml of each culture to 10 ml tubes of BHI, and incubating aerobically for 18 h at 37C to provide late stationary phase cells. On the day of the experiment, each culture was centrifuged (5,000 × g, 15 min, 4 C), the pellet was washed twice in 0.1% peptone water (wt/vol) and finally suspended in peptone water to a target level of 8-9 log10 cfu/ml. The population densities in each cell suspension were enumerated by spiral plating On Tryptic soy agar (TSA; Difco) plate and incubating at 37C for 48 h. . Dilutions: in 0.1% peptone water. Growth experiments: Brain heart infusion broth (BHIB, 100 ml) in 250 ml flasks were sterilized for 15 min at 121 C. Each flask was inoculated with 0.1 ml of the diluted inoculum of an 18-h culture of Salmonella to yield a starting level of approximately 2-3 log10 cfu/ml, and then incubated at 25C or 37C on a model G-26 rotary shaker (120 rpm). At intervals appropriate for the temperature, samples were withdrawn for determining the bacterial number by serial dilutions in peptone water, surface plating with a spiral plater onto TSA as described above. Thermal inactivation procedure: Bacterial suspensions obtained were heated at 55C using a submerged coil heating apparatus (Cole and Jones, 1990). The submerged coil heating apparatus is comprised of a stainless steel coil fully submerged in a thermostatically-controlled water bath which allows microbial suspensions to be heated between 20-90C with a short time to achieve temperature equilibrium. During the heating procedure, samples (0.2 ml) were removed at predetermined time intervals. Where low cell numbers were expected, 0.6 ml aliquots were removed. Samples were cooled rapidly in ice slurry. Enumeration of surviving bacteria: Decimal serial dilutions were prepared from duplicate samples at each sampling time in peptone water and appropriate dilutions were surface plated in duplicate on TSA, supplemented with 0.6% yeast extract and 1% sodium pyruvate, using a spiral plater. Samples not inoculated with Salmonella were plated as controls. Also, 0.1 and 1.0 ml of undiluted suspension were surface plated, where relevant. All plates were incubated at 30C for at least 48 h prior to counting colonies. Re-growth experiment: Heated bacterial suspensions (0.2 ml) were inoculated in BHIB (100 ml) in 250 ml flasks to yield a starting level of approximately 2-3 log10 cfu/ml, and then incubated at 25 or 37C on a model G-26 rotary shaker (120 rpm). Population densities were determined as above.

Measurement
By colony counts.

Comments
No comments available

Date Added
Not available

Annex 1 - continued