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PETITION FOR THE ADDITION OF

OAT PROTEIN CONCENTRATE

TO THE NATIONAL LIST OF ALLOWED SUBSTANCES IN ORGANIC FOODS 7 CFR 205.606

Confidential Business Information Deleted

Respectfully submitted by:

TATE & LYLE
Law Department/ Regulatory Affairs
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192 USA

Petition to Add to the National List 205.606:

Oat Protein Concentrate

>50% protein, water extracted, non-GMO enzymes,
no chemicals including those for pH adjustment and/or solvent extraction

Item A

1. Category

Non-organically produced agricultural products allowed in or on processed products labeled as "organic". §205.606.

2. Justification for this category

The petitioned substance is a natural component of an agricultural commodity: oats. There are no protein bonds broken in the process of isolating this component. There may be some carbohydrate bonds broken through an enzyme treatment. The oat protein remains intact and is therefore non-synthetic. The protein is isolated through a simple process of grinding, heating and water extraction and does not use any synthetic chemical additions or solvents. The only additives used in the manufacture of oat protein concentrate are water and enzyme; no chemicals are used for pH adjustment or solvent extraction.

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Item B

1. The common name of the substance.

Oat protein or oat protein concentrate

2. The manufacturers – name, address, phone number, contact information

PrOatein™ Oat Protein Concentrate

Tate & Lyle Oat Ingredients
Älvåsvägen 1
610 20 Kimstad
Sweden
Phone +46 11 253630
oat.info@tateandlyle.com

Contact for Tate and Lyle / Petitioner:
Lore Kolberg
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Oat Tech Inc. manufactures a product, Oat Protein 55, that appears to use a similar process resulting in a comparable product. While they indicate on their website that their process is "all natural", ingredients are "non-GMO" and that the products are made using "a natural enzymatic conversion of oat flour", we cannot verify they do not include a pH adjustment in the manufacture. Oat Tech patent US 2013/0183404 A1[5] refers to a related patent which includes pH adjustment. Since pH adjustment is a common practice during enzyme treatment and the information in their patent does not specifically exclude pH adjustment, it is uncertain if the Oat Tech oat protein concentrate meets the requirements of this petition. Therefore, it has not been included.

At this time, there does not appear to be any other oat protein concentrate that meets these requirements available to the US market: >50% protein, water extracted, non-GMO enzymes, no chemicals including those for pH adjustment and/or solvent extraction.

3. The intended or current use of the substance.

There is currently a demand for alternative protein sources which are vegan, non-GMO and have good nutritional value. Oat protein concentrate has high protein content and it is a good source of certain essential amino acids. Because it is primarily composed of globulin proteins, oat protein has better digestibility than other cereal proteins which are higher in the storage protein prolamin[3]. The digestibility of oat protein is 91% (based on rolled oats[6]). Oat protein concentrate is a beneficial protein source which allows a wider range for nutritional food development.

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4. The handling activities for which the substance will be used and its mode of action.

Oat protein concentrate is used as a protein supplement in a wide range of foods as a source of easily digestible vegan protein which will not elicit an allergic reaction in people suffering from milk, egg and soy protein allergies.

Oat protein concentrate has high levels of certain essential amino acids (Appendix 2):

- branched chain amino acids: leucine, isoleucine and valine
- sulfur amino acids: methionine and cysteine
- aromatic amino acids: phenylalanine, tyrosine, and tryptophan

These amino acids must be consumed as they cannot be manufactured in the human body. They are essential in muscle development with higher levels of branched chain amino acids in particular being important in the processes of muscle recovery and immune regulation. In addition, these essential amino acids are critical to a variety of physiological activities such as the manufacture of enzymes and other proteins and connective tissue throughout the body. [2]

PrOatein™ has a wide range of nutritional benefits as indicated in Appendix 1: Oat Protein: Health Benefits and Product Applications (Tate & Lyle). These are some of the benefits covered in this brochure:

Protein Consumption and Health Benefits

1. Increasing protein consumption benefits in older populations
2. Sarcopenia
3. Muscle growth and maintenance
4. Satiety and weight management

One of the important properties of oat protein is that it can be complementary with other proteins that are limiting in branched chain, sulfur and/or aromatic essential amino acids. For example, soy is limiting in sulfur amino acids and oat protein has an excess of the sulfur amino acids (methionine and cysteine) so when consumed together, the net protein quality is improved. The same is true for wheat protein which is deficient in branched chain amino acids.

It is well known that legumes (such as peas) and grains (such as oats) have a complementary effect. A detailed example of this complementary effect is provided in Appendix 2. The nutritional value of a 50:50 blend of pea and oat proteins meets the WHO Amino Acids Requirements profile whereas each protein on its own does not. This particular blend is particularly useful in that it does not contain milk, egg or soy allergens.

The unique qualities of oat protein include the following

- it can be used to supplement protein content in a wide range of foods because of its bland flavor and low impact on texture
- it can be used as a complementary protein with a wide range of other protein sources such as pea, wheat and soy
- it is vegetarian/vegan
- It can be used in foods designed for people with a wide range of allergies (for example: milk, soy and egg)

5. Source of the substance and detailed description of its manufacturing or processing procedures

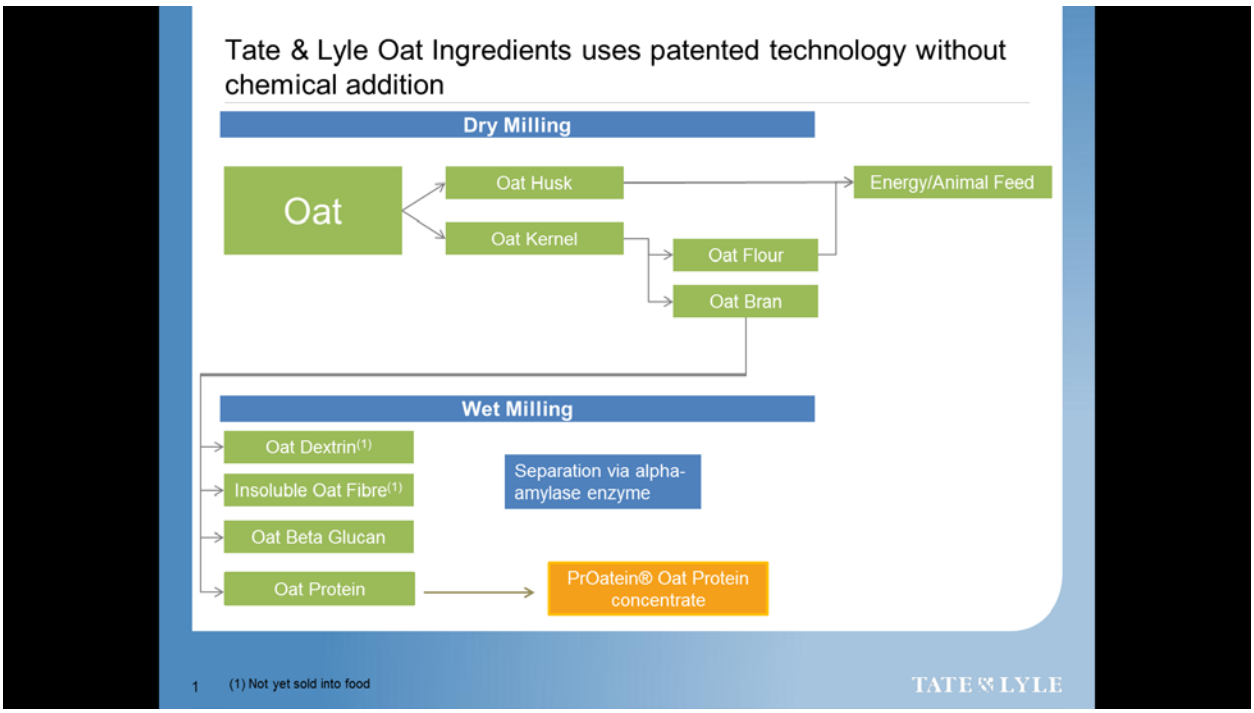
The oat protein concentrate that is the subject of this petition (PrOatein® oat protein concentrate), is a fraction of milled oat grain, derived from the bran, which is gently processed using physical separation and an alpha-amylase enzyme in down-stream processing. The end product is rich in the protein component of oats.

In manufacturing PrOatein® oat protein concentrate, oat protein is extracted from non-GE/ GM whole oats by first dehulling the oats and then dry milling to separate the oat bran from the oat flour. The bran is added to hot water and then treated with alpha-amylase to enhance the separation of the protein from other bran components. The protein and soluble fiber remain in solution; the insoluble fiber does not. The suspension is then decanted to remove the soluble oat proteins and soluble fiber. This solution is heated to denature the oat proteins and then decanted and centrifuged to separate the oat protein solids from the soluble fiber. The oat protein solids are then roller dried to yield oat protein concentrate, a fine powder that is neutral in color and has a clean, mild, oat flavor.

The alpha-amylase enzyme used in the process is derived from a non-pathogenic, non-GE/ GM microorganism (*Bacillus licheniformis*). Amylase from *B. licheniformis* is GRAS for use in food manufacturing per 21CFR §184.1027. In addition, the enzyme meets the requirements of 7CFR §205.605a of the National List.

No added chemicals are used in the manufacturing process for PrOatein® oat protein concentrate, including chemicals commonly used to adjust pH or bleach the color, as well as chemical solvents.

The process flow diagram is detailed below:



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6. A summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations.

To the best of our knowledge, oat protein has not been reviewed by State or private certification programs in the past. A GRAS notification was prepared and submitted to the FDA in 2015 (see point 7). As indicated in the GRAS notification, there is a long history of the safe use of oats and products derived from oats. An Expert Panel of qualified scientists agree that publically available scientific literature is sufficient to support the safety of oat protein concentrates that are produced consistent with current Good Manufacturing Practices.

In 2007, GTC Nutrition submitted a petition to the NOP to request that oat bran concentrate be added to the National List of Allowed Substances in organic production. This is the ink:

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067939&acct=nopgeninfo.

While oat bran concentrate and oat protein concentrate are both derived from oats, they are quite different in composition. The oat bran concentrate that was the subject of the 2007 petition (OatVantage), typically contains about 54% beta-glucan and only a small amount of protein. In contrast, as shown in the attached specification sheet, the oat protein concentrate of the current petition typically contains only 2% dietary fiber as beta-glucan soluble fiber, and it has 52-56% protein. Oat bran concentrate is used as a source of oat fiber/oat beta glucan whereas oat protein concentrate is used as a source of protein/amino acids. They both might be used to supplement foods but for different nutritional purposes.

7. Information regarding EPA, FDA, and State regulatory authority registrations.

A GRAS notification was prepared and submitted to the FDA in 2015. Receipt of this GRAS notification was acknowledged by the FDA on April 30th, 2015 (GRAS Notice No. GRN 00575). See Appendix 4.

On page 35 of the GRAS notification, it states: "Given that oat protein (PrOatein™) meets the proposed specifications for the use of protein as a food ingredient for human consumption, the safe use of oat protein is justified by scientific procedures. In addition, the publicly available scientific literature is sufficient to support the safety and GRAS status of the proposed oat protein product.
Therefore, since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination."

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8. The Chemical Abstract Service (CAS) numbers of the substance and labels of products that contain the petitioned substance.

Chemical Abstracts Service (CAS) Registry Number for "proteins, oat" is 134134-87-5.

At this time, this oat protein concentrate and the other components extracted from oats are only used in conventional food products. As PrOatein™ availability and awareness increases, it is expected that formulators of "Organic" healthy processed foods will want to use it.

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9. The substance's physical properties and chemical mode of action including:

(a) chemical interactions with other substances, especially substances used in organic production;

Oat protein concentrate that has been extracted from oat bran with water and then denatured to form an insoluble material. There are no known reports of it interacting with other substances in nature to form other compounds.

(b) toxicity and environmental persistence;

Oat protein concentrate is non-toxic. It exists in nature as a natural component of oats. There are no issues of environmental persistence. It is environmentally harmless.

(c) environmental impacts from its use or manufacture;

The manufacture of oat protein concentrate involves only substances found in nature. Separation of oat protein from oat bran has two objectives:

- isolate the oat protein for use as a protein supplement
- separate off the soluble fiber

The soluble fiber has clinically proven health benefits such as reduced risk of heart disease and support of healthy blood sugar levels. There is no residual in this process that must be discarded.

(d) effects on human health;

Oat protein concentrate is a useful food ingredient to supplement the protein content in a wide range of foods. Unlike other proteins used as supplements (milk, soy and egg), this ingredient can be used in foods targeted for individuals with these specific allergies. Oat protein can also be used in vegan and vegetarian foods designed to provide balanced nutrition.

(e) effects on soil organisms, crops, or livestock.

Oat protein concentrate is used in handling, not crop production. It has no effect on soil organisms, crops or livestock.

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10. Safety information about the substance.

Oats are a traditional food with a long history of safe use. Removal of some of the components from oats results in concentrates that are as safe as the oats from which the components were extracted.

The GRAS Determination (Appendix 4) provides a significant amount of information on the safety of oats and oat subcomponents.

The Material Safety Data Sheet (MSDS) for PrOatein® Oat Protein provides further information on the safety of oat protein concentrate (Appendix 5).

As far as we know, the National Institute of Environmental Health Services has not prepared a substance report for oat protein or oat protein concentrate.

11. Comprehensive research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions.

See references in the GRAS Determination which was prepared and submitted to the FDA in 2015 (Appendix 4). Both supporting and contrasting positions are presented in the papers and summaries detailed in the GRAS Determination.

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12 "Petition Justification Statement" which provides justification for inclusion of a non-organically produced agricultural substance onto the National List 205.606

Oat protein concentrate is isolated from oats for the primary purpose of enhancing the protein content of food. Oat protein is rich in certain essential amino acids and it can be used at low levels (2 - 4%) as a complementary protein for grain and legume derived proteins. Oat protein concentrate is needed as a protein supplement in the development of new "Organic" vegetarian/vegan foods targeted at individuals with food allergies.

In order to meet the needs of the wide range of organic consumers, it is necessary to identify protein sources that are not derived from meat or eggs (for vegetarian consumers), not derived from milk (for vegans and individuals with milk allergies), not derived from soy (for individuals with soy allergies) and/or not derived from gluten containing grains (for individuals with wheat allergies or celiac disease).1 Oat protein concentrate is unique from these various other common consumer protein sources and therefore allows for a wide range of options in the development of nutritious organic foods.

Because this product is bland in flavor, oat protein concentrate can be used to boost protein content in a wide range of products many of which are available or under development as Organic alternatives to conventional foods:

- Vegan entrees
- Cereal bars
- Baked goods
- Breakfast cereals
- Pasta
- Meal replacement shakes

While oats are widely available in an organic form in the US and Canada, this is not the case in the Nordic countries where the majority of oat protein concentrate is manufactured. There are sources of organic oats in this region but quantities are limited and require further development. Organic oats could now be purchased from the USA for use in this process due to the equivalency arrangement however this is not likely to occur soon due to an undetermined demand for oat protein concentrate in an organic form. Should the use of oat protein concentrate be successful in Organic foods (as a conventional ingredient authorized on the National List), sources of oat protein concentrate would likely be developed from organic oats originating in the USA and/or the Nordic region.

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13. Confidential Business Information Statement

The manufacturing process for PrOatein™ (Item 5 processing detail and Appendix 3) is confidential business information. Customer information (Item 8 customer information and Appendix 6) is also confidential business information. Two versions of the petitions have been provided, one containing Confidential Business Information (CBI) and one with CBI Deleted.

Appendices

Appendix 1

OAT PROTEIN: HEALTH BENEFITS AND PRODUCT APPLICATIONS (TATE & LYLE)

TATE & LYLE

Oat Protein: Health Benefits and Product Applications

Innovating to Meet Nutrition, Health, and Wellness Needs Every Day

PrOatein™ Oat Protein

Scan for more information.

To learn more about Tate & Lyle ingredients and innovation, please visit www.foodnutritionknowledge.info, www.tateandlyle.com, and www.proatein.info.

proatein™ Oat Protein

Protein Intake Recommendations and Needs

- Protein is an important part of the diet and plays essential roles in the body, both structurally (muscle and bone) and functionally (biochemical processes, neurotransmission, circulation)
- The branched chain amino acids (BCAAs) leucine, isoleucine, and valine stimulate and support muscle protein synthesis (MPS), a process that is important for maintaining muscle structure and function, and are critical for muscle growth and repair at all ages
- Meta-analyses and clinical studies indicate some favourable effects of higher protein versus lower protein diets on health outcomes including adiposity and cardiovascular risk factors
- It is recognised that dietary proteins may induce satiety in humans and thus may help with maintenance of body weight
- PrOatein™ Oat Protein contains significant amounts of indispensable BCAAs and can serve as a vegan-friendly protein source for a variety of beverage and food applications

Protein as a macronutrient

Protein is an important macronutrient in the diet and is required to meet nutritional needs and to support health and well-being[1]. This macronutrient is needed to meet human nitrogen requirements and provide indispensable amino acids (also known as essential amino acids). Amino acids (AA) are classified as those that cannot be synthesised by the body (indispensable or essential) and those that the body can synthesise (dispensable or nonessential)[2]. However, some are also conditionally indispensable, becoming essential under specific pathological or physiological conditions[2]. Protein is an important structural and functional component of organs, muscles, biological fluids, and hormones[2,3].

Tate & Lyle's PrOatein™ Oat Protein, like the oat grain it comes from, contains significant amounts of dietary indispensable branched chain amino acids (BCAAs). PrOatein™ Oat Protein is a natural protein concentrate ingredient from oats, which can help meet the fast-growing consumer demand for products containing oats and protein-enriched foods.

Global protein intakes

The 2007 World Health Organisation (WHO) Technical Report on protein and amino acid requirements for human nutrition estimates that the average protein requirement for maintenance is 105 mg nitrogen per kg body weight per day, or 0.66 g protein per kg body weight per day[4]. In the developed world, animal food products are the predominant sources of protein followed by cereals, whereas in developing countries this order is reversed. In countries with lower average income, 3% of total dietary energy is from animal protein sources; 11% is from roots and tubers; 6% is from pulses, nuts, and oilseeds; and the remainder is primarily from cereal-based staple foods[5]. Although the production of livestock has increased in developing countries, the consumption of protein in these countries remains inadequate[5]. Additionally, the protein consumed is generally low quality, lacking some of the amino acids required for proper growth and development[6].

Not every protein source provides all of the amino acids needed for growth and development, and not all protein is equally bioavailable from food sources; however, bioavailability can change with food processing[6-8].

Protein quality

Protein digestibility, a component of protein quality, determines the amount of ingested amino acids that are available to the body after digestion and absorption[7]. Ileal digestibility is the current recommended method for determination of dietary amino acid digestion (further described on the next page), and high levels of digestibility are characteristic for animal proteins and certain purified and concentrated vegetable proteins[4,7].

Table 1

Recommended amino acid scoring patterns[a]

	Scoring pattern (mg/g protein) requirements								
Age groups	**His**	**Ile**	**Leu**	**Lys**	**SAA[b]**	**AAA[c]**	**Thr**	**Trp**	**Val**
Child (aged 6 months to 3 years)	20	32	66	57	27	52	31	8.5	43
Older child, adolescent, and adult (> 3 years of age)	16	30	61	48	23	41	25	6.6	40

[a] Adapted from Chapter 4, Table 5 of the 2013 FAO report.
[b] Sulfur Amino Acids: Methionine and Cysteine
[c] Aromatic Amino Acids: Phenylalanine and Tyrosine

The Food and Agriculture Organisation (FAO) of the United Nations Expert Consultation on Protein Quality Evaluation, in conjunction with the WHO, reviewed protein quality assessment of foods and specifically evaluated the amino acid scoring used[9]. Based on this review, the 1991 Consultation Report was released, which concluded that the Protein Digestibility-Corrected Amino Acid Score (PDCAAS) method, which adjusts amino acid content of the protein source by faecal digestibility correction, was the most suitable approach for routine evaluation of protein quality for humans[2,9-11]. This method compares the indispensable amino acid content of the protein source to a reference value for each amino acid based on nutritional needs and corrects for the digestibility of the protein; this method is also recommended by the Codex Committee on Vegetable Proteins[11].

An update to this FAO/WHO report was published in 2013 and recommended that true ileal digestibility of amino acids from protein sources be accounted for rather than the overall faecal digestibility of a protein[1]. The updated report also includes the adjusted amino acid adequacy reference value recommendations by age group. The current FAO/WHO recommendations by age group are shown in Table 1.

The amino acid content of a protein is compared to the reference amino acid profile to determine if it is a nutritionally adequate protein (also known as a complete protein). Complete proteins provide all indispensable amino acids in the proportion that best supports human growth and development; this is then further corrected for the digestibility of the protein.

FAO/WHO now considers the digestible indispensable amino acid score (DIAAS), adjusted for ileal digestibility, to be a replacement for the PDCAAS[1,2,7,10]. However, PDCAAS is still widely used and more prominent than DIAAS.

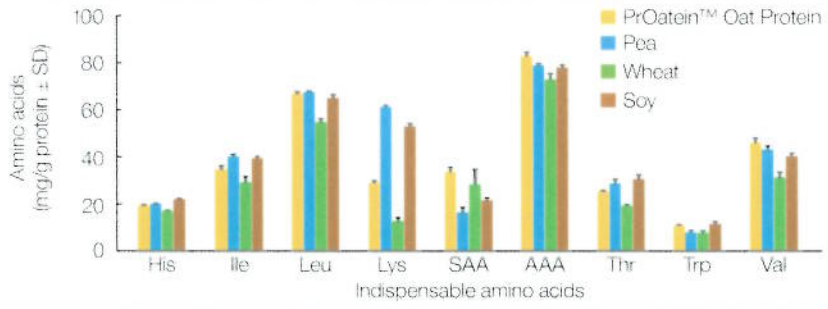
PrOatein™ Oat Protein meets nearly all of the FAO 2013 amino acids pattern requirements for adults except for lysine, the limiting amino acid in oat protein. PrOatein™ Oat Protein contains at least 10% more sulfur amino acids (SAA) and tryptophan than pea protein; more SAAs and valine than soy protein; and has more of each indispensable amino acid compared to wheat (Figure 1). Combining plant proteins can create a more complete amino acid content in finished food products.

Protein consumption needs for younger populations

Both the quantity and quality of the protein consumed is important to early growth and development as it is well-recognised that protein consumption during this development window can have effects on long-term health, including influencing body composition[12]. The recommended protein intake for children at two years of age is 0.97 g/kg body weight to ensure adequate intake, which is greater than the minimal amount of protein required for growth[12]. Additionally, the recommended amino acid scoring patterns for young children (aged three years and younger) were revised in the 2013 FAO/WHO report (Table 1)[1]. Protein requirements are greater during periods of rapid growth related to the increased demands of growth and increases in body mass and height (see Table 2); furthermore, development of muscles require additional amino acids[4].

Figure 1

Indispensable amino acid contents of selected vegetable protein ingredients[a,b]



[a]Three market comparison samples were obtained for soy, pea, and wheat (n=3 for each, n=6 for oat protein).
[b]The amino acid analyses were run at Medallion Laboratories (Minneapolis, MN) per their SOP using validated methods (AOAC Official Method 994.12): Amino Acids- Acid Hydrolysed Amino Acid Profile, Tryptophan, Cysteine and Methionine, and total protein by Dumas (using AOAC method 992.15).

Table 2

Protein requirements (g/kg/day)[4]

Age	Maintenance	Growth	Total Need
Birth to 6 months	0.66	0.46	1.12
1 to 2 years	0.66	0.20	0.86
3 to 10 years	0.66	0.07	0.73
11 to 14 years	0.66	0.07	0.73
15 to 18 years	0.66	0.04	0.70
18 years and older	0.66	0.00	0.66

Protein Consumption and Health Benefits

Increased protein consumption benefits for older populations

Current evidence suggests that older adults (aged 65 years and older) may need more dietary protein than younger adults to support good health, promote recovery from illness, prevent age-related muscle loss, and maintain muscle functionality[13,14]. Ageing muscle is less sensitive to the presence of amino acids and may require higher quantities of protein to stimulate muscle protein synthesis (MPS) and accrue muscle proteins[15]. Older adults also may need more protein to offset conditions associated with chronic and acute diseases that commonly occur with advanced age[13,16,17]. A recent systematic review examined the health effects of protein intake in healthy elderly adults and found that optimal protein intake is likely higher than the current estimated average requirement (EAR) based on nitrogen balance studies[16].

The European Union Geriatric Medicine Society, in cooperation with other scientific organisations, appointed an international group of experts representing a wide range of clinical and research areas, including geriatrics, internal medicine, endocrinology, nutrition, exercise physiology, gastroenterology, and nephrology, to review dietary protein needs with ageing[13]. This appointed international PROT-AGE Study Group published evidence-based recommendations in 2013 for optimal protein intake by older adults[13]. In their review, the PROT-AGE Study Group recommended an average daily intake of at least 1.0-1.2 g/kg body weight per day for people greater than 65 years of age to maintain and regain lean body mass and function[13]. Additionally, they recommended higher intakes (greater than 1.2 g/kg body weight per day) for those who are physically active. These increased intake targets are recommended due to the reduced ability to use available protein associated with advanced age, accompanied by an inadequate intake of protein, in order to prevent loss of function in older adults[13].

Sarcopenia

Sarcopenia, the loss of fat-free mass (FFM) during age-related muscle wasting, can compromise the functional abilities of the elderly[19,17]. BCAAs have been shown to attenuate muscle wasting[18], which is important in the prevention of sarcopenia[19]. Dietary leucine may attenuate age-related loss in muscle mass and strength, and leucine supplementation specifically may be important in preserving lean muscle mass during ageing[18].

Furthermore, emerging evidence suggests that the elderly specifically may benefit from distributing protein intake evenly throughout the day to promote an optimal per meal stimulation of MPS[15]. Leucine is thought to play a central role in mediating mRNA translation for MPS, and it is recommended that sufficient leucine is provided with dietary protein intake at each meal for the elderly population[15].

Muscle growth and maintenance

Dietary protein directly contributes to the maintenance of FFM, which requires different levels of protein across life stages and activity levels[20,21]. Maintaining skeletal muscle mass is important in conditions such as obesity, hyperlipidemia, cardiovascular disease (CVD), and type 2 diabetes because of the metabolic function of muscle in the body[22-26].

The ingestion of protein-containing meals results in stimulation of MPS[15]. In young adults (aged 18 to 30 years old), supplementation with a leucine-rich, high-quality protein can augment exercise-induced muscle mass development and lead to strength gains to a greater extent compared to other protein sources[15,21,27,28]. Additionally, supplementation with leucine-rich amino acid mixtures has been shown to improve strength and physical function and to increase muscle mass in the elderly[15,29]. When combined with exercise, protein ingestion helps to increase muscle synthesis, thus assisting in muscle protein accretion[15]. This increases muscle protein building response more than either stimulus alone[15].

Amino acid benefits of PrOatein™ Oat Protein

Leucine, isoleucine, and valine are BCAAs that are abundant in PrOatein™ Oat Protein and are known to influence MPS.

Protein consumption alone supports and maintains muscle mass; however, physical activity can increase the demands for protein consumption[4]. The indispensible BCAA leucine is a direct regulator of MPS through activation of the mTOR pathway, a cell signal known to stimulate muscle protein production[15,18]. Furthermore, the BCAAs leucine, isoleucine, and valine compose 14-18% of the total amino acids found in skeletal muscle protein and all of these amino acids are required for maintaining muscle health[18]. Leucine, along with isoleucine and valine, has been shown to stimulate MPS when administered in a protein-containing beverage in young men[30]. After exercise, the repeated ingestion of 20 g of high-quality protein containing leucine also has been shown to provide maximal muscle building stimulus during the recovery period[31].

Satiety and weight management

Obesity continues to be a major public health concern globally and may be improved through dietary protein consumption[4-32]. While energy balance is key to weight management, scientific research suggests that a diet rich in high-quality protein is one dietary strategy to aid in acute postprandial satiety and thus help with weight maintenance[14,20,25,26,33,35]. High protein diets have been successful at preserving lean body mass during weight loss[14,34,36], and diets using meal replacements that provide higher protein with moderate fat have been shown to assist in weight maintenance[37]. In the context of calorie reduction, a recent review found that a protein intake of 0.8-1.2 g/kg body weight per day is sufficient to sustain satiety, energy expenditure, and FFM independent of dietary carbohydrate content[20].

The protein content of the diet has long been recognised for its effect on food intake because high-protein diets may promote satiety and are associated with reduced calorie intake[14,25,35,38-41]. Protein can increase the postprandial perception of satiety as assessed by subjective measurements and stimulates the endocrine hormones in the gastrointestinal tract known to increase satiety[33,35,42]. Some research supports that a higher protein intake (25% of total energy) is effective for appetite control and satiety in overweight and obese men during hypocaloric-induced weight loss[43]. Additionally, recent research shows that when overweight and obese teen girls consumed a high-protein breakfast meal (35 g protein), there was a significant reduction in four-hour cravings for savory foods[40]. Also, it has been shown that consumption of an afternoon yoghurt snack (containing 14 g protein) versus crackers (containing 0 g protein) versus chocolate (containing 2 g protein) can increase the time to initiation of the next meal and decrease caloric intake in healthy women[41].

Gut hormones work collectively in response to meal consumption to help regulate food intake[44,45]. Appetite-suppressing hormones such as peptide YY (PYY) and glucagon-like peptide 1 (GLP-1) have been shown to be induced by dietary protein and are regulators of food intake[35,42,46]. Changes in short-term food intake have been shown to be directly modulated by PYY and GLP-1 in humans through signaling to the brain[46,47]. Cholecystokinin (CCK) is also an inhibitor of food intake and is released through postprandial stimulation by amino acids[42].

Animal studies have demonstrated that inhibition of food intake by high-protein meals occurs alongside the activation of nutrient-sensitive brain areas that contain specific neuronal cell types involved in satiety[48]. Furthermore, changes in perception of postprandial hunger, satiety, and food intake are positively associated with meals containing proteins in humans[43,49]. The ratio of macronutrients in a study of isocaloric meals demonstrated that a low carbohydrate/high protein diet (65.0% calories from protein, 17.2% calories from carbohydrate) significantly increased PYY and decreased hunger in humans when compared to a high-carbohydrate/low-protein diet (17.8% calories from protein and 64.5% calories from carbohydrates). This effect was seen in both lean and overweight individuals[35]. Although more research is needed in this area, increasing protein intake may be one way to help manage food intake and may help to maintain a healthy body weight through increased satiety.

Cardiovascular benefits

Research suggests the consumption of plant proteins may have protective effects against chronic diseases and may contribute to decreased circulating cholesterol levels[50-55]. Plant proteins are generally low in fat and can displace other dietary sources of protein that provide higher amounts of fat[20,55]. Furthermore, it is well known that diets high in fruits, whole grains, and vegetables are associated with a lower rate of CVD[20,51,56,57].

Prospective cohort studies support that high consumption of plant-based foods is also associated with a significantly lower risk of coronary artery disease and stroke[20,51]. Higher protein diets in general may improve blood pressure[51,57,58], triglyceride levels, and reduce adiposity according to a recent systematic review of 74 randomised clinical trials[34].

Appendices

Appendix 2

ESSENTIAL AMINO ACID COMPOSITIONS: OAT PROTEIN, PEA PROTEIN AND AN OAT-PEA PROTEIN BLEND RELATIVE TO THE WORLD HEALTH ORGANIZATION (WHO) AMINO ACID REQUIREMENTS

EAA	Oat Protein (mg/g protein)[1]	Pea Protein (mg/g protein)[2]	Blend: Pea Protein 50% Oat Protein 50% (mg/g protein)	WHO AA Requirements (mg/g protein)[3]	Blend Amino Acids Relative to WHO Requirements
Histidine	22.2	19.8	21.0	15	1.40
Isoleucine	43.8	40.0	41.9	30	1.40
Leucine	84.2	67.5	75.9	59	1.29
Lysine	33.8	61.0	47.4	45	1.05
Methionine + cysteine	46.8	16.2	31.5	22	1.43
Phenylalanine + tyrosine	100	78.7	89.3	38	2.35
Threonine	35.0	28.6	31.8	23	1.38
Tryptophan	11.0	7.8	9.4	6	1.57
Valine	57.8	43.0	50.4	39	1.29
Limiting Amino Acid (underlined)	Lysine	Methionine + Cysteine	Exceeds WHO Profile	---	Exceeds WHO Profile
Limiting Amino Acid (% WHO Profile)	75%	74%	105%		105%

Source of Information:

[1] GRAS Determination, page 8 (Appendix 4)

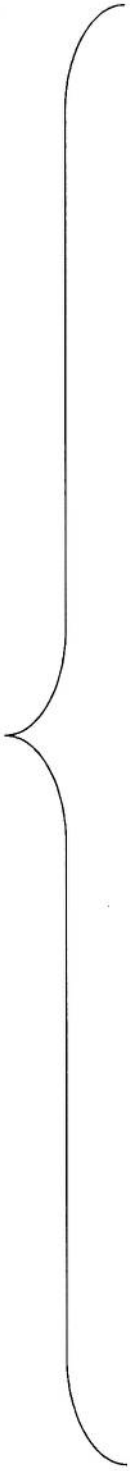
[2] Oat Protein: Health Benefits and Product Applications (Appendix 1).

[3] World Health Organization (WHO) Technical Report 935, 2002, Table 23: Summary of the adult indispensable amino acid requirements[4] http://whqlibdoc.who.int/trs/WHO_TRS_935_eng.pdf

Appendices
Appendix 3

DETAILED PROCESS FOR MANUFACTURE OF PrOatein™ OAT PROTEIN CONCENTRATE

Confidential Business Information (CBI) Deleted



Appendices

Appendix 4

GRAS DETERMINATION OF OAT PROTEIN FOR USE IN FOOD

Submitted by:
Tate & Lyle, March 5, 2015

GRAS Notification No GRN 000575

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-3835

April 30, 2015

Don Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 50650

Re: GRAS Notice No. GRN 000575

Dear Mr. Schmitt:

The Food and Drug Administration (FDA) has received the notice, dated March 13, 2015, that you submitted on behalf of Tate & Lyle in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received this notice on March 17, 2015, filed it on April 15, 2015, and designated it as GRN No. 000575.

The subject of the notice is oat protein. The notice informs FDA of the view of Tate & Lyle that oat protein is GRAS, through scientific procedures, for use as a protein source in a variety of foods including meat and poultry products.

A Memorandum of Understanding between FDA and the United States Department of Agriculture (USDA) provides for the review of food ingredients used in the production of meat, poultry, and egg products. FDA will send a copy of GRN No. 000575 to the Risk, Innovations, and Management Staff (RIMS) of the Food Safety Inspection Service (FSIS) of USDA for their review. In the event communication is needed between Tate & Lyle and RIMS/FSIS, all communication related to this submission would be sent to FDA, who will convey the communication to RIMS/FSIS.

In accordance with proposed 21 CFR 170.36(f), a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)) is available for public review and copying at www.fda.gov/grasnoticeinventory. If you have any questions about the notice, contact me at Judith.Dausch@fda.hhs.gov.

Sincerely yours,

Judith G. Dausch -S

Digitally signed by Judith G. Dausch -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000375513, cn=Judith G. Dausch -S
Date: 2015.04.30 14:35:11 -04'00'

Judith Dausch, Ph.D.
Division of Biotechnology and
GRAS Notice Review
Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740-3835

Donald Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 50650

Re: GRAS Notice No. GRN 000575

Dear Mr. Schmitt:

The Food and Drug Administration (FDA) is responding to the notice, dated March 13, 2015, that you submitted on behalf of Tate and Lyle in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on March 17, 2015, filed it on April 15, 2015, and designated it as GRAS Notice No. GRN 000575.

The subject of the notice is oat protein. The notice informs FDA of the view of Tate and Lyle that oat protein is GRAS, through scientific procedures, for use as a protein source in various food products at varying levels. These include meal replacements and nutritional bars (30%); vegetarian food products and meat analogues (20%); snack foods (20%); instant powdered nutritional beverages (15%); dry instant milkshake and protein drinks (9%); beverages, soups,[1] and nutritional beverages (5%); dairy products (4%); and bakery products (3%).

As part of its notice, Tate and Lyle includes the statement of a panel of individuals (Tate and Lyle's GRAS panel) that evaluated the data and information that are the basis for Tate and Lyle's GRAS determination. Tate and Lyle considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Tate and Lyle's GRAS panel evaluated information describing the identity and composition, manufacturing process and specifications, and estimated dietary exposure to oat protein, as well as published studies supporting the safety of oat protein. Based on this review, Tate and Lyle's GRAS panel concluded that oat protein is GRAS under the conditions of its intended use.

Oat protein is composed mainly of protein (52-56%), oil (16-18%), maltodextrin (18%), and fiber (2%). Tate and Lyle states that the major proteins in oat protein are avenalin (50–80%) and avenin (10–20%). The remainder is innocuous material, primarily moisture.

Tate and Lyle manufactures oat protein using a two-step process following current good manufacturing practice for food. In the first step, using a dry mill process, oat bran is produced from oat grains after the removal of the husk and most of the endosperm. The oat bran is then mixed with water and reacted with an alpha-amylase enzyme preparation to hydrolyze the starch in the bran into maltodextrins as specified

[1]Tate and Lyle states that the soups in which they intend to use oat protein contain less than 2% meat and poultry. Soups containing less than 2% meat and poultry do not fall under the U.S. Department of Agriculture's jurisdiction.

GRAS Determination of Oat Protein for Use in Food

SUBMITTED BY:

Tate & Lyle
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540

March 5, 2015

in 21 CFR 184.1012. In the second step, the soluble and insoluble oat fiber and maltodextrins are removed by physical separation. The final product is dried and packed.

Tate and Lyle provides specifications for oat protein. These include specifications for protein (52-56%), moisture (2-5%), lead (≤0.05 milligrams per kilogram (mg/kg), arsenic (≤0.1 mg/kg), cadmium (≤0.2 mg/kg), mercury (≤0.05 mg/kg), and limits for microbiological contaminants. Tate and Lyle provides analytical data from three lots of oat protein indicating that each lot complies with the specifications.

Tate and Lyle also provides results of stability tests of their product that indicate that after 12 months at both room temperature and 40°C, there is a slight change in the taste of the product; however, the protein content is stable. Tate and Lyle explains that their product is shipped fresh to the customers who would use it immediately and that even if their product were stored at ambient temperature for up to 12 months, any slight after-taste would probably be masked by the other food ingredients.

Tate and Lyle discusses exposure to oat protein. Tate and Lyle states that the consumption of foods containing oat protein would not result in a daily dietary exposure greater than the Recommended Dietary Allowance for protein. Tate and Lyle explains that it is reasonable to expect that most of the U.S. population's intake of protein is expected to remain in the form of unprocessed foods including meat, poultry, fish, and legumes. Therefore, Tate and Lyle concludes that the intended uses of oat protein will not result in an increase in the overall consumption of protein.

Tate and Lyle discusses the safety of oat protein by referencing the safety data provided in GRN 000327.[2] Tate and Lyle reports that the amino acid profile of oat protein is very similar to that of cruciferin-rich canola/rapeseed protein isolate (CRCPI) that was the subject of GRN 000327. Tate and Lyle cites a published subchronic 13-week rat feeding study that was reported in GRN 000327. Tate and Lyle reports that no adverse effects were observed for CRCPI at the highest dose tested, 20% of the diet, equivalent to 11.24 and 14.11 grams/kg body weight for males and females, respectively. Tate and Lyle states that the majority of the published literature shows that individuals with celiac disease can eat a moderate amount of pure uncontaminated oats. Tate and Lyle also states that the recommended ingredient labeling for their product is “oat protein” so that individuals who wish to avoid oat consumption for any reason would be able to identify the presence of an oat-derived ingredient.

Tate and Lyle concludes that oat protein meeting appropriate specifications and used as intended in GRN 000575 is GRAS.

Standards of Identity

In the notice, Tate and Lyle states its intention to use oat protein in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

In describing the intended use of oat protein, Tate and Lyle list meal replacements and nutritional bars, two food categories that often contain health or nutrient content claims. This raises a potential issue

[2]The subject of GRN 000327 is cruciferin-rich canola/rapeseed protein isolate (CRCPI) and napin-rich canola/rapeseed protein isolate (NRCPI). GRN 000327 informed FDA of the view of Archer Daniels Midland Company (ADM) that CRCPI and NRCPI are GRAS for use alone or together for the intended uses. FDA responded in a letter dated August 23, 2010, stating that the agency had no questions at that time regarding ADM’s GRAS determination.

under the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under section 403(a) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FD&C Act lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food or that characterize the relationship of a nutrient to a disease or health-related condition. If products that contain oat protein bear any claims on the label or in labeling, such claims are the purview of the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety neither consulted with ONLDS on this labeling issue nor evaluated the information in your notice to determine whether it would support any claims made about oat protein on the label or in labeling.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of Tate and Lyle's notice that oat protein is GRAS for the intended uses, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing oat protein. Accordingly, this response should not be construed to be a statement that foods that contain oat protein, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information provided by Tate and Lyle, as well as other information available to FDA, the agency has no questions at this time regarding Tate and Lyle's conclusion that oat protein is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of oat protein. As always, it is the continuing responsibility of Tate and Lyle to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000575, as well as a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying at www.fda.gov/grasnoticeinventory.

Sincerely,

Michael A. Adams -S

Digitally signed by Michael A. Adams -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300042713, cn=Michael A. Adams -S
Date: 2015.09.18 12:50:35 -04'00'

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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2

List of Acronyms

ACH	alcalase
ADME	absorption, distribution, metabolism, and excretion
bw	body weight
C	centigrade
CD	celiac disease
cGMP	current Good Manufacturing Practice
CAS	Chemical Abstracts Service
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CI	confidence interval
COA	certificate of analysis
dL	deciliter
DON	deoxynivalenol
DPPH	2,2'-diphenyl-2-picrylhydrazyl
DRV	dietary reference value
EDI	estimated daily intake
FDA	Food and Drug Administration
G	gram
GFD	gluten-free diet
GI	gastrointestinal
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRNs	Generally Recognized as Safe Notifications
IOM	Institute of Medicine
kDa	kilodalton
kg	kilogram
L	liter
LDL	low-density lipoprotein
mg	milligram
mL	milliliter
MoAb	monoclonal antibody
mRNA	messenger ribonucleic acid
ppm	parts per million
RDA	recommended dietary allowance
TG2	transglutaminase
TPH	protein hydrolysates from trypsin
US	United States
USDA	United States Department of Agriculture
WHO	World Health Organization
wk	week

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1.0. GRAS Exemption Claim

A. Name and Address of Notifier

Tate & Lyle, through its agent ToxStrategies, Inc., hereby notifies the Food and Drug Administration that the use of the identified oat protein product described below and which meets the specifications described herein is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Tate & Lyle has determined that such use is generally recognized as safe (GRAS) through scientific procedures.

Donald F. Schmitt 03/13/15

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Tate & Lyle

Date

B. Name of GRAS Substance

The name of the substance that is the subject of this GRAS determination is PrOatein® Oat Protein, an oat protein prepared from oat bran.

C. Intended Use in Food

Oat-derived protein is intended for use as a source of protein for enrichment of foods. It will be added to processed foods at per serving levels in an identical fashion (technical function and amount) to those described in other GRAS Notification submissions to the U.S. FDA for other protein sources such as canola protein isolates (all received no objection letters; GRNs 327 and 386). Example food categories include bakery products; snack foods; dairy products; processed meat products; beverages, soups, and nutritional beverages; dry instant milkshake and protein drinks; instant powdered nutritional beverages; vegetarian food products and meat analogues; and meal replacement/nutritional bars. The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

D. Basis for GRAS Determination

This Assessment documents the evidence of the safety and the "Generally Recognized As Safe" (GRAS) status of the proposed uses of Tate & Lyle's oat-derived protein product (PrOatein®). It consists of an evaluation of the safety and the GRAS status of the proposed uses of this ingredient, and the conclusion by a panel of experts (Expert Panel) qualified by scientific training and experience to evaluate the safety of substances added to food that the proposed uses of Tate& Lyle's oat protein ingredient are safe and GRAS as determined by scientific procedures.

Tate & Lyle's GRAS determination for the intended use of oat-derived protein is based on scientific procedures as described under 21 CFR § 170.30(b). The intended use of the oat protein product has been determined to be safe and GRAS, and the safety of intake exposure under the proposed conditions of use is based on knowledge and information that is both publicly available and widely accepted by experts qualified by scientific training and experience to evaluate the safety of substances in food. The publicly available safety data combined with the widely disseminated knowledge concerning the chemistry of protein from various sources such as oats, potatoes, wheat, canola, and whey combined with the long history of approval/use of such ingredients provide a sufficient basis for an assessment of the safety of oat-derived protein for the uses proposed herein.

To date, the FDA has issued "no questions" letters in response to Generally Recognized As Safe (GRAS) Notifications (GRNs) on protein concentrates and protein isolates from numerous plant and cereal grain-based sources (GRN No. 26, isolated wheat protein, 1999; GRN No. 37, whey protein isolate, 2000; GRN No. 182, hydrolyzed wheat gluten isolate and pea protein isolate, 2006; GRN No. 327, cruciferin-rich canola/rapeseed protein isolate and napin-rich canola/rapeseed protein isolate, 2010; GRN No. 386, canola protein isolate and hydrolyzed canola protein isolate, 2011; GRN No. 447, potato protein isolates, 2013). In addition to containing reviews of the published safety information, the GRNs included expert panel reports that reviewed and discussed in detail the metabolism, toxicology, and human health and safety data for protein and protein concentrates/isolates. Based on these GRAS notifications, FDA currently permits the use of protein preparations from a variety of plant-based sources at the use-levels indicated in the notifications.

There is common knowledge of a long history of human consumption of oats. As noted in the GRNs cited above, there is also a long history of safe use of plant-based protein concentrates and isolates in processed food. The focus of this GRAS determination is for an identical use of oat-derived protein, as an alternative source of dietary protein, as for currently available protein sources added to processed foods. There is a long history of the safe use of oats and products derived from oats. Furthermore, other natural sources of protein concentrates, such as canola, potato, and wheat, have been safely consumed for years. Tate & Lyle currently markets oat protein (PrOatein®) outside of the U.S. However, oat protein products are currently marketed in the U.S. (e.g., 55Oat Protein, Oat Tech, Inc.). While there is a noted lack of published safety studies on oat protein concentrates, the safety section that follows describes numerous animal and human safety studies of oats and other GRAS-notified protein sources currently added to processed foods.

Epidemiological studies and clinical trials have consistently revealed the cardiovascular benefits of oat consumption from its hypocholesterolemic effects. In 1997, the FDA approved a health claim for the association between oat consumption and coronary heart disease (Katz, 2001; FDA, 1997).

5

Protein is found throughout the body, in muscle, bone, skin, hair, and virtually every body part or tissue. At least 10,000 different proteins are found in the body. Proteins are made up of amino acids that act as building blocks to make all types of protein. Some amino acids cannot be made by the body and therefore must be provided by the diet (i.e., essential amino acids). While animal sources of protein tend to deliver all the amino acids the body requires for proper nutrition leading to normal or nominal nutriture, other protein sources also deliver most of these same essential amino acids and have become an important source of added protein in processed food. Current plant and cereal grain sources of protein include peas, lentils, soy, canola, rice, chickpeas, beans, wheat, and potato.

FDA has established a daily reference value (DRV) for protein of 50 g/day for adults and children four or more years of age. The Institute of Medicine (IOM, 2005) has established a Recommended Dietary Allowance (RDA) of 56 g/day for adult males and 46 g/day for adult females.

To date, FDA has reviewed extensive published information and data as part of GRAS notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no questions letters" (e.g., GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN 327 (canola/rapeseed protein isolates); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates)). No recent studies raising any new safety concerns concerning protein or protein isolates and their addition to processed foods have appeared in the published literature subsequent to these evaluations.

Given that oat protein (PrOatein®) meets the proposed specifications contained herein, the safe use of oat protein is justified by scientific procedures. In addition, the publicly available scientific literature is sufficient to support the safety and GRAS status of the proposed oat protein product. Therefore, since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of this oat-derived protein product described above for direct addition to food under its intended conditions of use was made through deliberation of an Expert Panel consisting of Michael Carakostas, DVM, Ph.D., Carol A. Knight, Ph.D., and Stanley M. Tarka, Jr., Ph.D, who reviewed a dossier prepared by ToxStrategies as well as other information available to them. These individuals are qualified by scientific training and experience to evaluate the safety of food and food ingredients. They individually and collectively critically evaluated published data and information pertinent to the safety of oat-derived protein, and unanimously concluded that the intended use of oat protein in food, produced consistent with cGMP and meeting appropriate specifications as delineated above, is "generally recognized as safe" ("GRAS") based on scientific procedures.

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E. Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent to the FDA upon request, or are available for the FDA's review and copying at reasonable times from ToxStrategies, Inc., Naperville, IL.

7

2.0 Description of Substance

A. Identity

Oat protein (PrOatein® Oat Protein) is a natural protein concentrate derived from oat bran and is rich in essential amino acids.

B. Common Name

Oat protein(s).

C. CAS Registry Number

The Chemical Abstracts Service (CAS) Registry Number for oat proteins is 134134-87-5.

D. Trade Names

The trade name of Tate & Lyle's oat protein is PrOatein® or PrOatein® Oat Protein.

E. Chemical/Structural Formulas

Oat protein (PrOatein®) is a protein concentrate, prepared from oat bran and rich in oat protein, typically containing 52-56% protein (dry basis). It also contains oat oil and oat maltodextrins (approved in 21 CFR §184.1444) both of which occur naturally in the oat, as well as a small amount of minerals and β-glucan (see Figure 1 below).

F. Oat Protein Composition

Among cereal grains, oats are considered unique due to their relatively high protein content and distinct protein composition. As indicated above and in Figure 1 below, PrOatein® contains oat oil. The PrOatein® oil fraction (16-18% of the PrOatein® product) is comprised of approximately 42% linoleic acid, 36%, oleic acid, 16% palmitic acid, 2% α-linolenic acid, and 4% other fatty acids (C20 - 24) normally found in oats. The high concentration of unsaturated fatty acids (namely the monounsaturated oleic acid, along with the high amount of monounsaturated and polyunsaturated fatty acids (mainly omega-6) provides a desirable nutritional profile. Oat protein is also rich in essential amino acids (including leucine, isoleucine and lysine). The composition and amino acid profile of PrOatein® Oat Protein is illustrated in the following two figures. The amino acid profile of a representative batch of PrOatein® (i.e., Batch No. 1334) can be found in Appendix A.

8

Figure 1. Oat Protein Composition and Amino Acid Profile

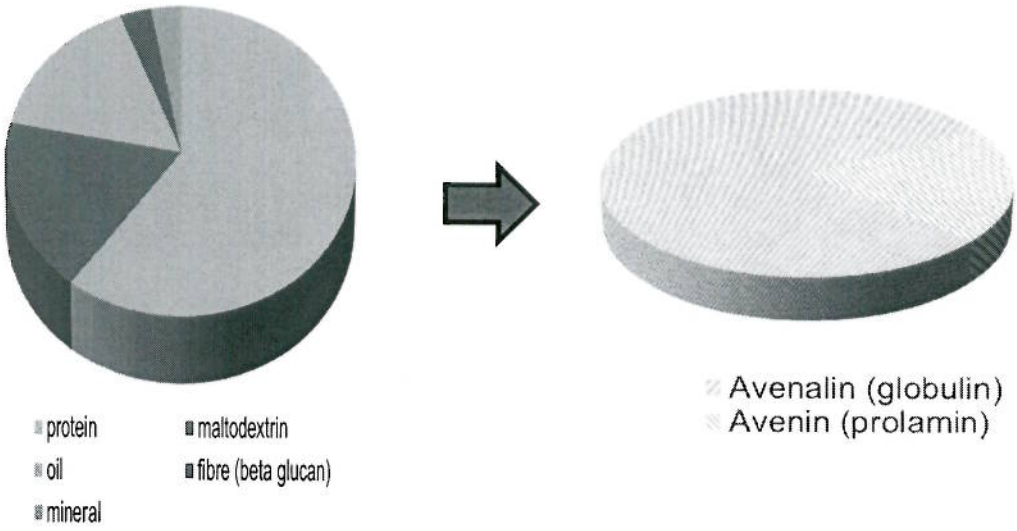
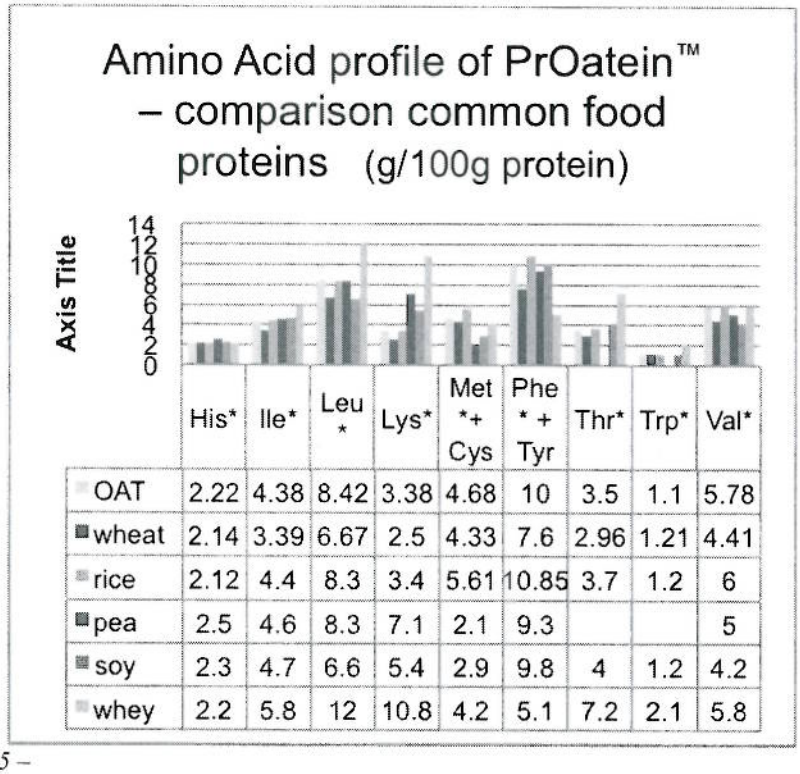


Figure 2. Amino Acid Profile

	2012	2013
Ala	4,37	4,39
Arg'	7,17	7,08
Asp'	7,48	7,60
Cys'	2,45	2,12
Glu	22,50	22,70
Gly'	4,13	4,21
His*	2,22	2,20
Ile*	4,38	4,62
Leu*	8,42	8,05
Lys*	3,38	3,42
Met*	2,23	1,79
Phe*	5,95	5,77
Pro'	5,57	5,35
Ser'	3,98	4,07
Thr*	3,22	3,01
Trp*	1,1	
Tyr'	4,05	3,87
Val*	5,78	6,08



	His*	Ile*	Leu*	Lys*	Met*+ Cys	Phe* + Tyr	Thr*	Trp*	Val*
OAT	2.22	4.38	8.42	3.38	4.68	10	3.5	1.1	5.78
wheat	2.14	3.39	6.67	2.5	4.33	7.6	2.96	1.21	4.41
rice	2.12	4.4	8.3	3.4	5.61	10.85	3.7	1.2	6
pea	2.5	4.6	8.3	7.1	2.1	9.3			5
soy	2.3	4.7	6.6	5.4	2.9	9.8	4	1.2	4.2
whey	2.2	5.8	12	10.8	4.2	5.1	7.2	2.1	5.8

Method ISO 13903:2005 – Values +/- 8% EUROFINS Sweden AB

Oats are the only cereal containing the globulin avenalin, as the major storage protein. Oat protein is nearly equivalent in quality to soy protein, which World Health

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Organization research has shown to be equivalent to meat, milk, and egg protein. The protein content of the hull-less oat kernel (groat) ranges from 15 to 20%, the highest among cereals. As summarized above, compared to other grains, oats contain a favorable ratio of lipids and contain unsaturated fats, including the essential fatty acid linoleic acid. On a per gram basis, oats have higher concentrations of protein, fat, calcium, iron, magnesium, zinc, copper, manganese, thiamin, folacin, and vitamin E than other whole grains, such as wheat, corn, rice, barley, and rye. (http://www.quakeroats.com/libraries/pdf/oa®eal_for_children_and_toddlers.sflb.ashx)

Oats have been recognized for superior nutritional value because of the high percentage of protein as well as the superior amino acid balance versus other grains. Oats also contain several antioxidant phytonutrients including vitamin E tocols, caffeic and ferulic acids, flavonoid and nonflavonoid phenolics including a group of novel antioxidants – avenanthramides. (http://www.quakeroats.com/libraries/pdf/oa®eal_for_children_and_toddlers.sflb.ashx)

The protein fraction itself (as demonstrated in Figure 1 above), is composed of mainly globulin (avenalin) and much less prolamin (avenin). Oat protein and PrOatein® contains less prolamin than typical cereal storage proteins (e.g., wheat, rye, barley), which results in better digestibility than proteins with higher prolamin content. It should also be noted that the prolamin fraction does not contain gluten. Overall, oats provide proteins with high nutritive quality and with digestibility greater than 90%, biological value around 75% and net protein utilization of 70%. (http://www.oatsandhealth.org/composition-oats-and-health-27; http://www.oatsandhealth.org/composition-oats-and-health-27/oat-protein)

G. Manufacturing Process

Tate & Lyle's PrOatein® product that is the subject of this GRAS determination is manufactured in a two-step process following current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110), without the use of chemicals or solvents and it does not contain additives or preservatives. The first-step is a dry mill process in which the oat grain is dehulled (husk and most of endosperm separated) and milled to specifications. The final output of the dry milling process is oat bran, which is employed in the second processing step, a wet process. In the wet fractionation process, the oat bran is mixed with water and food use-approved enzymes from non-GMOs (genetically modified organisms) at specified temperatures. The mixture is passed through physical separation procedures and sterilized. The process output provides insoluble fiber, protein, oat oil, maltodextrin (approved in 21 CFR §184.1444), and oat soluble fiber rich in β-glucan, all of which can be supplied as dry products (see Step 2 below).

A flow diagram of Tate & Lyle's manufacturing process can be found below.

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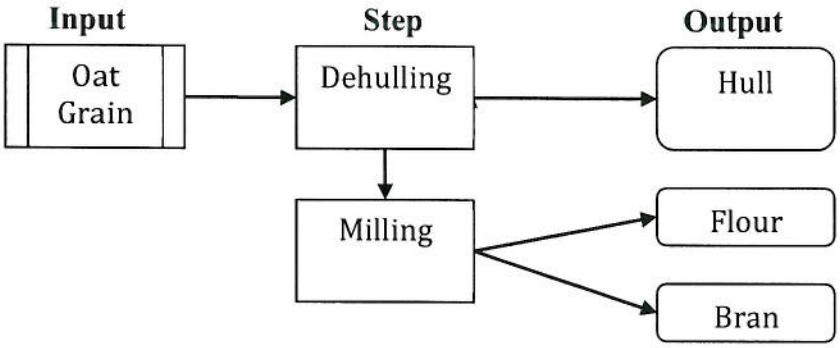
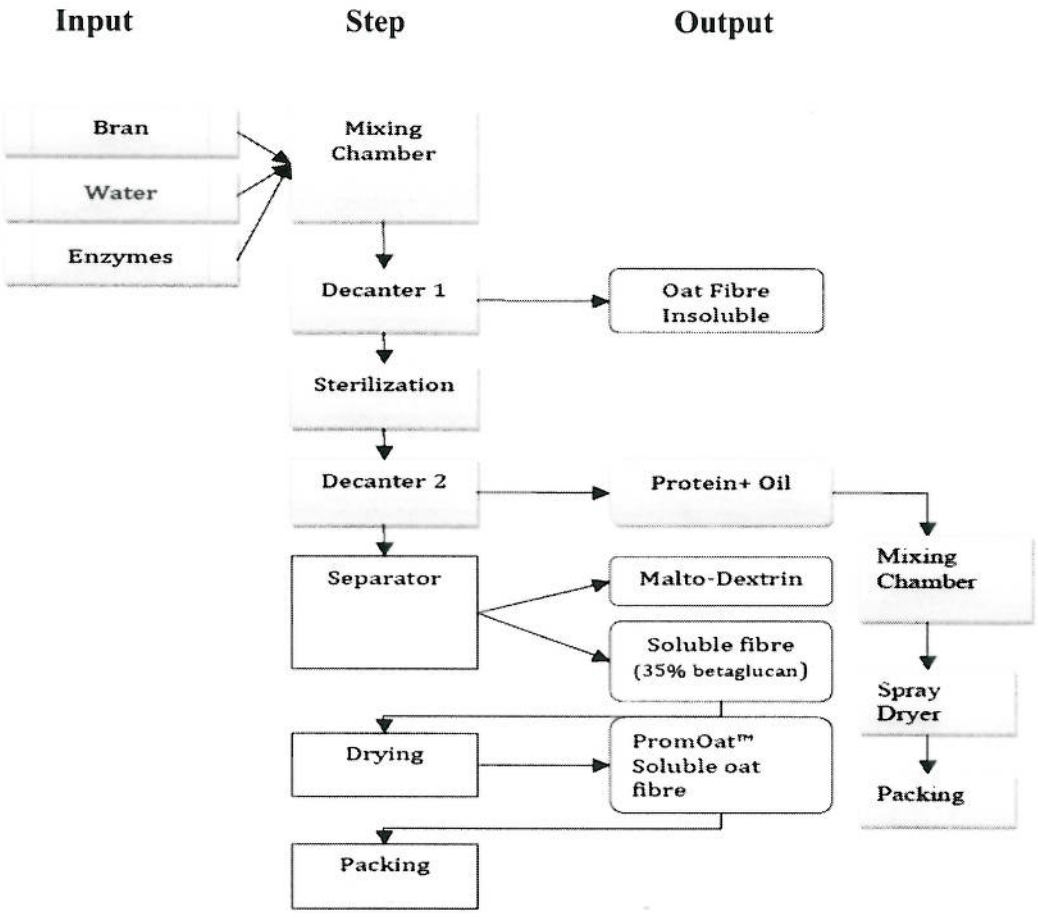
Step 1. Dry Process



Step 2. Wet Process



Reagents/processing aids used in the manufacture of oat protein are limited to water and the enzyme alpha-amylase, which is commonly used in food ingredient manufacturing processes. No chemical processing aids are employed in Tate &

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Lyle's manufacturing process. The alpha-amylase enzyme preparation employed in the process is GRAS per 21 CFR §184.1012, complies with Food Chemicals Codex specifications, and is used at levels not to exceed current good manufacturing practice.

H. Product Specifications

Food grade specifications for Tate & Lyle's PrOatein® Oat Protein are presented in Table 1. The typical protein content of PrOatein® is 52-56% on a dry matter basis. PrOatein® is a fine, beige-colored powder. Analytical results from three non-consecutive lots are provided in Appendix A (NOTE: Eurofins batch analysis for protein content is on an "as is" basis, not a dry matter basis as are the Tate & Lyle COAs). A comparison of three non-consecutive lots of PrOatein® to the specifications below can be found in Table 2.

Table 1. Specifications for Oat Protein (PrOatein®)

Parameter (Assay Method)	Specification
Physical Characteristics	
Appearance (Visual)	Fine, beige-colored powder
Moisture (IDF Standard 4A 1982)	Typically, 2-5% on a dry basis
Protein (IDF 20B 1993)	52-56%, on a dry basis
Heavy Metals*	
Lead (NMKL No 161 1998)	≤ 0.05 ppm
Arsenic (NMKL No 161 1998)	≤ 0.1 ppm
Cadmium (NMKL No 161 1998)	≤ 0.2 ppm
Mercury (NMKL No 161 1998)	≤ 0.05 ppm
Microbiological Analyses	
Total plate count (NMKL No 86 1999)	<10,000 cfu/g
Enterobacteriaceae (NMKL No 144 2000)	<10 cfu/g
Staphylococcus aureus (NMKL No 66, 3 ed, 1999 modified)	<20 cfu/g
Yeasts (IDF 94B; 1990 modified)	<100 cfu/g
Molds (IDF 94B; 1990 modified)	<100 cfu/g
Salmonella (NMKL No 71, 5 ed, modified)	Negative/25g
E.coli (NMKL No 125, 3 ed, 1996)	Negative

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* It should be noted that heavy metals levels are not routinely reported on COAs (see Appendix A), but are documented in routinely conducted analytical reports which are also included in Appendix A.

Table 2. Analytical Results for 3 Lots of Oat Protein (PrOatein®)

Specification		Lot No. 1332	Lot No. 1411	Lot No. 1413
Protein	52-56%, on a dry basis	52.9	55.0	56.0
Moisture	3-6%, on a dry basis	4.2	3.3	4.5
Heavy Metals*				
Lead	≤ 0.1 ppm	<0.020	<0.020	<0.020
Arsenic	≤ 0.1 ppm	<0.050	<0.050	<0.050
Cadmium	≤ 0.2 ppm	0.052	0.11	0.059
Mercury	≤ 0.1 ppm	<0.020	<0.020	<0.020
Microbiological Analyses				
Total plate count	<10,000 cfu/g	<1000	<1000	<1000
Enterobacteriaceae	<10 cfu/g	<10	<10	<10
Staphylococcus aureus	<20 cfu/g	<20	<20	<20
Yeasts	<100 cfu/g	<20	<20	<20
Molds	<100 cfu/g	<20	<60	<20
Salmonella	Negative/25g	Neg/25g	Neg/25g	Neg/25g
E.coli	Negative	Negative	Negative	Negative

* Heavy metals levels are not routinely reported on COAs (see Appendix A), but are documented in routinely conducted analytical reports which are also included in Appendix A.

Typical compositional and nutritional analyses of Tate & Lyle's PrOatein® product containing 52-56% protein are presented in Table 3.

Table 3. Nutritional Analyses of PrOatein®

Nutrient	Amount
Calories (kcal/100g)	445
Protein (g/100g)	54
Total fat (g/100g)	17
Saturated fat (g/100g)	3

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Carbohydrate (oat maltodextrins) (g/100g)	18
Fiber (oat beta-glucan soluble fiber) (g/100g)	2
Sugars (g/100g)	0.4
Iron (mg/100g)	400
Sodium (mg/100g)	20
Calcium (g/100g)	12

A COA and oat supplier (Lantmannen, Stockholm, Sweden) declaration of regulatory compliance on the starting material (food grade oats) is included in Appendix A. The supplier of the starting oats product regularly analyzes their oats for the presence of mycotoxins and guarantees that the oats meet the limits set for mycotoxins (e.g., aflatoxins, deoxynivalenol (DON), ochratoxin) and other foodstuff contaminants prescribed in EU regulation 1881/2006. It should be noted that the supplier Lantmannen was audited for GMP compliance by FDA in 2014. Compliance with the aforementioned EU regulations also results in compliance with FDA requirements regarding the presence of mycotoxins such as aflatoxins (20 ppb), DON (1 ppm) and ochratoxin A (3 ppb) in foodstuffs like oats. In addition, incoming oats are tested by plant operators for appearance, smell, color, density, and percent of other grains as well as other possible contaminants. Tate & Lyle analytical labs also analyze for dry matter and protein content. One batch of PrOatein® is the total production during one week. Therefore, given down time for plant maintenance, it is expected that approximately 50 batches of PrOatein® will be produced yearly. Based on an internal risk analysis on the raw material and final PrOatein® product (see Appendix C), Tate & Lyle has determined that a minimum of twice yearly analysis of the finished product is justified. The analyses include mycotoxins, pesticides, heavy metals, minerals, and other parameters as indicated in the attached COAs.

The analytical (chemical and microbiological) results for PrOatein® summarized in the above tables and included in the COAs and Technical Data Sheets in Appendices A and B confirm that the finished product meets the analytical specifications and demonstrates that the PrOatein® manufacturing process results in a consistently reproducible product, and confirms the lack of impurities/contaminants (e.g., heavy metals, pesticides, microbiological toxins).

I. Stability Data for Oat Protein

Tate & Lyle's oat protein product PrOatein® meets the above analytical specifications. Stability testing of PrOatein® has been conducted at room temperature, 0°C, and 40°C for up to 18 months. After an 18-month storage period under a variety of storage conditions, PrOatein® was found to be stable in terms of protein content, dry matter, β-glucan content, pH, appearance, color, volumetric weight (density), and microbiological parameters. Tate & Lyle currently

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recommends use "before 12 months after production." Stability test results can be found in Appendix D.

3.0 History of Use/Regulatory Approval of Cereal-Based Protein and Oat Protein

There is common knowledge of a long history of human consumption of oats. Oats contain the highest protein content of all the common grains (Katz, 2001). Tate & Lyle currently markets oat protein (PrOatein®) outside of the U.S. Additionally, similar oat-derived protein products are currently marketed in the U.S. (e.g., 55Oat Protein, Oat Tech, Inc.). Humans have consumed oats and the proteins from oats as well as other food sources providing protein such as meat, dairy, eggs, fruits, vegetables, grains, nuts, and seeds for centuries. Oats have been cultivated around the world for more than 2000 years. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (FDA, 2013). Numerous food products containing oats are currently marketed in the U.S. and around the world. In addition, there has been a global demand for less expensive proteins with good nutritional and functional properties (Ma, 1983). Oat protein has become a desirable ingredient for addition to a variety of food products as a source of dietary protein due to its protein quality, and excellent amino acid profile as compared to soy protein (Cluskey et al., 1979).

Epidemiological studies and clinical trials have consistently revealed the cardiovascular benefits of oat consumption due to its hypocholesterolemic effects. In 1997, the FDA approved a health claim for the association between oat consumption and coronary heart disease (Katz, 2001; FDA, 1997).

Protein is found throughout the body, in muscle, bone, skin, hair, and virtually every body part or tissue. At least 10,000 different proteins are found in the body. Proteins are made up of amino acids that act as building blocks to make all types of protein. Some amino acids cannot be made by the body and therefore must be provided by the diet (i.e., essential amino acids). Around the world (but not in the U.S.), many people do not get enough protein in their diet leading to protein malnutrition, resulting in a condition known as kwashiorkor. While animal sources of protein tend to deliver all the amino acids the body requires, other plant protein sources also deliver most of the essential amino acids and have become an important source of added protein in processed food. Current plant and cereal grain sources of added protein used in food include peas, lentils, soy, canola, rice, chickpeas, beans, wheat, and potato.

FDA has established a daily reference value (DRV) for protein of 50 g/day for adults and children four or more years of age. Furthermore, Dietary Guidelines for Americans (HHS/USDA, 2005) recommend that adults eat half their grains as whole grains, which include oats and wheat. The Institute of Medicine (IOM, 2005) recommends that adults consume a minimum of 0.8 grams of protein per kilogram of body weight. IOM also set a wide range for acceptable protein intake, ranging from

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10 - 35% of calories each day. In the U.S., the recommended daily allowance of protein is 46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age.

To date, FDA has reviewed extensive published information and data as part of GRAS notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no questions letters" (e.g., GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates)).

4.0 Intended Use and Estimated Intake (EDI)

Estimated intake

The focus of this GRAS assessment is for an identical food use of oat-derived protein as previously recognized in the GRNs identified above for current grain-based protein sources such as soy, canola, pea, lentils, wheat, rice, and whey. Similarly, oat-derived protein will be used as a source of protein for enrichment of processed foods. As described in GRN No. 386 (see below) for canola protein isolate and hydrolyzed canola protein isolate, the typical uses of protein for enrichment of foods includes bakery products, snack foods, nutritional beverages such as high protein drinks and milkshakes, instant powdered nutritional beverages, vegetarian food products and meat analogues, dairy products, and meal replacements/nutritional bars.

Application Usage Estimates

Food Category	Maximum Use Level in Canola Protein Products (%) as consumed	
	Isolexx™	Vitalexx™
Bakery products (*e.g.*, breads, rolls, doughnut, cookies, cakes, pies, batters, muffins, pasta, and cereal bars, etc.)	3	--
Snack foods (*e.g.*, crackers, cookies, candy ingredients, breakfast/energy bars, snack chips, etc.)	20	--
Beverages, soups, nutritional beverages (*e.g.*, protein fortified soft drinks, fruit juices, high protein drinks)	5	5
Dairy products (*e.g.*, cheese, frozen dairy dessert, whipped topping, yogurt, coffee whiteners, etc.)	4	--
Dry instant milkshake mixes and protein drinks	9	--
Instant powdered nutritional beverages	--	15
Processed Meat products (where the addition of vegetable proteins are acceptable, such as unspecified products or those where they are included within the Standard of Identity) *(subject to USDA approval)*	2	--
Vegetarian food products and meat analogues	20	--
Meal replacement/nutritional bars	30	25

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The proposed use concentrations and variety of food uses combined with the large average daily consumption of the described foods resulted in the calculated daily intake of the protein additives being a substantial fraction of the RDA (46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age), and even exceeded it at the 90th percentile consumption. This was also the case for GRN No. 327 (cruciferin-rich canola/rapeseed protein isolate and napin-rich protein canola/rapeseed protein isolate). As Tate & Lyle's proposed oat protein is only intended to be an alternative source of protein for current uses in food, a similar estimate of intake would be expected if oat protein was the only source of protein used in processed foods. As other GRAS notifications have stated, we do not realistically expect that the actual consumption of foods containing oat protein would result in daily consumption greater than the DRV or RDA for protein. It is reasonable to expect that most of the population's intake of protein is, and will remain, in the form of unprocessed foods including meat, poultry, fish, and legumes. As the proposed oat protein product is only one of many protein sources for use in processed foods, only the inherent conservatism of intake calculations such as those described in the aforementioned GRNs suggest the possibility of exceeding the RDA at the 90th percentile (FDA, 2011; FDA, 2010).

In summary, the proposed uses of PrOatein® will not result in an increase in the overall consumption of protein, but simply provide an alternative source of well-characterized protein from oats for use in food. Therefore, cumulative intake analysis is not considered necessary.

Self-limiting use

The use of oat protein in protein-enriched foods is considered to be self-limiting for technological reasons such as product texture and/or flavor profile either of which could affect consumer acceptability.

5.0 Safety

A. Introduction

Tate & Lyle currently markets oat protein (PrOatein®) outside of the U.S. However, oat protein products are currently marketed in the U.S. (e.g., 55Oat Protein, Oat Tech, Inc.). Humans have consumed oats and proteins from oats and other grains for centuries, along with proteins from many food sources such as meats, fruits, vegetables, nuts and seeds. Oats have been cultivated around the world for more than 2000 years. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (FDA, 2012). Numerous food products containing oats are currently marketed in the U.S. and around the world. Healthy diets include high-quality proteins (de Pee and Bloem, 2009) and high-protein diets may help with weight loss (Martin et al., 2005). In their MyPlate campaign, the US Department of Agriculture (USDA) recommends that half of one's meal consist of

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protein foods and grains (equal amounts), and the other half should contain fruits and vegetables, with an added serving of dairy (USDA, 2014).

According to the World Health Organization (WHO, 2002):

> *A source of protein is an essential element of a healthy diet, allowing both growth and maintenance of the 25,000 proteins encoded within the human genome, as well as other nitrogenous compounds, which together form the body's dynamic system of structural and functional elements that exchange nitrogen with the environment. The amount of protein that has to be consumed, as part of an otherwise nutritionally adequate diet, to achieve the desired structure and function is identified as the requirement.*

Oats are a popular cereal used for both human and animal foods due to the presence of high levels of protein and fatty acids. The protein content in oats is reported to be one of the highest among cereal grains (12-24%) and oats represent high quality protein. Oat proteins contain a nutritious amino acid composition, which is likely related to the high amount of lysine and higher proportion of globulins and albumins compared to proteins derived from other cereal grains. Oat proteins are 70-80% globulin. In oats, globulin (called avenalin) is the main storage protein. Prolamins (called avenin) are only a small fraction (Anderson, 2014; Nesterenko et al. 2013; Tsopmo et al., 2010; Wu et al., 1972). Over 40 years ago, Wu and co-workers (1972) stated:

> *The availability of high-protein oats, the favorable solubility properties of oat proteins, and their well-known nutritive value indicate a bright future for low-cost, high-protein, and highly nutritious food products being made from oat fractions.*

In oats, the majority of the metabolically active proteins, generally enzymes, are in the water-soluble albumin fraction. Enzymes present include maltase, α-amylase, proteases, lipases, lichenase, phenoxyacetic acid hydroxylase, tyrosinase, and phosphatase. Protease inhibitors, considered to be anti-nutritional, are also present. Oats are very nutritious; oat proteins exceed the requirements for all essential amino acids in children except threonine and lysine (Richman, 2012; Oats and Health, 2014).

The majority of safety-related information specifically pertaining to oat protein focuses on the potential for immune responses and intolerance in individuals with celiac disease. Celiac disease (CD) is an autoimmune condition with immunological, environmental and genetic components. In persons with CD, consumption of wheat gliadin/gluten and similar proteins elicits an immune response in the small intestine, causing inflammation and villous atrophy (Hoffenberg et al. 2000; Real et al., 2012; Thompson, 1997; Pulido et al., 2009).

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B. Safety Data

As would be expected for a food product widely consumed by humans for thousands of years, oats and oat proteins have not be subjected to traditional animal toxicology studies. The proteins in PrOatein® Oat Protein are the same as those found in oats, but in a more concentrated and isolated form. In addition, oats have been widely consumed by animals for centuries; horses as a major component of their diet and also cattle, swine, and dog feed/food, all without reported adverse effect. Several substantially similar protein isolates from other grain and plant sources have received GRAS designation, including wheat protein, canola protein and potato protein (FDA, 1999, 2011, and 2013, respectively). A chemically similar (i.e., amino acid profile) protein isolate from canola was recently tested for toxicity in a 90-day rat study and found to be without adverse effect (NOAEL of 20% in the diet, equivalent to 11.24 g/kg bw/day for males and 14.1g/kg bw/day for females). Given the information/data on the safety of oats and its common use in the diet of both humans and animals, conduct of toxicity studies on oat protein were considered unnecessary and not an ethical use of laboratory animals. A summary of the available safety information for oat protein and protein isolates considered substantially similar are presented below.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Protein and its breakdown products, peptides, amino acids and nitrogen, are required for maintenance of the human body (Bricker et al., 1945; WHO, 2002). Protein uptake can be confirmed by nitrogen absorption and retention (de Pee and Bloem, 2009). Dietary nitrogen is required to produce a sufficient flow of amino acids to maintain health (nitrogen balance; body weight; metabolic, physiological and psychological function) (WHO, 2002).

Oats can be a source of proteins with high nutritive quality, digestibility >90%, net protein utilization of 70%, and biological value around 75% (Oats and Health, 2014). Dietary oat proteins would therefore be expected to be almost completely digested and absorbed from the upper gastrointestinal (GI) tract by the time they reach the terminal ileum. Oat proteins would be broken down by gastric juices in the stomach and proteases in the small intestine and efficiently absorbed as small peptides or amino acids. Sherman and co-workers (1919) demonstrated that proteins present in oatmeal were very efficiently utilized in the maintenance metabolism of healthy adult volunteers. This indicates that oat proteins are effectively broken down into their constituent amino acids and small peptides that are typical of all food proteins. The known metabolism of oat proteins is a strong indicator of the safety of oat protein isolate.

Human and Animal Studies of Oats, Oat Protein, and/or Other Protein Isolates

According to USDA (2014), commonly consumed proteins include meat, seafood, beans and peas, poultry, eggs, processed soy products, seeds and nuts. A variety of protein-containing foods are necessary for adequate intake of all essential amino

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acids. In children at risk for malnutrition, de Pee and Bloem, (2009) recommend protein powder and protein extracts for children lacking adequate micronutrients and essential amino acids.

The antioxidant properties of many food protein concentrations and isolates (soy, milk, bean and chickpea) have been reported in the literature. Nutritional and functional properties of these food proteins can be enhanced using enzymatic hydrolysis. Following proteolytic hydrolysis of food proteins, various physiological activities have been found including radical scavenging, antihypertensive, immunomodulatory, antimicrobial, mineral binding and opioide activities (Tsopmo et al., 2010).

Graham et al. (1990) administered whole groat oat flour to 9 young children and infants as 22.5, 45, or 67% of total dietary energy (i.e., one half of 6.4%, all of 6.4%, or all of 9.6% protein energy). Controls consumed casein diets containing the same nitrogen and energy content. Absorptions of carbohydrate, fat and oat energy, as percentages of intake, decreased disproportionately as the oat flour intake increased. Apparent absorption of oat nitrogen measured approximately 75% of intake (casein, 87%). In children consuming 45% oats, fasting plasma free total essential amino acid levels were low and remained relatively constant after meals. Fasting molar proportions of individual essentials did not significantly vary 3 and 4 h after meals and were similar to those from milk protein consumption, which indicates that protein digestibility instead of an individual amino acid was first limiting to the retention of nitrogen. The authors concluded that oats are a satisfactory source of protein, fat and energy for infants and young children.

Bauer et al. (2013) discussed research indicating that older adults need more dietary protein than younger adults to support good health, promote recovery from illness, and maintain functionality. It is known that older adults need to make up for age-related changes in protein metabolism, such as high splanchnic extraction and declining anabolic responses to ingested protein. They also require more protein to offset inflammatory and catabolic conditions associated with chronic and acute diseases that occur commonly with aging. As a result, the European Union Geriatric Medicine Society (EUGMS), in cooperation with other scientific organizations, appointed an international study group to review dietary protein needs with aging (PROT-AGE Study Group). To help older people (>65 years) maintain and regain lean body mass and function, the PROT-AGE study group recommended average daily intake of at least 1.0 to 1.2 g protein per kilogram of body weight per day. Both endurance- and resistance-type exercises were recommended at individualized levels that are safe and tolerated, and higher protein intake (i.e., $\geq$ 1.2 g/kg body weight/day) was advised for those who were exercising and otherwise active. Most older adults who have acute or chronic diseases require even more dietary protein (i.e., 1.2-1.5 g/kg body weight/day). Older people with severe kidney disease but who are not on dialysis are an exception to the rule and those individuals may need to limit protein intake. Protein quality, timing of ingestion, and intake of other nutritional

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supplements may also be relevant, but the authors indicated that the evidence is not yet sufficient to support specific recommendations

Regarding oats, oat consumption has various health benefits, such as a decreased risk of coronary heart disease and lowering of low-density lipoprotein (LDL) cholesterol (FDA, 1997; Davy et al., 2002). In their meta-analysis of the literature and of unpublished trials on the cholesterol lowering effects of oat products, Ripsin et al. (1992) indicated that the addition of oat products to a diet yields a modest reduction in blood cholesterol level. For the 10 studies meeting the inclusion criteria, a summary effect size for change in blood total cholesterol level of -5.9 mg/dL (95% CI, -8.4 to -3.3 mg/dL) was calculated. The summary effect size for studies using wheat control groups was -4.4 mg/dL (95% CI, -8.3 to -0.38 mg/dL). The greatest reductions in blood cholesterol were seen in trials where participants had initially higher blood cholesterol levels (≥229 mg/dL). The authors concluded that their analysis provides strong support for the hypothesis that approx. 3 g/day soluble fiber from oat products can lower the total cholesterol level by 5-6 mg/dL. β-glucan concentrations were not specified.

Zhou and co-workers (2015) fed whole grain oat (WGO) flour or low bran oat (LBO) flour to 5-week-old male C57BL/6J mice for 8 weeks. Animals in the WHO group exhibited a 14.6% decrease in weight gain during week 7 (P= 0.04) and decreases in plasma total (9.9%) and non-HDL (11%) cholesterol. WGO improved insulin sensitivity, as demonstrated by significantly lower plasma insulin, C-peptide, and homeostasis model assessment-estimated insulin resistance. These effects were associated with alterations in cecal microbiota composition. Therefore, relative to LBO, WGO improved the plasma cholesterol profile and insulin sensitivity in mice. The authors concluded that increasing WGO consumption may help improve dyslipidemia and insulin sensitivity in chronic diseases.

Avenanthramides are polyphenols found in oats alone and may be involved in antiatherogenesis and anti-inflammation. Wang et al. (2015) studied the metabolism of avenanthramide-C (2c), an antioxidant, in mice and by the human microbiota, and evaluated the bioactivity of its major metabolites to identify new exposure markers to precisely reflect oat consumption. In urine from female CF-1 mice treated intragastrically with 2c (200 mg/kg), eight 2c metabolites were identified. In cultures of 2c with fecal slurries from 6 human donors, four 2c metabolites were identified. Avenanthramide-C and its major metabolite M4 were bioactive against HCT-116 human colon cancer cells, inhibiting cell growth and inducing apoptosis. The authors concluded that this is the first study to show that 2c from oats can be substantially metabolized by mice and the human microbiota to yield bioactive metabolites.

Mejia et al. (2009) conducted a study with the test article Puratein®, a cruciferin-rich canola protein (minimum 90% protein; GRN No. 327) with an amino acid profile that was very similar to that of PrOatein® found in Figure 2. Rats were fed ad libitum at levels of 5%, 10% and 20% for 90-days. Four groups of Crl:CD Sprague Dawley rats (20/sex/group) were used in the study, following FDA Red Book Guidelines. The

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animals were fed an AIN-93 diet, with the lower doses adjusted with casein to the required level of at least 18% protein in rodent diets. There were no treatment related effects in the animals fed Puratein® at any dose. These included survival, clinical, and functional observations. Food consumption was equivalent at all doses and body weight gains were the same for all animals of the same sex at all doses. While there were sporadic changes in neutrophil counts in 10% and 20% -treated females on study day 45, a similar trend was not seen for males, and the neutrophil counts for the females returned to normal on study day 91. There were no treatment related changes in serum chemistry or urinalysis. There were some non-dose related differences in some serum chemistry parameters (potassium, sorbitol dehydrogenase, alkaline phosphatase). The differences were very small and were not considered toxicologically significant. There were no treatment-related changes. The NOAEL for the dietary administration of Puratein® was the highest dose tested, 20% in the diet, equivalent to 11.24 g/kg bw/day for males and 14.1g/kg bw/day for females.

A GRAS notification for canola protein (FDA, 2011) stated that there is no scientific justification for performing mutagenicity tests on purified proteins. Pariza and Johnson (2001) reviewed the history of genotoxic testing of microbial enzymes used in food processing, and concluded no clastogen or mycotoxin has ever been identified that would not have been detected by limited animal feeding studies and properly conducted analytical chemistry analyses. Further, a series of clastogenicity and mutagenicity studies on canola proteins, as reported in GRAS Notification No. 327 showed negative results for canola proteins (FDA, 2011). Similar negative genotoxicity results would be expected from oat protein testing.

In summary, studies of oats, oat protein, and other protein isolate sources in humans and/or animals have demonstrated its beneficial effects as well as safety. Studies with other protein sources with similar amino acid profiles to oat protein have also demonstrated a lack of toxicity at high levels of consumption. Furthermore, given that the metabolism of oat protein to its constituent amino acids, peptides, and nitrogen is well understood and other protein isolate products derived from wheat, canola, and potatoes have a GRAS designation, the proposed oat protein product can also be considered safe as proposed for human consumption

Reported Safety Concerns

Extremely high protein consumption may be toxic. In persons who consumed diets consisting of 45% protein from rabbit meat (a very low fat diet), nausea and diarrhea occurred in 3 days, and death within several weeks. Preterm infants fed high-protein formula experienced lethargy, fever, poor feeding and increased incidence of strabismus and low IQ scores at 3- and 6-year evaluations. While it has been recommended that adults not consume more than two-fold the reference dietary amount of 1.5 g protein/kg, physically active individuals on normal diets easily exceed this amount, and persons involved in body-building consume much higher levels of protein (WHO, 2002). WHO (2002) recommends protein consumption rates for both sexes combined based on body weight. For example, the safe protein level

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for a 40-kg adult is 33 g/kg/day; that for an 80-kg adult is 66 g/kg/day. In terms of nitrogen, WHO (2002) reports the median adult protein requirement as 105 mg nitrogen/kg/day, with the 97.5 percentile value as 132 mg nitrogen/kg/day. PrOatein® is not intended for use in infant formula and its proposed food use result in consumption levels well below the safe protein consumption levels cited above.

Renal Function

Dietary protein can influence renal function. Increased protein intakes yield increased excretion of creatinine and urea, due to increased glomerular filtration rate (GFR) resulting from increased renal blood flow. Concern has historically been expressed that excess protein intake can promote chronic kidney disease via hyperfiltration and increased glomerular pressure (Martin et al., 2005; WHO, 2002). After a critical review of the literature, Martin et al. (2005) concluded that while protein restriction may be recommended for treatment of existing kidney disease, no significant evidence exists for a detrimental effect of high protein intakes on renal function in healthy persons after hundreds of years of high protein Western diets. In fact, several studies suggest that hyperfiltration, the suggested mechanism for kidney damage, is a normal adaptive response to increased nitrogen load and higher demands for renal clearance. The authors considered "high protein diet" as daily intake $\geq$1.5 g/kg-day, which is within the range of current Dietary Reference Intakes for protein and nearly twice the current Recommended Dietary Allowance. In persons with pre-existing kidney disease, increased dietary intake of animal protein has been found to accelerate the disease, but the association was not found in persons with healthy kidney function. In patients with compromised renal function, a high protein diet which results in a renal solute load in exceeding the kidneys' excretory abilities can contribute to progressive renal failure (Martin et al., 2005). Again, the proposed is not intended for use in infant formula and its proposed food use of PrOatein® results in consumption levels below those associated renal function concerns.

Calcium Balance

There is the potential for excess protein consumption to adversely affect the body's calcium balance and calcium in bone. High-protein diets can lead to increased urinary calcium excretion; doubling protein intake can amount to a 50% increase in urinary calcium. Further, increased resorption of bone is associated with increased protein intake. However, it appears that as part of a well-balanced diet, dietary protein is likely to be beneficial for bone, even possibly at dietary levels exceeding the recommended intakes (WHO, 2002).

Kidney Stones

An additional potential consequence of a high-protein diet is an increased incidence of kidney stones. Kidney stones are fairly common, and have been estimated to affect 12% of the US population. Urine is high in calcium and oxalate, and studies have shown that an increase in animal protein intake led to increased urinary calcium and

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oxalate, which was estimated to increase the likelihood of stone formation. However, conclusions cannot be drawn from the various studies, since dietary impacts occurred only in studies with a wide range of protein intakes (e.g., 80-185 g/day). Further, it was unclear whether there is a difference between plant and animal proteins. Therefore, it is recommended that to decrease the risk of kidney stones in those who are at risk, the diet should provide at least the safe level of protein (0.83 g/kg-day), ideally from vegetable sources, but not large amounts (<1.4 g/kg-day), (WHO, 2002).

Allergy

Allergy manifestation resulting from consumption of oats and oat products has been debated, and it has been alleged that oats may cause adverse effects in individuals with CD. Oats and protein are not listed among FDA's list of the 8 major food allergens (FDA, 2010).

However, children with atopic dermatitis and farmers with allergies to grain dust may experience allergic reactions to oat proteins. These proteins can act as skin and respiratory allergens (Boussault et al., 2007; FDA, 2012).

Celiac Disease

Regarding oats, some studies of patients with celiac disease (CD) indicate more frequent GI symptoms while consuming an oat-containing gluten-free diet (GFD) than consumption of a traditional GFD. Such symptoms are generally mild, and the appearance of flatulence and abdominal distension has previously been attributed to the increased intake of fiber from oat products (Holm et al., 2006; Pulido, 2009).

CD is an autoimmune condition with immunological, environmental and genetic components. In persons with CD, consumption of wheat gliadin/gluten and similar proteins elicits an immune response in the small intestine, causing inflammation and villous atrophy. It has been estimated that CD affects 1 in 250 Americans, many of whom have asymptomatic or "silent" CD, which may be 5-7 fold more common than symptomatic CD (Hoffenberg et al. 2000; Real et al., 2012; Thompson, 1997; Pulido et al., 2009).

Oats may increase the palatability of a gluten-free diet (GFD) and can be a valuable source of fiber in a diet that is typically fiber deficient (Lundin et al. 2003). Further, a GFD is very restrictive. If CD patients can consume oats, the restrictive nature of the diet would be reduced, which could then lead to an increase in the quality of life (Richman, 2012). In a systematic review of the clinical literature regarding the presence of oats in the diets of individuals with CD, Pulido et al. (2009) stated that incorporation of oats into a GFD provides increased palatability, high vitamin B and fiber content, and beneficial impacts on cardiovascular health.

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Studies reported in the literature present contradictory information regarding if oats can elicit abnormal immunological responses in persons with CD. Koskinen et al. (2009) evaluated the toxicity of oats in 23 children (median age 13 years, range 7–18 years, 7 female) with CD in remission during a 2-year follow-up by measuring jejunal transglutaminase 2 (TG2)-targeted IgA-class autoantibody deposits, which is likely a more sensitive disease marker than conventional histology or serum antibodies. Participants consumed oats and were randomized to undergo a gluten challenge allowing the consumption of wheat, rye, and barley in addition to oats. When histological relapse in the small intestine occurred after gluten challenge, patients continued to consume oats but not the other grains. At the beginning of the study, serum TG2 antibodies were negative in all participants, but 7 children had minor mucosal deposits. In the group that underwent the gluten challenge, the deposits clearly increased then decreased again when other grains were excluded and oat consumption continued; the same pattern occurred with the serum autoantibodies. In the group consuming oats, no significant change in the intensity of the deposits occurred within 2 years. The authors concluded that in children with CD, oat consumption does not induce TG2 autoantibody production at the mucosal level. These results showed that oats were tolerated by most CD patients, and were neither immunogenic nor toxic to the small-bowel mucosa.

Kemppainen and co-workers (2007) conducted a study demonstrating the long-term safety of inclusion of oats in a diet for patients with CD. In the study, the authors analyzed local cellular immunological responses after 5 years of oats consumption by adults with CD. Forty-two coeliac patients took part in an earlier oat intervention study for 6-12 months. Over a 5-year period, 20 celiac patients on a strict, conventional, GFD without oats served as the control; 12 celiac patients consumed oats. There were no differences in the densities of intraepithelial abIEL, CD3, and gdIEL T cells between the oat vs. control groups. The authors concluded that chronic oat consumption as part of a GFD in persons with CD does not initiate a local immunological response in the mucosa of the small intestine.

Sjoberg et al. (2014) investigated whether oat consumption can influence the immune status of the intestinal mucosa in children with CD. In children who had been on a GFD for >11 months, paired small intestinal biopsies were collected. Children participated in the randomized, double-blind intervention study by consuming either a standard GFD (5 boys, 8 girls, 4.2±3.5 years) (control) or a GFD containing non-contaminated oats (7 boys, 8 girls, 5.8±4.7 years). The authors measured expression levels of mRNAs for 22 immune effector molecules and tight junction proteins via quantitative reverse transcriptase polymerase chain reaction. In the group consuming oats, the number of mRNAs that remained elevated was significantly higher. The most significant differences were seen for KLRC3/NKG2E and claudin-4. However, only certain aspects of mucosal immunity seem to be affected; markers of down-regulatory and cytotoxic activities were not impacted. The authors concluded that a notable fraction of children with CD seem to not tolerate oats. In these children, oat consumption alters the immune status of the intestinal mucosa, and the mRNA profile suggests a stressed epithelium with affected tight junctions and the presence of

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activated cytotoxic lymphocytes and regulatory T cells. It appears that even avenin can cause an immune response in the intestinal mucosa in some CD patients, either on its own or by cross-reactivity. Pediatric CD patients with sensitivity to oats can be identified by assessing changes in mRNA levels for claudin-4 and KLC3/NKG2E from onset to after 1 year consuming oats as part of a GFD.

Real et al. (2012) conducted a study to evaluate the safety of prolamins from oat varieties with low, medium, and high reaction for CD patients. The avenin genes of these oat varieties were cloned and sequenced, and their expression measured throughout the grain development. The avenin sequences were classified into three different groups, which possess homology with the S-rich prolamins of Triticeae (barley, wheat and rye). Avenin proteins had a lower proline content than wheat gliadin, which may contribute to the low toxicity of oat avenins. A direct relationship was observed between the immunogenicity of the different oat types and the presence of the specific peptides with the potential for higher/lower immunotoxicity. The authors concluded that range of variation of potential immunotoxicity of oat cultivars varies widely, and this variation could result from differences in the level of immunogenicity in their sequences.

In an *in vitro* study, Maglio and coworkers (2011) investigated the immunological and biological properties of two oat varieties, *Avena potenza* and *Avena genziana*, to determine their safety for persons with CD. In contrast to peptic–tryptic digests from gliadin, the oat peptic–tryptic digests did not induce a significant decrease in transepithelial electrical resistance or an increase in extracellular signal-regulated kinase phosphorylation in CaCo-2 cells. In duodenal biopsies from 22 persons with CD, unlike the response to gliadin, oat digests did not significantly increase interleukin 15 expression, lamina propria CD25+ cells, nor crypt enterocyte proliferation. However, in 3/8 CD intestinal T cell lines, *Avena genziana* induced IFN-g production, and *Avena potenza* increased the density of intraepithelial T-cells. The authors concluded that the data showed that *Avena potenza* and *Avena genziana* do not display activities related to CD pathogenesis. Some of the observed T-cell reactivity may be below the threshold of clinical relevance.

In another *in vitro* study, Silano et al. (2014) evaluated the ability of three different oat varieties to activate gliadin-induced transglutaminase-2 (TG2)-dependent events in various *in vitro* CD models. This effect was also compared with the electrophoresis pattern of peptic–tryptic digests of the proteins of the oat varieties. The Nave oat cultivar triggered such events, but Irina and Potenza varieties did not. Further, results showed that a cultivar's ability to initiate these events was directly related to the electrophoretic pattern of the proteins and their reactivity to anti-gliadin antibodies. The authors concluded that before beginning a clinical trial, an oat variety's safety to CD patients could be screened by such *in vitro* biochemical and biological assays.

Previous studies have demonstrated that monoclonal antibodies (moAbs) against the primary immunotoxic 33-mer peptide (A1 and G12) react strongly against wheat, rye

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and barley, but less against oats. Comino et al. (2011) tested whether this reactivity may be related to the potential toxicity of oats in CD patients. The authors determined the immunogenicity of three oat varieties via interferon g production, 33-mer concentration and T cell proliferation using Western blot and ELISA. The three groups of oat cultivars reacted differently against moAb G12: substantial affinity, slight reactivity and no detectable affinity. Immunogenicity of the three oat types was assessed using isolated peripheral blood mononuclear T cells from patients with CD, by measuring interferon g release and cell proliferation. Potential immunotoxicity of the different prolamins was directly proportional to their reactivity with G12. Since immunogenicity differed between the oat cultivars, this may explain why some oats trigger an immunological response in CD patients. Further, these results indicate that the specific antibody is a reliable instrument for detecting oat varieties that are potentially safe for patients with CD (Comino et al. 2011).

Using a solid-phase radioimmunoassay, Troncone and co-workers (1987) examined sera from 6 children (median age 1.9 years, range 1-2.5 years; gender not reported) with active CD. The sera were examined for IgG antibodies against different cereal proteins. Similarly, elevated titers against gliadin from six age-matched controls were also examined. In coeliac sera, rice prolamins gave lower titers but high titers were measured when tested against oats, barley, and maize prolamins, as well as wheat albumins, glutenin and globulins. The authors concluded that these results indicated a dissociation between toxicity in CD patients and immunogenic properties of cereal proteins.

Using Western blotting, Freedman et al. (1988) created two monoclonal antibodies raised against wheat gliadin, and determined antibody binding to different cereal protein fractions. There results showed significant epitope sharing between rye and barley prolamins as well as gliadin subfractions, but less binding of the antibodies to oat avenins. The authors noted that the binding pattern closely corresponded to the toxicity of these proteins to persons with CD.

Various *in vivo* and *in vitro* studies support different conclusions with regards to the immune response elicited by oats in patients with CD. In the studies in which a response was observed, the data indicate that certain oat varieties may be immunogenic, but others are not. As further noted below, food product ingredient lists would state the presence of an oat-protein ingredient, and individuals who wish to avoid oats consumption for any reason would be able to identify the presence of an oat-derived ingredient.

Celiac Disease and Gluten Free Diets

Globulins are the major storage proteins in oats. Conversely, prolamins are the main storage protein in barley, wheat and rye. Common cereal prolamins include gluten (primarily in wheat) and zein (in maize). In wheat, barley and rye, gluten accounts for between 30-60% of the total protein. The small amount of prolamins present in oats are primarily avenins, which may make oats an option for those with gluten

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allergies (Oats and Health, 2014). Avenin accounts for 10-15% of the total protein in oats. The amino acid sequences believed to cause toxic responses in persons with CD are much less frequent in avenin than in gluten (Hoffenberg et al. 2000; Holm et al., 2006).

Historically, use of oats in GFDs has not been allowed. Evidence from more recent reports indicates that oats are safe for consumption by most individuals with celiac disease (Rashid et al., 2007). Health Canada (2007) critically reviewed the scientific literature and concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats that are uncontaminated with other cereal grains such as wheat, barley and rye. It is recognized that commercially available oats are variably contaminated with gluten-containing grains that can occur on the farms, during the growing cycle or during storage, cleaning, transportation or processing.

Historically, oat consumption by celiac disease patients was not widely recommended in the U.S. due to concerns of potential contamination of commercial oats (Kupper, 2005; American Celiac Society, 2014). According to the National Foundation for Celiac Awareness (NFCA, 2014), although oats do not contain gluten, a small percentage of persons with celiac disease react to pure, uncontaminated oats. Further, most mills that process oats also process grains that contain gluten, making cross contamination likely. However, up to 50 g /day of dry, gluten-free oats is now considered safe (NFCA, 2014).

Dickey and co-workers (2007) note that not every person with CD can tolerate pure oats. Some participants withdrew from oat challenge studies due to adverse gut symptoms. These symptoms were usually not associated with histological relapse, were temporary, and were not significantly more frequent than in groups on a GFD who were not consuming oats (Dickey, 2007).

The majority of studies suggest that oats can be tolerated by most CD patients. Hoffenberg et al. (2000) performed a study to assess whether oat consumption is safe in children who have been recently diagnosed with CD and are beginning a GFD. Ten children (6.8±4.0 years of age; 5 males, 5 females) completed the 6.6-month, self-controlled, open-label trial where they consumed commercial oat breakfast cereal product (24 g/day, 1.2 ±0.9 g/kg-day). At study completion, there was a significant decrease in the number of symptoms, small bowel biopsy score, anti-tissue transglutaminase IgA antibody titer and intra-epithelial lymphocyte count. The authors concluded that consumption of the oat cereal product for 6 months was safe for children with CD who were starting a GFD. However, studies were recommended to determine the long-term safety of oat cereal consumption for pediatric CD patients.

In a 2-year clinical trial, Holm and co-workers (2006) evaluated 32 children with CD to study the long-term safety of oats in the treatment of children with CD. Nine children recently diagnosed with CD consumed an oat-containing GFD; 23 children in remission were challenged with either oats or gluten. In the gluten challenge

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group, when small bowel histological relapse was evident, children were switched to a GFD including oats. After cessation of the trial, participants were allowed to freely consume oats; follow-up was up to 7 years. In the children who were in remission and consumed oats, no adverse effects on celiac serology or intestinal histology occurred during trial. In the gluten challenge group, however, relapses occurred after 3–12 months. During consumption of the oat-containing GFD, complete recovery occurred in all newly detected and relapsed patients. At the conclusion of the trial, all children remained in remission and 86% of the participants preferred to consume oats. The authors concluded that in most pediatric CD patients, long-term oat consumption did not result in immune activation or small bowel mucosal deterioration, and consumption was well-tolerated.

Sey et al. (2011) conducted a study whereby 15 adults (57±9 years, 2 males) with CD of ≥1 year duration were challenged with pure oats (350 g/wk) for 12 weeks. Duodenal histology scores were not significantly altered during oat challenge, and tissue transglutaminase remained negative in all participants. During oat consumption, no significant changes in symptom scores, albumin, ferritin, hemoglobin or weight occurred. There were no significant changes in mean pain, flatulence, diarrhea or abdominal distension scores. There was a single relapse, which was in a person who was noncompliant with a GFD. The authors concluded that this study supports the safety for CD patients of uncontaminated, pure oats manufactured under Canadian Celiac Association guidelines.

In CD patients, a rash, dermatitis herpetiformis, can occur when gluten is consumed. Reunala and co-workers (1998) conducted a study in 11 adults with CD to determine whether the participants could also tolerate oats. The volunteers included 5 men and 6 women, age 51 (range 30–67 years). Participants had dermatitis herpetiformis in remission, were on a GFD, and consumed oats at 50 g/day for 6 months. A separate control group of 11 volunteers with dermatitis herpetiformis in remission consumed a conventional GFD. Eight persons participating in the challenge with oats developed no symptoms, 2 experienced a transient rash, and 1 withdrew due to a mild but more persistent rash. A transient rash occurred in 3 of the controls. Densities of intraepithelial CD3 and α/β and γ/δ T cell receptor positive lymphocytes, crypt epithelial cell DR expression, and the villous architecture of small bowel remained unaltered; these changes are typically linked with the skin rash. IgA endomysial antibodies remained negative in all patients. The authors concluded that as oat toxicity on the gluten sensitive small bowel mucosa did not occur, and increased rashes were not observed in participants, dermatitis herpetiformis was not activated by eating oats.

Lundin et al. (2003) challenged 19 adults with CD who were on a GFD with oats (50 g/day) for 12 weeks. Before and after the oat challenge, gastroduodenoscopy and serological tests were performed. While oats were well tolerated by most participants, several experienced initial bloating and abdominal discomfort. One patient developed a rash and partial villous atrophy during the first challenge. The participant improved when oats were removed from the diet, but experienced

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dramatic dermatitis and subtotal villous atrophy during a second oats challenge. After the challenge, 5 patients showed positive levels of interferon c mRNA. The authors concluded that, due to the development of villous atrophy and dermatitis in one participant, concerns remain regarding the safety of oats for persons with CD.

In her review of studies evaluating the safety of oats in individuals with CD, Richman (2012) states that earlier studies are difficult to evaluate, as they were conducted using different methodologies and it is unknown whether oat samples used in the studies were contaminated with gluten from other grains. Many studies do not specify the strain of oat used. Recent research suggests that perhaps only certain oats strains cause a toxic response in CD patients. While proteins in oats are similar to those in barley, wheat and rye, oat prolamins (avenin) have substantially lower levels of proline, one of the triggers for intestinal damage in persons with CD. The author concluded that research suggests that the risk from consuming oats may be less harmful than first thought, but it may vary according to the oat strain. Handling this issue in clinical practice remains controversial.

Pulido et al. (2009) similarly reviewed the literature regarding introducing dietary oats to persons with CD. The studies at the time had limited numbers of volunteers in studies, lacked sufficient data on long-term consumption, and insufficient reporting regarding reasons for withdrawals from the studies.

Concerns remain about potential contamination of commercially available oat products by rye, wheat and barley. While pure oats have been confirmed as having undetectable levels of barley, wheat and rye prolamins, many commercial oat products had unacceptable levels of contamination from other grains. In the UK, 41-59% of oat foods exceeded the limit of 200 ppm, and 12-26% were in the 20 - 200 ppm range (Dickey, 2007). Analysis of oats from a Canadian oat supply showed that approximately 88% of the 133 oat samples tested were contaminated with other grains >20 mg/kg, and there were no differences noted between the oat types (Koerner et al., 2011).

In summary, the majority of data indicate that oat consumption is safe for persons with CD as part of a GFD. However, some studies indicate that some individuals may experience adverse effects, and these may be oat strain-specific.

C. Safety Data Summary

There is common knowledge of a long history of human consumption of oats. Oats have been cultivated around the world for more than 2000 years. Humans have consumed oats and proteins from oats and other grains for centuries, along with proteins from many food sources such as meats, fruits, vegetables, nuts and seeds. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (FDA, 2012). Numerous food products containing oats are currently marketed in the U.S. and around the world.

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Oat consumption has various health benefits, such as a decreased risk of coronary heart disease and lowering of cholesterol (FDA, 1997; Davy et al., 2002; Ripsin et al. 1992). Protein is necessary for a healthy diet; the Centers for Disease Control and Prevention (CDC, 2014) recommends that adult women and men consume 46 and 56 g protein per day, respectively. Further, several protein isolates have received GRAS designation, including wheat protein, canola protein and potato protein (FDA, 1999, 2011 and 2013, respectively).

WHO (2002) reports the digestibility of protein in oatmeal as 86% and that in cereal oats as 72%. Therefore, dietary oat proteins are expected to be almost completely digested and absorbed from the upper gastrointestinal (GI) tract by the time they reach the terminal ileum. Oat proteins would be broken down by gastric juices in the stomach and proteases in the small intestine and efficiently absorbed as small peptides or amino acids. Sherman and co-workers (1919) demonstrated that proteins present in oatmeal were very efficiently utilized in the maintenance metabolism of healthy adult volunteers. This indicated that oat proteins were effectively broken down into their constituent amino acids and small peptides that were typical of all food proteins. Therefore, the known metabolism of oat proteins is a strong indicator of the safety of oat protein isolate.

Oat protein isolates have been shown to have antioxidant activity. Following proteolytic hydrolysis of food proteins, various physiological activities have been found including radical scavenging, antihypertensive, immunomodulatory, antimicrobial, mineral binding and opioide activities (Tsopmo et al., 2010). Oat consumption decreases the risk of coronary heart disease and lowers LDL cholesterol (FDA, 1997; Davy et al., 2002; WHO, 2002). Oats are considered a satisfactory source of protein, fat and energy for infants and young children (Graham et al., 1990). Dietary protein has been shown to decrease blood pressure and may decrease the risk of cardiovascular disease (WHO, 2002).

Studies of oats, oat protein, and other protein isolate sources in humans and/or animals have demonstrated its beneficial effects as well as safety. Safety studies of other protein sources (e.g., canola protein isolates) with similar amino acid profiles to oat protein have also demonstrated a lack of toxicity at high levels of consumption.

Some studies of patients with celiac disease (CD) indicate more frequent GI symptoms while consuming an oat-containing gluten-free diet (GFD) than consumption of a traditional GFD. Such symptoms are generally mild, and the appearance of flatulence and abdominal distension has previously been attributed to the increased intake of fiber from oat products (Holm et al., 2006; Pulido, 2009). In women with breast cancer, high dietary protein intakes improved survival rates (WHO, 2002).

Extremely high protein consumption may be toxic. While it has been recommended that adults not consume more than two-fold the reference dietary amount of 1.5 g protein/kg, physically active individuals on normal diets easily exceed this amount,

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and persons involved in body-building consume much higher levels of protein (WHO, 2002). Dietary protein can influence kidney function, and high protein diets may be linked with increased incidence of kidney stones in susceptible individuals (Martin et al., 2005; WHO, 2002).

Various *in vivo* and *in vitro* studies show different results relative to whether oats can elicit an immune response in patients with CD. In studies which showed a response, the data indicated that certain oat varieties may be immunogenic, but others are not.

Children with atopic dermatitis and farmers with allergies to grain dust may experience allergic reactions to oat proteins. These proteins can act as skin and respiratory allergens (Boussault et al., 2007; FDA, 2012).

There are conflicting data indicating whether CD patients can tolerate oats. Allergy manifestation resulting from consumption of oats and oat products has been the subject of debate. It has been alleged that oats may cause adverse effects in individuals with celiac disease. As a result, use of oats in a GFD was not allowed. However, recent evidence indicates that oats are safe for consumption by most individuals with celiac disease (Rashid et al., 2007). Health Canada (2007) critically reviewed the scientific literature and concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats that are uncontaminated with other cereal grains such as wheat, barley and rye. In fact, pure oats may be beneficial to persons with celiac disease, as its palatability may increase patients' compliance with a GFD (Health Canada, 2007).

It should be emphatically stated that the recommended ingredient labeling for PrOatein® is "oat protein." Thus, food product ingredient lists would state the presence of an oat ingredient and individuals who wish to avoid oats consumption for any reason would be able to identify the presence of an oat-derived ingredient.

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6.0 Basis for the GRAS Determination

A. Introduction

The regulatory framework for determining whether a substance can be considered generally recognized as safe (GRAS) in accordance with section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of an oat-derived protein for use in food for human consumption is GRAS based upon scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

B. Safety Determination

The subject of this GRAS determination is the use of oat-derived protein as an alternative source of dietary protein for addition to processed foods. There is a long history of the safe use of oats and products derived from oats such as oat β-glucan and oat protein concentrates. Furthermore, other natural sources of protein concentrates, such as canola, potato, and wheat, have been safely consumed for years. Tate & Lyle currently markets oat protein (PrOatein®) outside of the U.S. However, oat protein products are currently marketed in the U.S. (e.g., 55Oat Protein, Oat Tech, Inc.). While there is a noted lack of published safety studies on oat protein concentrates, the safety section describes human safety studies of oats and oat protein as well as human and animal studies of other GRAS-notified protein sources currently added to processed foods.

The focus of this GRAS determination is a comprehensive assessment of the safety of an oat-derived protein for an identical use to that of other current grain-based protein sources such as soy, canola, pea, lentils, wheat, rice, and whey. Similarly, the nutritionally use is as a source of protein for enrichment of processed foods. The IOM recommends that adults consume a minimum of 0.8 grams of protein per kilogram of body weight. IOM also set a wide range for acceptable protein intake, ranging from 10 - 35% of calories each day. In the U.S., the recommended daily allowance of protein is 46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age.

As described in GRN No. 386 for canola protein isolate and hydrolyzed canola protein isolate, the typical uses of protein for enrichment of foods includes in bakery products, snack foods, nutritional beverages such as high protein drinks and milkshakes, instant powdered nutritional beverages, vegetarian food products and meat analogues, dairy products, and meal replacements/nutritional bars. The proposed use concentrations and variety of food uses combined with the large average daily consumption of the described foods resulted in the calculated daily intake of the protein additives being a substantial fraction of the RDA (46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age), and even exceeded it at the 90th percentile consumption. This was also the case for GRN No. 327 (cruciferin-rich canola/rapeseed protein isolate and napin-rich protein canola/rapeseed protein isolate). As Tate & Lyle's proposed oat protein is only intended to be an alternative source of protein for current uses in food, a similar estimate of intake would be expected if oat protein was the only source of protein used in processed foods. As GRAS notifications for other protein sources and isolates have previously noted, we do not realistically expect that the actual consumption of foods containing oat protein would result in daily protein consumption being any greater than the DRV or RDA for protein. It is reasonable to expect that most of the population's intake of protein is, and will remain, in the form of unprocessed foods including meat, poultry, fish, and legumes. As the proposed oat protein product is only one of many protein sources for use in processed foods, only the inherent conservatism of intake calculations such as those described in the aforementioned GRNs suggest the possibility of exceeding the RDA at the 90th percentile (FDA, 2011; FDA, 2010).

In summary, the proposed uses of PrOatein® will not result in an increase in the overall consumption of protein, but simply provide an alternative source of well-characterized protein from oats for use in food.

Oat consumption has various health benefits, such as a decreased risk of coronary heart disease and lowering of cholesterol and protein is necessary for a healthy diet. While there exists a lack of published preclinical safety studies on oat protein, products containing oats and other sources of grain-based protein concentrates have been employed in numerous clinical trials. Other than mild, transient gastrointestinal (GI) effects such as flatulence and abdominal discomfort, no significant adverse effects have been reported.

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Some studies of patients with celiac disease indicate more frequent GI symptoms while consuming an oat-containing gluten-free diet (GFD) than during consumption of a traditional GFD. Such reported symptoms were generally mild, and the appearance of flatulence and abdominal distension has previously been attributed to the increased intake of fiber from oat products. The majority of data indicate that oat consumption is safe for persons with CD as part of a GFD. However, some studies indicate that a few individuals may experience adverse effects, and these may be oat strain-specific. It should be noted that the recommended ingredient labeling for PrOatein is "oat protein." Thus, food product ingredient lists containing PrOatein would state the presence of an oat ingredient as "oat protein" and individuals who wish to avoid oats consumption for any reason would be able to identify the presence of an oat-derived ingredient.

C. General Recognition of the Safety of Oat Protein

The intended use of oat protein has been determined to be safe through scientific procedures as set forth in 21 CFR§170.3(b), thus satisfying the so-called "technical" element of the GRAS determination and is based on the following:

- PrOatein® Oat Protein is manufactured consistent with current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110). The raw materials used in the manufacturing process are food grade and/or approved for use as processing aids in food. No chemical processing aids are employed in the manufacturing process. The oat protein product containing approximately 52-56% protein has been characterized and meets appropriate food grade specifications found.

- There is common knowledge of a long history of human consumption of oats. Numerous food products containing oats are currently marketed in the U.S. and around world and oat protein has become a desirable ingredient for addition to a variety of food products as a source of dietary protein.

- The intended uses of PrOatein® (oat-derived protein) will provide an alternative to other dietary sources of protein as part of the total dietary protein intakes among the U.S. population.

- Epidemiological studies and clinical trials have consistently revealed the cardiovascular benefits of oat consumption from its hypocholesterolemic effects. In 1997, the FDA approved a health claim for the association between oat consumption and coronary heart disease (Katz, 2001; FDA, 1997).

- To date, FDA has reviewed extensive published information and data as part of GRAS notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no questions letters" (e.g., GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein

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isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN No. 327 (cruciferin-rich canola/rapeseed protein isolate and napin-rich canola/rapeseed protein isolate); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates)). Studies in both animal and humans have been evaluated, including a 90-day rat feeding study with a canola protein isolate (min. 90% protein) very similar in amino acid profile to the proposed oat protein product. No toxicity was evident at concentrations up to 20% in the diet. No recent human or animal studies raising any new safety concerns concerning protein or protein isolates and their addition to processed foods have appeared in the published literature subsequent to these evaluations.

- The publicly available scientific literature on oats, oat protein, and other plant-derived protein products and their subsequent utilization as a source of amino acids is sufficient to support the safety and GRAS status of the proposed oat protein product.

Since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of oat protein that is the subject of this assessment has been made through the deliberations of an Expert Panel convened by Tate & Lyle and comprised of Michael Carakostas, DVM, Ph.D., Carol A. Knight, Ph.D., and Stanley M. Tarka, Jr., Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that oat-derived protein, produced consistent with Good Manufacturing Practice and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that these uses of oat protein are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Tate & Lyle's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Tate & Lyle has concluded that oat protein is GRAS under the intended conditions of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Tate & Lyle is not aware of any information that would be inconsistent with a finding that the proposed use of oat protein in food for human consumption meeting appropriate specifications and used according to Good Manufacturing Practice, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

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7.0 References

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8.0 Appendices

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Appendix A. Certificates of Analysis – Characterization

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

SWEDAC ACKREDITERING 1977 ISO/IEC 17025

Eurofins Food & Agro Testing Sweden AB
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SE-53119 Lidköping
www.eurofins.se

Tlf: +46 10 490 8310

Tate&Lyle Sweden AB
Ingbritt Johansson
Älvåsvägen 1
610 20 KIMSTAD

AR-14-LW-018536-01

EUSELI-00064732

Kundnummer: LW9901581

Analysrapport

Provnummer:	**525-2014-04280071**
Provmärkning:	Havre B.04 04 14 oat
Provet ankom:	2014-04-28
Analysrapport klar:	2014-05-08
Analyserna påbörjades:	2014-04-28

	Analys	Resultat	MRL	Enhet	Mäto.	Metod/ref	Lab
LW00V	Råfett enl. Soxtec FAT	**3.83**		g/100 g	± 10%		*EUSELI*
SL403	Bly Pb	**< 0.020**		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL404	Kadmium Cd	**0.015**		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL402	Arsenik As	**< 0.050**		mg/kg	± 35%	NMKL No 161 1998 mod	*EUSELI2*
SL399	Kvicksilver Hg	**< 0.020**		mg/kg	± 30%	SS-EN 16277:2012	*EUSELI2*
JJ006	Aflatoxin B1	**<0.1**		µg/kg		EN 14123, mod.	*EUHAWE3*
JJ006	Aflatoxin B2	**<0.1**		µg/kg		EN 14123, mod.	*EUHAWE3*
JJ006	Aflatoxin G1	**<0.1**		µg/kg		EN 14123, mod.	*EUHAWE3*
JJ006	Aflatoxin G2	**<0.1**		µg/kg		EN 14123, mod.	*EUHAWE3*
LW020	Ochratoxin	**<0.10**		µg/kg	± 30%	NMKL 143	*EUSELI*
LW03Z	Deoxynivalenol (DON)	**220**		µg/kg	± 25%	In house metod (210)	*EUSELI*
LW03X	HT-2 Toxin	**14**		µg/kg	± 30%	In house metod (210)	*EUSELI*
LW03Y	T-2 Toxin	**<10**		µg/kg	± 30%	In house metod (210)	*EUSELI*
LW041	Zearalenone (ZON)	**<10**		µg/kg	± 35%	In house metod (210)	*EUSELI*
MJ011	Stärkelse inkl. enkla sockerarter (starch + sugar)	**42**		g/100 g		Intern metod	*EUNOTR2*

LP130: Inga pesticidrester påvisade (SLV K1-f4-m016.1). Not detected

Per-Olov Södergren, Rapportansvarig

Denna rapport är elektroniskt signerad.

Mäto: Mätosäkerhet

Förklaringar AR-004 v21

* : Ej ackrediterad analys

Utförande laboratorium om inte annat anges: Eurofins Food & Agro (Lidköping)

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Lantmännen

27/02/2015 Malmö

Lantmännen ek för

205 03 Malmö

Letter of Declaration

We Lantmännen as supplier of oats to Tate&Lyle Sweden AB hereby certify all oats delivered is in accordance with regulation EU 1881.2006 for unprocessed cereals – setting maximum levels for certain contaminants in foodstuff.

Regards

Lantmännen ek.för
Malmö

Göran Karlsson
Product Manager

Lantmännen ek för

Lantmännen

Visiting address
St Göransgatan 160 A
104 92 Stockholm
Box 30192
104 25 Stockholm

Tel 010-556 00 00
E-mail info@lantmannen.com
www.lantmannen.com

Company ID 769605-2856 Registered office
VAT no SE769605285601 Stockholm

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TATE & LYLE

CERTIFICATE OF ANALYSIS

Product: 200 200 prOATein™

Batch no: 1332

Prod. Date: 06-08-2013

Exp.Date: 05-08-2014

Chemical analysis	Result	Unit	Method
Average value			
Protein (N*6,25)	52,9	%	IDF 20B Kjeldahl
Dry matter	95,8	%	IDF Standard method
Bacteriological analysis			
Total plate count	<1000	cfu/g	NMKL Nr 86, 1999
Enterobacteriaceae	<10	cfu/g	NMKL Nr 144, 2000
Staph.aureus	<20	cfu/g	NMKL Nr 66 3 edt.1999 modified
Yeast	<20	cfu/g	IDF 94B modified
Moulds	<20	cfu/g	IDF 94B modified
Salmonella	Neg/25g.		NMKL Nr 71 5 edt. Modified
E.coli cfu/g	Negative		NMKL nr 125, 3edt.1996

Tate&Lyle Sweden AB
28-09-2014

Ingbritt Johansson
Quality Manager

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

Eurofins Food & Agro Testing Sweden AB
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610 20 KIMSTAD

AR-13-LW-031352-01

EUSELI-00047711

Kundnummer LW9901581

Analysrapport

Provnummer: **525-2013-08190021**
Provmärkning: prOAtein Oatprotein Batch 1332
Provet ankom: 2013-08-19
Analyserna påbörjades: 2013-08-19

	Analys	Resultat	MRL	Enhet	Mätn.	Metodref	Lab
SL408	Kalcium Ca	1400		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL411	Magnesium Mg	2300		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL413	Järn Fe	48		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL410	Kalium K	3200		mg/kg	± 15%	NMKL No 139 1991 mod	EUSELI2
SL409	Fosfor P	8200		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL418	Bor B	< 5.0		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL415	Zink Zn	61		mg/kg	± 10%	NMKL No 139 1991 mod	EUSELI2
SL400	Jod I	<0.10		mg/kg	± 35%	SS-EN 15111:2007	EUSELI2
SL403	Bly Pb	< 0.020		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL404	Kadmium Cd	0.052		mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL402	Arsenik As	< 0.050		mg/kg	± 35%	NMKL No 161 1998 mod	EUSELI2
SL399	Kvicksilver Hg	< 0.020		mg/kg	± 30%	SS-EN 16277 2012	EUSELI2
A0428	Aflatoxin B1	<0.01		µg/kg		EN 15851, mod	EUHAWE3
A0428	Aflatoxin B2	<0.01		µg/kg		EN 15851, mod	EUHAWE3
A0428	Aflatoxin G1	<0.01		µg/kg		EN 15851, mod	EUHAWE3
A0428	Aflatoxin G2	<0.01		µg/kg		EN 15851, mod	EUHAWE3
LW020	Ochratoxin	0.24		µg/kg	± 30%	NMKL 143	EUSELI
LW03Z	Deoxynivalenol (DON)	25		µg/kg	± 25%	In house metod (210)	EUSELI
LW041	Zearalenone (ZON)	<10		µg/kg	± 25%	In house metod (210)	EUSELI
JJ0BC	Fumonisin B1 (FB1)	<20		µg/kg		Internal method	EUHAWE3
JJ0BG	Fumonisin B2 (FB2)	<20		µg/kg		Internal method	EUHAWE3

Mätn: Mätosäkerhet

Förklaringar
* Ej ackrediterad analys

AR 004 v21

Utförande laboratorium om inte annat anges: Eurofins Food & Agro (Lidköping)

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eurofins

AR-13-LW-031352-01

EUSELI-00047711

LP130	OMST	0.024	mg/kg		SLV K1-f4-m016.1	EUSELI
SLB89	Svavel S	7300	mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2

LP130: För övrigt inga pesticidrester påvisade (SLV K1-f4-m016.1)

Rapportkommentar:
Eventuella pesticidrester har matrosäkerhet i intervallet 30-60%

Per-Olov Södergren, Rapportansvarig

Utförande Laboratorium

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUSELI	Eurofins Food & Agro Testing Sweden AB, Lidköping
EUSELI2	Eurofins Environment Sweden, Lidköping

Mato: Matosäkerhet

Förklaringar AR-004 v21

+ = Ej ackrediterad analys

Utförande laboratorium om inte annat anges: Eurofins Food & Agro (Lidköping)

Denna rapport får endast återges i sin helhet om inte utförande laboratorium i förväg skriftligen godkänt annat. Resultaten relaterar endast till det insända provet

*Analysis of crude protein was not conducted by Eurofins on batch number 1332.

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TATE & LYLE

CERTIFICATE OF ANALYSIS

Product: 200 200 prOATein™

Batch no: 1411

Prod. Date: 14-03-2014

Exp.Date: 13-03-2015

Chemical analysis	Result	Unit	Method
Average value			
Protein (N*6,25)	55	%	IDF 20B Kjeldahl
Dry matter	96,7	%	IDF Standard method
Bacteriological analysis			
Total plate count	<1000	cfu/g	NMKL Nr 86, 1999
Enterobacteriaceae	<10	cfu/g	NMKL Nr 144, 2000
Staph.aureus	<20	cfu/g	NMKL Nr 66 3 edt.1999 modified
Yeast	<20	cfu/g	IDF 94B modified
Moulds	<60	cfu/g	IDF 94B modified
Salmonella	Neg/25g.		NMKL Nr 71 5 edt. Modified
E.coli cfu/g	Negative		NMKL nr 125, 3edt.1996

Tate&Lyle Sweden AB
28-09-2014

Ingbritt Johansson
Quality Manager

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

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Tate&Lyle Sweden AB
Ingbritt Johansson
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610 20 KIMSTAD

AR-14-LW-050173-01

EUSELI-00080887

Client code:: LW9901581

ANALYTICAL REPORT

Sample code:	525-2014-11200147
Client Sample:	PrOatein 1411
Received:	2014-11-20
Report finished:	2014-12-03
Start of analysis	2014-11-20 13:27:18

	Analysis	Result: Unit	Uncert.	Method	Lab
LP021	Crude Protein Kjeldahl (Nx6.25)	**53.1** g/100 g	± 10%	NMKL 6	*EUSELI*
LP06X	Fat acc. SBR mod.	**17.4** g/100 g	± 10%	SLV VF 1980	*EUSELI*
SL412	Sodium (Na)	**95** mg/kg	± 25%	NMKL No 139 1991 mod	*EUSELI2*
SL408	Calcium (Ca)	**1200** mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL411	Magnesium (Mg)	**1700** mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL413	Iron (Fe)	**42** mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL410	Potassium (K)	**2500** mg/kg	± 15%	NMKL No 139 1991 mod	*EUSELI2*
SL409	Phosphorus (P)	**6900** mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL418	* Boron (B)	**<5.0** mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL415	Zinc (Zn)	**66** mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
JJ006	Aflatoxin B1	**<0.1** µg/kg		internal method based on EN 14123	*EUHAWE3*
JJ006	Aflatoxin B2	**<0.1** µg/kg		internal method based on EN 14123	*EUHAWE3*
JJ006	Aflatoxin G1	**<0.1** µg/kg		internal method based on EN 14123	*EUHAWE3*
JJ006	Aflatoxin G2	**<0.1** µg/kg		internal method based on EN 14123	*EUHAWE3*
LW020	Ochratoxin	**0.17** µg/kg	± 30%	NMKL 143	*EUSELI*
LW03Z	Deoxynivalenol (Vomitoxin)	**18** µg/kg	± 25%	In house method (210)	*EUSELI*
LW041	Zearalenone (ZON)	**<10** µg/kg	± 35%	In house method (210)	*EUSELI*
JJ0BG	Fumonisin B1 (FB1)	**<20** µg/kg		Internal method	*EUHAWE3*
JJ0BG	Fumonisin B2 (FB2)	**<20** µg/kg		Internal method	*EUHAWE3*
J1071	Iodine	**<0.2** mg/kg		Sandell-Kolthoff	*EUHAWE3*
MJ011	Starch and sugar	**14** g/100 g		Internal method	*EUNOTR2*
SLB89	Sulphur total (S)	**6900** mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description
* Not accredited

AR-003 v78
1 67 130516

Uncert: Measurement uncertainty

Measurement uncertainty, unless otherwise stated, are reported as expanded uncertainty with coverage factor 2. Exceptions related to analysis performed outside Sweden may occur. Additional information can be obtained upon request.

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUNOTR2	Eurofins Food & Agro Testing Norway AS (Skansen), Trondheim
EUSELI	Eurofins Food & Agro Testing Sweden AB, Lidköping
EUSELI2	Eurofins Environment Sweden, Lidköping

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description:
* Not accredited

AR-003 v78
1.67 130516

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AR-14-LW-043082-01

EUSELI-00076399

Kundnummer: LW9901581

Analysrapport

Provnummer:	525-2014-10010201
Provmärkning:	PrOatein Batch 1411
Provet ankom:	2014-10-01
Analysrapport klar:	2014-10-13
Analyserna påbörjades:	2014-10-01 14:36:54

	Analys	Resultat	Enhet	Mäto.	Metod/ref	Lab
SL403	Bly Pb	<0.020	mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL404	Kadmium Cd	0.11	mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL402	Arsenik As	<0.050	mg/kg	± 35%	NMKL No 161 1998 mod	*EUSELI2*
SL399	Kvicksilver Hg	< 0.020	mg/kg	± 30%	SS-EN 16277:2012	*EUSELI2*

Per-Olov Södergren, Rapportansvarig

Denna rapport är elektroniskt signerad.

Utförande Laboratorium

EUSELI2 Eurofins Environment Sweden, Lidköping

Laboratoriet/laboratoriema är ackrediterade av respektive lands ackrediteringsorgan. Ej ackrediterade analyser är markerade med *

Förklaringar
* Ej ackrediterad analys

AR-003 v78
1.67 130516

Mäto: Mätosäkerhet

Mätosäkerheten, om inget annat anges, redovisas som utvidgad mätosäkerhet med täckningsfaktor 2. Undantag relaterat till analyser utförda utanför Sverige kan förekomma. Ytterligare upplysningar kan lämnas på begäran. Upplysning om mätosäkerhet och detektionsnivåer för mikrobiologiska analyser lämnas på begäran.

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

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610 20 KIMSTAD

AR-14-LW-054885-01

EUSELI-00083017

Client code:: LW9901581

ANALYTICAL REPORT

Sample code:	**525-2014-12120146**
Client Sample:	Proatein 1411
Received:	2014-12-12
Report finished:	2014-12-17
Start of analysis	2014-12-12

Analysis	Result:	MRL	Unit	Uncert.	Method	Lab
LP130: No pesticide residue detected (SLV K1-f4-m016.1).						

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUSELI Eurofins Food & Agro Testing Sweden AB, Lidköping

Uncert: Measurement uncertainty

Symbol description:
* : (Not part of the accreditation)

AR-004 v22

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

TATE & LYLE

CERTIFICATE OF ANALYSIS

Product: 200 200 prOATein™

Batch no: 1413

Prod. Date: 31-03-2014

Exp.Date: 30-03-2015

Chemical analysis	Result	Unit	Method
Average value			
Protein (N*6,25)	56	%	IDF 20B Kjeldahl
Dry matter	95,5	%	IDF Standard method
Bacteriological analysis			
Total plate count	<1000	cfu/g	NMKL Nr 86, 1999
Enterobacteriaceae	<10	cfu/g	NMKL Nr 144, 2000
Staph.aureus	<20	cfu/g	NMKL Nr 66 3 edt.1999 modified
Yeast	<20	cfu/g	IDF 94B modified
Moulds	<20	cfu/g	IDF 94B modified
Salmonella	Neg/25g.		NMKL Nr 71 5 edt. Modified
E.coli cfu/g	Negative		NMKL nr 125, 3edt.1996

Tate&Lyle Sweden AB
28-09-2014

Ingbritt Johansson
Quality Manager

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

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AR-14-LW-022881-01

EUSELI-00064747

Client code:: LW9901581

ANALYTICAL REPORT

Sample code:	**525-2014-04280096**
Client Sample:	PrOatein 1413
Received:	2014-04-28
Report finished:	2014-05-28
Start of analysis	2014-04-28

		Analysis	Result:	MRL	Unit	Uncert.	Method	Lab
LP021		Crude Protein Kjeldahl (Nx6,25)	55.2		g/100 g	± 10%	NMKL 6	*EUSELI*
LW00V		Fat acc. Soxtec	17.2		g/100 g	± 10%		*EUSELI*
SL412		Sodium (Na)	120		mg/kg	± 25%	NMKL No 139 1991 mod	*EUSELI2*
SL408		Calcium (Ca)	1200		mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL411		Magnesium (Mg)	1600		mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL413		Iron (Fe)	38		mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL410		Potassium (K)	2600		mg/kg	± 15%	NMKL No 139 1991 mod	*EUSELI2*
SL409		Phosphorus (P)	6800		mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL418	*	Boron (B)	< 5.0		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL415		Zinc (Zn)	59		mg/kg	± 10%	NMKL No 139 1991 mod	*EUSELI2*
SL400	*	Iodine (I)	<0.10		mg/kg	± 35%	EN 15111:2007	*EUSELI2*
SL403		Lead (Pb)	< 0.020		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL404		Cadmium (Cd)	0.059		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL402		Arsenic (As)	< 0.050		mg/kg	± 35%	NMKL No 161 1998 mod	*EUSELI2*
SL399		Mercury (Hg)	< 0.020		mg/kg	± 30%	EN 16277:2012	*EUSELI2*
JJ006		Aflatoxin B1	<0.1		µg/kg		internal method based on EN 14123	*EUHAWE3*
JJ006		Aflatoxin B2	<0.1		µg/kg		internal method based on EN 14123	*EUHAWE3*
JJ006		Aflatoxin G1	<0.1		µg/kg		internal method based on EN 14123	*EUHAWE3*
JJ006		Aflatoxin G2	<0.1		µg/kg		internal method based on EN 14123	*EUHAWE3*

Uncert: Measurement uncertainty

Symbol description:

AR-004 v21

* : (Not part of the accreditation)

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

LW020	Ochratoxin	<0.10	µg/kg	± 30%	NMKL 143	*EUSELI*
LW03Z	Deoxynivalenol (Vomitoxin)	<10	µg/kg	± 25%	In house method (210)	*EUSELI*
LW041	Zearalenone (ZON)	<10	µg/kg	± 35%	In house method (210)	*EUSELI*
JJ0BG	Fumonisin B1 (FB1)	<20	µg/kg		Internal method	*EUHAWE3*
JJ0BG	Fumonisin B2 (FB2)	<20	µg/kg		Internal method	*EUHAWE3*
LP130	Diphenylamine	0.014	mg/kg		SLV K1-f4-m016.1	*EUSELI*
MJ011	Starch and sugar	13	g/100 g		Internal method	*EUNOTR2*
SLB89	Sulphur total (S)	8000	mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*

LP130: No other pesticide residues detected (SLV K1-f4-m016.1).

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUNOTR2	Eurofins Food & Agro Testing Norway AS (Skansen), Trondheim
EUSELI	Eurofins Food & Agro Testing Sweden AB, Lidköping
EUSELI2	Eurofins Environment Sweden, Lidköping

Uncert. Measurement uncertainty

Symbol description: AR-004 v21

* : (Not part of the accreditation)

Performing laboratory if nothing else is stated: Eurofins Food & Agro (Lidköping)

Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

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Tate&Lyle Sweden AB
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AR-13-LW-032664-01

EUSELI-00048231

Client code:: LW9901581

ANALYTICAL REPORT

Sample code:	525-2013-08270167
Client Sample:	prOATein oatprotein Batch1334 GI
Received:	2013-08-27
Report finished:	2013-09-09
Start of analysis	2013-08-28 08:43:20

	Analysis	Result	Unit	Uncert.	Method	Lab
LP021	Crude Protein Kjeldahl (Nx6,25)	50.8	g/100 g	± 10%	NMKL 6	*EUSELI*
LP00W	Alanine	22.3	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Arginine	36.0	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Aspartic acid (Total)	38.6	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Cystine	10.0	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Phenylalanine	29.3	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Glutamic Acid	115.4	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Glycine	21.4	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Histidine	11.2	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Hydroxyprolin	<0.1	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Isoleucine	23.5	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Leucine	40.9	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Lysine	17.4	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Methionine	9.1	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Ornithine	0.2	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Proline	27.2	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Serine	20.7	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Threonine	15.3	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Tyrosine	19.7	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Valine	30.9	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP00W	Sum of amino-acids	489.1	g/kg		ISO 13903:2005	*EUSELI*
LP00W	Ammonia (NH3)	14.3	g/kg	± 8%	ISO 13903:2005	*EUSELI*
LP056	C 6:0 (Caproic acid)	<0.1	% of fatty acids	± 20%	GC-FID	*EUSELI*

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *

Symbol description:
* Not accredited

AR-003 v77
1.67 130516

Uncert: Measurement uncertainty

Measurement uncertainty, unless otherwise stated, are reported as expanded uncertainty with coverage factor 2. Exceptions related to analysis performed outside Sweden may occur. Additional information can be obtained upon request.

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LP056	C 8:0 (Caprylic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 10:0 (Capric acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 12:0 (Lauric acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 14:0 (Myristic acid)	0.2 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 14:1 (Myristoleic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 15:0 (Pentadecanic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 15:1 n-5	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 16:0 (Palmitic acid)	16.2 % of fatty acids	± 10%	GC-FID	EUSELI
LP056	C 16:1 (Palmitoleic acid)	0.2 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 17:0 (Margaric acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 17:1 n-7 (Heptadecenoic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 18:0 (Stearic acid)	1.5 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 18:1 n-9 (Oleic acid)	35.7 % of fatty acids	± 10%	GC-FID	EUSELI
LP056	C 18:2 n-6 (Linoleic acid)	42.2 % of fatty acids	± 10%	GC-FID	EUSELI
LP056	C 18:3 n-3 (α-Linolenic acid)	2.0 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 18:3 n-6 (γ-Linolenic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 18:4 n-3	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:0 (Arachidic acid)	0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:1 n-9 (Gadoleic acid)	1.0 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:2 n-6	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:3 n-6	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:3 n-3	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:4 n-6 (Aracidonic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:4 n-3	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 20:5 n-3 (EPA)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 22:0 (Behenic acid)	0.3 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 22:1	0.4 % of fatty acids	± 20%	GC-FID	EUSELI
LP056	C 22:2 n-6 (Docosadienoic acid)	<0.1 % of fatty acids	± 20%	GC-FID	EUSELI

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Symbol description:
* Not accredited

AR-003 v77
1.67 130516

Uncert. Measurement uncertainty

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LP056	C 22:4 n-6	<0.1 % of fatty acids	± 20%	GC-FID	*EUSELI*
LP056	C 22:5 n-6	<0.1 % of fatty acids	± 20%	GC-FID	*EUSELI*
LP056	C 22:5 n-3 (Docosapentaenoic acid)	<0.1 % of fatty acids	± 20%	GC-FID	*EUSELI*
LP056	C 22:6 n-3 (DHA)	<0.1 % of fatty acids	± 20%	GC-FID	*EUSELI*
LP056	C 24:0 (Lignoceric acid)	<0.1 % of fatty acids	± 20%	GC-FID	*EUSELI*
LP056	C 24:1 n-9 (Tetracosenoic acid)	<0.1 % of fatty acids	± 20%	GC-FID	*EUSELI*
LP056	Saturated fatty acids	18.3 % of fatty acids		GC-FID	*EUSELI*
LP056	mono-unsaturated fatty acids total	37.3 % of fatty acids		GC-FID	*EUSELI*
LP056	poly-unsaturated fatty acids total	44.2 % of fatty acids		GC-FID	*EUSELI*
LP056	Total Fatty Acids	99.8 % of fatty acids		GC-FID	*EUSELI*
LP056	Unidentified Compounds	0.2 % of fatty acids		GC-FID	*EUSELI*
LP056	Fatty Acids, Sum Of Omega 6 Calc.	42.2 % of fatty acids		GC-FID	*EUSELI*
LP056	Fatty Acids, Sum Of Omega 3 Calc.	2.0 % of fatty acids		GC-FID	*EUSELI*
LP056	Fatty Acids, Omega6/Omega3 Ratio	21.10		GC-FID	*EUSELI*

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUSELI Eurofins Food & Agro Testing Sweden AB, Lidköping

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description:
* Not accredited

AR-003 v77
1.67 130516

Uncert: Measurement uncertainty

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Appendix B. Technical Product Data Sheet

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TATE & LYLE

proatein® Oat Protein

PRODUCT DATA SHEET: **PrOatein® Oat Protein**

Product Description: PrOatein® Oat Protein from Tate & Lyle Oat Ingredients is a natural protein concentrate, prepared from oat bran and rich in oat protein. It also contains oat oil and oat maltodextrins, both of which occur naturally in the oat. PrOatein® is produced without chemicals addition or use of solvents, and contains no additives or preservatives.

Appearance: fine, beige coloured powder
Odour: characteristic of oatmeal
Origin: 100% Swedish oat, non-GMO

Label declaration recommendation: Oat protein

Supply specification	**Value**	
Protein (N · 6,25, on dry matter)	> 50%	Typical 52-56%
Dry Matter	> 94%	

Microbiological data	**Value**	**Method**
Total plate count 30° cfu/g	<10 000	NMKL Nr 86, 1999
Enterobacteriaceae cfu/g	<10	NMKL Nr 144, 2000
S. aureus cfu/g	<20	NMKL Nr 66, 3 edt. 1999 modified
Yeasts	<100	IDF 94B: 1990 modified
Moulds	<100	IDF 94B: 1990 modified
Salmonella	negative / 25g	NMKL nr 71, 5 edt. modified
E. coli cfu/g	negative	NMKL nr 125 3 edt. 1996

Nutritional Data (Values per 100g PrOatein®, expressed on dry matter)

Energy	445 kcal or 1865 kJ
Fat	17g
of which Saturates	3g
Carbohydrate (oat maltodextrins)	18g
of which Sugars	0.4g
Fibre (oat beta-glucan soluble fibre)	2g
Protein (N• 6,25)	54g
Salt	<50mg
Sodium	<20mg

Minimum Order Quantity (MOQ): 400kg

Packaging: 200kg big bags. 2 bags/pallet.
Bag labelling includes batch code, label declaration and best before date

Storage and handling: Store unopened packaging in a clean, dry, well-ventilated warehouse at ambient temperature and humidity. Store away from odorous materials

Best Before: 12 months after production date

Tate & Lyle Oat Ingredients, Älvåsvägen 1, 610 20 Kimstad, Sweden t: +46 11 253630 oat.info@tateandlyle.com
Tate & Lyle Oat Ingredients is a trading name of Tate & Lyle Sweden AB

Rev19/12/2013

Appendix C. T&L Analytical Risk Assessment

TATE & LYLE

Risk assessment

PrOatein mycotoxins

Risk assessment for rawmaterial,oat. (See attached document)
Analysis results on finished product PrOatein

External analysis

During 2013 and 2014 finished product, PrOatein, has been sent to external laboratory, Eurofins, for analysis of mycotoxins. Mycotoxins analyzed are:
Aflatoxin
Ochratoxin
Deoxynivalenol
Zearalenone
Fumonisin
HT-2 toxin
T-2 toxin

All results has been in accordance with EU 1881.206 – setting maximum levels for certain contaminants in food stuff.

Internal analysis
Moister: max 6%

Based on risk assessmnt for rawmaterial ,oat, external and internal analysis performed on finished product, PrOatein, the overall risk has been judged as LOW.
Frequenzy of analysis on mycotoxin set to twice yearly.

Tate&Lyle Sweden AB, Kimstad
12-Dec-2014

Ingbritt Johansson
Quality Manager

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TATE & LYLE

Risk assessment raw material

	Potential hazard B=Biological C=Chemical P=Physical	Likelihood(L)		Severity(S)		Risk L x S	Overall Risk Low = 0-2 Moderate = 3-5 High = 6+
Raw material		Rating	Justification	Rating	Justification		
Oat	C -Mycotoxins	1	Supplier approval. Contract with supplier. Raw material specification: Oat of Food Grade Mycotoxins according to EU 1881/2006 - setting maximum levels of certain contaminants in foodstuff. Moister: max 14% At T&L production plant stored under dry conditions in silo max 48 hours.	3	Mycotoxins are known carsinogens in humans	3	Moderate
	C- Pesticides	1	Supplier approval. Contract with supplier. Raw material specification: Oat of Food Grade Pesticides according to EU 1881/2006 - setting maximum levels of certain contaminants in foodstuff. Dehulling of oat before milling.	3	Certain pesticides may have adverse side effects in humans	3	Moderate
	C- Heavy Metals	1	Supplier approval. Contract with supplier. Raw material specification: Oat of Food Grade Heavy Metals according to EU 1881/2006 - setting maximum levels of certain contaminants in foodstuff.	3	Heavy metals are known as health concerns in humans	3	Moderate

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Appendix D. Stability Test Results (Batch No. 1149)

Analysis	Start R	3 mos. R	3 mos. V	3 mos. F	6 mos. R	6 mos. V	6 mos. F	9 mos. R	9 mos. V	9 mos. F
Peroxide number mekv/kg	0.3	x	26	x	27	26	0.4	21	44	40
Free fatty acids g/100g	15	x	14.3	x	14	14	15	14.3	13.5	13.9
Protein content* g/100g	52.7	52.3	53	52.4	52.4	53.3	52.5	52.3	52.7	52.3
Dry matter g/100g	97.9	97.8	98	98.3	97.7	98.1	98.4	97.3	97.5	98.1
Beta-glucan g/100g	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.5	0.6	0.6
Mol. wt. milj.Dalton	x	x	x	x	x	x	x	x	x	x
pH 10% solution	6	5.7	5.8	5.8	6.2	6.2	6.2	5.7	5.8	5.8
Appearance	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Color	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Smell	OK	OK	OK	OK	OK	OK	OK	OK	Slight rancid	OK
Taste	OK	OK	OK	OK	OK	OK	OK	Slight after-taste	Rancid after-taste	OK
Vol. wt. kg/l								0.58/0.60	0.59/0.60	0.56/0.58
Total count cfu/g	70	200	300	200	280	190	200	750	550	550
Total thermophilic count cfu/g	100	<10	60	120	90	50	30	60	20	50
Enterobact. cfu/g	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Bacillus.cereus cfu/g	20	<20	<20	60	40	<20	<80	60	20	50
Staph. aureus cfu/g	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20
Yeast cfu/g	<20	<20	<20	<20	<20	<20	<20	<20	<20	<20
Molds cfu/g	20	<20	20	40	120	20	80	60	40	60
E. coli cfu/g	x	x	x	x	x	x	x	x	x	x

* R - room temperature; V - 40°C; F - freezer (0°C)

Analysis	12 mos. R	12 mos. V	12 mos. F		18 mos. R	18 mos. V	18 mos. F
Peroxide number mekv/kg	29	>70	28		x	x	x
Free fatty acids g/100g	15	14	13		x	x	x
Protein content* g/100g	50.8	50.3	51.9		52.1	51.7	51.6
Dry matter g/100g	96.8	96.9	98.1		96.5	97.3	97.9
Beta-glucan g/100g	0.7	0.7	0.6		0.6	0.6	0.6
Mol. wt. milj.Dalton	x	x	x		x	x	x
pH 10% solution	5.7	5.1	5.8		5.7	5.2	5.7
Appearance	OK	OK	OK		OK	OK	OK
Color	OK	OK	OK		OK	OK	OK
Smell	OK	Rancid	OK		OK	Rancid	Slight sweet
Taste	Slight after-taste	Rancid	OK		Bitter	Rancid	OK
Vol. wt. kg/l	0.58/0.59	0.60/0.62	0.55/0.56		0.58/0.60	0.61/0.63	0.55/0.56
Total count cfu/g	140	100	280		50	<50	<50
Total thermophilic count cfu/g	60	500	<50		<50	<50	100
Enterobact. cfu/g	<10	<10	<10		<10	<10	<10
Bacillus. cereus cfu/g	40	<20	<20		<20	<20	<20
Staph. aureus cfu/g	<20	<20	<20		<20	<20	<20
Yeast cfu/g	<20	<20	<20		<20	<20	<20
Molds cfu/g	40	<20	80		40	<20	<20
E. coli cfu/g	x	x	x		x	x	x

- R - room temperature; V - 40°C; F - freezer (0°

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Exhibit I. Report of the Expert Panel

OPINION OF AN EXPERT PANEL ON THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF OAT PROTEIN FOR USE IN FOOD

Introduction

An independent panel of experts, qualified by scientific training and experience to evaluate the safety of food and food ingredients was requested by Tate & Lyle to determine the safety and Generally Recognized As Safe (GRAS) status of oat-derived protein PrOatein®. Oat-derived protein is intended for use as a source of protein for enrichment of foods. It will be added to foods at per serving levels in an identical fashion (technical function and amount) to those described in other GRAS Notification submissions to the U.S. FDA for other protein sources such as canola protein isolates (all received no objection letters; GRNs 327 and 386). Example food categories include bakery products; snack foods; dairy products; processed meat products; beverages, soups, and nutritional beverages; dry instant milkshake and protein drinks; instant powdered nutritional beverages; vegetarian food products and meat analogues; and meal replacement/nutritional bars. The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

A safety review based on the existing scientific literature on the safety of oat-derived protein as well as other plant-derived protein and protein isolate ingredients (through October 2014) was conducted by ToxStrategies, Inc. and is summarized in the attached dossier. The Expert Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and agreed to the conclusions described below.

Description

Oat protein (PrOatein®) is a protein concentrate, prepared from oat bran and rich in oat protein, typically containing 52-56% protein (dry basis). It also contains oat oil and oat maltodextrins (approved in 21 CFR §184.1444) both of which occur naturally in the oat, as well as a small amount of minerals and β-glucan. The PrOatein® oil fraction (16-18% of the PrOatein® product) is comprised of approximately 42% linoleic acid, 36%, oleic acid, 16% palmitic acid, 2% α-linolenic acid, and 4% other fatty acids (C20 - C24) normally found in oats. The high concentration of unsaturated fatty acids (namely the monounsaturated oleic acid, along with the high amount of monounsaturated and polyunsaturated fatty acids (mainly omega-6) provides a desirable nutritional profile. Oat protein is also rich in essential amino acids (including leucine, isoleucine and lysine).

The Chemical Abstracts Service (CAS) Registry Number for oat proteins is 134134-87-5 and the trade name of Tate & Lyle's oat protein is PrOatein® or PrOatein® Oat Protein.

Manufacturing Process

Tate & Lyle's PrOatein® product is manufactured in a two-step process following current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110), without the use of

chemicals or solvents and it does not contain additives or preservatives. The first-step is a dry mill process in which the oat grain is dehulled (husk and most of endosperm separated) and milled to specifications. The final output of the dry milling process is oat bran, which is employed in the second processing step, a wet process. In the wet fractionation process, the oat bran is mixed with water and food use-approved enzymes from non-GMOs (genetically modified organisms) at specified temperatures. The mixture is passed through physical separation procedures and sterilized. The process output provides insoluble fiber, protein, oat oil, maltodextrin (approved in 21 CFR §184.1444), and oat soluble fiber rich in β-glucan, all of which can be supplied as dry products.

Reagents/processing aids used in the manufacture of oat protein are limited to water and the enzyme alpha-amylase, which is commonly used in food ingredient manufacturing processes. No chemical processing aids are employed in Tate & Lyle's manufacturing process. The alpha-amylase enzyme preparation employed in the process is GRAS per 21 CFR §184.1012, complies with Food Chemicals Codex specifications, and is used at levels not to exceed current good manufacturing practice.

Analytical (chemical and microbiological) results for PrOatein® confirm that the finished product meets the proposed specifications as demonstrated by the consistency of production, the lack of impurities/contaminants (e.g., heavy metals, pesticides, microbiological toxins), and its stability over an 12-month period.

History of Use

There is common knowledge of a long history of human consumption of oats. Oats contain the highest protein content of all the common grains (Katz, 2001). Tate & Lyle currently markets oat protein (PrOatein®) outside of the U.S. Additionally, similar oat-derived protein products are currently marketed in the U.S. (e.g., 55Oat Protein, Oat Tech, Inc.). Humans have consumed oats and the proteins from oats as well as other food sources providing protein such as meat, dairy, eggs, fruits, vegetables, grains, nuts, and seeds for centuries. Oats have been cultivated around the world for more than 2000 years. Numerous food products containing oats are currently marketed in the U.S. and around the world. In addition, there has been a global demand for less expensive proteins with good nutritional and functional properties (Ma, 1983). Oat protein has become a desirable ingredient for addition to a variety of food products as a source of dietary protein due to its protein quality, and excellent amino acid profile as compared to soy protein (Cluskey et al., 1979).

Epidemiological studies and clinical trials have consistently revealed the cardiovascular benefits of oat consumption due to its hypocholesterolemic effects. In 1997, the FDA approved a health claim for the association between oat consumption and coronary heart disease (Katz, 2001; FDA, 1997).

Protein is found throughout the body, in muscle, bone, skin, hair, and virtually every body part or tissue. At least 10,000 different proteins are found in the body. Proteins are

made up of amino acids that act as building blocks to make all types of protein. Some amino acids cannot be made by the body and therefore must be provided by the diet (i.e., essential amino acids). Around the world (but not in the U.S.), many people do not get enough protein in their diet leading to protein malnutrition, resulting in a condition known as kwashiorkor. While animal sources of protein tend to deliver all the amino acids the body requires, other plant protein sources also deliver most of the essential amino acids and have become an important source of added protein in processed food. Current plant and cereal grain sources of added protein used in food include peas, lentils, soy, canola, rice, chickpeas, beans, wheat, and potato.

FDA has established a daily reference value (DRV) for protein of 50 g/day for adults and children four or more years of age. Furthermore, Dietary Guidelines for Americans (HHS/USDA, 2005) recommend that adults eat half their grains as whole grains, which include oats and wheat. The Institute of Medicine (IOM, 2005) recommends that adults consume a minimum of 0.8 grams of protein per kilogram of body weight. IOM also set a wide range for acceptable protein intake, ranging from 10 - 35% of calories each day. In the U.S., the recommended daily allowance of protein is 46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age.

To date, FDA has reviewed extensive published information and data as part of GRAS notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no questions letters" (e.g., GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates)).

Intended Use and Intake Assessment

The focus of this GRAS assessment is for an identical food use of oat-derived protein as previously recognized in the GRNs identified above for current grain-based protein sources such as soy, canola, pea, lentils, wheat, rice, and whey. Similarly, oat-derived protein will be used as a source of protein for enrichment of processed foods. As described in GRN No. 386 (see below) for canola protein isolate and hydrolyzed canola protein isolate, the typical uses of protein for enrichment of foods includes bakery products, snack foods, nutritional beverages such as high protein drinks and milkshakes, instant powdered nutritional beverages, vegetarian food products and meat analogues, dairy products, and meal replacements/nutritional bars.

The proposed use concentrations and variety of food uses combined with the large average daily consumption of the described foods resulted in the calculated daily intake of the protein additives being a substantial fraction of the RDA (46 grams/day for women over 19 years of age, and 56 grams/day for men over 19 years of age), and even exceeded it at the 90th percentile consumption. This was also the case for GRN No. 327 (cruciferin-rich canola/rapeseed protein isolate and napin-rich protein canola/rapeseed protein isolate). As Tate & Lyle's proposed oat protein is only intended to be an

alternative source of protein for current uses in food, a similar estimate of intake would be expected if oat protein was the only source of protein used in processed foods. As other GRAS notifications have stated, we do not realistically expect that the actual consumption of foods containing oat protein would result in daily consumption greater than the DRV or RDA for protein. It is reasonable to expect that most of the population's intake of protein is, and will remain, in the form of unprocessed foods including meat, poultry, fish, and legumes. As the proposed oat protein product is only one of many protein sources for use in processed foods, only the inherent conservatism of intake calculations such as those described in the aforementioned GRNs suggest the possibility of exceeding the RDA at the 90th percentile (FDA, 2011; FDA, 2010).

In summary, the proposed uses of PrOatein® will not result in an increase in the overall consumption of protein, but simply provide an alternative source of well-characterized protein from oats for use in food. Therefore, cumulative intake analysis is not considered necessary.

While Tate & Lyle's PrOatein® product could be added at a higher per serving level, the use of oat protein in this manner is considered to be self-limiting for technological reasons such as product texture and/or flavor profile.

Safety Data

There is common knowledge of a long history of human consumption of oats. Oats have been cultivated around the world for more than 2000 years. Humans have consumed oats and proteins from oats and other grains for centuries, along with proteins from many food sources such as meats, fruits, vegetables, nuts and seeds. The U.S., Germany, Russia, Canada, France, Finland, Poland, and Australia are the largest producers of oats (FDA, 2012). Numerous food products containing oats are currently marketed in the U.S. and around the world.

Oat consumption has various health benefits, such as a decreased risk of coronary heart disease and lowering of cholesterol (FDA, 1997; Davy et al., 2002; Ripsin et al. 1992). Protein is necessary for a healthy diet; the Centers for Disease Control and Prevention (CDC, 2014) recommends that adult women and men consume 46 and 56 g protein per day, respectively. Further, several protein isolates have received GRAS designation, including wheat protein, canola protein and potato protein (FDA, 1999, 2011 and 2013, respectively).

WHO (2002) reports the digestibility of protein in oatmeal as 86% and that in cereal oats as 72%. Therefore, dietary oat proteins are expected to be almost completely digested and absorbed from the upper gastrointestinal (GI) tract by the time they reach the terminal ileum. Oat proteins would be broken down by gastric juices in the stomach and proteases in the small intestine and efficiently absorbed as small peptides or amino acids. Sherman and co-workers (1919) demonstrated that proteins present in oatmeal were very efficiently utilized in the maintenance metabolism of healthy adult volunteers. This indicated that oat proteins were effectively broken down into their constituent amino

acids and small peptides that were typical of all food proteins. The known metabolism of oat proteins is a strong indicator of the safety of oat protein isolate.

Oat protein isolates have been shown to have antioxidant activity. Following proteolytic hydrolysis of food proteins, various physiological activities have been found including radical scavenging, antihypertensive, immunomodulatory, antimicrobial, mineral binding and opioide activities (Tsopmo et al., 2010). Oat consumption decreases the risk of coronary heart disease and lowers LDL cholesterol (FDA, 1997; Davy et al., 2002; WHO, 2002). Oats are considered a satisfactory source of protein, fat and energy for infants and young children (Graham et al., 1990). Dietary protein has been shown to decrease blood pressure and may decrease the risk of cardiovascular disease (WHO, 2002).

Studies of oats, oat protein, and other protein isolate sources in humans and/or animals have demonstrated its beneficial effects as well as safety. Safety studies of other protein sources (e.g., canola protein isolates) with similar amino acid profiles to oat protein have also demonstrated a lack of toxicity at high levels of consumption.

Some studies of patients with celiac disease (CD) indicate more frequent GI symptoms while consuming an oat-containing gluten-free diet (GFD) than consumption of a traditional GFD. Such symptoms are generally mild, and the appearance of flatulence and abdominal distension has previously been attributed to the increased intake of fiber from oat products (Holm et al., 2006; Pulido, 2009). In women with breast cancer, high dietary protein intakes improved survival rates (WHO, 2002).

Extremely high protein consumption may be toxic. While it has been recommended that adults not consume more than two-fold the reference dietary amount of 1.5 g protein/kg, physically active individuals on normal diets easily exceed this amount, and persons involved in body-building consume much higher levels of protein (WHO, 2002). Dietary protein can influence kidney function, and high protein diets may be linked with increased incidence of kidney stones in susceptible individuals (Martin et al., 2005; WHO, 2002).

Various *in vivo* and *in vitro* studies show different results relative to whether oats can elicit an immune response in patients with CD. In studies which showed a response, the data indicated that certain oat varieties may be immunogenic, but others are not.

Children with atopic dermatitis and farmers with allergies to grain dust may experience allergic reactions to oat proteins. These proteins can act as skin and respiratory allergens (Boussault et al., 2007; FDA, 2012).

There are conflicting data indicating whether CD patients can tolerate oats. Allergy manifestation resulting from consumption of oats and oat products has been the subject of debate. It has been alleged that oats may cause adverse effects in individuals with celiac disease. As a result, use of oats in a GFD was not allowed. However, recent evidence indicates that oats are safe for consumption by most individuals with celiac disease

(Rashid et al., 2007). Health Canada (2007) critically reviewed the scientific literature and concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats that are uncontaminated with other cereal grains such as wheat, barley and rye. In fact, pure oats may be beneficial to persons with celiac disease, as its palatability may increase patients' compliance with a GFD (Health Canada, 2007).

It should be emphatically stated that the recommended ingredient labeling for PrOatein® is "oat protein." Thus, food product ingredient lists would state the presence of an oat ingredient and individuals who wish to avoid oats consumption for any reason would be able to identify the presence of an oat-derived ingredient.

General Recognition of the Safety of Oat Protein

The intended use of oat protein has been determined to be safe through scientific procedures as set forth in 21 CFR§170.3(b), thus satisfying the so-called "technical" element of the GRAS determination and is based on the following:

- PrOatein® Oat Protein is manufactured consistent with current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110). The raw materials used in the manufacturing process are food grade and/or approved for use as processing aids in food. No chemical processing aids are employed in the manufacturing process. The oat protein product containing approximately 52-56% protein has been characterized and meets appropriate food grade specifications found.

- There is common knowledge of a long history of human consumption of oats. Numerous food products containing oats are currently marketed in the U.S. and around world and oat protein has become a desirable ingredient for addition to a variety of food products as a source of dietary protein.

- The intended uses of PrOatein® (oat-derived protein) will provide an alternative to other dietary sources of protein as part of the total dietary protein intakes among the U.S. population.

- Epidemiological studies and clinical trials have consistently revealed the cardiovascular benefits of oat consumption from its hypocholesterolemic effects. In 1997, the FDA approved a health claim for the association between oat consumption and coronary heart disease (Katz, 2001; FDA, 1997).

- To date, FDA has reviewed extensive published information and data as part of GRAS notifications for animal and plant-based protein isolates and concentrates and subsequently issued "no questions letters" (e.g., GRN No. 26 (isolated wheat protein); GRN No. 37 (whey protein isolate and dairy product solids); GRN No. 168 (poultry protein); GRN No. 182 (hydrolyzed wheat gluten isolate; pea protein isolate); GRN No. 313 (beef protein); GRN No. 314 (pork protein); GRN No. 327 (cruciferin-rich canola/rapeseed protein isolate and napin-rich canola/rapeseed

protein isolate); GRN 386 (canola protein isolate and hydrolyzed canola protein isolate); GRN No. 447 (potato protein isolates)). Studies in both animal and humans have been evaluated, including a 90-day rat feeding study with a canola protein isolate (min. 90% protein) very similar in amino acid profile to the proposed oat protein product. No toxicity was evident at concentrations up to 20% in the diet. No recent human or animal studies raising any new safety concerns concerning protein or protein isolates and their addition to processed foods have appeared in the published literature subsequent to these evaluations.

- The publicly available scientific literature on oats, oat protein, and other plant-derived protein products and their subsequent utilization as a source of amino acids is sufficient to support the safety and GRAS status of the proposed oat protein product.

Since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use and safety of the oat-derived PrOatein® product. We conclude that oat-derived protein produced by Tate & Lyle under the conditions described in the attached dossier and meeting Tate & Lyle specifications is safe.

We further unanimously conclude that the intended use of oat-derived protein in food, meeting the specifications described above, is Generally Recognized As Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions.

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC
St. Helena Island, SC

3/6/15
Date

Carol Knight, PhD
Consultant
Knight International

3/11/15
Date

Stanley M. Tarka, Jr., PhD
Consultant
Tarka Group, Inc.

07 March 2015
Date

Appendices

Appendix 5

MATERIAL SAFETY DATA SHEET:
PrOatein® Oat Protein

TATE & LYLE

proatein® Oat Protein

MATERIAL SAFETY DATA SHEET: **PrOatein®** Oat Protein

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING

Product identity / name	**PrOatein® Oat Protein**
Product use	Food, beverage and nutritional supplement ingredient / cosmetics and personal care ingredient
Product make-up	PrOatein® from Tate & Lyle Oat Ingredients is a powder product, prepared from oat bran and rich in oat protein. It also contains oat oil and oat maltodextrins, both of which occur naturally in the oat. PrOatein® is produced without chemicals addition and contains no additives or preservatives.
Company	Tate & Lyle Oat Ingredients Älvåsvägen 1 SE 610 20 Kimstad Sweden
Tel no	+ 46 11 25 36 30
Email	PrOatein@tateandlyle.com

2. COMPOSITION / INFORMATION ON INGREDIENTS

PrOatein® from Tate & Lyle Oat Ingredients is a powder product, prepared from oat bran and rich in oat protein. It also contains oat oil and oat maltodextrins, both of which occur naturally in the oat. PrOatein® is produced without chemicals addition and contains no additives or preservatives. PrOatein® is designed for use in food, beverage, supplements, cosmetics and personal care products, and is supplied as a fine, beige-coloured powder.

Appearance: Fine, beige powder

Melting point: Not Applicable (decomposes before melting)

Boiling point: Not applicable

Vapour density: Not applicable

Vapour pressure: Not applicable

Density (g cm-3): circa 0.25

Flash point: Not applicable

Explosion limits: Avoid flames/sparks or equipment where sparks are generated

Auto ignition temperature: Not given

Water solubility: good to moderate

3. HAZARDS IDENTIFICATION

None identified

4. FIRST-AID MEASURES

INHALATION:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

INGESTION:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, or belt waistband.

SKIN CONTACT
Wash with soap and water

EYE CONTACT
Wash with running water, holding eyelids open, or use an eye fountain. In the unlikely event of any discomfort, or continuing discomfort, seek medical attention

5. FIRE-FIGHTING MEASURES

The product is in the form of a powder and may be flammable at high temperatures.

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet. Combustion of any dry residues releases CO2

6. ACCIDENTAL RELEASE MEASURES

SPILLAGE: Sweep up. Avoid formation of dust cloud.

WASTE DISPOSAL: Dispose of in accordance with national and regional regulations.
PrOatein™ is entirely biodegradable.

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

7. HANDLING AND STORAGE

STORAGE: Store in cool dry place away from heat and oxidizing agents.

No other special precautions needed.

USAGE PRECAUTIONS: Avoid spillage and direct skin and eye contact. Safety goggles should be worn when dealing with large volumes. No particular hand protection is required.

STORAGE CLASS: Unspecified storage

8. EXPOSURE CONTROL / PERSONAL PROTECTION

COMMENTS: No exposure limits noted for the ingredient
Those very few people who have a specific allergy to oat grain should consult a doctor before working with PrOatein™.

PROTECTIVE EQUIPMENT: Good laboratory practice.

RESPIRATORY EQUIPMENT
None needed or recommended

HAND PROTECTION
Good GLP: Use waterproof protective gloves made from, eg pvc, polyethylene, neoprene

EYE PROTECTION
Good GLP: Use of approved safety glasses or goggles is recommended only when eye exposure is probable

OTHER PROTECTION
None needed

HYGIENE MEASURES
Always wash at the end of each working shift, before eating, smoking or using toilet facilities

9. STABILITY AND REACTIVITY

The product is stable under normal conditions of temperature and pressure.
Combustible as it is a carbohydrate-containing powder.
Try to avoid formation of a PrOatein® dust cloud. Regard as equivalent to starch in this respect.

Avoid contact with extremely strong oxidizing agents.
No dangerous reactions are known or reasonably foreseen.

10. HEALTH HAZARDS / TOXICOLOGY

ACUTE EFFECTS: None

CHRONIC EFFECTS: None

TOXICITY DATA: None given

No known toxicity.
Not absorbed through the skin.

Inhalation of excessive dust may transiently irritate the nose, throat and respiratory tract. Eye contact with dust may cause mild and transient irritation. Ingestion of quantities sufficient to produce any adverse effects whatsoever is not plausible in an industrial or manufacturing situation.

Skin contact is not known to be hazardous.

Oat bran and proteins, oil and carbohydrates derived from it have no known carcinogenicity and are not classified as a reproductive toxin by any authoritative body or regulatory agency.

Appendices

Appendix 6

CUSTOMER LABELS:
PRODUCTS USING PROATEIN™

Confidential Business Information

attachments included in CBI Deleted Copy

References (available on request)

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4. Protein and Amino Acid Requirements in Human Nutrition: Report of a Joint FA/WHO/UNU Expert Consultation. Table 23: Summary of the adult indispensable amino acid requirements. Technical Report 935. Geneva: World Health Organization, 2002, http://whqlibdoc.who.int/trs/WHO_TRS_935_eng.pdf.

5. US Patent US 2013/0183404 A1, Method of Preparing an Oat Protein and Fiber Product, Oat Tech Inc., filed Jan 17, 2013.

6. Protein quality evaluation. Joint FAO/WHO. FAO Food Nutr Pap1991, 51:1-66.

Also, see references in Appendix 4: GRAS Determination of Oat Protein for Use in Food