Attachment A

Evidence to Support the Use of Polydextrose as a Source of Dietary Fiber in the United States: Evidence Summarizing its Physiological Effects and Caloric Content

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LIST OF ABBREVIATIONS USED IN TABLES

AUC = area under the curve

BH = breath hydrogen

BMI = body mass index

BW = body weight

C = control

CHO = carbohydrate

CO_2 = carbon dioxide

d = day

DF = dietary fiber

DP = degree of polymerization

E = energy

F = female

FOS = fructo-oligosaccharide

g = gram

GI = gastrointestinal

h = hour

HP = high protein

ILD = isotope-label disposition

ITT = intent-to-treat

iv = intravenous

kcal = kilocalorie

kg/m^2 = kilogram/meter^2

kJ = kilojoule

LP = low protein

M = male

min= minute

mo = month

NFC = no fiber control

PDX = polydextrose

PP = per protocol

Prt = protein

QG = quality grade

RS = resistant starch

SCF = soluble corn fiber

SCFAs = short-chain fatty acids

SFD = soluble fiber dextrin

Ss = subjects

Svg = serving

TT = total transit time

Tx = treatment

wk = week

XYL = xylitol

y = year

1.0 INTRODUCTION

On May 27, 2016, the U.S. Food and Drug Administration ("FDA") published the following definition for dietary fiber with regard to Nutrition Facts labeling (Fed Reg. 2016. 81:33979):

> *Dietary fiber is defined as:*
>
> *(1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants;*
>
> *(2) Isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.*

Although FDA has indicated that the agency will issue guidance to industry on submissions to demonstrate physiological effects that are beneficial to human health, no guidance has been provided to date.

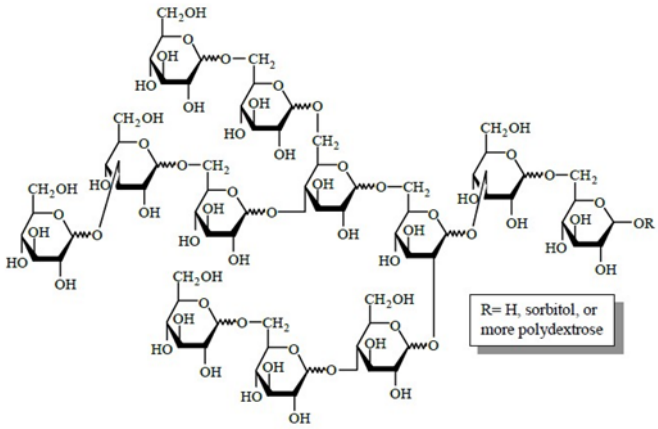
Polydextrose, such as Tate & Lyle Ingredients Americas' (Tate & Lyle) STA-LITE® Polydextrose and DuPont Nutrition & Health's (DuPont) Litesse® Polydextrose, fits within item 2 of *§ 101.9 (c)(6)(i)* above because it is a randomly bonded polysaccharide with α- and β-1,2, 1,3, and 1,4 linkages between glucose moieties that renders it resistant to human gastrointestinal enzymes. Polydextrose typically measures as 75-80% dietary fiber by AOAC methods 2001.03 or 2009.01. Polydextrose complies with the Codex definition of dietary fiber and is accepted as a dietary fiber by many countries, including Canada, the EU 28, Australia/New Zealand, Japan and Korea. Several studies have evaluated the physiological effects of STA-LITE® and Litesse® polydextrose, as well as other polydextrose. The polydextrose polymer is essentially the same in all of these studies. The primary purpose of this submission is to outline the scientific evidence in support of the physiological benefits of polydextrose. Although studies have shown that polydextrose may have several beneficial physiologic effects, this petition presents the evidence for two specific physiological effects, laxation and reduced energy intake at a subsequent meal. The secondary purpose of this submission is to demonstrate evidence that polydextrose has a caloric value of 1 kcal/g.

2.0 PHYSICAL PROPERTIES AND TYPICAL NUTRITIONAL PROFILE

2.1 Origin and Physical Form

Polydextrose is a randomly-linked glucose polymer produced by the thermal condensation of glucose in the presence of sorbitol and catalytic amounts of citric or phosphoric acid. Shown below is the molecular structure of polydextrose (Figure 2.1-1).

Figure 2.1-1 Representative Molecular Structure of Polydextrose



Source: Craig et al., 1998

2.2 Physical Properties and Typical Nutritional Profile

The physical properties and typical nutritional profile of polydextrose are summarized in Table 2.2-1. In addition to the polymer, polydextrose consists of small amounts of the starting materials glucose and sorbitol, as well as levoglucosan formed during the poly-condensation process. Analysis by AOAC accepted methods indicate it is primarily a dietary fiber. It has a caloric value of 1 kcal/g due to its indigestible carbohydrate content (see Section 5.0), and is not a source of protein, fat, vitamins or minerals. Due to its atypical linkages, polydextrose resists digestion and is partially fermented in the large intestine, with approximately 50% of the ingested dose being excreted undigested (Auerbach et al., 2007).

Table 2.2-1 Physical Properties and Typical Nutritional Profile of Polydextrose[1]

Parameter	Specifications, Nutrient Content per 100 g
Common or Usual Name	Polydextrose
Trade Name (leading brands)	STA-LITE®, Litesse®
Chemical Abstracts Service (CAS) Number	68424-04-04
Empirical Formula	$(C_6H_{10}O_5)_n$
Ash	0.3% max.
Solubility	>80% (dsb) @ 68°F (20°C) and 104°F (40°C)
Melting point	275-293 °F (135-145°C)
Dextrose	4.0% max.
% Polydextrose	90% min.
Sorbitol	2% max.
Levoglucosan	0-4.0%
Energy value (Calories)	100.0[a]
Water (g)	1.9
Total Carbohydrates (g)	98.1
Dietary fiber (g)	75-80[b]
Total Sugar (g)	5.9
Polyols	2.0
Other Carbohydrates (g)	3.9
Protein (g)	NS
Total Fat (g)	NS
Calcium (mg)	NS
Phosphorus mg)	NS
Iron (mg)	NS
Sodium (mg)	NS
Potassium (mg)	NS
Magnesium (mg)	NS
Vitamin A (IU)	NS
Vitamin B1 (Thiamine) (mg)	NS
Vitamin B2 (Riboflavin) (mg)	NS
Niacin (mg)	NS
Vitamin C (mg)	NS

[1]Complies with 21 CFR 172.841 and Food Chemicals Codex; NS: not significant.

[a]Polydextrose has a caloric value of 1 kcal/g. See Section 5.0 of this document.

[b]Measured by AOAC Method 2001.03 or AOAC 2009.01.

3.0 REGULATORY STATUS/ DIETARY FIBER STATUS

Polydextrose was introduced into the marketplace in the early-1980s. As a result, polydextrose has a long history of use; it has been used for more than 30 years in human food and beverage products around the world. Both the Joint Food and Agriculture Office of the United Nations (FAO) and the World Health Organization (WHO) Expert Committee on Food Additives (JECFA), and the European Commission's Scientific Committee on Food (EC/SCF, the predecessor of EFSA), have assigned an acceptable daily intake (ADI) as "not specified", which means that polydextrose can be used "quantum satis" as required to achieve the desired functionality, and concluded that polydextrose has a mean laxative threshold of about 90 g/day or 50 g as a single serving dose (Flood et al, 2004).

3.1 United States

In 1981, FDA approved polydextrose as a food additive (21 CFR §172.841). FDA noted that if a single serving of food contains more than 15 g of polydextrose, the label of the food shall bear the statement: "Sensitive individuals may experience a laxative effect from excessive consumption of this product" (21 CFR 172.841).

3.2 Codex Alimentarius

Polydextrose complies with the Codex Alimentarius definition of dietary fiber.

3.3 Other Countries

Health Canada, 2013

> Polydextrose was approved as a novel fiber source by the Food Directorate of Health Canada following a submission and review of the clinical scientific evidence that showed the positive impact of polydextrose on bowel function, including fecal bulk and production of energy-yielding metabolites during colonic fermentation.

EFSA, 2011; EC, 2012

Polydextrose meets the European Union definition of dietary fiber. It received a positive EFSA opinion and approval of an Article 13.1 health claim by the European Commission (EC) in relation to the following claim, "consumption of foods/drinks containing polydextrose instead of sugar induces a lower blood glucose rise after meals compared to sugar-containing foods/drinks". (EFSA, 2011). This opinion was adopted by the EC through Regulation 432/2012 on May 16, 2012.

AFSSA (Agence Française de Sécurité Sanitaire des Aliments –French Agency for Sanitary Security of Foods), 2002:

Polydextrose is a dietary fiber as it is consistent to the definition: "it is a randomly bonded glucose polymer with a DP > 3", and "it stimulates colonic fermentation." AFSSA also stated that there were already some studies on polydextrose showing an improvement of fecal excretion, via an increase in stool weight and improvement of its texture but suggested completing the existing set of data by further scientific studies.

FSANZ (Food Standards Australia New Zealand), 2004:

Polydextrose is considered to be a dietary fiber based on the rationale that it is resistant to absorption in the small intestine, promotes laxation and is an oligosaccharide with a degree of polymerization greater than two.

Japanese Health Ministry

Polydextrose is considered to be a functional food or food ingredient; rather than an additive, and is widely used in fiber-fortified foods. FOSHU products containing polydextrose are permitted to use the claim "provides improved intestinal function." A daily intake of 7 to 8 g/d is recommended to get the physiological effects.

Korean Ministry Food and Drug Administration and Ministry of Health and Welfare

Polydextrose-containing products are permitted to use the health claim “help to maintain a healthy bowel function.” A daily intake of 7 to 12 g is recommended to get the claimed physiological effects.

4.0 PHYSIOLOGICAL EFFICACY EVALUATION

4.1 Polydextrose Used in Efficacy Studies

The studies that measured physiological effects of polydextrose used either STA-LITE® or Litesse® polydextrose. Both polydextrose sources meet FCC specifications (Table 4.1-1) for manufacturing and properties. Internal analyses at both Tate & Lyle and DuPont have verified the structural and metabolic similarities. Hence the data in the Efficacy section reviews the data for polydextrose, irrespective of the brand name.

Table 4.1-1. FCC Specifications for Polydextrose

	FCC Specification[1]
Polymer Assay (%)	≥ 90.0
Arsenic (ppm)	≤ 3
Heavy metals as Pb (ppm)	≤ 5
Lead (ppm)	≤ 0.5
5-hydroxymethylfurfural (ppm)	< 1000
Molecular weight limit (Da)	< 20,000
1,6-anhydro-D-glucose (%)	≤ 4.0
Glucose (%)	≤ 4.0
Sorbitol (%)	≤ 4.0
Moisture (%)	≤ 4.0
pH (10% solution)	5.0 -6.0
Residue on ignition (%)	≤ 3.0

#HPLC methodology overestimates the actual amount of dextrose present.
*Measured on 50% dry solids solutions. Conductivity was too low at 10% solids for reliable measurements.
[1]Polydextrose Monograph. FCC III-Second Supplement. pp. 57-59 (1986). Polydextrose Monograph. FCC III-Third Supplement. p. 136 (1992).

4.2 Assessing the Quality of Clinical Studies

A literature search in PubMed in addition to reference lists compiled by Tate & Lyle and DuPont identified both published and unpublished studies for the physiological effects reviewed in this

petition. Only complete studies (i.e. not just in abstract form) conducted in subjects older than the age of 2 years and reported in English were evaluated for quality. Each clinical trial was assessed for methodology quality and given a grade of “high”, “moderate”, or “low” based on criteria in Table 4.2-1. A rating of “high” was given to a randomized controlled study with no obvious bias; a “moderate” rating was given to a randomized controlled study with some bias, but not enough to invalidate the results; and a “low” rating was given to a study with significant confounders or bias.

Table 4.2-1. Methodology Quality Ratings for Human Intervention Studies

High Quality	Moderate Quality	Low Quality
• Randomized, controlled • Use of placebo if appropriate • Double-blind • Clear description of subject characteristics • Baseline characteristics similar between control and treatment • Adequate sample size • No significant differences in food intake between treatment and control except for test substance • Good compliance • Appropriate statistical analysis • Adequate intervention period • Appropriate outcome measures • Less than 20% drop-out rate • Adequate washout period for crossover studies • No reporting errors or other obvious bias	• Randomized, controlled, but study has some deficiencies or uncertainties; susceptible to some bias, but not enough to invalidate results.	• Not randomized or unclear if randomized • No control • Less than 10 subjects (total study sample) for crossover study or per treatment) • Poor compliance • Subjects on medications that could interfere with measured outcome • Subjects with health conditions that could interfere with measured outcome • No statistical analysis performed or statistical analysis performed only on changes from baseline • High drop-out rate (i.e., more than 20%) • Inappropriate outcome measures in relation to claim • Large amounts of missing information and discrepancies in reporting • Study duration too short for the variable being measured • Any other factor that could induce significant bias in results

Adapted from: US FDA/CFSAN. Guidance for Industry: Evidence-based Review System for the Scientific Evaluation of Health Claims – Final. Jan. 2009.
(AHRQ)/Balk et al. Agency for Healthcare Research and Quality, US Department of Health and Human Services. Effects of Soy on Health Outcomes, 2005

.4.3 Evidence of Laxation

4.3.1 Assessment Criteria for Laxation

In order to evaluate the physiological effect of laxation, the criteria to measure laxation were determined from government authorities, health professional groups, and dietary fiber experts and researchers.

Institute of Medicine

Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids (IOM, 2002):

> "Consumption of certain *Dietary* and *Functional Fibers* is known to improve laxation and ameliorate constipation (Burkitt et al., 1972; Cummings et al., 1978; Kelsay et al., 1978; Lupton et al., 1993). In most reports there is a strong positive correlation between intake of *Dietary Fiber* and daily **fecal weight** (Birkett et al., 1997). Also, *Dietary Fiber* intake is usually negatively correlated with **transit time** (Birkett et al., 1997). Although what constitutes "constipation" is variously defined, diets that increase **the number of bowel movements per day**, improve the **ease with which a stool is passed**, or increase **fecal bulk** are considered to be of benefit."

References cited above:

Birkett AM, Jones GP, de Silva AM, Young GP, Muir JG. 1997. Dietary intake and faecal excretion of carbohydrate by Australians: Importance of achieving stool weights greater than 150 g to improve faecal markers relevant to colon cancer risk. *Eur J Clin Nutr* 51:625-632.

Burkitt DP, Walker ARP, Painter NS. 1972. Effect of dietary fibre on stools and transit-times, and its role in the causation of disease. *Lancet* 2:1408–1412.

Cummings JH, Southgate DAT, Branch W, Houston H, Jenkins DJA, James WPT.1978. Colonic responses to dietary fibre from carrot, cabbage, apple, bran, and guar gum. *Lancet* 1:5-9.

Kelsay JL, Behall KM, Prather ES. 1978. Effect of fiber from fruits and vegetables on metabolic responses of human subjects. I. Bowel transit time, number of defecations, fecal weight, urinary excretions of energy and nitrogen and apparent digestibilities of energy, nitrogen, and fat. *Am J Clin Nutr* 31:1149–1153.

Lupton JR, Morin JL, Robinson MC. 1993. Barley bran flour accelerates gastrointestinal transit time. *J Am Diet Assoc* 93:881–885.

Health Canada

Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products (Health Canada, 2012):

> …"many stakeholders asked for more explicit guidance on the physiological effects recognized by Health Canada. In response to this request, Health Canada considers that the physiological effects listed below are functions of dietary fibre and are acceptable as a physiological effect of novel fibre sources. However, they are not exclusive and other effects attributable to dietary fibre may be recognized by Health Canada as science evolves.
>
> Dietary fibre:
>
> - improves laxation or regularity by increasing **stool bulk**;
> - reduces blood total and/or low-density lipoprotein cholesterol levels;

- reduces post-prandial blood glucose and/or insulin levels;
- provides energy-yielding metabolites through colonic fermentation"

European Food Safety Authority (EFSA)

Guidance on the Scientific Requirements for Health Claims Related to the Immune System, the Gastrointestinal tract, and Defense Against Pathogenic Microorganisms (EFSA, 2016):

> "Functional constipation is a disorder characterised by the absence of a detectable organic or pathological cause for which diagnostic criteria have been established. Subjects in the general population may, however, experience one or more symptoms of functional constipation without meeting the diagnostic criteria for the disorder (e.g. low frequency of defecations, lumpy or harder stools, sensation of incomplete evacuation).
>
> Claims on the maintenance of normal defecation (a bowel function) have been proposed only in the context of facilitating defecation (e.g. by one or more of the following means: **increasing the frequency of bowel movements, increasing faecal bulk**, **decreasing the consistency of stools**, **decreasing transit time**) in subjects with one or more signs/symptoms of functional constipation. In this context, maintenance of normal defecation is considered a beneficial physiological effect for the general population provided that it does not result in diarrhoea.
>
> **…**
>
> Based on the experience gained during the scientific evaluation of these [several] claims, the Panel considers that maintenance of normal defecation may be assessed by a number of outcome variables which could provide information about the function and eventually about the underlying mechanism of action, some of which may be interrelated (e.g. stool frequency, stool consistency, sensation of complete/incomplete evacuation, faecal bulk, transit time). The Panel will consider the information provided on these variables to evaluate the claim."

The EU has approved fecal bulking claims for wheat bran, oat grain fiber and barley grain fiber:

> Wheat bran (EFSA, 2010); Commission Regulation (EU) 432/2012 of 16/05/2012
> Oat grain fiber (EFSA, 2011); Commission Regulation (EU) 432/2012 of 16/05/2012
> Barley grain fiber (EFSA, 201); Commission Regulation (EU) 432/2012 of 16/05/2012

Scientific Opinion on Dietary Reference Values for Carbohydrates and Dietary Fiber (EFSA, 2010):

> "Both observational and experimental data show that dietary fibre is the most important dietary determinant of **faecal bulk** and **transit time** (Cummings et al., 1992, Birkett et al., 1997). Dietary fibre from cereals, fruits, and vegetables increases stool

weight, which promotes normal laxation in children and adults. In general, the greater the weight of the stool and the more rapid the rate of passage through the colon the better the laxative effect (Birkett et al., 1997).

References cited above:
Birkett AM, Jones GP, de Silva AM, Young GP, Muir JG. 1997. Dietary intake and faecal excretion of carbohydrate by Australians: Importance of achieving stool weights greater than 150 g to improve faecal markers relevant to colon cancer risk. *Eur J Clin Nutr* 51:625-632.
EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), Scientific Opinion on the substantiation of health claims related to wheat bran fibre and increase in faecal bulk (ID 3066), reduction in intestinal transit time (ID 828, 839, 3067, 4699) and contribution to the maintenance or achievement of a normal body weight (ID 829) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1817 . [18 pp.]. doi:10.2903/j.efsa.2010.1817.
EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to oat and barley grain fibre and increase in faecal bulk (ID 819, 822) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2249. [13pp.]. doi:10.2903/j.efsa.2011.2249

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U.K. Scientific Advisory Committee on Nutrition (SACN)

Carbohydrates and Health (SACN, 2015):

"The parameters **faecal weight**, **moisture content** and intestinal **transit time** are quantifiable aspects of colo-rectal function used as measures of laxation. They have, to a limited extent, been associated with different diseases, but these relationships are, as yet, not well defined (Cummings et al., 1992; Lewis and Heaton, 1999). There is no single accepted definition of what constitutes normal laxation (Weaver, 1988). EFSA has suggested that an intestinal **transit time** of about two to three days, a **defecation frequency** of once a day and a fecal moisture of > 70%, with a **faecal weight** of about 150 g/day, may be considered adequate for normal laxation in adults and this requires an intake of about 25 g/day dietary fibre (EFSA, 2010a)."

"For this report, it was agreed that components would be considered in the context of SACN's position statement on dietary fibre. This states that for extracted natural carbohydrate components or synthetic carbohydrate products to be defined as dietary fibre, beneficial physiological effects, similar to those demonstrated for the naturally integrated component of foods, must be demonstrated by accepted scientific evidence. Such effects include **increasing stool bulk**, **decreasing intestinal transit time and constipation** or the lowering of total cholesterol and LDL-cholesterol concentration (SACN, 2008). …In this report, there is evidence to show that non-digestible oligosaccharides, resistant starch and **polydextrose increase fecal mass**. On this basis, SACN, consider that these three components can be considered as dietary fibre. With the inclusion of non-digestible oligosaccharides, resistant starch and polydextrose this broadens the definition of fibre beyond non-starch polysaccharides."

References cited above:
Cummings JH, Bingham SA, Heaton KW & Eastwood MA (1992) Fecal weight, colon cancer risk, and dietary intake of nonstarchpolysaccharides (dietary fiber). *Gastroenterology* **103**, 1783-1789.
EFSA (2010a) Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. *EFSA Journal* **8**, 1462.
SACN (2008) Draft SACN position statement on dietary fibre & health and the dietary fibre definition — August 2008. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/339271/SACN_Narrative_Synthesis_Dietary_Fibre.pdf
Lewis SJ & Heaton KW (1999) The metabolic consequences of slow colonic transit. *Am J Gastroenterol* **94**, 2010-2016.
Weaver LT (1988) Bowel habit from birth to old age. *J Pediatr Gastroenterol Nutr* **7**, 637-640.

CODEX Alimentarius Commission

Jones (2014) reviewed and compared the dietary fiber (DF) definition developed by CODEX to other definitions by authorities around the world:

> "In 2009 CODEX published its DF definition, which resulted from nearly two decades of discussion among scientist and delegates from member nations."
>
> "Most definitions require that at least one physiological benefit be shown for fibers added back to food, e.g. those fibers in CODEX categories 2 or 3. Some definitions list specific physiological effects, as did all iterations of the CODEX definition except the final one [1,3-5,24]. These were: 1) improved intestinal **transit time** and increased **stool bulk**; 2) fermentation by colonic microflora; 3) reduction in blood total and/or LDL cholesterol levels; and 4) reduction in post-prandial blood glucose and/or insulin levels. Other definitions may include other physiological effects [3-5,24]."

References cited above:
(1) Joint FAO/WHO Food Standards Programme, Secretariat of the CODEX Alimentarius Commission: CODEX Alimentarius (CODEX) Guidelines on Nutrition Labeling CAC/GL 2–1985 as Last Amended 2010. Rome: FAO; 2010.
(3) Bureau of Nutritional Sciences Food Directorate, Health Products and Food Branch, Health Canada: Policy for labelling and advertising of dietary fibre-containing food. 2013. www.hc-sc.gc.ca.
(4) Food Standards Australia New Zealand (FSANZ): Food standards Australia New Zealand code issue 115, standard 1.2.8. nutrition information requirements. http://www.nrv.gov.au/nutrients/dietary-fibre.
(5) European Food Safety Authority: Outcome of the Public consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition,and Allergies (NDA) on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 2010, 8:1508–1569. http://www.efsa.europa.eu/en/search/doc/1462.pdf.
(24) AACC Dietary Fiber Definition Committee: Definition of dietary fiber:Report of the Dietary Fiber Definition Committee to the Board of Directors of the American Association of Cereal Chemists. Cereal Foods World 2001, 46:112–126.

American Association of Cereal Chemists

The Definition of Dietary Fiber (AACC 2001):

> "…dietary fibers promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation."

"Increased dietary fiber in the diet results in an increase in **fecal bulk**, reduced **transit time** of fecal material through the large intestine, increased **frequency of defecation**, improved regularity of defecation, and reduced hardness of stools" (i.e. **stool consistency**). "Stool weights of less than 100 g/day have been associated with constipation and correlations have been established between dietary fiber and **stool weight** (70)."

Reference cited above:
(70) Schneeman, B.O. 1998. Dietary fiber and gastrointestinal function. Nutrition Research 18(4):625-632.

Academy of Nutrition and Dietetics

Position of the Academy of Nutrition and Dietetics: Health Implications of Dietary Fiber (Dahl and Stewart (2015):

"It is well established that dietary fiber aids in laxation.[56] Many dietary fibers impact laxation by increasing **fecal bulk**, increasing **stool frequency**, and reducing intestinal **transit time**.[57] These effects are mediated by the water-binding capacity of the dietary fiber and by fermentation, which alters osmotic balance and increases fecal biomass.[57]

References cited above:
56. Anderson JW, Baird P, Davis RH Jr, et al.Health benefits of dietary fiber. Nutr Rev.2009;67(4):188-205.
57. Eswaran S, Muir J, Chey WD. Fiber and functional gastrointestinal disorders. Am JGastroenterol. 2013;108(5):718-727.

Joanne Slavin, PhD., Researcher and Expert on Dietary Fiber

Dietary Fiber and Prebiotics—Mechanisms and Health Benefits (Slavin, 2013):

"It is well recognized that fiber is important for normal laxation. This is due primarily to the ability of fiber to increase **stool weight**. The increased weight is due to the physical presence of the fiber, water held by the fiber, and increased bacterial mass from fermentation. Larger and softer stools increase the **ease of defecation** and reduce **transit time** through the intestinal tract, which may help to prevent or relieve constipation. In general, cereal fibers are the most effective at increasing stool weight. Wheat bran is considered the "gold standard" when it comes to fecal bulking, since no other fiber or laxative has been shown to be as effective (27). Inulin, although extensively fermented has little effect on stool weight (28), with less than 1 g/increase in stool weight with each g fiber fed as inulin."

References cited above:
27. Cummings, J.H. The Effect of Dietary Fiber on Fecal Weight and Composition. In *CRC Handbook of Dietary Fiber in Human Nutrition*; Spiller, G.A., Ed.; CRC Press: Boca Raton, FL, USA, 1993; pp. 263–333.
28. Slavin, J.; Feirtag, J. Chicory inulin does not increase stool weight or speed up intestinal transit time in healthy male subjects. *Food Funct*. **2011**, *2*, 72–77.

Gastrointestinal Effects of Low-Digestible Carbohydrates (Grabitske and Slavin, 2009):

"Analysis of the frequency, consistency, and weight of bowel movements are used to evaluate bowel function. 'Normal' function varies widely between individuals. Constipation and diarrhea are two extremes of abnormal bowel function."

"Some researchers used the term 'laxation' to refer to a **slight increase in the frequency of bowel movements** and a **softer consistency of feces** (Livesey, 2001). A laxative effect is associated with **increased stool weight** and water content, **decreased gastrointestinal transit time**, loose stools, bloating and distention, borborygmi (flatulence in the bowels), abdominal discomfort, and flatus (Flood et al., 2004)."

"Many factors may contribute to changes in bowel function and adverse gastrointestinal effects... Both LDC and host factors affect gut motility, transit time, enzyme activity, and the composition of intestinal microflora, and these, in turn, affect digestion, absorption, and fermentation, which may increase or decrease laxation."

Abbreviation used above:
LDC: low digestible carbohydrates

References cited above:
Livesey, G. (2001). Tolerance of low-digestible carbohydrates: A general view. *Brit J Nutr.* **85**:S7-S16.
Flood, M. T., Auerbach, M. H. and Craig, S. A. S. (2004).Areviewof the clinical toleration studies of polydextrose in food. *FoodChem Toxicol*. **42**:1531-1542.

It is evident from our review that **fecal bulk/weight**, **ease of defecation**, **stool frequency**, **stool consistency** and intestinal **transit time** are the parameters that are critical to the measurement of laxation. Enhancement in any one or more of these criteria would contribute to improved laxation.

4.3.2 Overview – Laxation Effect of Polydextrose

Parameters related to laxation--fecal bulk, ease of defecation, stool frequency and transit time were assessed in 11 clinical studies that measured the laxative potential of polydextrose (Table 4.3.1-1). Two additional studies examined polydextrose in conjunction with other dietary components (Beards et al., 2010a; Magro et al., 2014).

Since low quality studies are subject to significant bias, the highest weight was given to studies with high and/or moderate quality ratings. Of the 11 clinical studies evaluated, five were of high and moderate quality (Timm et al., 2013; Costible et al., 2011; Jie et al., 2000; Vester Boler et al., 2011); T&L, unpublished).

The following was observed for each of the parameters of laxation in the five high and moderate quality studies:

Increased Fecal Bulk
5 out of 6 clinical arms[1] observed a significant effect with polydextrose doses ranging from 8 g to 21 g in healthy subjects and 18 g in mildly constipated subjects.

Improved Ease of Defecation
3 out of 4 clinical arms observed a significant effect with polydextrose doses ranging from 4 g to 12 g in healthy subjects.

Increased Stool Frequency
4 out of 6 clinical arms observed a significant effect with polydextrose doses ranging from 4 g to 20 g in healthy subjects.

Improved Stool Consistency
2 out of 4 clinical arms observed a significant effect with polydextrose doses of 8 g and 20 g in healthy subjects.

Reduced Transit Time
0 out of 2 clinical arms observed a significant effect.

Overall, the results show that **polydextrose significantly increases fecal bulk, ease of defecation, and stool frequency**. These findings are generally consistent with those found by Raninen et al. (2011) in their review. The increased fecal bulk is due to the partial degradation of polydextrose and an increase of total bacterial mass observed for fermentable dietary fibers (Rainen et al., 2011).

[1] Studies that evaluated multiple doses were each given equal weight as a separate clinical arm.

The effects on stool consistency are equivocal and it is unclear whether polydextrose has an effect on transit time, as only two studies evaluated this parameter and one of them was statistically underpowered and was conducted in constipated subjects. Observations have shown that constipated patients have lower fecal weight and/or slower transit time, possibly due to motility issues and that the addition of well-known dietary laxatives such as wheat bran and psyllium may not demonstrate a significant effect on either parameter (Müller-Lissner, 1988; Marlett et al., 1987). When evaluating transit time, there are considerable intra-individual differences in healthy adult men and women (Degen and Phillips, 1996). Normal colonic transit times can range between 40 and 60 hours (Degen and Phillips, 1996). A recent analysis of 93 laxation studies of cereal, vegetable and fruit dietary fiber demonstrated that when transit time is already optimal, i.e. between 24 and 48 hours, additional dietary fiber intake does not appear to alter it (deVries et al., 2016). Similarly, increasing dietary fiber intake from 16 to 30 g/day increased stool frequency to about once per day and increasing fiber intake to 42 g/day had no further effect on stool frequency, which remained at once per day (Haack et al., 1998).

Although reduced transit time could not be demonstrated in our review, the positive effect on fecal bulk, ease of defecation and stool frequency provides adequate evidence of the ability of polydextrose to beneficially impact bowel function. The Institute of Medicine notes that diets that increase the number of bowel movements per day, improve the ease of stool passage and increase fecal bulk are considered to be of benefit (IOM, 2002). EFSA (2011) also reports that more frequent bowel movements, increased fecal bulk, softer stools and reduced transit time are beneficial physiological effects. The Academy of Nutrition and Dietetics reports that many dietary fibers impact laxation by increasing fecal bulk, increasing stool frequency and reducing intestinal transit time (Dahl and Stewart, 2015). Slavin (2013) states that fiber is important for laxation, due primarily to the ability of fiber to increase stool weight; larger softer stools increase the ease of defecation and reduce intestinal transit time. Health Canada (2012) suggests improvement in laxation is synonymous with an increase in fecal bulk.

Increasing fecal bulk is an important component of laxation. In fact, psyllium or isphagula husk is commonly known and used as a fecal bulk forming laxative (Muller-Lissner and Wald, 2010). Furthermore, research suggests a significant relationship between fecal weight and colon cancer (Burkitt et al., 1971; Cummings et al., 2004), and diverticular disease (Painter et al., 1971; Cummings et al., 2004). Fecal weights of around 100 g/day were associated with a higher risk of colon cancer, whereas fecal weights of around 150 g/day reduce the risk to about 50% (Cummings et al., 2004). Both Timm et al. (2013) and Vester Boler et al. (2011) reported fecal weights of greater than 150 g/day when 20 to 21 g/d of polydextrose were consumed by healthy subjects.

Table 4.3.1-1. Summary of Polydextrose Laxation Studies

Reference	No. of Subjects/ Study Design	PDX Dose	Increased Fecal Bulk[1]	Improved Stool Consistency	Increased Ease of Defecation	Increased Stool Frequency	Reduced Transit Time
High Quality Clinical Study							
Timm et al., 2013	36 healthy adults (crossover)	20 g	yes	yes	-	yes	no
Moderate Quality Clinical Studies							
Costabile et al., 2011	31 healthy adults (crossover)	8 g	-	yes	-	-	-
Jie et al., 2000*	120 healthy adults (parallel)	4 g	no	-	yes	yes	-
		8 g	yes	-	yes	yes	-
		12 g	yes	-	yes	yes	-
Vester Boler et al., 2011	21 healthy adult males (crossover)	21 g	yes	no	-	no	-
Tate & Lyle, unpubl.	51 subjects with mild constipation (parallel)	18 g	yes	no	no	no	(no)[2]
Low Quality Clinical Studies							
Achour et al., 1994*	7 healthy adult males (fixed sequence)	30 g	trend	-	-	-	no
Endo et al., 1991*	8 healthy adults (fixed sequence)	15 g	yes	-	-	-	-
Hengst et al., 2008	45 healthy adults (parallel)	8 g	(no)[2]	(no)[2]	(yes for constipated Ss)[2]		(yes)[3]
Saku et al., 1991	61 healthy adults (fixed sequence)	15 g	yes	yes	-	-	-
Shimada et al., 2015	29 hemo-dialysis adlts (paralle)	10 g	-	no	-	yes	-
Tomlin and Reed, 1988*	12 healthy males (crossover)	30 g	yes	no	-	no	No

Table 4.3.1-1. Summary of Polydextrose Laxation Studies (Cont'd.)

Reference	No. of Subjects/ Study Design	PDX Dose	Increased Fecal Bulk[1]	Improved Stool Consistency	Increased Ease of Defecation	Increased Stool Frequency	Reduced Transit Time
Combination Clinical Studies							
Beards et al., 2010a	40 healthy adults (parallel)	22.8 PDX + maltitol	-	no	-	no	-
		34.2 PDX + maltitol		no		no	
		45.6 PDX + maltitol		no		no	
Magro et al., 2014	47 constipated adults (parallel)	3.6 g PDX + 10^9 cfu *L. acidophilus* + 10^9 cfu *L.*	-	-	-	no	yes

All outcome measures are based on significant ($p < 0.05$) changes compared to a control unless otherwise indicated. Trend represents a p value $p < 0.1$. [1]Stool bulk as measured by any of the following: total fecal weight, wet fecal weight, dry fecal weight, or fecal volume. [2]Study was underpowered to detect a statistical difference in transit time. [3]Results based on significant changes compared to baseline period. Dashes indicate the variable was not measured.

4.3.2 Clinical Studies - Laxation Effect of Polydextrose

Eleven studies have examined the laxative effect of polydextrose and five of these (Timm et al., 2013; Costabile et al., 2011; Jie et al., 2000, Vester-Boler et al., 2011; Tate & Lyle, unpublished;) were high quality and moderate quality studies. Two additional studies evaluated polydextrose in conjunction with other components (Beards et al., 2010a; Magro et al., 2014).

High and Moderate Quality Studies

Timm et al. (2013) investigated the independent consumption of 20 g/d of polydextrose on gastrointestinal function in 36 healthy adults utilizing a randomized, double-blind, placebo-controlled crossover design (Table 4.3.2-1). Subjects consumed each supplement incorporated

into breakfast cereal and a muffin, or the same products formulated with no fiber (placebo control) for ten days. A two-week washout occurred between each phase. Subjects kept a stool diary during each intervention. Fecal samples were collected on the last five days of the intervention. On days 1, 2, and 10 of each period, subjects completed a gastrointestinal tolerance survey using a 10-point scale that had been used in previous studies. Polydextrose significantly increased 5-day stool wet weight and the number of stools (by one) for the same period compared to the placebo control ($p < 0.05$, both). Stool consistency measured using the Bristol Stool Form Scale was softer ($p < 0.05$) with polydextrose intake. No differences were observed in whole gut transit time between polydextrose and the placebo control.

Table 4.3.2-1. Research Summary of Timm et al. (2013)

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test and Control Products	Results	Quality Grade (QG), Comments
Timm et al. 2013	To examine the effect on PDX or soluble corn fiber on GI function in healthy adults	36 healthy US adults (18 M, 18 F) Mean age: 25.8 y BMI:23.3 kg/m^2	Randomized, double-blind, placebo controlled crossover study. Ss consumed study supplement for 10 days during each of 3 periods. A 2 wk washout period occurred between each treatment. Ss kept a stool diary during each period. A single dose of radioopaque markers were swallowed on day 6 and fecal samples were collected for the last 5 days of each treatment. Stool consistency was rated by Ss using the Bristol Stool Form Scale. Ss also completed self-reported GI tolerance survey on days 1, 2, and 10 of each treatment period. Each survey consisted of 7 questions related to flatulence, bloating, cramping, stomach noises, constipation, and diarrhea. The scale was based on a 0-10 point scale that was published in Stewart et al., 2010. The sum of the 3 d was used to determine the tolerance of each treatment. Diet records were kept on d1, 2, and 10.	Breakfast cereal + muffin containing: 20 g/d PDX (Sta-Lite®, Tate & Lyle) 20 g/d soluble corn fiber (Tate & Lyle) No fiber breakfast cereal + muffin (Placebo/NFC)	Over a 5-day period: PDX / NFC Total stool weight (g): 830[a] / 623[b] No. of stools: 5.5[a] / 4.4[b] Weight/stool (g): 163 / 150 Stool weight/day (g): 166[a] / 125[b] Fecal weight/ g fiber: 2.07 / - 80% Transit time (h): 50 / 52 Stool consistency: 4.64[a] / 3.86[b] Over a 3-day period: Gastrointestinal tolerance Flatulence: 2.86[a] / 2.06[b] Bloating: 1.23 / 1.19 Cramping: 0.58 / 0.49 Borborygmi: 1.25[a] / 0.74[b] Nausea: 0.08 / 0.15 Constipation: 0.34 / 0.47 Diarrhea: 0.24 / 0.09 Values with a different letter are significantly different ($p < 0.05$) within each row.	QG: High No sig. differences in background dietary fiber intake between periods. Measures of compliance were not reported, but retention rate of Ss was 100%.

Costabile et al. (2011) evaluated the effects of 8 g/d of polydextrose on fecal microbiota, gastrointestinal symptoms and stool characteristics in 31 healthy British adults (Table 4.3.2-2). A randomized, double-blind, placebo-controlled, crossover design was used that required subjects to consume polydextrose or maltodextrin (placebo) for 3 weeks followed by a washout period of 3 weeks. Subjects kept diaries throughout the study to record stool frequency and consistency, as well as gastrointestinal disturbances. Fecal samples were collected at baseline, after polydextrose and placebo intake, and after the washout period. The number of stools did not differ between the two intervention periods, but a greater proportion of the subjects observed more formed (versus hard or soft) stools during the polydextrose period than during the placebo period ($p < 0.01$).

Table 4.3.2-2. Research Summary of Costable et al. (2011)

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test and Control Products	Results	Quality Grade (QG), Comments
Costabile et al., 2011	To determine the impact of PDX on fecal microbiota. GI symptoms and stool characteristics were also assessed.	31 healthy British adults (16 F, 15 M) Mean age: 33 y BMI: 24.1 kg/m^2	Randomized double blind, placebo-controlled, crossover study. For a period of 14 d, Ss refrained from consuming yoghurt, prebiotic supplements and probiotics. The first group consumed PDX for 3 wk and after a 3 wk washout, consumed a placebo for 3 wk. The second group received placebo for the first 3 wk, followed by a 3 wk washout, consumed PDX for 3 wk. Ss kept diaries throughout the study to record stool frequency, consistency (constipation, hard, formed, soft stool or diarrhea), abdominal pain (none, mild, moderate, or severe), intestinal bloating (none, mild, moderate, or severe) and flatulence (none, mild, moderate, severe) on a daily basis. Any medication and adverse effects were recorded. Fecal samples were collected at 5 different points: at baseline, after PDX intake, after washout 1, after maltodextrin intake, and after washout 2.	8 g/d PDX powder (Litesse Ultra, Danisco) 8 g/d maltodextrin (Placebo)	Stool Consistency (%) Stools/d — Hard — Formed — Soft PDX 1.3 — 7.8 — 69.7[b] — 22.5 Placebo 1.5 — 12.7 — 57.2 — 30.1 Abdominal Discomfort (%) None — Mild — Moderate — Severe PDX 83.5[a] — 13.4 — 2.5 — 0.5 Placebo 70.4 — 21.4 — 6.6 — 1.7 Bloating (%) None — Mild — Moderate — Severe PDX 76.4 — 17.3 — 4.9 — 1.3 Placebo 68.8 — 23.6 — 6.5 — 1.2 Flatulence (%) None — Mild — Moderate — Severe PDX 40.9 — 43.7 — 11.7 — 3.8 Placebo 45.0 — 36.4 — 14.7 — 3.8 Significant differences bet. PDX and placebo: a:$p < 0.05$; b: $p < 0.01$	QG: Moderate Diet records were not kept by Ss and it is not clear whether compliance was monitored.

Jie et al. (2000) conducted a randomized, parallel-group, double-blind, placebo-controlled study to determine the physiological effects of 4, 8, and 12 g /d of polydextrose in 120 healthy adult Chinese subjects (Table 4.3.2-3). Bowel function was one of the parameters measured. Subjects were randomized into a placebo group and three groups based on the dose of polydextrose for 28 days. Meals were provided to the subjects at baseline (days -4 to -1) and on days 26-28 of the intervention and a 3-day pooled fecal sample was collected during both these periods. During the intervention phase, subjects kept diet records and also recorded stool frequency, ease of defecation and gastrointestinal disturbances. Subjects made weekly clinic visits for biochemistry tests and to ensure compliance. Compared to the placebo control, stool frequency ($p < 0.01$) and ease of defecation ($p < 0.01$) significantly increased for all the doses of polydextrose tested. Fecal wet weight was significantly higher in the groups that consumed 8 g/d and 12 g/d of polydextrose compared to the placebo control ($p < 0.01$, both). Dry fecal weight was significantly higher than the placebo control for the 12 g/d polydextrose dose ($p < 0.01$). The researchers stated there was a dose response increase in stool frequency, ease of defecation, and in both wet and dry fecal weights after polydextrose intake.

Table 4.3.2-3. Research Summary of Jie et al. (2000)

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test and Control Products	Results	Quality Grade (QG), Comments
Jie et al., 2000 (cited by EFSA as Zhong et al., 2000)	To evaluate the effects of polydextrose (PDX) on glycated hemoglobin, glucose tolerance, glycemic index, bowel function, stool weight and pH, SCFA production, fecal microflora, and cecal mucosa cell proliferation in healthy Chinese subjects	120 healthy adult Chinese 66 M, Mean age: 32.9 y 54 F, Mean age 29.4 y. 0 g PDX: n=30 4 g PDX: n=30 8 g PDX: n=30 12 g PDX: n=30 Age and gender distribution did not differ between groups	Randomized, parallel group, placebo-controlled, double-blind study. Ss were randomized into 4 groups based on the dose of PDX for 28 days. Meals were provided by the clinic during dietary control days: days -4 to -1 and 26-28. Fruit consumption was limited to 1 piece/day. During the treatment phase, Ss recorded foods consumed, daily activities, and any adverse effects. Ss also recorded, stool frequency (no. per day), ease of defecation (scale of -3 to 3), abdominal distention (scale 1 to 10), abdominal cramps, and diarrhea. Ss made weekly visits to the clinic for biochemistry tests and to ensure compliance. Feces (3d pooled sample) was collected on day -1 (baseline) and day 28.	PDX (Litesse, Danisco) dissolved in 100 mL water: 4 g, 8 g, 12 g Placebo product: 0 g PDX, no additional info. provided	<u>Stool Frequency (times/d)</u> <u>PDX:</u> <u>0g</u> <u>4 g</u> <u>8 g</u> <u>12 g</u> day -1 1.04 1.05 1.11 1.05 day 28 1.10 1.47[ab] 1.74[ab] 1.89[ab] <u>Ease of defecation (scale -3 to 3)</u> <u>PDX:</u> <u>0g</u> <u>4 g</u> <u>8 g</u> <u>12 g</u> day -1 -0.21 -0.18 0.20 -0.14 day 28 0.41 1.36[ab] 1.88[ab] 2.35[ab] Most Ss reported a softening of feces and improved ease of defection after ~2 d of PDX. <u>Wet Stool weight (g/d)</u> <u>PDX:</u> <u>0g</u> <u>4 g</u> <u>8 g</u> <u>12 g</u> day -1 103 106 101 98 day 28 106 115 128[ad] 142[ab] <u>Dry Stool weight (g/d)</u> <u>PDX:</u> <u>0g</u> <u>4 g</u> <u>8 g</u> <u>12 g</u> day -1 32.2 34.0 31.5 29.6 day 28 34.5 38.3 41.8[d] 47.8[ab] [a]Significantly different from control, $p < 0.01$ [b]Significantly different from day -1, $p < 0.01$ [c]Significantly different from control, $p < 0.05$ [d]Significantly different from day -1, $p < 0.05$ There was a dose response increase in stool frequency, ease of defecation, and in both wet and dry stool weights (statistical tests between PDX doses not shown) <u>GI discomfort</u> No significant differences between groups in ratings of abdominal distension and no reports of abdominal cramps and diarrhea (data not provided).	QG: Moderate No info. on how Ss were recruited, and whether there were any dropouts. No info. on what the control product was. Meals were provided to the Ss during baseline, prior to intervention (days -4 to -1) and during the last days of the intervention (days 26-28). Fecal collection occurred during these periods. This feature prevented other dietary variables impacting the outcome. Unclear if info. on stool frequency, ease of defecation, abdominal distention etc. was recorded daily or only on days fecal collection occurred.

In a randomized, double-blind, placebo-controlled crossover trial, Vester Boler et al. (2011) investigated the effects of 21 g/d of polydextrose in 21 overweight, healthy adult men (Table 4.3.2-4). Snack bars containing polydextrose, soluble corn fiber, or no fiber (placebo) were consumed at breakfast, lunch, and dinner for 21 day periods. Subjects kept daily diet and stool records throughout the study. Stool consistency and ease of defecation were evaluated on a 5-point scale and gastrointestinal tolerance variables were measured on a 4-point scale. Food intake, including fiber intake, did not differ among the three treatments. Ease of stool passage, stool consistency, and the number of defecations also did not differ among the three periods. Polydextrose did not significantly increase 5-day fecal wet weight compared to the no fiber control, but 5-day dry fecal weight was significantly higher ($p < 0.05$). Not all the subjects collected a fecal sample on all 5 days, but all subjects collected a sample for 4 days.

Table 4.3.2-4. Research Summary of Vester Boler et al. (2011)

Study	Purpose	Subjects (Ss)	Study Design, Method[1], Duration	Test and Control Products	Results	Quality Grade (QG), Comments
Vester Boler et al., 2011	To determine the effects of PDX and soluble corn fiber (SCF) on laxation, bowel fermentation and microbiota compared to a no fiber control (NFC).	21 healthy overweight US adult men with an avg. intake of 13-15 g DF Mean age: 27.5 y BMI: 27 kg/m^2 Of the 25 Ss enrolled, 3 were removed (due to moving away, starting medication restricted in study) prior to the initiation of the study. One Ss was removed during the initial tolerance study due to watery stools throughout the study, prior to the initiation of this study.	Randomized, double-blind, placebo controlled crossover study (Latin square design). No washout between periods. There were 3 periods of 21 days, with 16 days of adaptation followed by 5 days of fecal collection. Ss consumed 3 treatment bars per day--one at breakfast, lunch, and dinner. Ss kept daily diet and stool records. They also recorded the date, time, consistency and ease of each bowel movement. Stool consistency was scored as: 1=hard, dry pellets – small, hard mass; 2=hard formed, dry stool – remains firm and soft; 3=soft, formed, moist – softer stool that retains shape; 4=soft, unformed – stool assumes shape of container; and 5=watery – liquid that can be poured. Ease of stool passage was ranked on a 5-point scale (1=very easy, 2=easy, 3=neither easy nor difficult, 4=difficult, 5=very difficult). Ss also ranked subjective tolerance variables daily: burping, cramping, bloating, flatulence, nausea, reflux, and vomiting (1=none, 2=mild, 3=moderate, 4=severe).	Three snack bars/day containing a total of 21 g PDX (Litesse II, Danisco) Three snack bars/ day containing no fiber (Placebo)	NFC PDX Ease of stool passage 2.60 2.52 Stool consistency 2.93 3.06 No. defecations/period 23.9 25.2 Fecal 5d wet weight (g) 735.2 809.0 Fecal 5 d DM weight(g) 155.9^a 184.8^b Fecal 4 d wet weight(g) 593.7 693.0 Fecal 4 d DM weight(g) 129.2^x 158.3^y Fecal mass per g fiber - 4.3 Fecal mass per g fiber, DM - 1.4 ^{ab}Mean values within a row with unlike superscript letters were significantly different ($p < 0.05$) ^{xy}Mean values within a row with unlike superscript letters were significantly different ($p < 0.10$) NFC PDX Gastrointestinal tolerance Burping 1.24 1.28 Cramping 1.11 1.20 Distension 1.33^x 1.52^y Flatulence 1.83^a 2.23^b Nausea 1.00 1.00 Reflux 1.03 1.03 Vomiting 1.00 1.00	QG: Moderate No washout between periods. Macronutrient intake did not differ between periods. Compliance was excellent. Both 5 d and 4 d fecal weights were reported because some Ss forgot to collect a sample on the first day.

Tate & Lyle (unpublished) investigated the effect of polydextrose on total fecal wet weight over a 4-day collection period in 73 mildly constipated men and women using a randomized, double-blind, placebo-controlled crossover design (Table 4.3.2-5). Secondary outcomes included average fecal wet weight (g/day), total fecal dry weight (g/4 days), average fecal dry weight (g/day), defecation frequency, stool consistency, total colonic transit time and ease of stool passage. The study began with a two-week run-in period, four-week intervention, and a six to eight-week washout period. During the treatment phase, subjects consumed 18 g of polydextrose a day in the form of a powdered drink (6 g polydextrose/serving), made with water, two times a day and a serving of three biscuits (6 g polydextrose/serving) once a day. In the control phase, maltodextrin replaced polydextrose in the study products. Subjects kept a daily diary of study product intake and collected stool for four days following three weeks of product consumption. Colonic transit time was measured by a radio-opaque marker the subjects consumed on the fourth day of stool collection. Ease of stool passage was reported by subjects in a questionnaire. Stool consistency was determined by investigators using the Bristol Form Scale. Dietary fiber intake was assessed by nutritionists who questioned subjects using a standardized questionnaire during the run-in, intervention and washout periods. A 24-hour dietary recall was also administered at the same time. Analysis of the data indicated there was a significant crossover and period effect and therefore the results and statistics were reported as a parallel design for a sample size of 51 subjects. Total fecal dry weight ($p=0.044$) and total fecal wet weight ($p=0.047$) was significantly higher for the polydextrose phase than for the control. Stool consistency, defecation frequency, and ease of stool passage were not significantly affected by polydextrose consumption. Total colonic transit time was about 4 hours shorter in the polydextrose group compared to the placebo group, but the difference did not reach statistical significance because the study was underpowered to detect a statistical difference for this measurement. The sample size was determined to detect a difference of 20 g in mean daily fecal bulk between treatments. The researchers indicate that in general, any increase in transit time could be considered beneficial. A decrease in transit time and increased fecal bulking may be beneficial in diluting potential carcinogenic material that may come into contact with the colonic epithelium.

The researchers noted that a dose of 18 g of polydextrose increased fecal bulk by approximately 120 g or 42% over four days compared to the control products. This translates to an increase in stool weight of 30 g/day. It has been suggested that an increase in stool weight of about 50 g/day or from 100 g/day to 150 g/day following fiber consumption may decrease the risk of colon cancer by about 50% (Cummings et al., 1992).

Table 4.3.2-5. Research Summary of Tate & Lyle, Unpublished, 2016.

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test and Control Products	Results	Quality Grade (QG), Comments
Tate & Lyle, unpublished.	To investigate the effect of PDX on total fecal weight (g/4 d) in mildly constipated subjects. Secondary objectives were avg. fecal wet wt. (g/d), total fecal dry weight (g/4 d), avg. fecal dry weight (g/d), stool frequency, stool consistency, colonic transit time, and ease of stool passage.	73 mildly constipated men and women in Finland and Sweden randomized Mildly constipated: 3-5 bowel movements/wk 21 Ss withdrawn; 11 (PDX), 10 (C) due to Ss request (7), protocol and inclusion criteria violations (such as antibiotic or other medication use) (8), not meeting criteria (3), poor compliance (1), and side effects (2). Ss that completed the study included in ITT (crossover/ parallel): n=52; 13 M, 39 F; avg. age: 47.9 y; BMI: 24.9 kg/m^2 1 Ss excluded from ITT due to repeated diarrhea: n=51 Ss protocol (parallel design, PP); 11 M, 38 F; avg. age: 48.8 y; BMI: 25 kg/m^2	Randomized, double-blind, placebo-controlled, crossover* design with a 2 wk run-in period, 4-wk intervention, and 6-8 wk washout period. During each intervention period, Ss collected stools for 4-d after 3 wk of study product consumption. Colonic transit time as measured by a radio-opaque marker technique on the 4th day. Ease of stool passage and GI tolerance were determined by Ss questionnaire. Stool consistency was assessed by investigators using the Bristol Stool Form Scale (BSF) at run-in, Tx period, and washout. Nutritionists assessed DF intake with a questionnaire by interviewing Ss at run-in, washout and end of Tx periods. Dietary intake was assessed by 24-hr recall at the same time as the DF questionnaire. Ss recorded daily intake of study products.	Sachet of drink mixture mixed with water 2x/d and 3 biscuits/d (one svg/d): 18 g/d PDX (Tate & Lyle) Maltodextrin (C: control)	*Total fecal wet weight* (g/4 d) was significantly higher for PDX (406.7) vs. C (286), p=0.047. This was equivalent to 101.7 g/d for PDX and 71.5 g/d for C. *Total fecal dry weight* (g/4 d) was significantly higher for PDX (110.4) vs. C (84.7), p=0.044. *Stool consistency*: ns. BSF score increased by 0.3 units for PDX and 0.7 for C. *Defecation frequency*: ns Freq. increased by 1/wk for PDX vs. 0.7 for C. *Ease of stool passage*: ns No diff. bet. groups in subjective feeling of ease of stool passage. *Total transit time (TT)*: ns TTT was 4 h shorter for PDX vs. C. The diff. did not reach statistical sig., since the study was underpowered to detect a statistical diff. for this secondary measurement. *Background DF intake*: ns *PDX was well tolerated*. There were no sig. diffs. for burping, abdominal cramping, abdominal distension/bloating, nausea, reflux, or vomiting between PDX and C groups. Flatulence (mild) was higher in the PDX group (2.7) vs. the C group (2.1), p=0.008. (GI tolerance score scale ranged from 1=none to 4=severe).	QG: Moderate Large number of Ss were withdrawn due to protocol deviations (many for antibiotic use). Also for unknown reasons, there was a significant carryover effect, possibly due to seasonal variation. Constipated Ss generally have either lower fecal wt. and/or slower TT, possibly due to motility issues. Sample size was determined on the basis of detecting a diff. of 20 g/d in mean daily stool bulk. *Because crossover/period effects were statistically significant after the washout period, the results of the 2nd intervention could not be used. Therefore, results and statistics of the study are reported as a parallel design, including only the first intervention period. Compliance was 98.9% in PDX group and 98% in C group.

Low Quality Studies

Appendix 8.1 provides the tabular research summaries for the six studies that had significant methodology concerns (Achour et al., 1994; Endo et al., 1991; Hengst et al., 2008; Saku et al., 1991; Shimada et al., 2015; Tomlin and Read, 1988). The following is a summary of each study.

The acute and chronic gastrointestinal effects of 30 g/d of polydextrose was tested by Achour et al. (1994) in 7 healthy French men enrolled in a fixed sequential study. The first 8 days were the control period, followed by an acute period of 9 to 16 days of polydextrose intake and a chronic period of 17 to 38 days of polydextrose intake. Subjects consumed all their meals at the study site during days 1 to 16 and 31 to 40. The controlled diet was moderate in fiber and free of pits and skins to limit fiber intake. During days 17 to 30, subjects ate their usual diet at home. Mean transit time was measured for 3 consecutive days on day 5, 13, and 35. On days 5 to 8, 13 to 16, and 35 to 38, subjects recorded any symptoms and collected feces. An attempt was made to collect flatus on days 13 and 35 for a 12-hour period by all subjects, but collection was complete only for 3 subjects. Results indicated a trend ($p = 0.06$) towards a higher fecal weight during both the acute and chronic polydextrose periods compared to the control period. No significant differences were observed in fecal dry weight, fecal water, or transit time between the control and polydextrose periods. This study was given a "low" quality rating because it was not a randomized study, no placebo-control was used, and the sample size was very small.

Endo et al. (1991) conducted a fixed sequential study in 8 healthy Japanese adults to determine the effect of a high cholesterol diet and 15 g/d polydextrose (source not specified) on gut microflora and bacterial enzyme activity. All subjects were given a low cholesterol diet for 2 weeks, followed by a high cholesterol diet for 2 weeks and an additional 2 weeks of a high cholesterol diet with polydextrose. Five-day food records were kept for each dietary period. Fecal specimens were collected from each subject during the last 6 days of each dietary period. Daily fecal output (g wet weight) increased significantly ($P < 0.05$) during the polydextrose period compared to the previous period with no polydextrose. Several limitations of this study included the lack of randomization, no placebo control, low number of subjects, and methods

used for statistical analysis were not reported. In addition, the fecal output data was not summarized for each period but was presented in such a way that it is difficult to decipher significance values.

Forty-five healthy German adults participated in a randomized, parallel-group, placebo-controlled study to evaluate the prebiotic and laxative effects of 8 g/d of polydextrose consumed in yoghurt (Hengst et al, 2008). The placebo consisted of the same yoghurt without polydextrose. At study entry, subjects kept 5-day diet records to determine usual food intake. After a baseline stool sample, subjects consumed the placebo for a 2-week run-in followed by an intervention period where subjects consumed either polydextrose or placebo for 3 weeks. Subjects were then followed for an additional 3-week washout period. At the end of each period, at least 3 stool samples were collected. Stool consistency was assessed with the Bristol stool form scale. Transit time was also measured for each period. Statistical analyses were performed for each period compared to the period before. For both the polydextrose and placebo groups, stool weight did not significantly differ among the run-in, intervention, and washout periods. Transit time, however, was significantly lower during the intervention period compared to the run-in period for the polydextrose group. In the placebo group, transit time was significantly lower during the washout period compared to the intervention period. Stool consistency was not affected by polydextrose intake, but subjects suffering from constipation reported improved ease of defecation after polydextrose consumption. This study was given a "low" rating because the statistical analyses performed evaluated only changes within a group and not between the polydextrose and placebo groups. Another limitation was that subjects only kept diet records on entry into the study and not during the course of the study.

The primary aim of the fixed sequential study by Saku et al. (1991) was to investigate the effects of 15 g/d polydextrose (source not specified) on serum lipids and lipoproteins in 61 healthy Japanese adults. Subjects consumed polydextrose for 2 months followed by a third month when polydextrose was not consumed. During this period subjects were instructed to maintain their normal daily lifestyles. Each month subjects were asked about bowel movements and stool characteristics. Compliance with consuming polydextrose was checked by interview

each month. Polydextrose intake at one month resulted in 56 % of the subjects reporting diarrhea or soft feces and 53 % at two months compared to 14 % post-treatment. At one and two months of polydextrose intake, 18 % and 15 % of subjects respectively, reported an increase in fecal volume compared to 0% of subjects' post-treatment. Both fecal characteristics and fecal volume were statistically different ($p < 0.01$) after polydextrose administration compared to the period without polydextrose. Results of this study were compromised by the absence of randomization, no placebo control, no diet records, and no details on how subjects were questioned about bowel movements and fecal characteristics. Specifically, it is unknown how subjects estimated fecal volume and whether subjects had to reflect over an entire month when they were interviewed.

Shimada et al. (2015) evaluated the effects of 10 g of polydextrose in 29 Japanese hemodialysis patients utilizing a randomized placebo-controlled, triple-blind, parallel-group study. Subjects were stratified by age, gender, and hemodialysis history. They consumed the polydextrose or placebo jelly for four weeks and kept daily records of stool frequency, stool consistency and gastrointestinal symptoms. During the polydextrose treatment, stool frequency significantly increased compared to the placebo ($p < 0.05$); stool consistency however, did not differ between the two groups. This study was compromised because some subjects consumed laxatives and many medications that hemodialysis patients are required to take cause constipation. Furthermore, dietary intake was not monitored during the intervention, only before and after.

Tomlin and Read (1988) compared the laxative effects of polydextrose and ispaghula (psyllium) and mixtures of the two substances in 12 healthy male British adults. Two studies were performed. In the first study, the first 10 days was the control period followed by three periods of 10 days of supplementation separated by a one-week washout period. Subjects randomly consumed 7 g/d ispaghula, 30 g/d polydextrose or a mixture of 2 g/d ispaghula and 30 g/d polydextrose. A similar protocol was implemented for a second study, except that subjects were randomized to receive 7 g/d ispaghula or mixture of 2 g/d ispaghula and 10 g/d polydextrose. During each 10-day period, all stools passed were collected and subjects rated

stool amount, stool frequency, and stool consistency. In study 1, fecal mass measurements were significantly higher ($p < 0.05$) during the ispaghula, the 30 g/d polydextrose, and the ispaghula plus 30 g/d polydextrose periods than during the control period. Additionally, stool consistency was reported to be significantly softer ($p < 0.05$) with 30 g/d polydextrose or with the ispaghula plus polydextrose mixture than during the control period, or with ispaghula alone. Transit time and stool frequency were not significantly impacted in study 1. Results of study 2 are not reported because polydextrose was not independently evaluated. This study received a "low" quality rating because no placebo control was used and randomization involved only the ispaghula and polydextrose treatments and not the control. In addition, subjects did not keep diet records to ensure that food habits did not significantly differ between study periods.

Combination Studies

Appendix 8.2 summarizes two studies that used combinations of polydextrose and other dietary components (Beards et al., 2010a; Magro et al., 2014). These studies were included in our review because in consumer food products, polydextrose is often formulated with other ingredients. Therefore, it is important to evaluate whether there are potential ingredient synergies in improving laxation.

Beards et al. (2010a) conducted a randomized, parallel-group, placebo-controlled, double-blind study in 40 healthy adults to assess the prebiotic potential of chocolate containing blends of maltitol and polydextrose or resistant starch. Increasing doses of maltitol + polydextrose (22 g, 34 g, 46 g) were consumed in a step-wise fashion over a 45-day period. Results indicated no significant changes in stool frequency or consistency with the combined intake of maltitol and polydextrose. There were several limitations to this study. Laxation was not a primary focus of the study; the dose of polydextrose in each maltitol combination was not reported; there were only 10 subjects per group; no diet records were kept and no information was provided regarding dropout rate (if any) or compliance.

Magro et al. (2014) investigated the combined effect of polydextrose and *L. acidophilus* + *B. lactis* on intestinal transit in 47 constipated adults. A randomized, controlled, double-blind, parallel-group study was performed. Subjects consumed yogurt containing 3.6 g polydextrose + 10^9 cfu *L. acidophilus* + 10^9 cfu *B. lactis* or yogurt with no additional ingredients for 14 days. A colonic transit marker capsule was consumed by subjects for 3 days prior to day 0 and just prior to day 14. Results indicated a shorter transit time for the polydextrose probiotic group compared to the control group (p=0.01). The Agachan score, a measure for constipation was significantly reduced in both groups, but tended to be better in the treatment group. However, the number of bowel movements did not differ between the groups.

4.4 Evidence of Decreased Energy Intake at Subsequent Meal

4.4.1 Overview– Decreased Energy Intake Effect of Polydextrose

The effect of polydextrose on energy intake at lunch was tested when consumed as a mid-morning snack in seven clinical trials (Table 4.4.1-1). Six of the studies were of moderate quality (Astbury et al., 2013; Hull et al., 2012; Ranawana et al., 2013; King et al., 2005; Soong et al., 2016; Monsivais et al., 2011); the seventh could not be evaluated because it was published only as an abstract (Astbury et al., 2008). One additional study investigated polydextrose combined with another dietary component (Astbury et al., 2014).

Results from the six high and moderate quality studies observed the following:

Reduced Energy Intake at Next Meal

7 out of 9 clinical arms[2] observed a significant reduction of energy intake at lunch when polydextrose doses ranging from 6 g to 25 g was consumed as a mid-morning snack in healthy

[2] Studies that evaluated multiple doses were each given equal weight as a separate clinical arm.

subjects. One additional study published only in abstract form also observed a significant effect with a polydextrose dose of 25 g.

A meta-analysis confirmed the overall finding of a beneficial effect (Ibarra et al., 2015). The meta-analysis also indicated that the dose of polydextrose was significantly correlated with energy reduction at the next meal.

Table 4.4.1-1. Summary of Polydextrose and Energy Intake at Next Meal

Reference	Subjects/ Study Design	PDX Dose	Decreased Energy (E) Intake at Next Meal[1]
Moderate Quality Clinical Studies			
Astbury et al., 2013	21 healthy adults (crossover)	6.3 g	yes[2]
		12.5 g	yes[2]
		25 g	yes[2]
Hull et al., 2012	34 healthy adults (crossover)	6.25 g	no
		12.5 g	yes
Ranawana et al., 2013	26 healthy males (crossover)	12 g	yes
King et al., 2005	15 healthy adults (crossover)	25 g	yes (when E differential was taken into account)
Soong et al., 2016	27 healthy men (crossover)	12 g	yes (calculated E residual)
Monsivais et al., 2011	36 healthy adults (crossover)	24 g	no (vs. low cal, low fiber control)
			no (vs. iso-cal control)
Quality Cannot be Assessed (Abstract only)			
Astbury et al., 2008	14 healthy men (crossover)	25 g	yes
Excluded			
Astbury et al., 2014	10 healthy men (crossover)	6.2 g; whey protein added (confounder)	yes
Meta-Analysis			
Ibarra et al., 2015	6 studies: all administered PDX as a mid-morning snack and measured E intake at an *ad libitum* lunch; Meta-analysis showed consumption of PDX was associated with a significant reduction in E intake at lunch. Dose of PDX correlated significantly with E reduction.		

[1]Significant ($p < 0.05$) changes compared to a control. [2]Increased PDX dose resulted in stepwise reduction in E

4.4.2 Clinical Studies – Decreased Energy Intake Effect of Polydextrose

Seven clinical trials have assessed the effect of polydextrose on energy intake at a subsequent meal. Six of these were moderate quality studies (Astbury et al., 2013; Hull et al., 2012; Ranawana et al., 2013; King et al., 2005; Soong et al., 2016; Monsivais et al., 2011). The quality of one study could not be assessed because it was only reported as an abstract (Astbury et al., 2008). Another study was excluded because it included whey protein in addition to polydextrose as part of the test protocol (Astbury et al., 2014).

Astbury et al. (2013) investigated the effects of 6.3 g, 12.5 g, and 25 g of polydextrose on appetite and subsequent energy intake in 21 healthy adults utilizing a randomized, single-blind, cross-over design with a 7-day washout (Table 4.4.2-1). Subjects fasted after the evening meal the previous day and consumed a breakfast of Rice Krispies and semi-skimmed milk in the morning at 8 a.m. They did not eat or drink anything else except water until they arrived at the testing site at 10:45 a.m. After subjects confirmed that they were compliant to pre-study procedures, they completed baseline appetite ratings. They then were asked to consume the chocolate-flavored preload beverage containing polydextrose or maltodextrin (control) within 15 minutes. All preload beverages were equivalent in energy, protein, carbohydrate and fat. Appetite ratings were completed right after the pre-load meal and 30, 60, and 90 minutes after. Subjects then consumed an *ad libitum* pasta meal and rested for 60 minutes before they were permitted to leave. Food and drink consumed for the rest of the day was recorded by the subjects in a food diary. Increasing the amount of polydextrose in the pre-load was accompanied by a stepwise reduction in energy intake at the lunch meal. Mean energy intake at lunch was significantly higher for the control preload compared to the 6.3 g, 12.5 g or 25 g polydextrose preloads ($p < 0.01$), and the energy intake following the 6.3 g polydextrose was significantly greater than that following the 25 g polydextrose preload ($p < 0.01$). Total energy intake for the day was also significantly higher for the control preload than for the 12.5 g and 25 g polydextrose preloads ($p < 0.05$).

Table 4.4.2-1. Research Summary of Astbury et al. (2013)

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Astbury et al., 2013	To investigate the effects of different doses of PDX in a iso-energetic liquid preload, on subjective appetite and subsequent energy intake in healthy men and women	21 healthy British adults (12 M, 9 F) 12 M Age: 22.5 y BMI: 23.2 kg/m^2 9 F Age: 24.7 y BMI: 22.3 kg/m^2 Prior to participation, Ss kept a 3-d food and activity diary so that habitual E intake and total E expenditure could be estimated.	Randomized, single-blind, cross-over design, with a 7-day washout. Ss did not consume alcohol or exercised rigorously 24 h prior to test day. They were provided a menu of foods and were instructed to consume this meal approx. 20.00 h the evening before each study day. Ss fasted after the evening meal until the morning. A standardized breakfast of Rice Krispies and semi-skimmed milk was provided to Ss to consume at home at 0.8.00 h after which they refrained from eating or drinking (except for water) until they arrived at the lab at 10:45 h. After Ss confirmed that they were compliant to pre-study procedures, they completed baseline appetite VAS ratings. Ss were then given attest liquid pre-load which was consumed in 15 min. Additional appetite ratings were taken right after the meal and 30, 60, and 90 min after. Ss then consumed an *ad libitum* pasta meal and rested in the lab for another 60 min before they were permitted to leave. Ss recorded all food and drink in a food diary for the remainder of the day.	Chocolate-flavored preloads containing: 6.3 g PDX (Litesse Ultra) 12.5 g PDX (Litesse Ultra) 25 g PDX (Litesse Ultra) Maltodextrin (control) All preloads were 837 kJ with exact amounts of protein, CHO and fat.	Both men and women demonstrated a significant main effect of PDX ($p < 0.05$), and there was a significant within-subject linear contrast ($p < 0.05$) in both genders. Increasing the amount of PDX in the preload was accompanied by a stepwise reduction in E intake at the lunch meal. Mean E lunch intake (M+F) after the control preload (5756 kJ) was significantly higher than the preloads containing 6.3 g PDX (5048 kJ), 12.5 g PDX (4722 kJ), or 25 g PDX (4362 kJ) ($p < 0.01$), and intake following the 6.3 g PDX preload was significantly greater than following the 25 g PDX preload ($p < 0.01$). There was a significant effect of gender ($p < 0.05$) on E intake at lunch. Over all four conditions, M consumed more E than women. Total E intake (breakfast + preload + *ad libitum* lunch + remainder of day) was significantly higher when the control preload was consumed (12051 kJ) compared with either the 12.5 g PDX (10854 kJ) or 25 g (10658 kJ) preload ($p < 0.05$).	QG: Moderate Ss were not under observation when they consumed breakfast. Study was single-blind.

Hull et al. (2012) examined the effect of consuming 6.25 g and 12.5 g of polydextrose in a strawberry yoghurt drink mid-morning on subsequent lunch and dinner intake in 34 healthy adults (Table 4.4.2-2). A randomized, placebo-controlled, single-blinded cross-over design was utilized with a glucose syrup control and a one-week washout period. All test meals were identical in energy, protein and fat content. Fasted subjects completed baseline satiety ratings before consuming a habitual portion of cornflakes and semi-skimmed milk with their habitual morning drink (tea/coffee/water) at 8:15 a.m. After breakfast, subjects completed satiety ratings every 30 minutes until prior to the consumption of the polydextrose or control drink at 11.00 a.m. Following the intake of the test meal, subjects completed satiety ratings every 15 minutes for 90 minutes and just prior to an *ad libitum* lunch of cheese and tomato sandwiches at 12:30 p.m. After lunch, subjects completed satiety ratings every 30 minutes until an *ad libitum* meal of pasta and sauce was consumed at 6 p.m. Subjects were permitted to leave after the dinner meal. The results indicated a significant reduction in energy intake at lunch following the mid-morning consumption of 12.5 g polydextrose compared to the control ($p=0.022$). Although there was a reduction in energy intake at lunch following the intake of 6.25 g polydextrose compared to the control, the difference was not statistically significant. There were no significant differences in energy intake at dinner or on the total day's energy intake.

Table 4.4.2-2. Research Summary of Hull et al. (2012)

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Hull et al., 2012	To determine whether consuming PDX in an acute intervention can show a response of satiety and energy intake over a whole day.	34 healthy adults 10 M Age: 32.8 y BMI: 23.8 kg/m^2 24 F Age: 38.7 y BMI: 22.5 kg/m^2	Randomized, single-blinded, placebo-controlled, cross-over design. Each Ss visited the lab 3x with a 1 wk washout period between each visit. Prior to each visit, Ss were not allowed to consume anything after 20.00 h and recorded everything eaten between 18.00 and 20.00 h. They also abstained from alcohol and vigorous exercise 24 h prior to the test. On arrival on test day, Ss completed baseline satiety ratings. At 8:15 a.m., Ss poured their own habitual portion of cornflakes and semi-skimmed milk (this was weighed the same amount was given to them for the remaining two tests to give a self-regulated standard baseline). Ss also were given their habitual morning drink (tea/coffee/water) and instructed to drink all of it (200 ml). Breakfast was to be consumed in 15 minutes and Ss were required to remain at the lab for the rest of the day. Questions on satiety were asked every 30 min until prior to consumption of the test fiber or control product at 11.00 h. Test meal was consumed in 15 minutes and satiety questions were asked at 15 min intervals for 90 min immediately prior to 30 min *ad libitum* meal of cheese and tomato sandwiches at 12:30. After the meal, Ss completed satiety ratings at 30 min intervals until 18.00 h when they were served a 30 min *ad libitum* meal of pasta and sauce. Immediately after the meal, Ss were free to leave.	200 g strawberry flavor drinking yoghurt to which one of the following was added: 6.25 g PDX (Litesse syrup) 12.5 g PDX (Litesse syrup) Glucose syrup (control) All test meals provided the same energy, protein, and fat content.	*Ad Libitum* Lunch (kJ) / Dinner (kJ) / Total E Intake Control: 3195 / 3268 / 8409 6.25 g PDX: 3060 (4.2%) / 3261 (0.2%) / 8264(1.7%) 13.5 g PDX: 2977[a](6.8%) / 3176 (2.8%) / 8121 (3.4%) [a]sig. diff. from control (p=0.022). Percentage reduction from the control is shown in brackets.	QG: Moderate Single-blinded study

Ranawana et al. (2013) conducted a repeated measures single-blind randomized cross-over study with a minimum of a 2-day washout period to investigate the effects of polydextrose on satiety and short-term energy intake (Table 4.4.2-3). Twenty-six healthy males consumed on two separate days a commercial fruit smoothie with 12 g of polydextrose or the same product without polydextrose. Subjects were advised to eat a meal of similar size and composition for dinner on the evenings prior to both test days. They arrived at the lab after a 10 hour overnight fast and consumed breakfast where they could select any combination and quantity of the same foods on both test days. Subjects were told not to eat anything except 250 ml of water and to return after 3 hours for the test smoothie preload. An *ad libitum* lunch was consumed one hour later where the exact amount of foods consumed was recorded by the researchers. Subjective satiety ratings were completed by the subjects before and one hour after breakfast, before the test smoothie and 15, 30 and 45 minutes after the smoothie, and before and after lunch. A significantly lower (~10%) energy intake was observed at lunch following polydextrose intake compared to the control ($p=0.007$). Carbohydrate ($p=0.011$), fat ($p=0.035$) and fiber ($p=0.016$) intakes at lunch were also significantly lower during the polydextrose period compared to the control period.

Table 4.4.2-3. Research Summary of Ranawana et al. (2013)

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Ranawana et al., 2013	To determine the effects of PDX on short-term satiety and energy intake	26 healthy males Age: 28 ± 7 y, BMI: 24.1 kg/m^2	A repeated-measures single-blind randomized cross-over design with Ss returning on 2 separate days. A gap of at least 2 d was maintained between the sessions. Ss were asked to restrict their intake of alcohol and caffeine and intense physical activity before each session. Ss were advised to eat a meal of similar size and composition for dinner on the evenings prior to both test days. Ss arrived at the lab after a 10 h overnight fast and consumed breakfast. Select foods were provided for breakfast and Ss could select any combination and quantity as long as the same foods and amounts were eaten at both test sessions Ss were told not to eat anything except for 250 ml water and to return after 3 h for the smoothie preload. Lunch was consumed 1 h after. Lunch was served *ad libitum* and Ss were presented with 6 sandwiches that were continuously replenished. Ss were unobtrusively watched during lunch and all plate waste was recorded. Subjective ratings for hunger, fullness, desire to eat and prospective food consumption were obtained with VAS scales before and 1 h after breakfast, before the smoothie, 15, 30 and 45 min after the smoothie, before and after lunch.	383 g commercial fruit smoothie + 12 g PDX (17 g Litesse , 211 kcal 400 g commercial fruit smoothie (control), 208 kcal	Ss rated both the treatment and control smoothies as equally tasty and pleasant. The control and treatment produced similar ratings of subjective hunger, fullness, desire to eat and prospective food consumption sensations. Energy intake at lunch differed between the control and PDX treatment. A significantly lower food intake was observed at lunch following PDX compared to the control (p=0.007). Consumption of PDX reduced calorie intake of ~100 kcal compared to the control. This equated to a E difference of 10%. During PDX and control periods there were also significant differences in carbohydrate (p=0.011), fat (p=0.035), and fiber intake (p=0.016) at lunch. The protein content showed a trend towards a significant difference (p=0.054)*. All four nutrients were consumed in greater amounts in the control period compared to the PDX period.	QG: Moderate Ss were permitted to leave after breakfast before they consumed the smoothie preload. This period was not monitored and Ss could have consumed something. Study was single-blind. *Discrepancy between Table which indicated p < 0.05 and text which says p=0.54.

A counter-balanced, controlled, repeated measures study with a one-week washout period was conducted by King et al. (2005) in 15 healthy adults (Table 4.4.2-4). The subjects consumed a control yoghurt or the same yoghurt with 25 g polydextrose, 25 g xylitol, or 12.5 g polydextrose + 12.5 g xylitol at 11:00 a.m. for 10 days. On days 1 and 10, subjects came to the lab at 8:30 a.m. for a fixed breakfast and an *ad libitum* lunch. A breakfast that was similar to their usual breakfast was consumed and the amount was fixed for each subsequent day. After breakfast, subjects were free to leave but were told to consume the yoghurt at 11:30 a.m. and not to consume any other food or drink. At 12:30 they returned to eat a test lunch to a comfortable level of fullness. The amount of food consumed was determined by weighing the food before eating and plate waste after. On test days 1 and 10, subjects completed computerized VAS scales on hunger and fullness immediately before and after breakfast, yoghurt, lunch, and at hourly intervals between meals. All three of the test yoghurts induced a slight suppression of energy intake compared to the control yoghurt, but the differences were not statistically significant. As the yoghurt pre-loads varied in energy content, with the energy inducing effect biased in favor of the control yoghurt, the analysis was repeated taking energy intake into account. When the energy differential of the yoghurts was accounted for, the polydextrose yoghurt significantly decreased energy intake compared to the control yoghurt ($p=0.002$). In regard to subjective ratings, there was a significant increase in the fullness rating immediately after consuming the xylitol/polydextrose yoghurt compared to the control yogurt, both with ($p=0.003$) and without ($p < 0.001$) energy adjustments.

Table 4.4.2-4. Research Summary of King et al. (2005)

	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
King et al., 2005	To assess the independent and combined effect of PDX and xylitol (XYL) on hunger and energy intake over 10 days	15 healthy adults (8F, 7 M) Age: 30.1 y BMI: 22.7 kg/m^2 (15 Ss, 1 dropout) Part of the screening included a taste test of the experimental yogurts. Volunteers who rated the test products less than 50 mm on a VAS scale (0 – 100 mm) were excluded.	Repeated measures, controlled, counterbalanced design with a 1 wk washout period. Ss consumed either a control yoghurt or yoghurt with 1 of 3 test formulations as a snack as part of their normal diet for 10 d. The yoghurt was consumed at 1100 h each day and Ss kept daily records on when they were consumed. On days 1 and 10, Ss came to the lab at 830 h for a fixed breakfast and an *ad libitum* lunch. They consumed a breakfast that was similar to their usual breakfast and the amount was fixed for each subsequent test day. After breakfast, Ss were free to leave but were told to consume the yoghurt at 1100h and not to consume any other food or drink. At 1230 h they returned to eat a test lunch to a comfortable level of fullness. The lunch food was weighed before and after consumption. On test days 1 and 10, Ss completed ratings of hunger and fullness using the validated Electronic Appetite Ratings System that uses VAS. These were completed immediately before and after breakfast, yoghurt, and test lunch, at hourly intervals between meals.	Yoghurt (200 g) with: 25 g/d PDX (Litesse) 25 g/d XYL 12.5 g PDX + 12.5 g XYL (XP) Control (no PDX or XYL)	<u>*Ad libitum* test lunch</u> There were no sig. differences between groups in E intake at the test lunch. However, when the E differential of the yoghurt preloads was taken into consideration, there was a significant difference between the control and PDX (p=0.002).	QG: Moderate Ss were not monitored when test products were consumed. Misreporting of p value for XYL. Counterbalanced design –one sequence followed by the opposite sequence attempts to minimize carryover effects. Ss kept daily records of test product consumption. This was to ensure compliance.

Soong et al. (2016) examined the effect of preloads containing soy protein and polydextrose on lunch energy intake in 27 healthy Singaporean Chinese men. A randomized, repeated measures crossover design was used (Table 4.4.2-5). Although polydextrose was not evaluated independently, the testing of low soy protein (LP) and high soy protein (HP) preloads in addition to LP + polydextrose and HP + polydextrose, allowed the residual effect of polydextrose to be determined. Each subject received four soybean curd preloads with high and low soy protein alone or combined with 12 g polydextrose on separate days with a washout period of at least five days. Subjects consumed a standardized dinner meal the day before the test and arrived at the center in the morning after a 10 hour fast. A standardized breakfast was consumed followed by a test preload three hours later. A buffet-style *ad libitum* lunch was provided to subjects where energy intake was monitored approximately 90 minutes after the preload. Energy intake at lunch was significantly lower following the consumption of LP + polydextrose, HP, and HP + polydextrose compared to the LP preload ($p < 0.05$). Consumption of LP + polydextrose, HP and HP + polydextrose preloads resulted in an energy reduction of approximately 394 kJ (11%), 445 kJ (12%) and 463 kJ (13%), respectively, compared with the LP preload. Therefore, the contribution of polydextrose on reducing energy intake was 11% when the preload was reduced in protein (15.8 g) and 1% when the preload was high in protein (30.8 g).

Table 4.4.2-5. Research Summary of Soong et al. (2016)

Study		Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG), Comments
Soong et al., 2016	To determine (1) whether a dose-response effect of soy protein (SP) on E intake exists; (2) whether there is a synergistic effect of SP + PDX on E intake. In addition, appetite ratings, gastric emptying, fasting and postprandial glucose, plasma insulin, ghrelin and GLP-1 were examined.	27 Singaporean Chinese, healthy men Age: 23.6 y BMI: 21.1 kg/m^2	Randomized, repeated measures, crossover design. Prior to each test day, Ss avoided alcohol, caffeinated drinks, or strenuous exercise. Ss were told the purpose of the study without disclosing the composition of the preload provided at each session. Each subject received 4 soybean curd preloads on separate days with a washout period of at least 5 d. Standardized, microwavable ready-meals were provided for dinner on the night preceding each test day. After a 10 h overnight fast, Ss arrived at the center bet. 8.00 and 8.30 h to consume breakfast. Preload was served 3 h post-breakfast. At baseline and at 15, 30, 45, 60, 75 and 90 min after preload consumption, finger-prick capillary blood glucose test, abdominal ultrasound for gastric emptying rate and assessment of subjective feelings (VAS) of hunger, fullness and desire to eat were performed. In a subgroup of 15 Ss, venous blood samples were taken to measure insulin, ghrelin and GLP-1. Buffet-style *ad libitum* lunch was served to Ss who ate alone until comfortably full. Lunch intake was only revealed after the study to avoid biasing the quantity eaten if this was made known to the Ss at the onset. Throughout the stud, Ss consumed standardized dinner (ready-meals) of 3 choices. Breakfast was also standardized.	Soybean curd preloads: *Low protein (LP)*: 15.8 g prt, 0 g PDX, 1.6 MJ, 16 g fat, 44 g CHO per 450.9 g svg. *LP + PDX*: 15.8 g prt, 12 g PDX, 1.6 g MJ, 16 g fat, 44.3 g CHO per 462.8 g svg. *High protein (HP*): 30.8 g prt, 0 g PDX, 1.6 MJ, 8.5 g fat, 46.3 g CHO per 461.3 g svg. HP + PDX: 30.8 g prt, 12 g PDX, 1.6 g MJ, 46.6 g CHO per 473.1 g svg. Preloads were isoenergetic. Soy protein isolate (True Nutrition); PDX: Litesse ultra	Energy intake at lunch was significantly lower following the consumption of LP + PDX, HP, and HP + PDX compared to the LP preload ($p < 0.05$). There were no significant diffs. in E intake between LP + PDX, HP, and HP + PDX. Consumption of LP + PDX, HP and HP + PDX preloads resulted in an E reduction of approximately 394 kJ (11%), 445 kJ (12%) and 463 kJ (13%), respectively, compared with the LP preload. Gut hormone responses mirrored the findings on E intake. Consumption of LP + PDX, HP, and HP + PDX led to a 29, 68, and 138% augmentation of plasma GLP-1 response compared to LP. The difference however was not statistically significant compared to LP. But HP + PDX produced a significantly greater response compared to LP + PDX ($p < 0.05$). Consumption of LP + PDX, HP, and HP + PDX led to a 28, 25 and 67% suppression of plasma ghrelin compared to LP. Plasma ghrelin was suppressed by HP + PDX and LP + PDX compared with LP at 90 min ($p < 0.05$).	QG: Moderate Although PDX was not evaluated independently, the use of LP and HP preloads, permitted the residual effect to be attributed to PDX when LP + PDX and HP + PDX were evaluated. Unclear if study was double-blind. Ss knew general purpose of study but were not aware of the composition of preloads or that the amount of lunch consumed was being recorded. The time lapse between the preload and lunch intake was not reported, but since blood samples and other tests were conducted until 90 min after preload, lunch was likely consumed 90 min. after.

Monsivais et al. (2011) determined the impact of polydextrose, soluble corn fiber, soluble fiber dextrin, and resistant starch on temporal profiles of hunger and fullness as well as energy intake at the next meal (Table 4.4.2-6). Two controls were used, a fiber-free but isoenergetic control and a low energy control. Thirty-six healthy adults participated in a randomized controlled, double-blind, crossover study in which each subject was exposed to each test fiber in a series of 6 testing days for 6 weeks with a minimum of a one-week washout period. Subjects reported to the lab on the same day of the week for each testing session and kept evening meals and activity levels on the day before the test as similar as possible. On test day subjects arrived in the morning after an overnight fast and provided baseline motivational ratings prior to receiving two servings of a preload at 08:40 h and at 10:20h. The two preloads of a puffed grain cereal and a sweetened beverage were designed to provide a total dose of 20-24 g of fiber from each of the test fibers prior to lunch. Each combination of the test snack and beverage were identical in appearance and were similar in energy and dietary fiber. Following the second preload, an *ad libitum* lunch of a variety of sweet and savory foods was served at 12:00 h. A final set of ratings was collected after lunch at 12:30 h. In regard to energy intake at lunch, consumption of polydextrose was not significantly different from the low energy or iso-energy controls.

Table 4.4.2-6. Research Summary of Monsivais et al. (2011)

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Monsivais et al., 2011	To determine the impact of polydextrose (PDX), soluble corn fiber (SCF), soluble fiber dextrin (SFD), and resistant starch (RS) on the temporal profiles of hunger and fullness as well as E intake at the next meal.	36 healthy US adults (14 M, 22 F) Mean age: 25 y BMI: 22.6 kg/m^2 40 Ss were enrolled, but data from 4 Ss were excluded because they failed to complete all study protocols.	Randomized controlled, double-blind, crossover study (Latin square design). Each Ss was exposed to each test fiber in a series of 6 testing days over 6 wk, with a minimum of 1 wk washout period. To minimize variability, all Ss reported to the lab on the same day of the wk for each testing session. Ss kept evening meals and activity levels on the day before the test as similar as possible. On test day, Ss arrived by 0830 h and baseline motivational ratings were obtained at 0840 h just before the first preload serving and every 20 min after. A second preload was given to Ss at 1020h. An *ad libitum* lunch consisting of a variety of savory and sweet foods was served at 1200 h. A final set of ratings was collected after lunch at 1230 h. All foods and water served were pre-weighed; plate waste was also weighed.	A puffed grain breakfast cereal or a sweetened beverage: 23.6 g/d DF from PDX (Sta Lite III) 23.6 g/d DF from SCF 70 (Promitor) 24 g/d DF from SFD (Promitor) 22.4 g/d DF from RS 60 (Promitor) Test fibers were similar in total energy and DF. Isocaloric, low fiber control (breakfast cereal + beverage) (iso-E) Low calorie, low fiber control (rice cake + beverage sweetened with aspartame)(low-E)	<u>E intake at lunch</u> PDX was not significantly different compared to the low E control.	QG: High Ss arrived after a morning fast. (Personal communication)

Astbury et al. (2008) investigated the effect of a chocolate-flavored drink containing 25 g of polydextrose versus a maltodextrin control on satiety and subsequent energy intake at a test lunch meal (Table 4.4.2-7). A randomized, controlled, single-blind, crossover study was employed with 14 healthy men. On two separate occasions, subjects consumed a standardized breakfast at home, then arrived at the lab at 11:00 h and were provided the test beverage. Subjective appetite ratings were collected at 30 minute intervals after the preload using visual analog scales (VAS). Subjects were provided an *ad libitum* pasta-meal 90 minute after the test drink. Following the lunch meal, VAS ratings were collected at 0, 30, and 60 min after. Subjects were then free to leave and were provided a food diary to record all food and drink consumed for the remainder of the day. Energy intake at lunch was significantly lower after the intake of the polydextrose beverage versus the control beverage ($p < 0.01$). Total daily energy intake however, did not differ between the two treatments.

Table 4.4.2-7. Research Summary of Astbury et al. (2008)

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Astbury et al., 2008 (Abstract only)	To investigate the effects of PDX on subjective appetite and E intake	14 healthy men Age: 25.3 y BMI: 23 kg/m^2	Randomized, controlled, single-blind, crossover study. On two separate occasions, Ss consumed a standardized breakfast at home, arrived at the lab at 11:00 h and were provided the test beverage. Subjective appetite ratings were collected at 30 min intervals after the preload using visual analog scales (VAS). Ss were provided an *ad libitum* pasta-meal 90 min after the test drink. Following the lunch meal, VAS ratings were collected at 0, 30, and 60 min after. Ss were then free to leave and were provided a food diary to record all food and drink consumed for the remainder of the day.	Chocolate-flavored milk shake (400 ml) with: 25 g PDX 6.25 g maltodextrin (control)	E intake at the lunch meal was significantly lower when PDX (4819 kJ) was consumed compared to the control (5556) ($p < 0.01$). Total E intake for the day was bit significantly different between the two treatments.	QG: Cannot be adequately assessed because study has been published only in abstract form. Study was single-blind.

Combination Study

Astbury et al. (2014) examined the effect of polydextrose combined with whey protein on energy intake in ten healthy men (Appendix 8.3). A randomized, double-blind, crossover trial of two 14-day intervention periods were used with a 14-day washout period. Subjects consumed a self-selected diet and consumed the treatment snack bar containing 6.2 g polydextrose and whey protein (amount not specified) and 12.9 g protein or a control snack bar providing 0.6 g protein. On day 1 and day 15 of each experimental period, subjects consumed a standardized meal the evening before and arrived at the lab the next morning fasted. A standard breakfast of cereal and milk was consumed and the test snack bars were consumed approximately 150 minutes after. Subjects were provided an *ad libitum* pasta meal about 90 minutes after the snack bar where they were instructed to consumed until they were comfortably full. The amount of food consumed was recorded by the investigators and subjects kept a diet record of all food and drinks consumed for the rest of the day. Subjects also kept diet records on day 4, day 8 and day 12. Results indicted energy intake at lunch was significantly lower when the polydextrose and whey protein snack was consumed at lunch on both day 1 ($p < 0.05$) and day 15 ($p < 0.05$) compared to the control snack. Similar results were observed when total daily intake was compared for both these days ($p < 0.05$), as well as for the three days diet records were kept ($p < 0.05$).

4.4.3 Meta-Analysis– Decreased Energy Intake Effect of Polydextrose

Ibarra et al. (2015) conducted a systematic review and meta-analysis to examine the effects of polydextrose on different levels of energy intake at an *ad libitum* lunch. Following an extensive literature search, six studies were identified that met eligibility criteria for the systematic review and meta-analysis (Astbury, 2014[3]; Astbury et al. (2013), Ranawana et al. (2013), Hull et al. (2012), Astbury et al., 2008, King et al., 2005). Data for a total of 120 subjects were analyzed.

[3] This study refers to an unpublished study: Astbury, 2014. Gut hormone study. Final report. (Unpublished). Note that the Astbury et al., 2014 reference cited in Section 4.4.2, is a different study. Ibarra et al. (2014) did not include Astbury et al. (2014) in their meta-analysis because the polydextrose test product also contained whey protein.

Of these studies, three measured energy intake for the rest of the day or at dinner time (Astbury et al., 2013; Hull et al., 2012; Astbury et al., 2008). Results of the random-effects model on energy intake at a subsequent *ad libitum* meal at lunch time indicate a significant effect of polydextrose over the placebo ($p < 0.01$). The Higgins I^2 statistic for this variable was zero, demonstrating the high consistency of the data. In addition, the indicator from the Egger's test was not significant, confirming a low level of bias. The random-effects results for the levels of energy intake for the rest of the day or dinner and the total daily energy intake were not statistically significant.

Level of energy intake was reduced at an *ad libitum* lunch in a dose-dependent manner according to the following regression model:

$$\text{Energy Intake}_{\text{lunch}}\ (\%) = -0.67 \times \text{polydextrose (g/d)}\ [R^2=0.80;\ p < 0.01]$$

The regression equation model of daily levels of intake were also reduced in a dose-dependent manner:

$$\text{Energy Intake}_{\text{daily}}\ (\%) = -0.35 \times \text{polydextrose (g/d)}\ [R^2=0.68;\ p < 0.05]$$

Overall, it was concluded that the meta-analysis supports that the consumption of polydextrose reduces voluntary energy intake levels at a subsequent meal, which occurs in a dose-dependent manner. No differences in energy intake during the rest of the day or for daily energy intake were observed, possibly due to the limited number of studies that estimated these parameters. Nevertheless, the regression equation showed a dose-dependent effect on the reduction of daily energy intake.

4.5 Evidence of Fermentation

Some dietary fibers are fermented in the colon by gut microbiota, resulting in the production of short chain fatty acids (SCFA) and gases (e.g., H_2) (Slavin, 2013). Five clinical studies (Konings et al., 2013; Timm et al. 2013; Achour et al., 1994; Livesey et al., 1993; Solomons and Rosenthal, 1985) measured breath hydrogen production and four out of five observed an increase with

polydextrose doses ranging from 11-57 g. Fecal SCFA (acetate, propionate, and butyrate) were also assessed in five clinical studies of polydextrose feeding (Konings et al., 2013; Timm et al., 2013; Lamichhane et al., 2014 (subset of Costabile et al., 2011); Costabile et al., 2011; Jie et al., 2000; Vester Boler et al., 2011; Hengst et al., 2008). Significant increases were observed for some of the SCFA in two of the studies (Lamichhane et al., 2014; Jie et al., 2000). It should be noted that when fermentable fibers are consumed, increases in fecal SCFA are not always observed in human studies, due to the fact that a significant portion of the SCFAs produced in the proximal colon are absorbed. Topping and Clifton (2001) estimate that approximately 95% of SCFAs are absorbed soon after production and have also suggested that fecal SCFAs are more representative of distal colon rather than proximal colon concentrations. Another reason for not seeing fecal SCFA increases in human studies with fermentable fibers is due to increases in fecal weight with fiber consumption, which leads to a dilution of SCFAs (Fastinger et al., 2008; Vester Boler et al., 2011, Timm et al., 2013). For the reasons above, *in vitro* and animal studies are accepted in the scientific community as a proxy for large bowel SCFA effects of fermentable fibers.

Four out of five studies conducted in dogs, pigs, and rats demonstrated an increase in specific SCFA production following polydextrose feeding (Beloshapka et al., 2012; Weaver et al., 2010; Fava et al., 2007; Peuranen et al., 2004). The study conducted in dogs fed polydextrose at three levels of intake observed a linear increase in acetate and propionate with increasing polydextrose dose (Beloshapka et al., 202). Nine *in vitro* studies noted the production of specific SCFA compared to a control, other fibers, or baseline levels (Hernot et al., 2009; Hoffman et al., unpublished; Vester Boler et al., 2009; Beards et al., 2010b, Mäkeläinen et al., 2007; Mäkivuokko et al., 2007; Probert et al., 2004; Pylkas et al.., 2005; Solomons and Rosenthal, 1985). Collectively, the data provide good evidence that polydextrose is fermented by the gut microflora in the gastrointestinal tract.

5.0 CALORIC AVAILABILITY

5.1. Overview[4]

Three reviews of the caloric availability studies on polydextrose have consistently concluded that 1 kcal/g is supported by the scientific evidence.

1. As part of the Pfizer polydextrose Food Additive Petition process in 1981, FDA wrote a letter stating:

   > "Our review of the data contained in the petition indicates that polydextrose has a biocalorie value of 1 kilocalorie/gram. We therefore have no objection to your claim relative to the caloric value of polydextrose." (FDA, 1981)

2. A 2007 review of the caloric availability studies on polydextrose to date in both human and animal studies concluded that the data support a caloric value of 1 kcal/g (Auerbach et al., 2007).
3. An updated analysis for this dossier is detailed below and continues to support a caloric value of 1 kcal/g.

Four estimates of the caloric availability of polydextrose have been assessed in three clinical studies (Achour et al., 1994—2 methods of analysis; Figdor and Biancine, 1983; and Oku and Nakumura, 2014) (Table 5.1-1). Two of the studies used isotope label disposition techniques (Achour et al., 1994—2 methods of analysis; Figdor and Biancine, 1983), whereas the third used

[4] To define ingredient energy values, there is a need for human data on the components of energy output. Metabolizable energy (ME) encompasses the energy available from the gross energy intake (GE, or energy content of food/ingredient as measured by complete combustion) then accounting for losses of the ingested energy in feces (FE), urine (UE), and in gases from fermentation in the large intestine (GaE), and in waste products such as loss from surface area (SE), i.e. ME=GE-(FE +UE +GaE + SE) (FAO 2003). Surface area energy losses are typically negligible in resting subjects.

Not all ME is available for the production of ATP, when energy losses as heat of microbial fermentation and obligatory thermogenesis (i.e. excess heat relative to glucose during ATP synthesis) are subtracted from ME, the resulting energy content of a food that will be available to the body for ATP production, which is referred to as NME (net metabolizable energy). NME is always lower than ME (FAO 2003).

the breath hydrogen technique (Oku and Nakumura, 2014). There were some limitations in each of the approaches used. If all four studies were given equal weight, the mean caloric value would be 1.05 kg/g. Overall, the data supports a caloric value of 1 kcal/g for polydextrose.

Table 5.1-1. Summary of Human Studies that Evaluated the Caloric Content of Polydextrose

References	Method	N	Energy Estimate
Achour et al., 1994; Method 1*	ILD	7 men	1.46 kcal/g
Achour et al., 1994; Method 2**	ILD	7 men	0.95 kcal/g
Figdor & Biancine, 1983	ILD	4 men	1 kcal/g
Oku & Nakumura, 2014	BH	9 women	0.77 kcal/g

BH: breath hydrogen; ILD: isotope-label disposition

*Method 1: From the amount of PDX fermented, E value was determined from the amount of SCFA produced and absorbed in the colon.

** Method 2: From the amount of PDX fermented, E value was determined from the percentage of radioactivity expired in breath as $^{14}CO_2$, corrected by $^{14}CO_2$ from bacterial fermentation.

Eight animal studies have also evaluated the caloric availability of polydextrose (Appendix 8.4a and 8.4b). These were excluded from our main review since FDA has indicated that animal studies cannot be used to provide information from which scientific conclusions can be drawn and are only to be used as background information in support of a claim (FDA, 2008). The caloric availability values from these studies ranged from 0.77 kcal/g to 2.9 kcal/g, but the methodologies used in most instances resulted in overestimation and underestimation of the true value. The most thorough study was a radio-labeled study of polydextrose in rats that measured all available energy losses (recovered energy in feces, urine and fermentation) as well as all available energy (expired in breath, incorporated in tissue, and fermentation) (Juhr and Franke, 1992). Conventional and germfree rats were used as a model for determining available energy, in order to distinguish between the polydextrose fraction that was absorbed directly and the fraction that underwent fermentation. The direct measurement of the amount of polydextrose that was digested, the amount deposited in tissue and the amount fermented

allowed fewer assumptions than studies that measured only labeled breath, as all of the ingested dose was accounted for. This study estimated the energy value of polydextrose as 1.12 kcal/g.

5.2 Clinical Studies

The following are the findings from each of the clinical studies:

Achour et al. (1994) determined the energy value of polydextrose in seven healthy men during acute polydextrose ingestion of one week (days 9-16) and during chronic polydextrose ingestion of three weeks (days 17-38). A one-week control period (days 1-8) with no polydextrose intake preceded both periods (Table 5.2-1). Subjects consumed a 30 g daily dose of polydextrose divided into three equal doses at each of the three meals. The energy value of polydextrose was assessed by the addition of [^{14}C] polydextrose to the 10 g morning dose of polydextrose during the acute phase and the end of the chronic phase. During all phases except for the initial part of the chronic phase, subjects consumed all their meals at the study site. During days 17-30, subjects consumed their usual diet. Urine, feces, breath, and flatus collections were obtained at specific times throughout the study when controlled diets were provided. The researchers compared the fermentation of polydextrose during the acute and chronic phases of polydextrose consumption and observed no significant differences. The energy value of polydextrose was determined by Miller and Wolin's equation[5] in two ways using the data that was collected: 1) from short-chain fatty acids (SCFAs; acetate, proprionate, butyrate) produced and 2) from $^{14}CO_2$ in breath corrected by $^{14}CO_2$ utilized in the fermentive process.

Method 1: From the 10 g of radio-labeled polydextrose consumed, 5% was absorbed as monomers and 33% was excreted in feces. The remaining 62% was fermented with 3% incorporated into bacterial mass and 59% converted to SCFA and gas. On the basis of Miller and Wolin's equation, 59% or 5.9 g of polydextrose would be incorporated into 2.7 g acetate, 0.08 propionate, and 0.4 g butyrate, yielding a total of 65.8 kJ. This is converted to ATP with an

[5] 34.5 $C_6H_{12}O_6$ + 37 H_2O → 48 acetate + 11 propionate + 5 butyrate + 34.25 CO_2 + 23.75 CH_4

efficiency of 80%, resulting in 52.6 kJ available to the host. To this is added 8.4 kJ available from directly absorbed monomers. Therefore, the energy value for polydextrose would be 61 kJ or 6.1 kJ/g or **1.46 kcal/g**.

Method 2: From the 10 g of radio-labeled polydextrose consumed, 31% of the radiolabel was recovered in breath CO_2 from bacterial CO_2, oxidized SCFA, and absorbed monomers. When glucose is ingested, approximately 60% is expired as CO_2, therefore the 5% monomeric fraction was adjusted to 3%. According to Miller and Wolin, 16.5% of the dose would be converted to CO_2 from bacteria. The amount of CO_2 determined from oxidation of SCFA was 31% - (16.5% + 3 %) or 11.5%. About 90% of [$U^{14}C$] acetate was available for absorption and 49% appeared in breath within 48 hours. This fraction was used to determine the amount of SCFA produced from 11.5% CO_2, i.e. 23.5% of the ingested dose. SCFA is converted to ATP with an efficiency of 80% (relative to glucose), yielding 18.8% of the energy of polydextrose. To this is added 5% of energy from absorbed monomers. Therefore, the energy value for polydextrose is 23.8% (18.8% +5%) or 4 kJ/g or **0.94 kcal/g**.

Both methods had some aspects that did not take into account potential losses and gains in the caloric availability of polydextrose, but from the review of the data, it appears Method 2 was more complete than Method 1 (Table 5.2-1).

Table 5.2-1. Summary of Achour et al., 1994

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test Product	Results	Comments
Achour et al., 1994	To reevaluate the E value of PDX in healthy, nonobese men, using the disposition method and to determine if prolonged administration influences the outcome.	7 healthy men Age: 27 y BW: within 10% of ideal To avoid undetected loss of carbon in the form of methane, Ss were nonmethane producers.	The study was divided into three periods: (1) control period (CP) 1-8 d; (2) acute PDX ingestion 9-16 d (PDX1); (3) chronic PDX ingestion 17-38 d (PDX2). From d 1-16 and 30-40 a controlled diet was given and Ss consumed all their meals at the study site. The controlled diet was free of pits and skins, and fiber intake was ~11 g/d each day. From d17-30, Ss ate their usual diet at home while consuming PDX 3x/d. On d 13 and 35, radio-labeled PDX was added to the morning dose. On d5, 13, and 35, Ss consumed 10 g polyethylene glycol as a fecal recovery marker. For 3 consecutive days starting on d5, 13, and 35, Ss also ingested 20 radio-opaque pellets to measure GI transit time. On d5-8, 13-16, and 35-38, urine and feces were collected. Starting on d5, 13, and 35, breath collections were obtained hourly from 0800h to 15 h and at 18, 21, 24, 30, 36, and 48 h. On d13 and 35, flatus was collected for 12 h in 3 Ss.	During PDX1 and PDX2, Ss ingested in each of the 3 daily meals, 10 g of PDX mixed into fruit juice (i.e., 30 g total. [^{14}C] PDX was added to the 10 g morning dose of PDX during PDX1 and at the end of PDX2.	There was no evidence of modified fermentation between PDX1 (acute intake) and PDX2 (chronic intake). From the amount of PDX that was fermented, the energy value of PDX was determined two ways: Method 1) from the amount of SCFA produced and absorbed in the colon; Method 2) from the percentage of radioactivity expired in breath as $^{14}CO_2$, corrected by $^{14}CO_2$ from bacterial fermentation. The two methods used the same data, utilizing different approaches to analyzing the data. Method 1: From the 10 g dose of radio-labeled PDX, 5% was absorbed as monomers and 33% (total fecal radioactivity minus radioactivity in bacteria and SCFAs) was excreted in feces (unchanged PDX). Remaining 62% was fermented with 3% incorporated into bacterial mass and 59% converted to SCFAs and gas. On the basis of Miller and Wolin's equation, 59% (5.9 g) would be incorporated into 2.7 g acetate, 0.8 g propionate, and 0.4 g butyrate. Multiplication of the gross E value of these SCFAs (14.57, 20.63, 24.8 kJ/g for acetate, propionate, and butyrate respectively) indicated a total of 65.8 kJ. This is converted to ATP with an efficacy of 80%, i.e. 52.6 kJ would be available to the host. To this is added 8.4 kJ available for directly absorbed monomers. Therefore, the E value for PDX is 61 kJ or 6.1 kJ/g or **1.46 kcal/g***	*This value did not correct the fermented PDX by the amount of $C0_2$ produced by bacteria (i.e. E availability overestimated). Nor did it subtract the radiolabel in urine or flatus, which were measured (i.e. E overestimated). Also, the researchers reported that colonic absorption of SCFAs may involve secretion of bicarbonate into the lumen, and hydration of bacterial $C0_2$ may involve bicarbonate. Thus, a small part of the radioactivity in stools may come from labeled bicarbonate. Because radioactivity in fecal bicarbonate was not measured, the calculated amount of fermented PDX was underestimated (i.e. E overestimated).

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test Product	Results	Comments
Achour et al., 1994 (cont'd.)					Method 2: 31% of the radioactive label was recovered in breath CO_2 within 48 h from bacterial CO_2, oxidation of SCFA, and oxidation of absorbed monomers. When labeled glucose is ingested, approximately 60% is expired as CO_2, therefore the amount of label expected with the 5% monomeric fraction is 3%. According to Miller and Wolin, 28% of the fermented PDX carbon, i.e. 16.5% of the dose was converted to CO_2 during the fermentation process by bacteria. To determine the amount of CO_2 produced from SCFA, 3% from monomers + 16.5% from bacteria was subtracted from the total radioactive label: 31% - (16.5% + 3%) = 11.5%. To calculate the amount of SCFAs formed, data from colonic infusion of labeled acetate was used [$U^{14}C$] acetate. It was estimated that 90% of [$U^{14}C$] acetate of the infused amount was available for absorption and 49% appeared in breath within 48 h. This fraction can be used to calculate the amount of SCFAs that must have been formed to provide 11.5% of the dose in breath, i.e, 23.5% of the ingested dose. The amount of SCFAs that is converted to ATP with an efficiency of 80% (relative to glucose), yielded 18.8% of the E of PDX. To this is added the 5% from absorbed monomers. Thus the E value of PDX is (18.8% + 5%) = 23.8% or 4 kJ/g or **0.95 kcal/g.***	*This did not subtract out the radiolabel in urine or flatus which was measured (i.e. E underestimated). Also, the researchers reported that colonic absorption of SCFAs may involve secretion of bicarbonate into the lumen, and hydration of bacterial $C0_2$ may involve bicarbonate. Thus, a small part of the radioactivity in stools may come from labeled bicarbonate. Because radioactivity in fecal bicarbonate was not measured, the calculated amount of fermented PDX was underestimated (i.e. E overestimated).

Figdor and Bianchine (1983) determined the caloric distribution and disposition of radio-labeled polydextrose in four healthy men (Table 5.2-2). Subjects consumed 10 g of unlabeled polydextrose for seven days followed by [^{14}C] polydextrose on the eighth day and two more days of unlabeled polydextrose. Breath CO_2, urine and fecal collections were made during the experimental period. Approximately 16% of the administered polydextrose was recovered from breath as $^{14}CO_2$, indicating an average caloric utilization of approximately 26.6% or 1 kcal/g. The exact calculations of this derivation was not provided. The researchers acknowledge that the value is an overestimate since the measured CO_2 includes bacteria-derived and small organic molecule derived $C0_2$. Other corrections attributed to flatus, fecal bicarbonate, and absorbed monomers were not taken into account.

Table 5.2-2. Summary of Figdor and Bianchine, 1983

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test Product	Results	Comments
Figdor and Bianchine, 1983	To discuss the techniques and the results that led to the conclusion that PDX has a caloric utilization in man of 1 kcal/g	4 healthy men	Ss consumed the PDX daily for 7 d. On the 8th d, Ss consumed [14C] PDX. On two subsequent days after receiving the labeled PDX, each Ss continued to receive 10 g of nonlabeled PDX. Prior to receiving the labeled dose, each Ss submitted a urine and fecal collection and gave a 4-min breath collection. Breath CO2 collections were obtained every hour after labeled dose until 8 h, and then every 2 h till 16 h, and then at 24, 36, and 48 h. During the first day after [14C] PDX, urine was collected at 0-6, 6-12, and 12-24 h. On day 2, each 24-h collection was pooled for a total of 7d. The time and date of fecal collections were recorded. Each 24-h collection was pooled for each Ss.	10 g [14C] PDX in chocolate milk consumed immediately after breakfast.	After oral administration of [14C] PDX, less than 1.5% of the administered radioactivity was recovered in urine or 0.03% of the original dose was absorbed. The main portion of the administered dose (50%) was expelled in feces. Most was recovered 24-48 h after PDX intake. Approx. 16% of the administered PDX was recovered from the breath as $14C0_2$, indicating an average caloric utilization of approx. 26.6% or **1 kcal/g***. The authors acknowledge that this is an overestimate since the measured CO_2 includes microbial-derived CO_2 and small organic molecule derived $C0_2$.	* Details were not provided of exactly how 1 kcal/g was derived from the 26.6% PDX dose that was utilized. Also this value was not corrected for bacteria generated $C0_2$ or losses in flatus (i.e. E overestimated). Losses from fecal bicarbonate noted by Achour et al., 1994 not taken into account (i.e. E overestimated) iThe amount of available CHO from absorbed monomers was also not taken into account (i.e. E overestimated) Method used for urine collection is unclear.

Oku and Nakamura (2014) evaluated the available energy of polydextrose on the basis of breath H_2 produced from the fermentation of polydextrose (Table 5.2-3). Nine healthy women who were not methane producers participated in the study. On test day, 5 g of polydextrose was consumed dissolved in miso soup and end-expiratory gas was collected at regular intervals for 24-hours. The relative available energy of polydextrose was estimated based on breath H_2 excretion in relation to the breath H_2 excreted from the ingestion of fructo-oligosaccharide (FOS), which is completely fermented by intestinal bacteria. FOS has been classified by the Japanese Health Promotion Law as providing an energy value of 2 kcal/g. The same subjects participated in a similar experiment with 5 g FOS. The amount of breath H_2 produced by polydextrose was markedly lower than for FOS; the ratio of breath H_2 AUC collected for 24 hours was 100 FOS: 38.5 polydextrose. Since the energy value for FOS is estimated at 2 kcal/g, the energy value for polydextrose was estimated at 0.77 kcal/g. However, this value underestimates the energy value of polydextrose because it does not take into account the available energy from absorbed polydextrose monomers that are not fermented. In addition, breath H_2 was not measured when subjects slept between 14 and 20 hours.

Table 5.2-3. Summary of Oku and Nakamura, 2014

Study	Purpose	Subjects (Ss)	Study Design, Method, Duration	Test Product	Results	Comments
Oku and Nakamura, 2014	To evaluate the relative available energy (RAE) for 9 major dietary fiber materials based on fermentability from breath hydrogen excretion in healthy human subjects. (Data only shown for PDX).	9 healthy females Prior to the expt., it was ensured that all Ss were hydrogen producers and not methane producers.	PDX was dissolved in soy flavored soup, which had previously been confirmed not to excrete breath H_2 in the subjects participating in the study. On the day of the expt., which was conducted for 24 h, Ss only consumed a cookie, tuna fish, boiled egg and sport drinks, green tea (or water) that were known not to produce breath H_2. A multivitamin tablet was also given to Ss. Ss health status, food intake for the previous wk was reviewed and BP and pulse rate were measured. Ss arrived on test day after an overnight fast. Prior to intake of PDX, 750 ml samples of end-expiratory gas were collected. After ingestion of the test substance, the end-expiratory gas was collected at 1-h intervals for 8 h, and then at 2-h intervals between 8 h and 12 h after the ingestion. The sleeping period was bet. 14 h and 20 h after ingestion of the test substance. Breath gas was collected 30 min after waking up and 24 h after ingestion. Other dietary fibers, including FOS were tested in a similar manner using a within-subject repeated measures design. All test substances were given in a random order with intervals of at least 1 wk.	5 g PDX dissolved in 120 ml soup 5 g fructo-oligosaccharide (FOS) dissolved in 120 ml tap water (reference)	The amount of available E of non-digestible and fermentable CHO is dependent on the amount SCFAs produced in fermentation by intestinal microbes. The RAE of PDX was estimated based on breath H_2 excretion and the relative ratio vs. breath H_2 excretion from the ingestion of FOS, which is fermented completely by intestinal microbes. FOS has been classified by the Japanese Health Promotion Law as providing an E value of 2 kcal/g. FOS: All Ss excreted breath H_2 and no methane gas. Breath H_2, which is produced only through fermentation started to be excreted ~ 3 h after the intake of FOS. Peak H_2 was reached at 5-6 h and decreased gradually until 14 h after ingestion. Breath H_2 was maintained 24 h after ingestion and did not recover to basal levels. Conc. of H_2 in the first collection of breath gas after waking was slightly higher than that before sleeping, but after 24 h was small. PDX: When 5 g PDX was ingested, breath H_2 started to increase 2-3 h after ingestion and reached a peak at 5 h. Thereafter H_2 decreased gradually and was excreted little by little until the end of the expt. The total amount of breath H_2 excreted was markedly lower than for FOS. Breath H_2 AUC 24 h collection Ratio vs. FOS (%) / Estimated E (kcal/g) FOS 100.0 / 2 **PDX** 38.5 / **0.77 rounded to 1 kcal/g***	*This method does not take into the account the E available from PDX monomers that are not fermented (i.e.E underestimated) Between 14 h and 20 h after PDX intake, Ss slept, and no breath H_2 measurements were taken (i.e. possible E underestimation) However, the researchers note that breath H_2 AUC expressed as a ratio of FOS did not differ significantly at 8 h, 14 h, and 24 h. Contradictory statements: re Ss prohibited from ingesting foods or beverages except for water, as well as from sleeping or smoking.

6.0 CONCLUSIONS

This research review provides evidence demonstrating that the non-digestible carbohydrate in polydextrose has physiological effects that are beneficial to health. It improves laxation in humans by increasing fecal bulk, stool frequency and improving stool consistency, as well as reduces energy intake at a meal when consumed prior to that meal. There is also significant evidence that polydextrose is fermented in the gastrointestinal tract, providing a source of SCFAs which are known to be beneficial to colonic cellular health. In light of this evidence, we believe that polydextrose should be considered a dietary fiber under FDA's definition of dietary fiber.

The secondary purpose of this petition was to demonstrate the caloric availability of polydextrose. Four clinical evaluations showed a range of caloric values between 0.77 kcal/g and 1.46 kcal/g, and a mean of 1.05 kcal/g. Hence, it is recommended that a caloric value of 1 kcal/g be used for polydextrose for labeling purposes instead of 2 kcal/g currently suggested for soluble fibers.

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8. APPENDIX

8.1. Polydextrose Laxation Studies with a Low Methodology Quality Rating

Study	Purpose	Subjects (Ss)[1]	Study Design, Method, Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Achour et al., 1994	To investigate the energy value and gastrointestinal effects of PDX	7 healthy male French adults Age: 27 ± 2 y BW: within 10% of ideal weight	Non-randomized, fixed sequence. Study was divided into a control period (CP: days 1-8); acute PDX period (PDX1: days 9-16), and chronic PDX period (PDX2: days 17-38). For CP, PDX1 and days 31-40 Ss consumed all their meal at the study site. The controlled diet was free of pits and skins, and moderate in fiber (~11 g/d). During days 17-30 in the PDX2 period, Ss ate their usual diet at home. On days 13 and 35, 740 kBq [U-^{14}C] PDX was added to the morning dose of PDX and consumed with breakfast. For 3 consecutive days on days 5, 13, and 35, Ss ingested at breakfast 20 radio-opaque pellets to measure mean GI transit time. On days 5-8, 13-16, and 35-38, Ss recorded any symptoms and collected urine and feces. A radiograph was taken of the first stool passed $\geq$ 24 h after the last pellet was ingested. On days 13 and 35, flatus was collected for 12 h by a flexible gas impermeable rubber tube inserted into the rectum.	30 g PDX (from **Pfizer**) ingested during PDX1 and PDX2; 10 g PDX mixed into fruit juice was consumed at 3 daily meals.	Compared with CP, total fecal weight showed a trend towards being higher during PDX1 and PDX2. (p=0.06). There were no significant differences in fecal dry weight, fecal water, or transit time s between CP and PDX periods.	QG: Low Not a randomized placebo-controlled study. Small sample size. An 8th subject was excluded because of incomplete stool recovery. An attempt was made to collect flatus from all Ss, however, collection was complete for only 3 Ss.

[1]Represents subjects that completed the study. [2]QC: High: randomized controlled study with no obvious bias; Moderate: randomized controlled study with some bias, but not enough to invalidate results; Low: study with potentially significant confounders or bias. Method and QG refer to laxation indices. BMI: body mass index; BW: body weight; CP: control period; d: day; E: energy; F: female; h: hour; M: male; PDX: polydextrose; wk: week

Study	Purpose	Subjects (Ss)[1]	Study Design, Method, Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Endo et al., 1991	To study the effects of a high cholesterol diet and PDX on microflora and bacterial enzyme activity in healthy Ss	8 healthy Japanese adults (6 M, 2 F) Mean age: 31.8 ± 6.4 y	Non-randomized, fixed sequence. All Ss were given a low cholesterol diet for 2 wk, followed by a high cholesterol diet for 2 wk, and a high cholesterol diet + PDX for 2 wk. 5-d food records were kept for each dietary period for measurement of E, CHO, fat, and cholesterol intake. Fecal specimens were collected from each Ss during last 6 days of each dietary period.	15 g PDX/d (source not specified) No placebo product	Fecal output (g wet weight/d) increased significantly during the high cholesterol + PDX period (data only presented in figure for each Ss, difficult to decipher). There were no differences in fecal water content among the 3 diets.	QG: Low Not a randomized, placebo-controlled study and low number of subjects. Data for each Ss was presented in a Figure that was difficult to decipher significance levels. Methods used for statistical analysis not reported. .

[1]Represents subjects that completed the study. [2]QC: High: randomized controlled study with no obvious bias; Moderate: randomized controlled study with some bias, but not enough to invalidate results; Low: study with potentially significant confounders or bias. Method and QG refer to laxation indices. BMI: body mass index; BW: body weight; CP: control period; d: day; E: energy; F: female; h: hour; M: male; PDX: polydextrose; wk: week

Study	Purpose	Subjects (Ss)[1]	Study Design, Method, Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Hengst et al., 2008	To demonstrate prebiotic effects of polydextrose	45 healthy German adults (37 F, 8 M0 Mean age: 24 y BMI: 21 kg/m^2 PDX:n=22 Placebo:n=23	Randomized, parallel group, placebo-controlled study. Ss were randomized into a PDX and placebo group. At study entry a 5-d food record was completed to determine usual food intake. Defecation discomfort (flatulence, constipation) was also assessed. After a baseline stool sample was obtained, Ss consumed the placebo for a 2 wk run-in. During the intervention period, the PDX group consumed the PDX yogurt and the placebo group continued eating the placebo. Ss were followed for an additional 3 wk washout period to evaluate whether the effects of PDX were persistent. At the end of each period, at least 3 stool samples were collected. Stool consistency was assessed with the "Bristol stool form scale." Transit time was determined via marker tablets. Ss ingested the tablets after the first defecation in each period and documented the time of intake as well as the time of appearance of red color in feces.	8 g/d PDX (**Litesse**) in 100 g low fat, sweetened yogurt 100 g low fat, sweetened yogurt (Placebo)	Run-in Intervention Washout Stool weight (g/defecation) PDX 101.8 102.7 107.2 Placebo 101.2 98.4 118.1 Transit time (d) PDX 1.88 1.57* 1.60 Placebo 1.63 1.55 1.29* *Significantly different to the period before, $p < 0.05$ Ss suffering from constipation reported improved ease of defecation after PDX intake (one unit of the Bristol stool form scale). In regard to the total study population, stool consistency was not affected by PDX (data not reported).	QG: Low Statistical analysis was compared to the period before. Statistics were not performed on the net change in the PDX compared to the net change in the placebo group. Ss kept diet records only on entry into the study not during the study. It was assumed that the lack of diff. in E, protein, fat, CHO, and DF between the PDX and placebo groups would continue throughout the study. While this assumption may be true, the results would have been strengthened if diet records demonstrated no diffs. during the study.

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Study	Purpose	Subjects (Ss)[1]	Study Design, Method, Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Saku et al., 1991	To investigate the effects of PDX on serum lipids, lipoproteins, and apo-lipoproteins in healthy Ss	59 healthy Japanese adults 25 men, mean age: 34.0 ± 9.4 y 36 women, mean age: 37.8 ± 10.2 y 2 Ss stopped taking PDX during the first month due to diarrhea, therefore 59 Ss were followed in month 2 and 3.	Non-randomized study, fixed sequence study. Ss consumed PDX daily for 2 months. Ss were followed a 3rd month when PDX was not consumed. All Ss were asked to maintain their normal daily lifestyles during the 3 months. Ss compliance with taking PDX was checked by interview each month. Ss were asked about bowel movements and feces (characteristics and volume) each month.	15 g PDX (5 g in 10 ml solution 3x daily after meals, source of PDX not specified) No placebo control	PDX 1 mo n=61 % PDX 2 mo n=59 % after PDX 1 mo n=59 % Stool Characteristics* No change 41 47 68 Diarrhea or soft 56 53 14 Constipation 3 0 19 Stool Volume* No change 69 76 90 Decrease 13 8 10 Increase 18 15 0 *P < 0.01, PDX1 and PDX2 compared with posttreatment	QG: low Not a randomized, placebo-controlled study. Not clear on details regarding how Ss were questioned about bowel movements and fecal characteristics—(i.e. if Ss were asked to reflect over entire month, and how Ss estimated volume etc.). Diet was not monitored during study. 2 Ss out of 61 Ss did not complete the study.

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Study	Purpose	Subjects (Ss)[1]	Study Design, Method, Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Shimada et al., 2015	To evaluate the bowel habits by the ingestion of 10 g PDX in hemo-dialysis patients	29 Japanese hemodialysis subjects 50 Ss consented and were randomized PDX: n=25 Age:62.3 y BMI: 22.5 kg/m^2 N=7 excluded* N=18 intervention N=2 excluded Final N=16 Placebo: n=25 Age:67.4 y BMI: 21.8 kg/m^2 N=5 excluded N=20 intervention N=7 excluded Final N=13 *Hospitalization, declined to participate, diarrhea **Poor compliance, laxative use, poor dietary intake	Randomized, placebo-controlled, triple-blind, parallel-group study. Ss were randomly stratified by age, gender, hemodialysis history, Dietary intervention occurred for 4 wk. Ss kept daily records of stool freq., stool consistency, abdominal pain, bloating, flatulence, intake of jelly and use of laxatives and other medications 2 wk prior to intervention, during 4 wk intervention and 2 wk after. A FFQ dietary questionnaire was used to determine dietary intake 2 wk prior and 2 wk after intervention.	10 g PDX (2 packs of 5 g PDX jelly; one after breakfast and one after dinner). Placebo (2 packs of placebo jelly)	Prior to intervention, stool frequency was 3 and 3.5/wk in the PDX and Placebo group, respectively. During the PDX treatment, stool frequency ranged from 5 to 8.5/wk for each week of intervention, which as significantly different from the baseline and placebo, $p< 0.05$. The higher stool frequency was still evident during the 2 wk washout period ($p < 0.05$ vs. baseline and placebo). During the Placebo treatment, stool frequency ranged from 3 to 5/wk for each week of intervention. Stool consistency score (based on a scale) did not significantly differ between PDX and Placebo.	QG: Low Although use of laxatives, prebiotics, and probiotics were prohibited, some Ss did use laxatives. Researchers reported that many medications that HD patients take may cause constipation. Dietary intake was not measured during the intervention, only 2 wk before and 2 wk after.

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Study	Purpose	Subjects (Ss)[1]	Study Design, Method, Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Tomlin and Read, 1988	To compare the effects of ispaghula (ISP) with PDX and mixtures of ispaghula and PDX on mass, frequency and consistency of stools and transit time in healthy Ss	12 healthy male British adults Age: 20-30 y 7 Ss participated in both studies. All had performed similar experiments before and were familiar with procedures	Study 1 (54 days) First 10 d was the control period. Ss then had 3 test periods of 10 d separated by 1 wk. Ss randomly consumed a) 7 g ISP; b) 30 g PDX; c) mixture of 2 g ISP + 30 g PDX Study 2 (37 days) First 10 d was the control period. Ss then had 3 test periods of 10 d separated by 1 wk. Ss randomly consumed a) 7 g ISP; b) mixture of 2 g ISP + 10 g PDX Ss followed their usual diet but avoided foods known to affect their bowel habits or cause flatulence. During each 10-day period, Ss kept a diary of time of defecation, the form and consistency of their stools (by comparison with a set of standard photographs and descriptions), the time of any episodes of flatulence (Study 2 only) and any subjective feelings. All stools passed were collected. Radio-opaque plastic markers were ingested at same time each day and time noted. These were used to assess transit time. In study 2, Ss rated stool amount, frequency, consistency, ease of defecation, and flatulence on visual analogue scales.	Study 1 Orange-flavored supplements: a) 7 g/d ISP provided as 2 sachets of Fybogel; b) 30 g/d PDX in 2 100-ml bottles; c) 2 g ISP + 30 g PDX in 2 100-ml bottles Study 2 Orange-flavored supplements: a) 7 g/d ISP provided as 2 sachets of Fybogel; b) 2 g ISP + 10 g/d PDX in 2 100-ml bottles Source of PDX was not specified.	Study 1 Fecal mass (kg/wk): Control 1.20; ISP 1.26[a]; PDX 1.22[a]; ISP+PDX 1.28[a] Transit time (h): 53.9; 58.9; 59.0; 59.2 Stool freq./wk: 7.6; 7.6; 7.7; 7.6 Stool consistency: 5.1; 5.2; 4.6[ab]; 4.4[ab] [a]Significant diff. from control ($p < 0.05$) [b]Significant diff. from ISP ($p < 0.05$) Study 2 Fecal mass (kg/wk): Control 1.54; ISP 1.76[a]; ISP+PDX 1.63[a] Transit time (h): 33.4; 35.2; 36.2 Stool freq/wk: 7.8; 9.8; 9.0 Stool consistency: 4.5; 4.5; 4.4 Flatulent episode/wk: 48; 73[a]; 106[ab] [a]Significant diff. from control ($p < 0.05$) [b]Significant diff. from other test period ($p < 0.05$) Ease of defecation was significantly easier for ISP (4.9 control, 5.9 mixture, 6.0 for ISP, $p < 0.05$). ISP also significantly increased the subjective ratings of the amount of feces produced and the stool consistency compared with the control period. Ss thought ISP produced larger and softer stools. Combined Results (n=7)To minimize interstudy variations, results from the 2 studies were compared in 7 Ss who participated in both. The only significant difference was that the ISP+ 30 g PDX produced significantly more softening of stool consistency than ISP + 10 g PDX compared to the control.	QG: Low Although there was a control period, no placebo control was used. The control period was not part of the randomization procedure, only the ISP and PDX treatments. Subjects did not keep diet records to ensure that food habits did not significantly differ between periods.

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8.2. Combination Polydextrose Laxation Studies

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Beards et al., 2010a	To assess the potential prebiotic potential of chocolate containing blends of sugar (maltitol=MTL, polydextrose= PDX, resistant starch=RS) replacers compared to traditional sucrose-based chocolate.	40 healthy U.K. adults (37 F, 13 M). Mean age: 33 y, BMI: 22.7 kg/m^2 MTL: n=10 MTL+PDX: n=10 MTL+RS: n=10 Placebo: n=10	Randomized, parallel-group, placebo-controlled, double-blind, dose-response study. Ss were randomly split into 4 groups. A pre-treatment stool sample was taken on day 0. On days 1-14, Ss consumed 49 g of assigned chocolate. A stool sample was collected on day 15. On days 15-29, Ss consumed 75 g of assigned chocolate and a stool sample was collected on day 30. Ss consumed 100 g of assigned chocolate and a stool sample was taken on day 45. Ss kept daily diaries throughout to record stool frequency, consistency, abdominal pain, intestinal bloating and gas. Any concomitant medication, adverse events, or comments were also recorded.	49 g chocolate: 22.8 g MTL 22.8 g (MTL+PDX) 22.8 g (MTL+RS) C: Sucrose (placebo) 75 g chocolate: 34.2 g MTL 34.2 g (MTL+PDX) 34.2 g (MTL+RS) C: Sucrose (placebo) 100 g chocolate: 45.6 g MTL 45.6 g (MTL+PDX) 45.6 g (MTL+RS) C: Sucrose (placebo) PDX: **Litesse**, Danisco RS: **Nutriose**, Roquette MTL was blended with PDX or RS. Amount of PDX or RS blended was not reported.	No significant changes in stool frequency or consistency in the MTL + PDX group compared to the control.	QG: Low Laxation was not a focus of this study, but was measured as an aside to measuring the prebiotic potential of PDX + MTL. Amount of PDX or RS blended with MTL was not reported. Only 10 subjects per group. No diet records were kept. No information provided on dropout rate (if any), and product compliance.

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Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Magro et al., 2014	To investigate the combination of PDX + *L. acidophilus* + *B. lactis* on intestinal transit in constipated subjects	47 consti-pated Brazilian adults Tx: n=26 24 F, 2 M Age:31.5 y BMI: 28.2 kg/m^2 C: n=21 19 F, 2 M Age: 32.7 y BMI: 26.8 kg/m^2 71 were recruited and 24 were excluded due to normal colonic transit time (12); changed mind on participation (10); intolerant to yogurt (2)	Randomized, controlled, double-blind, parallel-group study. Ss consumed yogurt every morning for 14 d. Clinical evaluations for the Agachan score and the colon transit time were done immediately before the beginning of the experiment and at the end. Ss recorded daily bowel evacuations and were told not to take any laxatives, fiber supplements, yogurt or fermented milk during the course of the study. Ss took one capsule a day of colonic transit time markers for 3 consecutive days and had an abdominal x-ray the day after ingesting the 3rd capsule. An evaluation was made before day 0 and on day 14 of the study.	180 ml unflavored yogurt with: 3.6 g PDX (4 g Litesse) + 10^9 cfu *L. acidophilus* NCFM +10^9 cfu *B. lactis* HN019 Control: no additional ingredients	The PDX group had a shorter transit time at the end of the intervention compared to the control group (p=0.01). Agachan score had a significant reduction at the end of the study in both groups, but tended to be better in the PDX group. However, the number of bowel movements per day did not change during the duration of the study in either group.	QG: Moderate Symbols for statistical significance confusing in Tables. Inclusion criteria was a Agachan score (measure of constipation) range of 10 to 20. Subjects were instructed to avoid laxtives, foods and supplements that may impact laxation. Diet profiles and recommended liquid consumption levels were evaluated and developed for each subject.

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8.3. Combination Polydextrose Study that Evaluated Energy Intake at Next Meal

Study	Purpose	Subjects (Ss)[1]	Study Design, Method[2], Duration	Test and Placebo Products: Dose, Source	Results	Quality Grade (QG)[2], Comments
Astbury et al., 2014	To compare the effects of 2 energy-matched snack bars on appetite, E intake and metabolic and endocrine responses.	10 healthy men Age: 30.7 y BMI: 23.2 kg/m^2	Randomized, double-blind, crossover trial of two 14-d intervention phases and a 14-d washout period. During each phase, Ss remained free-living the diet was self-selected; however, Ss consumed one of the test snack bars each day as a mid-morning snack. On the 4th, 8th, and 12th day, Ss recorded all food and drinks consumed for a 24-h period. On d1 and d15 of each phase, Ss participated in an experimental protocol. Ss consumed a standardized meal at 20.00h the evening before each study day. Nothing other than water was to be consumed until they arrived at the lab 7:45 h the next morning. A fasting blood sample was collected and Ss completed baseline appetite ratings using VAS. Ss were then provided Rice Krispies and semi-skimmed milk for breakfast which was consumed in 15 min. After 150 min, another blood sample was taken and appetite ratings were completed before consuming the test bars. Additional VAS ratings immediately and 30, 60, 90 mins after the snack. Ss then consumed an *ad libitum* pasta-based meal until they were comfortably full. VAS ratings were taken right after and 30 and 60 min. later. Blood samples were taken and Ss were permitted to leave. Ss kept a record of all food and drinks consumed for the rest of the day.	Snack bar with 6.2 g PDX + whey protein (12.9 g protein) Snack bar with no PDX or whey (control; 0.6 g protein) Both snack bars were equivalent in E and fat content.	D1: *Ad libitum* E intake at lunch was significantly lower after PDX snack (4085 kJ) than the control snack (4880 kJ) ($p < 0.05$). Total E intake was significantly lower after the PDX snack (9248 kJ) than the control snack (11,466 kJ) ($p < 0.05$) D15: *Ad libitum* E intake at lunch was significantly lower after PDX snack (4330 kJ) than the control snack (5344 kJ) ($p < 0.05$). Total E intake was significantly lower after the PDX snack (10,214 kJ) than the control snack (12,080 kJ) ($p < 0.05$) Free-Living Intake: Total E intake on 3 recorded days was significantly lower during the intake of the PDX snack (7904 kJ) than during the control snack (9041 kJ) ($p < 0.05$).	QG: Moderate Small sample size. Self-reported intake during the free-living phase was lower than the E recorded on any experimental day. Researchers believe the differences are due to underreporting typically observed with self-reported measures of the diet.

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Appendix 8.4a. Radioactive-isotope Labeled Animal Studies of Polydextrose

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Juhr and Franke, 1992	To develop a method to estimate the available E from CHO (PDX, cellulose, bacterial cellulose) that are unavailable or partially unavailable through direct digestion and absorption in rats Data provided only for PDX.	23 male Wistar rats (CN: conventional) 23 germfree (GF) male Wistar rats	Rats were given free access to food and water. The basal diet was supplemented with 1% PDX for 2 wk before receiving the test radiolabeled PDX. To obtain data on the contribution of noncecal fermentation to the degradation of these compounds at least 14 d before the study, 4 germfree and 4 conventional rats were cecectomized. After the rats were dosed with [^{14}C] PDX, the rats were placed in metabolism chambers for the next 30 h. Respired CO_2, urine and feces were collected. Radioactivity was determined in a scintillation counter.	[359 kBq [^{14}C] PDX [^{14}C] tobacco cellulose [^{14}C] bacterial cellulose	Component — % PDX Dose — How determined Unavailable E Excreted in feces 53.5 Meas'd. in CN rats Excreted in urine 4.0 Meas'd. in CN rats Loss to fermentation 15.1 Calculated: CN vs. GF rats and corrected for efficiency Total 72.6 Available E Respired in breath 6.6 Meas'd. in GG rats Incorporated in tissue 5.7 Calculated: CN vs GG rats Fermentation 15.1 Calculated: CN vs. GF rats and corrected for efficiency Total 27.4 E value of PDX = 0.274 x 17 kJ/g (accepted E value for all CHO) = 4.7 kJ/g or **1.12 kcal/g**	Complete approach, including the amount incorporated into tissue.

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Cooley & Livesey, 1987	To compare the digestible E (DE) and metabolizable E (ME) of PDX by energy balance in rats compared to values obtained by radiochemical balance using radio-isotopes.	4 male Wistar rats	Animals were provided with water and the *ad libitum* control basal diet for 7 d before the 4 d radiochemical expt. The expt. was initiated by gastric intubation of [^{14}C] PDX, following which, each animal was placed into glass metabolism cages and provided water and the control diet in which 50 g maize starch was replaced with PDX. $C0_2$ was collected as well as urine and feces at 3, 12, 24, 48, 72 and 96 h. DE was calculated as the diff. bet. the gross E value of food intake and the gross E value of collected feces. ME was calculated as the diff. in DE in the diet and the gross E collected in urine. The following equations were used: $DE\ (kJ/g) = (DE_t - DE_c + iDE_\delta)/i$ $ME\ (kJ/g) = (Me_t - ME_c + iME_\delta/i$ i is the quantity of maize starch replaced by PDX (g/d diet), DE_t, DE_c, and DE_δ are the test PDX diet, the control diet and the maize starch respectively (kJ/g) and ME_t, ME_c and ME_δ are the corresponding ME values (kJ/g). The digestibility (D) of the radiochemical analogue of PDX was calculated as the proportion of the radiolabeled dose that was not recovered in feces and the availability (A) as the proportion of the dose that was not recovered in the urine and feces combined. Estimates of the DE and ME were determined by multiplying the gross E of PDX by the values of D and A respectively. It was assumed that the free glucose contained in PDX was completely absorbed. Gross E of PDX was derived from the analyzed components, i.e. 930 polymer derived from glucosyl: hydrodenated glucosyl ratios of 9:1, 43 glucose monohydrate and 10 anhydrous glucose; total value =16.95 kJ or 4.05 kcal/g	[^{14}C] PDX	% of PDX dose recovered in $C0_2$ Feces Urine 33 48 4.6 [^{14}C] PDX Whole material / Polymer fraction Gross E (kJ/g) 16.9 17.5 Radiochemical balance study: DE (kJ/g) 8.8 8.6 ME (kJ/g) 8.0 7.8 ME: 7.8 kJ/g = **1.86 kcal/g***	Caloric availability was determined for commercial PDX and the PDX polymer it contains. *ME was not corrected for bacterial use of PDX, therefore this is an overestimate

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Figdor and Rennhard, 1981	To use [^{14}C] PDX in the rat to characterize caloric utilization and disposition of PDX	3 rats (i.v. dose) 4 rats (oral administrat-ion)	*i.v. administration*: rats received an intravenous dose of [^{14}C] at 25 mg/kg or 50 mg/kg PDX. Collection of CO_2 was carried out at hourly intervals for 13 h and as a single collection during 13-24 h. *oral administration*: rats received a single dose of 55 mg/kg by gavage. Collection of $^{14}CO_2$ was conducted at hourly intervals for 13 h. *stressed rats*: rats had free access to normal rat chow containing nonlabeled PDX at 1 or 10 g/kg BW) for 90 days. A group of rats eating normal food served as a control. At the end of the 90 days, 2 rats were selected from each of the 3 groups and given 14.7 mg [^{14}C] PDX (~ 30 mg/kg). Immediately after receiving the tracer dose, each rat was placed in a metabolism chamber designed to collect exhaled $^{14}C0_2$ at hourly intervals for 13 h; urine and feces were separately collected at 24-h intervals for 3 d. *SCFA determination*: (1) Rats received [^{14}C] PDX and feces was collected 0-24 h; (2) A rat dose as in (1) was killed 5 h after receiving the [^{14}C] PDX dose. The cecum was removed and the contents were homogenized in water and extracted. (cont'd.)	[^{14}C] PDX at 25 mg/kg or 50 mg/kg. Rats on avg. weighed 200 g.	*i.v. administration*: Following this admin. route, PDX was rapidly and completely eliminated in urine within 3 h. Recovery of $^{14}C0_2$ was ~ 1% of [^{14}C] PDX dose. *oral administration*: 21% of radioactivity was recovered as ^{14}C0, less than 2% in urine, and the remainder in feces. Nearly all the radioactivity is recovered in urine and feces within 24 h. Max. excretion of $^{14}C0_2$ occurred 6-8 h after [^{14}C] PDX, indicating that PDX was not absorbed from the upper gut. The $^{14}C0_2$ collected is obtained from two sources: mammalian enzyme-degraded SCFA which were derived from bacterial fermentation of PDX (caloric) and CO_2 formed directly from fermentation of PDX (non-caloric). Since it is not possible to distinguish $^{14}C0_2$ from SCFA and $^{14}C0_2$ produced by bacteria, caloric utilization estimates based on recovered $^{14}C0_2$ are high estimates, due to the inclusion on non-caloric $^{14}C0_2$. Results of experiments on SCFA and intestinal microflora confirmed that PDX is fermented by microflora in the lower intestinal tract, resulting in the production of SCFA. *stressed rats*: Feeding PDX at 1 or 10 g/kg/d for 90 day prior to a test dose of [^{14}C] PDX showed no difference in the metabolism compared to control rats not fed PDX. *Calorie determination*: 21% or orally administered radioactivity was recovered as $^{14}C0_2$. This is the sum of CO_2 formed directly by gut microflora and CO_2 from the utilization by the rat of SCFA which are absorbed from the lower intestines. Expts. of labeled glucose and acetate indicate ~60% is absorbed and utilized and exhaled as CO_2. Since only 60% of PDX is utilized by rats and exhaled, a max. caloric value of 35% is computed as available (i.e. 1.4 kcal/g). In reality, the true caloric value of PDX in the rat is closer to 25% or approximately **1 kcal/g** when corrected for bacterial activity.	Expts. were conducted with a very small number of rats.

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Figdor and Rennhard, 1981 (cont'd.)			*Caloric utilization* of PDX: Calculated from the quantity of $^{14}C0_2$ after labeled PDX administration. Expts. Have shown that administration of [^{14}C] glucose, which is rapidly absorbed and utilized results in the exhalation of ~60% of the radioactivity as $^{14}C0_2$ within 24 h. Therefore, the $^{14}C0_2$ that is actually recovered is corrected by a catabolic conversion factor of 0.6 in estimating the total caloric utilization of PDX			

Appendix 8b. Energy Balance Animal Studies of Polydextrose

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Knapp et al., 2008	To quantify *in vitro d*igestion, true metabolizable energy (TME_n), glycemic and insulinemic response, and GI tolerance to fructose, maltodextrin, PDX, pullulan, resistant starch, sorbitol, and xantham gum using canine and avian models. (Info. provided here will only include TME determination for PDX).	4 conventional single comb white leghorn roosters	Birds were housed individually in an environmentally controlled room and subjected to a 16 h light and 8 h dark photoperiod. Roosters were deprived of feed for 24 h and then crop-intubated with PDX using the precision-fed rooster assay. Following intubation, excreta (urine and feces) were collected for 48 h on plastic trays placed under each cage. Excreta were than lyophilized, weighed and ground to pass through a 60 mesh screen and analyzed for gross E (GE) using a bomb calorimeter. The nitrogen corrected TME_n values for endogenous E excretion using fasted roosters were calculated using the following equation: TME_n (kcal/g) = (E intake – E excreted by fed birds + E excreted by fasted birds)/feed intake	14.3 g PDX	Of all the CHO tested, PDX had the lowest TME_n value of **1.74 kcal/g*.** Details of this derivation was not provided. The method used overestimates the E content.	* This value is an overestimate as this model only takes into account the amount of PDX lost in urine and feces. It does not take into account the bacterial degradation and utilization of PDX.

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Lowry et al., 1986 (abstract)	To determine the metabolizable energy (ME) of PDX using an *in vivo* methodology	Adult roosters	Roosters were crop intubated with 50 ml of a 60% PDX solution (i.e. 30 g) and excreta was collected for 48 h.	30 g PDX	The ME of PDX was determined to be **1.06 kcal/g**. Details of the calculation were not provided.	Incomplete information, as study was only reported in abstract form.

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Cooley and Livesey, 1987	To determine the E value of PDX by the conventional energy-balance procedure	Male Wistar rats	All rats were kept in pairs in wire-bottom cages and provided with the control diet for 7 d *ad libitum*. For the next 6 d, rats consumed the control diet or the control diet in which some of the maize starch was replaced with PDX. Feces and urine were collected at the end of the 3^{rd} and 6^{th} d. At the end of the 6 d period, the animals were killed and pellets of digesta residue were removed. DE was calculated as the diff. bet. the gross E value of food intake and the gross E value of collected feces. ME was calculated as the diff. in DE in the diet and the gross E collected in urine. The following equations were used: $DE\ (kJ/g) = (DE_t - DE_c + iDE_\delta)/i$ $ME\ (kJ/g) = (Me_t - ME_c + iME_\delta/i$ i is the quantity of maize starch replaced by PDX (g/d diet), DE_t, DE_c, and DE_δ are the test PDX diet, the control diet and the maize starch respectively (kJ/g) and ME_t, ME_c and ME_δ are the corresponding ME values (kJ/g). DE_δ and ME_δ were taken to be 16.58 kJ/g (Metta & Mitchell, 1954). ME corrected by subtracting from it 26.33 kJ/g N (Metta & Mitchell, 1954) retained in the control animals.	100 g/kg diet PDX	The derived value of ME for the PDX commercial product using the balance procedure uncorrected to zero N balance was 13 kJ/g. Including the PDX product in the diet, decreased the digestibility of dietary N from 0.86 to 0.84 and may have increased the retention of N in the body from 67 to 74% of the dietary N. Because of these small potential differences in the distribution of dietary N, the derived value for PDX product may be overestimated by 0.25 kJ/g. Hence, the N-corrected ME for PDX product was calculated to be 12.7 kJ/g. By assuming complete utilization of the free glucose in the PDX product, the polymeric fraction of PDX was calculated to have a DE of 12.8 kJ/g and an ME of or 12.1 kJ/g or **2.9 kcal/g.*** This value is an overestimate. Authors report that it is more usual for the utilization of a substance to be greater than expected from ME-balance studies, which may be explained by the fecal loss of other substances.	*This value is an overestimate because bacterial utilization of PDX was not taken into account.

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Krüger et al., 1990	To determine the small-intestinal digestibility of PDX in rats using a realistic low dose range	Male Wistar rats	1 hr after intra-gastric administration of PDX and 0.08% penol red marker, the whole gastro-intestinal tract was excised and subdivided. The contents of the segments were collected quantitatively and analyzed for PDX and phenol red. The PDX recovery was corrected by subtracting values obtained from negative controls.	300 mg/kg BW PDX	The total mean recovery of the transit marker was 89.9%. The marker indicated that as early as 1 h after intra-gastric administration more than 90% of the dye which had entered the small intestine had accumulated in its distal part but did not enter the cecum and large intestine. PDX analysis revealed a similar GI distribution, but only 53% of the ingested dose could be recovered, indicating a small-intestinal disappearance of about 47%. The authors suggest 41% of the initial amount of PDX must have been absorbed in the small intestine. It was concluded that PDX supplies at least 1.6 kcal/g. The researchers indicate this value does not include the caloric salvage of the unabsorbed fraction of PDX which is mediated by bacterial fermentation in the lower gut, therefore the physiological E value of PDX corresponds to at least **2 kcal/g**.*	*Caloric value was grossly overestimated. Study was only conducted for 1 h. No correction for E utilization by gut bacteria.

Study	Purpose	Animals	Study Design, Method, Duration	Test Product	Results	Comments
Ranhotra et al., 1993	To determine usable E of PDX and other fibers based on efficiency of conversion of gross food E to net E (carcass E).	65 male, 3 wk Sprague-Dawley rats	Rats were fed rat chow for the first 7 d and then randomly assigned to six groups (10 rats/group) for the 3 wk study. A control group of 5 rats were sacrificed just before the start of the expt. During the study period, each rat was allowed to consume adequate and increasingly higher, but otherwise identical, amounts of the diet. Deionized water was offered *ad libitum*. BW records were maintained. At the end of wk 3, all rats were sacrificed, their gut contents removed and discarded, and the carcass weighed and then frozen for additional analyses. Rats fed PDX showed a pronounced laxative effect. These rats also consumed less compared to the controls and therefore dietary intake was used to regulate the diet so that all groups consumed the same amount.	PDX Starch (+ control) Silica (- control)	Body weight gains was highest on the starch diet and lowest on the silica diet. Since PDX intake had a weight gain higher than those fed silica, there was evidence that PDX provided some E. Net increase in total carcass E: E gained during the 3 wk test period - initial carcass E (57 kcal) From the 176 g diet consumed by each rat during the 3 wk study, the amount of PDX consumed was 61.6 g. Net increase in carcass E: 72 kcal Relative increase in relation to silica: 14 kcal Starch: 61.6 g x 3.67 kcal/g = 226 kcal; Net carcass E= 67 kcals; ratio of 3.37:1. An equation based on this ratio, indicated PDX has a E value of **0.77 kcal/g*.**	*Rats fed PDX showed a pronounced laxative effect. Also diarrhea impacts microflora activity and the production of SCFA may have been impaired. For this reason, the caloric value of PDX may have been underestimated.