Appendix 7. ANIMAL STUDIES: OATRIM [INCLUDING OATRIM (BETATRIM™)], OAT EXTRACTS, OAT GUMS AND ENRICHED OAT BRANS

Study	Animal Model, Test Duration, Lipotrophic Substances	Intervention Products	Results % Change Compared to Control	Comments
Chen et al, 1981	Male rats, 4 per group; test period: 3 wks; addition of 1% CHOL plus 0.2% cholic acid.	10% oat gum (**66% β-glucan**); 36.5% oat bran; 10% cellulose (control)	TC HDL-C TG LC LTG OG: -41* +76* -59* -74* -65* OB: -24* +62* -7 -46* -46* *Sig. different from control.	Both oat gum and oat bran significantly lowered plasma and liver TC and increased HDL-C.
Freiburger and Gallaher, 2000 [Quaker: Study 1]	Single meal-fed study; male rats, 12 per test group; 5 per control group; test duration: 2 hours.	5 g meal + one of the three formulations of Oatrim (BetaTrim™): **4% β-glucan** -Low **12% β-glucan** -Med **20% β-glucan** – Hi; Oatmeal; CE -Cellulose control	VISCOSITY (mPa*s) Oatrim (BetaTrim™) 4% 12% 20% 17.4 367.9 1,426.8 A strong correlation (R = 0.986) was observed between log viscosity and the percent of β-glucan in the fiber source.	The Med and Hi Oatrim (BetaTrim™) had similar and significantly higher viscosity than oatmeal and oat bran. Intestinal contents viscosity increased progressively from Low to Hi Oatrim (BetaTrim™).
Freiburger and Gallaher, 2001 [Quaker: Study 2]	Male rats, 10 per group; test duration: 28 days – Chronic feeding study; CHOL added at 0.25%, and fiber was at 5% of all diets.	Test formulations included; Oatrim BetaTrim™): **4% β-glucan**- Low **12% β-glucan**- Med **20% β-glucan**- Hi; Low viscosity HPMC; Hi viscosity HPMC; CE -Cellulose control	VISCOSITY (mPa*s) Oatrim (BetaTrim™) 4% 12% 20% L-HPMC H-HPMC CE 11.2 62.0 321.9 541.5 714.2 4.6 Intestinal contents supernatant viscosity for all 3 Oatrim (BetaTrim™) were significantly different from control CE. A significant decrease in total liver CHOL was found in all groups compared to the control CE ($p<0.05$). A significant inverse correlation was observed between total liver cholesterol and log viscosity (R=0.90; P=0.015). Fecal bile acid excretion was significantly increased in all 3 Oatrim (BetaTrim™) compared to control CE and inversely correlated with total liver cholesterol (R=0.87; P=0.02).	The cholesterol lowering and increased bile acid excretion was observed with all 3 Oatrim (BetaTrim™). These results are consistent with previous observations with rolled oats and oat bran. However, no significant effect on was observed for cholesterol absorption.

Abbreviations: CHOL: cholesterol; TC: Total cholesterol; LDL-C: Lipoprotein cholesterol: HDL-C: high-density cholesterol; TG: triglyceride; LC: liver cholesterol; LTG: liver triglyceride OG: Oat gum; OB: Oat bran: HPMC: hydroxypropylmethylcellulose; CE: cellulose; EOF: enriched oat flour;

Appendix 7. ANIMAL STUDIES: OATRIM [INCLUDING OATRIM (BETATRIM™)], OAT EXTRACTS, OATS GUMS AND ENRICHED OAT BRANS (cont'd.)

Study	Animal Model, Test Duration, Lipotrophic Substances	Intervention Products	Results % Change Compared to Control	Comments
Gallaher et al, unpublished [Quaker: Study 3]	Single meal-fed study; male rats, 12 per test group; 5 per control group; test duration: 2 hours.	Oatrim (BetaTrim™) processed enzymatically; **20% β-glucan** concentration Oatrim (BetaTrim™) processed using the acid/base method; **20% β-glucan** concentration	Intestinal contents supernatant viscosity of the sample from both processing methods was >1000 mPa*s/% β-glucan. No statistically significant difference was observed between the two sample (p=0.43).	Significant viscosity was observed for Oatrim (BetaTrim™) from both processing methods. The similarity in viscosity/% β-glucan of sample from both processing methods indicates efficacy per gram β-glucan is not different for either processing method.
Inglett & Newman, 1994	Chicks, 8 per group; test period: 10 days; addition of 0.5% CHOL	26.4% Oatrim-10 **(10% β-glucan);** 26.4% corn (control)	TC -18* LDL-C -48* HDL-C +18 TG -15 *Sig. different from control.	Significant reductions in TC and LDL-C. No significant reductions for HDL-C and TG. Oatrim chicks gained significantly less weight than controls.
Inglett et al, 1994	Chicks, 24 per group; test period: 14 days; addition of 0.5% CHOL	38% Oatrim-10 **(8.6% β-glucan);** 29.35% corn (control)	TC -40* LDL-C -61* HDL-C -6 TG -3 *Sig. different from control.	This study confirms the cholesterol lowering efficacy findings that Inglett & Newman (1994) observed in the pilot study.

Abbreviations: CHOL: cholesterol; TC: Total cholesterol; LDL-C: Lipoprotein cholesterol; HDL-C: high-density cholesterol; TG: triglyceride; LC: liver cholesterol; LTG: liver triglyceride; OG: Oat gum; OB: Oat bran; HPMC: hydroxypropylmethylcellulose; CE: cellulose; EOF: enriched oat flour.

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Study	Animal Model, Test Duration, Lipotrophic Substances	Intervention Products	Results % Change Compared to Control	Comments
Malkki et al, 1995	Male rats, 10 per group; test period: 3 wks; addition of 1% CHOL and 0.2% cholic acid	OBC* to provide: **1.5% β-glucan; 3.0% β-glucan; 4.5% β-glucan;** 7.2% cellulose control *highly concentrated, like Oatrim	All 3 doses lowered TC compared to control, but increasing the dose caused no significant increase in effect. All 3 doses had significantly higher HDL-C levels than the control.	Authors state that this study confirms early observations (Malkki et al, 1992; Cereal Chem. 69:647-653) on the superiority of the hypocholesterolemic effect of enriched/concentrated oat bran over untreated regular oat bran at a similar level of β-glucan
Oda et al, 1994	Male rats, 8 per group; test period: 14 days; addition of 20% coconut oil	Diet: 2% oat gum (using **65% β-glucan** source); Control diet: 2% cellulose	TC -17* TG -46* LC -25* LTG -46* *Sig. different from control.	The β-glucan in the oat gum significantly lowered TC and TG in both serum and liver.
Ranhotra et al, 1990	Male rats, 10 per group; test period: 4 wks; addition of 1% CHOL and 0.2% cholic a. to diets A-D; Diets AA-DD did not have any lipotrophic substances added	B, BB: 50% oat bran; C, CC: 20.67% OBC (OBC: **14% β-glucan**); D, DD: 50% (OBC: **(14% β-glucan);** A, AA: (8% cellulose control) OBC: oat bran concentrate	TC / HDL-C / TG B: -9 / -1 / +3 C: -14* / +27* / +3 D: -34* / +27* / -36* BB: -12* / -8 / -11 CC: -39* / +7 / -4 DD: -41* / +3 / +11 *Sig. different from control.	B-D: The β-glucan in both oat bran[1] and OBC[2] decreased TC at wk 2 but only OBC had significant reductions at wk 4 (B vs C, D). Higher levels of OBC in the diet produced a more pronounced effect on TC (C vs D). [1]regular oat bran [2]enriched, highly concentrated oat bran
Welch et al, 1988	Chicks, 6 per group; test period: 14-19 days; addition of 14% dried whole egg	3.4% oat gum **(59.5% β-glucan)** ; 40% oat bran; 60% corn starch (control)	TC HDL-C LC LTG -45* +4 -33* +7 -46* -6 -48* -10 *Sig. different from control.	The β-glucan in both oat bran and oat gum significantly reduced serum and liver cholesterol.

Abbreviations: CHOL: cholesterol; TC: Total cholesterol; LDL-C: Lipoprotein cholesterol; HDL-C: high-density cholesterol; TG: triglyceride; LC: liver cholesterol; LTG: liver triglyceride; OG: Oat gum; OB: Oat bran; HPMC: hydroxypropylmethylcellulose; CE: cellulose; EOF: enriched oat flour.

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Study	Animal Model, Test Duration, Lipotrophic Substances	Intervention Products	Results % Change Compared to Control	Comments
Yokoyama et al, 1998	Male hamsters, 6 per group; test period: 21 days; addition of 10% hydrogenated coconut oil and 0.2% cholesterol	14.9% EOF (**29.1% β-glucan);** 39.6% Oatrim-10 (**10.6% β-glucan);** 67.3% Oatrim-5 (**6.4% β-glucan);** 40.1% OH (**0% β-glucan);** Control: 14.7% cellulose and 50.8% cornstarch	TC / LDL-C / HDL-C EOF: -21 / +16 / -26* O-10: -36* / -42* / -22* O-5: -32* / -67* / -20* OH: -17* / -51* / -6 EOF: enriched oat flour O-10: Oatrim-10 O-5: Oatrim-5 OH: Oat hydrolyzate	TC, LDL-C, and HDL-C were significantly reduced by Oatrim-10 and Oatrim-5. TC and LDL-C were significantly reduced by OH. EOF did not significantly reduce TC or LDL-C. The authors suggest the high Molecular Weight of EOF and processing may have contributed to EOF's weak effect. (The viscosity of linear polymers is related to molecular weight.)

Abbreviations: CHOL: cholesterol; TC: Total cholesterol; LDL-C: Lipoprotein cholesterol; HDL-C: high-density cholesterol; TG: triglyceride; LC: liver cholesterol; LTG: liver triglyceride; OG: Oat gum; OB: Oat bran; HPMC: hydroxypropylmethylcellulose; CE: cellulose; EOF: enriched oat flour

Note: One Oatrim study found in the literature in abstract form is not included here because the β-glucan concentration was not reported. Newman RK, Inglett GE, Newman CW, Hofer PJ, Wang DL, 1993. Beta-glucan concentrates from oats and barley lower cholesterol in chicks. FASEB J A:739 (Abstract).