

TABLE A3
Statistical Analysis of Primary Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
Adrenal Medulla: Benign Pheochromocytoma					
Overall rate ^a	11/47 (23%)	4/22 (18%)	6/25 (24%)	3/31 (10%)	8/47 (17%)
Adjusted rate ^b	29.6%	26.5%	34.8%	16.7%	20.7%
Terminal rate ^c	6/18 (33%)	0/0	1/2 (50%)	1/3 (33%)	5/25 (20%)
First incidence (days)	631	607	523	720	629
Poly-3 test ^d	P= 0.2116N	P= 0.5841N	P= 0.4284	P= 0.2203N	P= 0.3071N
Kidney (Renal Tubule): Adenoma					
Overall rate	0/48 (0%)	0/40 (0%)	0/48 (0%)	2/48 (4%)	5/48 (10%)
Adjusted rate	0.0%	0.0%	0.0%	5.7%	12.9%
Terminal rate	0/18 (0%)	0/17 (0%)	0/25 (0%)	2/20 (10%)	5/25 (20%)
First incidence (days)	— ^e	—	—	740 (T)	740 (T)
Poly-3 test	P= 0.0004	— ^f	—	P= 0.2293	P= 0.0314
Kidney (Renal Tubule): Carcinoma					
Overall rate	0/48 (0%)	0/40 (0%)	0/48 (0%)	7/48 (15%)	10/48 (21%)
Adjusted rate	0.0%	0.0%	0.0%	20.0%	25.4%
Terminal rate	0/18 (0%)	0/17 (0%)	0/25 (0%)	6/20 (30%)	8/25 (32%)
First incidence (days)	—	—	—	680	594
Poly-3 test	P= 0.0001	—	—	P= 0.0059	P= 0.0008
Kidney (Renal Tubule): Adenoma or Carcinoma					
Overall rate	0/48 (0%)	0/40 (0%)	0/48 (0%)	9/48 (19%)	15/48 (31%)
Adjusted rate	0.0%	0.0%	0.0%	25.7%	38.1%
Terminal rate	0/18 (0%)	0/17 (0%)	0/25 (0%)	8/20 (40%)	13/25 (52%)
First incidence (days)	—	—	—	680	594
Poly-3 test	P= 0.0001	—	—	P= 0.0011	P= 0.0001
Liver: Adenoma					
Overall rate	0/48 (0%)	2/40 (5%)	2/48 (4%)	0/48 (0%)	1/48 (2%)
Adjusted rate	0.0%	6.2%	5.2%	0.0%	2.6%
Terminal rate	0/18 (0%)	1/17 (6%)	2/25 (8%)	0/20 (0%)	1/25 (4%)
First incidence (days)	—	677	740 (T)	—	740 (T)
Poly-3 test	P= 0.5375N	P= 0.1993	P= 0.2412	—	P= 0.5050
Liver: Adenoma or Carcinoma					
Overall rate	0/48 (0%)	3/40 (8%)	3/48 (6%)	0/48 (0%)	1/48 (2%)
Adjusted rate	0.0%	9.2%	7.7%	0.0%	2.6%
Terminal rate	0/18 (0%)	1/17 (6%)	2/25 (8%)	0/20 (0%)	1/25 (4%)
First incidence (days)	—	607	685	—	740 (T)
Poly-3 test	P= 0.3391N	P= 0.0905	P= 0.1223	—	P= 0.5050
Mammary Gland: Fibroadenoma					
Overall rate	2/40 (5%)	0/20 (0%)	0/24 (0%)	0/24 (0%)	4/42 (10%)
Adjusted rate	6.5%	0.0%	0.0%	0.0%	11.5%
Terminal rate	1/15 (7%)	0/0	0/4 (0%)	0/2 (0%)	4/23 (17%)
First incidence (days)	705	—	—	—	740 (T)
Poly-3 test	P= 0.0838	P= 0.4520N	P= 0.4128N	P= 0.4151N	P= 0.3607

TABLE A3
Statistical Analysis of Primary Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
Pancreas: Adenoma					
Overall rate	6/47 (13%)	0/24 (0%)	2/25 (8%)	4/30 (13%)	6/48 (13%)
Adjusted rate	16.2%	0.0%	12.5%	21.9%	15.1%
Terminal rate	1/18 (6%)	0/1 (0%)	1/2 (50%)	0/2 (0%)	4/25 (16%)
First incidence (days)	633	—	666	606	594
Poly-3 test	P= 0.4038	P= 0.1273N	P= 0.5543N	P= 0.4737	P= 0.6106N
Pancreas: Carcinoma					
Overall rate	3/47 (6%)	2/24 (8%)	2/25 (8%)	0/30 (0%)	3/48 (6%)
Adjusted rate	8.4%	12.2%	12.7%	0.0%	7.7%
Terminal rate	2/18 (11%)	0/1 (0%)	1/2 (50%)	0/2 (0%)	2/25 (8%)
First incidence (days)	729	656	727	—	673
Poly-3 test	P= 0.4837N	P= 0.5033	P= 0.4891	P= 0.2751N	P= 0.6477N
Pancreas: Adenoma or Carcinoma					
Overall rate	9/47 (19%)	2/24 (8%)	3/25 (12%)	4/30 (13%)	9/48 (19%)
Adjusted rate	24.2%	12.2%	18.7%	21.9%	22.6%
Terminal rate	3/18 (17%)	0/1 (0%)	1/2 (50%)	0/2 (0%)	6/25 (24%)
First incidence (days)	633	656	666	606	594
Poly-3 test	P= 0.4464	P= 0.2963N	P= 0.5005N	P= 0.5191N	P= 0.5853N
Pituitary Gland (Pars Distalis): Adenoma					
Overall rate	30/43 (70%)	18/28 (64%)	23/33 (70%)	18/33 (55%)	24/45 (53%)
Adjusted rate	80.0%	73.2%	77.5%	72.5%	60.6%
Terminal rate	13/17 (77%)	5/6 (83%)	12/12 (100%)	5/7 (71%)	15/24 (63%)
First incidence (days)	284	561	454	477	319
Poly-3 test	P= 0.0320N	P= 0.4394N	P= 0.6001N	P= 0.2336N	P= 0.0661N
Pituitary Gland (Pars Distalis): Adenoma or Carcinoma					
Overall rate	30/43 (70%)	19/28 (68%)	23/33 (70%)	18/33 (55%)	25/45 (56%)
Adjusted rate	80.0%	77.2%	77.5%	72.5%	63.0%
Terminal rate	13/17 (77%)	6/6 (100%)	12/12 (100%)	5/7 (71%)	15/24 (63%)
First incidence (days)	284	561	454	477	319
Poly-3 test	P= 0.0434N	P= 0.5999N	P= 0.6001N	P= 0.2336N	P= 0.1016N
Skin: Basal Cell Adenoma					
Overall rate	3/48 (6%)	0/27 (0%)	0/28 (0%)	1/32 (3%)	3/48 (6%)
Adjusted rate	8.1%	0.0%	0.0%	5.3%	7.7%
Terminal rate	0/18 (0%)	0/4 (0%)	0/5 (0%)	0/4 (0%)	2/25 (8%)
First incidence (days)	560	—	—	715	697
Poly-3 test	P= 0.3408	P= 0.2777N	P= 0.2808N	P= 0.5442N	P= 0.6624N
Skin: Squamous Cell Papilloma or Keratoacanthoma					
Overall rate	3/48 (6%)	1/27 (4%)	3/28 (11%)	1/32 (3%)	1/48 (2%)
Adjusted rate	8.2%	5.3%	16.0%	5.2%	2.5%
Terminal rate	1/18 (6%)	0/4 (0%)	3/5 (60%)	0/4 (0%)	0/25 (0%)
First incidence (days)	631	687	740 (T)	673	629
Poly-3 test	P= 0.1615N	P= 0.5760N	P= 0.3146	P= 0.5384N	P= 0.2984N

TABLE A3
Statistical Analysis of Primary Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
Skin: Squamous Cell Papilloma, Keratoacanthoma, Trichoepithelioma, or Basal Cell Adenoma					
Overall rate	6/48 (13%)	2/27 (7%)	4/28 (14%)	2/32 (6%)	4/48 (8%)
Adjusted rate	15.9%	10.5%	21.4%	10.4%	10.1%
Terminal rate	1/18 (6%)	1/4 (25%)	4/5 (80%)	0/4 (0%)	2/25 (8%)
First incidence (days)	560	687	740 (T)	673	629
Poly-3 test	P= 0.2892N	P= 0.4700N	P= 0.4165	P= 0.4158N	P= 0.3716N
Skin (Subcutaneous Tissue): Fibroma					
Overall rate	3/48 (6%)	3/27 (11%)	2/28 (7%)	2/32 (6%)	0/48 (0%)
Adjusted rate	8.3%	15.9%	10.7%	10.4%	0.0%
Terminal rate	1/18 (6%)	3/4 (75%)	1/5 (20%)	1/4 (25%)	0/25 (0%)
First incidence (days)	645	740 (T)	727	615	—
Poly-3 test	P= 0.0365N	P= 0.3202	P= 0.5560	P= 0.6047	P= 0.1146N
Skin (Subcutaneous Tissue): Fibroma, Fibrous Histiocytoma, Histiocytic Sarcoma, or Sarcoma					
Overall rate	4/48 (8%)	3/27 (11%)	3/28 (11%)	3/32 (9%)	3/48 (6%)
Adjusted rate	10.9%	15.9%	15.9%	15.3%	7.6%
Terminal rate	1/18 (6%)	3/4 (75%)	1/5 (20%)	1/4 (25%)	0/25 (0%)
First incidence (days)	645	740 (T)	720	615	655
Poly-3 test	P= 0.2682N	P= 0.4332	P= 0.4339	P= 0.5007	P= 0.4863N
Testis: Adenoma					
Overall rate	33/48 (69%)	30/39 (77%)	34/46 (74%)	35/46 (76%)	37/48 (77%)
Adjusted rate	80.9%	85.6%	86.4%	89.6%	89.2%
Terminal rate	15/18 (83%)	16/16 (100%)	23/23 (100%)	15/18 (83%)	24/25 (96%)
First incidence (days)	600	582	442	519	594
Poly-3 test	P= 0.1518	P= 0.2412	P= 0.1901	P= 0.2334	P= 0.0984
Thyroid Gland (C-cell): Adenoma					
Overall rate	9/48 (19%)	2/24 (8%)	4/25 (16%)	2/31 (7%)	11/48 (23%)
Adjusted rate	24.4%	11.9%	24.0%	10.2%	27.9%
Terminal rate	5/18 (28%)	0/1 (0%)	2/2 (100%)	1/4 (25%)	9/25 (36%)
First incidence (days)	635	561	442	284	669
Poly-3 test	P= 0.2150	P= 0.2730N	P= 0.6082	P= 0.1839N	P= 0.4135
All Organs: Mononuclear Cell Leukemia					
Overall rate	24/48 (50%)	22/40 (55%)	21/48 (44%)	20/48 (42%)	16/48 (33%)
Adjusted rate	59.2%	59.3%	50.5%	52.6%	39.0%
Terminal rate	9/18 (50%)	6/17 (35%)	10/25 (40%)	10/20 (50%)	7/25 (28%)
First incidence (days)	390	550	461	580	533
Poly-3 test	P= 0.0369N	P= 0.4932	P= 0.3653N	P= 0.3532N	P= 0.0775N
All Organs: Benign Neoplasms					
Overall rate	45/48 (94%)	36/40 (90%)	45/48 (94%)	44/48 (92%)	43/48 (90%)
Adjusted rate	99.3%	94.2%	97.2%	98.0%	98.2%
Terminal rate	17/18 (94%)	16/17 (94%)	25/25 (100%)	19/20 (95%)	25/25 (100%)
First incidence (days)	61	561	442	284	319
Poly-3 test	P= 0.3807	P= 0.4184N	P= 0.7592N	P= 0.5916N	P= 0.7033

TABLE A3
Statistical Analysis of Primary Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
All Organs: Malignant Neoplasms					
Overall rate	30/48 (63%)	26/40 (65%)	28/48 (58%)	30/48 (63%)	30/48 (63%)
Adjusted rate	72.0%	67.7%	63.4%	71.8%	69.0%
Terminal rate	11/18 (61%)	7/17 (41%)	12/25 (48%)	13/20 (65%)	13/25 (52%)
First incidence (days)	390	550	442	238	533
Poly-3 test	P= 0.4515	P= 0.5501N	P= 0.3735N	P= 0.5860N	P= 0.5879
All Organs: Benign or Malignant Neoplasms					
Overall rate	46/48 (96%)	38/40 (95%)	48/48 (100%)	46/48 (96%)	44/48 (92%)
Adjusted rate	99.7%	96.6%	100.0%	98.5%	99.1%
Terminal rate	17/18 (94%)	16/17 (94%)	25/25 (100%)	19/20 (95%)	25/25 (100%)
First incidence (days)	61	550	442	238	319
Poly-3 test	P= 0.5095	P= 0.6422N	P= 0.4594	P= 0.6167N	P= 0.6343

(T)Terminal sacrifice

^a Number of neoplasm-bearing animals/number of animals examined microscopically

^b Poly-3 estimated neoplasm incidence after adjustment for intercurrent mortality

^c Observed incidence at terminal kill

^d Beneath the control incidence are the P values associated with the trend test. Beneath the exposed group incidence are the P values corresponding to pairwise comparisons between the controls and that exposed group. For all tissues except the kidney, liver, and testis, only the pairwise comparisons between the 150 ppm group and control group are unbiased; overall rates and all other pairwise comparisons may not be valid. The Poly-3 test accounts for differential mortality in animals that do not reach terminal sacrifice. A negative trend or a lower incidence in an exposure group is indicated by N.

^e Not applicable; no neoplasms in animal group

^f Value of statistic cannot be computed.