

Cost-benefit analysis of repeating the chronic study of the potential effects of PFOS on reproduction in quail.

In the previously conducted study, the experimental design and the fact that some equivocal effects were observed at the least dose in the diet (10 mg/kg), precluded accurate assignment of a No Observable Adverse Effects Concentration (NOAEC). Results of the previously conducted study will be evaluated in conjunction with known sensitivity ranges, and uncertainty factors to determine the potential benefits that could be gained by repeating the study at lesser concentrations to obtain a NOAEC.

Work product

A short report summarizing the potential benefits, or lack thereof, for repeating the quail chronic PFOS exposure study in addition to a rough estimate of the cost range for the study. The analysis will present the likely effect on the revised risk assessments if a more accurate estimate of the threshold NOAEL were to be made available. The greatest impact would be on obtaining a lower NOAEL that is not driven by the doses in the experimental design.

Assumptions

Information necessary to do this analysis is currently available at the ENTRIX office.

Cost

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	8	\$ 2,200	Review report
John Newsted	\$ 175	30	\$ 5,250	Assess benefits, estimate cost range, write report
Denise Kay	\$ 150		\$ -	
Paul Jones	\$ 135		\$ -	
Shaun Roark	\$ 120		\$ -	
Melissa Shotwell	\$ 95		\$ -	
Karen Smyth	\$ 75	5	\$ 375	Admin support
			\$ 470	Communications (6% of labor)
			\$ 8,295	Total estimated cost

Cost-benefit analysis of kestrel chronic feeding study

Based on the information available in the literature, the threshold for effects seems to be similar in a number of species. However, since the quail and mallard are not top carnivores, but eat seeds, vegetation and invertebrates, an among-species uncertainty factor is used in risk assessments. If data were available for an additional species, such as a top predator, an argument could be made to reduce or eliminate the among-species uncertainty factor. ENTRIX will conduct an analysis of the currently known species sensitivity range and applied uncertainty factors to determine the potential benefits to be gained from conducting a chronic feeding study with a top predator such as kestrel.

Work product

A short report summarizing the potential benefits, or lack thereof, for conducting a kestrel chronic PFOS exposure study in addition to a rough estimate of the cost range for the study.

Assumptions

Information necessary to do this analysis is currently available at the ENTRIX office.

Cost

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	8	\$ 2,200	Review report
John Newsted	\$ 175	20	\$ 3,500	Assess benefits, estimate cost range, write report
Denise Kay	\$ 150		\$ -	
Paul Jones	\$ 135		\$ -	
Shaun Roark	\$ 120		\$ -	
Melissa Shotwell	\$ 95		\$ -	
Karen Smyth	\$ 75	5	\$ 375	Admin support
			\$ 365	Communications (6% of labor)
			\$ 6,440	Total estimated cost

Cost-benefit analysis of egg injection study

Another possibility in addition to, or separate from, the chronic feeding studies discussed above, is an egg injection study with 5 or 6 bird species. This study would include quail and mallard for comparison to existing data along with additional species such as kestrels or bald eagles. From this data we could derive a species-sensitivity distribution, which could be used to obviate the need for among-species sensitivity factors all together for birds.

Work product

A short report summarizing the potential benefits, or lack thereof, for conducting a PFOS egg injection study in addition to a rough estimate of the cost range for the study.

Assumptions

Information necessary to do this analysis is currently available at the ENTRIX office.

Cost

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	8	\$ 2,200	Review report
John Newsted	\$ 175	20	\$ 3,500	Assess benefits, estimate cost range, write report
Denise Kay	\$ 150		\$ -	
Paul Jones	\$ 135		\$ -	
Shaun Roark	\$ 120		\$ -	
Melissa Shotwell	\$ 95		\$ -	
Karen Smyth	\$ 75	5	\$ 375	Admin support
			\$ 365	Communications (6% of labor)
			\$ 6,440	Total estimated cost

***Chironomus tentans* toxicity test**

The one study that is published in the literature on *Chironomus tentans* reports a very low threshold value that drives the values calculated for water quality criteria. Because the value is much lower than that observed for other species, it is likely that if the test is repeated under GLP, that the values will be greater. This will have a great benefit in reducing uncertainty in ecological risk assessments for aquatic invertebrates. If such a test is conducted, it must include the same endpoints measured in the previous study and also measure standard ecologically-relevant endpoints, such as survival, growth and reproduction (fertility and fecundity). In addition, it would be useful to measure PFOS concentration in both the overlying water as well as in the sediment. At your request, ENTRIX has initiated these toxicity tests in conjunction with Wildlife International. ENTRIX will design the experiments in conjunction with Wildlife International, arrange to have these studies to be conducted, oversee the studies, interpret the results, and prepare a report and manuscript based on the results.

Work product

Initial interpretation of the results presented verbally. Final written report based on the results and a manuscript to be submitted for publication in the peer-reviewed, open literature that will compare and contrast the results with the previously published work to either confirm the previous conclusions or "correct" the literature.

Assumptions

Wildlife International will conduct the in-life phase of the study and provide all laboratory reports, and documentation to ENTRIX. The Wildlife International portion of the study and any costs associated with chemical analysis will be provided separately as decisions are made regarding the most appropriate approach. 3M may wish to arrange for the analytical support internally or through one of their contract laboratories directly. ENTRIX can also make these arrangements and pay for the analyses with no mark-up. The cost estimate is for ENTRIX tasks only and does not include costs of analytical or for Wildlife International to conduct the test.

Cost

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	24	\$ 6,600	Data analysis, report review
John Newsted	\$ 175	45	\$ 7,875	Design, oversight, data analysis, report writing
Denise Kay	\$ 150		\$ -	
Paul Jones	\$ 135		\$ -	
Shaun Roark	\$ 120		\$ -	
Melissa Shotwell	\$ 95	10	\$ 950	Table and figure prep
Karen Smyth	\$ 75	16	\$ 1,200	Admin support
			\$ 998	Communications (6% of labor)
			\$ 17,623	Total estimated cost

White paper on ecological risk assessments of PFCs including PFOS and PFOA

This white paper will review currently published ecological risk assessments of PFCs. Contrasts and comparisons will be made regarding various conclusions concerning impacts of PFCs, evaluations of uncertainty, and data reporting.

Work product

Peer-reviewed literature publication based on currently published ecological risk assessments of PFCs including PFOS and PFOA. The document will describe the approaches and conclusions of previously conducted assessments and identify mistakes, uncertainties and data gaps. The document will give a discussion of current status and trends and provide a risk assessment based on the most current information and scientifically valid methods.

Assumptions

Published ecological risk assessments to be reviewed for this white paper have already been acquired by ENTRIX or are otherwise readily available.

Cost

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	60	\$ 16,500	Oversee data analysis, review and input for final draft
John Newsted	\$ 175	200	\$ 35,000	Write primary draft
Denise Kay	\$ 150	25	\$ 3,750	Assist with data analysis, draft review
Paul Jones	\$ 135	25	\$ 3,375	Assist with data analysis, draft review
Shaun Roark	\$ 120	40	\$ 4,800	Table and figure prep
Melissa Shotwell	\$ 95	30	\$ 2,850	Literature search
Karen Smyth	\$ 75	30	\$ 2,250	Admin support
			\$ 4,112	Communications (6% of labor)
			\$ 72,637	Total estimated cost

White paper on the impact of the 2000 phase out of PFOS

This white paper will include a meta analysis of the existing publicly available data from peer-reviewed literature on the concentrations of PFOS in the environment to assess the historical trend pre- and post-2000. It may be possible to include comparisons to other chemicals like DDT that have undergone similar phase-outs. This paper will rely on the PFOS analytical results database that ENTRIX has already generated for 3M. The existing data can be evaluated for use in this review and the white paper can be outlined and established in the first year of this task. ENTRIX would also like to propose that a lower level effort be put forth during the following 3 to 5 years to maintain a database of PFOS analytical results with annual updates to the white paper review of trends.

Work product

White paper assessing the impact of the 2000 phase-out on the concentrations of PFOS in the environment based on publicly available peer-reviewed literature. Referential database of PFOS analytical results as reported in the reviewed literature. Annual update of trends of environmental concentrations of PFOS.

Assumptions

The published PFOS literature rarely reports concentrations and specific sampling locations of individual samples. Rather, mean values and general sampling locations are more common reporting methods. The budget presented here assumes that the data will be sufficient as it can be obtained from publicly available literature and it will not be necessary to obtain further specific details from investigators.

Cost**Year 1 budget**

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	30	\$ 8,250	Oversee data analysis, review and input for final draft
John Newsted	\$ 175	130	\$ 22,750	Identify pertinent literature, write primary draft
Denise Kay	\$ 150	40	\$ 6,000	Data base design and maintenance
Paul Jones	\$ 135		\$ -	
Shaun Roark	\$ 120	40	\$ 4,800	Table and figure prep
Melissa Shotwell	\$ 95	40	\$ 3,800	Literature search and data entry
Karen Smyth	\$ 75	50	\$ 3,750	Admin support
			\$ 2,961	Communications (6% of labor)
			\$ 52,311	Total estimated cost

Annual ongoing budget

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	24	\$ 6,600	Review annual update
John Newsted	\$ 175	40	\$ 7,000	Identify pertinent publications, draft annual update
Denise Kay	\$ 150	30	\$ 4,500	Data base design and maintenance
Paul Jones	\$ 135		\$ -	
Shaun Roark	\$ 120	8	\$ 960	Table and figure prep
Melissa Shotwell	\$ 95	45	\$ 4,275	Literature search and data entry
Karen Smyth	\$ 75	15	\$ 1,125	Admin support
			\$ 1,468	Communications (6% of labor)
			\$ 25,928	Total estimated cost

Monitor R&D and environmental issues and initiative involving PFCs in the Asia-Pacific region

At your request, John Giesy has initiated this effort. Toward this end, we will continue to establish working relationships with the key laboratories and agencies in Asia. In this way, we can assure that the science that is done will be of the highest quality.

Work product

Oral reports as issues arrive or information becomes available and prepare quarterly written reports upon request as well as making all pertinent documents available to 3M.

Assumptions

John Giesy will attend meetings and develop joint projects with Chinese colleagues from whom he can obtain information and over whom he can exert some influence to maintain quality of the results. To achieve these goals JPG will need to "buy favors" in the form of supplying standards and reference materials and validation of methods by analyzing split samples at the 3M laboratories or their designated contract lab.

Cost

John Giesy: time and materials as usual. Costs for travel to key meetings may be incurred, but cost estimates will be provided and approved before any travel is undertaken. Costs will be tracked quarterly accountings and rolling estimates of costs in the next quarter provided. Costs will vary from quarter to quarter depending upon activities.

Maintain Reference Manager data base of literature on perfluorinated compounds

This is an ongoing effort to maintain a referential database of peer-reviewed publicly available literature on perfluorinated compounds. We perform searches of available literature and continuously update this database.

Work product

Monthly reports are provided with information on the number of recently published PFC related articles. Electronic updates to the 3M database are provided quarterly. Any article included in the database can be obtained and provided to 3M upon request.

Assumptions

The focus of the database continues to be limited to published articles and reports related to PFCs.

Cost

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	24	\$ 6,600	Identify pertinent literature
John Newsted	\$ 175	15	\$ 2,625	Identify pertinent literature
Denise Kay	\$ 145		\$ -	
Paul Jones	\$ 135		\$ -	
Ryan Holem	\$ 120	50	\$ 6,000	Database maintenance, monthly and quarterly updates
Melissa Shotwell	\$ 95	10	\$ 950	Literature search
Karen Smyth	\$ 75	100	\$ 7,500	Enter articles in database
			\$ 1,421	Communications (4% of labor)
			\$ 25,096	Total estimated cost

Collect and monitor PFCs in mussels from near-shore North American marine environments

ENTRIX will provide oversight, QA/QC and report preparation for a project (subcontract) to the University of Saskatchewan to analyze samples of mussels obtained from the NOAA Mussel Watch Program. ENTRIX has already made arrangements to obtain historical samples from NOAA and then to obtain samples annually in the future (about a two to three year delay) when NOAA has finished all of the analyses that they want to conduct on these samples. The results will include up to 60 analytes of various chain lengths and functional moieties.

Work product

The initial work products will be a Sampling and Analysis Plan (SAP) and a Quality Assurance Project Plan (QAPP) produced by ENTRIX and cost estimate provided separately below. On an ongoing basis, ENTRIX will provide an annual report, including status and trends. When enough data has been accrued, a manuscript will be prepared for publication in the peer-reviewed, open literature.

Assumptions

3M will provide technical assistance as needed. This may include purchase of standards and access to instrumentation in the first year until the necessary instruments are purchased by the U of S. The U of S will conduct the instrumental analyses and arrange for inter-laboratory spit sample analyses and other QA as appropriate. It is estimated that approximately 300 to 400 samples will be analyzed per year, depending on availability from NOAA. In addition, an additional 20% of samples will be conducted as QA samples, either as reference materials, duplicates or spike-recovery samples. 3M will provide directly or indirectly, through a designated contract lab analytical services for validation of sample splits.

Cost**Cost summary for first year of mussel monitoring program including initial QAPP and SAP**

Description	Direct cost	Markup	Category subtotal
U of S subcontract	\$ 142,750		\$ 142,750
ENTRIX labor	\$ 51,400	4%	\$ 54,484
ENTRIX expenses	\$ 8,300	10%	\$ 9,545
TOTAL ESTIMATED COST			\$ 206,779

Write QAPP and SAP for biomonitoring program

Name	Rate	Hours	Subtotal	Responsibilities
John Giesy	\$ 275	10	\$ 2,750	Review final document
John Newsted	\$ 175	20	\$ 3,500	Statistical sampling design
Denise Kay	\$ 150	40	\$ 6,000	Write draft documents
Paul Jones	\$ 135	40	\$ 5,400	Write draft documents
Patrick Bradley	\$ 120	10	\$ 1,200	QA/QC design
Melissa Shotwell	\$ 95	10	\$ 950	Table and figure prep, document editing
Karen Smyth	\$ 75	20	\$ 1,500	Admin support
			\$ 1,278	Communications (6% of labor)
			\$ 22,578	Total estimated cost

Annual budget for U of S portion of mussel monitoring program

Description	Salary	Benefits	Total costs	% on project	Subtotal
U of S labor					
Graduate assistant (benefits 14.11%)	\$ 2,000	\$ 3,104	\$ 25,104	100%	\$ 25,104
Laboratory manager (benefits 34%)	\$44,000	\$ 14,960	\$ 58,960	25%	\$ 14,740
Post doctoral fellow (benefits 34%)	\$32,000	\$ 10,880	\$ 42,880	25%	\$ 10,720
Hourly labor (500hr@\$7.50/hr)					\$ 3,750
U of S - Subtotal Labor					\$ 54,314
U of S Expenses					
Laboratory supplies					\$ 10,000
Instrument supplies/Nitrogen etc.					\$ 12,000
Instrument maintenance					\$ 8,000
Travel					\$ 5,600
Publication costs					\$ 2,500
Office supplies, computer, telephone, copy					\$ 1,500
U of S - Subtotal Expenses					\$ 39,600
U of S Subtotal Labor and Expenses					\$ 93,914
Overhead (52%)					\$ 48,835
U of S Total Labor + Expenses					\$142,750

Annual budget for ENTRIX portion of mussel monitoring program

Description	Unit cost	Unit	Quantity	Cost
ENTRIX Labor				
John Giesy	\$ 275	hour	40	\$ 11,000
Paul Jones	\$ 135	hour	20	\$ 2,700
Denise Kay	\$ 145	hour	40	\$ 5,800
John Newsted	\$ 175	hour	40	\$ 7,000
Melissa Shotwell	\$ 95	hour	20	\$ 1,900
Karen Smyth	\$ 75	hour	20	\$ 1,500
ENTRIX - Subtotal Labor				\$ 29,900
Communications (4% of Labor)				\$ 1,196
ENTRIX Labor Total				\$ 31,096
ENTRIX Expenses				
Travel	\$ 2,150	trips	2	\$ 4,300
Sample shipping	\$ 4,000			\$ 4,000
ENTRIX - Subtotal Expenses				\$ 8,300
Expense markup (15%)				\$ 1,245
ENTRIX Expenses Total				\$ 9,545
ENTRIX Total Labor + Expenses				\$ 41,451

Consider methods to assess the nature and characteristics of the total PFC load in the environment and develop methods to determine sources

This task is to look at methods to assess the nature and characteristics of the total PFC load in the environment. This will be a joint project that will involve the University of Saskatchewan but may also provide an opportunity to partner with key laboratories and institutions in Asia to maintain a working relationship that allows access to information and to influence the quality of studies in Asia. The project will investigate possible sources of PFCs in the environment from historical and/or on-going sources. The project will include, among other things the development of methods to identify sources. These will include, analyses of samples of different types of samples, including abiotic and biotic samples for individual PFCs, including the isomers of each compound. Then, by use of relative ratios of the various PFC, and their isomers, and pattern recognition techniques, the relative contributions of various sources will be determined. In addition, this project will develop and provide proof of concept on the use of stable isotopes to determine potential sources of various PFCs, but will focus initially on PFOS, PFOA and their primary precursors. It is possible to determine the source of anthropogenic chemicals in the environment using $C^{12}:C^{13}$ or O^{15} and O^{16} ratios. In some cases ratios of stable nitrogen isotopes may also be possible. Finally, this research project will develop and apply methods for the measurement of total, organically-bound F in samples so that a mass balance can be developed for the organically-bound F that can be accounted for in the currently identified and quantified organic F compounds.

Work product

The products of this research project will be annual reports, including an oral discussion of the results. The results will be published in the peer-reviewed, open literature and presented at scientific meetings as appropriate. 3M employees will be extended the opportunity to co-author papers at their discretion.

Assumptions

This is a three year project. 3M will provide technology, methods, standards, materials and equipment as needed. It is assumed that 3M has the necessary expertise to do the measurements of total organically-bound F. The work will be conducted by a student, post-doc and technician at the U of S, under the direction of JP Giesy. The student and/or post doc and technician will go to the 3M laboratories or their designated contractor as necessary to develop the methods and analyze samples. The U of S will purchase a new LC-MS/MS in early 2007 and use this instrument for subsequent analyses. A more complete proposal from the U of S will be developed that will outline all of the specific experiments to be conducted and the personnel.

Cost

ENTRIX will manage a sub-contract to the U of S and provide oversight as well as QA/QC and data management and report preparation. There will be no mark-up on the funds passed through to the U of S.

Cost summary for first year of U of S research program on PFC load and sources in the environment

Description	Direct cost	Markup	Category subtotal
U of S subcontract	\$ 209,113		\$ 209,113
ENTRIX labor	\$ 23,900	6%	\$ 25,334
ENTRIX expenses	\$ 8,300	15%	\$ 9,545
TOTAL ESTIMATED COST			\$ 243,992

Annual budget for U of S research program on PFC load and sources in the environment

Description	Salary	Benefits	Total Costs	% on project	Subtotal
U of S labor					
Graduate assistant (benefits 14.11%)	\$22,000	\$ 3,104	\$ 25,104	100%	\$ 25,104
Laboratory manager (benefits 34%)	\$44,000	\$ 14,960	\$ 58,960	25%	\$ 14,740
Post doctoral fellow (benefits 34%)	\$32,000	\$ 10,880	\$ 42,880	100%	\$ 42,880
Graduate tuition waiver			\$ 6,500		\$ 6,500
Hourly labor (500hr@\$7.50/hr)					\$ 3,750
U of S - Subtotal Labor					\$ 92,974
U of S Expenses					
Laboratory supplies					\$ 15,000
Instrument supplies/Nitrogen etc.					\$ 12,000
Instrument maintenance					\$ 8,000
Travel					\$ 5,600
Publication costs					\$ 2,500
Office supplies, computer, telephone, copy					\$ 1,500
U of S - Subtotal Expenses					\$ 44,600
U of S Subtotal Labor and Expenses					\$137,574
Overhead (52%)					\$ 71,539
U of S Total Labor + Expenses					\$209,113

Annual budget for ENTRIX portion of U of S research program on PFC load and sources in the environment

Description	Unit cost	Unit	Quantity	Cost
ENTRIX Labor				
Giesy, John	\$ 275	hour	30	\$ 8,250
Kay, Denise	\$ 150	hour	40	\$ 6,000
Newsted, John	\$ 175	hour	40	\$ 7,000
Shotwell, Melissa	\$ 95	hour	20	\$ 1,900
Smyth, Karen	\$ 75	hour	10	\$ 750
ENTRIX - Subtotal Labor				\$ 23,900
Communications (6% of Labor)				\$ 956
ENTRIX Labor Total				\$ 24,856
ENTRIX Expenses				
Travel	\$ 2,150	trips	2	\$ 4,300
Sample shipping	\$ 4,000			\$ 4,000
ENTRIX - Subtotal Expenses				\$ 8,300
Expense markup (15%)				\$ 1,245
ENTRIX Expenses Total				\$ 9,545
ENTRIX Total Labor + Expenses				\$ 34,401