US Environmental Protection Agency
Office of Pesticide Programs

Chronic/Sub-Chronic Studies

July 2003

U.S. Environmental Protection Agency

Office of Pesticide Programs

Electronic Submission Guidance

Standard Format for Electronic Submission of Supplemental Data Files in Support of

Chronic/Sub-Chronic Studies

July 31, 2002

The following formats and instructions are designed to be used as an example or guide for registrants to format electronic files for submission of animal toxicology data to the USEPA Office of Pesticide Programs for review in support of registration and re-registration of pesticides. They are based upon, and are intended to be consistent with, similar guidance published by the Food and Drug Administration (FDA).

The USEPA Office of Pesticide Programs has identified SAS Transport as the preferred means of supplying the supplemental data. SAS Transport Format, published by the SAS Institute, allows data to be translated to other commonly used formats without the need for other programs from the SAS Institute or other specific vendors. It is compatible with widely used spreadsheet and statistical software. Additionally, SAS transport files can be readily transferred to common database applications.

There are two SAS transport file formats: The open source version 5 XPORT and proprietary version 6 CPORT. In keeping with federal guidelines, OPP is specifying use of version 5 XPORT. Technical specifications for the XPORT Transport format may be found on the SAS Institute web site under Technical Document TS-140.

The following data definition tables, developed jointly by OPP and Bayer Corp., should be used when submitting supplemental toxicity data. If changes are made to the data definition, an updated data definition table should be supplied in PDF format and include variable name, a description of the variable, type of variable, and codes used.   A single transport file should be supplied for each dataset.

Standard Format for Electronic Submission of Supplemental Data Files
in Support of Chronic/Sub-Chronic Studies.

July 31, 2002

Table of Contents

Dataset	
TUMOR	Tumor frequency.
WEIGHTS	Body weights.
FOOD	Food consumption.
WATER	Water consumption.
SIGNS	Clinical signs.
CHEM	Plasma clinical chemistry.
HEMAT	Hematology.
URINE	Urinalysis.
MORTAL	Mortality information.
ORGANWT	Organ weights.
MACRO	Macroscopic examination of tissues.
MICRO	Microscopic examination (histopathology).
FOBOBS	Adult FOB observations.
FOBNUM	Adult FOB numeric parameters.
AMA	Motor activity.
Other	Other datasets as needed.

Tumor Dataset (TUMOR.V5X) [1]

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
ANIMLNUM	Animal Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Time in Days to Death or Sac	Num	
DTHSACST	Death or Sac Status	Num	
DTHDESC	Description of Death or Sac Status	Char	Use to define DTHSACST codes.
ANIMLEXM	Animal Microscopic Examination Code	Num	0 = No tissues examined. 1 = At least one tissue was examined.
ORGANNAM	Organ/Tissue Name	Char	
TUMORFLG	Is There a Tumor Present in This Organ?	Num	0=No, 1=Yes, 2=Organ not Examined.
TUMORNAM	Tumor Name	Char	
DETECTTM	Time in Days of detection of Tumor	Num	

Variable	Label	Type	Codes and Comments
ORGANEXM	Organ/Tissue Microscopic Examination Code	Num	1 = Organ/tissue was examined and usable. 2 = Organ/tissue was examined but was not usable (e.g. autolyzed). 3 = Organ/tissue was not examined.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Not Measured, etc.

[1] Dataset includes all organs for every animal with a tumor flag indicating whether or not a tumor is present in each organ.

Body Weights for Each Animal (WEIGHTS.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric dose value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Day of Measurement	Num	
WEIGHT	Body weight	Num	
UNIT	Unit of weight measurement	Char	G = gram, KG = kilograms, etc.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Not Measured, etc.

Food Consumption for Each Animal (FOOD.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose group	Num	Example: 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Day of measurement	Num	
FFED	Food Fed	Num	
FLEFT	Food Left	Num	
PREVFED	Previous Day's Food Fed	Num	
DAYDIFF	Number of Days From Previous Measurement	Num	
UNIT	Unit of Measurement	Char	G = gram, KG = kilograms, etc.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	S, NM, O, etc. (if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Spiller, Not Measured, Outlier, etc.

Water Consumption for Each Animal (WATER.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGRP	Dose Group	num	Example: 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG, etc. plus dose level (e..g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Day of Measurement	Num	
WFED	Water Fed	Num	
WLEFT	Water Left	Num	
PREFED	Previous Day's Water Fed	Num	
DAYDIFF	Number of Days from Previous Measurement	Num	
UNIT	Unit of Measurement	Char	G = gram, KG = kilogram, etc.
EXCLUDE	Is this Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	S, NM, O, etc. (if codes are used).
EXCDESC	Exclusion Description or Reason	Char	Spiller, Not Measured, Outlier, etc.

Clinical Signs for Each Animal (SIGNS.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Example: 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Day of Clinical Sign	Num	
SIGN	Clinical Sign	Char	
START	Days on drug sign first seen	Num	
SEVERITY	Severity	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Not Observed, etc.

Plasma Clinical Chemistry for Each Animal (CHEM.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Days on drug at time of test	Num	
LABTEST	Lab test name	Char	
RESULT	Test result value	Num	
UNIT	Unit of lab test	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Hematology Results for Each Animal (HEMAT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Days on drug at time of test	Num	
LABTEST	Name of lab test	Char	
RESULT	Test result value	Num	
UNIT	Unit of lab test	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used)
EXCDESC	Exclusion Description or Reason	Char	Text Description

Urinalysis Results for Each Animal (URIN.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DAYS	Days on drug at time of test	Num	
LABTEST	Name of lab test	Char	
RESULT	Test result value	Num	
UNIT	Unit of lab test	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Mortality Data for Each Animal (MORTAL.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
DTHSACST	Death or Sac Status	Num	
DTHDESC	Description of Death or Sac Status	Char	Use to define DTHSACST codes.
WEIGHT	Terminal body weight	Num	
UNIT	Unit of measurement	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Organ Weight for Every Organ for Each Animal (ORGANWT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
FNLBDYWT	Final body weight	Num	
UNITBODW	Body weight units	Num	
DAYS	Days on drug at observation	Num	
ORGANNAM	Organ name	Char	
ORGANWT	Weight of organ	Num	
UNIT	Organ Weight Unit of measurement	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Macroscopic Findings for Each Animal (MACRO.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG)
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
OBS_DATE	Date of Observation	Char	
ORGANNAM	Name of organ	Char	
MACRO	Macroscopic findings	Char	Do not include comments associated with findings. Full details for abnormal findings should be described in study report.
MODIFIER	Modifier	Char	
GRADE	Grade or severity of abnormality	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used)
EXCDESC	Exclusion Description or Reason	Char	Text Description

Microscopic Findings (histopathology) for Each Animal (MICRO.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
ORGANNAM	Name of organ	Char	
MICRO	Microscopic findings	Char	Do not include comments associated with findings. Full details for abnormal findings should be described in study report.
GRADE	Grade or severity of abnormality	Char	
TUMOR	Tumor flag	Char	None, Benign, Malignant, or Indeterminate.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Adult FOB Observations (FOBOBS.V5X)

Variable	Label	Type	Codes
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
OBS_DATE	Date of Observation	Num	
DAY	Nominal Day of Observation	Char	
CATEGORY	Category of obs	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
SEVERITY	Severity	Char	
COLOR	Color	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Adult FOB Numeric Observations/Parameters (FOBNUM.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
OBS_DATE	Date of Observation		
DAY	Nominal Day of Observation	Char	
CATEGORY	Category of Numeric Observation	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
VALUE	Result	Num	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

Adult Motor Activity (AMA.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, MG/KG etc. plus dose level (e. g. 50 MG/KG).
DOSEVAL	Numeric Dose Value	Num	In 50 MG/KG example above, DOSEVAL would equal 50.
OBS_DATE	Date of Testing	Num	
DAY	Nominal Day of Testing	Num	
STRTTIME	Session Start Time	Num	hh:mm:ss
DURATION	Duration of test	Num	
MAZENUM	Maze Number	Num	
BEAMNUM	Number of Beam being interrupted	Num	
BEAM_DUR	Duration of Beam Break	Num	msec
B_TIME	Time of Beam Break	Num	hh:mm:ss
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.