CHAPTER 8
RISK CHARACTERIZATION

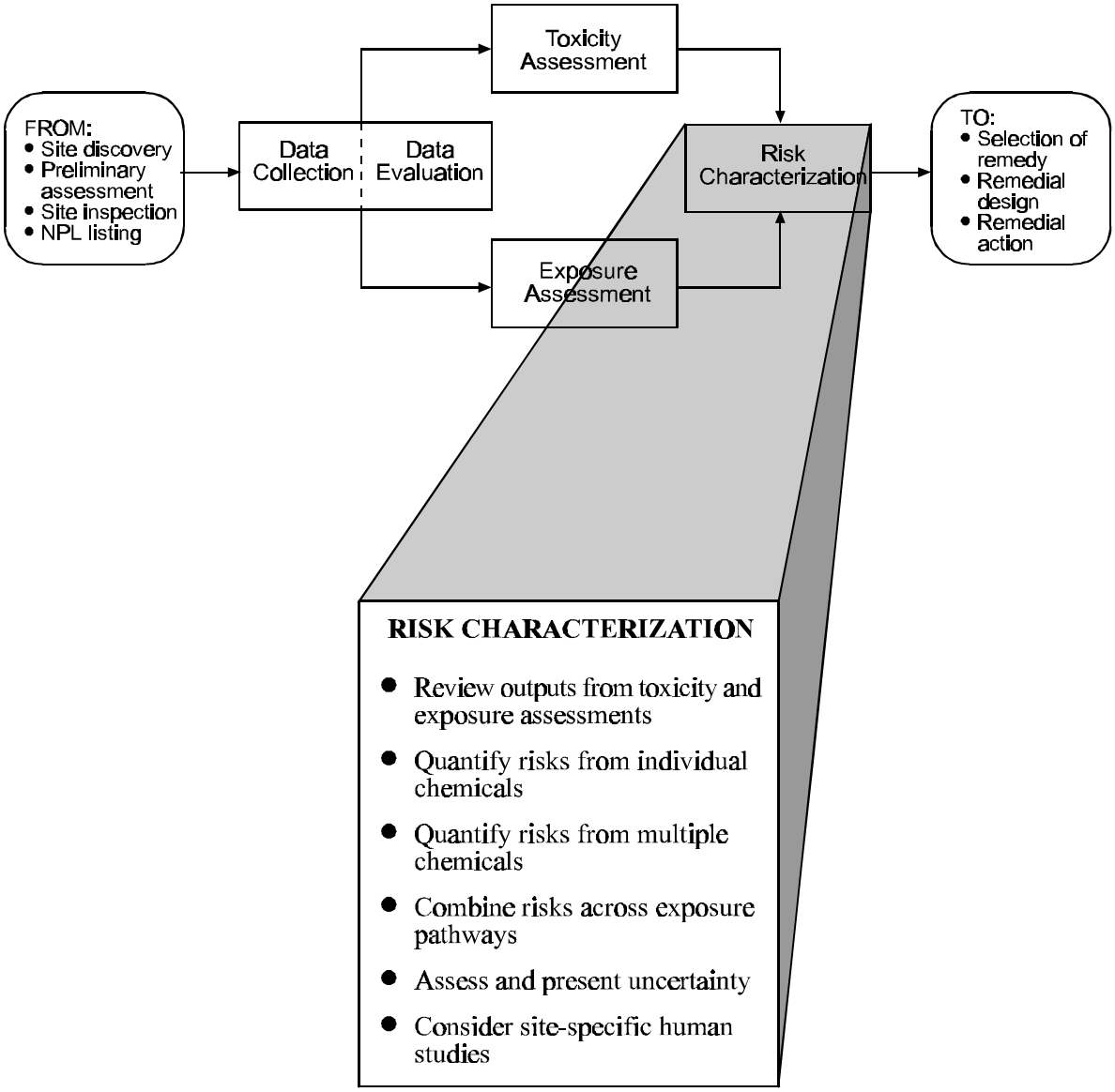


EXHIBIT 8-1
STEPS IN RISK CHARACTERIZATION

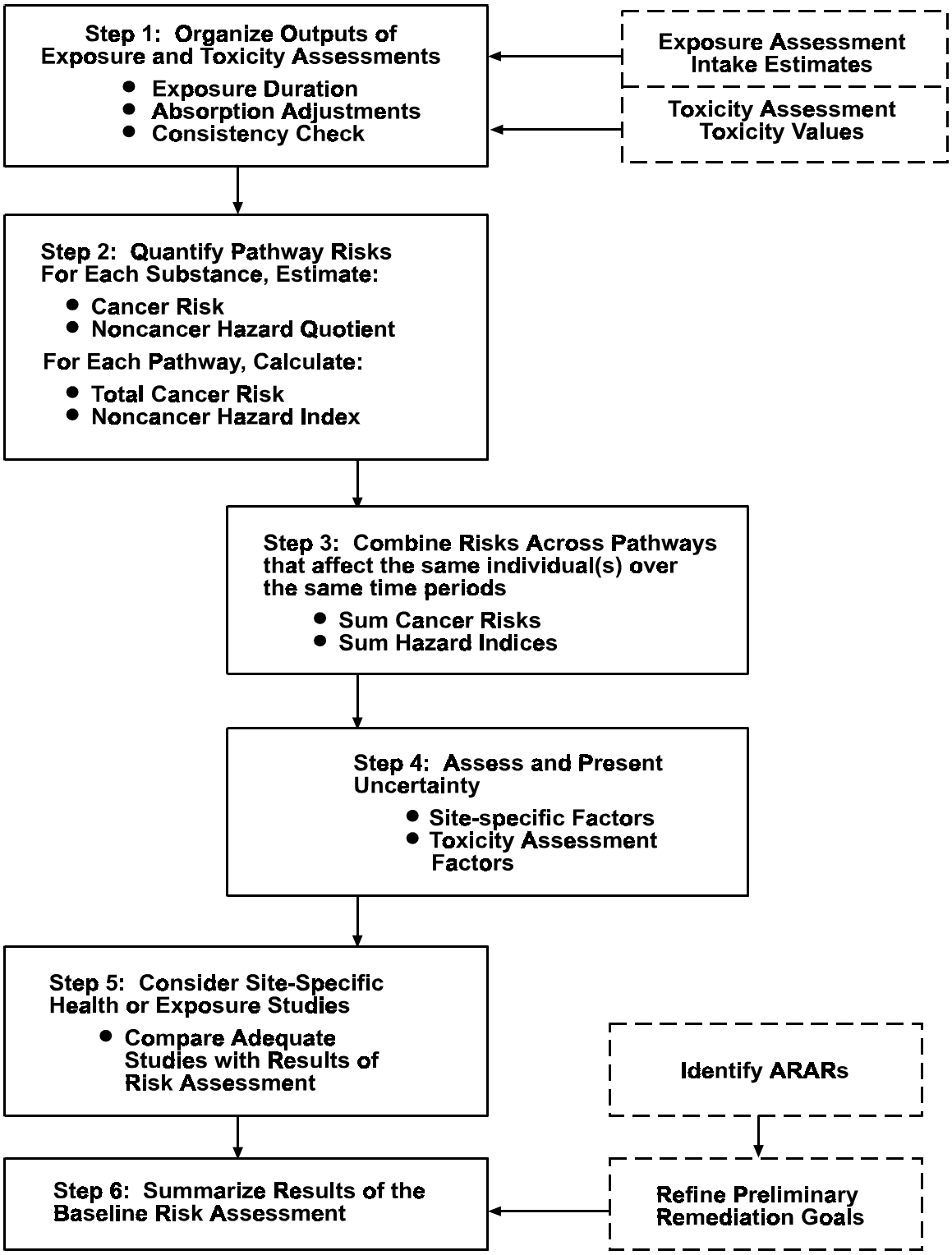


EXHIBIT 8-2

EXAMPLE OF TABLE FORMAT FOR CANCER RISK ESTIMATES

Chemical	CDI (mg/kg-day)	CDI Adj. for Absorp.	SF $(mg/kg\text{-}day)^{-1}$	Weight of Evidence	Type of Cancer[a]	SF Source	SF Basis (Vehicle)	Chemical-specific Risk[b]	Total Pathway Risk[b]	Total Exposure Risk[b]
Exposure Pathway: Ingestion of Contaminated Private Well Water										
Benzene	0.00025*	No	0.029*	A*	Leukemia	HEA	Water[c]	$7x10^{-6}$		
Chlordane	0.00015*	No	1.3*	B2*		IRIS	Water[c]	$2x10^{-4}$	$2x10^{-4}$	
Exposure Pathway: Ingestion of Contaminated Fish										
Chlordane	0.00008*	No	1.3*	B2*		IRIS	Water[c]	$1x10^{-4}$	$1x10^{-4}$	
Nearby Residential Population in Area Y – Total Cancer Risk (weight of evidence predominantly B2)[d]										$3x10^{-4}$

* Values for illustration only.
[a] Identify type of cancer in this table for Class A carcinogens only.
[b] All cancer risks should be expressed as one significant figure only.
[c] Slope factor based on dose administered in drinking water and assumed absorption fraction of 1.0.
[d] Summarize weight of evidence for carcinogens contributing most to the total cancer risk estimate.

SF = Slope Factor
CDI = Chronic Daily Intake

EXHIBIT 8-3

EXAMPLE OF TABLE FORMAT FOR CHRONIC HAZARD INDEX ESTIMATES

Chemical	CDI (mg/kg-day)	CDI Adjusted for Absorption	RfD (mg/kg-day)	Confidence Level	Critical Effect	RfD Source	RfD Basis (Vehicle)	RfD Uncertainty Adjustments	Modifying Factor	Hazard Quotient[a]	Pathway Hazard Index[a]	Total Exposure Hazard Index[a]
Exposure Pathway: Ingestion of Contaminated Private Well Water												
Phenol	0.1*	No	0.6*	M	Kidney, liver	IRIS	Water[c]	H,A,S,L*[d]	1*	0.2		
Nitrobenzene	0.0001*	No	0.0005*	M	Several	IRIS	Water[c]	H,A,S,L*	1*	0.2		
Cyanide	0.0003*	No	0.02*	M	Thyroid	IRIS	Water[c]	H,A*	5*	0.02	0.4[b]	
Exposure Pathway: Ingestion of Contaminated Fish												
Phenol	0.08*	Yes	0.6*	M	Kidney, liver	IRIS	Water[c]	H,A,S,L*[d]	1*	0.1		
MEK	0.005*	Yes	0.05*	M	CNS fetotox	IRIS	Water[c]	H,A,S*	1*	0.1	0.2[b]	
Nearby Residential Population in Area Y – Total Chronic Hazard Index												0.6[b]

* Values for illustration only.

[a] All hazard indices and hazard quotients should be expressed as one significant figure only.

[b] If the hazard index is greater than 1.0, see Section 8.2.2 for guidance on possible segregation of hazard index by endpoint.

[c] RfD expressed as administered dose.

[d] Uncertainty adjustment of 1,000 used to represent combined H, A, S, & L extrapolations.

Abbreviation for Uncertainty Adjustments: Factor of 10 used for each adjustment, unless indicated otherwise.

H = variation in human sensitivity
A = animal to human extrapolation
S = extrapolation from subchronic to chronic NOAEL
L = extrapolation from LOAEL to NOAEL

Confidence Level: L = low, M = medium, H = high.

MF = Modifying factor for EPA verified RfDs. This factor represents professional judgement on overall data base not specifically addressed by uncertainty adjustments.

CDI = Chronic Daily Intake
RfD = Chronic Reference Dose

EXHIBIT 8-4

EXAMPLE OF TABLE FORMAT FOR SUBCHRONIC HAZARD INDEX ESTIMATES

Chemical	SDI (mg/kg-day)	SDI Adjusted for Absorption	RfD_S (mg/kg-day)	Critical Effect	RfD_S Source	RfD_S Basis (Vehicle)	RfD_S Uncertainty Adjustments	Modifying Factor	Hazard Quotient[a]	Pathway Hazard Index[a]	Total Exposure Hazard Index[a]
Exposure Pathway: Ingestion of Contaminated Schoolyard Soil/Six Years											
Manganese	0.02*	Yes	0.5*	CNS, repro.	HEA	Water[c]	H, A*	1*	0.04		
Selenium	0.0008*	Yes	0.004*	Several	HEA	Water[c]	H, A*	1.5*	0.2		
Mercury	0.00001*	Yes	0.0003*	CNS	HEA	Water[c]	H*	1*	0.03		
Tin	0.006*	No	0.6*	Liver, kidney	HEA	Food[c]	H, A*	1*	0.01		0.3[b]
Nearby Elementary Schoolyard – Total Subchronic Hazard Index											0.3[b]

* Values for illustration only.

[a] All hazard indices and hazard quotients should be expressed as one significant figure only.

[b] If hazard index is greater than 1.0, see Section 8.2.2 for guidance on possible segregation of hazard index by endpoint.

[c] RfDs expressed as administered dose.

Abbreviation for Uncertainty Adjustments: Factor of 10 used for each adjustment, unless indicated otherwise.

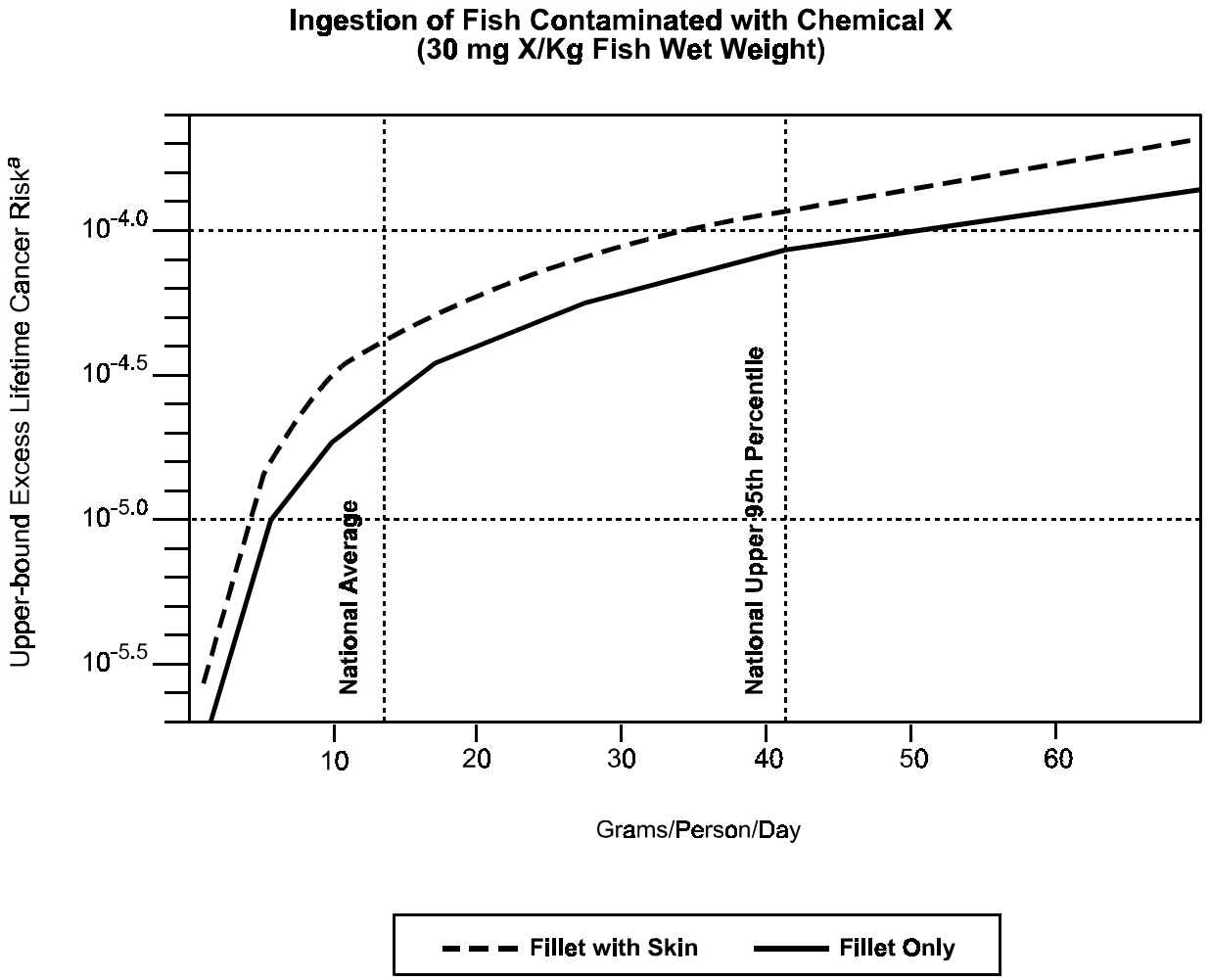
H = variation in human sensitivity
A = animal to human extrapolation
L = extrapolation from LOAEL to NOAEL

MF = Modifying factor for EPA RfD_Ss. This factor represents professional judgement on overall data base not specifically addressed by uncertainty adjustments.

SDI = Subchronic Daily Intake
RfD_S = Subchronic Reference Dose

EXHIBIT 8-5

EXAMPLE OF PRESENTATION OF IMPACT OF EXPOSURE ASSUMPTIONS ON CANCER RISK ESTIMATE



[a] The risk of developing cancer is plotted on a log scale. A risk of 10^{-4} indicates a probability of 1 chance in 10,000 and a risk of 10^{-5} indicates a probability of 1 chance in 100,000 of an individual developing cancer.

EXHIBIT 8-6

EXAMPLE OF PRESENTATION OF IMPACT OF EXPOSURE ASSUMPTIONS ON HAZARD INDEX ESTIMATE

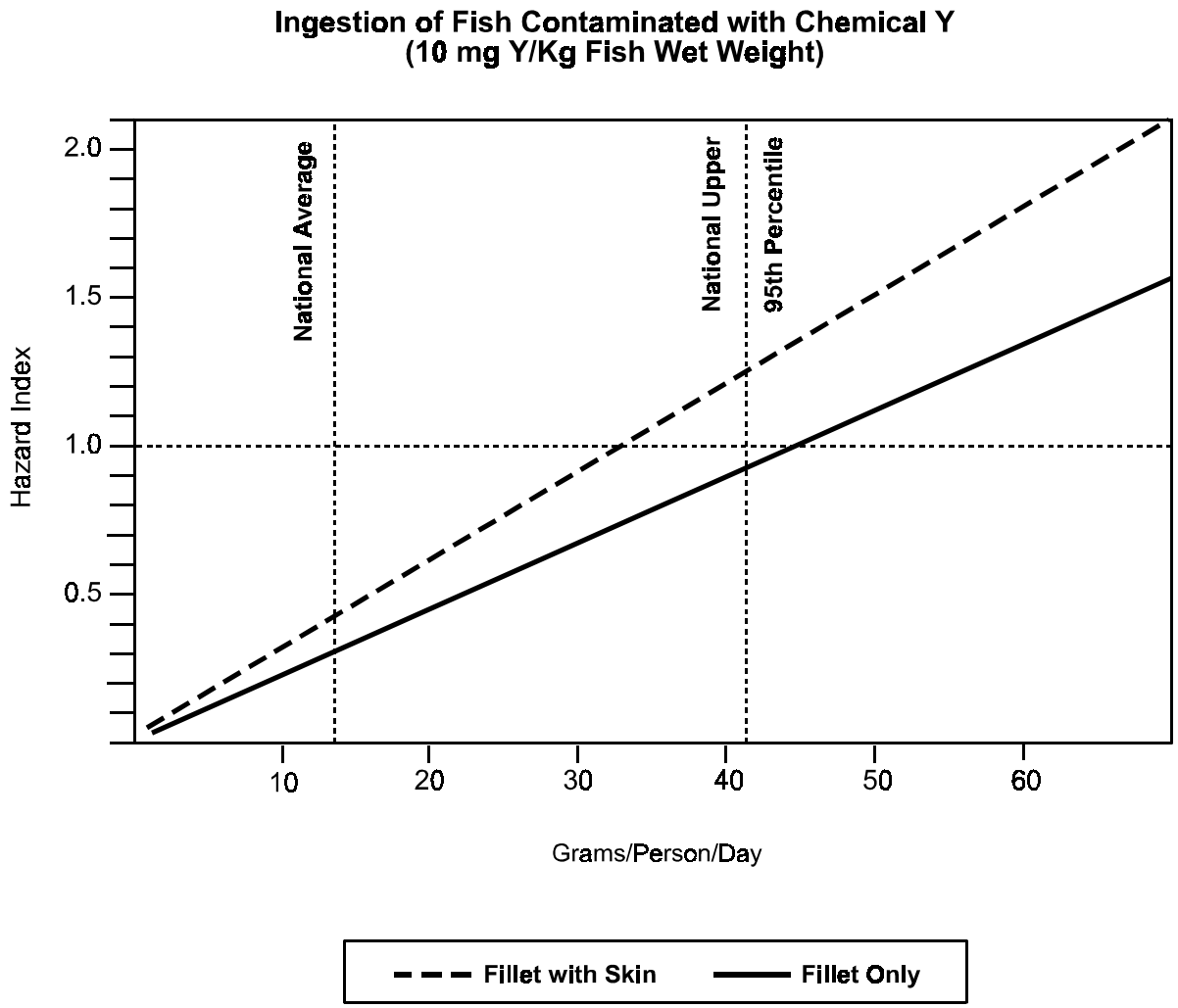
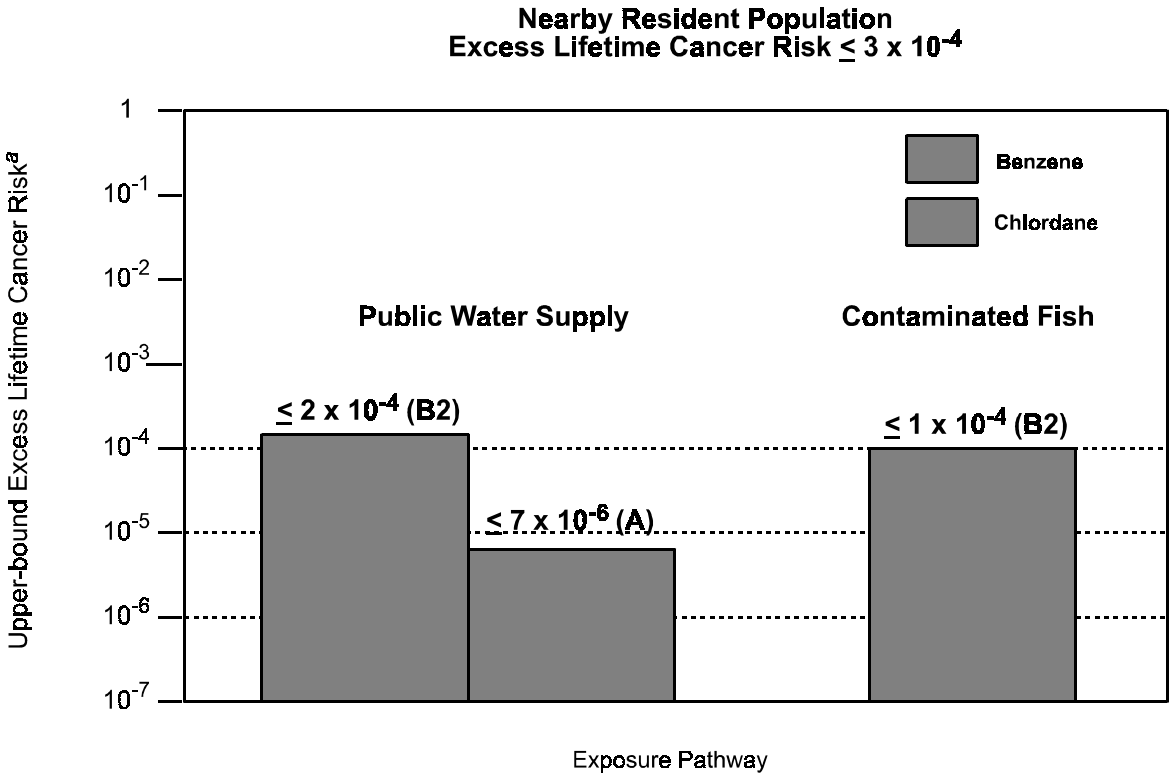


EXHIBIT 8-7

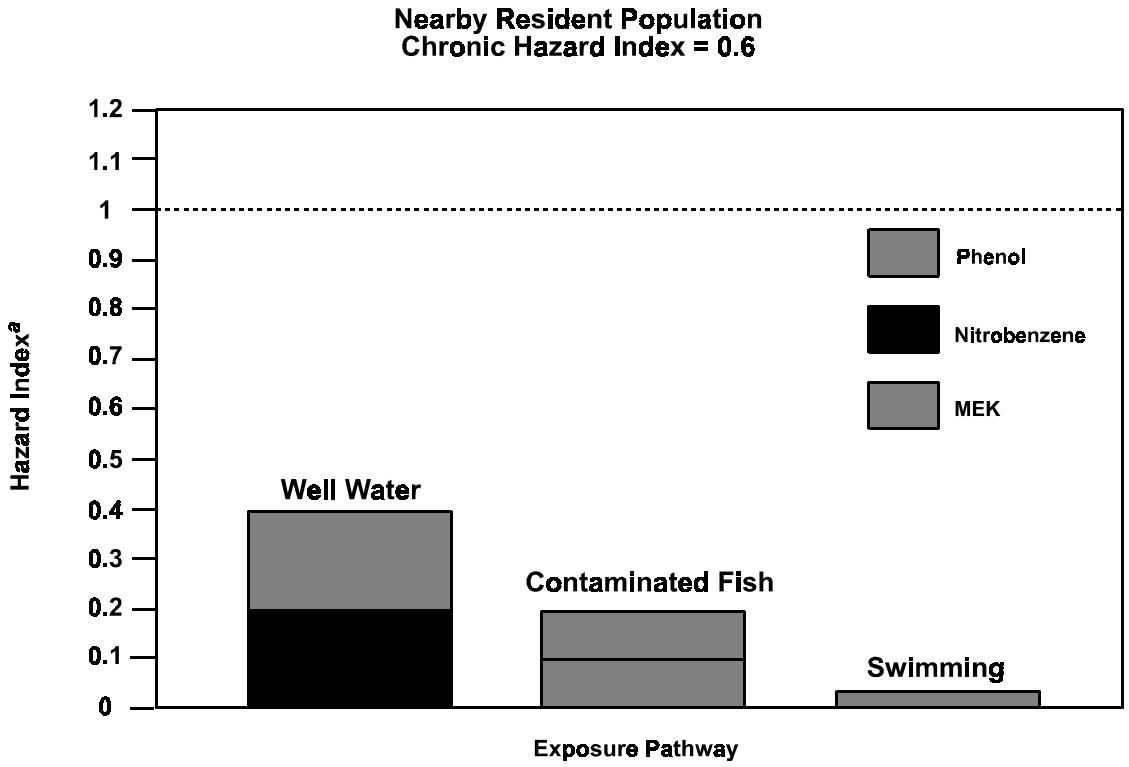
EXAMPLE OF PRESENTATION OF RELATIVE CONTRIBUTION OF INDIVIDUAL CHEMICALS TO EXPOSURE PATHWAY AND TOTAL CANCER RISK ESTIMATES



[a] The risk of developing cancer is plotted on a log scale. A risk of 10^{-4} indicates a probability of 1 chance in 10,000 of an individual developing cancer. Risks of 10^{-5} and 10^{-6} correspond to probabilities of 1 chance in 100,000 and 1 chance in 1,000,000 respectively. Values in parentheses represent EPA's weight-of-evidence classification of the agent as a potential human carcinogen: A = human carcinogen; and B2 = probable human carcinogen (with sufficient evidence in animals and inadequate or no evidence in humans).

EXHIBIT 8-8

EXAMPLE OF PRESENTATION OF RELATIVE CONTRIBUTION OF INDIVIDUAL CHEMICALS TO EXPOSURE PATHWAY AND TOTAL HAZARD INDEX ESTIMATES



[a] The hazard Index Is equal to the sum of the hazard quotlents (I.e., exposure level/RfD) for each chemlcal. It Is not a probabllIty; a hazard Index or quotient of ≤ 1.0 indicates that it is unlikely for even sensitive populations to experience adverse health effects.