



Using RISK21 for Risk Communication: TSCA Risk Evaluations

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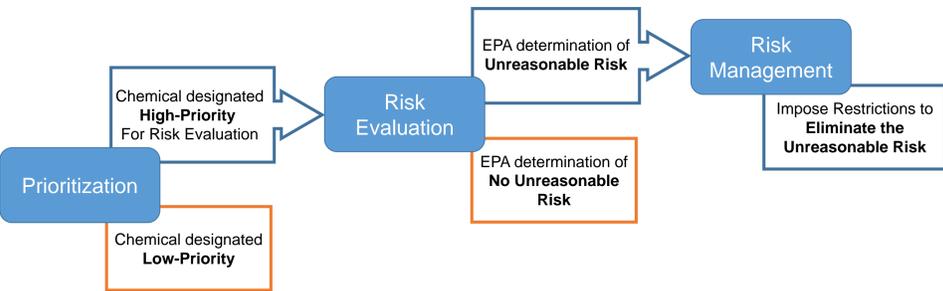
Toxic Substances Control Act (TSCA)

- The Toxic Substances Control Act (TSCA), enacted in 1976, is the primary national chemical management law in the United States.
- Key elements of TSCA:
 - Section 4 – testing of chemicals by manufacturers, importers, and processors where risks or exposures of concern are found
 - Section 5 – pre-manufacture notification for "new chemical substances" before manufacture
 - Section 6 – regulate on the basis of "unreasonable risk"
 - Section 8 – maintain TSCA Inventory, require reporting and record-keeping by persons who manufacture, import, process, and/or distribute chemical substances in commerce.
- Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides.
- First significant amendment in 2016 – Frank R. Lautenberg Chemical Safety Act of the 21st Century

Existing Chemicals Under Amended TSCA

- A largely new process mandating prioritization and risk evaluation of existing chemicals already in commerce under their conditions of use.
- Conditions of use are defined as the circumstances, as determined by EPA, under which chemical is intended, known, or reasonably foreseen to be manufactured, processed distributed in commerce, used, or disposed of.
- The amendments also codified the mandate to use scientific information and approaches that are consistent with the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

USEPA Process for Existing Chemicals



TSCA Risk Evaluations

- Determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to relevant potentially exposed or susceptible subpopulations.
- EPA must evaluate both hazard and exposure and exclude consideration of costs or other non-risk factors.
- Components of TSCA Risk Evaluations:
 - Scope – including conceptual model and analysis plan
 - Hazard assessment
 - Exposure assessment
 - Risk characterization
 - Risk determination



- EPA established rules for:
- Chemical manufacturers to notify EPA of active chemicals
 - Identification of low & high priority chemicals
 - Risk evaluation process for high priority chemicals
 - Establishment of Science Advisory Committee on Chemicals

RISK21 Matrix Webtool: www.risk21.org



- Users can interact with the RISK21 webtool application to visualize their own risk data and create a custom plot which will be displayed on the screen.
- Users can input estimated exposure and toxicity data for each chemical, and the tool will automatically intersect these toxicity and exposure distributions, and plot the intersection area, overlaying a risk matrix represented as a heat map.
- Can be a very effective communication tool for risk management as well as resource allocation

Conclusions

- TSCA Risk Evaluations consider and evaluate risk for chemicals for a broad range of conditions of use which can be challenging to summarize and communicate.
- HESI RISK21 plots can provide a supplemental way to effectively communicate both human health and environmental risk for the TSCA risk evaluations for different conditions of use.
- The plots might be a useful tool to help communicate both ranges of exposure estimates as well as ranges of hazard values across different toxicity endpoints; future case studies could explore this application.
- These plots can help identify where further information could inform the assessment.

References

- U.S. EPA, October 2019, Draft Risk Evaluation for N-Methylpyrrolidone CASRN: 872-50-4. EPA Document# EPA-740-R1-8009. Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency: Washington, D.C.
- U.S. EPA, October 2019, Draft Risk Evaluation for Methylene Chloride CASRN:75-09-2. EPA Document# EPA-740-R1-8010. Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency: Washington, D.C.

Example #1: Occupational Assessment of N-methylpyrrolidone (NMP)

- Occupational exposures are considered in the TSCA Risk Evaluation of each of the first 10 chemicals.
- The Risk Evaluation for N-methylpyrrolidone (NMP) evaluated acute and chronic exposure to workers, to allow for development of non-cancer risk estimates for 16 different occupational scenarios.
- For each occupational scenario, both central tendency and high-end exposures were considered, as well as with and without personal protective equipment (PPE). The data were presented in 32 Tables in the draft Risk Evaluation (Tables 4-5 through 4-36). Table 1 below is provided as an example.
- Figure 1 shows chronic data for some of the conditions of use presented in the 32 Tables of the draft Risk Evaluation and allows the evaluator to quickly single out which exposures may require additional refinement.

Table 1: Example table from NMP 2019 Risk Evaluation (Table 4-6)

Health Effect, Endpoint, and Study	Chronic POD, AUC (hr mg/L)	Exposure Level	Chronic Exposure, AUC (hr mg/L)			MOE			Benchmark MOE (=Total UF)
			No gloves	Gloves PF10	Gloves PF20	No gloves	Gloves PF10	Gloves PF20	
REPRODUCTIVE EFFECTS Decreased Fertility (Exxon, 1991)	183	Central Tendency	8.6	0.86	0.43	21	213	423	30
		High-End	81.4	7.4	3.82	2.2	25	48	

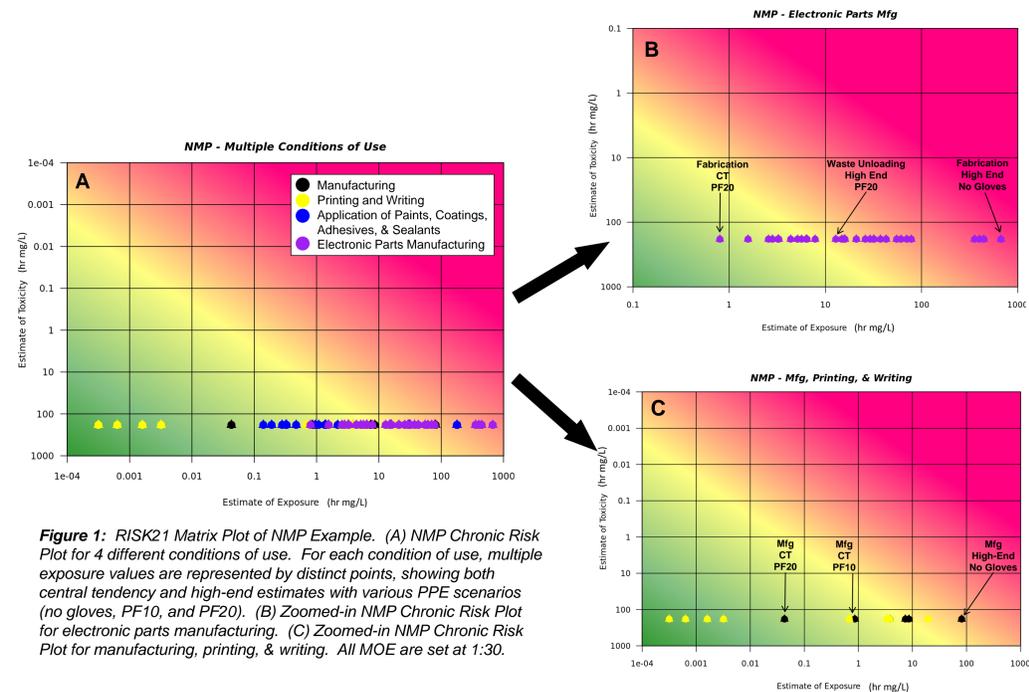


Figure 1: RISK21 Matrix Plot of NMP Example. (A) NMP Chronic Risk Plot for 4 different conditions of use. For each condition of use, multiple exposure values are represented by distinct points, showing both central tendency and high-end estimates with various PPE scenarios (no gloves, PF10, and PF20). (B) Zoomed-in NMP Chronic Risk Plot for electronic parts manufacturing. (C) Zoomed-in NMP Chronic Risk Plot for manufacturing, printing, & writing. All MOE are set at 1:30.

Example #2: Ecological Assessment of Methylene Chloride (MC)

- Environmental exposure to aquatic species is considered in TSCA Risk Evaluations for several of the first 10 chemicals.
- The Risk Evaluation for methylene chloride evaluated acute and chronic exposure to aquatic species, based on modeled data near facilities and monitoring data from ambient water.
- EPA compared these exposure values to concentrations of concern (CoCs) for amphibians, fish, and aquatic invertebrates, to develop risk quotients (RQs) (Table 2).
- Figure 2 summarizes the data presented in Table 2 and illustrates what exposures may require additional refinement and for which taxa.

Table 2: Edited example table from MC 2019 Risk Evaluation (modified from Table 4-1)

Name, Location, and ID of Active Releaser Facility	Release Media	E-FAST Waterbody Type	COC Type	COC (ppb)	7Q10 SWC (ppb)	RQ
NJ Facility #1	Non-POTW WWT	Surface Water	Chronic Amphib	90	137.42	1.53
			Chronic Fish	151		0.91
			Chronic Invert	1,800		0.08
			Acute Amphib	2,630		0.05
TX Facility #1	Non-POTW WWT	Surface Water	Chronic Amphib	90	115.81	1.29
			Chronic Fish	151		0.77
			Chronic Invert	1,800		0.06
			Acute Amphib	2,630		0.04
NJ Facility #2	Non-POTW WWT	Still body	Chronic Amphib	90	0.00482	5.36e-5
			Chronic Fish	151		3.19e-5
			Chronic Invert	1,800		2.68e-6
		Surface Water	Acute Amphib	2,630		1.83e-6
			Chronic Amphib	90		188.89
			Chronic Fish	151		112.58
NY Facility #1	Surface Water	Still Body – 250 release days	Chronic Invert	1,800	27.94	9.44
			Acute Amphib	2,630		6.46
			Chronic Amphib	90		0.31
		Still Body – 20 release days	Chronic Fish	151		0.19
			Chronic Invert	1,800		0.02
			Acute Amphib	2,630		0.01
NY Facility #1	Surface Water	Still Body – 20 release days	Chronic Amphib	90	352.94	3.92
			Chronic Fish	151		2.34
			Chronic Invert	1,800		0.20
NY Facility #1	Surface Water	Still Body – 20 release days	Acute Amphib	2,630	352.94	0.13

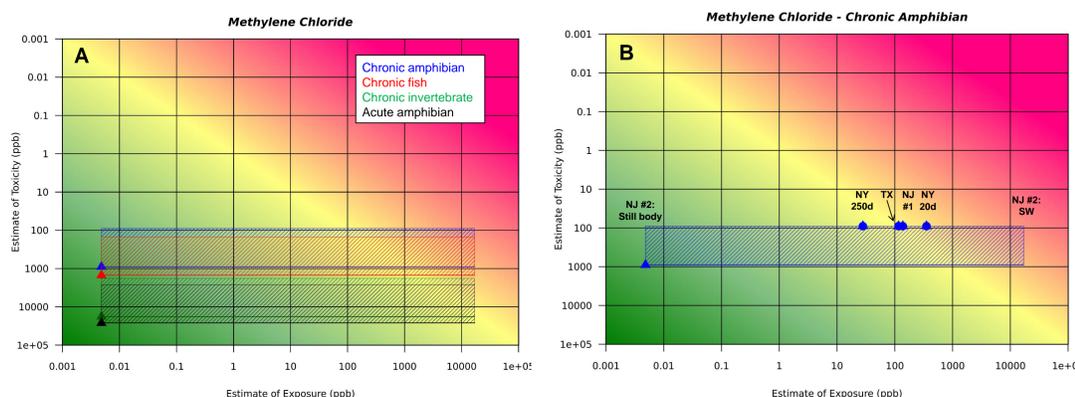


Figure 2A: RISK21 Matrix Plot of MC Example. Triangles represent the selected chronic or acute toxicity values used in the assessment for the various taxa. An Application Factor (AF) of 10 was applied to all toxicity values (acute and chronic) to derive the Concentration of Concern (CoC) used in the assessment and is represented by the vertical height of each rectangle. The exposure range (horizontal width of the rectangle) represents the lowest and highest 7Q10 SWC values as modeled using E-FAST per Table 2, above. MOE is set at 1:1.

Figure 2B: RISK21 Matrix Plot of MC Example – chronic amphibian scenario. The same parameters were used to develop this plot as per 2A. Point estimates of the specific exposure estimates from E-FAST modeling for different scenarios are represented by the separate blue circles.