Abstract #1578
Poster Board #639

Is There Overlap in U.S. Hazard Characterization Programs that Focus on Environmental Exposure? An Evaluation of the Data

Nancy B. Beck, Richard A. Becker, Adam Twardowski

American Chemistry Council

ABSTRACT

We have recently seen much interest, at the Executive and Legislative levels, directed towards evaluating how to reform and streamline government to improve efficiencies and decrease costs. In January 2010, President Obama, acknowledging challenging economic times, began an effort to decrease waste and inefficiencies in the government. Public Law 111-139 (February 2010) required GAO to identify federal programs with duplicative goals and activities. When it comes to evaluating the hazards associated with environmental contaminants, in the U.S. Government, there are four significant programs that have seemingly overlapping, although not perfectly aligned goals.

- The EPA Integrated Risk Information System (IRIS) typically evaluates risk information relating to chronic non-cancer and cancer effects.
- The Agency for Toxic Substances and Disease Registry (ATSDR), in their Toxicological Profiles, provides risk information relating to non-cancer effects for acute, sub-chronic and also chronic exposures.
- The Office of Health Assessment and Translation, within the National Toxicology Program (NTP), evaluates reproductive and developmental endpoints.
- The NTP, although it does not develop quantitative risk values, provides cancer descriptors, similar in nature to the IRIS program, in their Report on Carcinogens (RoC).

To understand whether the government programs provide redundant reviews we examined the similarities and differences between the programs. The results presented will help the agencies and stakeholders assess the value in having these distinct chemical programs.

METHODS

IRIS: http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList. The IRIS advanced search tool was used to create a list of carcinogenicity assessments (searching "by human carcinogenicity" Date of last revision was accessed by looking at each chemical's "Quick Statistics" option. RfD and RfC data were obtained by using the "By Toxicity Value" search, selecting "Oral RfD" or "Inhalation RfC" and a range from 0.0001 x 10^{-10} to 1000 x 10^{10} (http://www.epa.gov/iris/search_critical.htm). For this analysis, the last update of IRIS section of EPA website was August 1, 2012.

ATSDR Minimum Risk Levels (MRLs): http://www.atsdr.cdc.gov/mrls/index.asp. This link was used to obtain MRL data. We filtered the list for "chronic" and "inhalation" or "oral." ATSDR values were updated February 2013.

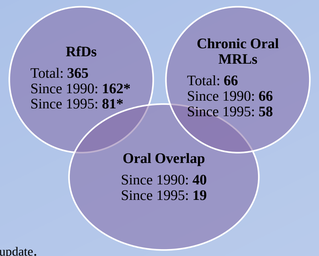
RoC: http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-DBA9EC0928DF8B1. In addition, a list of substances in the 12th RoC was obtained from NIH/NIEHS via e-mail request.

Hazardous Air Pollutants (HAPs): http://www.epa.gov/ttn/atw/188polls.html.

Safe Drinking Water Act (SDWA) chemicals: http://water.epa.gov/drink/contaminants/basicinformation/index.cfm.

Dose Conversions (ppm to mg/m³): http://www.cdc.gov/niosh/docs/2004-101/calc.htm. Molecular weights were obtained from TOX21S: Tox21 Chemical Inventory for High-Throughput Screening Structure-Index File.

NON CANCER ORAL



*Date reflects a file update.

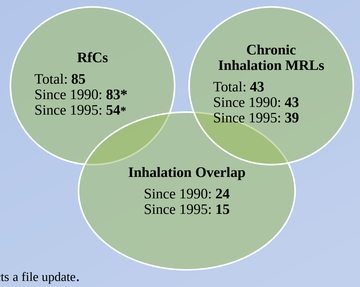
- Since 1990, 61% of ATSDR assessments (40/66) are also assessed by IRIS.
- Since 1990, 25% of IRIS assessments (40/162) are also assessed by ATSDR.
- Of the 40 chemicals assessed by both programs, 19 (48%), have the same value (aroclor 1254, arsenic, barium, beryllium, bromoform, cadmium, chloroform, dichlorvos, dieldrin, 2,4-dinitrotoluene, endrin, formaldehyde, malathion, perchlorate, selenium, trichloroethylene, vinyl chloride, xylenes, and zinc).
- For the 18 with similar values, only 12 applied the same Uncertainty Factors (UFs). The remaining 6 were developed with different PODs and different UFs.

22 of the Duplicative Oral Assessments Have Different Values

Oral MRL (mg/kg/day) lower than RfD (mg/kg/day)	RfD (mg/kg/day) lower than oral MRL (mg/kg/day)
Benzene 0.0005 vs. 0.004 **(8x)**	Cadmium (food) 0.0005 vs. 0.001 **(2x)**
Chromium (VI) 0.001 vs. 0.003 **(3x)**	Chlorodecone (kepone) 0.0003 vs. 0.0005 **(1.7x)**
Dichloromethane 0.06 vs. 0.6 **(10x)**	DEHP 0.02 vs. 0.06 **(3x)**
1,3-Dichloropropene 0.007 vs. 0.03 **(4x)**	Dibromochloromethane 0.02 vs. 0.09 **(4.5x)**
Endosulfan 0.002 vs. 0.006 **(3x)**	1,2-Dichlorobenzene 0.09 vs. 0.3 **(3x)**
Hexachlorobenzene 0.00005 vs. 0.0008 **(16x)**	1,1-Dichloroethylene 0.009 vs. 0.2 **(22x)**
Pentachlorophenol 0.001 vs. 0.005 **(5x)**	DIMP 0.08 vs. 0.6 **(7.5x)**
	1,4-Dioxane 0.03 vs. 0.1 **(3x)**
	RDX 0.003 vs. 0.1 **(33x)**
	Methyl Parathion 0.00025 vs. 0.0003 **(1.2x)**
	Methylmercury 0.0001 vs. 0.0003 **(3x)**
	2-Methylnaphthalene 0.004 vs. 0.04 **(10x)**
	Mirex 0.0002 vs. 0.0008 **(4x)**
	TCDD 0.0000000007 vs. 0.00000001 **(14x)**
	1,2,4-Trichlorobenzene 0.01 vs. 0.1 **(10x)**

- Of the 22 duplicative assessments, in 15 cases (68%) the IRIS value was lower
- There are 9 assessments whose most recent final values are lower than the older final value. 5 of these are IRIS values; 4 are ATSDR
- There are 13 assessments where the most recent assessment was higher. 3 of these are IRIS values; 10 of these are ATSDR

NON CANCER INHALATION



*Date reflects a file update.

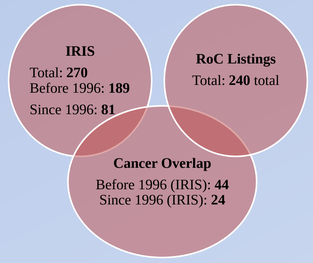
- Since 1990, 53% of ATSDR assessments (23/43) are also assessed by IRIS
- Since 1990, 28% of IRIS assessments (24/83) are also assessed by ATSDR
- Of the 23 chemicals assessed by both programs, only dichlorvos, naphthalene, and trichloroethylene have similar values. Dichlorvos was derived similarly by both programs (same UFs) but naphthalene was not.
- 88% of the time the agencies reached different conclusions (21/24)

21 of the Duplicative Inhalation Assessments Have Different Values

Inhalation MRL (mg/m³) lower than RfC (mg/m³)	RfC (mg/m³) lower than Inhalation MRL (mg/m³)
1,4-Dichlorobenzene 0.06012 vs. 0.8 **(13.3x)**	1,3-Dichloropropene 0.02 vs. 0.031770 **(1.6x)**
Ammonia 0.06966 vs. 0.1 **(1.4x)**	1,6-Hexamethylene Diisocyanate 0.00001 vs. 0.00007 **(7x)**
Benzene 0.00958 vs. 0.03 **(3.1x)**	Carbon disulfide 0.7 vs. 0.93 **(1.3x)**
Bromomethane 0.005 vs. 0.01942 **(3.9x)**	Carbon Tetrachloride 0.1 vs. 0.19 **(1.9x)**
Chromium VI 0.000005 vs. 0.000008 **(1.6x)**	Dichloromethane 0.6 vs. 1.04 **(1.7x)**
Ethylbenzene 0.26 vs. 1 **(2.6x)**	HCCPD 0.0002 vs. 0.00223 **(11x)**
EGBE 0.97 vs. 1.6 **(1.6x)**	Manganese 0.0001 vs. 0.0003 **(3x)**
MTBE 2.52 vs. 3 **(1.2x)**	Mercury, elemental 0.0003 vs. 0.00164 **(5.5x)**
Styrene 0.85 vs. 1 **(1.2x)**	n-Hexane 0.7 vs. 2.11 **(3x)**
Toluene 0.3 vs. 5 **(16.6x)**	Tetrachloroethylene 0.04 vs. 0.27 **(7x)**
	Xylenes 0.1 vs. 0.22 **(2.2x)**

- For inhalation compounds, while no program consistently provided lower or higher values, for 15/21 compounds (71%) the more recent assessment consistently provided a lower value
- There are 15 assessments whose most recent final values are lower than the older final value. 8 of these are IRIS values; 7 are ATSDR
- There are 6 assessments where the most recent assessment was higher. 2 of these are IRIS values; 4 of these are ATSDR

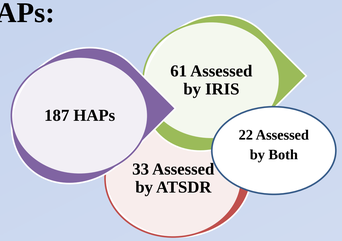
CANCER EVALUATION



- 25% (68/270) of IRIS chemicals are also assessed by the RoC
- Since 1996, 30% of IRIS chemicals (24/81) are also assessed by the RoC

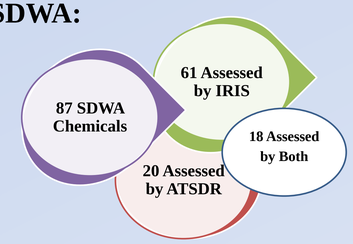
MEETING REGULATORY NEEDS

HAPs:



- IRIS has only assessed 33% (61/187) of the HAPs

SDWA:



- IRIS has assessed 70% of SDWA chemicals. ATSDR is highly duplicative (90% redundancy) of EPAs work

SUMMARY

- When looking at Oral non-cancer values, since 1990, 61% of ATSDR values are assessed in IRIS; 25% of IRIS values are assessed in ATSDR. Of the chemicals assessed by both, 48% of the time, the Agencies reach the same final conclusion. When they don't reach the same conclusion, 68% of the time the IRIS value is lower.
- When looking at Inhalation non-cancer values, since 1990 53% of ATSDR values are assessed in IRIS, 29% of IRIS assessments are assessed in ATSDR. Of the chemicals assessed by both, only 13% (3/24) of the time did Agencies reach a similar conclusion. When a similar conclusion was not reached (87% of the time) there was no trend in which Agency provided a higher or lower value. However, we did find that 71% of the time the more recent assessment provided the lower value.
- When looking at cancer assessments, 30% of the chemicals IRIS evaluated (since 1996) have also been evaluated by RoC.
- 67% of HAPs have not been addressed by the IRIS program.

FOR DISCUSSION

- Is this a good use of limited government resources?
- What is gained by having multiple assessments with similar values?
- What is gained if assessments have different values? Do multiple values assist risk managers?
- Would the Federal chemical assessment program be more efficient if resources were combined and duplicative work was not conducted? This analysis would, conservatively, support gains of 25-30%. True gains would likely be much higher.
- Should Federal Assessment prioritization be re-evaluated such that pollutants of greatest regulatory concern are addressed? This analysis would support such an approach, particularly within EPA, as 67% of HAPS have no IRIS value.

The authors greatly appreciate the input from the ACC Risk Assessment team.