Requirements and Evaluation of Toxicity Testing in the TSCA* New Chemicals Program

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*Toxic Substances Control Act

New Chemicals Process

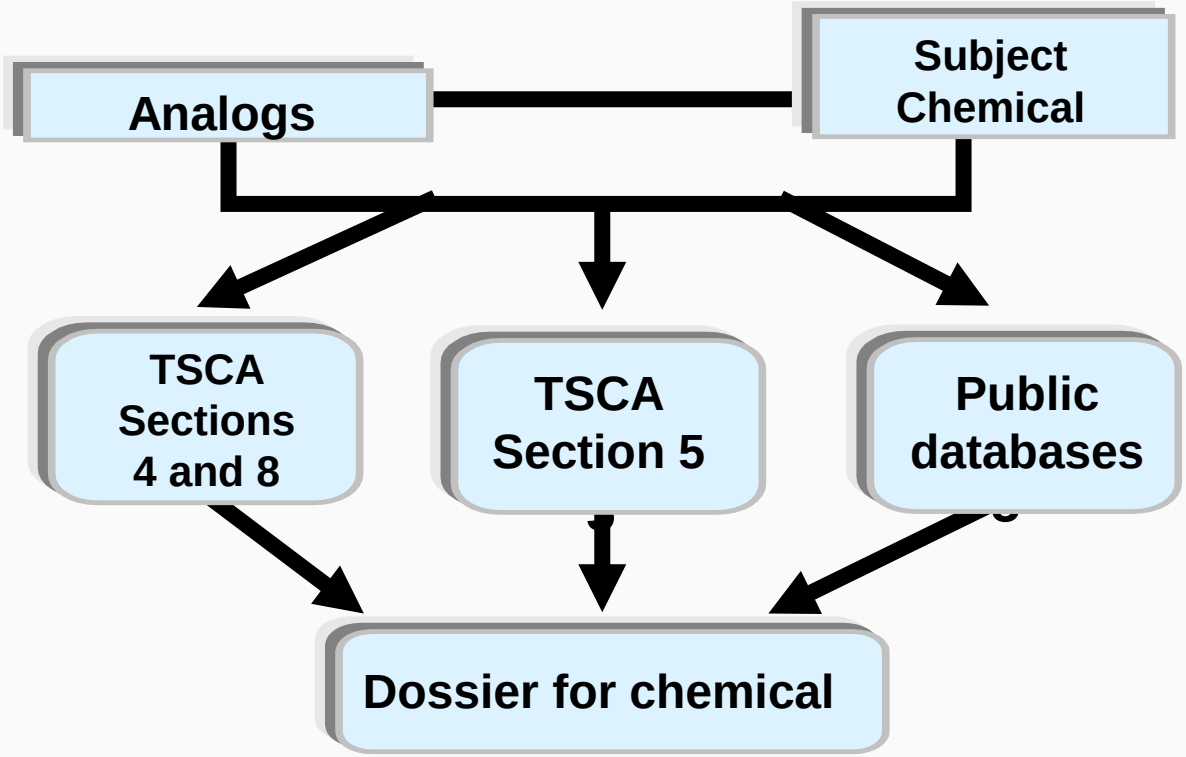
- TSCA New Chemical Program – Premanufacture Notifications (PMNs)
- How we evaluate toxicity
- Some data on what we receive

Overview of EPA Assessments

- EPA has 90 days to review a new chemical notification (PMN)
- TSCA requires new chemical manufacturers to submit only studies/data in their possession or control (i.e., **no minimum set of toxicity or other studies are required**)
- Because no test data are required to be submitted, predictive models/technical tools and professional judgment are used by EPA to assess potential risks

Structure Activity Team Search Strategies

Identify information for the subject chemical and analogs from the submission, in-house sources, public databases



Structure Activity Team (SAT) Meeting

Human Health Hazard Evaluation

- Determine the likelihood of absorption (by route)
- Identify possible effects/concerns based on all the information (submitted data, data with analogs, professional judgement)
- HOW WE USE: (M)SDS; occupational risk assessment and Personal Protective Equipment (PPE)

Structure Activity Team (SAT) Meeting

Ecotoxicity (Aquatic) Hazard Evaluation

- Use of available data, analogs and ECOSAR approach/model
- ECOSAR: A computer program that integrates knowledge about chemical structure and toxic effects to predict aquatic toxicity
- Fish, aquatic invertebrates, algae, and others
- Has library of > 120 class-based QSARs for predicting toxicity of a chemical to aquatic organisms
- ECOSAR is freely available to download (http://www.epa.gov/oppt/newchems/tools/21ecosar.htm)
- HOW WE USE: Develop acceptable levels in receiving waters; mitigate water releases

Since 1979…

- **New Chemical Notifications Reviewed (as of March 2015)**
  - Total valid PMN Notifications: ~39,200
  - Total valid Exemption Notifications: ~15,000
  - Total valid Notifications reviewed: ~54,000

EPA currently reviews about 1,000 PMNs/Exemptions per year

More Stats and Data…

- **TSCA Inventory**
  - Original TSCA Inventory: ~62,000 substances
  - New Chemicals added since 1979: >22,400
  - Total Chemicals now on TSCA Inventory: >84,400
  - New Chemicals as a % of the TSCA Inventory: 27%
  - CBI Chemicals as a % of the TSCA Inventory: 19%
- **Testing data received: ~10-15% (next two slides)**

Health Study Stats

	Total Notifications	Notifications with No Health Data	Initial Submission Stats: Notifications Initially Containing Health Data	Initial Submission Stats: % With Initial Health Data	Post Submission Stats: Notifications with Post Submission Health Data	Post Submission Stats: % With Post Submission Health Data
2004	1330	1031	268	20.15%	31	2.33%
2005	1184	946	200	16.89%	38	3.21%
2006	1137	905	203	17.85%	29	2.55%
2007	1097	896	169	15.41%	32	2.92%
2008	1114	893	181	16.25%	40	3.59%
2009	1009	833	136	13.48%	40	3.96%
2010	1021	857	143	14.01%	21	2.06%
2011	1129	933	150	13.29%	46	4.07%
2012	932	746	134	14.38%	52	5.58%
Averages	1106	893	176	15.74%	37	3.36%

Ecotox Study Stats

			Initial Submission Stats		Post Submission Stats	
	Total Notifications	Notifications with No Ecotoxicity Data	Notifications Initially Containing Ecotoxicity Data*	% With Initial Eco Data	Notifications with Post Submission Ecotox Data	% With Post Submission Ecotox Data
2004	1330	1167	154	11.58%	9	0.68%
2005	1184	1056	119	10.05%	9	0.76%
2006	1137	1017	110	9.67%	10	0.88%
2007	1097	981	112	10.21%	4	0.36%
2008	1114	996	105	9.43%	13	1.17%
2009	1009	923	76	7.53%	10	0.99%
2010	1021	927	89	8.72%	5	0.49%
2011	1129	1001	113	10.01%	15	1.33%
2012	932	847	82	8.80%	3	0.32%
Averages	1106	991	107	9.56%	9	0.78%

* On Average 15% of the data noted above for initial submission is actually studies for an analogous chemical - not the PMN itself. However, the analog data must still be reviewed for appropriateness (requires staff/contractor time) so it was included in this excersice.

Thank You!

www.epa.gov/oppt/newchems

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The views expressed in this presentation are those of the author and do not represent Agency policy or endorsement.