

Implementing the Vision for Toxicity Testing in the 21st Century:

If You Build It, Will They Come?

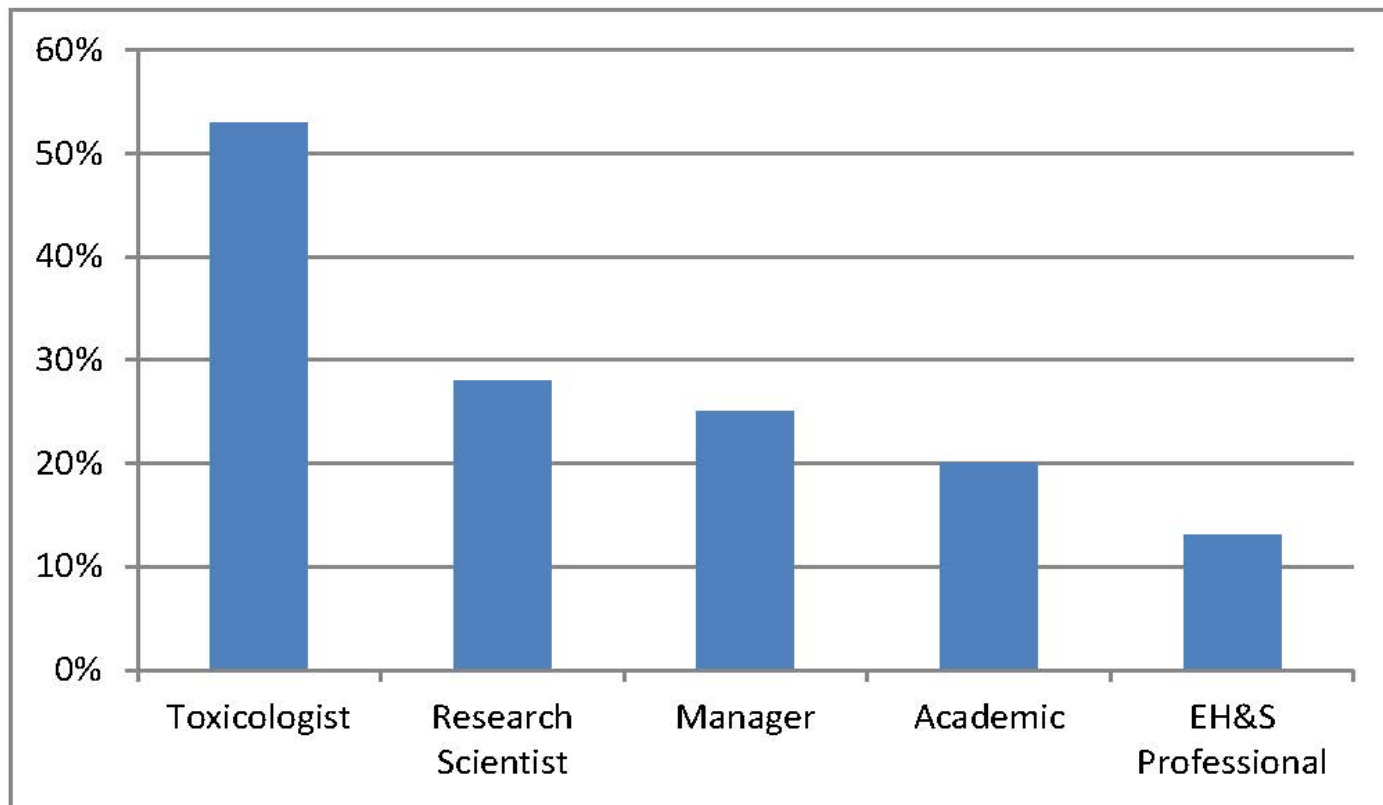
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Where We Are Headed

- Survey Background
- Socio-Legal Barriers to Adoption
- Socio-Legal Drivers of Adoption
- Conclusions

The Survey

Position



Methods and Applications

Methods	Applications
Quantitative Structure Activity Relationship (QSAR)	Screening/prioritization for further testing
Mechanistically based <i>in vitro</i> assays	Screening/prioritization for other actions (e.g. risk assessment, risk management)
Mechanistically based <i>in vivo</i> assays	Setting doses for <i>in vivo</i> testing
High throughput <i>in vitro</i> assays	Weight of evidence in quantitative risk assessment (scoping to determine most sensitive endpoints)
High throughput <i>in vivo</i> assays	Qualitative risk assessment (e.g., control banding)
Biomarkers	Quantitative risk assessment (identifying NOAEL or other levels)
	Comparative assessment of alternative chemicals/products/processes (alternatives analysis)

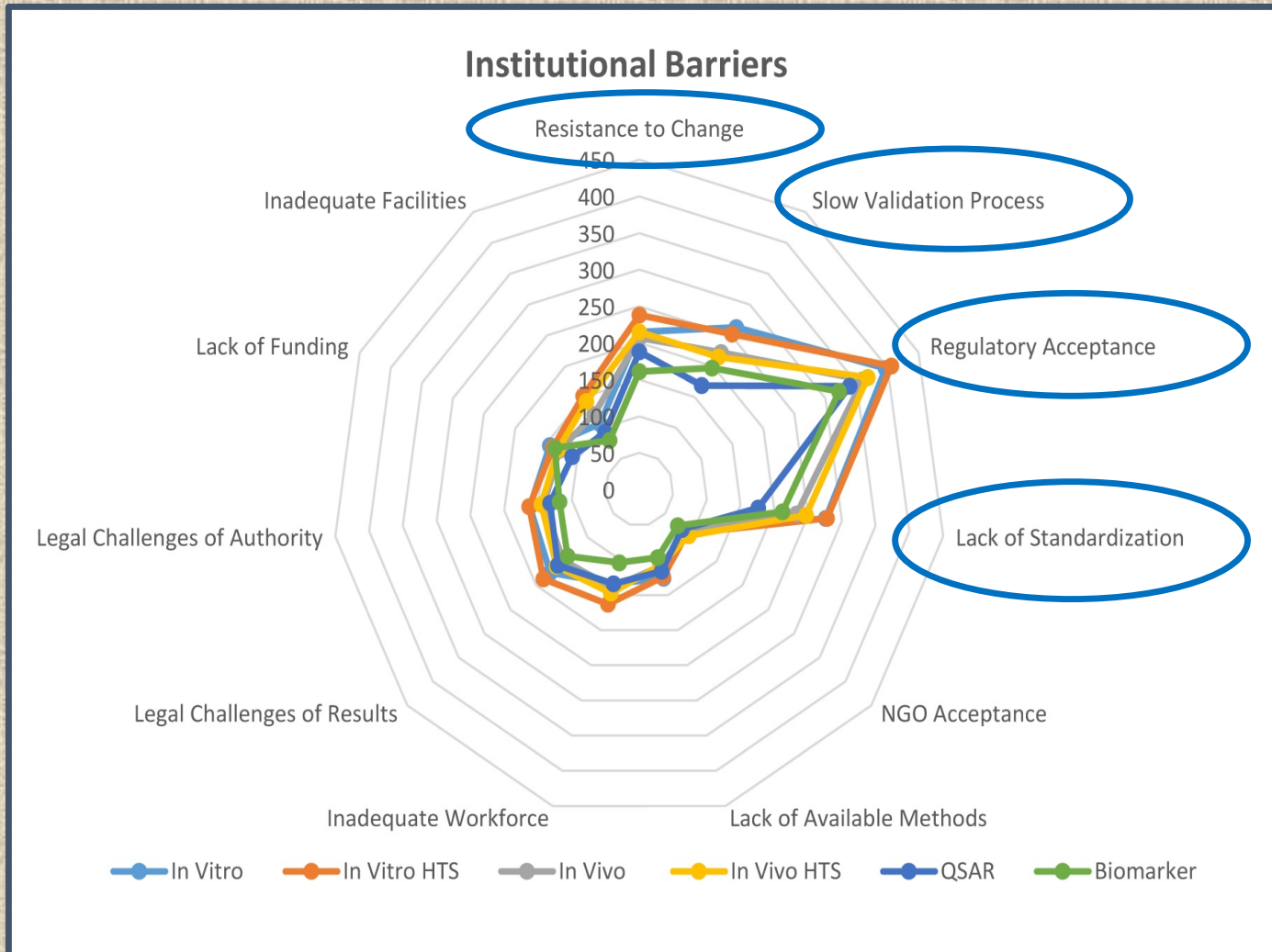
Use and Viability

Technology	Mech <i>in vitro</i>	HTS <i>in vitro</i>	Mech <i>in vivo</i>	HTS <i>in vivo</i>	QSARs	Bio- markers
Use						
Screening/prioritization for further testing	83.9% (1.2%)	81.6% (1.3%)	74.2% (1.6%)	70.1% (1.7%)	86.4% (1.1%)	82.5% (1.3%)
Screening/prioritization for other actions	71.7% (1.5%)	67.7% (1.6%)	64.4% (1.7%)	59.2% (1.8%)	76.6% (1.4%)	77.0% (1.4%)
Comparative assessment of alternative chemicals	65.9% (1.7%)	58.0% (1.8%)	57.9% (1.8%)	53.2% (1.9%)	69.2% (1.6%)	68.5% (1.7%)
Weight of evidence in quantitative risk assessment	58.8% (1.7%)	47.1% (1.8%)	52.1% (1.8%)	41.1% (1.9%)	64.6% (1.6%)	68.8% (1.6%)
Qualitative risk assessment	55.9% (1.8%)	45.2% (1.9%)	51.4% (2.0%)	43.1% (2.0%)	62.6% (1.8%)	67.0% (1.8%)
Setting doses for in vivo testing	49.8% (1.7%)	36.9% (1.7%)	45.3% (1.8%)	38.0% (1.8%)	52.6% (1.7%)	63.9% (1.7%)
Setting NOAEL or other levels in quantitative risk assessment	32.8% (1.7%)	25.5% (1.6%)	33.0% (1.7%)	26.9% (1.7%)	42.8% (1.7%)	53.5% (1.8%)

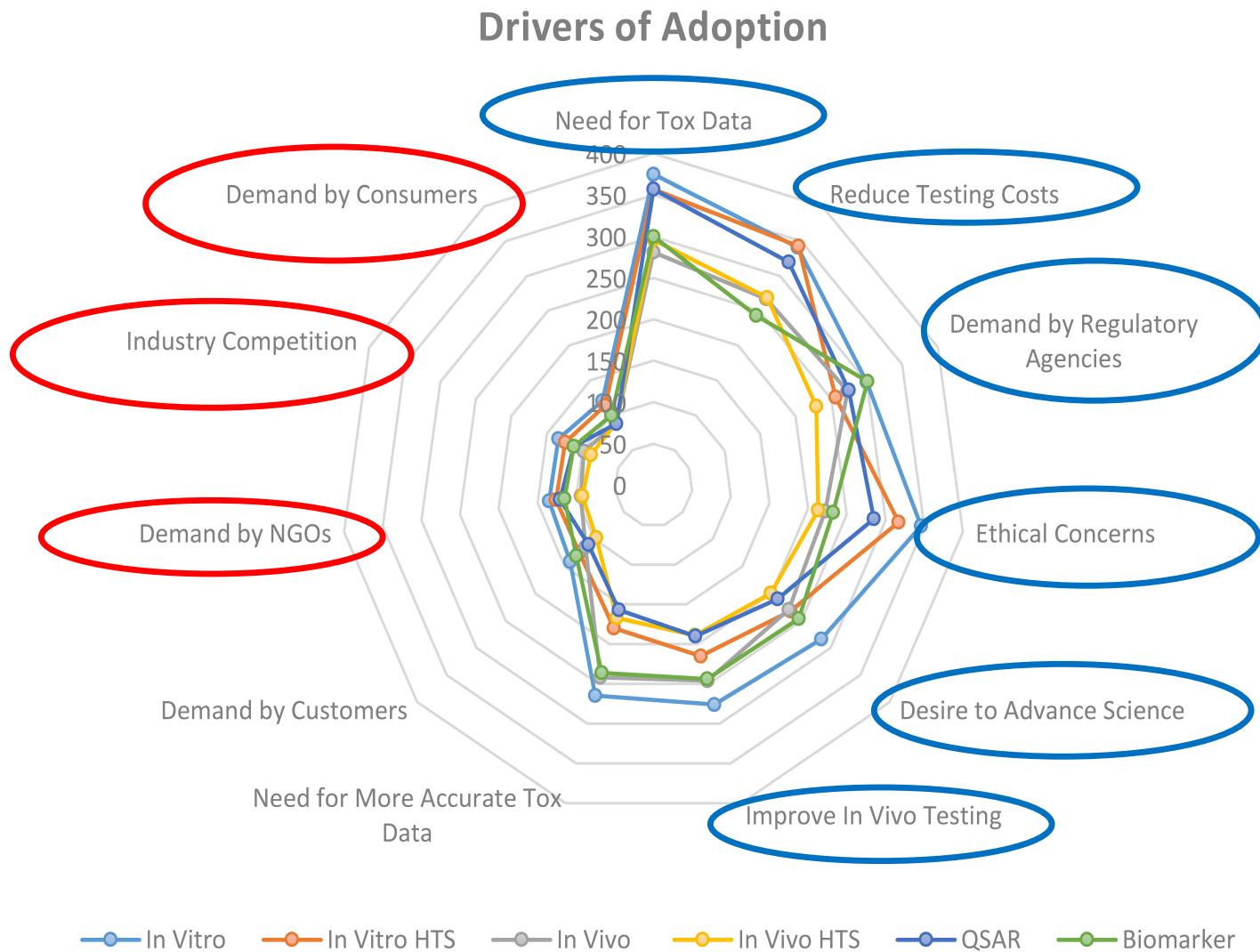
Least viable

Most viable

Socio-Legal Barriers



Socio-Legal Drivers



The Role of TSCA Reform

- Explicit provisions regarding alternative methods create positive context
 - Create “soft” mandate for alternative methods for screening
 - Mandate planning and evaluation of alternative methods
- Provision do not address certain institutional barriers
 - Organizational Inertia
 - Slow Validation

The Team



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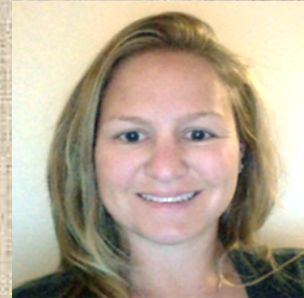
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