ASSOCIATION FOR THE ADVANCEMENT OF ALTERNATIVES ASSESSMENT

International Symposium on Alternatives Assessment Virtual 2020

Current Practices and Future Prospects

October 27-29, 2020

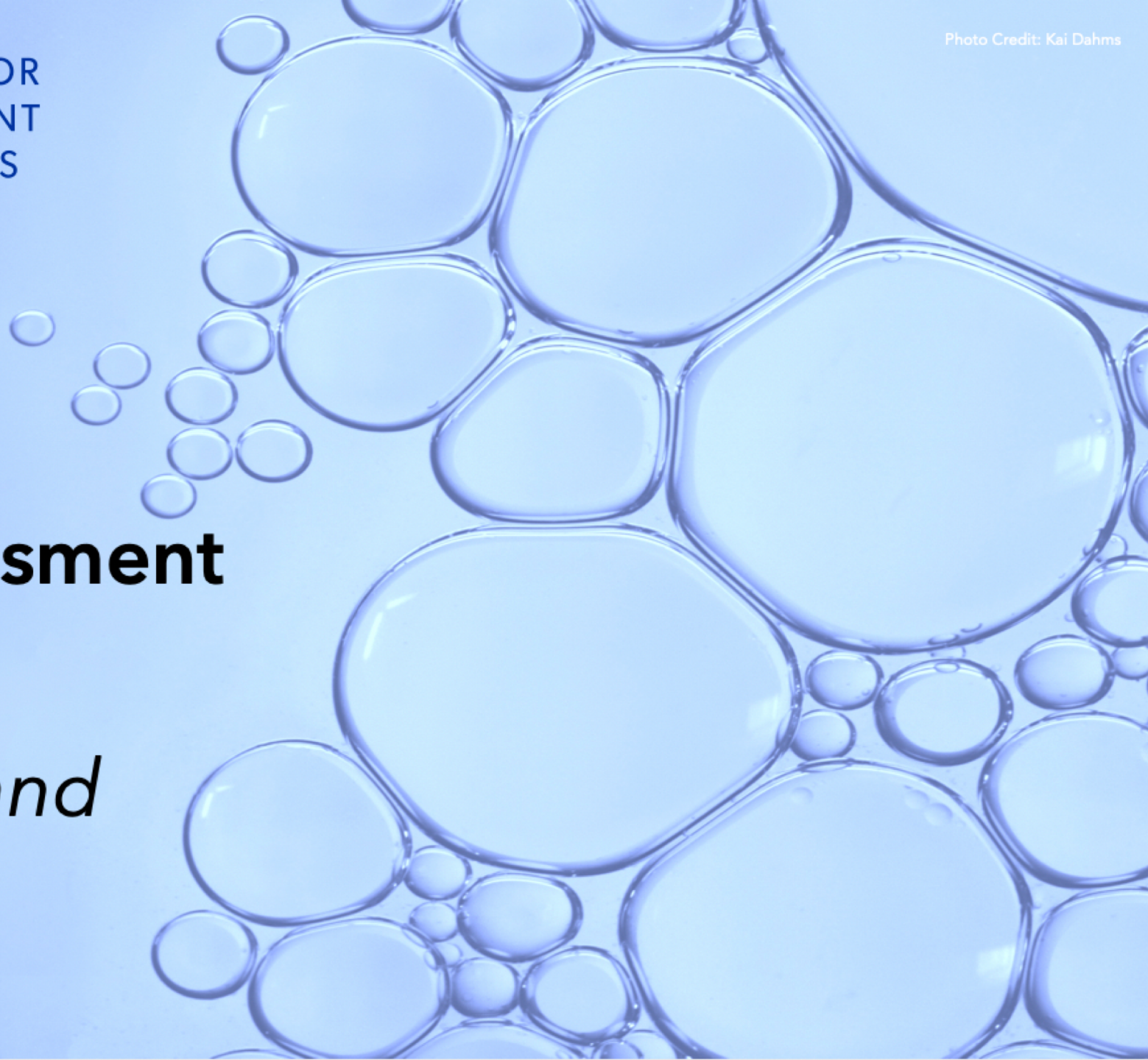


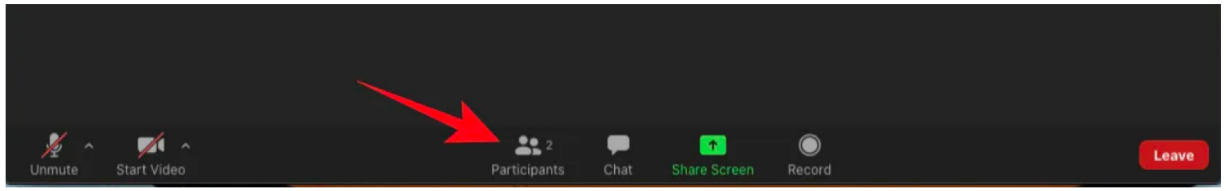
Photo Credit: Kai Dahms

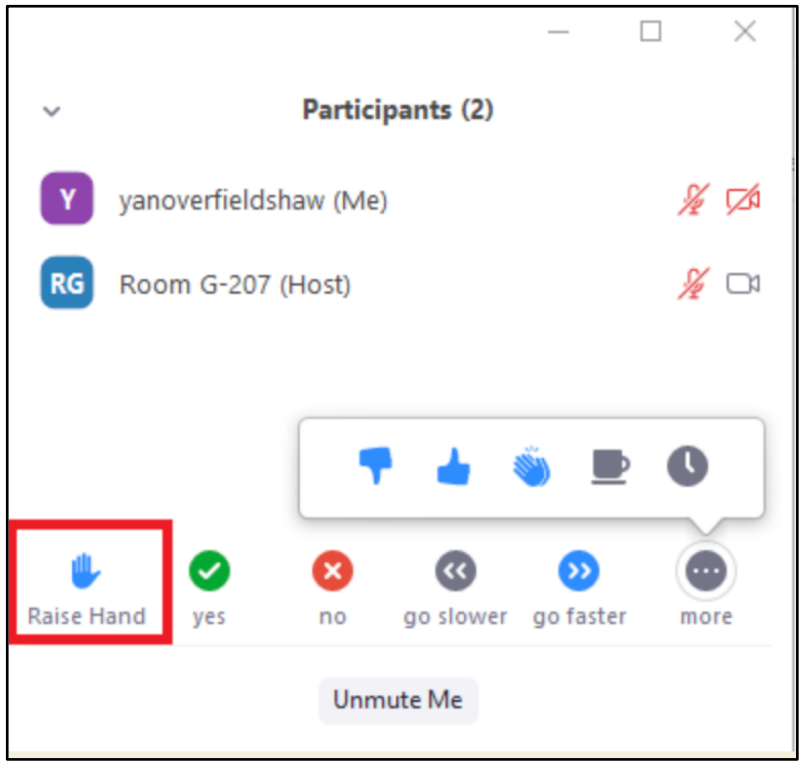
Thank You Sponsors

Session Etiquette

- Please keep your **lines muted and your videos off**.
- Please make sure your **full name and organization** are noted. You can change your name by clicking on the … next to your name/image.
- Use "**speaker view**" in Zoom – it will offer the best viewing experience.
- We encourage you to drop questions in the chat during the panel presentations.
- During the discussion portion of the session, if you wish to ask a question or offer a comment, please raise your hand.
  - Also feel free to use the chat.
- This session is being recorded and will be posted with the slide deck on the A4 website: www.saferalternatives.org

Raising your hand in Zoom





- To “raise you hand”
  - first open the participants icon on the bottom of your computer screen
  - When the participants view opens, you’ll find the “raise hand” icon in the icon list at the bottom.
  - Help us by lowering your hand (toggle the icon) when you finished with your question/comment
- The chat will work too

Symposium Session 5

Part I: Considering Uncertainty:
Real-world strategies to make decisions

Group Discussion (or perhaps debate)?

- What do you do to address uncertainty in your assessments?
- What lessons would you pass on to this community?
- Is our practice coalescing around specific strategies?
  - Should it?

Moderator & Panelists

TIM MALLOY

University of California Los Angeles

TOM LEWANDOWSKI

Gradient

SHARI FRANJEVIC

Clean Production Action/GreenScreen®

MARTIN WOLF

Seventh Generation

Decision Making In the Face of Uncertainty

29 October 2020

Outline

- Introduction to Seventh Generation
- Sustainable Product Design
- Tiered Risk Management
- The Problem
- The Decision
- Q&A and Discussion

WE DO BUSINESS *differently*

Certified B Corporation

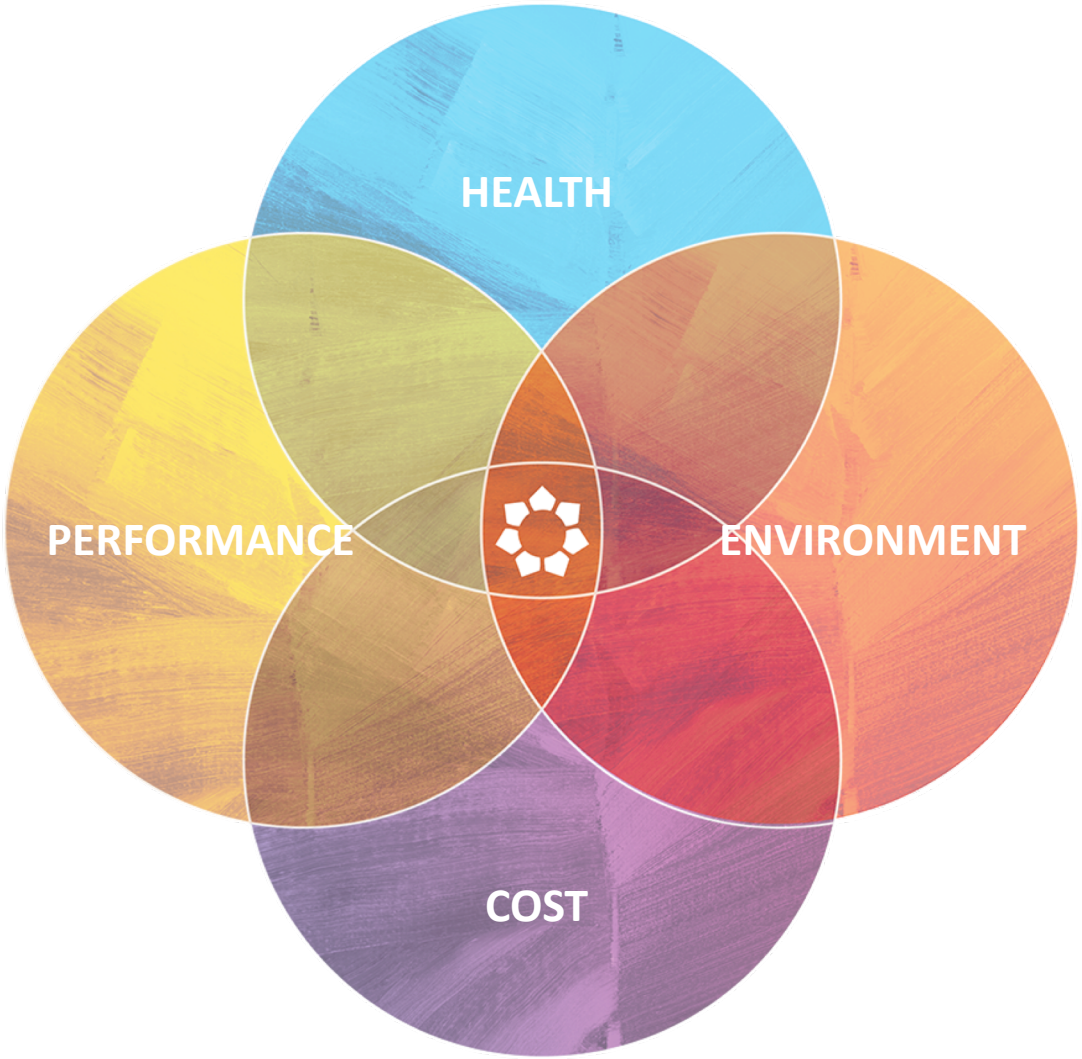
to transform the world into

A HEALTHY, SUSTAINABLE, & EQUITABLE PLACE

for the next seven generations

seventh generation

Sustainable Product Design



Products should be at the center of serving the environment and human health ***without*** compromising efficacy or an accessible price point.

Risk Assessment

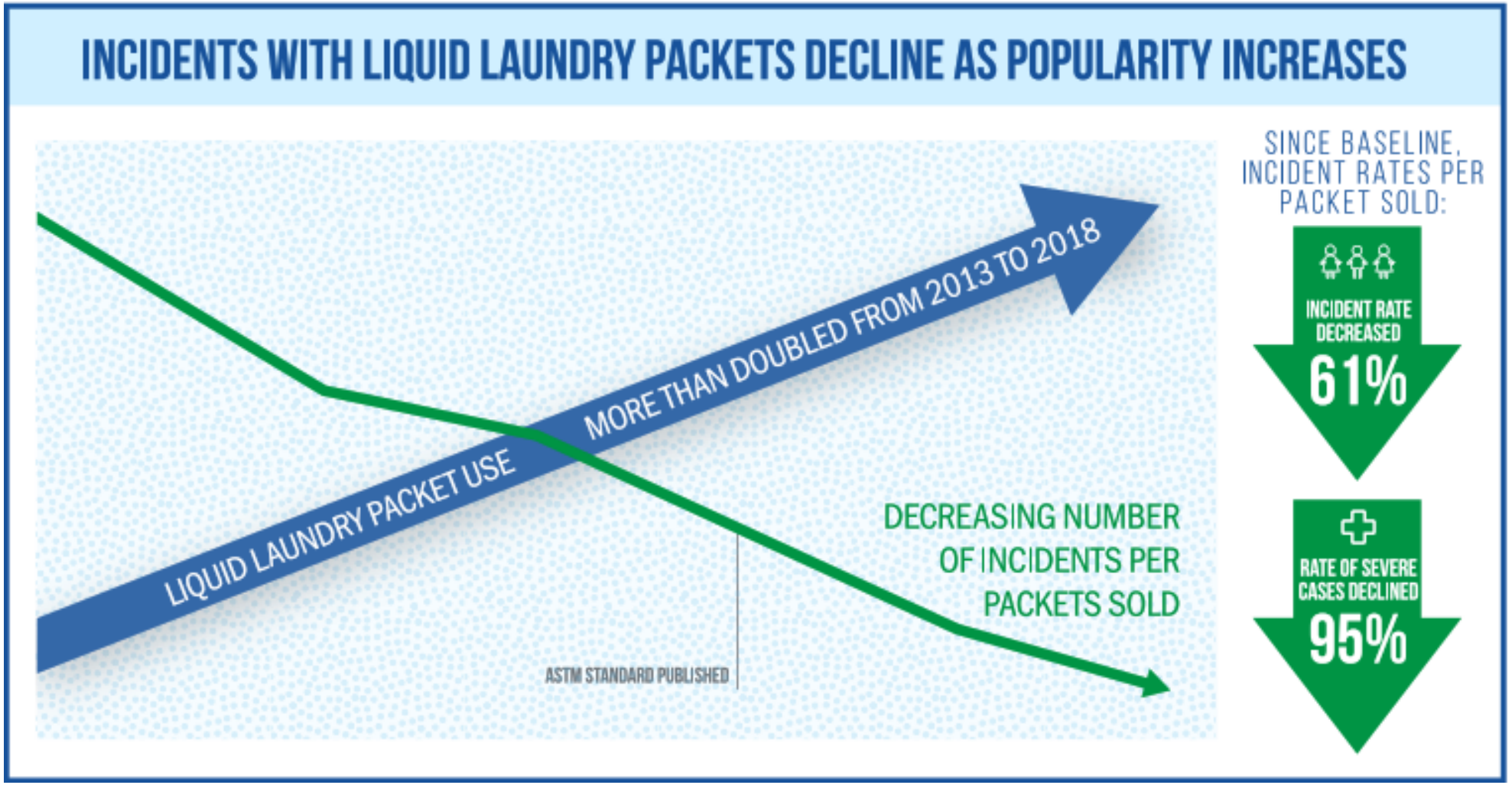
Risk of Harm = Hazard x Exposure

Tiered Risk Management

Increasing Uncertainty

1. Eliminate Hazards
2. Consider exposure
3. Use precaution

The Problem



The Problem

Laundry Detergents: Liquids and Granules with Liquids (Unit Dose)*

	2013	2014	2015	2016	2017	2018
Sales ($M)	625	820	980	1,222	1,380	1,476
Sales (% of all liquid detergents)	9%	12%	14%	17%	19%	19%
Incidents	10,967	13,013	14,058	13,124	12,519	12,135
Incidents (% of all liq. dets.)	65%	66%	66%	63%	65%	65%
Moderate & Major Outcomes	872	938	902	719	699	667
Mod & Maj Outcomes (% of all)	84%	84%	85%	78%	85%	86%
Deaths	2	4	1	0	1	1
Deaths (% of all deaths)*	100%	100%	33%	0%	33%	50%

*American Association of Poison Control Centers, Annual Reports, 2013-2018

The Uncertainty

"The mechanisms of toxicity are ***not completely understood*** but it is probable that the primary cause is the high concentration of non-ionic surfactants present in some capsules, though anionic surfactants, ethanol and propylene glycol may also contribute."

Rachael Day, Sally M. Bradberry, Simon H. L. Thomas & J. Allister Vale (2019): Liquid laundry detergent capsules (PODS): a review of their composition and mechanisms of toxicity, and of the circumstances, routes, features, and management of exposure, Clinical Toxicology, DOI: 10.1080/15563650.2019.1618466

Managing Exposure

- Packaging
  - Opaque
  - Child resistant
- Packet envelope (soluble film)
  - Aversive (bittering) agent
  - Enhanced burst strength
  - Reduced rate of dissolution
- Enhanced hazard warnings

Tiered Risk Management

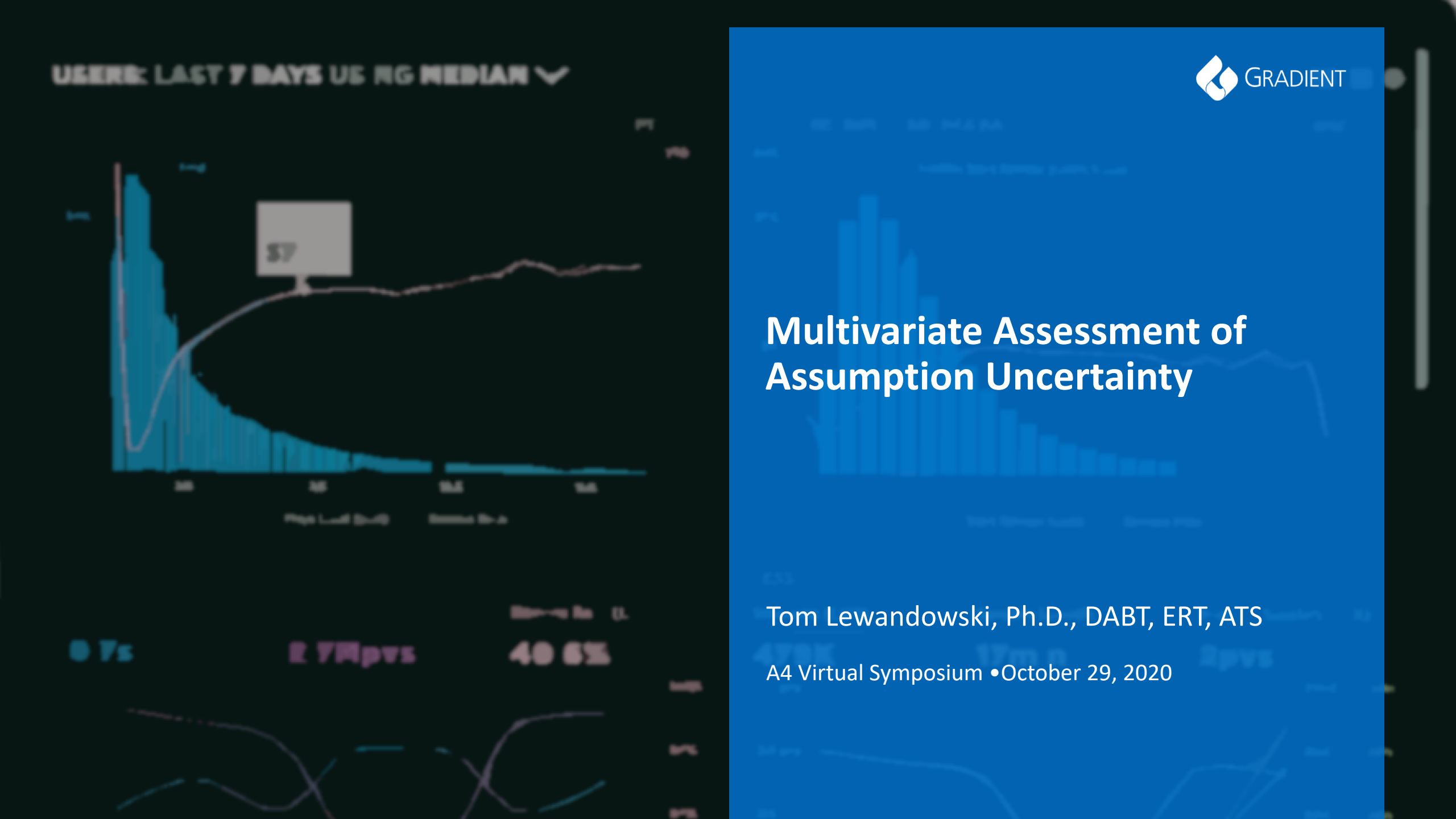
Increasing Uncertainty

1. Eliminate Hazards
2. Consider exposure
3. Use precaution

Questions, Discussion

Thank you!

martin.wolf@seventhgeneration.com



GRADIENT

Multivariate Assessment of Assumption Uncertainty

Tom Lewandowski, Ph.D., DABT, ERT, ATS

A4 Virtual Symposium •October 29, 2020

The Issue

- Until recently automotive air conditioning systems used R-134a (tetrafluoroethane) as the refrigerant
- R-134a is a potent greenhouse gas
  - The chemical stability of R-134a is part of the problem; it doesn't degrade and can reach the upper atmosphere
- When air conditioning systems leak slowly over time, R-134a is released into the environment
- Under US law, replacements for R-134a (and similar gases) have to have an equivalent overall impact (with trade off among possible impacts)
- No free lunch; lower global warming potential may mean less ideal for other hazards

Overall Evaluation of Refrigerant Alternatives

Property	R-134a	CO_2	HFO-1234yf	Comparison
Toxicity				
Human Health Toxicity	Low	Slightly higher	Slightly lower	More favorable to HFO-1234yf
Ecological Toxicity	Low	Low	Low	Equivalent
Flammability	Not flammable	Not flammable	Weakly flammable	More favorable to CO_2
ODP	0	0	0	Equivalent
100 year GWP (CO_2=1)	1,430	1	4	Much more favorable to CO_2 and HFO-1234yf
Performance	NA	Limitations for mobile AC	Slightly better than 134a	More favorable to HFO-1234yf
Technical feasibility	NA	Notable implementation challenges	Drop in replacement	Much favorable to HFO-1234yf

ODP – Ozone Depletion Potential
GWP – Global Warming Potential

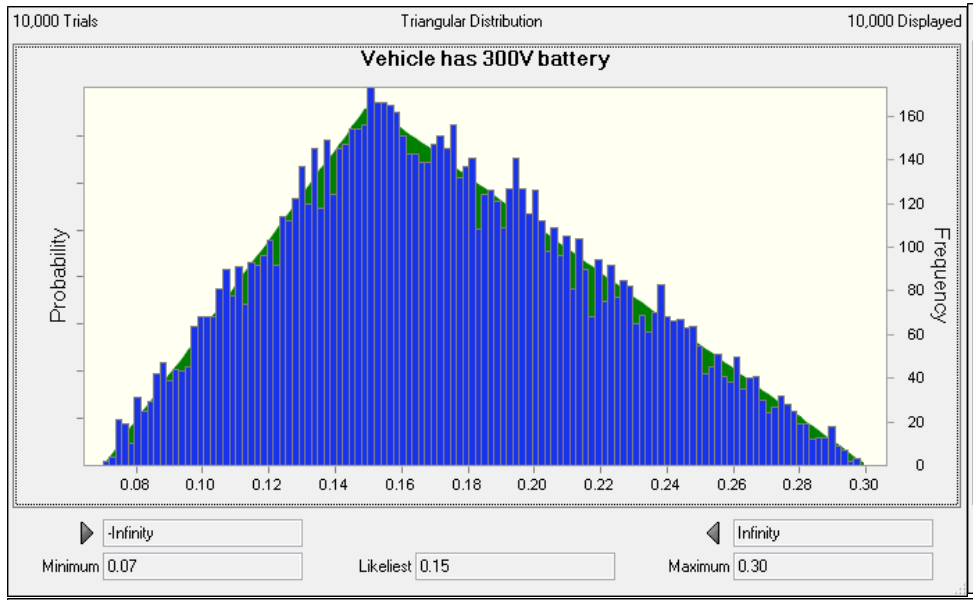
Deciding on an Alternative

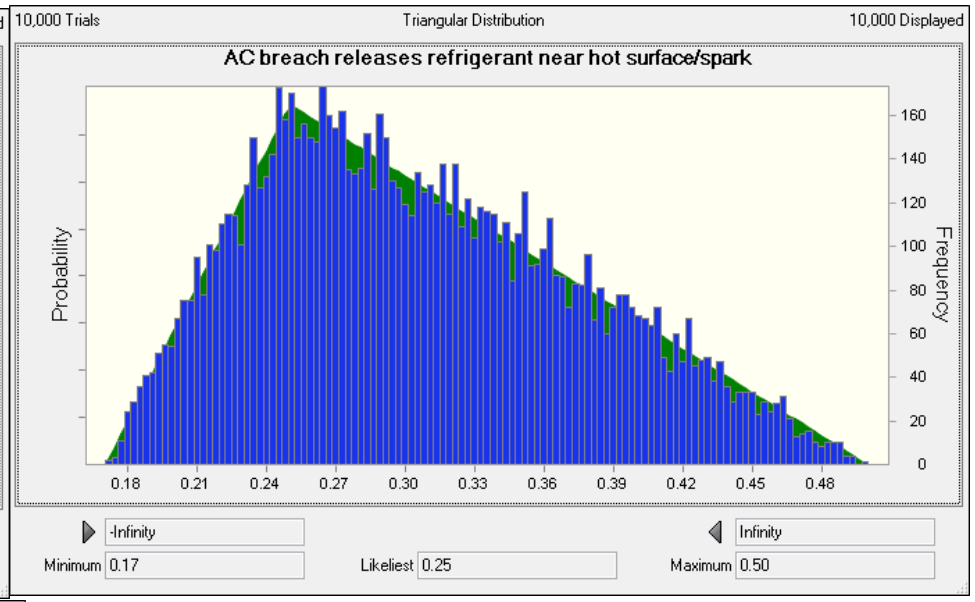
- Over a multi-year process, global industry stakeholders came together to evaluate the merits of each alternative
- Ultimate goal was to estimate the likelihood/probability of an adverse event in the event of a vehicle crash or leak
  - Multiple factors were involved (e.g., severity of crash, geometry of crash, aging of parts over time)
- Much of the analysis required expert judgement regarding various assumptions in the evaluation
  - Different opinions were evident, based on differences in experience, philosophy, goals
- Sensitivity analysis was a way to ensure that everyone's position was acknowledged

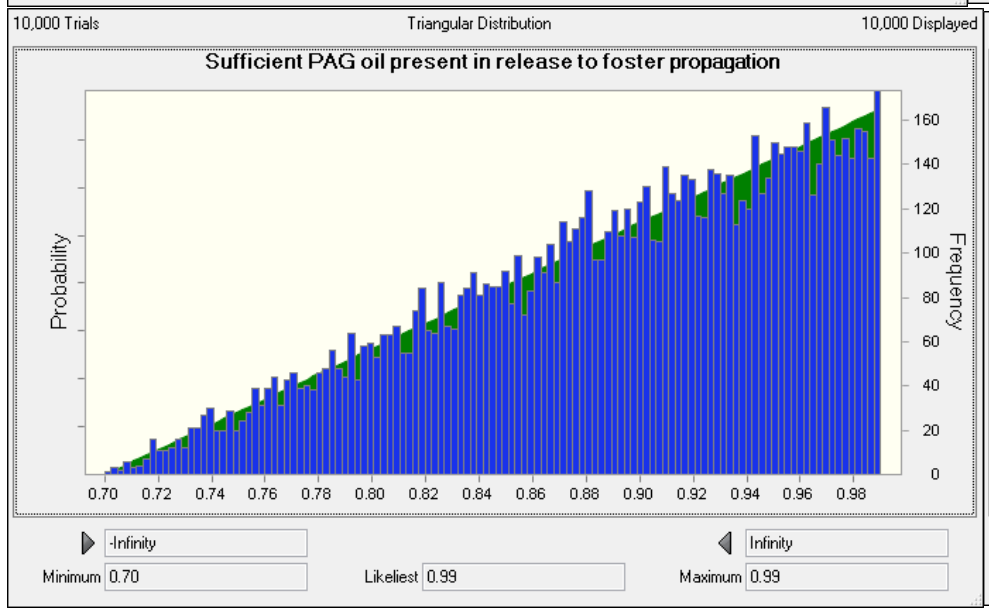
Sensitivity Analysis

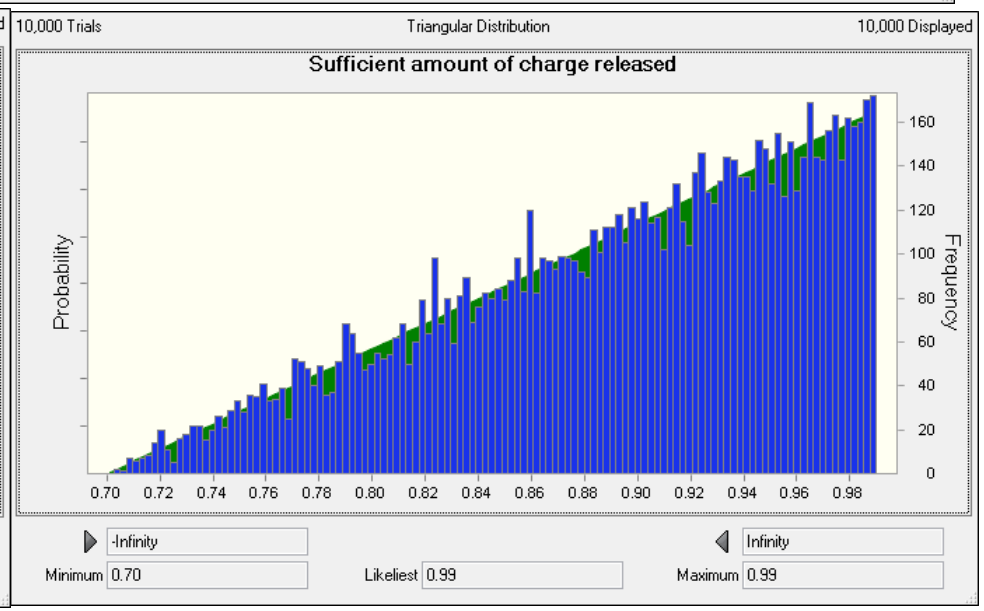
- The easiest approach is simply to redo the analysis, changing one value at a time to see the difference
  - May not be realistic, since assumptions may go together
- Multivariate probabilistic sensitivity analysis allows for understanding the range of uncertainties
- Ask experts to determine ranges/probabilities for key variables of interest
  - Those with the least data, the largest expected variability, or those based on expert judgment
- Perform the analysis using a forecasting/simulation program to generate a probability distribution of the results

Examples of Input Distributions



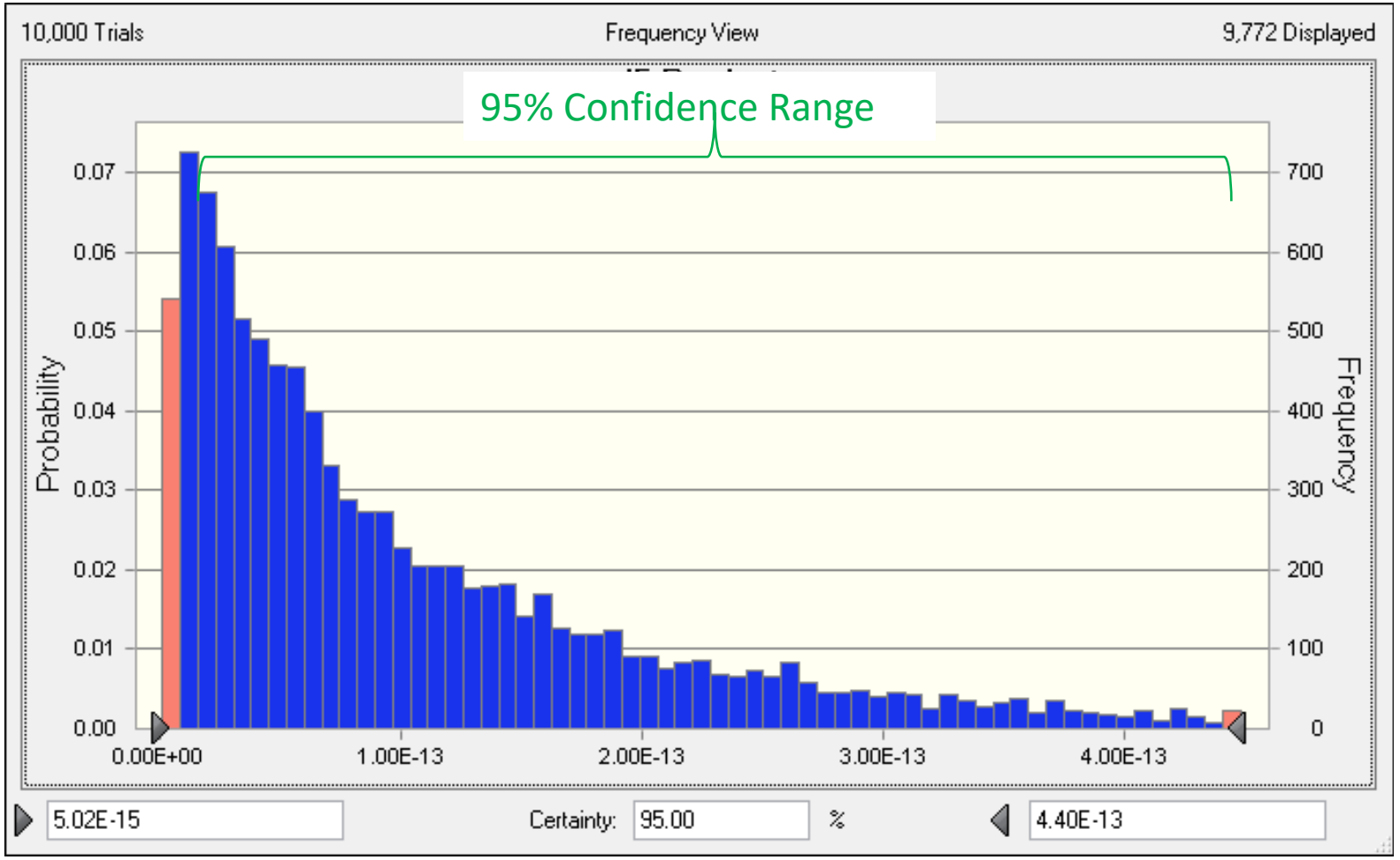






Outcome: 95% Confidence Intervals on Estimated Outcome

- Shown is the probability of an ignition event due to a flammable refrigerant
  - Gave regulators more confidence in overall conclusions
  - Gave stakeholders greater satisfaction their views were addressed
  - Replacement refrigerants were accepted and are currently in use
- Could just as easily be a score for a set of different alternatives



Possible Use in an AA

Alternative Score = w_1 x hazard score + w_2 x performance score +
w_3 x exposure score + w_4 x cost score …..

where $w_{1\text{-}4}$ are weighting factors for each module

- Probabilities could be assigned to different scores and/or different weighting factors
  - Result would be a confidence distribution for each alternative
  - Issues
  - Assigning distributions itself is uncertain
  - Fancy seeming results can (1) be confusing, (2) over-instill confidence

CLEAN PRODUCTION ACTION

Considering Uncertainty with GreenScreen for Safer Chemicals

GREENSCREEN® FOR SAFER CHEMICALS

SHARI FRANJEVIC

GREENSCREEN PROGRAM MANAGER, CLEAN PRODUCTION ACTION

ASSOCIATION FOR THE ADVANCEMENT OF ALTERNATIVES ASSESSMENT
VIRTUAL SYMPOSIUM 2020
CONSIDERING UNCERTAINTY: REAL-WORLD STRATEGIES TO MAKE DECISIONS
OCTOBER 28, 2020

Clean Production Action – solutions for a safer & healthier tomorrow

CLEAN PRODUCTION ACTION

Hazard Endpoints: 18 mandatory

Human Health Group I	Human Health Group II and II*	Environmental Toxicity & Fate	Physical Hazards
Carcinogenicity	Acute Toxicity	Acute Aquatic Toxicity	Reactivity
Mutagenicity & Genotoxicity	Systemic Toxicity & Organ Effects	Chronic Aquatic Toxicity	Flammability
Reproductive Toxicity	Neurotoxicity	*Other Ecotoxicity Studies when available*	
Developmental Toxicity	Skin Sensitization	Persistence	
	Respiratory Sensitization		
Endocrine Activity	Skin Irritation	Bioaccumulation	
	Eye Irritation		

CLEAN PRODUCTION ACTION

Hazard Summary Table

Group I Human					Group II and II* Human									Ecotox		Fate		Physical	
Carcinogenicity	Mutagenicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability
						single	repeated*	single	repeated*	*	*								
L	**L**	**L**	**M**	*M*	**L**	**L**	**L**	**vH**	*H*	**L**	DG	**L**	**L**	**H**	**H**	**vL**	**L**	**M**	*L*

vH = very High H = High M = Moderate L = Low vL = very Low DG = Data Gap

Benchmark Score

GREENSCREEN BENCHMARK–4

Low P* + Low B + Low T (Ecotoxicity, Group I, II and II* Human) + Low Physical Hazards (Flammability and Reactivity) + Low (additional ecotoxicity endpoints when available)

Prefer—Safer Chemical

GREENSCREEN BENCHMARK–3

a. Moderate P or Moderate B
b. Moderate Ecotoxicity
c. Moderate T (Group II or II* Human)
d. Moderate Flammability or Moderate Reactivity

Use but Still Opportunity for Improvement

GREENSCREEN BENCHMARK–2

a. Moderate P + Moderate B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
b. High P + High B
c. High P + Moderate T (Ecotoxicity or Group I, II, or II* Human)
d. High B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
e. Moderate T (Group I Human)
f. Very High T (Ecotoxicity or Group II Human) or High T (Group II* Human)
g. High Flammability or High Reactivity

Use but Search for Safer Substitutes

GREENSCREEN BENCHMARK–1

a. PBT = High P + High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
b. vPvB = very High P + very High B
c. vPT = very High P + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
d. vBT = very High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
e. High T (Group I Human)

Avoid—Chemical of High Concern

GREENSCREEN BENCHMARK–U

Unspecified Due to Insufficient Data

CLEAN PRODUCTION ACTION

Strategies for Uncertainty

To communicate uncertainty:

- Transparency in hazard classifications
- Transparency in Benchmark scores

To choose a chemical or determine if it is safer

- Minimum data requirements
- Benchmark score
- Confidence in hazard classifications

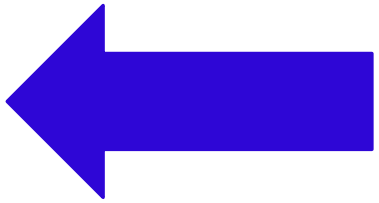
CLEAN PRODUCTION ACTION

Transparency – Data Gaps

GreenScreen Hazard Summary Table clearly displays unknown hazards

DG

Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*
	single	repeated*	single	repeated*	*	*
L	L	L	vH	H	L	DG



Transparency – Confidence in Hazard Classifications

GreenScreen Hazard Summary Table clearly indicates confidence in hazard levels

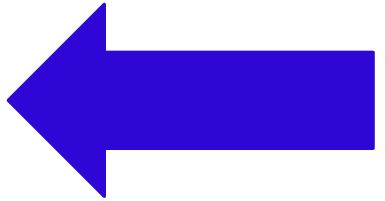
High Confidence

M

Low Confidence

M

Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*
	single	repeated*	single	repeated*	*	*
L	**M**	***M***	***vH***	**H**	**L**	DG



Minimum Data Requirements – Defined by method

Benchmark 4 – Max 0 DGs

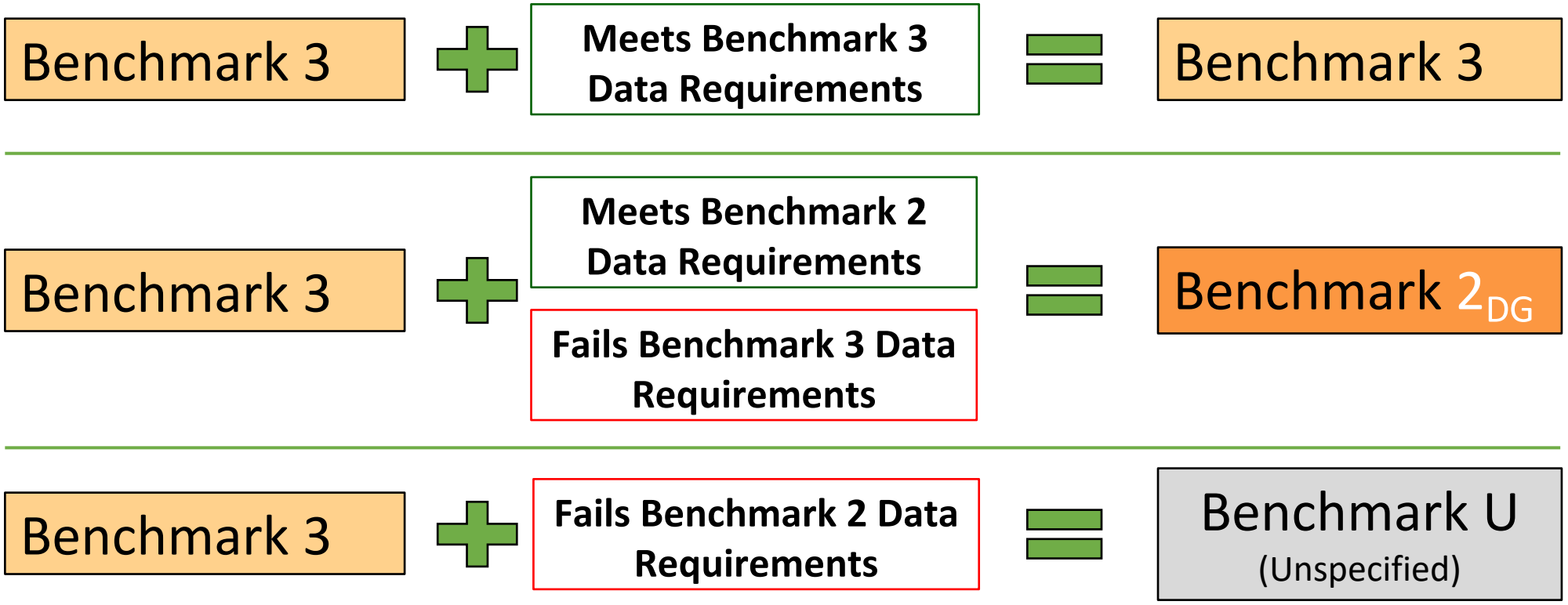
Benchmark 3 Data Requirements	
3a – Group I Human	Max 1 DG
3b – Group II Human	Max 2 DGs
3c - Ecotoxicity	Max 0 DGs
3d - Fate	Max 0 DGs
3e - Physical	Max 0 DGs

Benchmark 2 Data Requirements	
2a – Group I Human	Max 2 DGs
2b – Group II Human	Max 3 DGs
2c – Ecotoxicity	Max 1 DG
2d - Fate	Max 0 DGs
2e - Physical	Max 0 DGs

Benchmark 1 Data requirements minimum of 1 data point

CLEAN PRODUCTION ACTION

Changes in Benchmark Score



CLEAN PRODUCTION ACTION

Minimum Data Requirements – Defined by user

E.g., Endocrine Activity is an unacceptable data gap for this situation.

		Endocrine Activity
Chemical of Concern	Benchmark-1	H
Alternative 1	Benchmark-2	DG
Alternative 2	Benchmark-2	DG
Alternative 3	Benchmark-2	*M*
Alternative 4	Benchmark-2	**M**

CLEAN PRODUCTION ACTION

Strategies for Uncertainty

Interpreting the data:

- Guidance
- External panel of experts

Thank you!

Contact Clean Production Action:

Shari Franjevic
shari@cleanproduction.org

https://www.greenscreenchemicals.org/

CLEAN PRODUCTION ACTION

Group Discussion (or perhaps debate)?

- What do you do to address uncertainty in your assessments?
- What are the lessons that would you pass on to this community?
- Is our practice coalescing around specific strategies?
  - Should it?

Up Next After 30-Minute Break

Symposium Session 6

Part II: Considering Trade-offs: Real-world strategies to make decisions

Moderator: Molly Jacobs, University of Massachusetts Lowell

Panelists:

- Matteo Kausch, Cradle to Cradle Products Innovation Institute
- Tom Lewandowski, Gradient
- Heather McKenney, The Honest Co.
- Mallory McMahon, The Honest Co.
- Martin Wolf, Seventh Generation

Use Zoom Link for Session 6 [requires registration]


Thank you for
joining us!