Redefining possible®

Recent Developments in Hazard Assessment

Catherine Rudisill, M.S.
SRC, Inc.

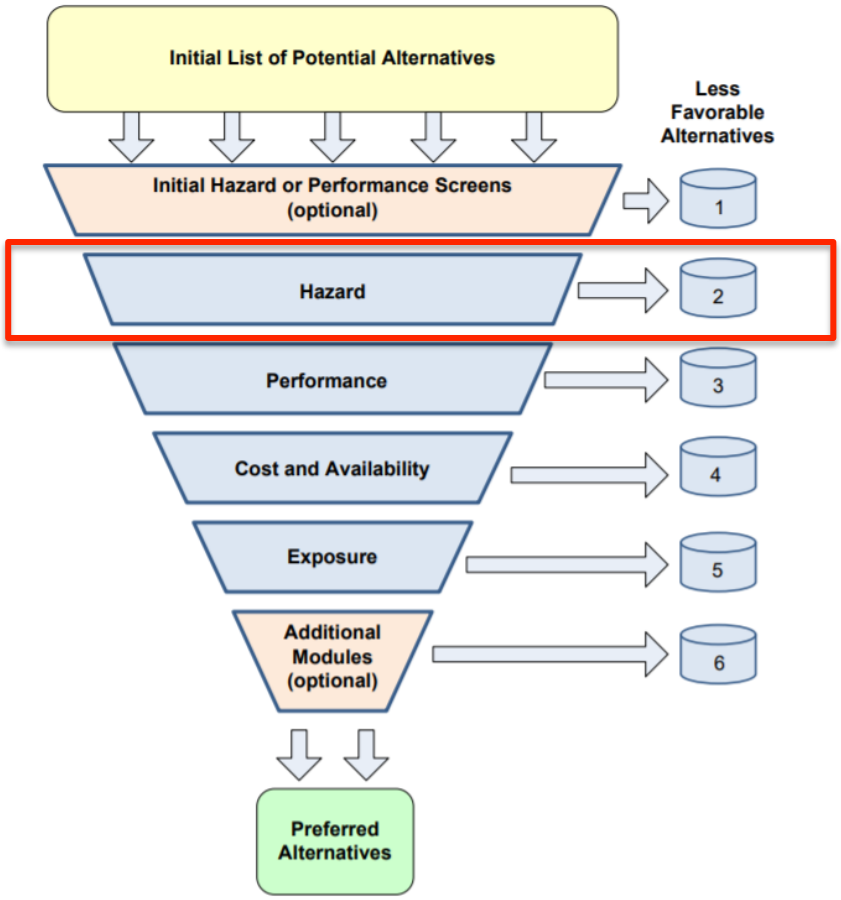
Defense › Environment › Intelligence

SRC Background

- Environmental Health Analysis (EHA)
- Providing Technical Support for >40 years
- Leader in Green Chemistry, pollution prevention (P2), and sustainability initiatives
- Not-for-Profit, Research & Development Organization

Hazard Assessment in AA's

IC2 Guide for Alternatives Assessment v1.1



Principle: Focus on reducing hazard

New Approach Methodologies (NAM's)
- Reduce the need for vertebrate testing

AA's uniquely positioned to incorporate these methodologies:

- Emerging field, establishing best practices
- Alternatives identified at the design-phase, requiring verification
- Existing substances (often data poor) utilized for new uses

New Approach Methodologies (NAM's)

Cost Advantage

Type of Toxicity		Study Cost ($US)
Genetic toxicity		
Chromosome aberration	animal test	$30,000
	in vitro test	$20,000
Sister chromatid exchange	animal test	$22,000
	in vitro test	$8,000
Unscheduled DNA synthesis	animal test	$32,000
	in vitro test	$11,000

*Humane Society International: http://www.hsi.org/issues/chemical_product_testing/facts/time_and_cost.html

Ethical Considerations

Propionic acid (undiluted)

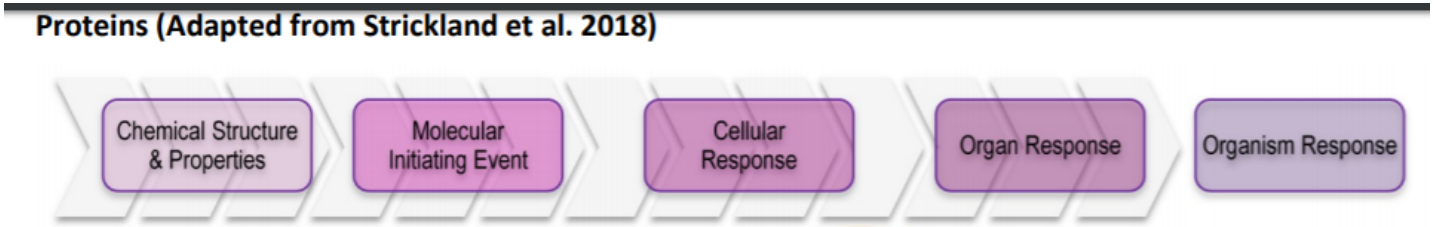
Rabbit Eye Irritation Study (1975):

"…Clinical signs included severe discomfort recorded as squealing, pawing and thrashing…"

The Future Is Now!

EPA's NAM for Skin Sensitization

- **April 2018** - *Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing*

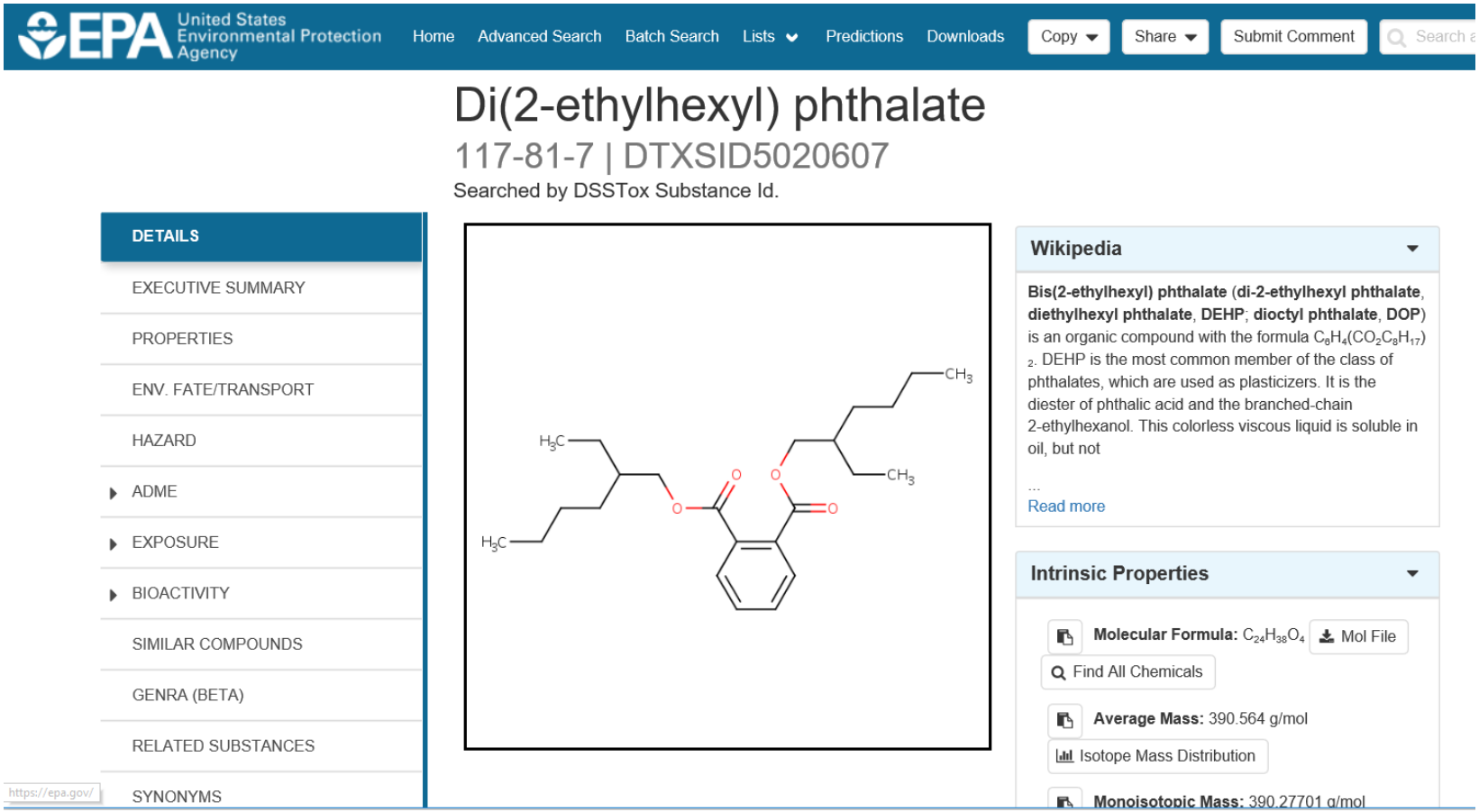


- Defined Approaches:
  - AOP "2 out of 3"
  - KE 3/1 sequential testing strategy (STS)
- Validity must be at least that for reliable animal methods. For Mouse LLNA:
  - **70-80% Hazard prediction**
  - **60-70% Potency prediction**

NAM should be just as accurate

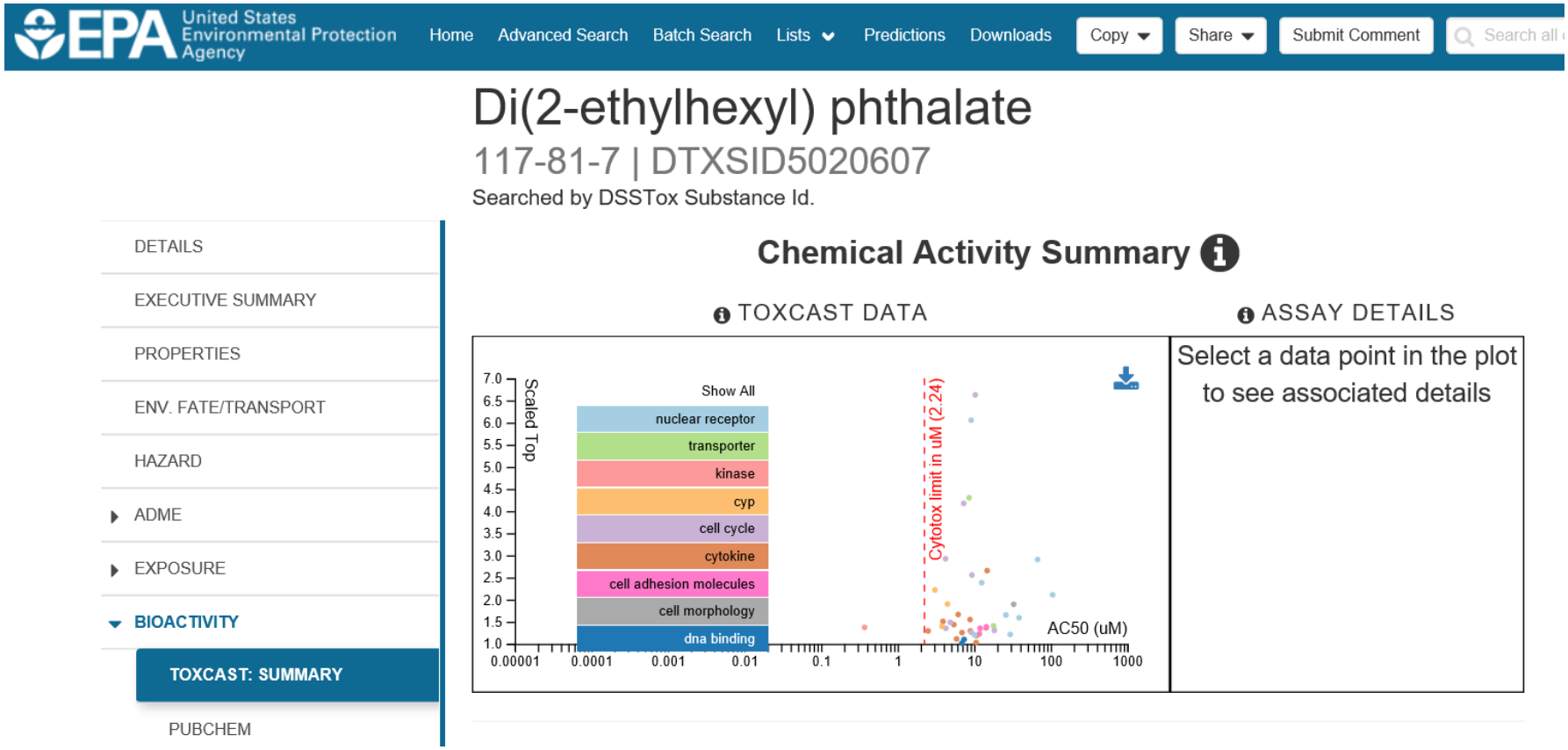
EPA Chemistry Dashboard v3.0

- Released August 2018



EPA Chemistry Dashboard v3.0

- Access the TOXCAST data summaries and model outputs!



NURA meeting in RTP

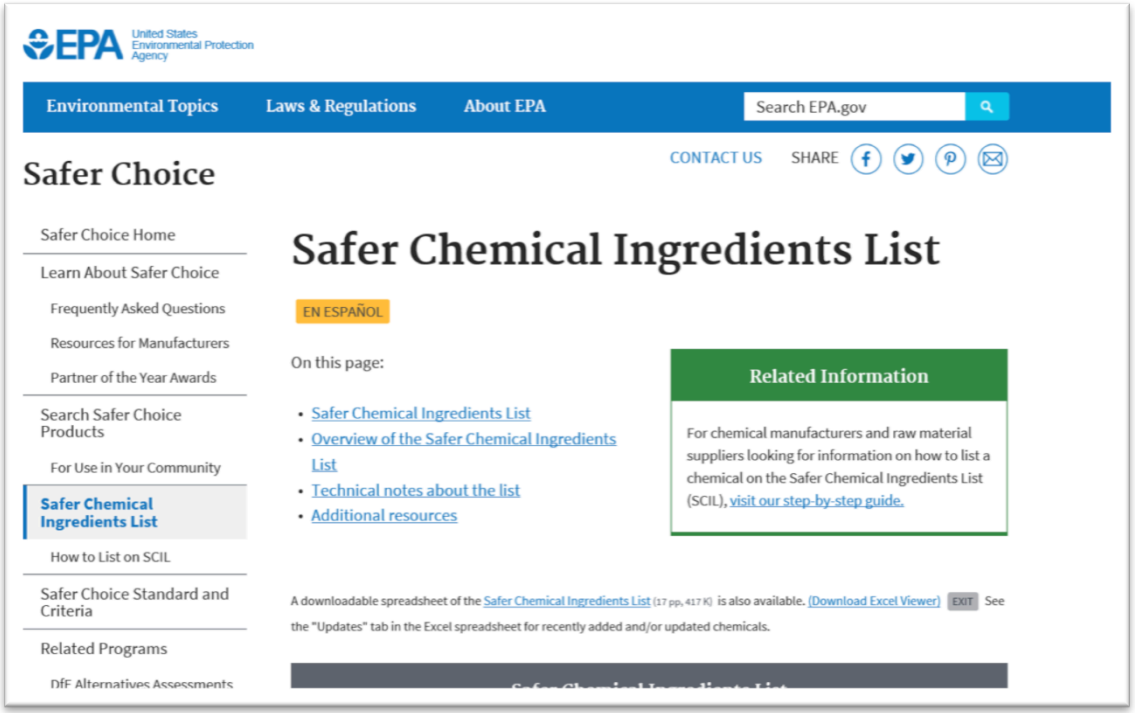
- In vitro Methods
- QSAR's
- High-Throughput Screening Data
- Etc.

What's Old is New Again!

EPA Safer Chemicals Ingredients List

- Started with 500 in 2012, Last updated in September 2018
- Now with 1,000 listings (>950 unique)
- Functional & evaluated against standard hazard criteria
- Positive list: https://www.epa.gov/saferchoice/safer-ingredients

SAFER CHOICE
Meets U.S. EPA Safer Product Standards
epa.gov/saferchoice



GreenScreen®

- Updated March 2018
- Includes new hazard criteria for polymers and products (mixtures)

<u>Fun Fact:</u>

TSCA Public Inventory contains:

~25% - UVCB's

~25% - Polymers

The World of QSARs

Released in 2016!

MultiCASE Incorporated

Leadscope®

SciMatics From Disorder to Discovery

ACD/Labs

EPI

LMC Laboratory of Mathematical Chemistry Oasis

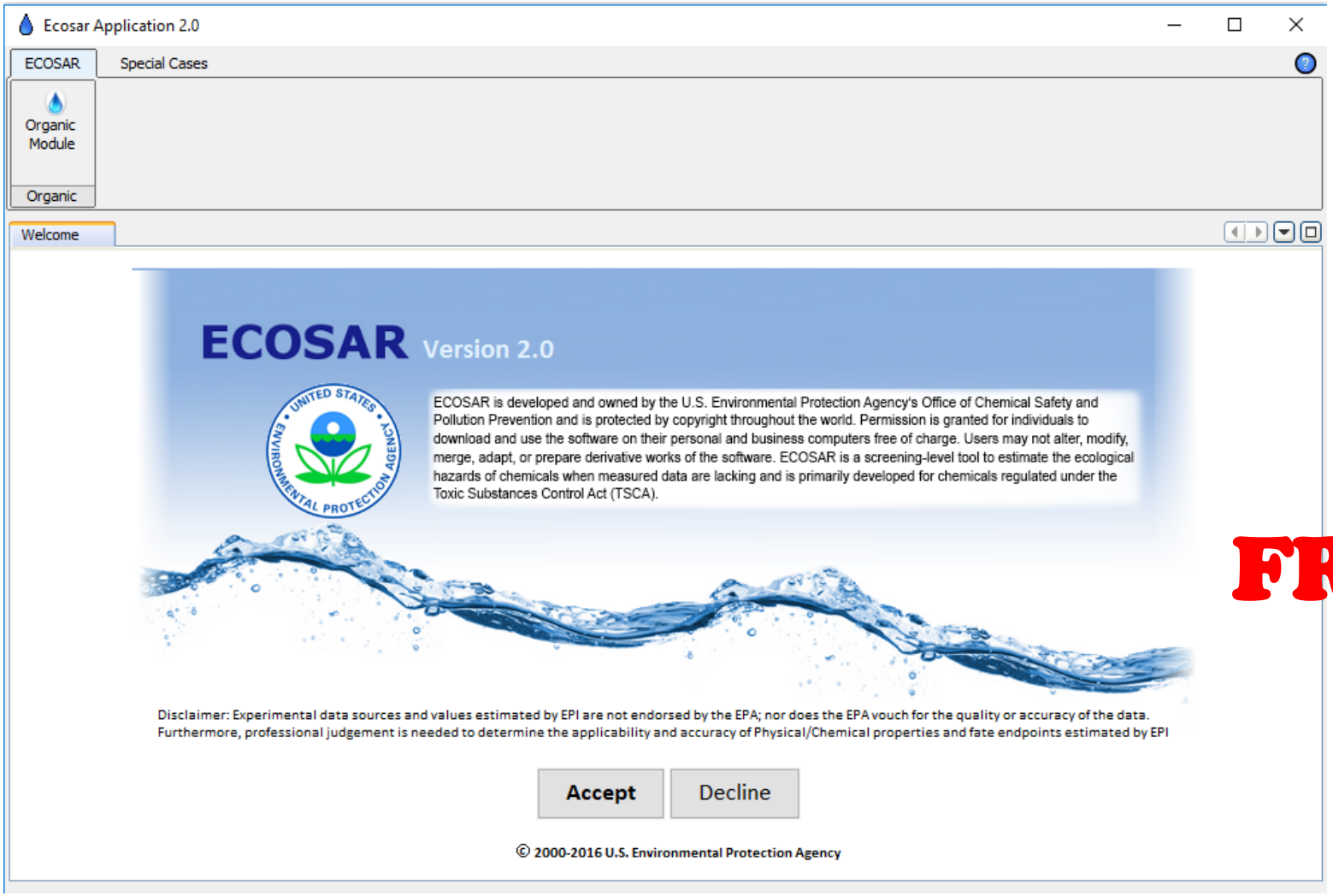
FREE!

http://qsar.food.dtu.dk/

OECD QSAR Toolbox: v4.2 (Feb 2018)

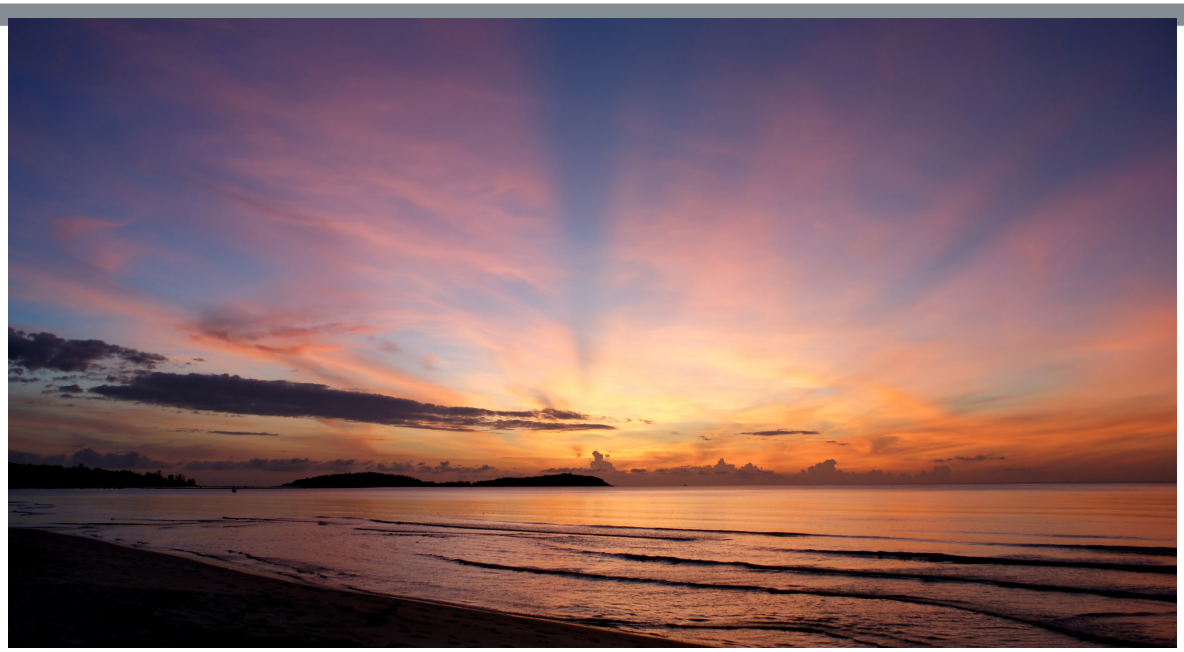
FREE!

ECOSAR v2.0 (Nov 2017)



FREE!

Conclusions



Pamela Spencer & Cathy Rudisill - Co-chairing afternoon session on Hazard Assessment in Alternatives Assessment Methods

Time: 1:15-3:15 PM
Location: Coastal Room

And Posters Too!