		SINGLE PLY ROOMING INDUSTRY	
		Opal Sands Resort Clearwater, FL	
	Friday, January 10, 2020		
	Opal Sand	Beach Salon	Sand Salon
7:15 AM	Breakfast		
7:30 AM			
7:45 AM	Codes & Standards 7:30-8:30 Ober		
8:00 AM			
8:15 AM			
8:30 AM	Codes Development 8:30-9:30 Hickman		D6878 TPO Considerations for Revision
8:45 AM			
9:00 AM			8:30-9:30 Sanborn
9:15 AM			
9:30 AM	DORA Listing Service 9:30-10:30 Malpezzi	Annual Conference Timing 9:30-10:15 Carpenter / Reel	
9:45 AM			
10:00 AM			Voc Reg Monitoring
10:15 AM			10:00-11:00
10:30 AM		Code Compliance Interface	Bates
10:45 AM	DORA Rule for Adding Fire & Impact 10:45-11:30 Morrison/ Sherwin	10:30-11:30 Hull / Cadena / Younkin	
11:00 AM			Very Severe Hail FAQ McQuillen
11:15 AM	Air Intrucion	Digital Contant & Communications	11:00-11:45
11:30 AM	Air Intrusion 11:30-12:00, Janni	Digital Content & Communications 11:30-12:00, Burzynski	
11:45 AM 12:00 PM	·	· •	
12:00 PM		Lunch	
12:30 PM			
12:35 PM			
1:00 PM	Air Barrier Details	IA-1 Revision	Fastener Plate Pull-Through
1:15 PM	12:45-1:45 Janni	12:45-1:45 Childs	12:45-1:45 Mader
1:30 PM			
1:45 PM		Code Official Training	
2:00 PM	Wetting Curves	1:45-2:15, Chamberlain	IBHS Training
2:15 PM	2:00-2:30, Hawn		1:45-2:45 Darsch
2:30 PM			
2:45 PM	Tech Committee		
3:00 PM	2:45-3:30		
3:15 PM	Mader		
3:30 PM			
3:45 PM			

Codes and Standards Task Force Hilton Denver City Center Clearwater, FL January 10, 2020



### MINUTES

### Call to Order

The Codes and Standards Task Force meeting was called to order at 7:30 a.m. EST by Task Force Chair Randy Ober. The SPRI Antitrust Statement was read.\*

Roll Call- please note that the sign-in sheet was not distributed during the meeting. If you were in attendance and would like your name added below send an email to info@spri.org.

Those present were: Randy Ober, SPRI Vinny Abbondanza, OMG Roofing Products John Baetz, Ashland Warren Barber, National Gypsum Justin Bates, H.B. Fuller Construction Products Keith Berg, CertainTeed LLC Brian Buckler, SFS Group USA Brian Chamberlain, Carlisle Construction Materials Stephen Childs, OMG Roofing Products Stan Choiniere, StanCConsulting Mike Darsch, Sika Sarnafil Phillip David, IB Roof Systems Heather Estes, GAF Tony Fuller, National Gypsum David Hawn, Dedicated Roof & Hydro-Solutions Mike Hubbard, Firestone Building Products Co Al Janni, Duro-Last Roofing, Inc. Brendan Knapman, ROCKWOOL Mikael Kuronen, Georgia-Pacific Gypsum LLC Bob LeClare, ATAS International, Inc.

Chris Mader, OMG Roofing Products Chris Meyer, FiberTite Roofing Systems Paul Michalec, The Ruscoe Co. Steve Moskowitz, Atlas Roofing Corporation Brian Randall, National Gypsum Ron Reed. Intertek Bob Reel, H.B. Fuller Construction Products Greg Sagorski, Atlas Roofing Corporation CJ Sharp, ICP Building Solutions Group Jenny Sherwin, Firestone Building Products Co Dwayne Sloan, UL LLC Todd Taykowski, Firestone Building Products Co Diana Vitiritti, SITURA Inc. Steve Wadding, Polyglass USA, Inc. Frederick Walnut, ITW Polymers Sealants Riku Ylipelkonen, ICP Building Solutions Group

Guests present: André Desjarlais, ORNL

#### Discussion

The proposal developed by Jay Crandell allows calculation of parapet heights for ballasted systems greater than 150 feet in height for inclusion in ASCE7 was discussed. Mr. Crandell's three options were presented and his recommendation not to ballot through ASCE but instead to add the proposal to the ANSI SPRI RP-4 standard will be pursued.

The Power Point presentation provided during the meeting is attached to these minutes.

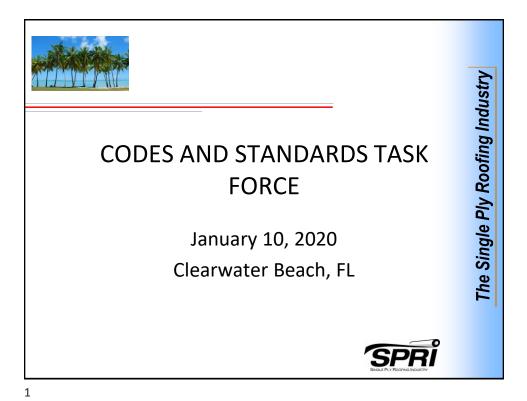
\*SPRI Antitrust Statement: SPRI complies with antitrust laws and requires participants in its programs to comply with antitrust laws. Discussions which could affect competitive pricing decisions or other competitive factors are forbidden. There may be no discussions of pricing policies or future prices, production capacity, profit margins or other factors that may tend to influence prices. In discussing technical issues, care should be taken to avoid discussing potential or planned competitive activities. Members and participants should be familiar with the SPRI Antitrust Policy and act in conformity with it.

## Adjournment

There being no further business, the meeting adjourned at 8:30 a.m. EST.

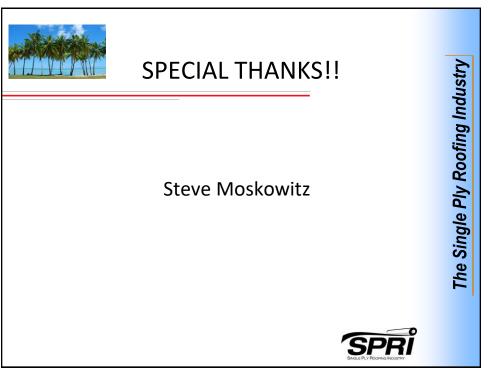
Submitted: Randy Ober, Task Force Chair

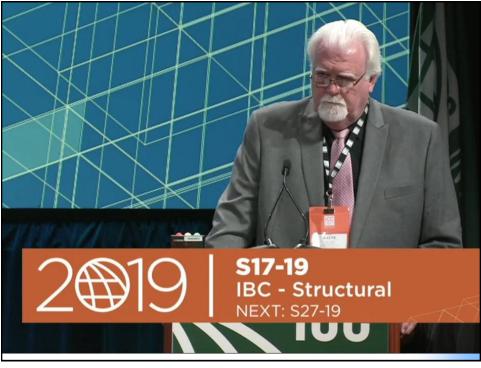
These minutes were reviewed by SPRI Legal Counsel.













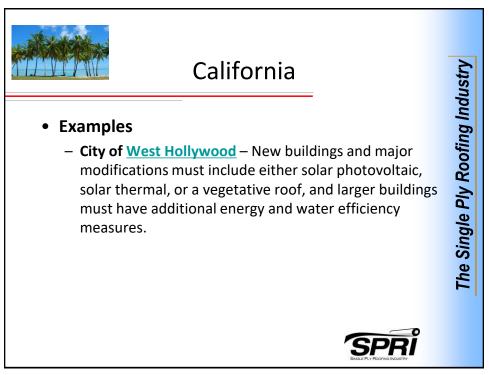


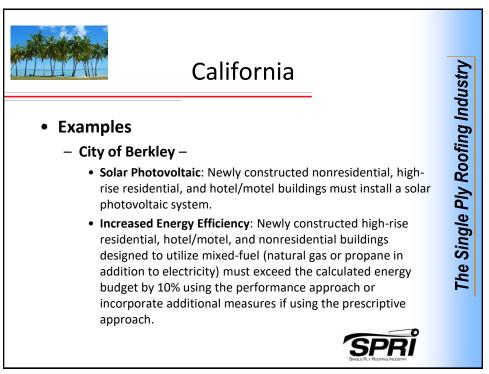


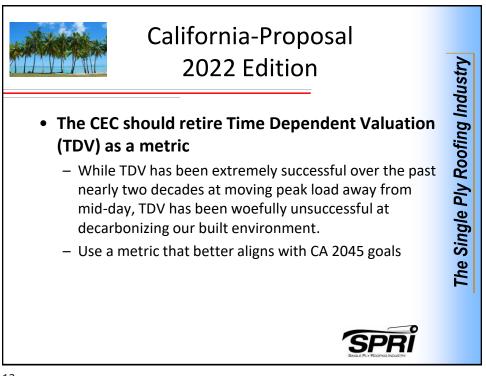






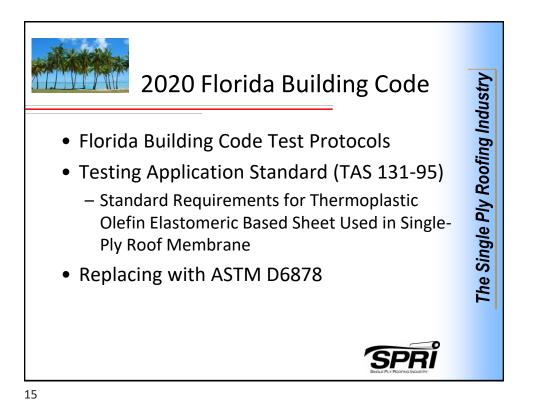


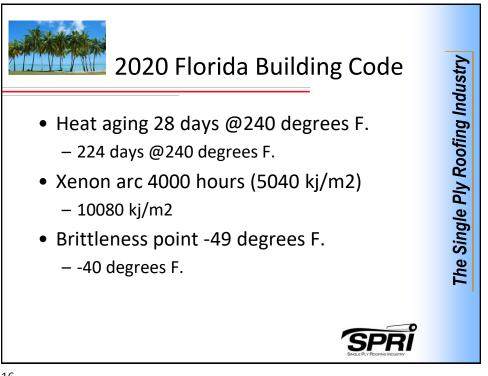




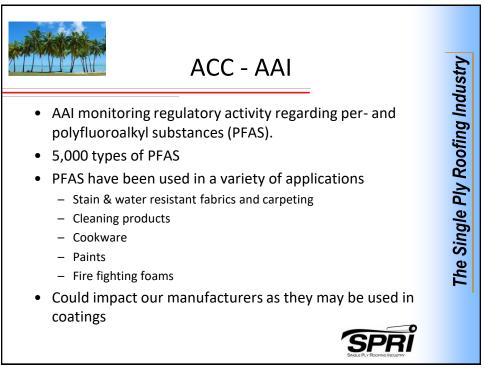


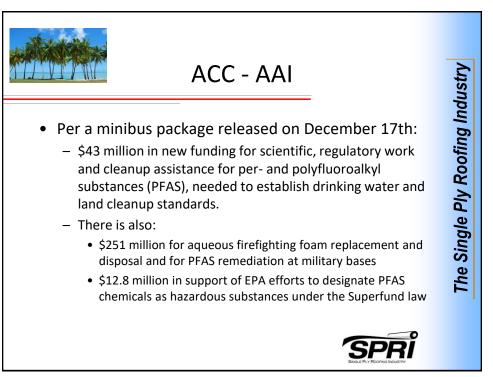




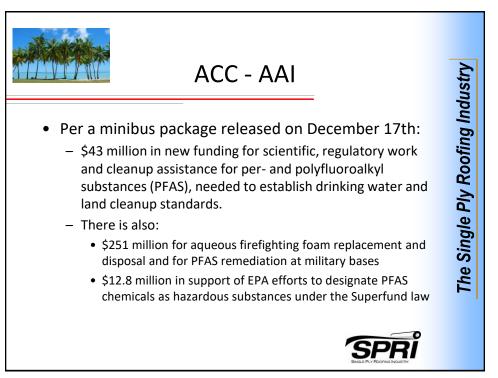


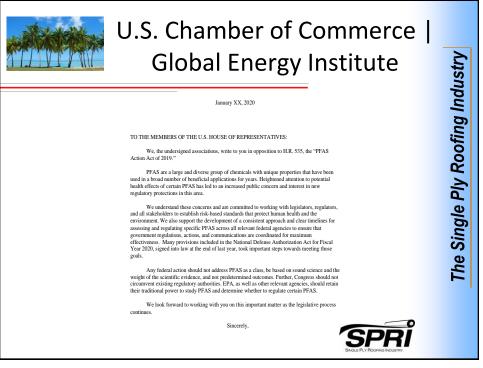








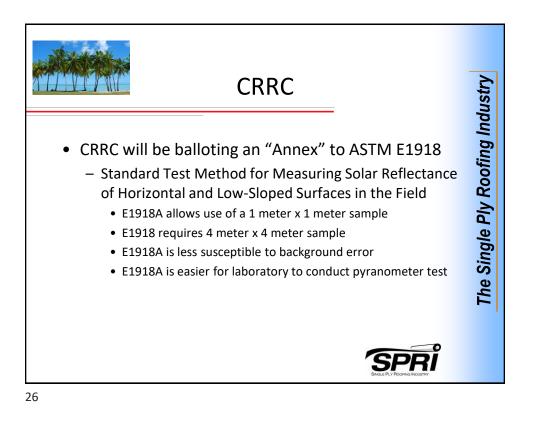


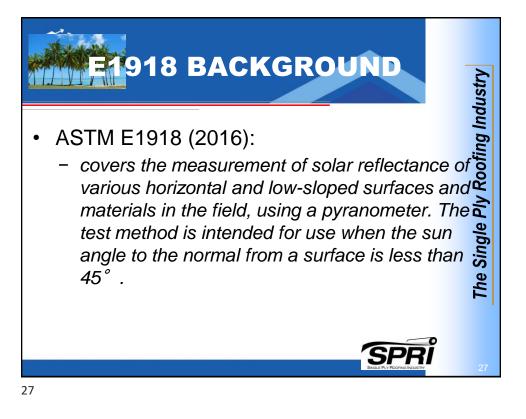


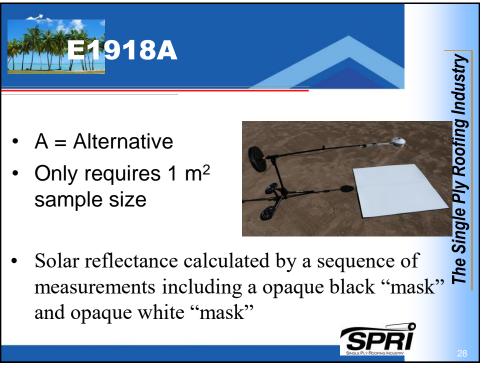




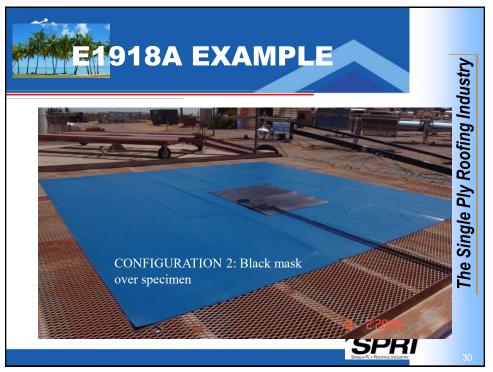












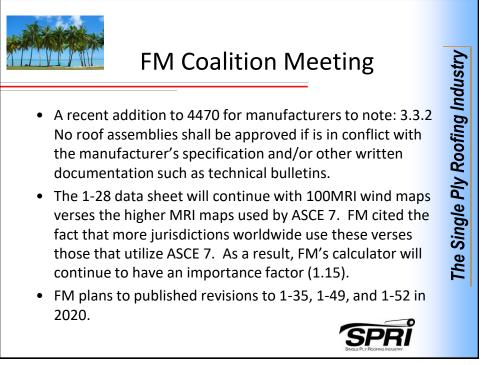


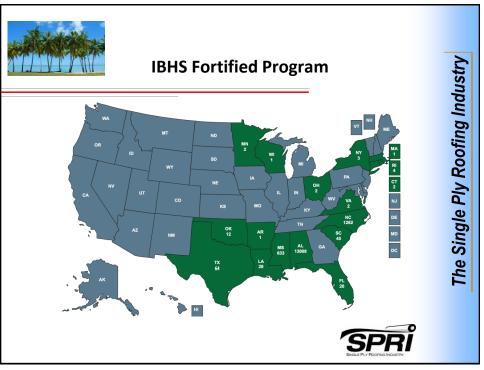






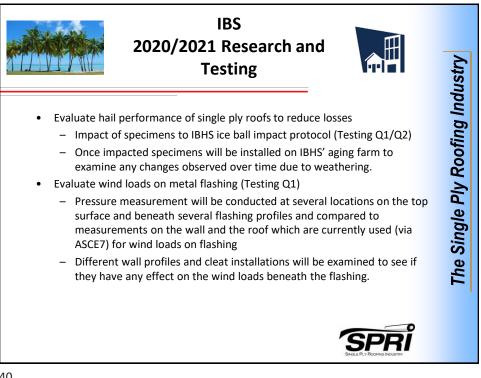


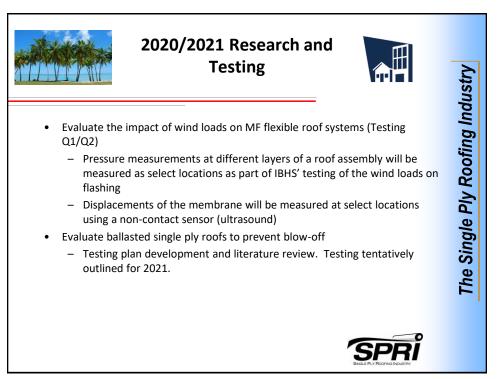
















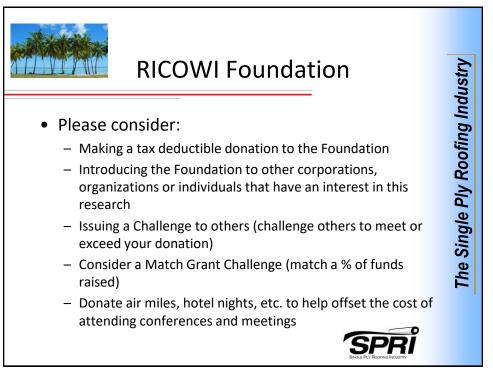


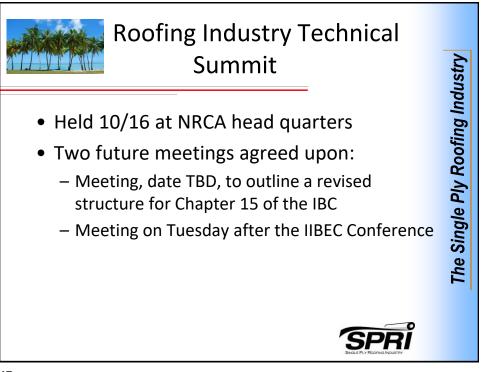
# **RICOWI** Foundation

- The RICOWI Foundation, Inc. is officially recognized as a 501(c)(3) nonprofit. Any donations made to the Foundation will be tax deductible, and the Foundation is eligible to apply for grants.
- The Foundation will support roofing industry projects that investigate climate resiliency and related issues through evaluation and funding.

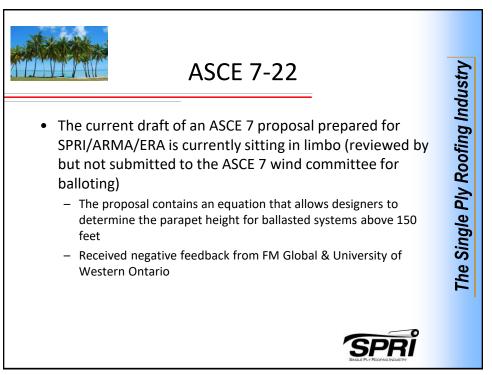


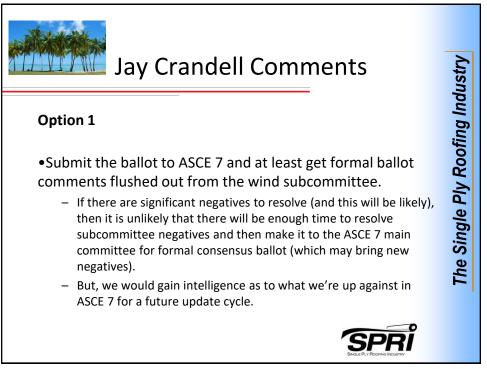
The Single Ply Roofing Industry

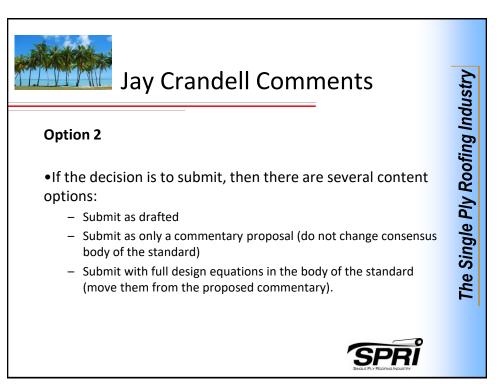


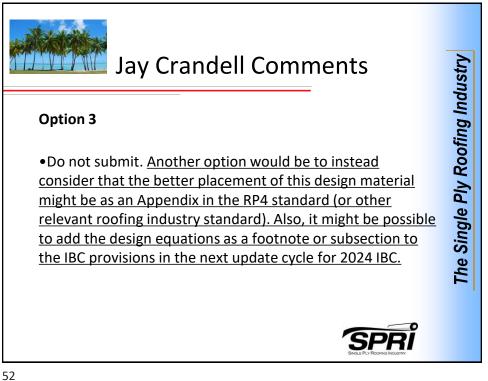


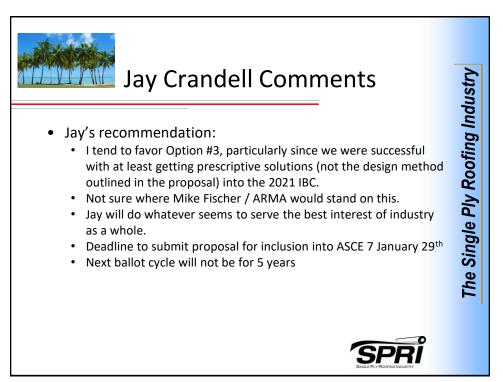








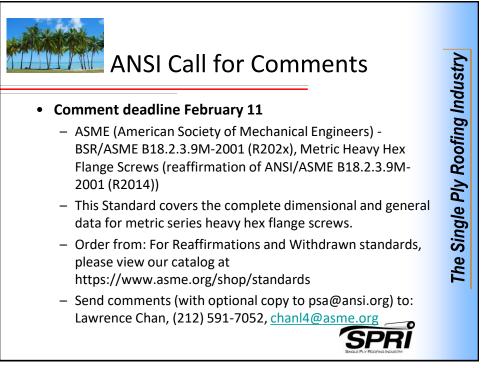


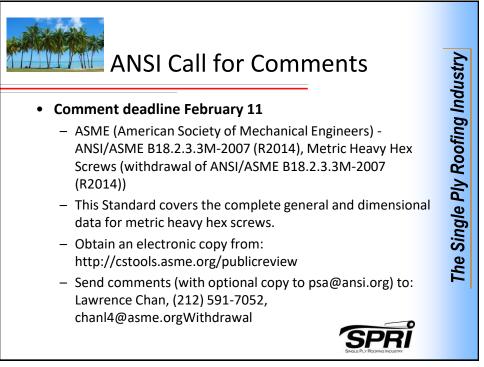






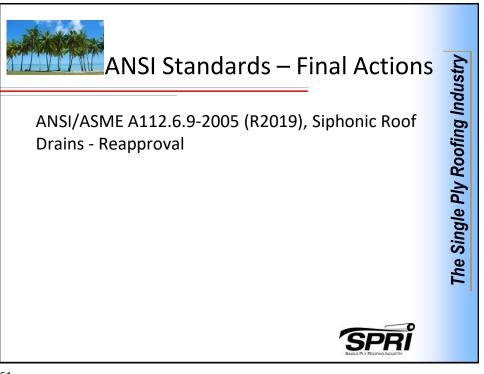


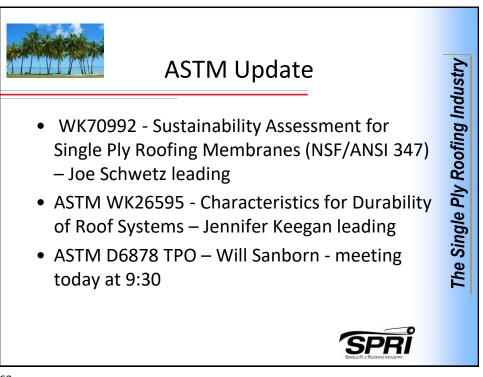


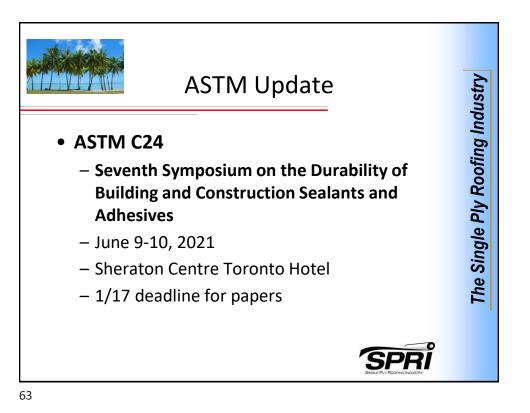












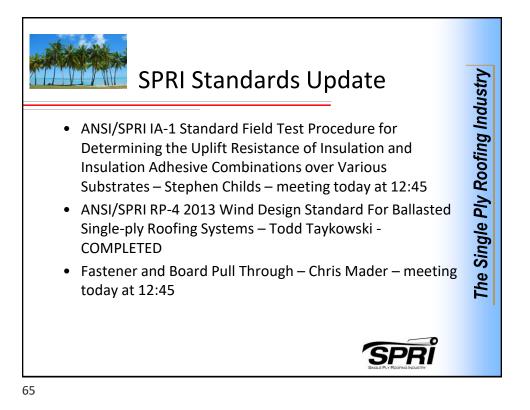


# SPRI Standards Update

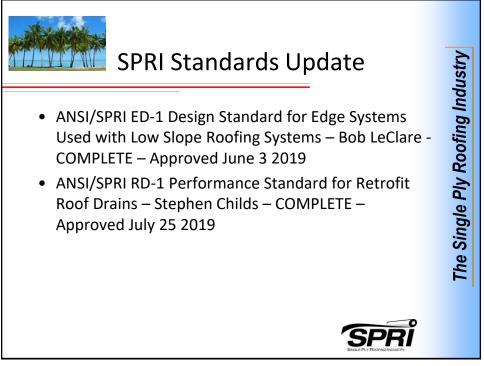
- EPD's on Reinforced and Non-reinforced EPDM; Low VOC adhesives; and TPO will be due for updates in 2022
- thinkstep developed SPRI's current EPD's
- Company has been purchased by sphera
- Maggie Wildnauer (SPRI's focal point) has stayed with sphera.



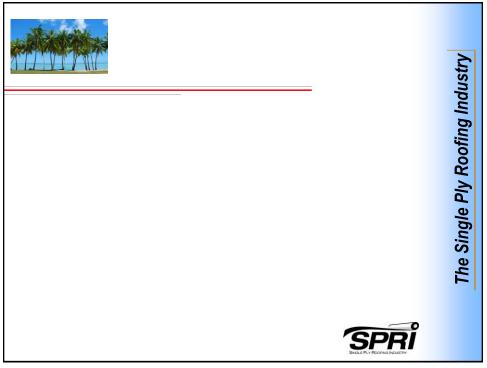
The Single Ply Roofing Industry











SPRI Code Development Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

# Call to Order

The Task Force meeting was called to order at 8:35 a.m. EST by Task Force Chair Amanda Hickman. The SPRI Antitrust Statement was read.\*

# Roll Call- please note that the sign-in sheet was not distributed during the meeting. Some present may mot be listed. If you were in attendance and would like your name added below send an email to info@spri.org.

*Those present were:* Amanda Hickman, The Hickman Group Brian Alexander, TruFast Maury Alpert, Polyglass USA, Inc. Bas Baskaran, NRCC Justin Bates, H.B. Fuller Construction Products Adam Bembenek, Mule-Hide Products Co., Inc. Keith Berg, CertainTeed Corporation Brian Chamberlain, Carlisle Construction Materials Stephen Childs, OMG Roofing Products Stan Choiniere, StanCConsulting Gareth Christopher, IKO Industries Ltd Todd Corley, Siplast Phillip David, IB Roof Systems Brian Davis, GAF Joseph Fay, BASF Corporation Carl Flieler, Canadian General Tower Limited Mike Giangiacomo, Flex Membrane Int'l Corp. Taylor Gingerich, Carlisle Construction Materials Keith Grzybowski, Firestone Building Products Jason Hackman, Benchmark Inc. Joseph Kalwara, Firestone Building Products Shaun Kerschen, Atlas Roofing Corporation Stephanie Kiriazes, Firestone Building Products Brendan Knapman, ROCKWOOL James Kopcha, BASF Corporation Edward Krusec, Hunter Panels Curtis Large, Acme Cone Company Norbert Lash, H.B. Fuller Construction Products William Lashway, INEOS Pigments

Bob LeClare, ATAS International, Inc. Colin Litow, Continuus Materials, LLC Chris Mader, OMG Roofing Products Joe Malpezzi, Carlisle Construction Materials Rick Martelon, Johns Manville Corporation Saverio Marzella, ROCKWOOL Tim McQuillen, Johns Manville Corporation Scott Morrison, J.S. Held LLC Steve Moskowitz, Atlas Roofing Corporation Jim Pieczynski, Blue Ridge Fiberboard, Inc. Zach Priest, PRI Brian Randall, National Gypsum Andrew Reynolds, Benchmark, Inc. William Sanborn, Johns Manville Corporation Michael Schwent, GAF Joe Schwetz, Sika Sarnafil Flonja Shyti, NRCC Kurt Sosinski, Tremco, Inc. Myles Sosnoff, Metal-Era, Inc. Matt Spencer, Continuus Materials Emily Standard, PRI Joel Stanley, Anchor Products, LLC Zeb Sukle, Johns Manville Corporation Todd Taykowski, Firestone Building Products Mike Taylor, Blue Ridge Fiberboard, Inc. Sid Teachey, USG Corporation Diana Vitiritti, SITURA Inc. Steve Wadding, Polyglass USA, Inc. Martin Ward, GAF

Staff present were: Randy Ober, SPRI Carl Silverman, Esq., SPRI *Former staff present:* Mike Ennis, Ennis Associates

#### Discussion

The following items were discussed:

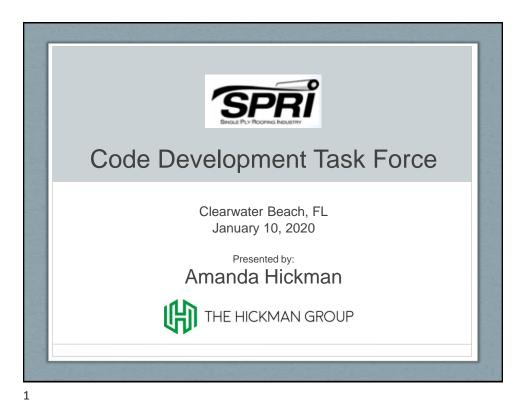
- 1. ICC Final votes on code change proposals;
- 2. What led to the success of the code change proposals;
- 3. 2020 plans to prepare for next ICC code change cycle; and
- 4. Other code and standard activities that impact SPRI members including: ASHRAE 90.1 and 189.1 and Florida Code.

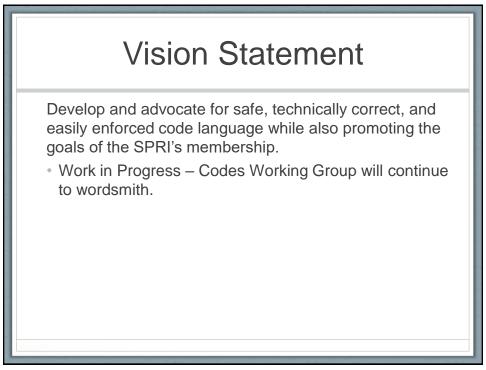
The Power Point presentation provided during the Task Force meeting is posted on the SPRI website in the Members Only Area and is attached to these minutes.

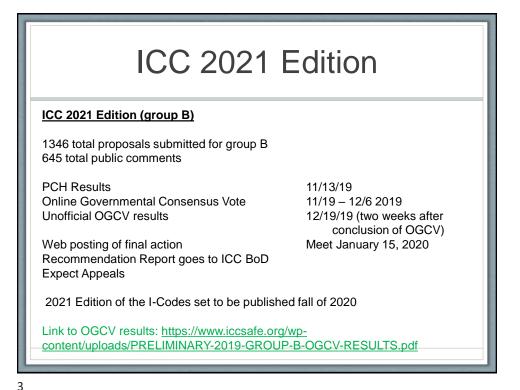
#### Adjournment

There being no further business, the meeting was adjourned at 9:24 a.m. EST.

Submitted: Amanda Hickman, Task Force Chair







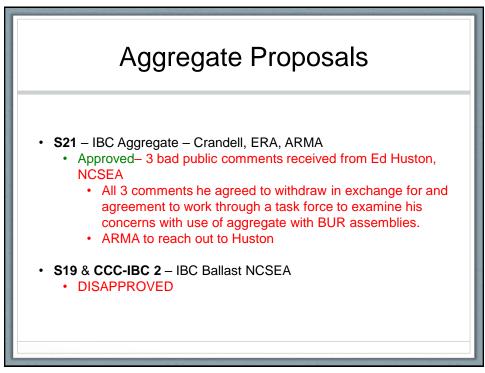


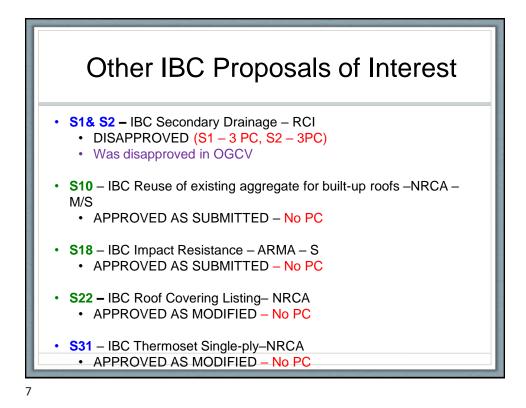
- S13 Parapet Walls Revise 1503.3 coping of parapet walls to permit the membrane to be wrapped over the top of the parapet wall. Address different parapet wall types from 705.11 Approved
- ✓ S15 Ballast Revise 1504.4 so that ballasted roofs comply with SPRI RP-4 and not 1504.8 Approved
- ✓ S16 Edge Securement Revises 1504.5 to clarify that securement applies to the edge system itself. Approved
- ✓ S17 Gutter Securement Adds GT1 for low slope roofs where the gutter is used as part of the membrane securement. Approved (originally disapproved at CAH but over turned at PCH and OGCV)

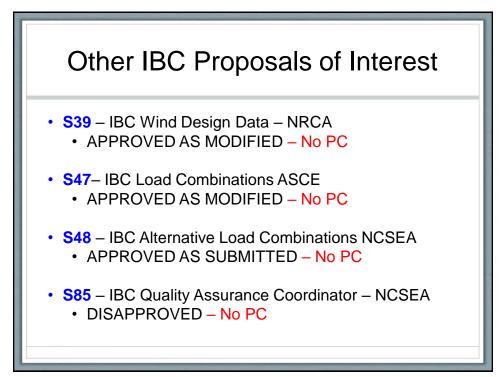
# Codes Development Working Group

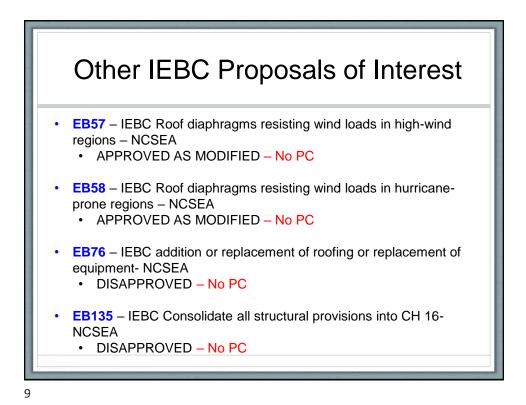
- Bob LeClare
- Al Janni
- Chris Mader
- Marty Ward
- Brad Van Dam
- Brian Chamberlain
- Jenny Sherwin
- Mike Ennis/Randy Ober
- Amanda Hickman
- This Working Group meets between meetings to develop code change proposals and to consider input received from other interested parties

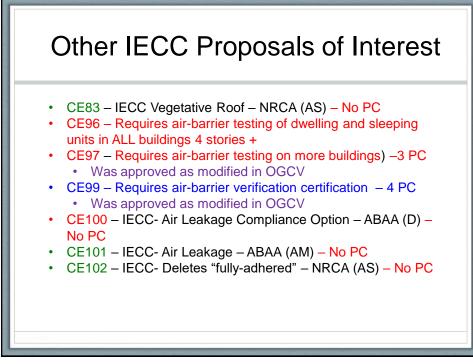


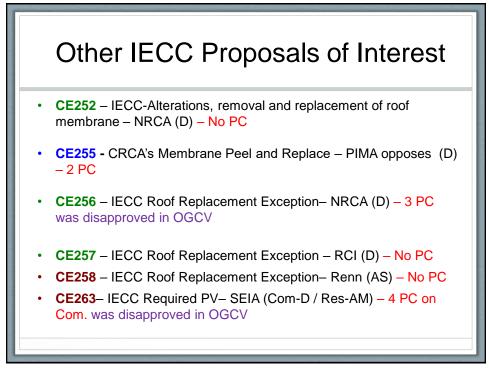














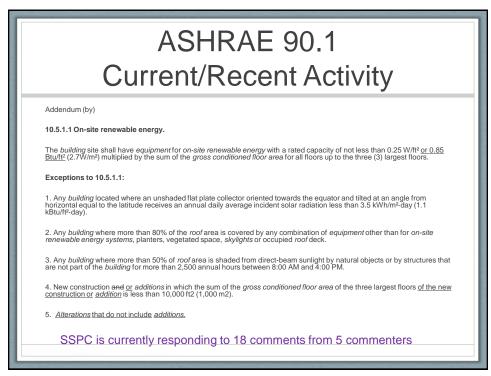


# ASHRAE 90.1 Current/Recent Activity

Thermal Bridging (Addendum AV) got a clear exception allowing blocking to be used with any of the thermal bridging requirements for roof-wall intersections so that parapets could be wrapped.

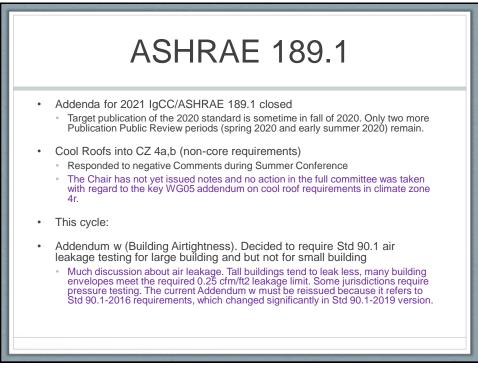
SSPC is currently responding to 247 comments from 41 commenters The ESC reviewed the multiple submissions of proposed modifications to the text and grammar since the 3 November 2019 ESC meeting. The ESC stopped the review process at Section 5.5.5.3, and will resume the discussion starting with the Section at the next ESC meeting.

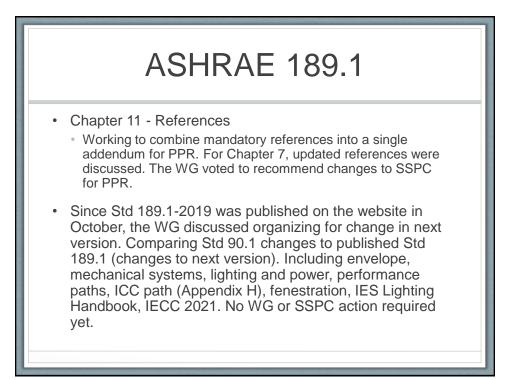
It was agreed that the discussions about the example buildings (as shown in the forward) would not take place until the regulations of Addendum "av" were completed.

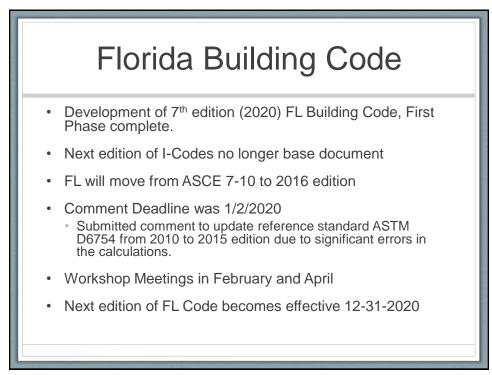




- Thermal Bridging
  - Language in Thermal Bridging Proposal. Thermal bridging constructability and cost analysis
- Air Leakage
  - Improve air leakage requirements. Mandatory air leakage testing. Test air leakage on all buildings under 25,000 sqft Improve mandatory air tightness per Army Corps/DOE studies. Under Full Draft review.
- Opaque
  - Lower opaque and fenestration U-factors
    - Roofing U-factors averaging Volumetric, tapered. Re-roofing requirements.
    - Target Public Review Draft June 2020
- Verification
  - Mandatory envelope commissioning



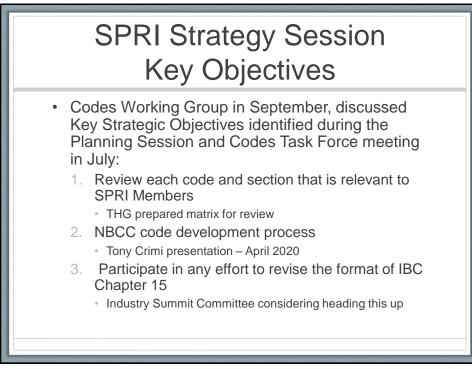


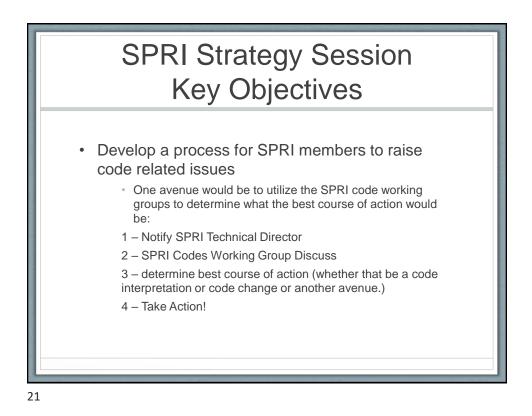




- Resiliency ICC is a member of the FEMA <u>Resilient National</u> <u>Partnership Network</u>, a founding member of the <u>U.S.</u> <u>Resiliency Council</u> and a signatory to the <u>NIBS Industry</u> <u>Statement on Resilience</u>.
- Air Leakage Whole Building Testing
- Renewables PV
- 10% Increase in IECC looking for same in ASHRAE 90.1

19







SPRI DORA® Listing Service Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

# Call to Order

The Task Force meeting was called to order at 9:30 a.m. EST by Task Force Chair Joe Malpezzi. The SPRI Antitrust Statement was read. \*

# **Roll Call**

*Those present were:* Joe Malpezzi, Carlisle Construction Materials Adam Aharonian, SFS Group USA Brian Alexander, TruFast John Baetz, Ashland Warren Barber, National Gypsum Brian Buckler, SFS Group USA Stan Choiniere, StanCConsulting Todd Corley, Siplast Joan Crowe, AIA, GAF Brian Davis, GAF Mike DeSouto, Cooley Engineered Membranes Carl Flieler, Canadian General Tower Limited David French, Carlisle Construction Materials Tony Fuller, National Gypsum Mike Giangiacomo, Flex Membrane Int'l Corp. Kirk Goodrum, Siplast John Greko, Carlisle Construction Materials, LLC Richard Hein, Metal-Era, Inc. Al Janni, Duro-Last Roofing, Inc. Brendan Knapman, ROCKWOOL Steve Kuhel, FiberTite Roofing Systems Mikael Kuronen, Georgia-Pacific Gypsum LLC Chris Mader, OMG Roofing Products

Sean McKay, Ashland, Inc. Chris Meyer, FiberTite Roofing Systems Rick Montoya, Acme Cone Company Scott Morrison, J.S. Held LLC Steve Moskowitz, Atlas Roofing Corporation Jim Pieczynski, Blue Ridge Fiberboard, Inc. Brian Randall, National Gypsum Ron Reed, Intertek Greg Sagorski, Atlas Roofing Corporation Jenny Sherwin, Firestone Building Products Co Dwayne Sloan, UL LLC Emily Standard, PRI Zeb Sukle, Johns Manville Corporation Todd Taykowski, Firestone Building Products Co Brad Van Dam, Metal-Era, Inc. Diana Vitiritti, SITURA Inc. Steve Wadding, Polyglass USA, Inc. Jarrod Woodland, SFS Group USA Riku Ylipelkonen, ICP Building Solutions Group

Staff present were: Randy Ober, SPRI Carl Silverman, Esq., SPRI

# **Program overview**

- There are 47 participating companies;
- 1,746 registered products; and
- 3,534 listed assemblies.

# Software Updates

Assembly requests from users are now available. This will allow for faster searches. Also, there is improved layer ordering, especially for multi-layer and Modified Bitumen systems.

# Topics to be Addressed:

- Induction Welded Systems over LWIC;
- Wording on rational analysis for perimeter and corner areas;
- Developing a "contractor printout" for selected assembly products (similar to the FM RoofNav) "contractor package"; and
- Procedure for handling "expired plants" need to re-submit Q.A. inspection verification.

# Adjournment

There being no further business, the meeting adjourned at 10:30 a.m. EST.

Submitted by: Joe Malpezzi, Task Force Chair

SPRI DORA<sup>®</sup> Rule Fire & Impact Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### **Call to Order**

The meeting was called to order at 10:45 a.m. EST by Task Force Co-Chair Scott Morrison. The SPRI Antitrust Statement was read. \*

# **Roll Call**

Those present were:
Jenny Sherwin, Firestone Building Products Co
Scott Morrison, J.S. Held LLC
Warren Barber, National Gypsum
Bas Baskaran, NRCC
Brian Buckler, SFS Group USA
Joan Crowe, AIA, GAF
Mike DeSouto, Cooley Engineered Membranes
Joseph Fay, BASF Corporation
Tony Fuller, National Gypsum
Kirk Goodrum, Siplast
David Hawn, Dedicated Roof & Hydro-Solutions
Al Janni, Duro-Last Roofing, Inc.
James Kopcha, BASF Corporation
Joe Malpezzi, Carlisle Construction Materials

Steve Moskowitz, Atlas Roofing Corporation Zach Priest, PRI Brian Randall, National Gypsum Ron Reed, Intertek Jim Rubenacker, Sika Sarnafil Dwayne Sloan, UL LLC Nathan Vail, Intertek Ryan VanWert, Duro-Last Roofing, Inc. Steve Wadding, Polyglass USA, Inc.

*Former staff was:* Mike Ennis, Ennis Associates

Staff present: Carl Silverman, SPRI

# Discussion

The following items were discussed on Fire:

- UL and other Member companies raised concerns about competing with Product IQ if external fire classifications were placed on DORA<sup>®</sup>;
- 2. Member companies stated the cost of using the directory would be too great for them. Other companies were supportive of the initiative; and
- 3. At this time, only UL 790 SOF and ASTM E 108 were considered to be noted on the directory.

Both marketing and technical discussions were had among the Task Force.

The following was discussed on Impact:

- 1. There were similar concerns with Impact as there were for Fire; and
- 2. Mr. Morrison and Ms. Sherwin will address concerns in 45 days via email with the Task Force and vote at the April meeting to continue/discontinue this initiative.

# Adjournment

There being no further business, the meeting adjourned at 11:30 a.m. EST.

Submitted by: Jenny Sherwin, Task Force Co-Chair

SPRI Air Intrusion Task Force Opal Sands Resort Clearwater. FL January 10, 2020



# MINUTES

# Call to Order

The Task Force meeting was called to order at 11:30 a.m. EST by Task Force Chair Al Janni. The SPRI Antitrust Statement was read.\*

# **Roll Call**

*Those present were:* Al Janni, Duro-Last Roofing, Inc. Bas Baskaran, NRCC Joan Crowe, AIA, GAF Mike DeSouto, Cooley Engineered Membranes Carl Flieler, Canadian General Tower Limited Tony Fuller, National Gypsum Kirk Goodrum, Siplast David Hawn, Dedicated Roof & Hydro-Solutions Amanda Hickman, The Hickman Group Mike Hubbard, Firestone Building Products Co Rick Martelon, Johns Manville Corporation Sean McKay, Ashland, Inc. Scott Morrison, J.S. Held LLC Steve Moskowitz, Atlas Roofing Corporation Zach Priest, PRI

Brian Randall, National Gypsum Jim Rubenacker, Sika Sarnafil Dwayne Sloan, UL LLC Ryan VanWert, Duro-Last Roofing, Inc. Diana Vitiritti, SITURA Inc. Steve Wadding, Polyglass USA, Inc.

Staff present were: Randy Ober, SPRI Carl Silverman, Esq., SPRI

*Former staff present was:* Mike Ennis, SPRI

*Guest present was:* André Desjarlais, ORNL

# Discussion

Al Janni informed the Task Force that SPRI has two RFP's and a third on its way.

Randy Ober discussed the follow up conference call with Elizabeth Grant, Virginia Tech (VT), on her proposed RFP. Dr. Grant reminded Mr. Ober that she wants SPRI to narrow the different scenarios that could be in the roof assemblies. André Desjarlais, Oak Ridge National Laboratory (ORNL), offered to share ORNL's outline RFP with VT to help SPRI narrow its RFP down.

Mr. Janni also mentioned that the Sub Task Force would have a conference call after receiving the VT RFP. This group consists of the following SPRI members: Joe Schwetz, Stan Choiniere, Mike Hubbard, Marty Ward, and Tim McQuillen.

# Adjournment

There being no further business, the meeting adjourned at 11:45 a.m. EST.

Submitted by: Al Janni, Task Force Chair

SPRI Air Barrier Details Task Force Opal Sands Resort Clearwater, FL January 10, 2020



# MINUTES

# Call to Order

The Task Force meeting was called to order at 12:45 p.m. EST by Task Force Chair Al Janni. The SPRI Antitrust Statement was read.\*

# **Roll Call**

Those present were:	
Al Janni, Duro-Last Roofing, Inc.	Scott Morrison, J.S. Held LLC
Warren Barber, National Gypsum	Jim Pieczynski, Blue Ridge Fiberboard, Inc.
Bas Baskaran, NRCC	Jim Rubenacker, Sika Sarnafil
Brian Buckler, SFS Group USA	Dwayne Sloan, UL LLC
Brian Chamberlain, Carlisle Construction Materials	Matt Spencer, Continuus Materials
Brian Davis, GAF	Emily Standard, PRI
Heather Estes, GAF	Nathan Vail, Intertek
George Howell, Martin Marietta Magnesia Specialties	Diana Vitiritti, SITURA Inc.
Brendan Knapman, ROCKWOOL	Steve Wadding, Polyglass USA, Inc.
Bob LeClare, ATAS International, Inc.	
Joe Malpezzi, Carlisle Construction Materials	Guest present was:
Rick Martelon, Johns Manville Corporation	André Desjarlais, ORNL

# Discussion

Al Janni updated the Task Force that Adam Ugliuzza, Intertek, did not have details for SPRI to review at this meeting. Mr. Ugliuzza said that he would be working on them. SPRI will have details to review before the next meeting in April.

# **New Business**

Task Force asked Mr. Ugliuzza to the April meeting so SPRI could have an in-person meeting to review the details. He will not be able to attend due to the ABAA Conference.

# Adjournment

There being no further business, the meeting adjourned at 1:05 p.m. EST.

Submitted by: Al Janni, Task Force Chair

These minutes have been reviewed by SPRI Legal Counsel.

SPRI Wetting Curves Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

# Call to order

The Task Force meeting was called to order at 2:00 p.m. EST by Task Force Chair David Hawn. The SPRI Antitrust Statement was read. \*

# **Roll Call**

Those present were:	Jim Pieczynski, Blue Ridge Fiberboard, Inc.
David Hawn, Dedicated Roof & Hydro-Solutions	Brian Randall, National Gypsum
Warren Barber, National Gypsum	Brandon Reynolds, Carlisle Construction Materials
Bas Baskaran, NRCC	Greg Sagorski, Atlas Roofing Corporation
Luis Cadena, NEMO   etc.	William Sanborn, Johns Manville Corporation
David French, Carlisle Construction Materials, LLC	Steve Wadding, Polyglass USA, Inc.
Tony Fuller, National Gypsum	
Mike Giangiacomo, Flex Membrane Int'l Corp.	Guest present was:
Kirk Goodrum, Siplast	André Desjarlais, ORNL
Mikael Kuronen, Georgia-Pacific Gypsum LLC	
Saverio Marzella, ROCKWOOL	Staff present was:
Scott Morrison, J.S. Held LLC	Carl Silverman, Esq., SPRI
Steve Moskowitz, Atlas Roofing Corporation	

# Discussion

It was discussed that the work-in-progress information conveyed at this meeting was to stay within SPRI until it is agreed by the Technical Committee and SPRI Board to be published.

The Task Force determined that the data required more time for review prior to a vote and to publish. A Sub Task Force group was established to expedite this process. Said group includes entities for each of the major generic material classifications. For issues that require global input, those material suppliers will be contacted with the material pertinent to their product only, if needed. This will be accomplished before the April meeting.

# The action items discussed above were approved.

# Adjournment

There being no further business, the meeting adjourned at 2:30 p.m. EST.

Submitted: David Hawn, Task Force Chair

SPRI Technical Committee Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### **Call to Order**

The Technical Committee meeting was called to order at 2:45 p.m. EST by Technical Committee Chair Chris Mader. The SPRI Antitrust Statement was read. \*

#### **Roll Call**

*Those present were:* Chris Mader, OMG Roofing Products Adam Aharonian, SFS Group USA Warren Barber, National Gypsum Bas Baskaran, NRCC Brian Buckle, Intertek Adam Burzynski, Carlisle Construction Materials Luis Cadena, NEMO | etc. Brian Chamberlain, Carlisle Construction Materials Stan Choiniere, StanCConsulting Joan Crowe, AIA, GAF Phillip David, IB Roof Systems Brian Davis, GAF Heather Estes, GAF Carl Flieler, Canadian General Tower Limited David French, Carlisle Construction Materials, LLC Tony Fuller, National Gypsum Mike Giangiacomo, Flex Membrane Int'l Corp. Kirk Goodrum, Siplast David Hawn, Dedicated Roof & Hydro-Solutions Amanda Hickman, The Hickman Group George Howell, Martin Marietta Magnesia **Specialties** Lynsey Hull, NEMO | etc. Al Janni, Duro-Last Roofing, Inc. Joseph Kalwara, Firestone Building Products Co Brendan Knapman, ROCKWOOL Mikael Kuronen, Georgia-Pacific Gypsum LLC

Bob LeClare, ATAS International, Inc. Tony Mallinger, Metal-Era, Inc. Joe Malpezzi, Carlisle Construction Materials, LLC Saverio Marzella, ROCKWOOL Rick Montoya, Acme Cone Company Steve Moskowitz, Atlas Roofing Corporation Jim Pieczynski, Blue Ridge Fiberboard, Inc. Brian Randall, National Gypsum Ron Reed. Intertek Brandon Reynolds, Carlisle Construction Materials William Sanborn, Johns Manville Corporation Joe Schwetz, Sika Sarnafil Dwayne Sloan, UL LLC Zeb Sukle, Johns Manville Corporation Todd Taykowski, Firestone Building Products Co Brad Van Dam, Metal-Era, Inc. Steve Wadding, Polyglass USA, Inc. Jarrod Woodland, SFS Group USA Eric Younkin, Soprema, Inc.

Guest present was: André Desjarlais, ORNL

Staff present were: Randy Ober, SPRI Carl Silverman, Esq., SPRI

# Discussion

On motion duly made, the minutes of the October 2019 Technical Committee meeting were approved as <u>distributed</u>.

# **Review of Completed Objectives**

- 1. ED-1 Edge June 2019;
- 2. MCA Standard development June 2019;
- 3. PCR Update July 2019;
- 4. RD-1 Revision RD-1 July 2019;
- 5. RP-4 Revision October 2019; and
- 6. WD-1 ANSI approved January 2020.

# **Task Force Reports**

- 1. Air barrier details Task Force Chair Al Janni reported the following items:
  - a. The Task Force is working with Air Barrier Association of America to create updated air barrier details; and
  - b. Reviewing comments on draft details.
- 2. Air Intrusion Task Force Chair Al Janni reported the following item Developing a test protocol to determine if there is an energy loss in MF single ply systems (due to membrane movement).
- 3. Code Development The Task Force Chair Amanda Hickman reported the following items:
  - a. All ICC Code proposals were approved;
  - b. American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) is working on determining the effect of thermal bridging on energy usage; and
  - c. FL building code is being updated SPRI has submitted one comment.
- 4. Codes & Standards Task Force Chair Randy Ober reported the following items:
  - a. WD-1 ANSI/SPRI WD-1 Wind Design Standard Practice for Roofing Assemblies was approved January 6, 2020;
  - b. FL Building Code is replacing "Testing Application Standard (TAS 131-95);
  - c. Standard Requirements for Thermoplastic Olefin Elastomeric Based Sheet Used in Single-Ply Roof Membrane" with ASTM D6878; and
  - d. The Task Force decided not to ballot the proposal that allows calculation of parapet height for ballasted systems >150 feet for inclusion in ASCE7.
- 5. Code Compliance and Product Approval Task Force Chair Lyndsay Hull reported the following items:
  - a. Task Force Members met with Miami-Dade (MD) officials regarding receiving notices of acceptance (NOA) for private labeled products. As a result of this meeting, nothing will be required if the private label customer is requesting the identical NOA approvals of the original manufacturer (i.e. just changing the name);
  - b. The Dade County website is outdated and does not include the entire process that a manufacturer must follow to gain Dade County approvals;
  - c. Dade County is working with SPRI to allow 3<sup>rd</sup> party labs to submit data for approvals; and
  - d. An outside consultant called in during the Task Force meeting to describe various methods to get relief from some of the problems associated with Dade County FL.
- 6. Code Official Training Task Force Chair Brian Chamberlain reported the following items:
  - a. SPRI currently has 12 hours of training modules, but most are higher level learning. However, SPRI has basic training for code officials that need it as well; and
  - b. SPRI missed the deadline for the 2020 EduCode due to lack of communication from ICC.
- 7. Annual Conference Task Force Chair Bob Reel reported the following items:

- a. The Annual Conference will remain in January
- 8. D6878 TPO Considerations for Revision Task Force Chair Will Sanborn reported the following items:
  - a. Adding a new "Type" of TPO that includes a fleece backing within ASTM D6878;
  - b. Working through ASTM & SPRI to conduct an ASTM round robin ILS program for fleece adhesion. Samples have been submitted by several TPO manufacturers and are in the process of being tested; and
  - c. Addition of an impact test is being discussed as well.
- 9. DORA® Listing Service: Task Force Chair Joe Malpezzi reported the following items:
  - a. Updates are being made to the DORA<sup>®</sup> software;
  - b. 1750 products are now listed in DORA® / 3500 assemblies;
  - c. Multi-ply systems will now be included in the program;
  - d. Looking at adding a contractor print-out feature which can be activated once the user finds an assembly that meets their needs;
  - e. DORA<sup>®</sup> will be displayed at EduCode, IIBEC & IRE;
  - f. Need to move forward with the promotion of DORA®; and
  - g. Need to educate the potential users regarding what DORA<sup>®</sup> actually is, how it will benefit them, and how to use the program.
- 10. DORA<sup>®</sup> Rules for adding fire and impact Task force Co-Chair Scott Morrison reported the following items:
  - a. Discussed adding fire and impact to the DORA® program;
  - b. Discussed why SPRI / DORA<sup>®</sup> may want to remain only in wind (what they are experts in) and not dabble in fire and impact. UL had 5000 hits in 90 days on its website which features fire resistance ratings.
- 11. Fastener Plate Pull-Through Task Force Chair Chris Mader reported the following items:
  - a. Changing name to BPT-1 Test Standard for Comparative Pull Through Strengths of Stress Plates and Substrate Board Materials Used with Low Slope Roofing Systems; and
  - b. This subject was discussed with Factory Mutual (FM) and the standard development may become a joint effort between SPRI and FM.
- 12. IA-1 Revision Task Force Chair Stephen Childs reported the following items:
  - a. The standard was partially rewritten with the suggestions from the Task Force's initial meeting. No additional submissions from the Task Force were submitted since then;
  - b. The Task Force discussed the size of the test sample and the need to cut around the test sample to isolate it from the rest of the existing roofing assembly.
  - c. Mr. Childs will update the document and send it to the Task Force by the end of January for review.
  - d. The Task Force decided that cutting around the sample is still needed. Without cutting to the roof deck to isolate the sample, the test may show a false positive result. The test area will be affected by the testing device due to the fact the surface being tested will be held down by the frame of the testing equipment.
- 13. IBHS training Task Force Chair Mike Darsch reported the following items:
  - a. Chuck Miccolis and Mark Zehnal from IBHS presented information regarding the Fortified Commercial Program and how SPRI can work together with them to train applicators in the use of this program.
  - b. Discussion ensued regarding what role manufacturers will play in training contractors in the specifics of the Fortified Commercial Program.
- 14. Very Severe Hail FAQ Task Force Chair Tim McQuillen reported the following items:
  - a. Creating a SPRI hail impact test may not in SPRI's best interest since there are many other impact testing methods currently in place;

- b. SPRI may want to work with IBHS in creating a test method. IBHS is conducting testing and research for ice ball impact on single-ply membranes;
- c. The evaluation method used by FM to determine the impacted sample for pass / fail was discussed;
- d. The Task Force will attempt to meet with FM to discuss pass / fail parameters;
- e. SPRI may want to take pictures of various conditions of the membrane and substrate after impact and assign a pass / fail designation to each (this would make the judgement less subjective).
- 15. VOC Regulatory Monitoring Task Force Chair Justin Bates reported the following items:
  - a. Will conduct a Webex to discuss the ARI survey results;
  - b. The PCBTF Survey was not approved by the TF and a follow-up meeting will be scheduled to discuss and resolve any issues;
  - c. SCAQMD Rule 102 Proposed Changes were discussed; and
  - d. The Task Force would like to form a team and begin planning technology assessment that is due in 2022.
- 16. WD-1 update Task Force Chair Joe Malpezzi reported the following items:
  - a. There is one remaining negative. The Task Force revised the document to address this negative; and
  - b. The revised copy will be sent to the National Roofing Contractors Association (NRCA) for review with a request to withdraw its negative.
- 17. Wetting Curves Task Force Chair Dave Hawn reported the following items:
  - a. Data that has been produced by NRCA needs additional review;
  - b. The various manufacturers of tested insulation will be given additional time to review data; and
  - c. A group will be formed to review the data after the manufacturers get a chance to review and digest the information.
- 18. Website/Digital Content & Communication Chair Adam Burzynski reported the following items:
  - a. New content has been developed for the website;
  - b. The standards page where users typically land on SPRI's website is not easy to navigate. The Task Force group is in the process of redesigning this webpage and which project should cost no more than \$1000; and
  - c. Mr. Burzynski requested that people forward any relevant content to him.

# Adjournment

There being no further business, the meeting was adjourned at 3:30 p.m. EST.

Submitted by: Randy Ober, SPRI Technical Director

SPRI Technical Committee Task Force Hilton Denver City Center Denver, CO October 22, 2019



#### MINUTES

#### **Call to Order**

The Technical Committee meeting was called to order at 3:30 p.m. MDT by Technical Committee Chair Chris Mader. The SPRI Antitrust Statement was read. \*

#### **Roll Call**

*Those present were:* Chris Mader, OMG Roofing Products Adam Aharonian, SFS Group USA Brian Alexander, TruFast Maury Alpert, Polyglass USA, Inc. Warren Barber, National Gypsum Bas Baskaran, NRCC Justin Bates, H.B. Fuller Construction Products Adam Bembenek, Mule-Hide Products Co., Inc. Adam Burzynski, Carlisle Construction Materials Scott Carpenter, SFS Group USA, Division Construction Brian Chamberlain, Carlisle Construction Materials Stephen Childs, OMG Roofing Products Stan Choiniere, StanCConsulting Gareth Christopher, IKO Industries Ltd Todd Corley, Siplast Mike Darsch, Sika Sarnafil Phillip David, IB Roof Systems Brian Davis, GAF Carl Flieler, Canadian General Tower Limited Mike Giangiacomo, Flex Membrane Int'l Corp. Kirk Goodrum, Siplast Keith Grzybowski, Firestone Building Products Jason Hackman, Benchmark Inc. David Hawn, Dedicated Roof & Hydro-Solutions George Howell, Martin Marietta Magnesia Specialties Lynsey Hull, NEMO | etc. Al Janni, Duro-Last Roofing, Inc. Joseph Kalwara, Firestone Building Products

Shaun Kerschen, Atlas Roofing Corporation Stephanie Kiriazes, Firestone Building Products Brendan Knapman, ROCKWOOL Sara Krompholz, Intertek Edward Krusec, Hunter Panels Mikael Kuronen, Georgia-Pacific Gypsum LLC Bob LeClare, ATAS International, Inc. Colin Litow, Continuus Materials, LLC Joe Malpezzi, Carlisle Construction Materials **Rick Martelon, Johns Manville Corporation** Saverio Marzella, ROCKWOOL Tim McFarland, Mule-Hide Products Co., Inc. Tim McQuillen, Johns Manville Corporation Scott Morrison, J.S. Held LLC Steve Moskowitz, Atlas Roofing Corporation Jim Pieczynski, Blue Ridge Fiberboard, Inc. Brian Randall, National Gypsum Ron Reed, Intertek Bob Reel, H.B. Fuller Construction Products Andrew Reynolds, Benchmark, Inc. Jim Rubenacker, Sika Sarnafil William Sanborn, Johns Manville Corporation Michael Schwent, GAF Joe Schwetz, Sika Sarnafil CJ Sharp, ICP Building Solutions Group Flonja Shyti, NRCC Kurt Sosinski, Tremco, Inc. Myles Sosnoff, Metal-Era, Inc.

Emily Standard, PRI Zeb Sukle, Johns Manville Corporation Todd Taykowski, Firestone Building Products Mike Taylor, Blue Ridge Fiberboard, Inc. Sid Teachey, USG Corporation Nathan Vail, Intertek Ryan VanWert, Duro-Last Roofing, Inc. Diana Vitiritti, SITURA Inc. Steve Wadding, Polyglass USA, Inc. Martin Ward, GAF Riku Ylipelkonen, ICP Building Solutions Group

Staff present were: Mike Ennis, SPRI Randy Ober, SPRI Carl Silverman, Esq., SPRI

# Discussion

On motion duly made, the minutes of the July 2019 Technical Committee meeting were approved as distributed.

# On motion duly made, the Technical Strategic Plan was approved for submission to the SPRI Board.

# Task Force Reports

- 1. Air barrier details Task Force Chair Al Janni reported the following items:
  - a. Responses were received from AABA & GAF & Fibertite; and
  - b. There were good comments that will be forwarded to AABA.
- 2. Air Intrusion Task Force Chair Al Janni reported the following items:
  - a. Two responses have been received on the request for proposal (RFP), with one more expected;
  - b. The responses will be reviewed by the Task Force, which may elect to have an in-person meeting with the respondents.
- 3. Code Development Mike Ennis reported the following items for Task Force Chair Amanda Hickman:
  - a. Reviewed plans for the upcoming Public Comment hearings in Vegas;
  - b. The Code Development Strategic plan was approved; and
  - c. SPRI's increased participation in the National Building Code of Canada (NBCC) was discussed.
  - d. <u>On motion duly made, it was approved, with one abstention, to request that the SPRI</u> <u>Board allocate an amount not to exceed \$5000 to have Tony Crimi provide a summary</u> <u>of the NBCC process and key contacts at the next available meeting.</u>
- 4. Codes & Standards Task Force Chair Mike Ennis reported the following items:
  - a. International Code Council Evaluation Service (ICC ES) and Innovation Research Lab have signed a cooperating agreement to offer testing services;
  - b. The National Research Council Canada, (NRCC) is developing a resiliency standard that will cover membrane roof systems and will be included in the NBCC;
  - c. Oak Ridge National Laboratory (ORNL) is offering a nonexclusive, royalty free license for use of the roof savings calculator.
- 5. Code Compliance and Product Approval Task Force Chair Lyndsay Hull reported the following items:
  - a. Miami Dade (MD) recently decided to no longer allow Private Labeled Products (PLA) for membranes; and
  - b. Phil Smith, FM Approvals, called Jorge Acebo at MD and is working with them to allow PLAs.
- 6. Code Official Training Task Force Chair Mike Ennis reported the following items:
  - a. Polyisocyanurate Insulation Manufacturers Association (PIMA) would like to participate in these Code Official training programs with SPRI. The Task Force agreed to have PIMA help at EduCode and SPRI would work with them at a program scheduled in Denver, CO.

- 7. Annual Conference Task Force Chair Bob Reel reported the following items:
  - a. The Task Force is evaluating the potential for moving the Conference to a different time of the year; and
  - b. In 2020, the Conference will be held at the Opal Sands in Clearwater.
- 8. D6878 TPO Considerations for Revision Task Force Chair Will Sanborn reported the following items:
  - a. Including new type for FleeceBACK Thermoplastic Polyolefin (TPO) in ASTM D6878;
  - b. 4 out of 5 manufacturers have submitted samples to SRI;
  - c. Made several modifications to original test procedures; and
  - d. Impact testing was discussed and will be refined before the next meeting.
- 9. DORA Listing Service: Task Force Chair Joe Malpezzi reported the following items:
  - a. The program overview includes:
    - i. 52 participating companies;
    - ii. 1647 products listed; and
    - iii. 3312 listed assemblies.
  - b. Revising search function for modified bitumen assemblies;
  - c. Google Analytics will determine who & how people are using DORA;
  - d. DORA was presented at several trade association shows; and
  - e. <u>On motion duly made, the Technical Committee approved the recommendation that the</u> <u>SPRI Board fund \$1,000 to trademark the full name for DORA.</u>
- 10. DORA Rules for adding fire and impact Task force Co-Chair Scott Morrison reported the following items:
  - a. Seven members are investigating rules for fire, Jenny Sherwin is leading this effort; and
  - b. Rules for impact will be completed by the end of the first quarter.
- 11. Fastener Plate Pull-Through Task Force Chair Chris Mader reported the following items:
  - a. The Task Force reviewed the minutes from the meeting held with FM and discussed how the proposed standard will be used; and
  - b. The Task Force will create an ANSI Standard based on the FM standard, an ANSI Project Initiation Notification Form (PIN) has been issued.
- 12. IA-1 Revision Task Force Chair Stephen Childs reported the following items:
  - a. This was the first meeting of this Task Force; and
  - b. The canvass list was reviewed, and potential revisions were discussed.
- 13. IBHS training Task Force Chair Mike Darsch reported the following items:
  - a. This was the first meeting of this Task Force;
  - b. The proposed training will mimic the Fortified program and will train the contractor;
  - c. DORA will identify which assemblies are Fortified; and
  - d. A meeting with IBHS will be conducted.
- 14. RP-4 Revision Task Force Chair Todd Taykowski reported the following items:
  - a. 11 out of 15 members of the canvass group voted affirmative regarding the actions taken to address the Tom Smith negative, two abstained and two did not vote. The revision is now complete; and
  - b. Bas Baskaran suggested that a new task force be created to study roofs with parapets.
- 15. Very Severe Hail FAQ Task Force Chair Tim McQuillen reported the following items:
  - a. This was the first meeting of this Task Force; and
  - b. Possible action items identified were:
    - i. Development of an FAQ white paper document to be presented at IIBEC;
    - ii. Possibly develop a SPRI Hail Resistance Standard; and
    - iii. Have a meeting with FM.
- 16. VOC Regulatory Monitoring Task Force Chair Justin Bates reported the following items:

- a. Parachlorobenzotrifluoride (PCBTF) has been added to Prop 65. Roof Coatings Manufacturers Association (RCMA) has concerns that as a result, the exemption currently in place at South Coast Air Quality Management District (SCAQMD) will be lost.
- b. <u>On motion duly made, the Technical Committee approved submission of the recommendation to the SPRI Board, to hire Association Research Inc. (ARI), at an expense not to exceed \$3,500, to prepare, facilitate and compile the results of a survey of the SPRI Members on the usage data of PCBTFs.</u>
- 17. WD-1 update Task Force Chair Joe Malpezzi reported the following items:
  - a. There is one remaining negative. The Task Force revised the document to address this negative; and
  - b. The revised copy will be sent to the National Roofing Contractors Association (NRCA) for review with a request to withdraw its negative.
- 18. Wetting Curves Task Force Chair Dave Hawn reported the following items:
  - a. A limited number of tests remain. NRCC hopes to have all testing completed by the end of December;
  - b. Notification and an opportunity to review the data will be provided on the SPRI website; and
  - c. The Task Force plans to vote on the approval of the NRC report at the January Conference.
- 19. Website/Digital Content & Communication Chair Adam Burzynski reported the following items:
  - a. Several links to SPRI Member Resources are non-functional, they will be repaired;
  - b. Google Analytics shows where people are mostly landing on the SPRI website (Standards);
  - c. The Task Force will attempt to improve users experience;
  - d. SPRI is changing the Members Only section password to "SPRImember20";
  - e. Blog content continues to be developed and posted; and
  - f. Use of social media to promote SPRI will be increased to include such items as SPRI events attended and new blogs.

# **New Business**

Mr. Janni asked for submission of names of people to be recognized for their contribution to SPRI during the past year. Submissions should be sent to info@spri.org.

# Adjournment

There being no further business, the meeting was adjourned at 4:05 p.m. MDT.

Submitted by: Mike Ennis, SPRI Technical Director

SPRI Annual Conference Timing Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### Call to order

The Task Force meeting was called to order at 9:30 a.m. EST by Task Force Co-Chairs Scott Carpenter and Bob Reel. The SPRI Antitrust Statement was read. \*

# Roll Call

Those present were: Scott Carpenter, SFS Group USA Bob Reel, H.B. Fuller Construction Products Vinny Abbondanza, OMG Roofing Products Brian Buckler, SFS Group USA Mike Darsch, Sika Sarnafil Norbert Lash, H.B. Fuller Construction Products Bob LeClare, ATAS International, Inc. Ron Reed, Intertek CJ Sharp, ICP Building Solutions Group Eric Younkin, Soprema, Inc.

Staff present was: Linda King, SPRI

#### Discussion

The Task Force discussed the possibility of moving the Annual Conference from the historical January time slot. There was a lot of good dialogue for pros and cons. Final unanimous decision by the Task Force was to keep the Annual Conference as is, in January.

#### Adjournment

There being no further business, the meeting was adjourned at 10:15 a.m. EST.

Submitted: Bob Reel, Task Force Co-Chair

These minutes were reviewed by SPRI Legal Counsel.

SPRI Code Compliance Interface Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

# Call to Order

The Task Force meeting was called to order at 10:30 a.m. EST by Task Force Co-chair Lynsey Hull. The SPRI Antitrust Statement was read. \*

# **Roll Call**

Those present were: Luis Cadena, NEMO | etc. Lynsey Hull, NEMO | etc. Eric Younkin, Soprema, Inc. Brian Chamberlain, Carlisle Construction Materials Mike Darsch, Sika Sarnafil Heather Estes, GAF Carl Flieler, Canadian General Tower Limited Frank Greco, IKO Industries Ltd Richard Hein, Metal-Era, Inc. Amanda Hickman, The Hickman Group Norbert Lash, H.B. Fuller Construction Products Chris Mader, OMG Roofing Products Rick Martelon, Johns Manville Corporation Chris Meyer, FiberTite Roofing Systems

Rick Montoya, Acme Cone Company Joe Schwetz, Sika Sarnafil CJ Sharp, ICP Building Solutions Group Emily Standard, PRI Todd Taykowski, Firestone Building Products Co Brad Van Dam, Metal-Era, Inc.

*Staff present was:* Randy Ober, SPRI

*Call-in participant was:* Kevin Doyle, HBW Resources

# **Review of Miami Dade Meeting**

The meeting was held on January 9<sup>th</sup> at Miami Dade (MD) County. The following is a review of inconsistencies in the approval process;

- Verification testing;
  - When and how it can be used (product modifications, alternate plants);
  - It does not apply for roofing physical properties testing;
  - It can be more towards wind-uplift verification for products that have undergone change and/or new products to be dropped in as replacements. Verification testing to be reviewed and approved by MD examiner prior to testing;
- Online Checklist;

- SPRI was informed that the online checklist is not accurate to low-slope roofing Notices of Acceptance (NOAs);
- $\circ$   $\;$  MD staff is working on getting a revised roofing checklist updated and online; and
- Any changes SPRI would like to see implemented should be put in writing to Jorge Acebo and Alex Penelas for them to process the request.
- Data release requirements set forth by MD:
  - Re-issuing reports for Private Label Products (PLA) NOA's is not required if it is a 1:1 PLA NOA;
  - Roofing Component Manufacturer's Uplift/Performance test reports will not need to be re-issued in the applicant's name;
  - Roofing Component Manufacturer's Physical Properties Testing report(s) will not need to be reissued in applicant's name;
  - Membrane Manufacturer's Uplift/Performance test reports shall be re-issued in the applicant's name; and
  - Membrane Manufacturer's Physical Properties Testing report(s) will not need to be re-issued in the applicant's name.

# *Note: A data release statement from manufacturer, listing all reports, along with quality assurance (QA) items will suffice.*

- Florida Building Code (FBC) does not allow conclusion of 3<sup>rd</sup> party labs- Lynsey Hull will work with Mr. Acebo to develop guidelines for qualifying 3<sup>rd</sup> party labs; and
- TAS 103-20 shall require foam on tile testing per ASTM D1623. Nemo will work on a proposal to minimize the number of specimens for "new" products/facilities;

# Action Items

- It was determined that SPRI needs to follow up with a letter to MD outlining the meeting to reassure and verify the conversations;
- It was discussed to possibly work with ARMA on MD concerns. Eric Younkin will reach out to Chadwick Collin with ARMA and report back;
- Amanda Hickman will speak with contact at the State of Florida about the possible addition of 3rd party labs conclusions to FBC. The code cycle is in April;
- There was a conference call with Kevin Doyle of HBW Resources. Mr. Doyle has vast experience in Florida Legislative efforts, specifically MD county. He is putting a proposal together for SPRI to use and potentially solve the MD issues legislatively; and
- Mr. Hull will set up a conference call with all meeting attendees to identify the goals of possibly working with Mr. Doyle.

# Adjournment

There being no further business, the meeting adjourned at 11:30 a.m. EST.

Submitted by: Lynsey Hull, Task Force Co-chair

SPRI Digital Content & Communications Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

# Call to Order

The Task Force meeting was called to order at 11:30 a.m. EST by Task Force Chair Adam Burzynski. The SPRI Antitrust Statement was read. \*

# Roll Call

Those present were:
Adam Burzynski, Carlisle Construction Materials
Warren Barber, National Gypsum
Scott Carpenter, SFS Group USA
Stephen Childs, OMG Roofing Products
Mike Darsch, Sika Sarnafil
Joseph Fay, BASF Corporation
David French, Carlisle Construction Materials

John Greko, Carlisle Construction Materials James Kopcha, BASF Corporation Bob LeClare, ATAS International, Inc. Rick Montoya, Acme Cone Company Brad Van Dam, Metal-Era, Inc.

Staff present was: Amanda Crotty, SPRI

# Discussion

The following items were discussed:

- Website Update on standards webpage:
  - Amanda Crotty is working on the updates for easier navigation;
  - The Task Force reviewed examples of "standard" pages from other associations and discussed how they might work for the SPRI website. Many visitors land on this page; and the Task Force believes it can be more "user friendly".
  - o Bob LeClare suggested a way to categorize the standards; and
    - Make each box have a standard name and title with a drop-down option showing all versions of the standard;
    - Titles to be larger and bold; and
    - The list will be in alphabetical order by standard name.
  - Ms. Crotty will request an estimate from Ashdown. The cost estimate is to be less than \$1,000. This cost may be built into the budget for the website.
- Blogs/Content Review Schedule and Topics:
  - Define topics and schedule for 2020;
  - Reviewed schedule and topics; and
    - Mr. Van Dam submitted an idea for a topic about code changes; and
    - Ms. Crotty will reach out to Amanda Hickman for a summary.
  - Mr. Barber has a blog written about reasons to use cover boards and offered to put together several more about wind performance and cover boards.

• Social Media - Schedule & strategy for Linkedin Content: Every member company will receive an alert when new content goes up and will be asked to repost with their own SM accounts.

#### Adjournment

There being no further business, the meeting adjourned at 12:00 p.m. EST.

Submitted: Task Force Chair Adam Burzynski

These minutes were reviewed by SPRI Legal Counsel.

SPRI IA-1 Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### Call to Order

The Task Force meeting was called to order at 12:45 p.m. EST by Task Force Co-chair Stephen Childs. The SPRI Antitrust Statement was read. \*

## Roll Call

Those present were: Stephen Childs, OMG Roofing Products Justin Bates, H.B. Fuller Construction Products Stan Choiniere, StanCConsulting David French, Carlisle Construction Materials Norbert Lash, H.B. Fuller Construction Products Joe Schwetz, Sika Sarnafil Zeb Sukle, Johns Manville Corporation

Staff present was: Linda King, SPRI

#### Discussion

The following items were discussed:

- The standard was partially rewritten with the suggestions from the Task Force's initial meeting. No additional submissions from the Task Force were submitted since then;
- 2. The updated document was reviewed by the Task Force and revisions were discussed;
- 3. The Task Force discussed, at length, the size of the test sample and the need to cut around the test sample to isolate it from the rest of the existing roofing assembly. This was the case in the first meeting as well;
- 4. Mr. Childs will update the document and send it to the Task Force by the end of January for review. Any additional edits will be sent back to Mr. Childs prior to the April meeting; and
- 5. The Task Force decided that cutting around the sample is still needed. Without cutting to the roof deck to isolate the sample, the test may show a false positive result. The test area will be affected by the testing device due to the fact the surface being tested will be held down by the frame of the testing equipment.

#### Prepare for Canvassing

The canvas list was not discussed in detail. Time expired prior to getting to this topic. This will be discussed in April.

\*SPRI Antitrust Statement: SPRI complies with antitrust laws and requires participants in its programs to comply with antitrust laws. Discussions which could affect competitive pricing decisions or other competitive factors are forbidden. There may be no discussions of pricing policies or future prices, production capacity, profit margins or other factors that may tend to influence prices. In discussing technical issues, care should be taken to avoid discussing potential or planned competitive activities. Members and participants should be familiar with the SPRI Antitrust Policy and act in conformity with it. The following action items were discussed:

- 1. Mr. Childs will update the standard with new revisions to distribute to the task for prior before the End of month;
- 2. Mr. Childs will update the scope statement and send to Linda for the PINS submission;
- 3. The Task Force will review the updated document and submit any suggested edits to Mr. Childs prior to April meeting; and
- 4. Ms. King will submit for PINS after scope is updated.

## Adjournment

There being no further business, the meeting adjourned at 1:45 p.m. EST.

Submitted by: Stephen Childs, Task Force Co-chair

These minutes were reviewed by SPRI Legal Counsel.

SPRI Code Official Training Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### **Call to Order**

The Code Official Training Task Force meeting was called to order at 1:45 p.m. EST by Task Force Chair Brian Chamberlain. The SPRI Antitrust Statement was read.\*

#### **Roll Call**

Those present were: Brian Chamberlain, Carlisle Construction Materials Adam Burzynski, Carlisle Construction Materials Stephen Childs, OMG Roofing Products Stan Choiniere, StanCConsulting Bob LeClare, ATAS International, Inc. Paul Linton, OMG Roofing Products Joe Schwetz, Sika Sarnafil Jenny Sherwin, Firestone Building Products

Staff present were: Linda King, SPRI Randy Ober, SPRI

## Discussion

For the year 2020, there are no plans to present at EduCodes in Las Vegas or in Colorado. However, SPRI will be an exhibitor at the Las Vegas EduCode.

The Task Force is working with PIMA to provide a full day of seminars for the 2021 EduCode. Right now, including the Wind Presentation, SPRI has approximately 12-hours of education. The Task Force is considering a bridge presentation between 101 Roofing and the 301 level code presentation, with a possibility of a 201.

The following are inclusions of new code changes developed by SPRI:

• Parapet Walls;

Ballast Charts; and

• Aggregate vs Ballast;

GT-1 (gutter testing).

It was suggested that all the presentations be in 1-hour modules to create a list of programs that can be presented at other times. In addition, these may then be formatted as a webinar for easier access to those interested.

#### Adjournment

There being no further business, the meeting adjourned at 2:15 p.m. EST.

Submitted: Brian Chamberlain, Task Force Chair

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#### MINUTES

## Call to Order

The meeting was called to order at 8:30 a.m. EST by the Task Force Chair William Sanborn. The SPRI Antitrust Statement was read. \*

## Roll Call

Those present were: William Sanborn, Johns Manville Corporation Adam Burzynski, Carlisle Construction Materials Luis Cadena, NEMO   etc. Mike DeSouto, Cooley Engineered Membranes	Joseph Kalwara, Firestone Building Products Co James Kopcha, BASF Corporation Steve Kuhel, FiberTite Roofing Systems Sean McKay, Ashland, Inc. Zach Priest, PRI
Heather Estes, GAF	Ralph Raulie, FiberTite Roofing Systems
Joseph Fay, BASF Corporation	Ron Reed, Intertek
Carl Flieler, Canadian General Tower Limited	Joe Schwetz, Sika Sarnafil
David French, Carlisle Construction Materials	
Mike Giangiacomo, Flex Membrane Int'l Corp.	Call-in participants were:
Scott Gipson, FiberTite Roofing Systems	Marty Ward
Kirk Goodrum, Siplast	Brian Calaman
John Greko, Carlisle Construction Materials, LLC	Jim Kirby
George Howell, Martin Marietta Magnesia Specialties	Jennifer Keegan
Mike Hubbard, Firestone Building Products Co	Joshua Wilson
Roger Johnson, INEOS Olefins & Polymers USA	Brittney Walls

## Discussion

Jim Kirby discussed timing of the meeting. Meetings need to be scheduled for 11:00 a.m. EST or later to accommodate call-in participants.

Will Sanborn updated the status of the ASTM Interlaboratory Study (ISL) Fleece Adhesion Test Program.

- All five sample sets were submitted to Matt Dupuis at SRI and distributed to all seven testing laboratories; and
- Three of the seven testing laboratories have submitted data to Mr. Dupuis at SRI. The testing laboratories were asked to submit data by the end of January.

## Impact Testing of Fleece Back Membranes

Mr. Sanborn reviewed the origin of the impact testing on fleece back membranes and the July and October SPRI meeting updates. At the December 2017 ASTM meeting, a comment was made by Rene Dupuis that a fleece back membrane may provide impact resistance over fastener plates as compared to a smooth back membrane.

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ASTM D5635 Standard Test Method for Dynamic Puncture Resistance of Roofing Membrane Specimens was selected for use as a scanning study. Mr. Sanborn will perform initial testing and provide recommendations to two other volunteer labs, PRI and Firestone. Those initial test methods are the following:

- Impact will occur on the back/core side of the membrane;
- Comparing smooth-back membrane to fleece-back membrane;
- Substrates: Metal plate to start and standardized polypropylene plaques if the metal plate is too aggressive; and
- Failure criteria will be visual damage to the back/core side of the membrane.

## Adjournment

There being no further business, the meeting was adjourned at 9:35 a.m. EST.

Submitted by: William Sanborn, Task Force Chair

These minutes were reviewed by SPRI Legal Counsel.

SPRI VOC Regulation Monitoring Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

## Call to Order

The Task Force meeting was called to order at 10:00 a.m. EST by Task Force Chair Justin Bates. The SPRI Antitrust Statement was read. \*

## **Roll Call**

Those present were: Justin Bates, H.B. Fuller Construction Products John Baetz, Ashland Adam Burzynski, Carlisle Construction Materials Tom Cleverdon, ITW Heather Estes, GAF Mike Hubbard, Firestone Building Products Co Joseph Kalwara, Firestone Building Products Co Colin Litow, Continuus Materials Paul Michalec, The Ruscoe Co. William Sanborn, Johns Manville Corporation Frederick Walnut, ITW

*Staff present was:* Randy Ober, SPRI

## Discussion

The following PCBTF Survey results from Association Research Inc. (ARI) were reviewed:

- The updated draft is attached;
- The survey was not approved by the Task Force (TF). A follow-up meeting will be scheduled to discuss and resolve issues related to square footage estimates;
- The TF agreed to change the time needed to reformulate to > 24 months;
- The TF agreed to report averages on VOC limits needed if PCBTF were removed, when applicable as they were consistent with limits prior to VOC regulation. The TF is asked to report maximum value for adhesives to add context if negotiating with SCAQMD;
- ARI did not report data when received due to limited responses for a category;

The following square footage estimates of impacted roof system in question for Primers and Sealants were discussed:

- Square footage and the number of products seem high and coverage rate seems low (~30ft<sup>2</sup>/gal); and
  - Coverage rate could be impacted primer type (i.e. primer for self-adhered sheets) or how the primer was calculated (i.e. reporting square footage of entire sheet, even though small area of perimeter primed); and
  - Mr. Bates will request additional data from ARI.
- There was a question if square footage of sealants and primers should be reported. As accessories, the area will be double counted with adhered systems and do not have info to separate from mechanically attached systems.

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- Per David Darling of ACA, OEHHA's November workshops were somewhat useless in that OEHHA didn't take testimony for or against PCBTF Prop 65 information, but did answer questions that ACA incorporated into its above attachments;
  - ACA is consulting with Ramboll US Corp (Environmental, Health, Water, etc. consultation services) to prepare statements;
  - ACA takes issue with OEHHA's PCBTF assessment, specifically, items below, and requests that OEHHA retract the assessment as it does not accurately reflect PCBTF's hazard;
    - No Significant Risk Level (NSRL) factor set at 23ug/day; and
      - Inadequate documentation/information on modeling and assumptions that make it difficult for 3<sup>rd</sup> parties to validate; and
      - The Cancer Slope Factor (CSF) use to estimate NSRL, did not use best available science and relied on inappropriate default assumptions.
        - ✓ It is worth noting that the NTP 2018 reporting concluded PCBTF is not mutagenic or genotoxic, but OEHHA erred on the side of applying a model (linear low dose) that led to the potential over estimation of PCBTF carcinogenic risk to humans; and
        - ✓ Using animal exposures is not representative of human exposures and inconsistent within the guidance of California's Code of Regulations.
    - Inhalation Unit Risk (IUR) factor.
      - Similar complaints on CSF relative to NSRL; and
      - OEHHA did not appear to rely upon generally accepted models for doseresponse, and it appears that OEHHA failed to adequately assess the goodnessof-fit of its models.
- David Darling talked with Mike Morris, SCAQMD, who gave a brief update.
  - Mike is requesting South Coast Management that he be added to future risk assessment work Mr. Darling thinks this is good as long as Mr. Morris is logical.
  - SCAQMD is waiting on OEHHA to finalize unit risk factor; and NSRL will wait for Science Review Board to approve the risk factor before SCAQMD starts its risk assessment; and
  - Mr. Morris seemed to understand that limits may need to be raised or compliance time added if PCBTF were removed.

# SCAQMD Rule 102 Proposed Changes

- Review changes with group Exempt Solvent list hasn't changed; and
- David Darling at ACA agrees. Mr. Darling noted that the changes seem to be purely administrative and unrelated to SCAQMD's position on PCBTF. Link to the proposal -par102.pdf and board letter - par102-brd-ltr-(w-draft-findings)-(003).pdf

## Rule 1168 Technology Assessment

- The TF would like to form a team and begin planning technology assessment that's due in 2022;
- Current volunteer member companies / contacts include: Justin Bates, H.B. Fuller; Fred Walnut, ITW; Joe Kalwara, Firestone; Adam Burzynski, Carlisle; and John Baetz or William Xia, Ashland.
- Rule 1168 Proposed VOC limits pending technology assessment:

	VOC Limit (grams/liter)			
Category	Current VOC Limit	Proposed VOC Limit (1/1/2023)		
Single-ply roof membrane adhesive	250	200°		
All other roof adhesives	250	200*		
Single-ply roof membrane sealant	450	250°		
All other roof sealants	300	250°		

a. Pending technology assessment conducted in 2022.

## Adjournment

There being no further business, the meeting adjourned at 11:00 a.m. EST.

Submitted by: Justin Bates, Task Force Chair

These minutes were reviewed by SPRI Legal Counsel.

# PCBTF Advocacy Survey

Please complete and submit your survey by November 18, 2019. Send your completed form to Mike Egart at Association Research, Inc. at megart@associationresearch.com

If applicable, please make a copy of the form to be completed by each division and submit all the division forms to ARI					Impact of VOC exemption removal				
Coating or Product Type (SCAQMD Rule 1168 or SCAMQD Rule 1171)	Category (Per SCAQMD Rule 1168 and 1171)	Current VOC Limit (g/L) - Per Rule 1168 or 1171 Product Category	VOC Limit needed if PCBTF were removed (g/L)	% PCBTF in Product	Time needed to Reformlate/ Commercialize	Reported # of products impacted	Reported volume of products impacted (Gal) - Based 2019 SCAQMD QER	Calculated ft <sup>2</sup> of roof systems impacted	General Statements on other impacts
SCAQMD Rule 1168 (Adhesives & Sealants)	Single Ply Roof Membrane Adhesive	250	560 Max: 1000g/L	10 - 75%	>24 Months	19	677,465	40,723,824	See attachment for comments
SCAQMD Rule 1168 (Adhesives & Sealants)	Single Ply Roof Membrane Sealant	450	700	50 - 75%	>24 Months	5	13,444	830000 (under review - see meeting notes)	See attachment for comments
SCAQMD Rule 1168 (Adhesives & Sealants)	All Other Adhesive Primers	250	720	50 - 75%	>24 Months	212	1,557,902	48328840 (under review - see meeting notes)	See attachment for comments



December 17, 2019

Dr. John Budroe Chief, Air Toxicology and Risk Assessment Section Air and Site Assessment and Climate Indicators Branch Office of Environmental Health Hazard Assessment P.O. Box 4010, MS-12B Sacramento, California 95812-4010 Submitted electronically through <u>https://oehha.ca.gov/comments</u>

Re: Draft Hot Spots Cancer Inhalation Unit Risk Factors for p Chloro-α,α,α-trifluorotoluene (p-chlorobenzotrifluoride, PCBTF) - October 18, 2019

The American Coatings Association (ACA) offers the following comments on the Office of Environmental Health Hazard Assessment (OEHHA) draft document, titled "p-Chloro- $\alpha$ , $\alpha$ , $\alpha$ -trifluorotoluene (p-Chlorobenzotrifluoride, (PCBTF) Cancer Inhalation Unit Risk Factor Technical Support Document for Cancer Potency Factors: Appendix B (October 2019).<sup>1</sup> The ACA has serious concerns with the draft document and believes that it should be revised before review by the Scientific Review Panel. In several key aspects of the draft document, it appears that OEHHA did not use the best available science, failed to evaluate all of the available data, and did not employ generally accepted methods, as discussed in further detail throughout this letter.

Because of the highly technical nature of the OEHHA (2019) draft document, it should be noted that the ACA worked closely with consultants from Ramboll US Corporation to review the draft document and prepare these comments.

## SUMMARY

OEHHA should revise the draft document because the evaluation contained within it demonstrates that, in key places, OEHHA did not employ the best available science, it did not

<sup>&</sup>lt;sup>1</sup> ACA is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA's mission includes programs and services that support the coatings industry's commitment to environmental protection, sustainability, product stewardship, health and safety, corporate responsibility, and the advancement of science and technology. Additional information is available on the ACA website, https://www.paint.org.

account for all of the data, and it did not rely on generally accepted methods. Specifically, the ACA has the following concerns:

- In the estimation of the Cancer Slope Factor (CSF) or Inhalation Unit Risk (IUR) for PCBTF, OEHHA (2019) has applied linear low-dose extrapolation. This default assumption is incorrect, because it assumes that PCBTF is mutagenic. The available data show that PCBTF is <u>not</u> mutagenic. The weight of evidence also demonstrates that PCBTF and its metabolites are not genotoxic. OEHHA's approach is inconsistent with conclusions reached by NTP (2018), which found that PCBTF is neither mutagenic nor more generally genotoxic. OEHHA (2019) itself observed that "All studies of PCBTF mutagenicity have reported negative findings." In the absence of data supporting mutagenicity, it is inappropriate for OEHHA to use a linear no-threshold approach to derive a CSF/IUR for PCBTF. Instead, OEHHA should have used a nonlinear approach.<sup>2</sup> OEHHA's use of linear, low-dose extrapolation likely overestimated the potential carcinogenic risk of PCBTF to humans, if any such risk actually exists. <sup>3</sup>
- OEHHA (2019) concluded that the mechanisms by which PCBTF causes tumors are not known. However, for the mouse liver tumors -- the endpoint upon which the recommended IUR is based -- OEHHA gave no consideration to the mode of action proposed by the National Toxicology Program (NTP 2018) for these tumors. Moreover,

<sup>&</sup>lt;sup>2</sup> The existence of a threshold for effects should be welcome news to all stakeholders, including regulators and public health advocates. Even if one accepts OEHHA's assertion that PCBTF poses a risk of cancer to humans, if the risk of those effects only occurs above a certain threshold -- which could possibly be at a level that is above most, if not all, levels of human exposure -- then health protective measures can be clearly identified and communicated to users of the chemical, while also enabling the public to continue receiving the health benefits of reduced ground level ozone that is achieved through industry's use of this chemical as an "exempt" solvent in coatings. Results from available worker studies provide evidence of exposures for which higher than expected rates of the types of cancers observed in animals following exposure to PCBTF were not observed in the workers (Occidental Chemical Corporation 1992). This resulted despite PCBTF exposure having occurred in combination with more than 80 other chemicals and workers potentially having elevated levels of exposure compared to traditional consumers. Currently, there are no viable alternatives available to replace PCBTF where it is used as an exempt solvent. Hence, any regulatory action taken on this chemical must be based on an accurate, carefully calibrated and datadriven assessment of the potential risks to human health, if any. Over-regulating this chemical to avoid an uncertain hazard (i.e., potential health effects in humans) will only bring about the near-certain public health impacts of increased ground level ozone. If OEHHA questions this assertion, it should consult with CARB and other air regulators throughout the state.

<sup>&</sup>lt;sup>3</sup> The ACA continues to assert that the data are insufficient to support listing PCBTF under Proposition 65. As indicated in its letter to Dr. Lauren Zeise, Ph.D., dated September 19, 2019, the association has chosen not to seek judicial review of the listing at this time. OEHHA should not interpret the ACA's decision as agreement with the PCBTF listing. As discussed in it comments to the proposed listing, the association believes that the PCBTF listing is inconsistent with the applicable legal and factual requirements for listing. ACA reviewed OEHHA's response to the Association's comments and did not find it persuasive.

it appears that OEHHA made no attempt to evaluate the available toxicity data relevant to understanding the mode of action. Had OEHHA undertaken such a review, it would have discovered that the available data for PCBTF are consistent with NTP's (2018) proposed mode of action and that tumors occurring in rodents by this mode of action are <u>not</u> relevant to human health. As such, the mouse liver tumor data should <u>not</u> be used to derive the CSF/IUR. Use of these data likely overestimates the potential for human health risk.

• When estimating the recommended IUR for PCBTF, OEHHA (2019) does not appear to have relied upon generally accepted methods for selecting a dose-response model. In addition, it appears that OEHHA (2019) failed to adequately assess the goodness-of-fit of the models it applied to the data. The agency also failed to use generally accepted time-to-tumor models to adjust for survival. These failures may have resulted in the agency over- or under-estimating the potential potency of PCBTF.

## DISCUSSION

# I. <u>OEHHA Is Not Using the Best Available Science to Derive the CSF/IUR –</u> <u>Specifically, Assuming the Mutagenicity of PCBTF and Low-Dose Linearity for</u> <u>Cancer Risk is Incorrect.</u>

In the estimation of the CSF or IUR for PCBTF, OEHHA (2019) has assumed linear lowdose extrapolation. This default assumption is incorrect. The available data show that PCBTF is <u>not</u> mutagenic. The available data also demonstrate that PCBTF and its metabolites are not genotoxic. OEHHA's approach is inconsistent with conclusions reached by NTP (2018), which found that PCBTF is neither mutagenic nor more generally genotoxic. OEHHA (2019) itself observed that "All studies of PCBTF mutagenicity have reported negative findings." In the absence of data supporting mutagenicity, it is inappropriate for OEHHA to use a linear nothreshold approach to derive a CSF/IUR for PCBTF. Instead, OEHHA should have used a nonlinear approach, as explained further in the paragraphs below.

The linear no-threshold methods that OEHHA (2019) used assume that there is a risk of cancer with any exposure to PCBTF. This assumption is premised on exposure to a chemical causing alterations in the DNA (e.g., mutagenicity) that are transmitted to successive cell generations. OEHHA's (2009) Technical Support Document for Cancer Potency Factors, which sets forth the methods OEHHA uses to derive IURs and CSFs, states:

"The procedures used to extrapolate low-dose human cancer risk from animal carcinogenicity data <u>assumed that a carcinogenic change induced in a cell is transmitted</u> to successive generations of cells descendants, and that the initial change in the cell is an <u>alteration (e.g., mutation, rearrangement, etc.) in the cellular DNA</u>. Non-threshold models are used to extrapolate to low dose human cancer risk from animal carcinogenicity data." (Emphasis added.)

However, when a chemical is <u>not</u> mutagenic – as is the case with PCBTF – the application of non-threshold or linear approaches are inappropriate. This opinion is shared by other authorities such as the United States Environmental Protection Agency (USEPA). OEHHA (2009) refers to and relies on the USEPA (2005) Cancer Guidelines for additional details on the dose-response modeling used for estimation of CSFs/IURs. The USEPA (2005) guidelines indicate that linear extrapolation should be used for agents that are DNA-reactive and have direct mutagenic activity. However, when a chemical is <u>not</u> mutagenic – as is the case with PCBTF -- USEPA (2005) provides guidelines for a nonlinear approach.

When evaluating the potential for mutagenicity of PCBTF or for any compound, it is important to understand the differences between mutagenicity and genotoxicity, two terms which are often used interchangeably. Mutagenicity refers to direct damage to DNA that can be heritable or passed on from cell to cell, while genotoxicity covers a broader range of endpoints that are not transmissible from cell to cell or generation to generation. In other words, if a chemical is mutagenic, it is also genotoxic, but a chemical could be genotoxic without being mutagenic. Assays that measure mutagenicity are also considered measures of genotoxicity; however, all assays that measure genotoxicity are not indicative of mutagenic potential. Examples of assays that are measures of genotoxicity include unscheduled DNA synthesis (UDS), sister chromatid exchanges (SCEs) and DNA strand breaks. While UDS and SCEs are measures of genotoxicity, they are <u>not</u> measures of mutagenicity because the endpoints measured are not transmissible from cell to cell or generation to generation (Preston and Hoffman 2013). These differences need to be kept in mind when evaluating the data that NTP and others have generated in determining the potential mode of action of PCBTF and the relevant dose-response modeling approach.

In reviewing the available genotoxicity data for PCBTF, NTP (2018) concluded that PCBTF "may not directly cause mutations and initiate carcinogenesis," and that it "may be capable of inducing chromosomal damage at high levels of inhalation exposure in male mice," but that the mode of action for the carcinogenicity observed in rats and mice is "unlikely to be driven by genotoxicity." In other words, NTP (2018) found that PCBTF is neither mutagenic nor genotoxic. These NTP (2018) conclusions are critical as the results from this study are the only ones relied upon by OEHHA (2019) for the estimation of an IUR for PCBTF. NTP (2018) also is the authoritative review that initiated the Proposition 65 listing of PCBTF as a potential carcinogen.

In the Public Review Draft of the PCBTF IUR factor, OEHHA (2019) provides a summary of all available genotoxicity data for PCBTF from published and unpublished studies considered by OEHHA. (*See* Table 4.) The evidence provided in this table demonstrates that the weight of evidence for the genotoxicity and mutagenicity of PCBTF is negative. OEHHA (2019) itself concluded that "All studies of PCBTF mutagenicity have reported negative findings."

The limited positive evidence summarized in Table 4 has uncertainties related to the association between PCBTF administration and the endpoints observed. In addition, the *in vivo* and *in vitro* assays reported only provide measures of potential genotoxicity, but <u>not</u> mutagenicity. Each measure has serious limitations, as discussed below.

The only positive evidence of *in vivo* genotoxicity (and not mutagenicity) provided in Table 4 of OEHHA (2019) is micronucleus formation reported in NTP (2019). The increase in the incidence of micronuclei is only reported in male mice at the highest concentration of PCBTF tested (2000 ppm), with no similar increase noted in female mice or in male or female rats tested at similar concentrations. Further, the concentrations at which micronucleus formation was observed did not correspond with the concentrations at which tumors were observed in the NTP (2018) study, suggesting micronuclei are <u>not</u> part of the mode of action for the observed tumors in rodents. Considering the results from this *in vivo* assay, NTP (2018) concluded that genotoxicity is not part of the mode of action for the tumors observed in rodents following PCBTF exposure.

Regarding *in vitro* measures of potential genotoxicity, only two out of twenty entries in Table 4 of the IUR documentation provided evidence of genotoxicity *in vitro* (Benigni et al. 1982; Litton Bionetics 1979). The *in vitro* assays reported in these studies are the UDS assay in human embryonic epithelial cells (Benigni et al. 1982) and the SCE assay conducted in mouse lymphoma cells (Litton Bionetics (1979b). In addition to being nearly forty (40) years old, these assays have other serious limitations.

Although Benigni et al. (1982) reports a significant increase in the incidence of UDS following administration of the 3 highest concentrations of PCBTF (1, 2 and 10  $\mu$ l/ml) administered to cells from human skin and muscle explants, the incidences of UDS did not increase with increasing concentration. This may be related to the potential cytotoxicity of PCBTF. Importantly, as noted in a separate entry in Table 4 of OEHHA (2019), Benigni et al. (1982) also provides <u>negative</u> results for mutagenicity in the Ames assays. Benigni et al. (1982) reported that the lack of mutagenicity observed in the Ames assay they conducted was consistent with a lack of mutagenicity of PCBTF in a separate study in which Wistar rats were administered 100 mg PCBTF/kg bw/day for three days.

The Litton Bionetics (1979) study, in addition to being nearly 40 years old, is an unpublished report that provides the results of a SCE assay conducted in mouse lymphoma cells. While the frequency of SCEs reported is statistically significantly increased compared to the solvent control (DMSO), the frequency following administration of PCBTF is much closer to the solvent control incidences of SCE and much lower than those reported with the positive control (EMS). This would suggest only weak genotoxic potential for PCBTF, at best. In addition, as with the Benigni et al. (1982) study, the incidence of the measurement of genotoxicity, SCE/chromosome or SCE/cell, does <u>not</u> increase with increasing concentrations of PCBTF. This adds uncertainty to the association between PCBTF and the genotoxicity reported. As noted in Preston and Hoffman (2013), the results from both the UDS and SCE *in vitro* assays provide evidence of potential genotoxicity, but <u>not</u> mutagenicity.

Lastly, in addition to evaluating the potential mutagenicity and genotoxicity of PCBTF, OEHHA considered metabolites of PCBTF. In its report, OEHHA (2019) noted concern regarding the generation of a reactive and genotoxic metabolic intermediate that could potentially be of concern in determining the mutagenic potential of PCBTF. However, the potential for a mutagenic metabolite is <u>not</u> supported by the available evidence provided in Table 4 of OEHHA (2019) – the results from all mutagenicity assays incorporating metabolic activation are negative. Litton Bionetics (1979) provides results from the SCE assay in the presence of metabolic activation. The authors characterize the results of the assay as erratic. While three of the five dose levels yielded frequencies that were significantly greater than the solvent control frequency, there were concentrations, including the highest concentration tested, that failed to show any significant effect. The authors considered the results of the assay as positive but noted the lack of a clearly defined dose-response.

Accordingly, based on the evidence provided in Table 4 of OEHHA (2019), there is <u>no</u> evidence that PCBTF is mutagenic. There is, at best, limited evidence *in vitro* that PCBTF is genotoxic (Benigni et al. 1982: Litton Bionetics 1979); however, there is uncertainty in the results from these studies because there is no clearly defined association with exposure to PCBTF. Considering the uncertainties in the available positive assays, it is important to consider NTP's conclusions that PCBTF is <u>not</u> genotoxic or mutagenic and therefore, the assumption of low-dose linearity in estimating the potential carcinogenic risk from exposure to PCBTF is incorrect. As such, OEHHA should abandon use of its linear, no-threshold approach and instead derive a CSF/IUR using a threshold model. The available data suggests that there is a threshold below which exposure to PCBTF is without an appreciable increase in the risk of cancer.

# II. <u>OEHHA Did Not Consider All Available Data For the Mouse Liver Tumors –</u> <u>Specifically, OEHHA Did Not Conduct a Proper Assessment of the Mode of Action</u> <u>Identified by NTP, which is Supported by Available Data.</u>

OEHHA (2019) concluded that the mechanisms by which PCBTF causes tumors are not known. However, for the mouse liver tumors -- the endpoint upon which the recommended IUR is based -- OEHHA gave no consideration to the mode of action proposed by NTP (2018) for these tumors. Moreover, it appears that OEHHA made no attempt to evaluate the available mode of action data. Had OEHHA undertaken such a review, it would have discovered that the mode of action proposed by NTP (2018) for liver tumors in rodents is <u>not</u> relevant to human health. As such, the mouse liver tumor data should not be used to derive the CSF/IUR. A discussion of the available data is set forth below.

In the discussion of the NTP (2018) study, NTP offers the following conclusions related to the mode of action for mouse liver tumors:

- There is evidence that PCBTF exposure can lead to cytochrome P4502B (CYP2B) induction in the liver of rodents (Pelosi et al. 1998).
- Other cytochrome isoforms evaluated (e.g., cytochrome P4502E) showed higher activity in animals exposed to PCBTF; however, the strongest induction was CYP2B.
- CYP2B activation via the constitutive androstane receptor (CAR) is a known mechanism for tumor promotion activity in the liver of rodents (Sakamoto et al. 2013).
- Liver weights and nonneoplastic lesions observed in the NTP 3-month and 2-year studies are also consistent with a potential CAR-mechanism (Bucher et al. 1994; Parkinson et al. 2006).

Based on NTP's conclusion that the increased incidence of hepatocellular carcinomas reported in male and female mice following inhalation exposure to PCBTF could occur through a potential CAR-mechanism of action (MOA), Ramboll scientists conducted a review of the available results from toxicity studies for PCBTF. NTP (2018) suggested a CAR mode of action for the observed mouse liver tumors based on: (1) the observation of key events for the CAR-

MOA including reported increases in CYP2B activity in rats following oral exposure to PCBTF (Pelosi et al. 1998), (2) concentration-related increased liver weights in mice exposed to PCBTF via inhalation for 3 months (NTP 2018), and (3) the consistent evidence from standard *in vitro* assays that PCBTF is not genotoxic (NTP 2018). The key events focused on by NTP (2018) are also consistent with an adverse outcome pathway (AOP) for CAR activation available on the AOP Wiki (Figure 1), which is hosted by the Society for the Advancement of Adverse Outcome Pathways (SAAOP) and endorsed and supported by the US Army Engineer Research & Development Center (ERDC), the USEPA, the Organisation for Economic Co-operation and Development (OECD), the NTP and the European Commission (EC).

The data for PCBTF follow a familiar pattern for other well-known CAR-mediated chemicals, such as phenobarbital. Phenobarbital induced hepatocellular carcinomas in rodents are reported to occur through a CAR-MOA (Holsapple et al. 2006). Phenobarbital has been well-studied and the mode of action for rodent hepatic tumors well established; therefore, potential modes of action of other chemicals are often compared to the evidence for phenobarbital to establish the potential of a CAR-MOA. Holsapple et al. (2006) reports that phenobarbital is the prototype rodent hepatocarcinogen that induces liver tumors through the activation of CAR (a non-genotoxic mechanism) with associated key events that include increased cell proliferation, inhibition of apoptosis, hypertrophy, and the development of altered hepatic foci (Holsapple et al. 2006). The authors conclude that for compounds for which the data are consistent with a phenobarbital-like or CAR-MOA, the carcinogenic response is <u>not</u> relevant to humans. Evaluations for other compounds have concluded that rodent hepatocellular tumors occurring by the CAR-MOA are considered not relevant to human health (Elcombe et al. 2014; Yamamoto et al. 2004; Holsapple et al. 2006; Yamada et al. 2009).

The results from Ramboll's review of the toxicity data for PCBTF provide evidence of dose-response relationships (both oral and inhalation) between PCBTF and multiple key events and associative events in an established adverse outcome pathway for CAR-MOA for the induction of hepatocellular adenomas and carcinomas in rodents (Peffer et al. 2016). These key events and associative events are also consistent with the proposed AOP for CAR (Peffer et a. 2016) and those associated with phenobarbital-induced liver tumors in rodents (Holsapple et al. 2006; Elcombe et al. 2014; Yamamoto et al. 2004; Numazawa et al. 2005; Yoshiniari et al. 2001; Waxman and Azaroff 1992), all of which are <u>not</u> relevant to human health.

Accordingly, OEHHA's decision to rely on the male mouse liver tumors reported in the NTP (2018) study to establish the potential for carcinogenicity in humans is <u>not</u> based on a critical review of the available science for PCBTF. The available science for PCBTF is consistent with a mode of action (CAR activation) proposed by the NTP (2018) for male mice liver tumors (the endpoint relied upon for the OEHHA recommended IUR). Further, tumors occurring by this mode of action in rodents are <u>not</u> relevant to human health. As such, OEHHA should either abandon use of the mouse liver tumor data when developing the CSF/IUR or conduct a thorough analysis of the available data to evaluate the CAR mode of action and the

relevance of the mouse liver tumor data to human health. OEHHA should not proceed any further with the draft CSF/IUR without making these changes.

# III. <u>OEHHA Did Not Use Generally Accepted Modeling Approaches – Specifically, the</u> <u>Agency Relied Upon Draft Guidance, Ignoring OEHHA's Own Peer-Reviewed Final</u> <u>Guidance.</u>

When estimating the recommended IUR for PCBTF, OEHHA (2019) does not appear to have relied upon generally accepted methods for selecting a dose-response model. In addition, it appears that OEHHA (2019) failed to adequately assess the goodness-of-fit of the models it applied to the data. The agency also failed to use generally accepted time-to-tumor models to adjust for survival. These failures may have resulted in the agency over- or under-estimating the potential potency of PCBTF.

When selecting a dose-response model, OEHHA (2019) appears to have used methods taken from a 2014 draft operating procedure for USEPA subcontractors (reference to USEPA 2016 is incorrect in the IUR documentation) that was <u>never finalized</u>. These methods are inconsistent with those found in USEPA's well-established final BMDS Guidance (2012), as well as the OEHHA (2009) Technical Support Document. As noted previously, for detailed methods on dose-response, OEHHA (2009) defers to USEPA (2005) Guidelines for Carcinogen Risk Assessment.

In selecting the model for estimation of the IUR, a draft operating procedure (USEPA 2014) was cited by and relied on by OEHHA (2019) to choose the number of stages for cancer modeling. The approaches in that draft document are inconsistent with the well-established USEPA (2012) BMDS Guidance which has been through inter- and intra-agency review, an external peer review and a public workshop. This 2012 USEPA BMDS Guidance is recommended on the USEPA website accompanying the BMDS model and "provides guidance on the application of the benchmark dose approach for determining the point of departure for health effects data." Therefore, USEPA's (2012) BMDS Guidance represents accepted scientific methods across the scientific community whereas the draft operation procedure that OEHHA relied upon does <u>not</u>.

Assessing the goodness-of-fit of a model to the data is critical in selecting a benchmark dose and the first item listed in both Standard Operating Procedure for USEPA subcontractors (USEPA 2014) and USEPA BMDS Guidance (USEPA 2012) is reliance upon the Akaike's Information Criterion (AIC) for comparison across models. The AIC is <u>not</u> reported or relied upon for modeling decisions in the OEHHA (2019) Public Review Draft of the documentation of the IUR for PCBTF. OEHHA (2019) only reported p-values to characterize goodness-of-fit. However, according to the USEPA (2012) BMDS Guidance, goodness-of fit values, such as p-values, are <u>not</u> designed to compare results across models. Therefore, the lack of consideration of the AIC indicates that the fit of the models to the data has <u>not</u> been adequately assessed.

The method OEHHA (2019) used to adjust for differential early mortality or significant differences in survival is a crude approach and is not recommended in either the USEPA (2005) Guidelines for Carcinogen Risk Assessment or the OEHHA (2009) Technical Support Document. Rather, the application of time-to-tumor models are noted in both Guidance documents to account for significant decreases in survival. And therefore, currently accepted scientific approaches were <u>not</u> relied upon to adjust for survival.

The application of modeling approaches that are inconsistent with both finalized USEPA Guidelines and OEHHA Guidelines have resulted in the use of dose-response models that may not adequately characterize the available data. This may result in significant over- or underestimates of the potential potency of PCBTF. As such, OEHHA should re-evaluate the potential potency using generally accepted methods.

#### CONCLUSION

ACA and its members take their environmental stewardship responsibilities very seriously. PCBTF was developed as a substitute for use in ACA member products precisely because it assists in reducing the public health effects of ground level ozone. Currently, there are no viable alternatives available to replace PCBTF where it is used for this purpose. Accordingly, it is imperative that OEHHA's CSF/IUR accurately characterize the potential carcinogenicity of PCBTF, assuming there is such potential in humans. ACA urges OEHHA to revise its draft CSF/IUR before submitting it to the Scientific Review Panel. We believe the current draft document includes significant errors by not using the best available science, by failing to evaluate all available data, and by not using generally accepted methods.

Respectfully submitted,

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David Darling,

Vice President of Health, Safety and Environmental Affairs

cc: Philip A. Moffat, Verdant Law, PLLC

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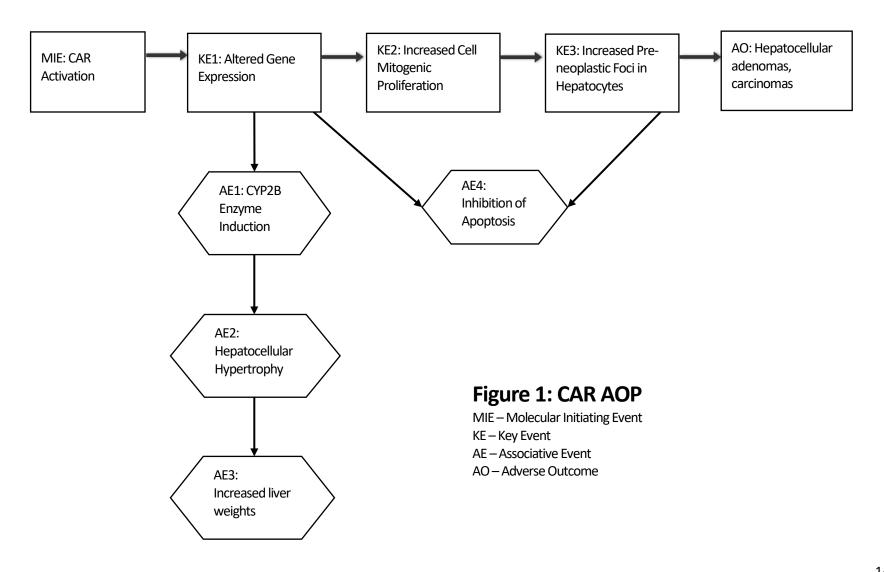
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December 17, 2019

Ms. Monet Vela Office of Environmental Health Hazard Assessment P.O. Box 4010, MS-23-11F Sacramento, California 95812-4010 *Submitted electronically through <u>https://oehha.ca.gov/comments</u>* 

Re: <u>Notice of Proposed Rulemaking Title 27, California Code of Regulations Amendment to</u> <u>Section 25705 Specific Regulatory Levels Posing No Significant Risk: P-Chloro-α,α,α-</u> <u>Trifluorotoluene (PCBTF)</u>

The American Coatings Association (ACA) offers the following comments on the Office of Environmental Health Hazard Assessment (OEHHA) proposed action to adopt a Proposition 65 No Significant Risk Level (NSRL) of 23 micrograms per day for p-Chloro- $\alpha$ , $\alpha$ , $\alpha$ trifluorotoluene (p-Chlorobenzotrifluoride, (PCBTF), by amending Title 27, California Code of Regulations, section 25705(B).<sup>1</sup> As explained throughout this letter, the ACA has serious concerns with the proposal. We are concerned about the lack of transparency related to the documentation of the Cancer Slope Factor (CSF) used in derivation of the proposed NSRL. We also are concerned about the scientific validity of the evidence and rationale that OEHHA has provided to the public in support of the NSRL. Accordingly, we request that OEHHA withdraw the current proposal and revise it as necessary to enable a meaningful public review as well as to correct deficiencies that we were able to identify after scrutinizing what information was made available to the public. We welcome the opportunity to discuss our comments with you in the near future.

Because of the highly technical nature of the science and approaches used in estimating the proposed NSRL, it should be noted that the ACA worked closely with consultants from Ramboll US Corporation to prepare these comments.

<sup>&</sup>lt;sup>1</sup> ACA is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA's mission includes programs and services that support the coatings industry's commitment to environmental protection, sustainability, product stewardship, health and safety, corporate responsibility, and the advancement of science and technology. Additional information is available on the ACA website, https://www.paint.org.

#### SUMMARY

OEHHA should withdraw and reissue the proposed NSRL. First, the Initial Statement of Reasons provides inadequate documentation to enable the ACA or others to validate the results of the modeling provided, frustrating effective public participation in OEHHA's development of the NSRL. Second, the CSF relied upon for the estimation of the NSRL does not employ the best available science, relying instead on inappropriate default assumptions. Moreover, the CSF is based on the results from an animal bioassay that is not representative of human exposure. And finally, the approach for deriving the CSF does not consider all of the available data. More specifically the ACA has the following concerns:

- The Initial Statement of Reasons provides limited information on the modeling approaches and assumptions used in estimation of the CSF. In the absence of assuming reliance on the Inhalation Unit Risk documentation under the Air Toxics Hot Spots Program (OEHHA 2019), the documentation provided in the Initial Statement of Reasons is inadequate to enable meaningful public evaluation of certain key aspects of the NSRL.
- In other places, OEHHA has not relied upon the best available science, opting instead to rely on default assumptions that are inconsistent with available data. The available data provide evidence of principles or assumptions that are scientifically more appropriate than the default no-threshold approach noted in the guidance provided in Title 27, California Code of Regulations, section 25703. Specifically, the available data show that PCBTF is not mutagenic. OEHHA (2019) itself observed this. The weight of evidence also demonstrates that PCBTF and its metabolites are not genotoxic. The National Toxicology Program (NTP 2018) also concluded that PCBTF is neither mutagenic nor genotoxic. Hence, OEHHA erred in applying linear low-dose extrapolation to PCBTF. OEHHA's use of linear, low-dose extrapolation in the estimation of the CSF likely overestimated the potential carcinogenic risk of PCBTF to humans, if any such risk actually exists, and impacts the determination of the NSRL.<sup>2</sup> Therefore, as the scientific

<sup>&</sup>lt;sup>2</sup> The ACA continues to assert that the data are insufficient to support listing PCBTF under Proposition 65. As indicated in its letter to Dr. Lauren Zeise, Ph.D., dated September 19, 2019, the association chose not to seek judicial review of the listing at that time. OEHHA should not interpret the ACA's decision as agreement with the PCBTF listing. As discussed in it comments to the proposed listing, the association believes that the PCBTF listing is inconsistent with the applicable legal and factual requirements for listing. ACA reviewed OEHHA's response to the association's comments and did not find it persuasive. ACA has attached its prior comments to today's letter and incorporates them by reference into the association's comments on the proposed NSRL. (*See* Attachment A.) Inasmuch as the association continues to challenge the basis of the listing decision, it also challenges OEHHA's assessment of the data when deriving the NSRL. Because OEHHA's "assessment [for purposes of deriving a NSRL] shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer[]" the ACA contends that both are legally defective.

evidence supports a threshold<sup>3</sup> approach for dose-response modeling, this approach should be applied in the derivation of the CSF and NSRL.

- In estimating the CSF, OEHHA relied on an animal bioassay that was conducted using exposures that are not representative of human exposures. The use of these data in the conduct of a quantitative risk assessment is inconsistent with the guidance in CCR section 25703.
- In deriving the CSF and the NSRL, OEHHA ignored available data. In the Initial Statement of Reasons, OEHHA states that the mechanisms by which PCBTF causes tumors are not known. However, for the mouse liver tumors relied upon -- the endpoint upon which the recommended CSF is based OEHHA gave no consideration to the mode of action proposed by NTP (2018) for these tumors. Moreover, it appears that OEHHA made no attempt to evaluate the available toxicity data in the publicly available literature relevant to understanding the mode of action. Had OEHHA undertaken such a review, it would have discovered that the available data for PCBTF are consistent with NTP's proposed mode of action and that tumors occurring in rodents by this mode of action are <u>not</u> relevant to human health. As such, the mouse liver tumor data should <u>not</u> be used to derive the CSF. Use of these data likely overestimates the potential for human health risk.

<sup>&</sup>lt;sup>3</sup> The existence of a threshold for effects should be welcome news to all stakeholders, including regulators and public health advocates. Even if one accepts OEHHA's assertion that PCBTF poses a risk of cancer to humans, if the risk of those effects only occurs above a certain threshold -- which could possibly be at a level that is above most, if not all, levels of human exposure -- then health protective measures can be clearly identified and communicated to users of the chemical, while also enabling the public to continue receiving the health benefits of reduced ground level ozone that is achieved through industry's use of this chemical as an "exempt" solvent in coatings. Results from available worker studies provide evidence of exposures for which higher than expected rates of the types of cancers observed in animals following exposure to PCBTF were not observed in the workers (Occidental Chemical Corporation 1992). This resulted despite PCBTF exposure having occurred in combination with more than 80 other chemicals and workers potentially having elevated levels of exposure compared to traditional consumers. Currently, there are no viable alternatives available to replace PCBTF where it is used as an exempt solvent. Hence, any regulatory action taken on this chemical must be based on an accurate, carefully calibrated and datadriven assessment of the potential risks to human health, if any. Over-regulating this chemical to avoid an uncertain hazard (i.e., potential health effects in humans) will only bring about the near-certain public health impacts of increased ground level ozone. If OEHHA questions this assertion, it should consult with CARB and other air regulators throughout the state.

## DISCUSSION

# I. <u>OEHHA Provided Limited Information on the Modeling Approaches and</u> Assumptions Used in Estimating the CSF, Resulting in Difficulties Determining if the Guidance in CCR Section 25703 Was Followed.

In the Initial Statement of Reasons, documentation of the methods and assumptions that OEHHA used in the estimation of the CSF potency is limited and not fully transparent. This made it difficult for the ACA to conduct a full review of the underlying assumptions and results. For example, no modeling results or data are provided to support the decision that the two-year inhalation studies conducted by NTP (2018) in male and female mice met the criterion in CCR section 25703 as being the most sensitive study of sufficient quality. Further, there are no results to demonstrate that the models applied in the estimation of the CSF adequately fit the data from the NTP (2018) study.

It could be assumed that the conclusions provided in the Initial Statement of Reasons are based upon modeling approaches and results that were conducted as part of the development of the Inhalation Unit Risk Factor under the Air Toxics Hot Spots Program (OEHHA 2019). However, there is no reference to this document. Therefore, in the absence of relying on the IUR documentation, there are inadequate details provided in the Initial Statement of Reasons on the methods and approaches relied on in estimating the CSF. This deficiency in the record also may have frustrated effective participation by other members of the public and the Cancer Identification Committee (CIC) in OEHHA's derivation of the NSRL.

However, if ACA assumes that, when estimating the CSF, OEHHA relied upon the modeling results provided in the IUR documentation (OEHHA (2019)), then the ACA asserts that OEHHA did <u>not</u> rely on generally accepted methods for selecting a dose-response model. In addition, OEHHA (2019) appears to have failed to adequately assess the goodness-of-fit of the models it applied to the data. These failures may have resulted in the over- or under-estimation of the potential potency of PCBTF and therefore affected the CSF relied upon in the Initial Statement of Reasons.

When selecting a dose-response model, OEHHA (2019) appears to have used methods taken from a 2014 draft operating procedure for United States Environmental Protection Agency (USEPA) subcontractors (reference to USEPA 2016 is incorrect in the IUR documentation) that was never finalized. These methods are inconsistent with those found in USEPA's well-established final BMDS Guidance (2012), as well as the OEHHA (2009) Technical Support Document. As noted previously, for detailed methods on dose-response, OEHHA (2009) defers to USEPA (2005) Guidelines for Carcinogen Risk Assessment.

In selecting the model for estimation of the IUR, a draft operating procedure (USEPA 2014) was cited by and relied on by OEHHA (2019) to choose the number of stages for cancer modeling. The approaches in that draft document are inconsistent with the well-established USEPA (2012) BMDS Guidance which has been through inter- and intra-agency review, an

external peer review and a public workshop. This 2012 USEPA BMDS Guidance is recommended on the USEPA website accompanying the BMDS model and "provides guidance on the application of the benchmark dose approach for determining the point of departure for health effects data." Therefore, USEPA's (2012) BMDS Guidance represents accepted scientific methods across the scientific community whereas the draft operation procedure that OEHHA relied upon does <u>not</u>.

Assessing the goodness-of-fit of a model to the data is critical in selecting a benchmark dose and the first item listed in both Standard Operating Procedure for USEPA subcontractors (USEPA 2014) and USEPA BMDS Guidance (USEPA 2012) is reliance upon the Akaike's Information Criterion (AIC) for comparison across models. The AIC is <u>not</u> reported or relied upon for modeling decisions in the OEHHA (2019) Public Review Draft of the documentation of the IUR for PCBTF. OEHHA (2019) only reported p-values to characterize goodness-of-fit. However, according to the USEPA (2012) BMDS Guidance, goodness-of fit values, such as pvalues, are <u>not</u> designed to compare results across models. Therefore, the lack of consideration of the AIC indicates that the fit of the models to the data has not been adequately assessed.

The application of modeling approaches by OEHHA (2019) that are inconsistent with both finalized USEPA Guidelines and OEHHA Guidelines would have resulted in the use of dose-response models that may not adequately characterize the available data in the estimation of the IUR. If these same approaches were applied in the estimation of the CSF, and therefore the NSRL, provided in the Initial Statement of Reasons, this may have resulted in significant overor underestimates of the potential potency of PCBTF. As such, OEHHA should re-evaluate the potential CSF using generally accepted methods. If, instead, OEHHA used different modeling approaches than those used in OEHHA (2019), the agency should make those available for public review and comment.

# II. <u>OEHHA Is Relying on an Inappropriate Default Assumption and Is Not Using the</u> <u>Best Available Science to Derive the CSF Used for Calculation of the NSRL –</u> <u>Specifically, Assuming the Mutagenicity of PCBTF and Low-Dose Linearity for</u> <u>Cancer Risk is Inconsistent with Available Data.</u>

In the estimation of both the CSF and NSRL for PCBTF, OEHHA has assumed linear low-dose extrapolation which is based on the mutagenic potential of a chemical. This default assumption is incorrect. The available data show that PCBTF is <u>not</u> mutagenic. The available data also demonstrate that PCBTF and its metabolites are <u>not</u> genotoxic. OEHHA's approach in the Initial Statement of Reasons is inconsistent with conclusions reached by NTP (2018), which found that PCBTF is neither mutagenic nor more generally genotoxic. In OEHHA (2019), it is stated that "All studies of PCBTF mutagenicity have reported negative findings." In the absence of data supporting mutagenicity, it is inappropriate for OEHHA to use a linear no-threshold approach to derive a CSF/IUR or NSRL for PCBTF. Instead, OEHHA should have used a nonlinear approach, as explained further in the paragraphs below.

The linear no-threshold methods that have been used in the estimation of the CSF and NSRL assume that there is a risk of cancer with any exposure to PCBTF. This assumption is premised on exposure to a chemical causing alteration in the DNA (e.g., mutagenicity) that are transmitted to successive cell generations. OEHHA's (2009) Technical Support Document for Cancer Potency Factors, which sets forth the methods OEHHA uses to derive CSFs, states:

"The procedures used to extrapolate low-dose human cancer risk from animal carcinogenicity data <u>assumed that a carcinogenic change induced in a cell is transmitted</u> to successive generations of cells descendants, and that the initial change in the cell is an <u>alteration (e.g., mutation, rearrangement, etc.) in the cellular DNA</u>. Non-threshold models are used to extrapolate to low dose human cancer risk from animal carcinogenicity data." (Emphasis added.)

However, when a chemical is <u>not</u> mutagenic – as is the case with PCBTF – the application of non-threshold or linear approaches is inappropriate. The lack of mutagenicity of PCBTF provides scientific evidence in contrast to the default assumptions outlined for quantitative risk assessment in CCR section 25703, which are to be applied only in the absence of principles or assumptions scientifically more appropriate. This lack of evidence of mutagenicity for PCBTF, combined with the available toxicity data for PCBTF, indicate that OEHHA's assumption of the absence of a carcinogenic threshold is <u>not</u> supported by the scientific evidence for PCBTF.

Other authorities, such as the USEPA, also agree that a no-threshold approach is inappropriate for compounds that are not mutagenic. For example, OEHHA (2009) refers to and relies on the USEPA (2005) Cancer Guidelines for additional details on the dose-response modeling used for estimation of CSFs. The USEPA (2005) guidelines indicate that linear extrapolation should be used for agents that are DNA-reactive and have direct mutagenic activity. However, when a chemical is <u>not</u> mutagenic – as is the case with PCBTF -- USEPA (2005) provides guidelines for a <u>nonlinear</u> approach.

When evaluating the potential for mutagenicity of PCBTF or for any compound, it is important to understand the differences between mutagenicity and genotoxicity, two terms which are often used interchangeably. Mutagenicity refers to direct damage to DNA that can be heritable or passed on from cell to cell, while genotoxicity covers a broader range of endpoints that are not transmissible from cell to cell or generation to generation. In other words, if a chemical is mutagenic, it is also genotoxic, but a chemical could be genotoxic without being mutagenic. Assays that measure mutagenicity are also considered measures of genotoxicity; however, all assays that measure genotoxicity are not indicative of mutagenic potential. Examples of assays that are measures of genotoxicity include unscheduled DNA synthesis (UDS), sister chromatid exchanges (SCEs) and DNA strand breaks. While UDS and SCEs are measures of genotoxicity, they are <u>not</u> measures of mutagenicity because the endpoints measured are not transmissible from cell to cell or generation to generation (Preston and Hoffman 2013). These differences need to be kept in mind when evaluating the data that NTP and others have

generated in determining the potential mode of action of PCBTF and the relevant dose-response modeling approach.

In reviewing the available genotoxicity data for PCBTF, NTP (2018) concluded that PCBTF "may not directly cause mutations and initiate carcinogenesis," and that it "may be capable of inducing chromosomal damage at high levels of inhalation exposure in male mice," but that the mode of action for the carcinogenicity observed in rats and mice is "unlikely to be driven by genotoxicity." In other words, NTP (2018) found that PCBTF is neither mutagenic nor genotoxic. These NTP (2018) conclusions are critical as the results from this study are the only ones relied upon in the Initial Statement of Reasons for the estimation of an CSF for PCBTF. NTP (2018) also is the authoritative review that initiated the Proposition 65 listing of PCBTF as a potential carcinogen.

In the Initial Statement of Reasons for the NSRL, OEHHA notes the mostly negative findings from genotoxicity assays reported by NTP (2018), but few details are provided. However, if ACA assumes OEHHA used the same data as was used in derivation of the CSF and IUR (OEHHA (2019)), a summary of all available genotoxicity data for PCBTF from published and unpublished studies is available. (See Table 4 in OEHHA 2019.) The evidence provided in that table demonstrates that the weight of evidence for the genotoxicity and mutagenicity of PCBTF is negative. OEHHA (2019) itself concluded that "All studies of PCBTF mutagenicity have reported negative findings." However, in the Initial Statement of Reasons for the NSRL, limited information is provided regarding the genotoxicity assays conducted, potentially frustrating stakeholder review. Positive results are reported in the Initial Statement of Reasons for the induction of sister chromatid exchanges in mouse lymphoma cells and micronuclei in mature erythrocytes of male mice following a three-month exposure to PCBTF. The remaining assays listed were reported to be negative. Based on Table 4 from OEHHA (2019), the positive assays listed in the Initial Statement of Reasons are assumed to be the NTP (2018) study (micronuclei) and the Litton Bionetics (1979) study (sister chromatid exchanges). The results from these assays only provide measures of potential genotoxicity, but not mutagenicity. In addition, each measure has serious limitations, as discussed below.

The positive evidence of *in vivo* genotoxicity (and not mutagenicity) is micronucleus formation reported in NTP (2019). It has uncertainties related to the association between PCBTF administration and the endpoints observed. The increase in the incidence of micronuclei is only reported in male mice at the highest concentration of PCBTF tested (2000 ppm), with no similar increase noted in female mice or in male or female rats tested at similar concentrations. Further, the concentrations at which micronucleus formation was observed did <u>not</u> correspond with the concentrations at which tumors were observed in the NTP (2018) study, suggesting micronuclei are <u>not</u> part of the mode of action for the observed tumors in rodents. Considering the results from this *in vivo* assay, NTP (2018) concluded that genotoxicity is <u>not</u> part of the mode of action for the tumors observed.

The Litton Bionetics (1979) study, in addition to being nearly 40 years old, is an unpublished report that provides the results of an *in vitro* SCE induction assay conducted in mouse lymphoma cells. While the frequency of SCEs reported is statistically significantly increased compared to the solvent control (DMSO), the frequency following administration of PCBTF is much closer to the solvent control incidences of SCE and much lower than those reported with the positive control (EMS). This would suggest only weak genotoxic potential for PCBTF, at best. In addition, the incidence of the measurement of genotoxicity, SCE/chromosome or SCE/cell, does <u>not</u> increase with increasing concentrations of PCBTF. This adds uncertainty to the association between PCBTF and the genotoxicity reported. As noted in Preston and Hoffman (2013), the results from the SCE *in vitro* assay provide evidence of potential genotoxicity, but <u>not</u> mutagenicity.

Accordingly, there is <u>no</u> evidence that PCBTF is mutagenic. There is, at best, limited evidence *in vitro* that PCBTF is genotoxic (Litton Bionetics 1979); however, there is uncertainty in the results from this study because there is no clearly defined association with exposure to PCBTF. Considering the uncertainties in the noted positive assays, it is important to consider NTP's conclusions that PCBTF is <u>not</u> genotoxic or mutagenic and therefore, the assumption of low-dose linearity in estimating the potential carcinogenic risk from exposure to PCBTF is incorrect. As such, OEHHA should abandon use of its linear, no-threshold approach and instead derive a CSF/IUR using a threshold model. The available data suggests that there is a threshold below which exposure to PCBTF is without an appreciable increase in the risk of cancer.

## III. <u>The Animal Bioassay that OEHHA Relies on to Estimate the NSRL Does Not</u> <u>Resemble the Expected Manner of Human Exposure</u>

The lack of mutagenic evidence for PCBTF suggests a potential nonlinear mode of action by which carcinogenic effects, if any, may occur in humans following exposure to high concentrations above a threshold concentration. This threshold could possibly be higher than expected human exposures. The National Research Council (2014) notes the importance of assessing evidence that environmental chemicals can cause adverse health effects based on what is known about current human exposure levels. The exposures administered to mice in the NTP (2018) study, as well as the exposures at which tumors were observed, are concentrations orders of magnitude higher than human exposures (100 ppm in mice, compared to 1.15 ppm occupational exposure) (Lee 2015). Therefore, the dosing in the NTP (2018) study does not resemble the expected manner of human exposure, calling into question its use for the derivation of the NSRL. Accordingly, the use of these data in the conduct of a quantitative risk assessment appears inconsistent with the guidance in CCR section 25703.

# IV. <u>OEHHA Did Not Consider All Available Data for the Mouse Liver Tumors –</u> <u>Specifically, OEHHA Did Not Conduct a Proper Assessment of the Mode of Action</u> <u>Identified by NTP, which is Supported by Available Data.</u>

In the Initial Statement of Reasons, OEHHA states that the mechanisms by which PCBTF causes tumors are not known. However, for the mouse liver tumors -- the endpoint upon which the recommended CSF is based – OEHHA gave <u>no</u> consideration to the mode of action proposed by NTP (2018), the very authoritative body upon which OEHHA has relied for the Proposition 65 listing and the derivation of the CSF, IUR, and NSRL. Moreover, it appears that OEHHA made no attempt to evaluate the publicly available mode of action data. Had OEHHA undertaken such a review, it would have discovered that the mode of action proposed by NTP (2018) for liver tumors in rodents is <u>not</u> relevant to human health. As such, the mouse liver tumor data should <u>not</u> be used to derive the CSF or NSRL. A discussion of the publicly available data is set forth below.

In the discussion of the NTP (2018) study, NTP offers the following conclusions related to the mode of action for mouse liver tumors:

- There is evidence that PCBTF exposure can lead to cytochrome P4502B (CYP2B) induction in the liver of rodents (Pelosi et al. 1998).
- Other cytochrome isoforms evaluated (e.g., cytochrome P4502E) showed higher activity in animals exposed to PCBTF; however, the strongest induction was CYP2B.
- CYP2B activation via the constitutive androstane receptor (CAR) is a known mechanism for tumor promotion activity in the liver of rodents (Sakamoto et al. 2013).
- Liver weights and nonneoplastic lesions observed in the NTP 3-month and 2-year studies are also consistent with a potential CAR-mechanism (Bucher et al. 1994; Parkinson et al. 2006).

Based on NTP's conclusion that the increased incidence of hepatocellular carcinomas reported in male and female mice following inhalation exposure to PCBTF could occur through a potential CAR-mechanism of action (MOA), Ramboll scientists conducted a review of the available results from toxicity studies for PCBTF. NTP (2018) suggested a CAR mode of action for the observed mouse liver tumors based on: (1) the observation of key events for the CAR-MOA including reported increases in CYP2B activity in rats following oral exposure to PCBTF (Pelosi et al. 1998), (2) concentration-related increased liver weights in mice exposed to PCBTF via inhalation for 3 months (NTP 2018), and (3) the consistent evidence from standard *in vitro* assays that PCBTF is not genotoxic (NTP 2018). The key events focused on by NTP (2018) are also consistent with an adverse outcome pathway (AOP) for CAR activation available on the AOP Wiki (Figure 1), which is hosted by the Society for the Advancement of Adverse Outcome Pathways (SAAOP) and endorsed and supported by the US Army Engineer Research & Development Center (ERDC), the USEPA, the Organisation for Economic Co-operation and Development (OECD), the NTP and the European Commission (EC).

The data for PCBTF follow a familiar pattern for other well-known CAR-mediated chemicals, such as phenobarbital. Phenobarbital induced hepatocellular carcinomas in rodents are reported to occur through a CAR-MOA (Holsapple et al. 2006). Phenobarbital has been well-studied and the mode of action for rodent hepatic tumors well established; therefore, potential modes of action of other chemicals are often compared to the evidence for phenobarbital to establish the potential of a CAR-MOA. Holsapple et al. (2006) reports that phenobarbital is the prototype rodent hepatocarcinogen that induces liver tumors through the activation of CAR (a non-genotoxic mechanism) with associated key events that include increased cell proliferation, inhibition of apoptosis, hypertrophy, and the development of altered hepatic foci (Holsapple et al. 2006). The authors conclude that for compounds for which the data are consistent with a phenobarbital-like or CAR-MOA, the carcinogenic response is <u>not</u> relevant to humans. Evaluations for other compounds have concluded that rodent hepatocellular tumors occurring by the CAR-MOA are considered not relevant to human health (Elcombe et al. 2014; Yamamoto et al. 2004; Holsapple et al. 2006; Yamada et al. 2009).

The results from Ramboll's review of the toxicity data for PCBTF provide evidence of dose-response relationships (both oral and inhalation) between PCBTF and multiple key events and associative events in an established adverse outcome pathway for CAR-MOA (Figure 1) for the induction of hepatocellular adenomas and carcinomas in rodents (Peffer et al. 2016). These key events and associative events are also consistent with the proposed AOP for CAR (Peffer et a. 2016) and those associated with phenobarbital-induced liver tumors in rodents (Holsapple et al. 2006; Elcombe et al. 2014; Yamamoto et al. 2004; Numazawa et al. 2005; Yoshiniari et al. 2001; Waxman and Azaroff 1992), all of which are <u>not</u> relevant to human health.

Accordingly, OEHHA's decision to rely on the male mouse liver tumors reported in the NTP (2018) study to establish the potential for carcinogenicity in humans in the Initial Statement of reasons is <u>not</u> based on a critical review of the available science for PCBTF. The available science for PCBTF is consistent with a mode of action (CAR activation) proposed by the NTP (2018) for male mice liver tumors (the endpoint relied upon for the OEHHA proposed NSRL). Further, tumors occurring by this mode of action in rodents are <u>not</u> relevant to human health. As such, OEHHA should either abandon use of the mouse liver tumor data when developing the CSF and NSRL or conduct a thorough analysis of the available data to evaluate the CAR mode of action and the relevance of the mouse liver tumor data to human health. OEHHA should not proceed any further with the proposed NSRL without making these changes.

#### CONCLUSION

ACA and its members take their environmental stewardship responsibilities very seriously. PCBTF was developed as a substitute for use in ACA member products precisely because it assists in reducing the public health effects of ground level ozone. Currently, there are no viable alternatives available to replace PCBTF where it is used for this purpose. Accordingly, it is imperative that OEHHA's CSF and NSRL accurately characterize the potential

carcinogenicity of PCBTF, assuming there is such potential in humans. ACA urges OEHHA to consider these comments prior to finalizing the NSRL. We believe the current data and assumptions used in the derivation of the NSRL includes significant errors by not using the best available science and by failing to evaluate all available data. Further, the available data for PCBTF provides evidence of principles or assumptions that are scientifically more appropriate than the default no-threshold approach from CCR section 25703 applied in the estimation of the CSF and NSRL. Therefore, as the scientific evidence supports threshold approach for dose-response modeling, this approach should be applied in the derivation of the CSF and NSRL. We request that OEHHA withdraw the proposal and reissue it after correcting its deficiencies.

Respectfully submitted,

and Darly

David Darling,

Vice President of Health, Safety and Environmental Affairs

cc: Philip A. Moffat, Verdant Law, PLLC

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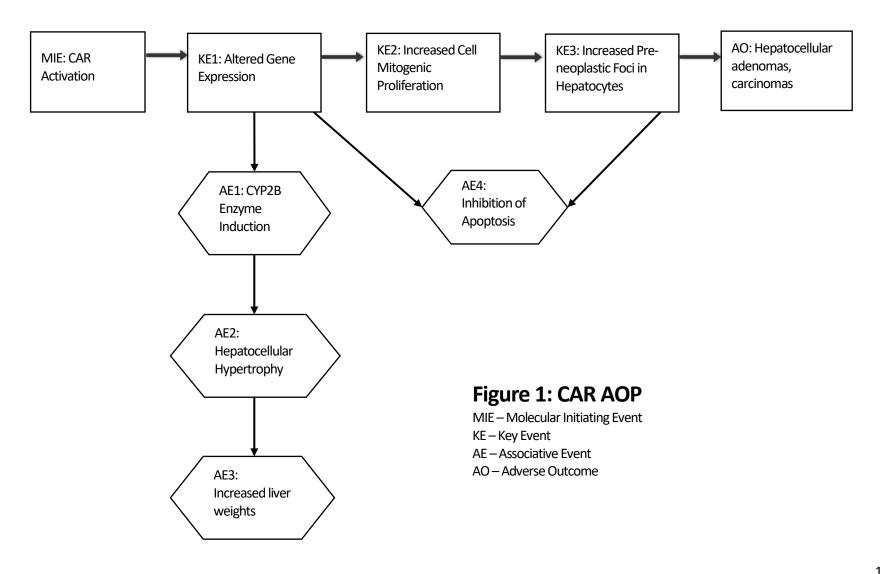
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# ATTACHMENT A



January 23, 2019

Julian Leichty Office of Environmental Health Hazard Assessment P.O. Box 4010, MS-12B Sacramento, California 95812-4010

Submitted electronically through <u>https://oehha.ca.gov/comments</u>

# Re: Notice of Intent to List: p-Chloro-α,α,α-trifluorotoluene (Para-Chlorobenzotrifluoride, PCBTF) (November 23, 2018)

Dear Mr. Leichty:

The American Coatings Association (ACA) offers the following comments on the Office of Environmental Health Hazard Assessment (OEHHA) Notice of Intent to List: p-Chloro- $\alpha$ , $\alpha$ , $\alpha$ -trifluorotoluene (Para-Chlorobenzotrifluoride, PCBTF) (CASRN 98-56-6).<sup>1</sup>

ACA's comments may be summarized as follows:

- 1. Use of PCBTF in paint, sealant, and similar products assists in reducing ambient concentrations of ozone, thereby providing important public health benefits that may be eliminated unnecessarily if PCBTF is listed. Currently, there are no viable alternatives available to replace PCBTF in those formulations in which it is being used.
- 2. OEHHA is required to perform a weight of evidence analysis, considering the record as a whole, to determine whether PCBTF should be listed as known to cause cancer.

<sup>&</sup>lt;sup>1</sup> ACA is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA's mission includes programs and services that support the coatings industry's commitment to environmental protection, sustainability, product stewardship, health and safety, corporate responsibility, and the advancement of science and technology. Additional information is available on the ACA website, https://www.paint.org.

- 3. The available record as a whole does not provide "sufficient evidence" of carcinogenicity as required by the "authoritative body" regulation (27 CCR 25306). OEHHA is required to "determine which chemicals have been formally identified by an authoritative body as causing cancer under 27 CCR 25306(c). "As causing cancer" means "sufficient evidence" of carcinogenicity exists from studies in experimental animals. "Sufficient evidence" means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors: (1) in multiple species or strains; (2) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (3) to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset (27 CCR 25306(e)(2)).
  - a. <u>PCBTF has not been "formally identified."</u> The National Toxicology Program (NTP) Report on which OEHHA relies does not "formally identify" PCBTF as an animal carcinogen because the Report does not conclude that PCBTF causes cancer after applying a proper weight of evidence analysis.
  - b. <u>OEHHA lacks sufficient evidence in "multiple species."</u> The NTP Report, which discusses the study that the NTP conducted as well as the scientific literature for PCBTF at the time of the report, does not demonstrate sufficient evidence of carcinogenicity in "multiple species" – malignancy in particular – as required in the authoritative body regulation. Results were produced in mice and rats, but NTP concluded that there is only "some evidence" of carcinogenicity in the rat. Further, because historical control data were not available for the rat, NTP could not clearly determine whether the observed tumors were occurring at rates above background. Importantly there was not substantial evidence of a progression to malignancy. Accordingly, the rat data do not demonstrate an "increased incidence" of malignant tumors as required by the authoritative body regulation at 27 CCR 25306(e)(2) and therefore the "multiple species" requirement is not satisfied.
  - c. <u>OEHHA lacks sufficient evidence in "multiple experiments."</u> The NTP Report does not demonstrate sufficiency of evidence in "multiple experiments" utilizing different routes of administration or different dose levels, as required by the authoritative body regulation. While the 2-year mouse bioassay found evidence of tumors in both sexes of the mouse, this finding has not been replicated in two or more independent studies carried out at different times or in different laboratories or under different protocols. Further, all of the results in the mouse involved the same route of administration (inhalation) and the same three dose

levels, yet they failed to produce a consistent tumor response across doses within the species. And even if male and female mouse data from a single study were to be considered "multiple experiments," such data are not definitive proof of causality alone. This is particularly true for PCBTF when the same route of administration and dosing were utilized, the observations are inconsistent, the tumor types are known to commonly occur in this strain of mice spontaneously, and the most plausible mode of action suggested by the NTP is of questionable relevance.

- d. <u>No Mode of Action Has Been Identified</u>. PCBTF was not found to be genotoxic, leading NTP to propose no mode of action and to suggest that further mechanistic studies are needed. Although the NTP did not propose a mode of action at this time for the liver tumors in the mouse, the agency noted that the data are consistent with a potential constitutive androstane receptor (CAR)-mode of action, which is not considered relevant to humans.
- e. <u>Exposure Levels are Not Representative of Human Exposures</u>. The observed effects occurred at concentrations orders of magnitude higher than human exposures, and further review is required to determine whether the observed animal tumors are relevant to human health and whether there is a threshold below which carcinogenicity would not be expected.

For these reasons, ACA urges OEHHA to determine that the NTP Report is not a sufficient basis for listing PCBTF. These points are discussed in detail below. To develop these points, the ACA enlisted the assistance of Ramboll US Corporation (f/k/a Environ International Corporation, Inc.). Attached and incorporated into this letter is a memorandum prepared by Ramboll (hereinafter "the Ramboll report") evaluating the sufficiency of the NTP Report as support for the proposed listing.

#### **PCBTF Uses**

To improve air quality, attain federal and state ozone standards and protect public health, air quality regulatory agencies such as the South Coast Air Quality Management District (SCAQMD), adopt regulations that limit emissions of VOCs and oxides of nitrogen (NOx), which form ground level ozone in the atmosphere. Certain VOCs are less reactive in the atmosphere and, therefore, do not contribute significantly to the formation of ozone. Exempting solvents with negligible reactivity helps agencies meet air quality goals while allowing manufacturers the flexibility to formulate products meeting strict VOC content limits. Industries affected by VOC regulations petition air quality regulators to exempt from the VOC definition compounds that have been deemed negligibly reactive by EPA. One of those exempt compounds is PCBTF. Currently, there are no viable alternatives available to replace PCBTF in those formulations in which it is being used. If the substance is listed by OEHHA, air quality regulators may be prompted to remove the exemption, eliminating the public health benefits from ozone reductions that flow from use of PCBTF in paint, sealant, and similar products. The Proposition 65 statute was intended to protect public health. See *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 258 (2011). Use of PCBTF in paint, sealant, and similar products provides important public health benefits, through related reductions in ambient ozone that may be eliminated unnecessarily if PCBTF is listed. Prior to listing PCBTF, OEHHA should perform a thorough weight of evidence analysis as required by the authoritative body regulations.

#### Weight of Evidence Analysis

The 1990 Statement of Reasons underlying the OEHHA authoritative body regulation explains that the regulation "utilizes the EPA's Classification System for Categorizing Weight of Evidence for Carcinogens From Human and Animal Studies (51 Fed. Reg. 33999 (Sept. 24, 1986))" (p.15) (hereinafter "EPA's 1986 Cancer Classification Guidelines"). In describing this system, EPA stated:

EPA has developed a system for stratifying the weight of evidence . . . This classification is not meant to be applied rigidly or mechanically. At various points in the above discussion, EPA has emphasized the need for an overall, balanced judgment of the totality of the available evidence . . . Therefore, the hazard identification section should include a narrative summary of the strengths and weaknesses of the evidence as well as its categorization in the EPA scheme (51 Fed. Reg. 33996).

The 1990 Statement of Reasons also explains that "Under the regulation, there is no automatic adoption of an authoritative body's list. The Agency [i.e., OEHHA] will investigate to make certain that there are sufficient animal or human data" (p. 17).

Similarly, the courts have recognized that OEHHA must scrutinize the whole record compiled by an authoritative body to determine whether there is substantial evidence to support a listing. In *Exxon Mobil v. OEHHA*, 169 Cal. App. 4<sup>th</sup> 1264, 1278, 1280-81 (2009) (emphasis in original):

[O]nce the chemical is "formally identified" by an authoritative body . . . *OEHHA* reviews the scientific record before the authoritative body to determine whether there is substantial evidence to support a listing.

\* \* \* \*

Nothing in [the authoritative body regulation] suggests, however, that OEHHA must base this conclusion *solely* on the authoritative body's report. Rather, as OEHHA suggests, the language of [the regulation] is

broad enough to allow OEHHA to premise its conclusion on the authoritative body's report *and other factors*, such as the scientific literature on which the authoritative body relied and OEHHA's knowledge of the authoritative body's methodology. In other words, so long as OEHHA is able to conclude on the basis of the authoritative body's report *and the underlying scientific record* that an authoritative body has identified a chemical . . . and that the identification takes the regulatory criteria into account, OEHHA may list it . . .

\* \* \* \*

We do not agree . . . that the authoritative body's *report* is the only permissible evidence that the authoritative body made the regulatory findings. Rather, as we have said, we believe that OEHHA properly can conclude that the authoritative body made the necessary findings based on OEHHA's review of the scientific literature on which the authoritative body relied and its knowledge of the authoritative body's methodology. So long as OEHHA can conclude, on the basis of the <u>entire record</u> before it, that the authoritative body made the [required] findings, it may list a chemical pursuant to the authoritative body provision of the statute.

With respect to PCBTF, consideration of the scientific body of evidence reported by NTP in the agency's technical report leads to a conclusion that the available evidence is not sufficient to list PCBTF as a carcinogen, for reasons to which we now turn.

#### The NTP Report and OEHHA Authoritative Body Regulation

OEHHA's Notice of Intent to List PCBTF relies on the NTP report, which presents the results of animal testing and discusses the available scientific body of literature at the time of the NTP report. OEHHA's authoritative body regulation for listing based on determinations by an authoritative body consist of several elements:

- 1. OEHHA is required to "determine which chemicals have been formally identified by an authoritative body as causing cancer;"
- 2. A chemical is "formally identified" by an authoritative body when [OEHHA] determines that the chemical has been included on a list of chemicals causing cancer issued by the authoritative body; or is the subject of a report which is published by the authoritative body and <u>which concludes that the chemical causes cancer</u> or reproductive toxicity; or has otherwise been identified as causing cancer or reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action;
- 3. "As causing cancer" means "sufficient evidence" of carcinogenicity exists from studies in experimental animals;

4. "Sufficient evidence" means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in <u>multiple species or strains</u>, [or] <u>in multiple experiments</u> (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset (27 CCR 25306(c)-(e)). (Emphasis added.)

The NTP report and associated record do not satisfy these listing requirements.

First, NTP does not "formally identify" PCBTF as an animal carcinogen within the meaning of the "authoritative body regulation because the required weight of evidence (as discussed above) was not performed by NTP.<sup>2</sup> Further, the NTP Report does not specifically conclude that PCBTF "causes cancer." NTP merely finds "clear evidence" of carcinogenicity in mice, and "some evidence" in rats. These conclusions are explained in the Report as follows:

**Clear evidence** of carcinogenic activity is demonstrated by studies that are interpreted as showing a dose-related (i) increase of malignant neoplasms, (ii) increase of a combination of malignant and benign neoplasms, or (iii) marked increase of benign neoplasms if there is an indication from this or other studies of the ability of such tumors to progress to malignancy.

**Some evidence** of carcinogenic activity is demonstrated by studies that are interpreted as showing a chemical-related increased incidence of neoplasms (malignant, benign, or combined) in which the strength of the response is less than that required for clear evidence (p. 13).

Accordingly, while the NTP Report and associated record describe the strength of the evidence provided by the animal testing, NTP does not apply a weight of the evidence approach to determine that the evidence is sufficient, as defined in the authoritative body regulation, to conclude that PCBTF is an animal carcinogen.<sup>3</sup> Therefore, NTP did

<sup>&</sup>lt;sup>2</sup> At present, PCBTF has not been added to the NTP Report on Carcinogens, and NTP has not proposed to do so. The NTP Criteria for listing a substance as a "reasonably anticipated" human carcinogen, on the basis of animal studies alone, are nearly identical to the OEHHA criteria for "sufficient evidence" in animals.<sup>2</sup> However NTP has not yet performed that weight of the evidence analysis. See <a href="https://ntp.niehs.nih.gov/pubhealth/roc/process/index.html">https://ntp.niehs.nih.gov/pubhealth/roc/process/index.html</a>.

<sup>&</sup>lt;sup>3</sup> The 1990 Statement of Reasons notes that "if an authoritative body properly applies a strength-of-theevidence approach, the Agency will not substitute its judgment on the basis of negative data, unless new data not considered by the authoritative body clearly establishes that there is not sufficient evidence in either animals or humans" (p. 17). In this case, however, the NTP approach does not rise to the level of a proper "weight of evidence" analysis or meet the criteria for sufficiency in the OEHHA regulations. Further, the evidence against listing PCBTF is not limited to negative data, but also includes the limitations of the positive data, as discussed further throughout these comments.

not "formally identify" PCBTF because it did not conclude that the chemical causes cancer.<sup>4</sup>

Second, a proper weight of evidence analysis of the entire NTP record indicates that the evidence is insufficient to support listing at this time because the "as causing cancer" requirement is not met. As discussed above, "as causing cancer" means "sufficient evidence" of carcinogenicity exists from studies in experimental animals (27 CCR 25306(e)). "Sufficient evidence" means studies in experimental animals indicate that there is an increased incidence of malignant tumors *or* combined malignant and benign tumors: (1) in multiple species or strains; (2) in multiple experiments (e.g., with different routes of administration or using different dose levels); *or* (3) to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset. Given the NTP database, Element 3 is not relevant here.<sup>5</sup>

The evidence provided in the NTP Report is not sufficient for listing under Elements 1, 2, or 3.<sup>6</sup> With respect to Element 1, clear evidence of carcinogenicity has not been demonstrated in "multiple species." As explained further in the attached analysis of the NTP record prepared by Ramboll US Corporation, which is incorporated herein by reference, the NTP record does not provide "sufficient evidence" because, among other things, it fails to "indicate that there is an increased incidence of <u>malignant</u> tumors <u>or</u> combined <u>malignant and benign</u> tumors <u>in multiple species</u> or strains." (Emphasis added.)

The NTP does not consider the tumors observed in rats as clear evidence, only providing some evidence. The increase in thyroid and adrenal tumors that were noted to support the conclusions of carcinogenic activity were almost all benign. Only a few animals, including a control, developed a malignant tumor. Hence, substantial evidence of a progression to malignancy was not found. Further, because historical control data were not available for the rats, NTP could not definitively determine whether the observed tumors were occurring at rates above background. Accordingly, the rat data do not demonstrate an "increased incidence" of malignant tumors as required by the authoritative body regulation. Thus, the rat data provide "limited" evidence, not "sufficient" evidence, and therefore should not be relied upon to support listing PCBTF as a carcinogen.

<sup>&</sup>lt;sup>4</sup> If OEHHA is in fact arguing that the NTP Report was a "list" or "final action" pursuant to 27 CCR 25306(d), OEHHA has not met its burden. Including PCBTF in the NTP Report does not, in and of itself, render the chemical eligible for listing on NTP's Report on Carcinogens. Additionally, publishing the NTP report is not considered "final action" by NTP.

<sup>&</sup>lt;sup>5</sup> The NTP results do not demonstrate any unusual degree of incidence, site or type of tumor, or age at onset. Specifically, as explained in the attached Ramboll report, the liver tumors observed in mice do not represent an increase in rare or unusual tumors, but rather tumors that NTP has noted are common in this strain of mice, so do not represent tumors to an unusual degree from a single experiment. The age of first incidence of the combination of malignant tumors considered in the treated mice is also similar to the age of first incidence in the corresponding control mice; therefore, there does not appear to be a difference in age of onset.

<sup>&</sup>lt;sup>6</sup> Element 3 is not met for reasons explained immediately above, in footnote 5.

Nor can listing be justified under sufficiency Element 2, which requires positive results in "multiple experiments" utilizing different routes of administration or dose levels. The evidence in the mouse upon which OEHHA expressly relied in its Notice of Intent to List is limited mainly to a combination of liver tumors in a single strain of mice with varied response across sexes within that strain. Liver carcinomas in male mice were the only tumor type that was significantly increased at the lowest concentration tested. In contrast, a similar dose-response relationship for carcinomas was not observed in female mice, with the incidence significant only at the highest concentration tested. These results do not justify listing under Element 2, as explained below.

The NTP findings are not the result of "multiple experiments," as that term is properly understood in the historical context in which the sufficiency criteria were adopted. As noted above, OEHHA's 1990 Statement of Reasons supporting adoption of the authoritative body regulation explains that the regulation is based on EPA's 1986 Cancer Classification Guidelines. Indeed, the language of the OEHHA sufficiency criteria is identical to the EPA criteria for sufficiency of animal evidence (51 Fed. Reg. 33999). The EPA criteria, in turn were drawn from the criteria developed by the International Agency for Research on Cancer (IARC) (51 Fed. Reg. 33996). In its 1986 Cancer Classification Guidelines, EPA explicitly acknowledges its reliance on IARC, making clear to OEHHA and the regulated community the origin and meaning of EPA's and OEHHA's sufficiency criteria. IARC describes the "multiple experiment" criterion as follows:

The Working Group considers that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms (as described on p.23) in (a) two or more species of animals **or** (b) in two or more independent **studies** in one species carried out at different times or in different laboratories or under different protocols.<sup>7</sup> (Emphasis added.)

The NTP study does not meet this requirement – the mouse data were generated as part of *single study*. As the Methods and Materials section of the NTP report shows, both sexes of mice were exposed at the same laboratory, beginning at the same timepoint, for the same duration, using the same protocol.<sup>8</sup> If OEHHA wants to adopt an interpretation of the sufficiency criteria that differs from the interpretation the agency provided when it promulgated the regulation, the agency should provide notice and accept public comments, rather than adopting and implementing this different interpretation on a case-by-case basis.

<sup>&</sup>lt;sup>7</sup> "IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans," Supp. 7 p. 30 (1987).

<sup>&</sup>lt;sup>8</sup> As discussed in the attached Ramboll Report, standard carcinogenicity testing guidelines require testing in both sexes of a species as part of the standard protocol for a long-term animal experiment. NTP's standard protocol for a chronic toxicity and carcinogenicity study requires testing in multiple species, in both sexes for each species and with multiple exposure or dosing groups.

Further, there's no mention in the sufficiency criteria of reliance on the results from "two sexes" of the same species from a single study, except under extraordinary circumstances in which malignancy is found "to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset." As explained in the attached Ramboll report, the NTP database does not meet this requirement. If the agency wants to adopt a criterion that permits consideration of data from two sexes of the same species generated through a single study under less than extraordinary circumstances, the agency should amend the regulation and permit public notice and comment, rather than implementing such a criterion on a case-bycase basis.

Even if OEHHA wanted to interpret the mice data as having been generated through separate "experiments," the NTP experiments would not satisfy the plain language of the sufficiency criteria. All of the testing involved the same route of administration: inhalation. And both sexes received the same three dose levels.<sup>9</sup> Yet, if OEHHA wants to ignore or minimize these concerns, the fact that the experiments did not produce consistent observations of tumors across species or the same dose-response patterns within species -- as explained above and in detail in the attached Ramboll report -- should still cause the agency to question whether the NTP report provides substantial evidence of causality.

Further, a finding of sufficiency also would be inconsistent with the Chemical identification Committee "Guidance Criteria for Identifying Chemicals for Listing As 'Known to the State to Cause Cancer'" (March 2001), guidance which, unlike the authoritative body regulation, explicitly provides for consideration of tumors found in significant excess in both sexes of a species. However, the CIC Guidance describes the evidence accorded to a finding in two sexes of the same species as part of the discussion of the proper weighting of a list of characteristics, stating that "none of these individual characteristics provides an absolute criterion of causality by itself."<sup>10</sup> (Emphasis added.) A blanket rule allowing listing whenever tumors are found in only the two genders of a single species, tested as part of a single study, conducted in the same laboratory, and utilizing the same exposure pathway and dose levels, does not provide substantial evidence of causality. That is particularly true where, as here, the findings in a single species are extremely limited – for example, the liver tumors observed in mice do not represent an increase in rare or unusual

<sup>&</sup>lt;sup>9</sup> Moreover, as IARC has explained, the three dosing levels are part of a single experiment, and *not* separate experiments themselves.

The primary purpose of a long-term carcinogenicity experiment is to determine if the administration of a test substance to animals of some species alters the normal pattern of tumour development in that species. In a typical long-term carcinogenicity experiment, a pool of animals is divided by randomization into several groups. One group serves as a concurrent control group, while the remaining groups are exposed to various dose levels of the test substance by some appropriate route of administration.<sup>9</sup> (Emphasis added.)

<sup>&</sup>lt;sup>10</sup> See also, EPA, "Guidelines for Carcinogenic Risk Assessment" (2005).

tumors (i.e., they commonly occur in mice), there appears to be no meaningful difference in the age of onset between the treated and controlled mice, the three dose levels failed to produce a consistent tumor response within the species, and the most plausible mode of action is of questionable relevance.

Apart from our concerns about the lack of substantial evidence from multiple species or multiple experiments, there are other reasons to consider the NTP Report an insufficient basis for listing at this time. The NTP report does not propose a mode of action. Further, the NTP report indicates that the mode of action is unlikely to be genotoxic. It is also possible that the mode of action is species-specific. The data in the NTP Report do not indicate that PCBTF is genotoxic, and the results from the analysis of liver tumors observed in mice indicate a *decrease* in gene mutations with increasing PCBTF exposure. As a result of this analysis and the results from other assays, NTP proposed no mode of action for the reported animal tumors but concluded that the mode of action for the tumors observed is unlikely to be driven by genotoxicity and suggested that further mechanistic studies are needed. However, as noted in the Ramboll report, NTP suggested that the PCBTF data are consistent with a potential constitutive androstane receptor (CAR)-mechanism of action. Liver tumors induced in rodents via CAR-activation are not considered relevant to humans.<sup>11</sup> Thus the limited available evidence on mode of action further calls into question the sufficiency of the evidence to support the proposed listing.

In addition, the observed effects occurred at concentrations orders of magnitude higher than human exposures (100 ppm in mice and rats compared to 1.15 ppm occupational exposure). Further review of the evidence is required to determine whether the observed animal tumors are relevant to human health and, because PCBTF is not genotoxic, whether there is a threshold above current human exposures below which an increased risk of carcinogenicity would not be expected.

Accordingly, as demonstrated in the attached Ramboll report and in these comments, a proper analysis of the weight of the evidence in the NTP Report considered as a whole indicates that the NTP record does not currently support listing of PCBTF.

#### **Conclusion**

ACA and its members take their environmental stewardship responsibilities very seriously. PCBTF was developed as a substitute for use in ACA member products precisely because it assists in reducing the public health effects of ground level ozone. Currently, there are no viable alternatives available to replace PCBTF where it is used for this purpose. Accordingly, it is imperative that OEHHA's listing decision is based on sufficient evidence within the meaning of the authoritative body regulation. ACA urges OEHHA to review the NTP Report carefully in the context of the Proposition 65 listing

<sup>&</sup>lt;sup>11</sup> EPA's 1986 Cancer Classification Guidelines also note that mouse liver tumors may be questionable as a result of high spontaneous background incidence, and may be considered limited evidence where, as here, warranted by the specific information available (51 Fed. Reg 33999 n.2).

criteria, and to consider additional information such as we have provided. We believe that such an analysis will show that the National Toxicology Program (NTP) Report on PCBTF, and the data it provides, do not satisfy the OEHHA listing criteria.

Respectfully submitted,

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David Darling, Vice President of Health, Safety and Environmental Affairs



# MEMO

To From David Darling American Coatings Association Robinan Gentry, PhD

#### 1. Summary

At the request of the American Coatings Association (ACA), Ramboll US Corporation (Ramboll) conducted a review of the NTP (2018)<sup>1</sup> Technical Report to evaluate the conclusions by NTP (2018)<sup>1</sup> regarding the strength of evidence of carcinogenicity for p-chloro-a,a,a-trifluorotoluene (PCBTF) based on the results provided in the Technical Report for Sprague Dawley rats and B6C3F1/N mice. This memorandum was prepared to support ACA's Comments on the Proposed Listing of PCBTF recently announced by the Office of Environmental Health Hazard Assessment (OEHHA).

The results of the NTP study were evaluated to determine how they inform sufficiency criteria for listing a chemical under Proposition 65 as known to cause cancer. These sufficiency criteria are focused on the observation of malignant or malignant and benign tumors combined in multiple species or the observation of tumors in multiple studies in the same species. The only evidence of statistically significant increases in malignant tumors was limited to liver tumors in mice in the NTP (2018)<sup>1</sup> study. In comparing the results from the mice to the rats, no significant increase in the incidence of liver tumors of the thyroid and adrenal gland were reported in rats, mainly at the highest concentration tested (1000 ppm). In drawing conclusions regarding evidence of carcinogenic activity in male and female mice, based on the incidence of hepatocellular tumors (individual incidences or combinations of adenoma, carcinoma or hepatoblastoma), with only some evidence of carcinogenic activity in male and female mice needed to list PCBTF as known to cause cancer under Proposition 65.

#### 2. Results of Review and Discussion

In the 2-year carcinogenicity inhalation study conducted in rats, NTP (2018)<sup>1</sup> reported several tumor types with statistically significant increased incidences, compared to incidences in control animals (Table 1). In male rats, there were statistically significant increases in the incidence of thyroid adenomas and carcinomas (combined) exposed to 1000 ppm when compared to incidences of these tumors in the corresponding control group. However, these tumors were largely benign, with a single malignant carcinoma observed in the control group, as well as in a single animal from the 300 and 1000 ppm exposure groups. Statistically significant increases in the incidence of C-cell adenoma and carcinoma (combined) of the thyroid in females exposed to 1000 ppm, in the incidence of C-cell adenoma and carcinoma (combined) of the thyroid in females exposed to 1000 ppm, and benign pheochromocytoma of the adrenal medulla in animals exposed to

<sup>1</sup> NTP. 2018. NTP Technical Report on the Toxicology and Carcinogenesis Studies of *p*-Chloro-*a*,*a*,*a*-Trifluorotoluene (CAS NO 98-56-6) in Sprague Dawley (Hsd:Sprague Dawley SD) and B6C3F1/N Mice (Inhalation Studies). National Toxicology Program. NTP TR 594. June.

100 ppm. As with the male rats, these tumors were largely benign, with 2 thyroid carcinomas reported in females exposed to 100 ppm and 1 in females exposed to 1000 ppm. While not statistically significantly increased when incidences in exposed groups were compared to incidences in controls, a significant trend was reported for the incidence of alveolar/bronchiolar carcinoma in male rats and adenocarcinoma in the uterus in female rats.

Regarding the observation of thyroid tumors in male and female rats, according to NTP (2018)<sup>1</sup>, historical control tumor incidences are typically considered when interpreting the results of studies; however, there are no inhalation historical control data available for the Hsd:Sprague Dawley rats. Therefore, NTP (2018)<sup>1</sup> could not determine if the incidence of thyroid C-cell tumors reported in male and female rats were occurring at rates higher than historical controls.

In the 2-year carcinogenicity inhalation study conducted in mice, NTP (2018)<sup>1</sup> also reported several tumor types with statistically significant increased incidences compared to controls (Table 2). However, the tumors observed were different than those reported in rats. In male mice, statistically significant increases in the incidence of hepatocellular carcinoma were reported in animals exposed to 100, 200 or 400 ppm, hepatocellular hepatoblastoma in animals exposed to 400 ppm, and hepatocellular adenoma, carcinoma or hepatoblastoma (combined) in animals exposed to 200 or 400 ppm. In female mice, there were significant increases in the incidence of hepatocellular carcinoma in animals exposed to 200 or 400 ppm, hepatocellular hepatoblastoma in animals exposed to 400 ppm, and hepatocellular adenoma in animals exposed to 200 or 400 ppm, hepatocellular carcinoma in animals exposed to 200 or 400 ppm, hepatocellular hepatoblastoma in animals exposed to 200 or 400 ppm, and hepatocellular adenoma, carcinoma or hepatoblastoma in animals exposed to 200 or 400 ppm. A similar dose-response relationship for these tumors was not observed in the female mice compared to the male mice, with the incidence of hepatocellular carcinomas significant only at the highest concentration tested (400 ppm). Significant increases in the incidence of Harderian gland adenoma or adenocarcinoma (combined) were also reported in female mice exposed to 200 or 400 ppm.

NTP (2018)<sup>1</sup> reports that hepatocellular adenomas and carcinomas are the most common primary liver tumors, both spontaneously occurring, and treatment related, in B6C3F1/N mice and they occur more commonly in male mice compared to females. NTP (2018)<sup>1</sup> evaluated specific genetic mutations from hepatocellular carcinomas (genetic *Hras* or *Ctnnb* 1 mutations) from both control and exposed groups of mice reported in the NTP (2018)<sup>1</sup> study in order to provide some information regarding the potential mechanisms of the hepatocellular carcinomas observed in mice following exposure to PCBTF. Results of the NTP evaluation indicated a statistically significant trend and pairwise differences in the **negative** direction for *Hras* mutations between spontaneous hepatocellular carcinomas in chamber control mice and hepatocellular carcinomas in treated mice, suggesting a decrease in mutations with increasing PCBTF exposure and additional evidence of a lack of the involvement of mutagenicity in the development of the mouse liver tumors. No significant changes were noted in *Ctnnb* 1 mutations in mouse hepatocellular carcinomas. NTP (2018)<sup>1</sup> offered no conclusion based on this genetic testing and suggested, in light of the negative genotoxicity results for PCBTF, further mechanistic studies are needed to better understand PCBTF-induced liver tumors.

Based on the results of the PCBTF 2-year inhalation carcinogenicity study in rats and mice, NTP (2018)<sup>1</sup> concluded that there was **some** evidence of carcinogenicity in male and female rats based on the incidence of thyroid tumors and **clear** evidence of carcinogenicity in male and female mice

based on the incidence of liver tumors. In considering these results in informing the strength of evidence of carcinogenicity to support listing under Proposition 65 as known to cause cancer, these results alone do not provide sufficient evidence. Under the OEHHA regulations, "sufficient evidence" of carcinogenicity from studies in experimental animals exists if there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels) or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age of onset. The NTP (2018) results do not provide clear evidence of carcinogenicity in multiple species, as the tumors observed in the rats were almost all benign with little progression to malignancy demonstrated and mainly observed in animals receiving the highest concentration tested (1000 ppm). Thus, there is not sufficient evidence of malignancy in two species. In addition, the liver tumors observed in mice do not represent an increase in rare or unusual tumors, but rather tumors that NTP has noted are common in this strain of mice, so do not represent tumors to an unusual degree from a single experiment. The age of first incidence of the combination of malignant tumors considered in the treated mice is also similar to the age of first incidence in the corresponding control mice; therefore, there does not appear to be a difference in age of onset.

In considering the results reported in male and female mice, this would not be considered multiple studies or experiments. In reviewing documentation from the International Agency for Research on Cancer (IARC) that is consistent with the definition of sufficient evidence of carcinogenicity in experimental animals in the OEHHA regulations, multiple experiments are considered to be conducted in two or more independent studies in one species carried out at different times or in different laboratories or under different protocols (IARC 1987)<sup>2</sup>. In addition, standard carcinogenicity testing guidelines provided by the OECD (2018)<sup>3</sup> and the U.S. Environmental Protection Agency (USEPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS) (USEPA 1998)<sup>4</sup> require testing in both sexes of a species as part of the standard protocol. NTP's standard protocol for a chronic toxicity and carcinogenicity study (NTP 2011)<sup>5</sup> requires testing in multiple species, in both sexes for each species and with multiple exposure or dosing groups. Further, the Guidance Criteria for Identifying Chemicals for Listing as "Known to the State to Cause Cancer" (March 2001), indicates that the observation of tumors in two genders of a species does not provide an absolute criterion of causality by itself.

According to NTP (2018)<sup>1</sup>, there are no reports of the carcinogenic potential of PCBTF in animals in any other reports provided in the literature. Therefore, the evidence of carcinogenicity in animals is limited to the tumors reported by NTP (2018)<sup>1</sup>. In addition, NTP (2018)<sup>1</sup> further discusses an epidemiological assessment conducted in a cohort of workers (4000) exposed to PCBTF in a mixture with more than 80 other chemicals. The results from this study do not provide any evidence of higher than expected rates of the cancer types reported in NTP (2018)<sup>1</sup>, even though the workers were exposed to a large number of chemicals, including PCBTF. Therefore, because

<sup>&</sup>lt;sup>2</sup> IARC. 1987. IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans. Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42. World Health Organization, International Agency for Research on Cancer. Supplement 7. Lyon, France.

<sup>&</sup>lt;sup>3</sup> OECD. 2018. OECD Guideline for the Testing of Chemicals: Carcinogenicity Studies. Test No. 451. Available at: <u>https://read.oecd-</u>

ilibrary.org/environment/test-no-451-carcinogenicity-studies\_9789264071186-en#page1.

<sup>&</sup>lt;sup>4</sup> USEPA. 1998. Health Effects Test Guidelines OPPTS 870.4200 Carcinogenicity. United States Environmental Protection Agency, Prevention, Pesticides and Toxic Substances (7101). EPA 712-C-98-211. August 1998.

<sup>&</sup>lt;sup>5</sup> NTP. 2011. Specification for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program (NTP).

the evidence is limited to one study conducted in animals, with only clear evidence concluded by NTP (2018)<sup>1</sup> for the mouse, the results from the NTP (2018)<sup>1</sup> study do not provide sufficient evidence of carcinogenicity. In addition, as similar tumor responses were not observed across species, it is possible that the mode of action associated with PCBTF exposure and the occurrence of liver and thyroid tumors in mice or rats may be species-specific and not relevant to humans.

In considering data reported in NTP (2018)<sup>1</sup> that may be relevant in further evaluating the sufficiency of the evidence, as well as understanding the potential mode of action for the cancers observed in rats or mice and whether these observations may be relevant to humans, NTP (2018)<sup>1</sup> reported that the available data do not indicate that PCBTF is genotoxic, based on the results from standard in vitro assays. In addition, no significant increases in micronucleated erythrocytes were observed in peripheral blood samples from male and female rats exposed to PCBTF for 3 months via inhalation. While NTP (2018)<sup>1</sup> did not propose a mode of action for the tumors observed in mice and rats, NTP (2018)<sup>1</sup> concluded that the mode of action for carcinogenicity observed in the animals in the current study is unlikely to be driven by genotoxicity. This, in combination with the observation of the majority of the tumors reported in animals following exposure to high concentrations of PCBTF, suggests a potential mode of action resulting from repeated cytotoxicity and cell regeneration and therefore, provide support for a nonlinear mode of action. NTP (2018)<sup>1</sup> notes strong nonneoplastic responses in the lung and liver of both sexes in both rats and mice suggestive of inflammation and cytotoxicity. NTP (2018)<sup>1</sup> also notes that PCBTF has been reported to increase CYP2B activity and CYP2B activation via the constitutive androstane receptor (CAR) which is a known mechanism of tumor promotion activity in the liver of rodents. They further note that the liver weight changes and nonneoplastic lesions observed in the 3-month and 2-year studies for both rodent species is consistent with a potential CAR-mechanism of action. While NTP proposes further mechanistic studies to investigate the mode of action for the liver tumors observed in mice, the development of liver tumors in rodents that are induced via CARactivation is not considered relevant to humans.<sup>7</sup> Integration of the available data for PCBTF from other studies, as well as the results from the NTP (2018)<sup>1</sup> study, may provide additional evidence for a mode of action for the carcinogenicity observed in animals that is animal-specific and may also indicate a threshold below which no increase in tumor incidence would be expected. Therefore, the assumption of linearity in low-dose extrapolation (e.g., any exposure is associated with some level of risk of cancer), which is the default assumption for most regulatory assessments if a chemical is genotoxic, is inconsistent with the NTP (2018)<sup>1</sup> results for PCBTF, which provide support for a non-linear mode of action for carcinogenicity. Further evaluation of the PCBTF database may provide additional support for a non-linear mode of action and allow for the identification of a threshold concentration in animals, below which cancer would not be expected to occur.

Of additional importance is that the observed tumors were not consistent across animal species. While significant increases in liver tumors in male mice and liver and Harderian gland tumors in female mice were reported, no significant increase in these tumors was reported in rats, further suggesting a possible mode of action for liver carcinogenicity that could be mouse-specific and raise questions of relevance to human health (Klaunig et al. 2003<sup>6</sup>; Holsapple et al. 2006<sup>7</sup>; Corton

<sup>&</sup>lt;sup>6</sup> Klaunig JE, Babich MA, Baetcke KP, Cook JC, Corton JC, David RM, DeLuca JG, Lai DY, McKee RH, Peters JM, Roberts RA, Fenner-Crisp PA. 2003. PPARa agonist-induced rodent tumors: modes of action and human relevance. Critical Reviews in Toxicology, 33(6): 655-780.

<sup>&</sup>lt;sup>7</sup> Holsapple MP, Pitot HC, Cohen SM, Boobis AR, Klaunig JE, Pastoor T, Dellarco VL, Dragan YP. 2006. Mode of action in relevance of rodent liver tumors to human cancer risk. Toxicological Sciences, 89(1): 51-56.

et al. 2018<sup>8</sup>). The lack of genotoxicity evidence for PCBTF suggests a potential nonlinear mode of action by which carcinogenic effects may occur following exposure to high concentrations above a threshold concentration. This threshold could possibly be higher than expected human exposures. The National Research Council (2014)<sup>9</sup> notes the importance of assessing evidence that environmental chemicals can cause adverse health effects based on what is known about current human exposure levels. The observed effects reported in NTP (2018)<sup>1</sup> occurred at concentrations orders of magnitude higher than human exposures (100 ppm in mice and rats compared to 1.15 ppm occupational exposure) (Lee 2015)<sup>10</sup>. Further review of the evidence relevant to the mode of action of PCBTF is required to determine both if the tumors observed in animals are relevant to people and if the results from NTP (2018)<sup>1</sup> demonstrate a threshold higher than expected.

<sup>&</sup>lt;sup>8</sup> Corton JC, Peters JM, Klaunig JE. 2018. The PPARa-dependent rodent liver tumor response is not relevant to humans: addressing misconceptions. Archives in Toxicology, 92(1): 83-119.

<sup>&</sup>lt;sup>9</sup> National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press.

<sup>&</sup>lt;sup>10</sup> Lee EG, Lewis B, Burns DA, Kashon M, Kim SW, Harper M. 2015. Assessing Exposures to 1-chloro-4-(trifluoromethyl) benzene (PCBTF) in U.S. Workplaces, Journal of Occupational and Environmental Hygiene, 12:7 D123-D130.



Table 1. Male and Female Rats Tumor Incidence (NTP 2018)						
Endpoint	0 ppm	100 ppm	300 ppm	1000 ppm		
Male Rats						
Thyroid gland C-cell adenoma	2/50 <sup>a,b</sup>	5/49	3/49	12/50**		
Thyroid gland C-cell adenoma and carcinoma (combined)	3/50 <sup>a,b</sup>	5/49	4/49	13/50**		
Lung alveolar/bronchiolar carcinoma	0/50	0/50	0/50	2/50		
Female Rats						
Thyroid gland C-cell adenoma	2/50 <sup>b</sup>	8/50	8/50	14/50**		
Thyroid gland C-cell adenoma or carcinoma (combined)	2/50 <sup>b</sup>	10/50*	8/50	15/50**		
Adrenal medulla benign pheochromocytoma	0/49 <sup>b</sup>	3/50	4/50	6/50*		
Uterus adenocarcinoma	1/50 <sup>b</sup>	1/50	0/50	5/50		

<sup>a</sup> Incidence data are presented as number of animals with tumor over number of animals examined

<sup>b</sup> Statistically significant trend

\*Statistically significant at p < 0.05\*\*Statistically significant at p < 0.001

Table 2. Male and Female Mice Tumor Incidence (NTP 2018)							
Endpoint	0 ppm	100 ppn	n 200 ppm	400 ppm			
Male Mice							
Hepatocellular carcinoma	8/50 <sup>a,b</sup>	19/50*	16/50*	35/50**			
Hepatoblastoma	1/50 <sup>b</sup>	1/50	1/50	15/50**			
Hepatocellular adenoma, carcinoma or hepatoblastoma (combined)	31/50 <sup>b</sup>	37/50	40/50*	48/50**			
Female Mice							
Hepatocellular adenoma	12/50 <sup>b</sup>	14/50	24/50*	34/50**			
Hepatocellular carcinoma	7/50 <sup>b</sup>	8/50	12/50	34/50**			
Hepatoblastoma	0/50 <sup>b</sup>	0/50	1/50	8/50*			
hepatocellular adenoma, carcinoma or hepatoblastoma (combined)	18/50 <sup>b</sup>	18/50	29/50*	46/50**			
Harderian gland adenoma or adenocarcinoma (combined)	2/50 <sup>b</sup>	6/50	9/50*	8/50*			

<sup>a</sup> Incidence data are presented as number of animals with tumor over number of animals examined

<sup>b</sup> Statistically significant trend

\*Statistically significant at p < 0.05

\*\*Statistically significant at p < 0.001

SPRI Very Severe Hail Task Force FAQ Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

## Call to Order

The Task Force meeting was called to order at 11:00 a.m. EST by Task Force Co-chair Tim McQuillen. The SPRI Antitrust Statement was read. \*

#### **Roll Call**

Those present were: Tim McQuillen, Johns Manville Corporation Joe Schwetz, Sika Sarnafil Brian Alexander, TruFast Stephen Childs, OMG Roofing Products Stan Choiniere, StanCConsulting Todd Corley, Siplast Heather Estes, GAF David French, Carlisle Construction Materials Mike Giangiacomo, Flex Membrane Int'I Corp. Scott Gipson, FiberTite Roofing Systems Frank Greco, IKO Industries Ltd George Howell, Martin Marietta Magnesia Specialties Roger Johnson, INEOS Olefins & Polymers USA Ankit Kadakia, Owens Corning Joseph Kalwara, Firestone Building Products Co, LLC Brendan Knapman, ROCKWOOL Steve Kuhel, FiberTite Roofing Systems Mikael Kuronen, Georgia-Pacific Gypsum LLC Colin Litow, Continuus Materials, LLC Chris Mader, OMG Roofing Products Saverio Marzella, ROCKWOOL Sean McKay, Ashland, Inc. Chris Meyer, FiberTite Roofing Systems Jim Pieczynski, Blue Ridge Fiberboard, Inc. Brandon Reynolds, Carlisle Construction Materials Greg Sagorski, Atlas Roofing Corporation William Sanborn, Johns Manville Corporation Sally Schomp, Plastex Matting Inc. Matt Spencer, Continuus Materials Todd Taykowski, Firestone Building Products Co

# **Objective #1**

During the October meeting there was discussion if SPRI should create a new hail impact test or work with a group to do so. UL 2218 A was mentioned as a possible second standard for the industry. During the Technical Committee, Dwayne Sloan, UL stated that UL is not going to proceed with the 2218 A standard.

IBHS has expressed interest in pursuing a standard similar to its residential standard for the commercial market. The Task Force will reach out to those at IBHS to determine if and how it intends to pursue. The Task Force discussed inviting IBHS to present during the April meeting.

During the Technical Committee meeting, it was noted that IBHS, at this time, is looking at an R&D program for hail impact on low slope roofs and not necessarily looking to create a new standard. The Task Force will have to confirm what direction they intend to proceed.

\*SPRI Antitrust Statement: SPRI complies with antitrust laws and requires participants in its programs to comply with antitrust laws. Discussions which could affect competitive pricing decisions or other competitive factors are forbidden. There may be no discussions of pricing policies or future prices, production capacity, profit margins or other factors that may tend to influence prices. In discussing technical issues, care should be taken to avoid discussing potential or planned competitive activities. Members and participants should be familiar with the SPRI Antitrust Policy and act in conformity with it. The Task Force agreed that there is no need or interest at this time for SPRI to create a "Very Severe Hail" (VSH) Task Force type impact standard.

#### **Objective #2**

The Factory Mutual (FM) coalition meeting was rescheduled for Thursday March 5. The VSH Task Force is looking for questions and/or comments from the membership to be presented and discussed at the coalition meeting. Questions must be submitted to SPRI by February 7, at which time they will be reviewed and submitted (to be included for discussion).

#### Adjournment

There being no further business, the meeting adjourned at 11:45 a.m. EST.

Submitted by: Tim McQuillen, Task Force Co-chair

These minutes were reviewed by SPRI Legal Counsel.

SPRI Fastener & Board Pull-Through Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### Call to Order

The Task Force meeting was called to order at 11:45 a.m. EST by Task Force Chair Chris Mader. The SPRI Antitrust Statement was read. \*

# Roll Call

Those present were: Chris Mader, OMG Roofing Products Vinny Abbondanza, OMG Roofing Products Adam Aharonian, SFS Group USA Brian Alexander, TruFast Bas Baskaran, NRCC Brian Buckler, SFS Group USA Luis Cadena, NEMO | etc. Scott Carpenter, SFS Group USA Joan Crowe, AIA, GAF Mike Darsch, Sika Sarnafil Tony Fuller, National Gypsum Mike Giangiacomo, Flex Membrane Int'l Corp. Joseph Kalwara, Firestone Building Products Co Mikael Kuronen, Georgia-Pacific Gypsum LLC Bob LeClare, ATAS International, Inc.

Paul Linton, OMG Roofing Products Colin Litow, Continuus Materials, LLC Saverio Marzella, ROCKWOOL Chris Meyer, FiberTite Roofing Systems Steve Moskowitz, Atlas Roofing Corporation Zach Priest, PRI Ron Reed, Intertek Brandon Reynolds, Carlisle Construction Materials Greg Sagorski, Atlas Roofing Corporation William Sanborn, Johns Manville Corporation Todd Taykowski, Firestone Building Products Co Jarrod Woodland, SFS Group USA, Division Construction

*Staff present was:* Randy Ober, SPRI

# Discussion

Motion to change Task Force name to BPT-1 approved.

The following items were discussed:

- Review of BPT-1 draft standard -
  - Discussion around sample size;
  - Discussion around population size; and
  - Discussion to include testing section Chris Mader to work with Zach Priest on adding this to the draft.
- Editorial changes; and
- Will distribute an updated draft following the discussed changes and additions.

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# Adjournment

There being no further business, the meeting adjourned at 1:45 p.m. EST.

Submitted by: Chris Mader, Task Force Chair

These minutes have been reviewed by SPRI Legal Counsel.

SPRI IBHS Training Task Force Opal Sands Resort Clearwater, FL January 10, 2020



#### MINUTES

#### Call to Order

The Task Force meeting was called to order at 1:45 p.m. EST by Task Force Chair Mike Darsch. The SPRI Antitrust Statement was read.\*

#### **Roll Call**

Those present were: Mike Darsch, Sika Sarnafil Vinny Abbondanza, OMG Roofing Products Todd Corley, Siplast Joan Crowe, AIA, GAF John Doyle, Flex Membrane International Corp. Heather Estes, GAF David French, Carlisle Construction Materials Frank Greco, IKO Industries Ltd Richard Hein, Metal-Era, Inc. Al Janni, Duro-Last Roofing, Inc. Joseph Kalwara, Firestone Building Products Co Brendan Knapman, ROCKWOOL Steve Kuhel, FiberTite Roofing Systems Bob LeClare, ATAS International, Inc. Ron Reed, Intertek Jim Rubenacker, Sika Sarnafil Dwayne Sloan, UL LLC Todd Taykowski, Firestone Building Products Co

Guests present were: Christopher Cioffi, IBHS Chuck Miccolis, IBHS Mark Zenhal, IBHS

Staff present was: Randy Ober, SPRI

#### Discussion

Chuck Miccolis, IBHS, gave a presentation on the Fortified IBHS Program. Following this presentation, there was a brief discussion on how he was looking for help to reach out to the contractors and thought SPRI was the perfect avenue to reach out to them. If SPRI can educate the contractors on the how and the why, the Fortified Program can be a successful avenue for SPRI membership. Mr. Miccolis was short on time and had to leave before the Task Force could have further discussion. There seemed to be some confusion at the end as to how exactly SPRI could help. A conference call needs to be set up to review what IBHS is looking for:

- 1. SPRI members going to their biggest contractors explaining to them the Fortified Program; or
- 2. SPRI is creating an outlined training program based of the Fortified Program to hand out to contractors.

#### **Action Items:**

IBHS will get back to Mike Darsch and Al Janni with dates for the conference call for further calcification.

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# Adjournment

There being no further business, the meeting adjourned at 2:45 EST p.m.

Submitted: Task Force Chair, Mike Darsch

These minutes were reviewed by SPRI Legal Counsel.