

# **TSCA Year 3: Impact of TSCA on Low Volume Exemption (LVE) Submissions**

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# Conflict of Interest

- I am employed by PPG Industries, which is subject to regulation under TSCA (LSCA).
- I have no other actual or potential conflicts of interest to declare.



Headquartered in Pittsburgh, PA, with operations in more than 70 countries



Founded in 1883



Paints, coatings, and specialty materials



Construction, Consumer Products, Industrial and Transportation



# Overview

## PPG submits Low Volume Exemptions (LVE) for specialty materials to support market demand

- PPG produces specialty materials at low volume
- These materials have a rapid commercialization schedule
- Market demand can require up to 20 LVE submissions per year

## To accomplish market demand, PPG developed a process to evaluate new LVE materials

- Hazard assessment includes search for publically available data, analogs for read-across, *in silico* modeling and toxicology testing as needed
- Exposure is evaluated to characterize risk
- LVEs submitted with expectation of 30 day review per EPA

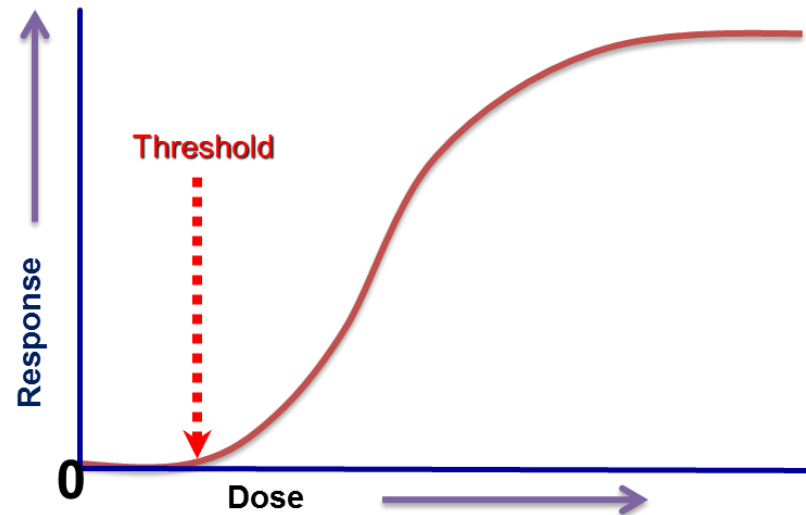
**Limited success has been achieved with this process; there are opportunities for improvement**



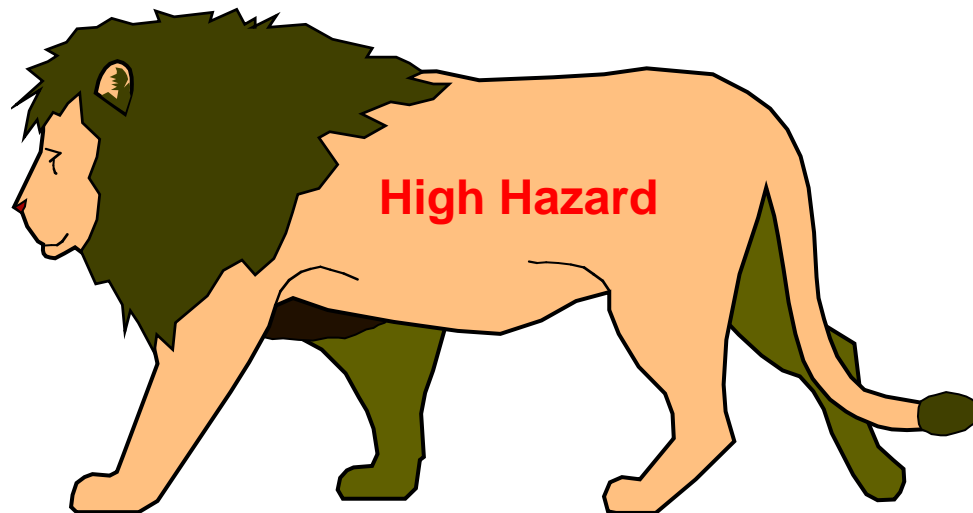
# All You Need to Know About Risk Assessment...

$$\text{RISK} = \text{HAZARD} \times \text{DOSE (Exposure)}$$

The likelihood of injury or disease resulting from exposure to a potential hazard

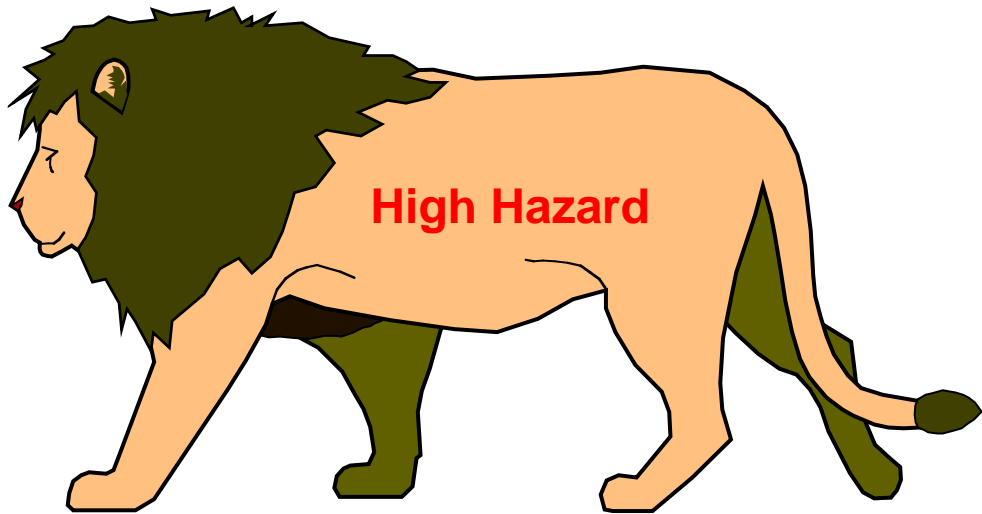


# Risk Depends on Hazard & Exposure

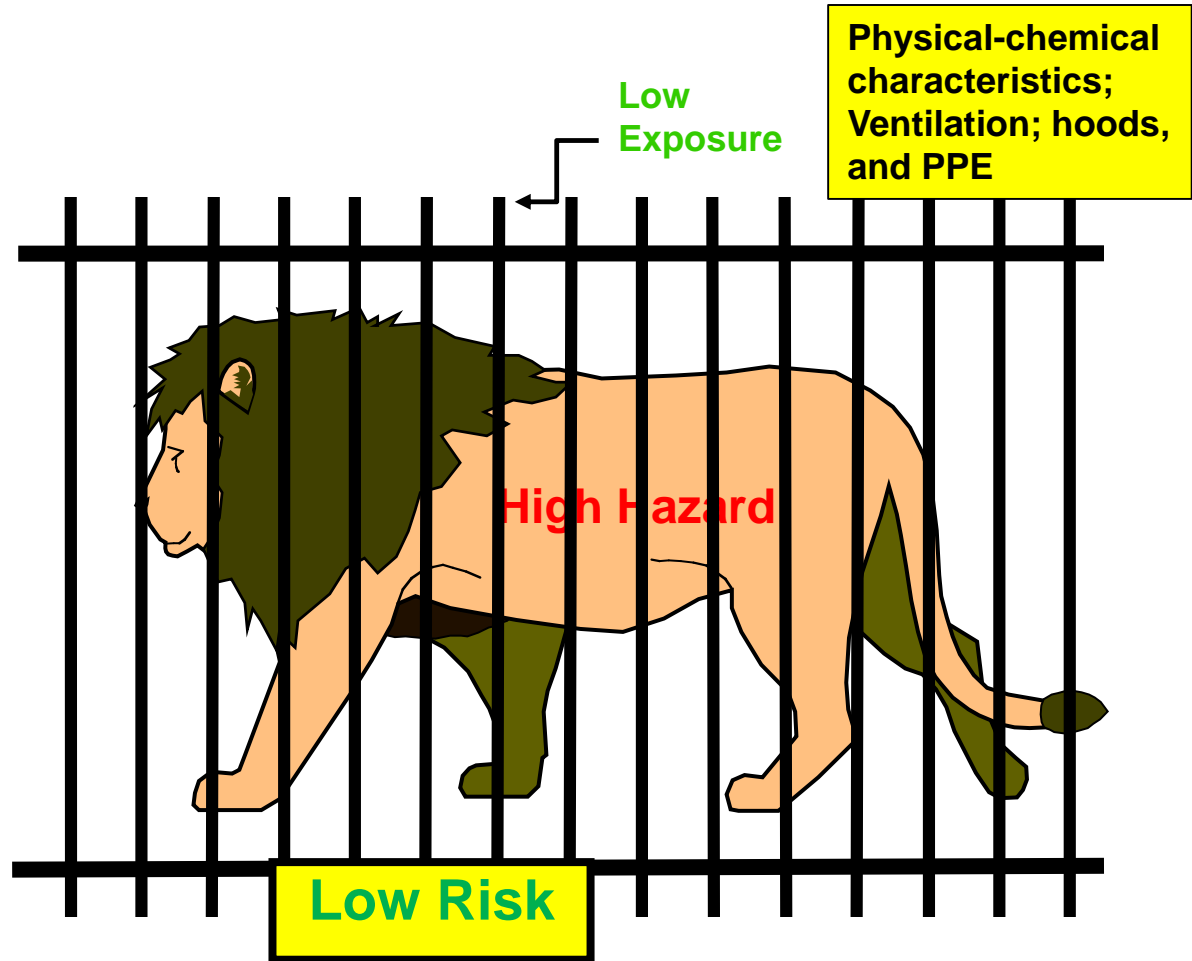




**High Exposure**



**High Risk**

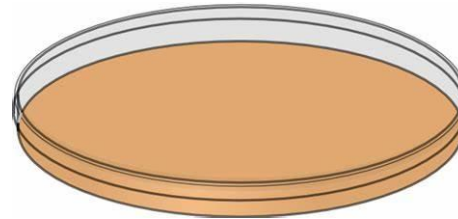




# Risk Assessment for LVE Submissions

$$\text{RISK} = \text{HAZARD} \times \text{DOSE (Exposure)}$$

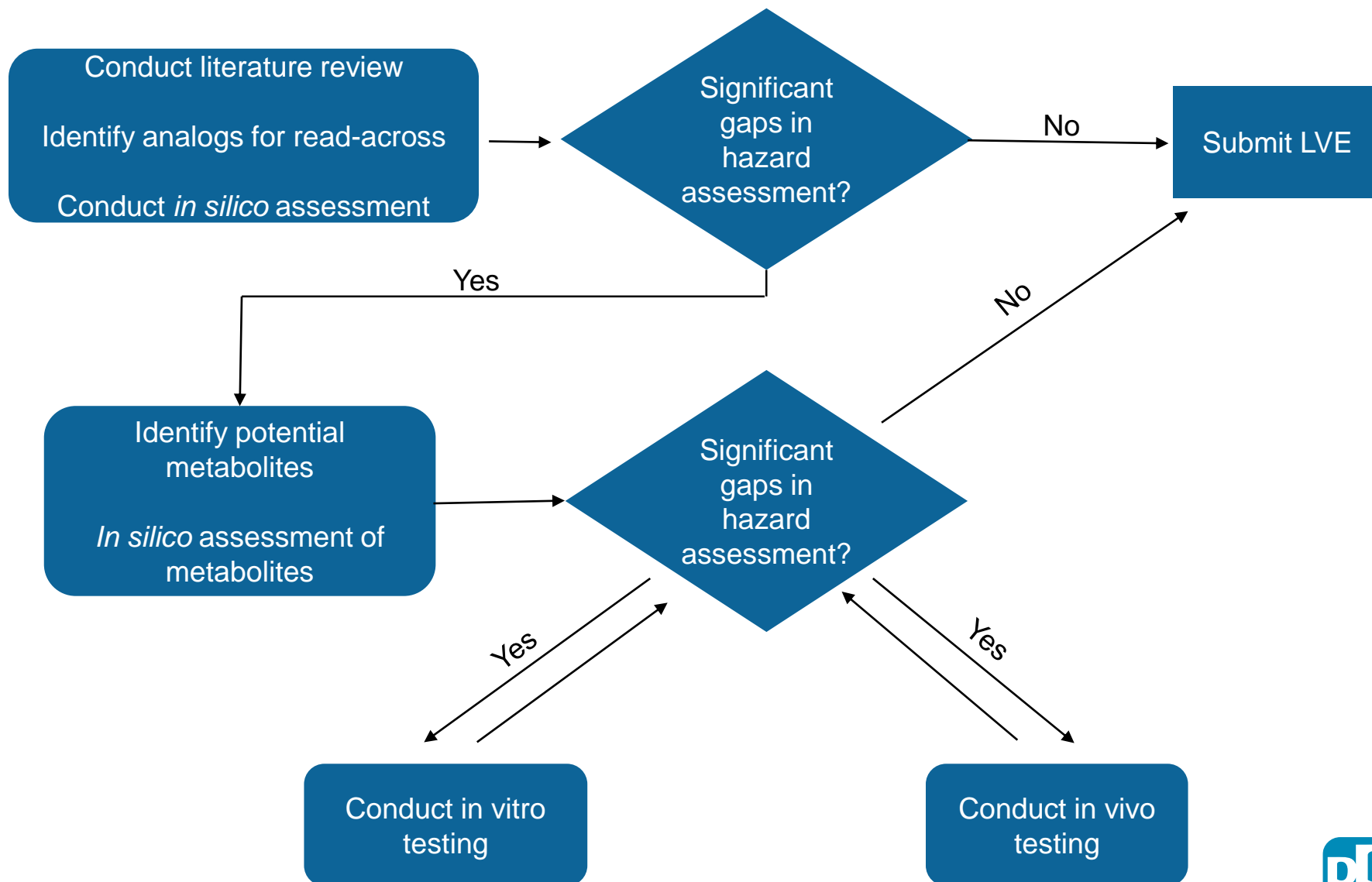
- Hazard Assessment: Stepwise process to assess hazards



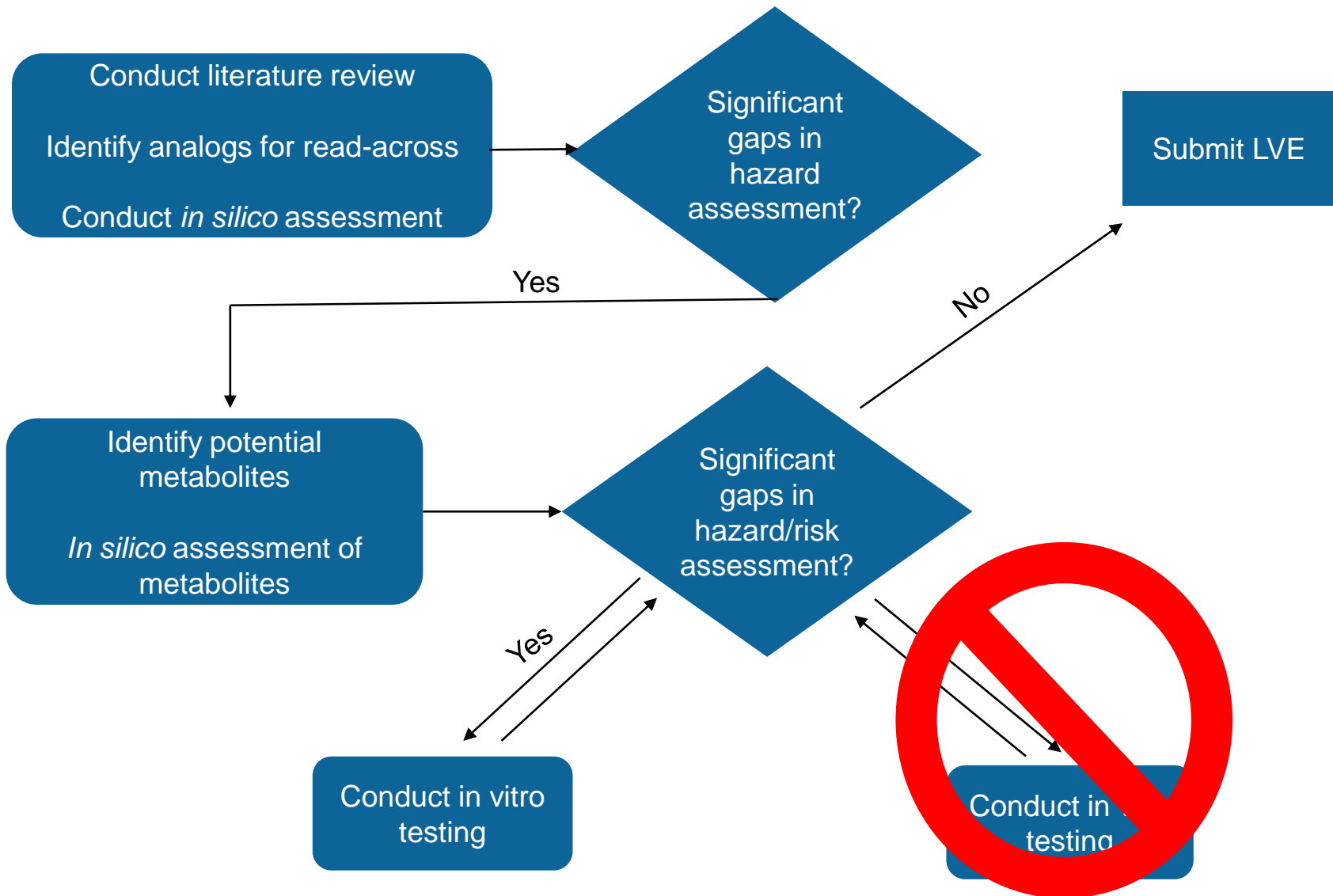
- Exposure Assessment: Exposure is *de minimis* due to occupational controls, no environmental release, no exposure to the general public

= Low Risk to Workers and the Environment

# PPG Hazard Assessment Process



# PPG Process - Example



# PPG Exposure Assessment

**Risk = Hazard + Exposure**

**Worker exposure is *de Minimis*:**

- Low volume materials
- Batch process with less than 30 minutes exposure per batch; 20 batches per year
- Engineering Controls: All substances are handled under local ventilation
- PPE: Chemically impervious gloves and respirator used

**Environmental and general population exposure**

- Material is completely consumed and is not found in final product
- No stack emissions
- No release to water

**= Low Risk to Workers and the Environment**



# LVE Submission Summary

## 2018

Number of LVE Submissions	Average Number of Extensions	Average Number of Days to Approve	Common Reasons for Delay
8	3	109	<ul style="list-style-type: none"><li>• Information provided not considered</li><li>• Rejected due to concerns about environmental release</li><li>• Rejected due to PPE</li></ul>

## 2019

Number of LVE Submissions	Average Number of Extensions	Average Number of Days to Approve	Common Reasons for Delay
1	0	34	Not Applicable

# Lessons Learned and Path Forward

## LVE submissions following this process are lengthy

- Important information should be in cover letter
- Once review is underway, teleconference with EPA is helpful to answer questions
- Delays in approval due to missed information in the submission

## Exposure Assessments

### CDX Submissions

- Agency vs. submitter view
- Submissions sections sent to different groups can result in missed information

### New Approach Methodology (NAMs)

- In silico, in vitro, read-across, category approaches utilized and accepted

## How to Improve Submissions?



We protect and  
beautify the world

