

# Battle of the Bands: Overture

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# Overture: Background and History

## Problem Stated:

- Need to protect pharmaceutical workers from exposures to APIs
- OELs can be used to determine containment necessary for the safe handling of a material
- Early in development insufficient quantitative data to set OELs
- Determining handling on a case-by-case basis is:
  - Time consuming
  - Inconsistent
  - Result: Confusion for the employee

## Solution:

- Assign chemicals into a few categories based on their inherent properties
- List all unit operations in all facilities
- Pre-assign safe handling procedures for each operation based on their potential for exposure (operations matrix)

# Toxicity/Potency Categories of Chemicals

- Band 1: Low Toxicity / Potency
- Band 2: Intermediate Toxicity / Potency
- Band 3: Toxic / Potent
- Band 4: Highly Toxic / Potent

***No standard system of banding across the industry***

## Advantages of OEBs

- Categorizes chemical into common class that can be easily recognized
- Helps put hazard in perspective
- If data are insufficient for establishing an OEL, an OEB can be assigned
  - Early in development – limited data
  - Low volume of production
  - Small population exposed

## Criteria Matrix for Assigning OEBs

- Criteria that are used focus on the degree to which exposure impacts on human health
- Inherent property of a material
- Dictates level of control necessary for given operations to maintain risks at acceptable levels

## Establishing a Banding System

- How many bands should we have?
- What should the corresponding airborne concentrations (“cutoffs”) be for each band.



## How Many Bands Should We Have?

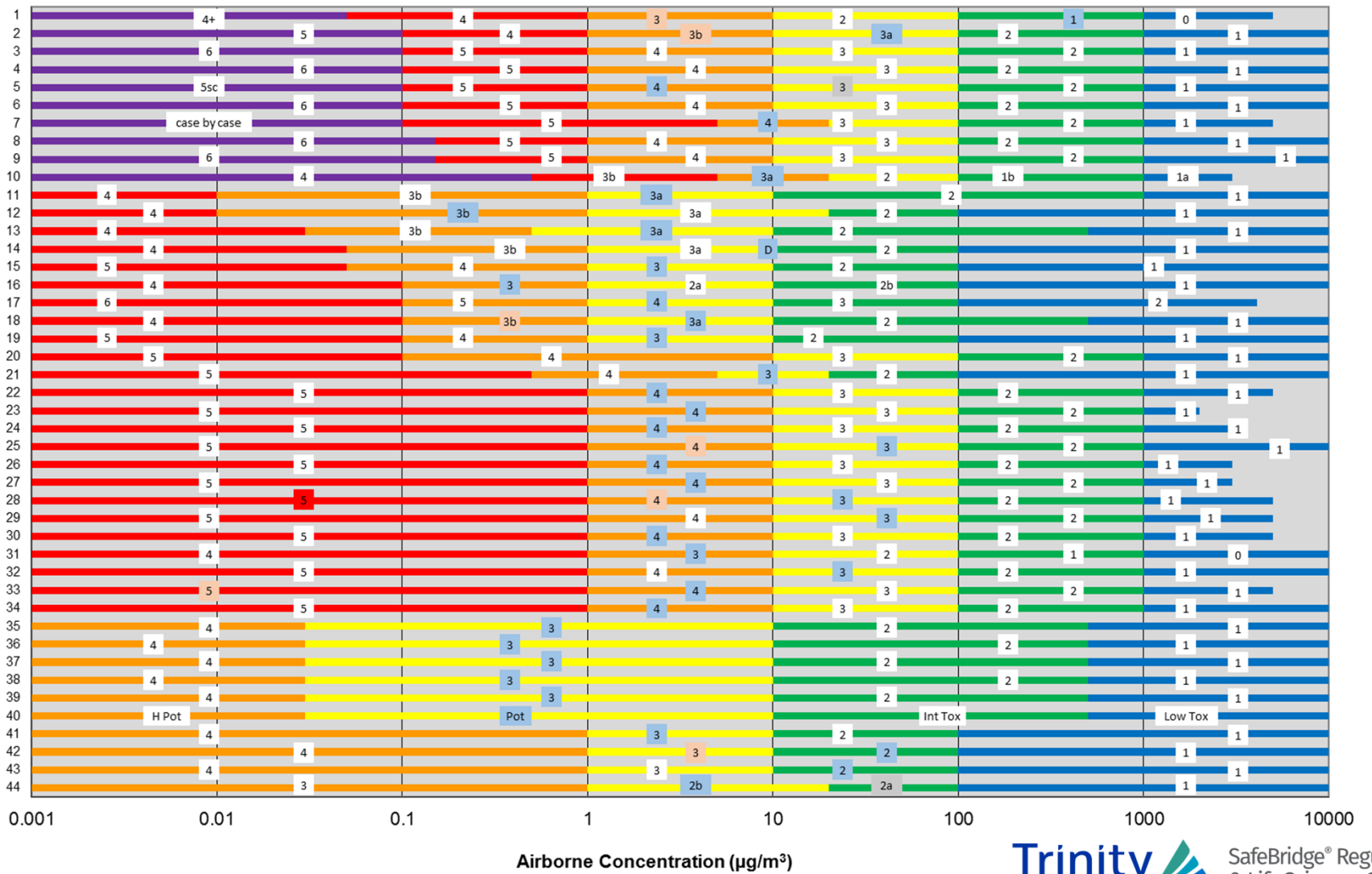
- How many workplace environments can be described?
- What is the range of products you will handle?
- Are there plans to handle more potent compounds in the future?

# What are the “Correct” Cutoffs for Airborne Limits for these Bands?

- Occ Tox asks Safety:
  - What are airborne limits associated with a band?
  - I need to determine characteristic criteria for each band.
- Safety responds to Occ Tox:
  - What are the airborne limits associated with High, Moderate, and Low hazard materials?
  - I need to work with engineering to contain to those limits

# What are the “Correct” Cutoffs for Airborne Limits for these Bands?

- Engineering says to both:
  - These are airborne limits to which available engineering technologies can control.
  - Occ Tox >>> design your characteristic criteria based on materials with OELs in this range.
  - Safety >>> design handling procedures and PPE requirements to complement the use of these technologies



## Why So Many Different Systems in Pharma?

- Therapeutic substances differ among companies
- Work environments and equipment can also be different

*What should we do?*

## Evaluate the Reason for Your Banding System

- Understand the system is for internal use only
- Your band will not necessarily translate to another company's band
- Systems may evolve due to changes in manufacturing technology, containment options and potency of products
  - Your system may change in the future

## Banding System Statistics

- 44 companies included in survey (last performed in 2016)
- Number of bands:
  - 4 bands: 10
  - 5 bands: 24
  - 6 bands: 10
- Upper limit of most potent band:
  - 1  $\mu\text{g}/\text{m}^3$ : 17
  - <1  $\mu\text{g}/\text{m}^3$ : 27

## Summary

- A banding system is a valuable tool to identify handling practices of substances with similar toxicology and/or potency profiles
- Bands cannot be compared across companies without information on:
  - Criteria used for categorizing materials
  - Corresponding cutoffs for airborne limits



