

Models vs. Measurement: Are we on the right track?

The Promise and Limitations of Occupational Exposure Banding

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As more toxicological and epidemiological data become available, we move up the hierarchy of OELs.

Hierarchy of OELs

Most Extensive Data Requirements

Quantitative Health Based OELs

Health Based OELs

Risk-based Prioritization

Moderate Data Requirements

Working Provisional OELs

Prescriptive Process Based OELs

Least Data Requirements

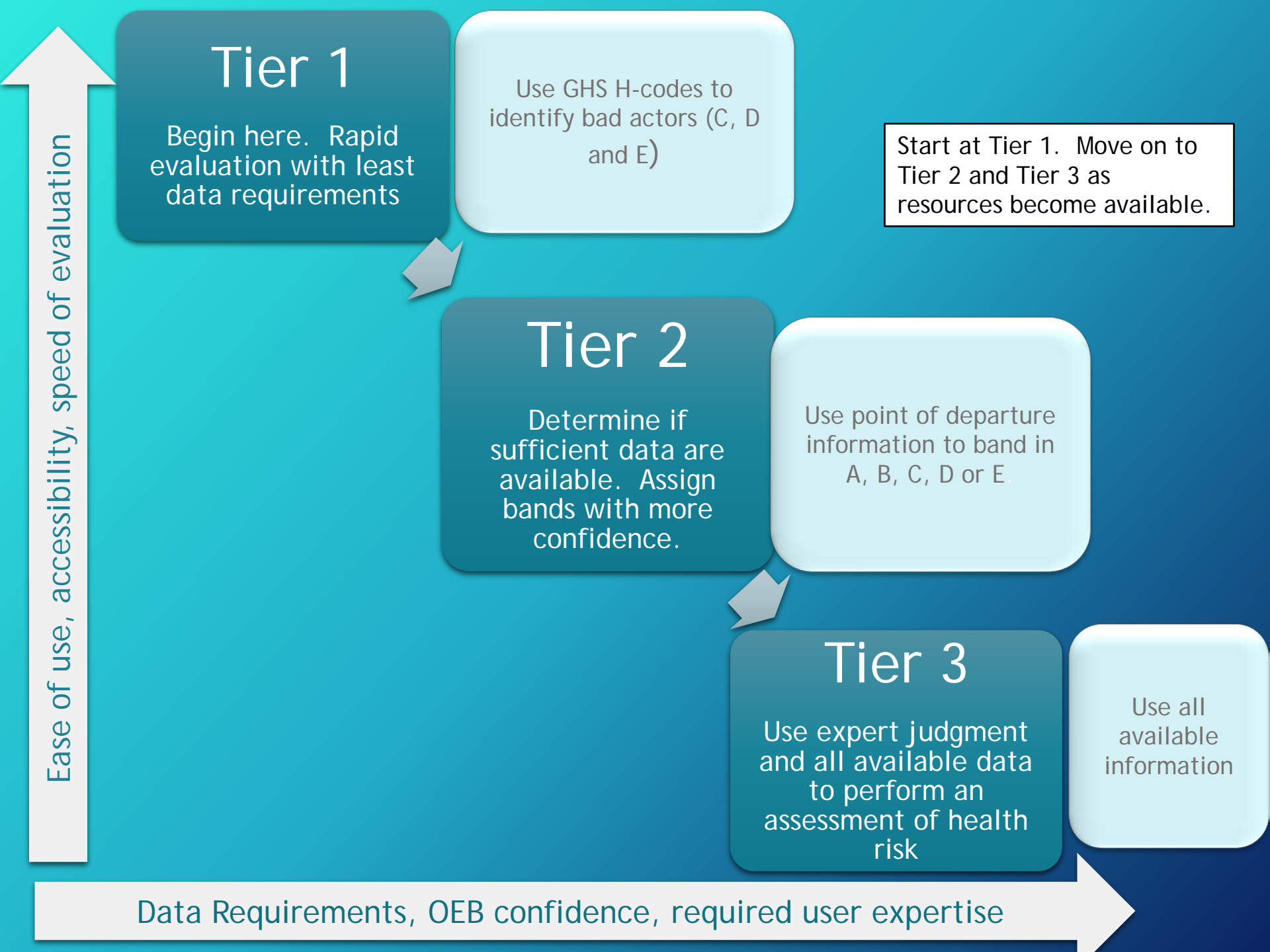
Hazard Banding Strategies
(Occupational Exposure Bands)

Risk-based Prioritization

The promise of Occupational Exposure Banding

- NIOSH
 - Facilitates more rapid evaluation of health risk
 - Used with minimal data
 - Highlights areas where data are missing
 - Supports the definition of OEL-ranges for families of materials
 - Provides a screening tool for the development of RELs
- Stakeholders
 - Provides guidance for materials without OELs
 - Identifies hazards to be evaluated for elimination or substitution
 - Aligned with GHS for hazard communication
 - Facilitates the application of Prevention through Design principles

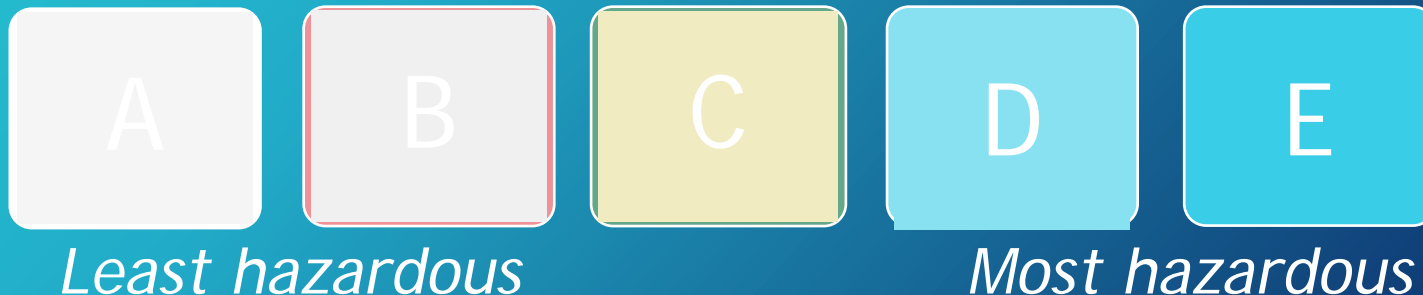




How is the decision logic organized?

Tiers 1 and 2 are based on the findings for eight standard toxicological endpoints and/or health outcomes:

- acute toxicity
- skin corrosion and irritation
- serious eye damage and irritation
- respiratory and skin sensitization
- germ cell mutagenicity
- carcinogenicity
- reproductive/developmental toxicity
- target organ toxicity resulting from repeated exposure

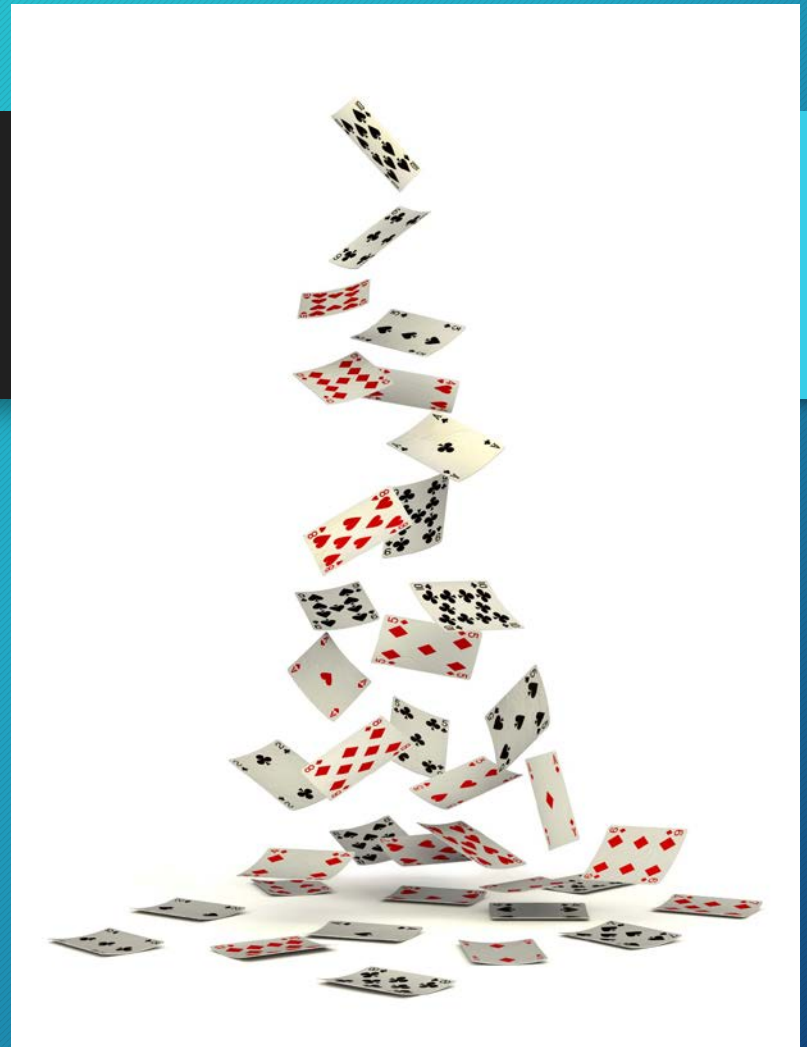


OEBs are trendy

OEBs are hot

OEBs are great!

OEBs solve everything



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Tier 1 Validation

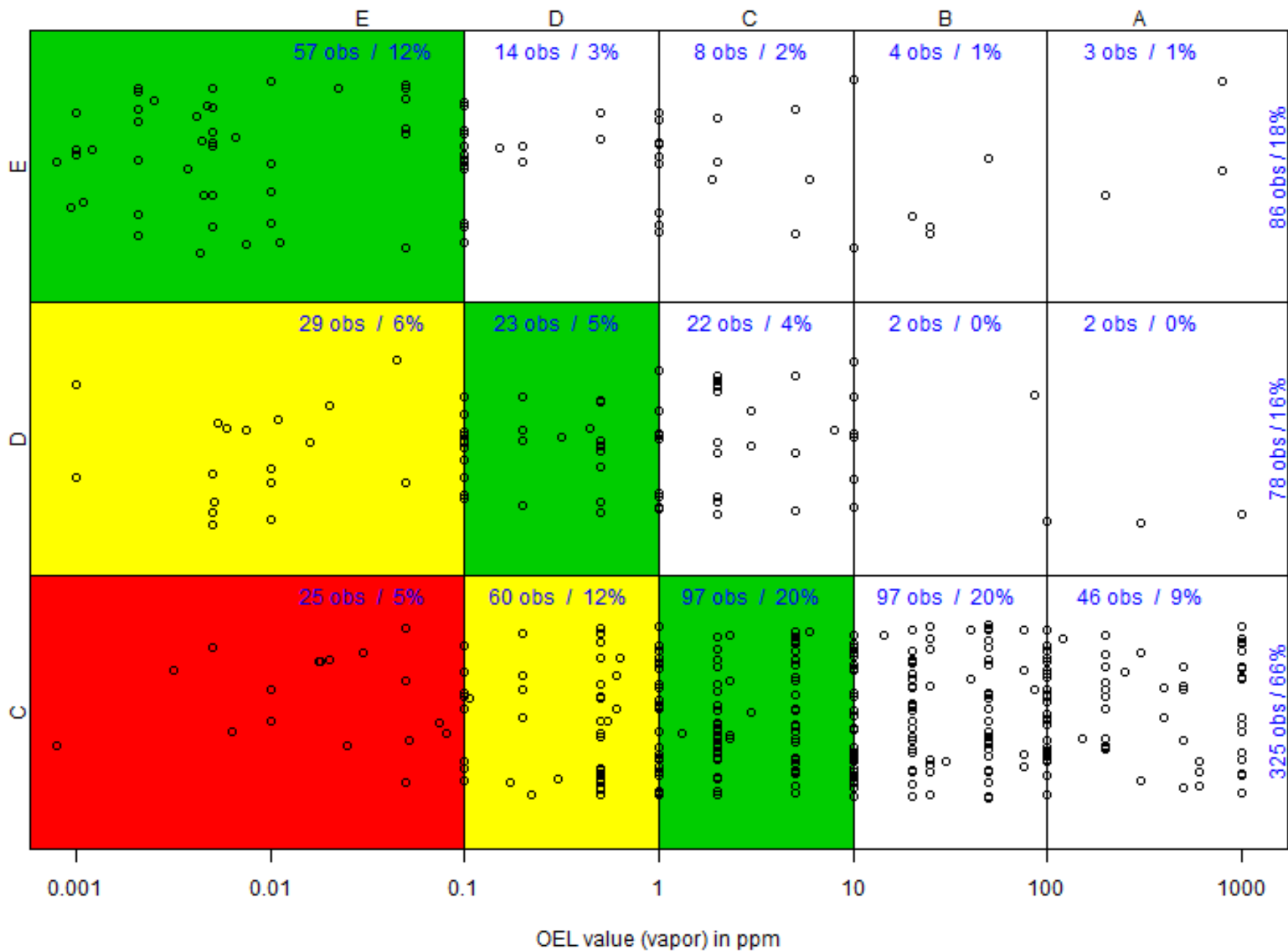
Compared bands obtained from Tier 1 process for 744 chemicals with full shift OELs from the following authoritative bodies:

- National Institute for Occupational Safety and Health (NIOSH) - Recommended Exposure Limits (RELs)
- Occupational Safety and Health (OSHA) - Permissible Exposure Limits (PELs)
- American Conference of Governmental Industrial Hygienists (ACGIH) - Threshold Limit Values (TLVs)
- American Industrial Hygiene Association (AIHA) - Workplace Environmental Exposure Levels (WEELs)
- California OSHA Program (Cal/OSHA) - PELs
- German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area - Maximale Arbeitsplatz-Konzentration (MAK, translated as Maximum Workplace Concentration)
- Greater than 80% of Tier 1 bands at least as protective as the OEL



VAPORS - Minimum OEL values vs. Overall Band (n=489)

Overall Band using H-codes & classifications



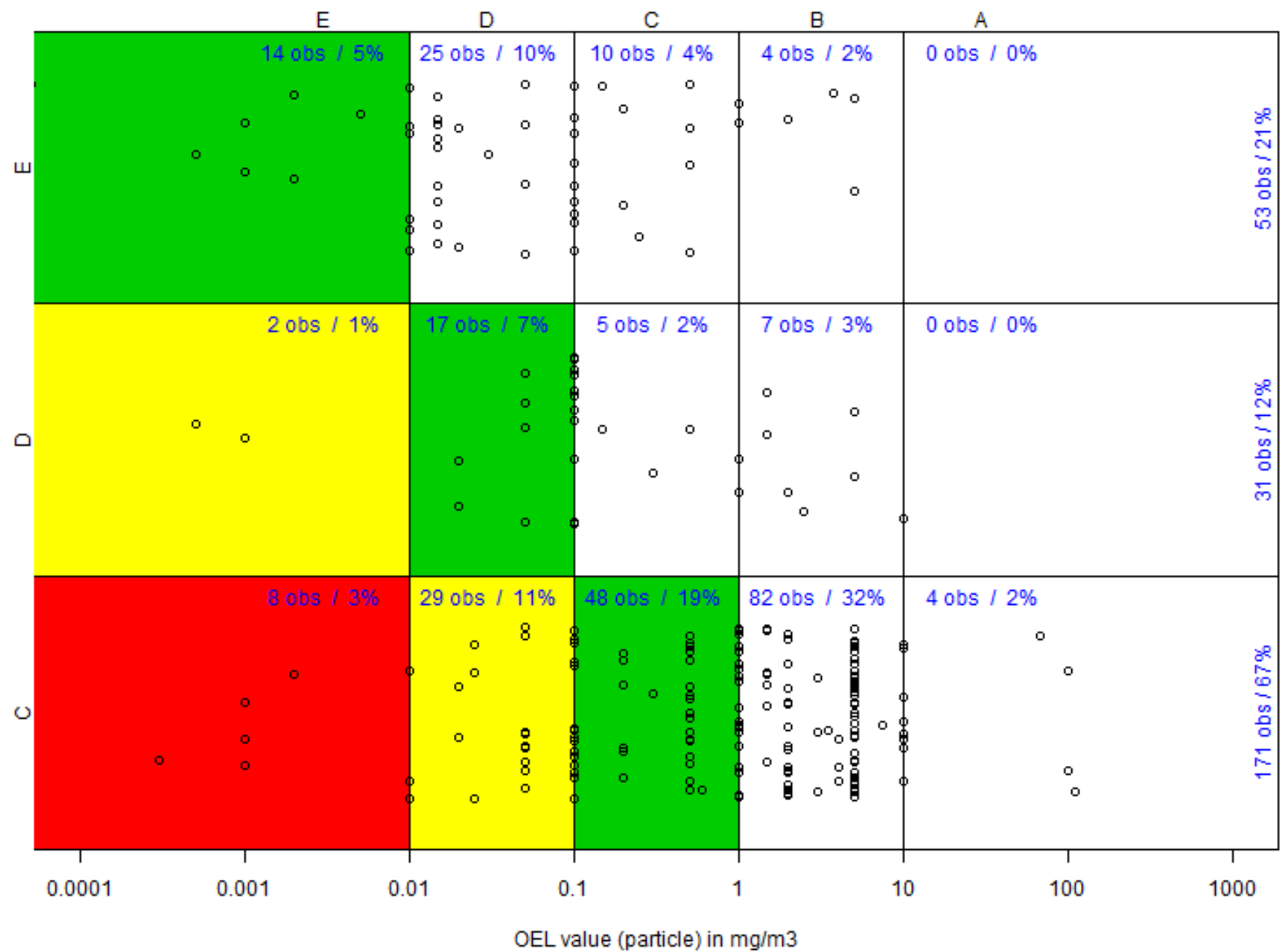
Tier 1 Validation - Vapors

- 76.7% of chemicals had Tier 1 Bands equally or more protective than corresponding OEL-based bands
- 23.3% of chemicals had Tier 1 Bands less protective than the corresponding OEL-based bands



PARTICLES - Minimum OEL values vs. Overall Band (n=255)

Overall Band using H-codes & classifications



Tier 1 Validation Results

- 84.7 % of chemicals had Tier 1 bands equally or more protective than the corresponding OEL-based bands
- 15.3% of chemicals had Tier 1 bands less protective than the corresponding OEL-based bands



Tier 1 Validation -Thoughts

- The overall rate of Tier 1 bands being at least as protective as the OEL was 79.4% (combined vapor and particulate)
- Recommend always doing a Tier 2 assessment since about 20% of the time the Tier 1 band is not as protective as the OEL.
- Possible to skip the Tier 2 process if you get band E in Tier 1



Tier 2

- Tier 2 - Semi-Quantitative
 - Skilled professional
 - Based on readily available secondary data from authoritative sources (government, professional health agencies, authoritative toxicological benchmarks)
 - Needs sufficient data to generate reliable OEB
 - Prescriptive analytical strategy to ensure consistency
 - Potential for chemicals to be moved from the Tier 1 OEB to a more or less protective OEB



What is Tier 2?

Tier 2 is an additional level of analysis used when:

- there are no GHS H codes
- the outcome of the Tier 1 analysis is incomplete, or an insufficient reflection of the health potency of the chemical



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- germ cell mutagenicity
- carcinogenicity
- reproductive/developmental toxicity
- target organ toxicity resulting from repeated exposure



Tier 2 Banding Principles

- For 8 specified health endpoints, search authoritative databases for summary toxicity information
- Collate results for each endpoint
- Find a Total Determinant Score and/or Occupational Exposure Band (this is done automatically in the electronic spreadsheet)

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Tier 2 Validation

- Is the Tier 2 process consistent and specific to independent users?
- Do the Tier 2 banding criteria reflect toxicity as determined by an independent evaluation (e.g. OELs)?
- Do new users get the same Tier 2 bands as expert users?
- Do users get the same endpoint specific bands as other users?
- Are there any health effects that band more reliably than others?

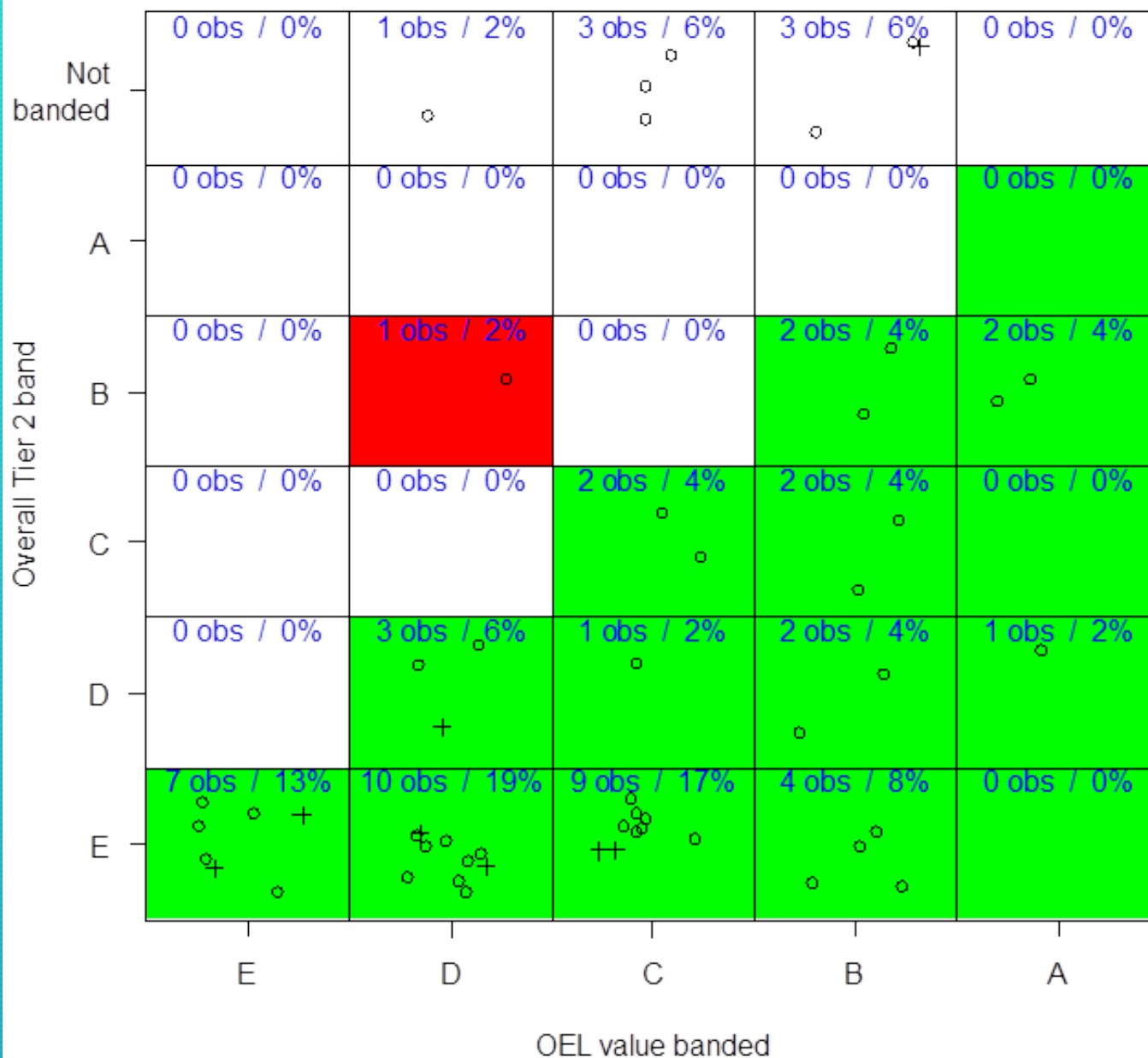


Tier 2 Validation - phase 1

- Two groups (Expert users and new users) completed Tier 2 process on 102 chemicals
- Comparisons of the chemicals with OELs to the OELs banded
- Used different scales and units for vapors (ppm) and particles (mg/m³)
- Separately for NIOSH and both users



Minimum OEL values banded vs. NIOSH Overall Tier 2 Band (o = vapors, + = particles) (n=53)



Lessons Learned

- Needed improved descriptions for some endpoints- skin and respiratory irritation
- Need to limit data trawling
- Toxicology primer to get everyone on same page



Tier 2 Validation - phase II

- NIOSH will provide the following items to volunteers:
 - The OEB guidance document
 - An electronic collection template in the form of an Excel spreadsheet
 - A list of the same 5 chemicals without OELs
- 2 chemicals with OELs - well characterized and known toxicity - will be provided to the volunteers and NIOSH experts to demonstrate the decision logic
- The chemicals without OELs have enough toxicity data across a variety of health effects assessed in Tier 2 to allow for detailed comparisons



Looking for Bandits

Volunteer to
help verify
the NIOSH OEB
decision logic

Provide a business card or
email LMcKernan@cdc.gov

