NIOSH OCCUPATIONAL EXPOSURE BANDING: A NEW TOOL FOR EVALUATING CHEMICAL HAZARDS

THOMAS J. LENTZ, PH.D., MPH

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

CENTERS FOR DISEASE CONTROL AND PREVENTION

DOCUMENT OBJECTIVE

To create a consistent and documented process to characterize chemical hazards so timely and well-informed risk management decisions can be made for chemicals lacking OELs.

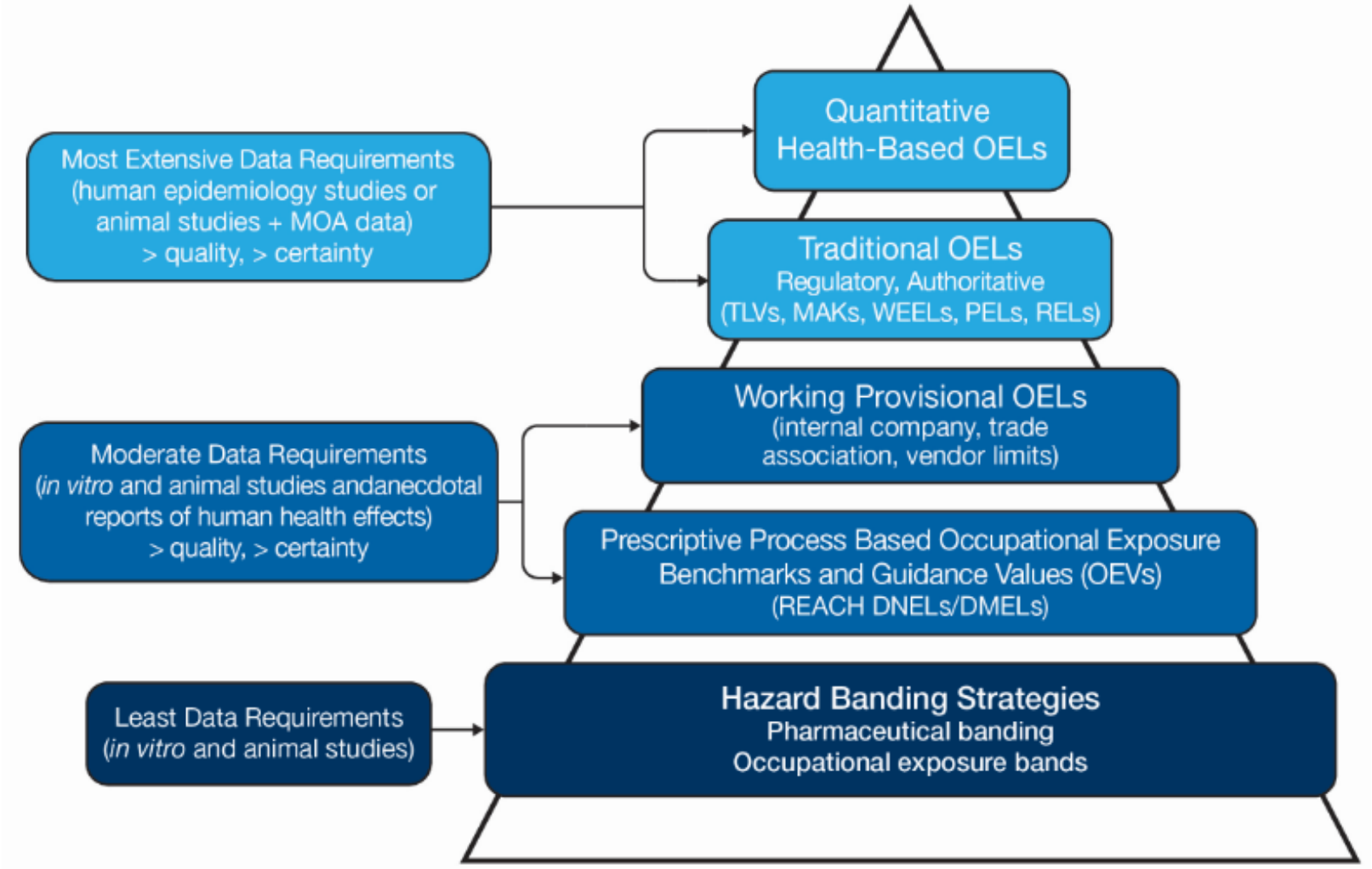
IMPORTANT POINT

An OEB is not meant to replace an OEL, rather it serves as a starting point to inform risk management decisions.

HISTORY

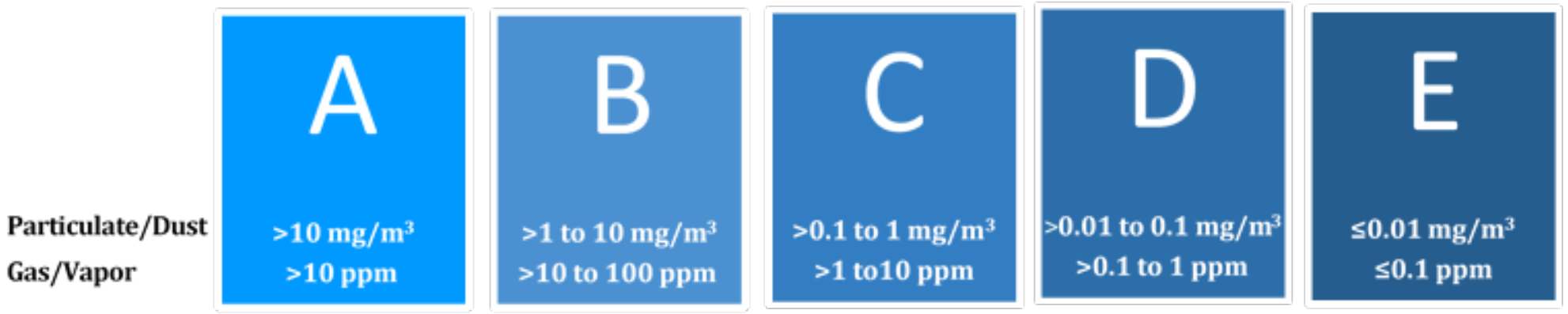
- One of the best ways to prevent and control occupational injuries, illnesses, and fatalities is to "design out" or minimize hazards and risks.
- NIOSH leads a national initiative called Prevention through Design (PtD).
- PtD encompasses all of the efforts to anticipate and design out hazards to workers in facilities, work methods and operations, processes, equipment, tools, products, new technologies, and the organization of work.
- The Occupational Exposure Banding Initiative emerged from this fundamental philosophy

HIERARCHY OF OELS

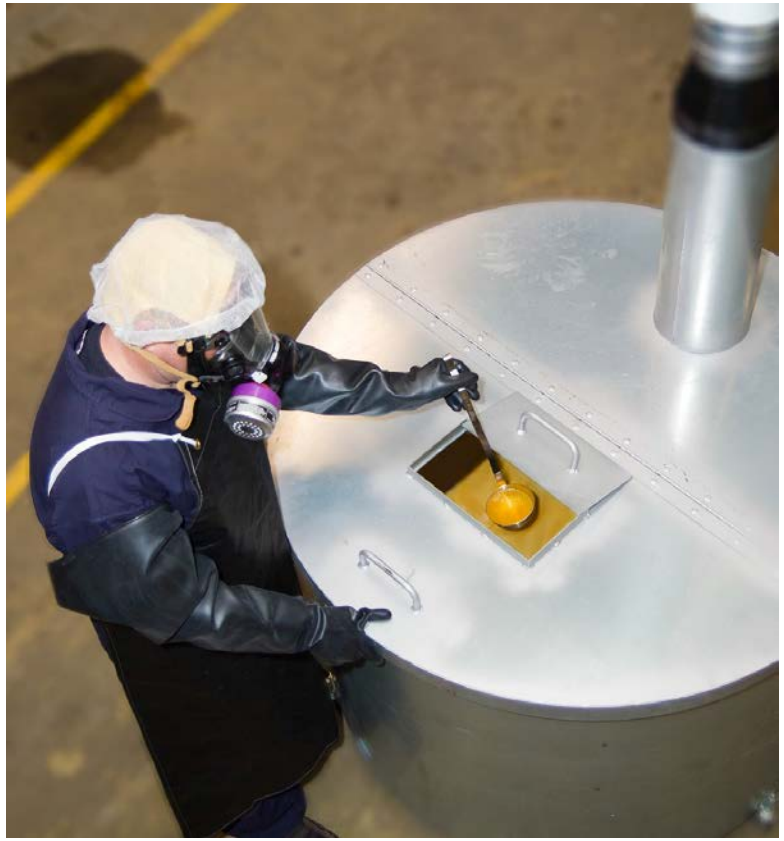


WHAT IS OCCUPATIONAL EXPOSURE BANDING?

A mechanism to quickly and accurately assign chemicals into "categories" or "bands" based on their health outcomes and potency considerations



WHY DO WE NEED OEBs?



CHEMICALS IN COMMERCE

OCCUPATIONAL EXPOSURE LIMITS

- Approximately 85,000 chemicals in commerce.

- Approximately 1,000 chemicals with authoritative OELs

PROPOSED NIOSH OCCUPATIONAL EXPOSURE BANDS

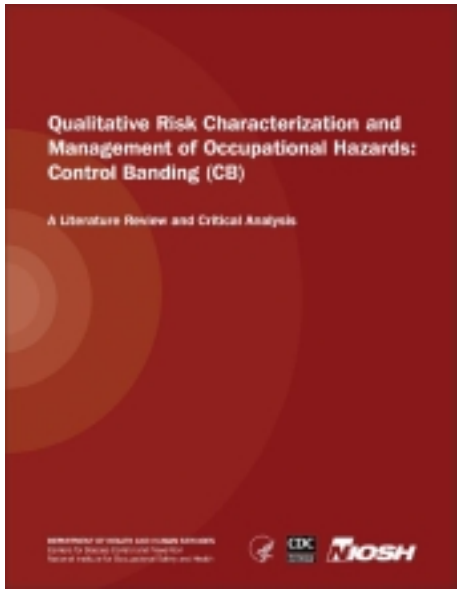
Occupational Exposure Band	Airborne Target Range for Particulate Concentration (mg/m^3)	Airborne Target Range for Gas or Vapor Concentration (ppm)
A	>10mg/m^3	>100 ppm
B	>1 to 10 mg/m^3	>10 to 100 ppm
C	>0.1 to 1 mg/m^3	>1 to10 ppm
D	>0.01 to 0.1 mg/m^3	>0.1 to 1 ppm
E	≤0.01 mg/m^3	≤0.1 ppm

THE PROMISE OF OCCUPATIONAL EXPOSURE BANDING

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

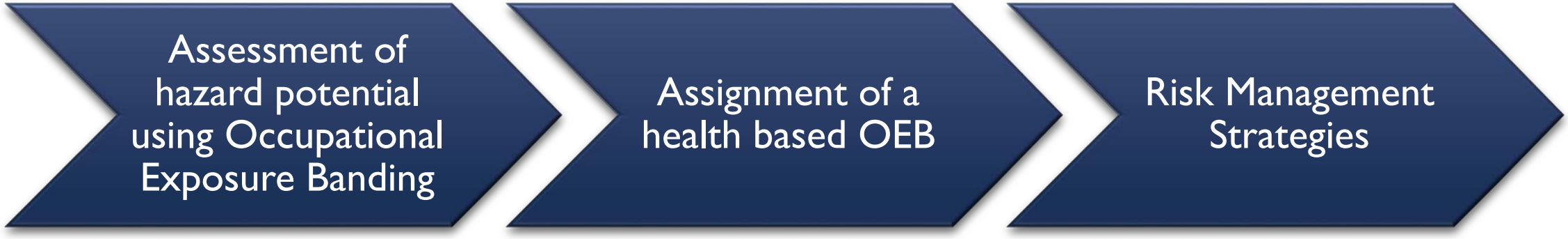
IS THIS THE SAME AS CONTROL BANDING? NO.

- ***COSHH Essentials*** is a control banding tool that helps small and medium-sized enterprises to do risk assessments for chemicals and mixtures of chemicals
  - identifies the control band (control approach),
  - produces advice on controlling risk from the chemical used in the specified task, and
  - provides written guidance and documentation as a result of the assessment
- NIOSH has reviewed control banding strategies previously



OCCUPATIONAL EXPOSURE BANDING IS DIFFERENT!

- OEBs derived from ***toxicology*** and ***potency***
- OEBs can be used to identify one of many control strategies



TOOLS FOR THE OCCUPATIONAL HYGIENIST

GHS classifications

Hazard Communication

Exposure Monitoring

Medical Surveillance

Engineering Controls

PPE

Occupational Exposure Bands

OELS

Quantitative Risk Assessments

HOW IS THE PROCESS ORGANIZED?

Bands are assigned based on the findings for nine standard toxicological endpoints:

1. Carcinogenicity
2. Reproductive toxicity
3. Specific target organ toxicity resulting from repeated exposure
4. Acute toxicity
5. Genotoxicity
6. Skin corrosion and irritation
7. Respiratory sensitization
8. Skin sensitization
9. Serious eye damage and irritation

Tier 1 —GHS Hazard Codes

User: Health and safety generalist

A Tier 1 evaluation utilizes GHS Hazard Statements and Categories to identify chemicals that have the potential to cause irreversible health effects.

Tier 2— Secondary Data Sources

User: Properly trained occupational hygienist

A Tier 2 evaluation produces a more refined OEB, based on point of departure data from reliable sources. Data availability and quality are considered.

Tier 3—Expert Judgement

User: Toxicologist or experienced occupational hygienist

Tier 3 involves the integration of all available data and determining the degree of conviction of the outcome.

GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

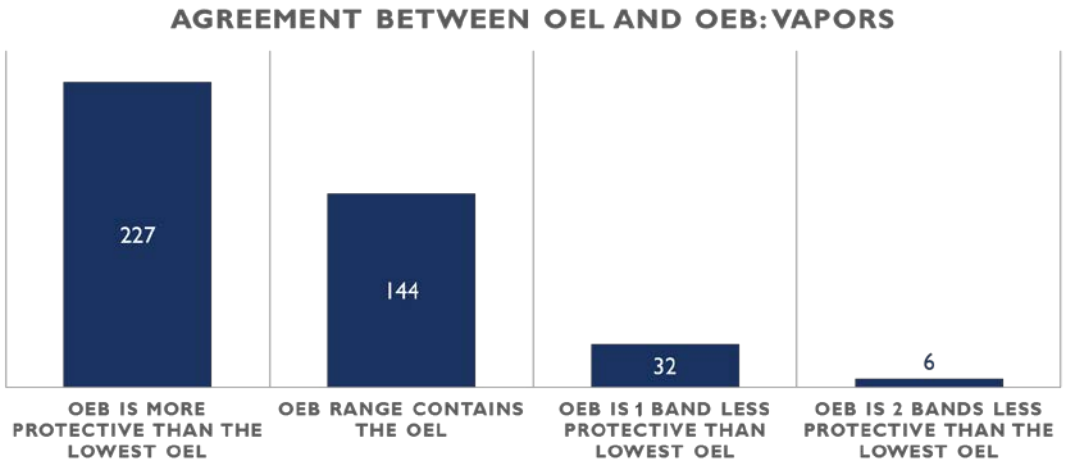
- GHS is a hazard classification system developed by the United Nations to standardize chemical regulations in different countries
  - Within GHS, each physical or health hazard is a **hazard class** (e.g., Carcinogenicity is a hazard class)
  - A hazard class may be sub-divided into several **hazard categories** based on the severity of the hazard
  - GHS uses alphanumeric **hazard codes** to represent these hazards

TIER 1 Criteria		C	D	E
OEL Ranges	Particle	> 0.1 to ≤ 1 milligrams per cubic meter of air (mg/m^3)	> 0.01 to ≤ 0.1 mg/m^3	≤ 0.01 mg/m^3
	Vapor	> 1 to ≤ 10 parts per million (ppm)	> 0.1 to ≤ 1 ppm	≤ 0.1 ppm
Acute Toxicity		H301 Category 3	H300 Category 2	H300 Category 1
		H302 Category 4		
		H331 Category 3	H330 Category 2	H330 Category 1
		H332 Category 4		
		H311 Category 3	H310 Category 2	H310 Category 1
		H312 Category 4		
Skin Corrosion/ Irritation		H315 Category 2		H314 Category 1, 1A, 1B, or 1C
Serious Eye Damage/ Eye irritation		H319 Category 2, 2A or 2B		H318 Category 1
Respiratory and Skin Sensitization		H317 Category 1B	H317 Category 1 or 1A	
		H335 Category 3	H334 Category 1B	H334 Category 1 or 1A
Genotoxicity			H341 Category 2	H340 Category 1, 1A or 1B
Carcinogenicity				H350 Category 1, 1A, or 1B
				H351 Category 2
Toxic to Reproduction		H361 Category 2	H360 Category 1B	H360 Category 1 or 1A
Specific Target Organ Toxicity		H371 Category 2		H370 Category 1
		H373 Category 2		H372 Category 1

TIER 1 EVALUATION

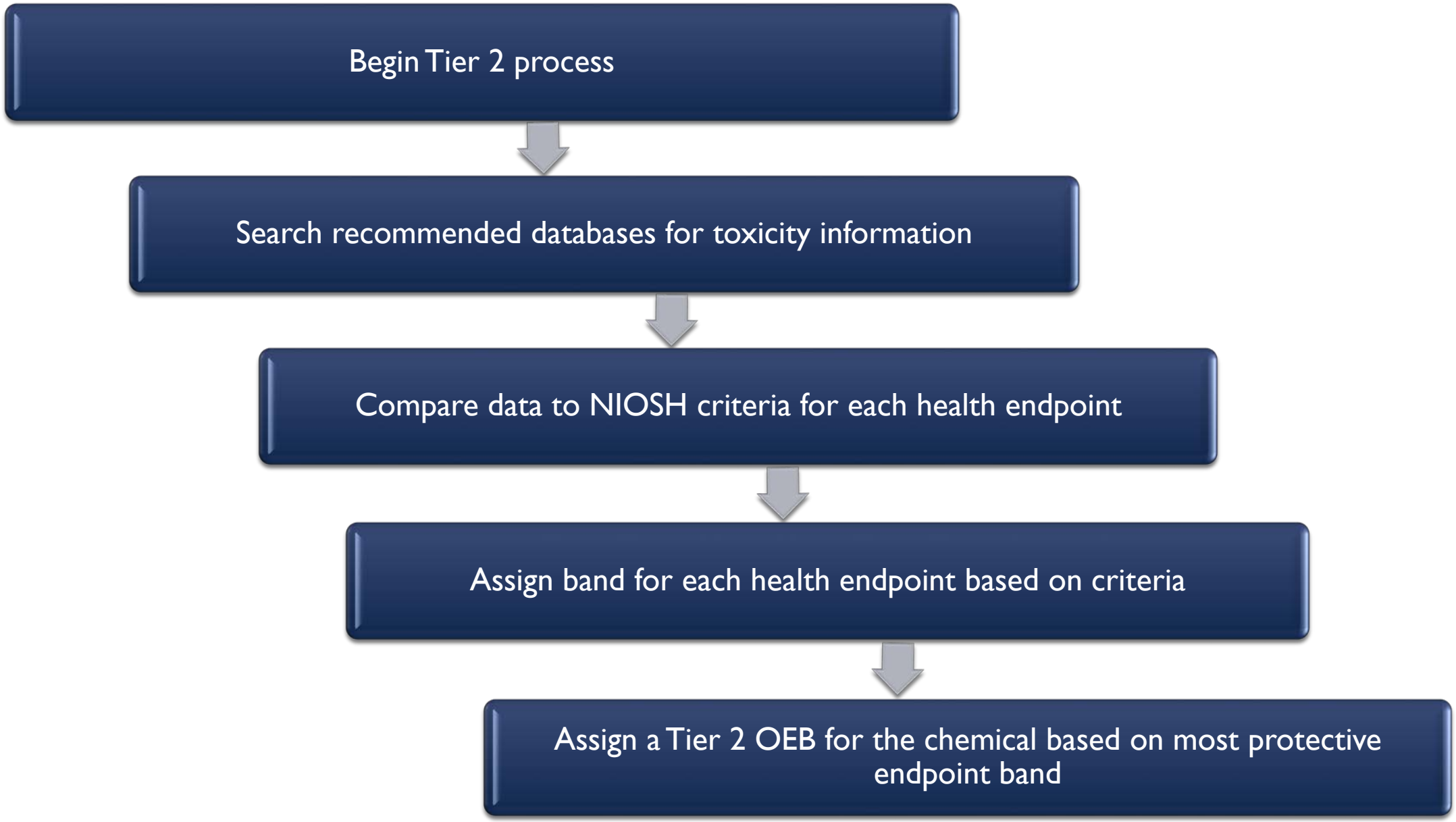
Compared bands obtained from Tier 1 process for 744 chemicals with full shift OELs from the following authoritative bodies:

- NIOSH Recommended Exposure Limits (RELs)
- OSHA – Permissible Exposure Limits (PELs)
- ACGIH– Threshold Limit Values (TLVs)
- AIHA – Workplace Environmental Exposure Levels (WEELs)
- California OSHA Program (Cal/OSHA) – PELs
- German Maximale Arbeitsplatz-Konzentration (MAK)



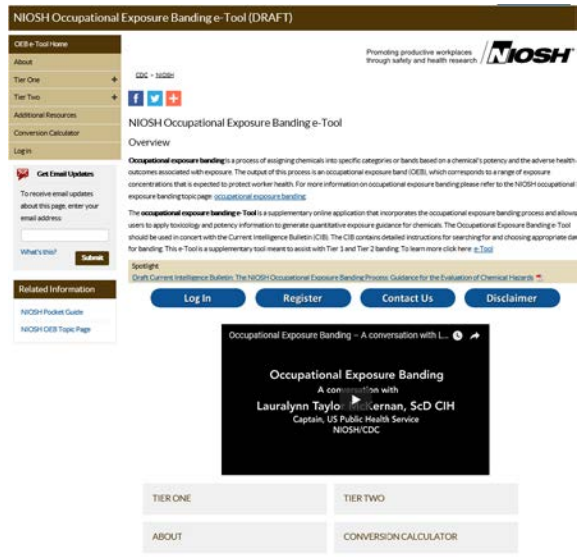
** Greater than 80% of Tier 1 bands at least as protective as the OEL

TIER 2 OVERVIEW



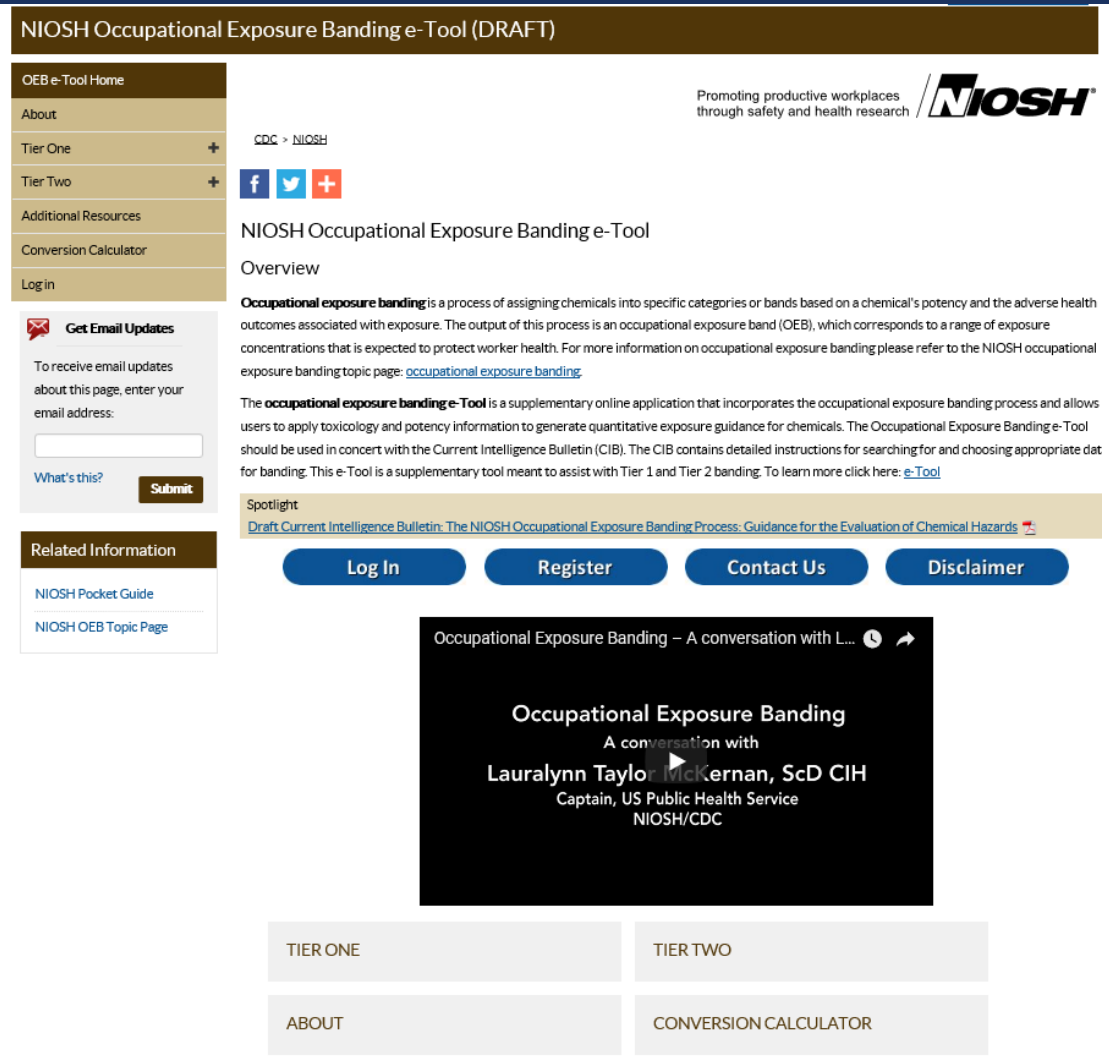
HOW TO COMPLETE THE OEB PROCESS

Pencil and Paper



Online using
draft NIOSH OEB e-tool

NIOSH OEB E-TOOL



TIER 3 OVERVIEW

- Requires expertise in toxicology
- Requires intensive review and evaluation of primary data
- Is required when insufficient data for Tier 2 banding
- Completed when no detailed guidance is available

TIER 1 OVERVIEW AND EXAMPLE

THE FINDINGS AND CONCLUSIONS IN THIS PRESENTATION HAVE NOT BEEN FORMALLY DISSEMINATED BY THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY.

TIER 1 PROCESS

- GHS hazard codes and categories provide the basis for Tier 1 criteria
- Relatively low data requirements
- Chemicals can be banded in bands C, D, and E
- Chemicals are assigned Tier 1 OEBs based on severity and reversibility of effects
- Tier 1 is useful as a screening tool, but Tier 2 is recommended if data and expertise are available

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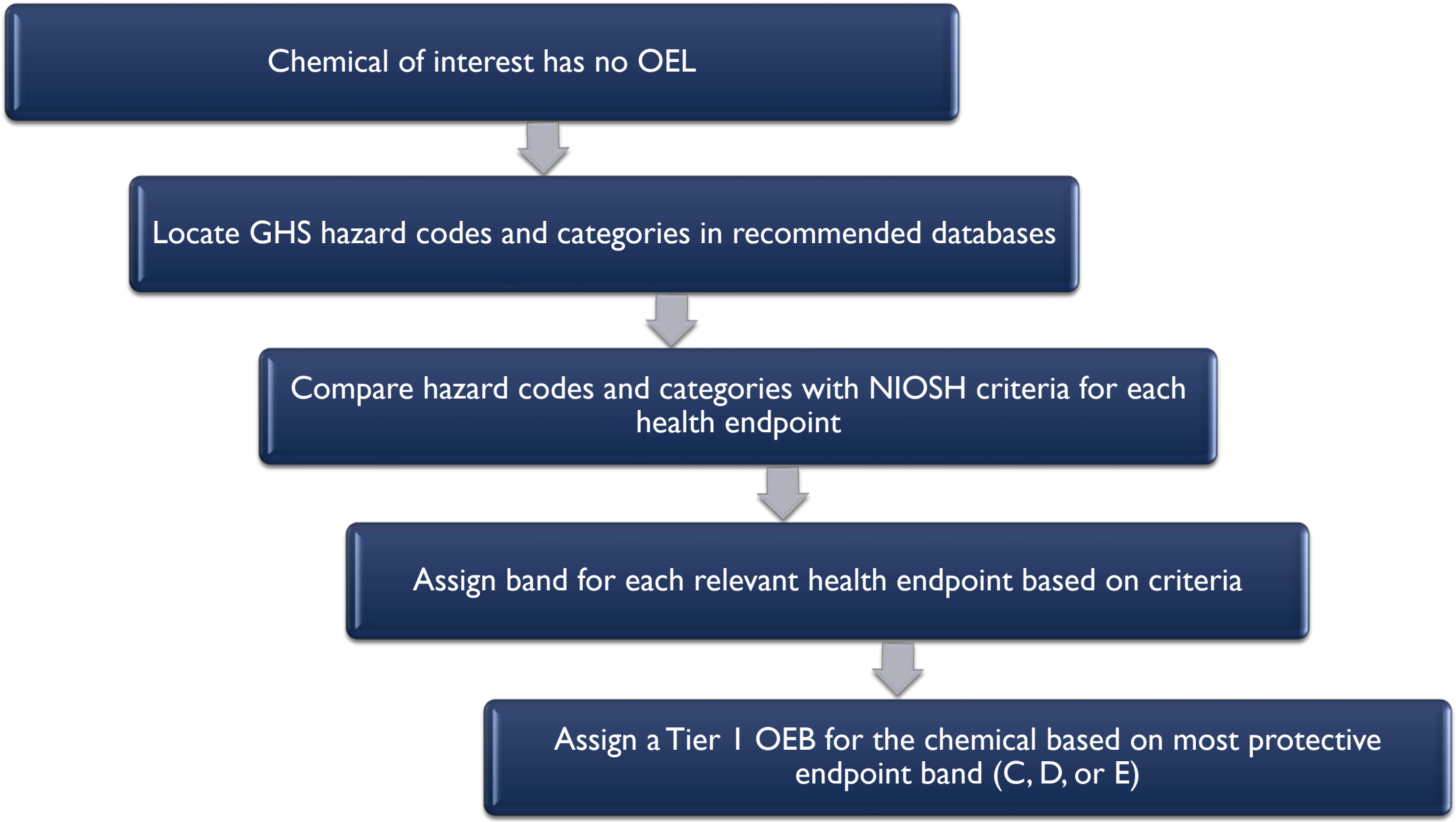

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Acute Toxicity		H301 Category 3	H300 Category 2	H300 Category 1
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Acute Toxicity		H301 Category 3 H302 Category 4	H300 Category 2	H300 Category 1
		H331 Category 3 H332 Category 4	H330 Category 2	H330 Category 1
		H311 Category 3 H312 Category 4	H310 Category 2	H310 Category 1
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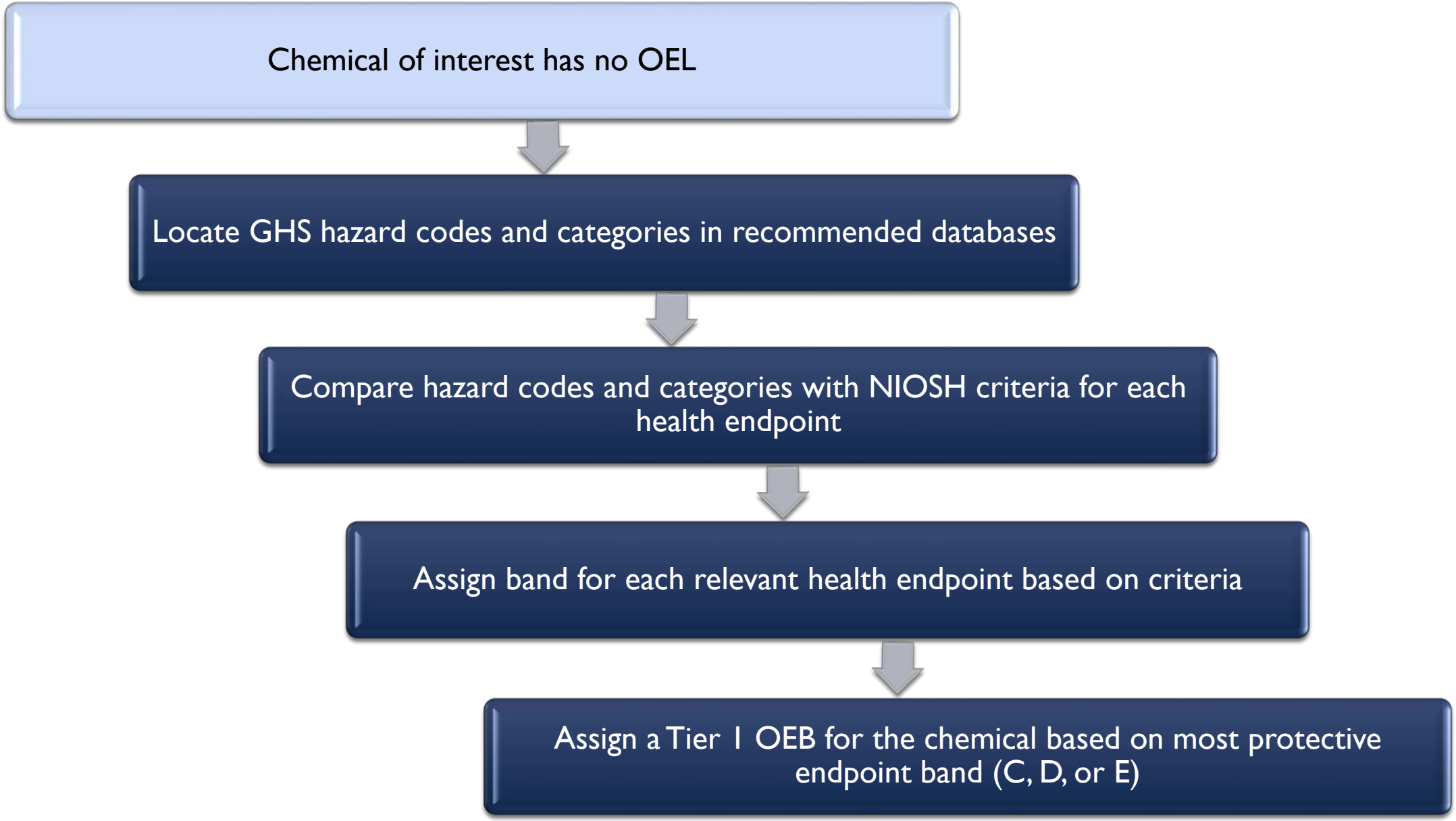
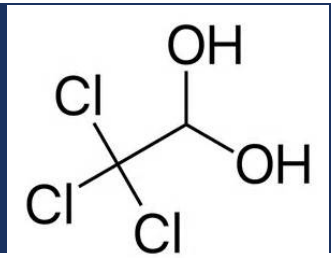
GHS CODES NOT USED IN BANDING

- H200 codes (physical hazards)
- H400 codes (ecological hazards)
- H303, H304, H305, H313, H316, H320, H333, H336, H362
  - Not occupationally relevant, OR
  - Not sufficient to affect the result of Tier 1 banding

TIER I OVERVIEW

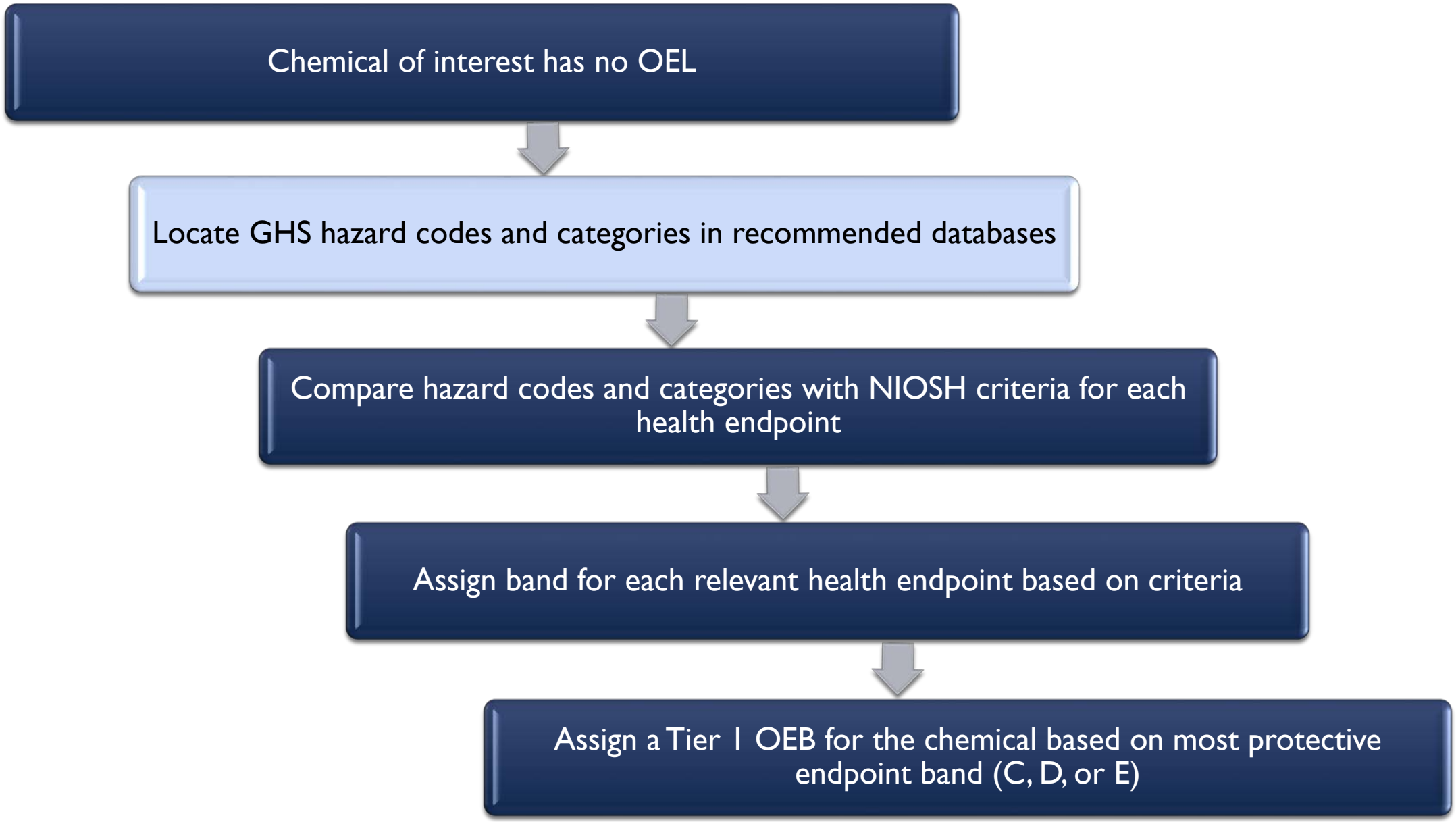


TIER 1 EXAMPLE: ABIETIC ACID



- CAS# 514-10-3
- Organic compound that occurs naturally in trees
- Extracted from tree rosin, used for
  - Caulking ships
  - Treating bows on musical instruments
  - Depackaging integrated circuits from epoxy coatings
- Known to be an allergen
- Some qualitative and quantitative data exist, but…
- **No OEL exists**

TIER 1 OVERVIEW



RELIABLE SOURCES FOR TIER 1

- GESTIS Substance Database
  - www.dguv.de/ifa/gestis-database
- ECHA Annex VI to CLP
- Safety Data Sheets

LOCATE GHS H-CODES AND CATEGORIES FROM RECOMMENDED DATABASES

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REGULATIONS

GHS Classification/Labelling | Workplace labelling | Air quality control | Transport Regulations | MAK recommendations | Seveso III | Further regulations

EUROPEAN GHS CLASSIFICATION AND LABELLING

Classification:
Skin irritation, Category 2; H315
Eye irritation, Category 2; H319
Specific Target Organ Toxicity (single exposure), Category 3; H335
Hazardous to the aquatic environment, Acute Category 1; H400

Skin irritation, Category 2; H315
Eye irritation, Category 2; H319
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Hazardous to the aquatic environment, Acute Category 1; H400

H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H400: Very toxic to aquatic life.

Precautionary Statement - P-phrases:
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

TIER I EXAMPLE: ABIETIC ACID

- Locate GHS H-codes and categories from recommended databases

Abietic Acid CAS: 514-10-3				
Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity				
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation				
Respiratory and Skin Sensitization				
Germ Cell Mutagenicity				
Carcinogenicity				
Toxic to Reproduction				
Specific Target Organ Toxicity				

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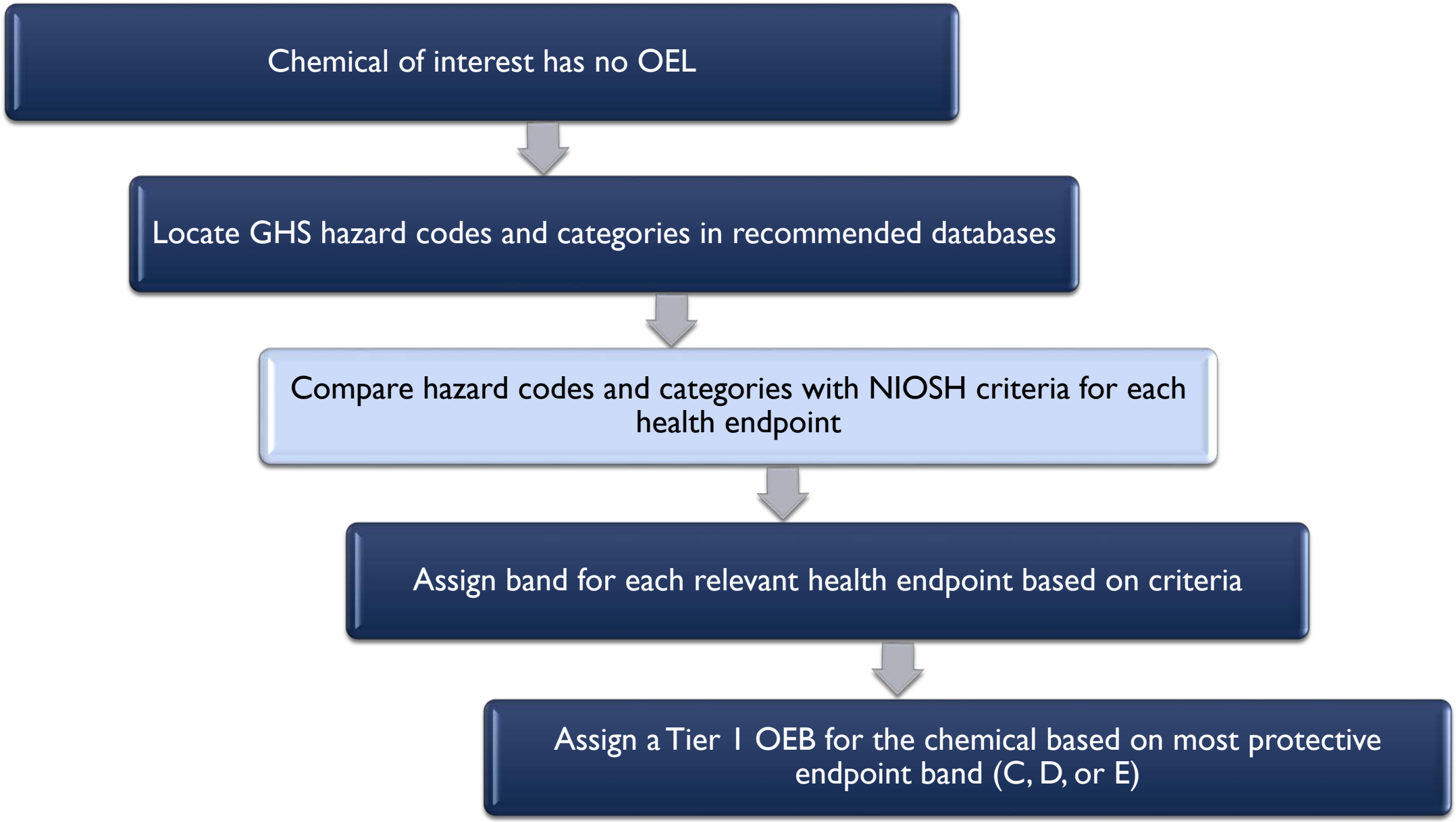
Abietic Acid CAS: 514-10-3				
Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity				
Skin Corrosion/Irritation	H315	2	GESTIS	
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	
Respiratory and Skin Sensitization				
Germ Cell Mutagenicity				
Carcinogenicity				
Toxic to Reproduction				
Specific Target Organ Toxicity	H335	3	GESTIS	

TIER 1 OVERVIEW



TIER 1 EXAMPLE: ABIETIC ACID

- Compare codes and categories with NIOSH Tier 1 OEB Criteria Chart

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Skin Corrosion/Irritation	H315	2	GESTIS	**C**
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	
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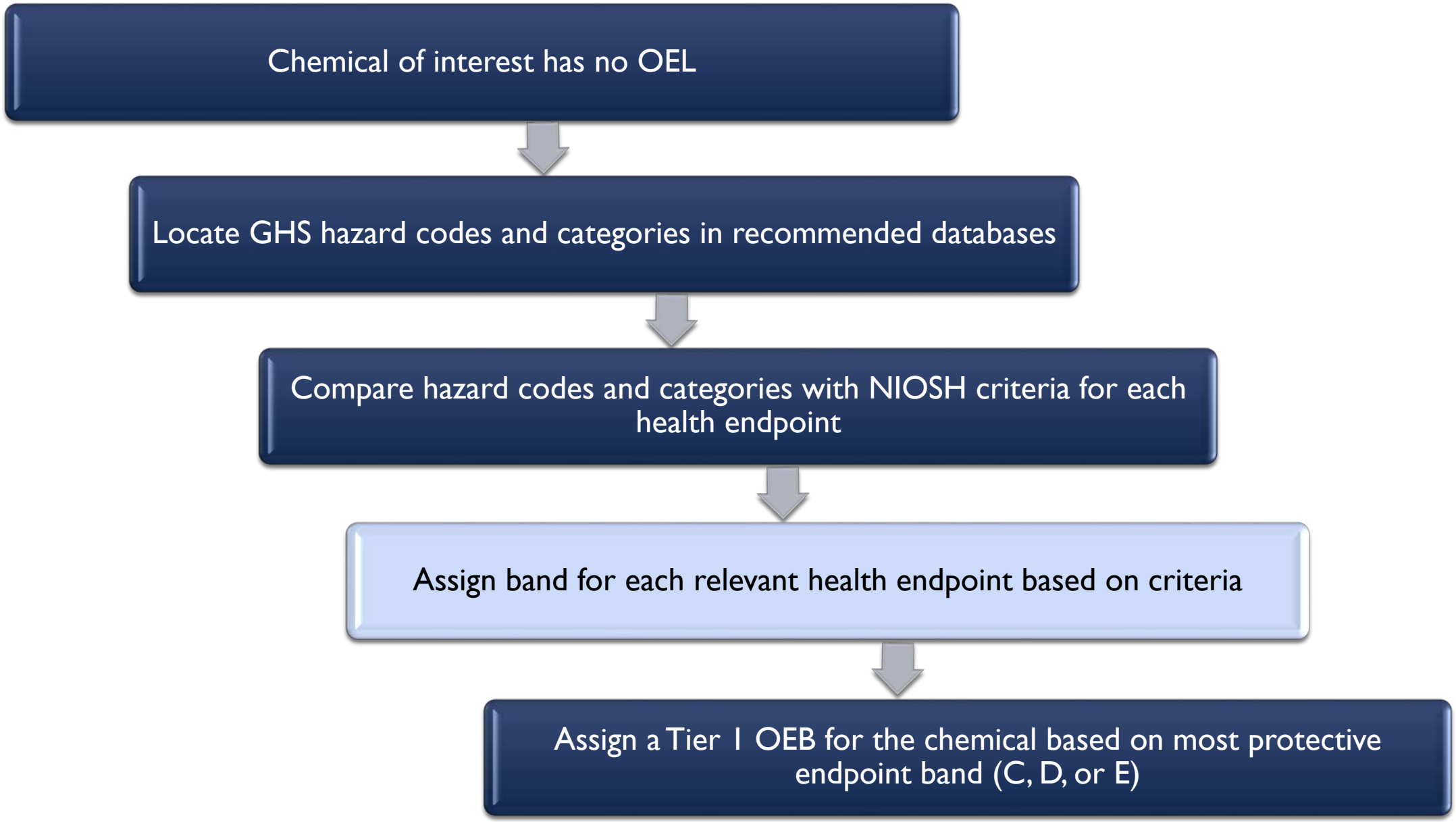

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Toxic to Reproduction				
Specific Target Organ Toxicity	H335	3	GESTIS	**No Band**

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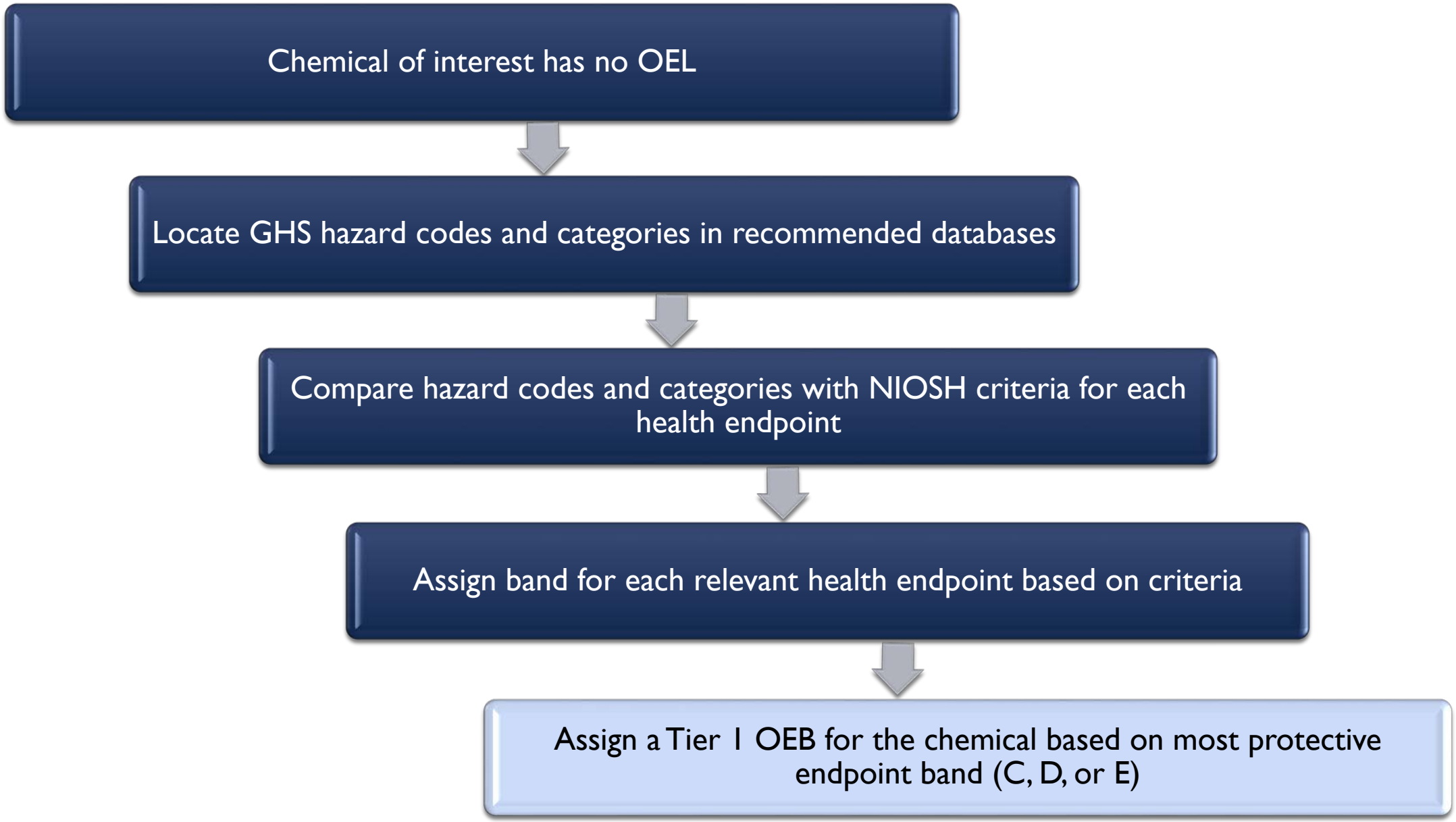

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Respiratory and Skin Sensitization				
Germ Cell Mutagenicity				
Carcinogenicity				
Toxic to Reproduction				
Specific Target Organ Toxicity	H335	3	GESTIS	**No Band**

Most protective band: Band C

TIER I RESULT

- Based upon the Tier I banding process, the chemical should be in **Band C.**

- Tier 2 is recommended.

TIER 1 EVALUATION

- Compared bands obtained from Tier 1 process for 744 chemicals with full shift OELs from the following authoritative bodies:
  - NIOSH Recommended Exposure Limits (RELs)
  - OSHA – Permissible Exposure Limits (PELs)
  - ACGIH– Threshold Limit Values (TLVs)
  - AIHA – Workplace Environmental Exposure Levels (WEELs)
  - California OSHA Program (Cal/OSHA) – PELs
  - German Maximale Arbeitsplatz-Konzentration (MAK)
- The overall rate of Tier 1 bands being at least as protective as the OEL was 91.5% (combined vapor and particulate).
- This exceeds our original goal of 80%.
- It is recommended to proceed to Tier 2
  - GHS hazard codes may not be as up-to-date as the literature.
  - Some H-codes (e.g. , Cancer codes) automatically lead to band E

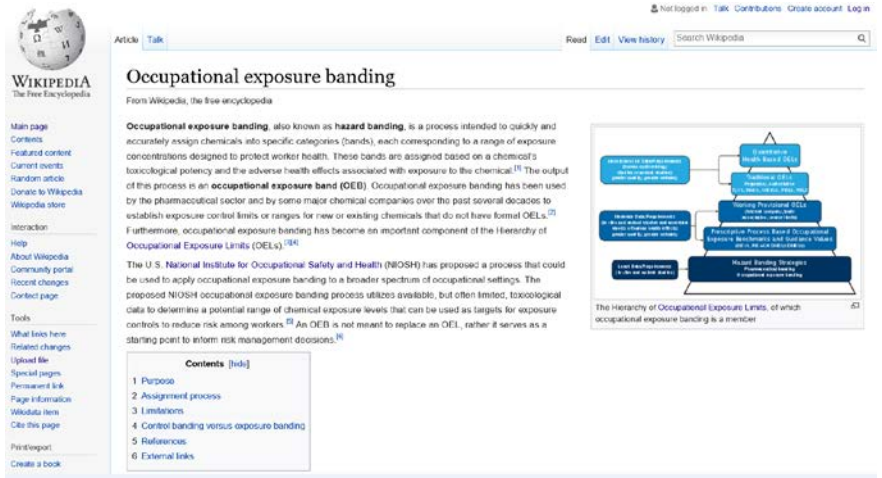
MORE THAN A BAND

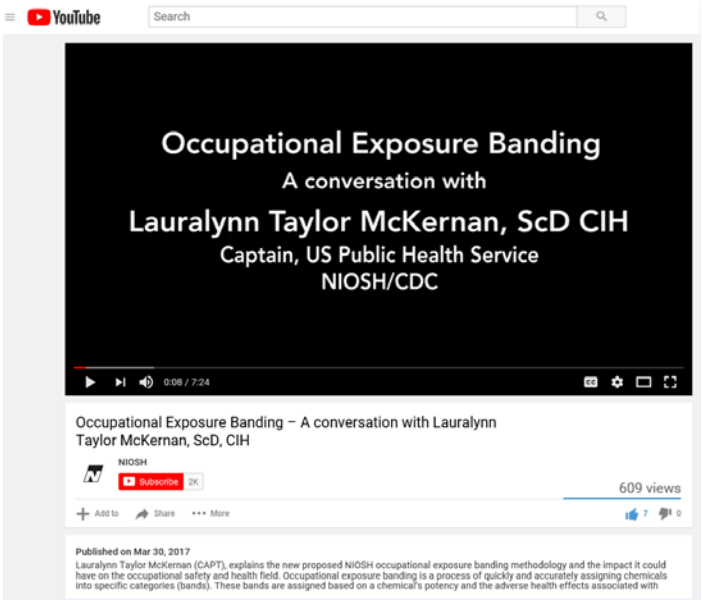
- Identify potential health effects and target organs
- Identify health risks to improve health communication
- Inform implementation of control interventions
- Inform medical surveillance decisions
- Provide critical information in a timely fashion

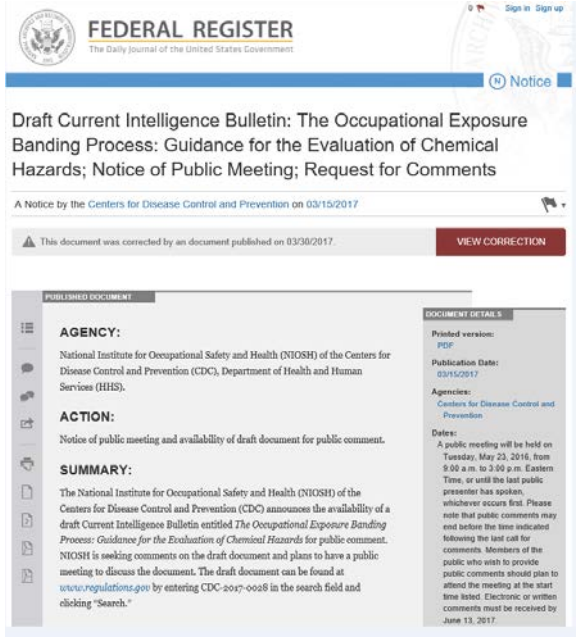
DISSEMINATION

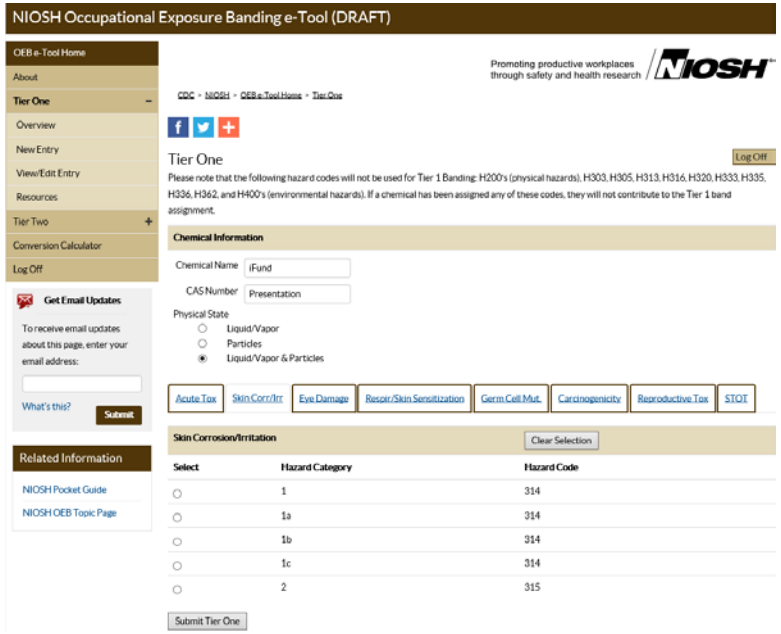
- Occupational safety and health professionals who serve small- and medium-sized businesses
- Stakeholders from multiple organizations, including organized labor, industry safety and health professionals, and government agencies
  - Feedback is overwhelmingly positive
  - Confirmed need for a banding approach and tool
  - Suggestions for improvement – simplicity and training

GUIDANCE









NIOSH Occupational Exposure Banding

NIOSH Occupational Exposure Banding e-Tool (DRAFT)

Related Information

NIOSH Pocket Guide

NIOSH OEB Topic Page

Promoting productive workplaces through safety and health research NIOSH

Tier One

Log Off

Please note that the following hazard codes will not be used for Tier 1 Banding: H200's (physical hazards), H303, H305, H313, H316, H320, H333, H335, H336, H362, and H400's (environmental hazards). If a chemical has been assigned any of these codes, they will not contribute to the Tier 1 band assignment.

Chemical Information

Chemical Name

CAS Number

Physical State

- ○ Liquid/Vapor
- ○ Particles
- ◉ Liquid/Vapor & Particles

Acute Tox | Skin Corr/Irr | Eye Damage | Respir/Skin Sensitization | Germ Cell Mut. | Carcinogenicity | Reproductive Tox | STOT

Acute Toxicity

Select	Hazard Category	Hazard Code	
☐	1	300	Oral
☐	2	300	Oral
☐	3	301	Oral
☐	4	302	Oral

NIOSH Occupational Exposure Banding

PROJECTED SUCCESS

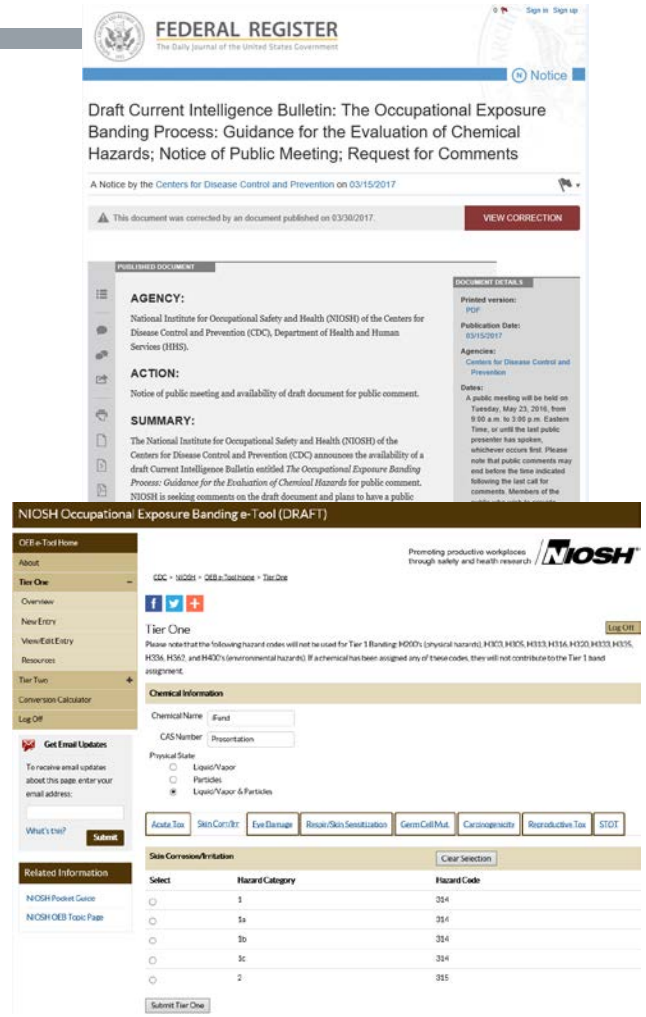
- Automating the e-Tool and finalizing banding guidance
- Overcoming the public health challenge of protecting workers from the myriad chemicals lacking guidance
- Partnering with AIHA and ASSP for initial dissemination and continuing widespread use in the occupational safety and health community

PARTNERSHIP ACTIVITIES

- AIHA Body of Knowledge Occupational Exposure Banding Workgroup Meeting (October 2017)
- Presentations at AIHA Fall Conference (October 2017)
- AIHA Exposure and Control Banding Committee
- AIHA OEB User Workgroup?
- Synergist Article (May 2018)
- IOHA (September 2018)

SUMMARY

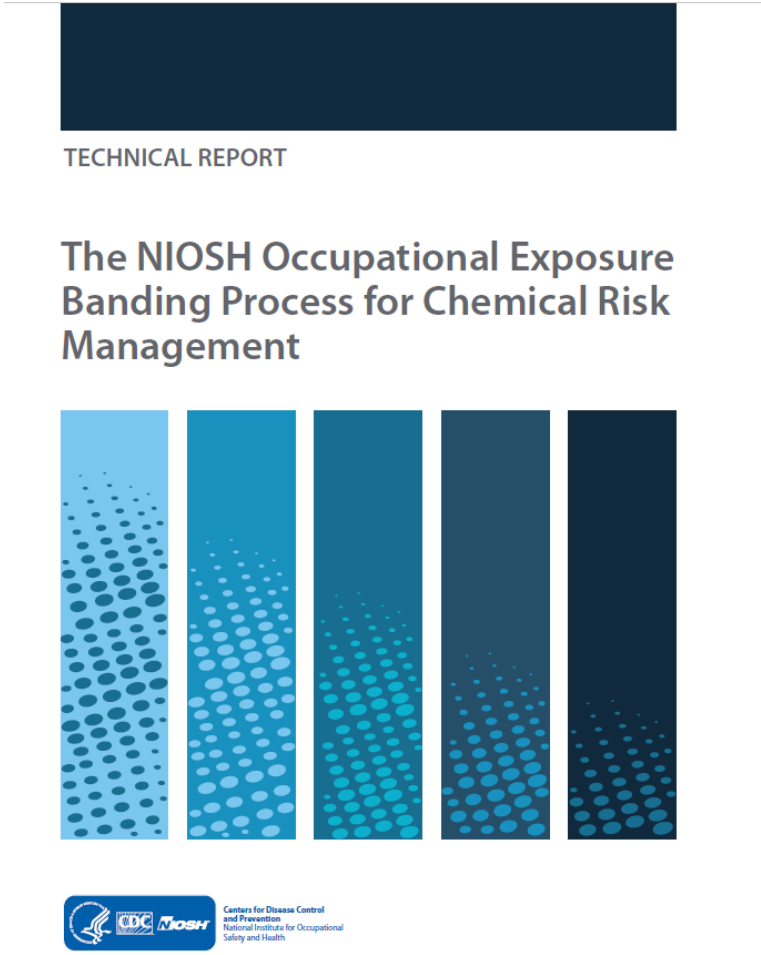
- Innovative approach to provide guidance prescriptive enough to be used by small- and medium-sized establishments
- Draft Occupational Exposure Banding process to provide guidance for chemicals without OELs
- Accompanying electronic tool (e-Tool) also created



NIOSH Occupational Exposure Banding

OEB TEAM MEMBERS

- Jane Chen, M.S.
- Stephen J. Gilbert, M.S.
- Thomas J. Lentz, Ph.D.
- Andy Maier, Ph.D., CIH, DABT
- Lauralynn Taylor McKernan, Sc.D., CIH,
- Pranav Rane, M.P.H
- Melissa Seaton, M.S.
- Christine Whittaker, Ph.D.



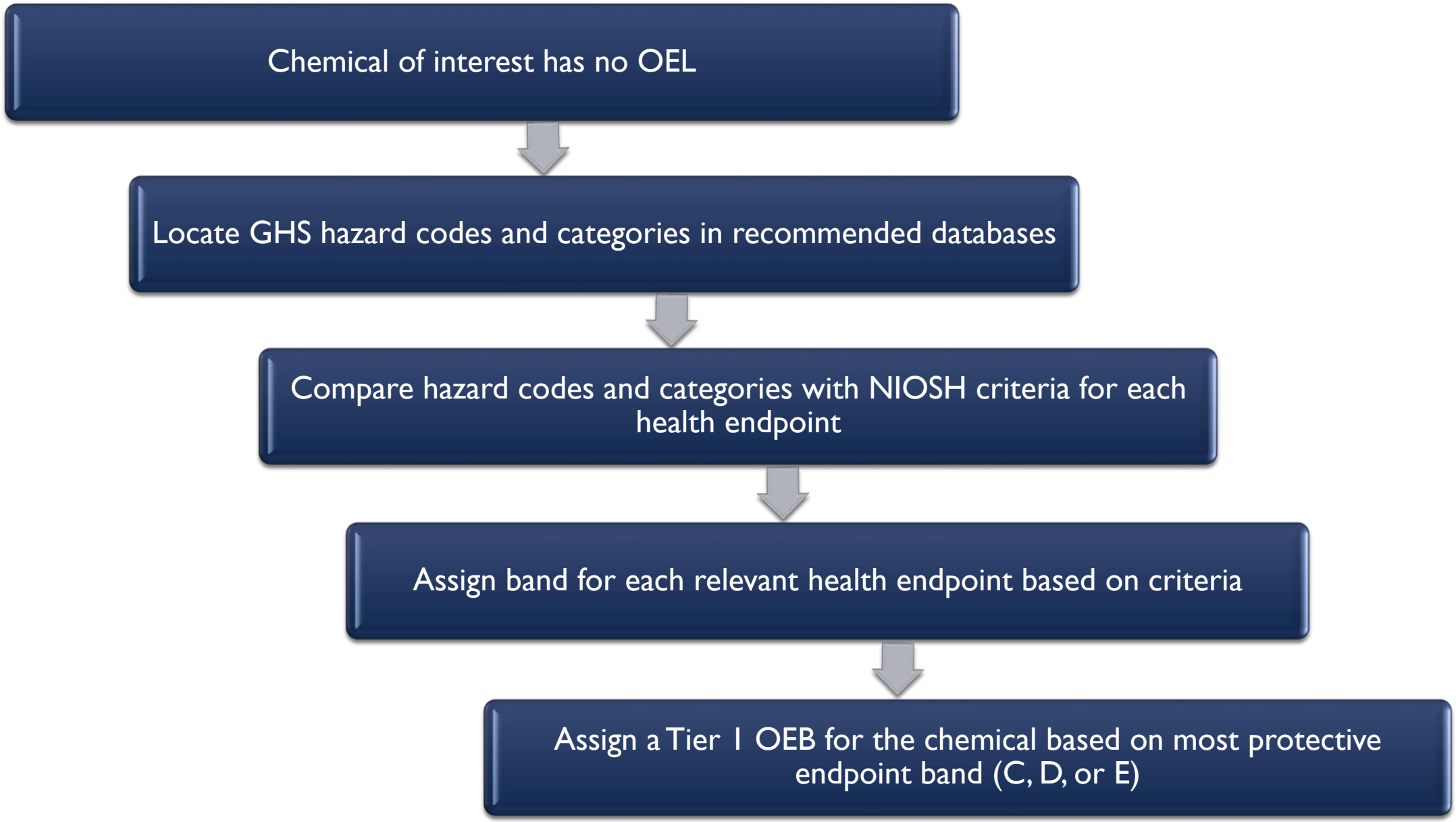
QUESTIONS FOR THE BOARD OF SCIENTIFIC COUNSELORS

- What additional dissemination strategies should NIOSH consider to promote occupational exposure banding?
- Is there value in exploring additional applications for occupational exposure banding (e.g., emergency response, dermal exposures)?
- Are there other groups who could benefit from or assist NIOSH with research efforts with occupational exposure banding?

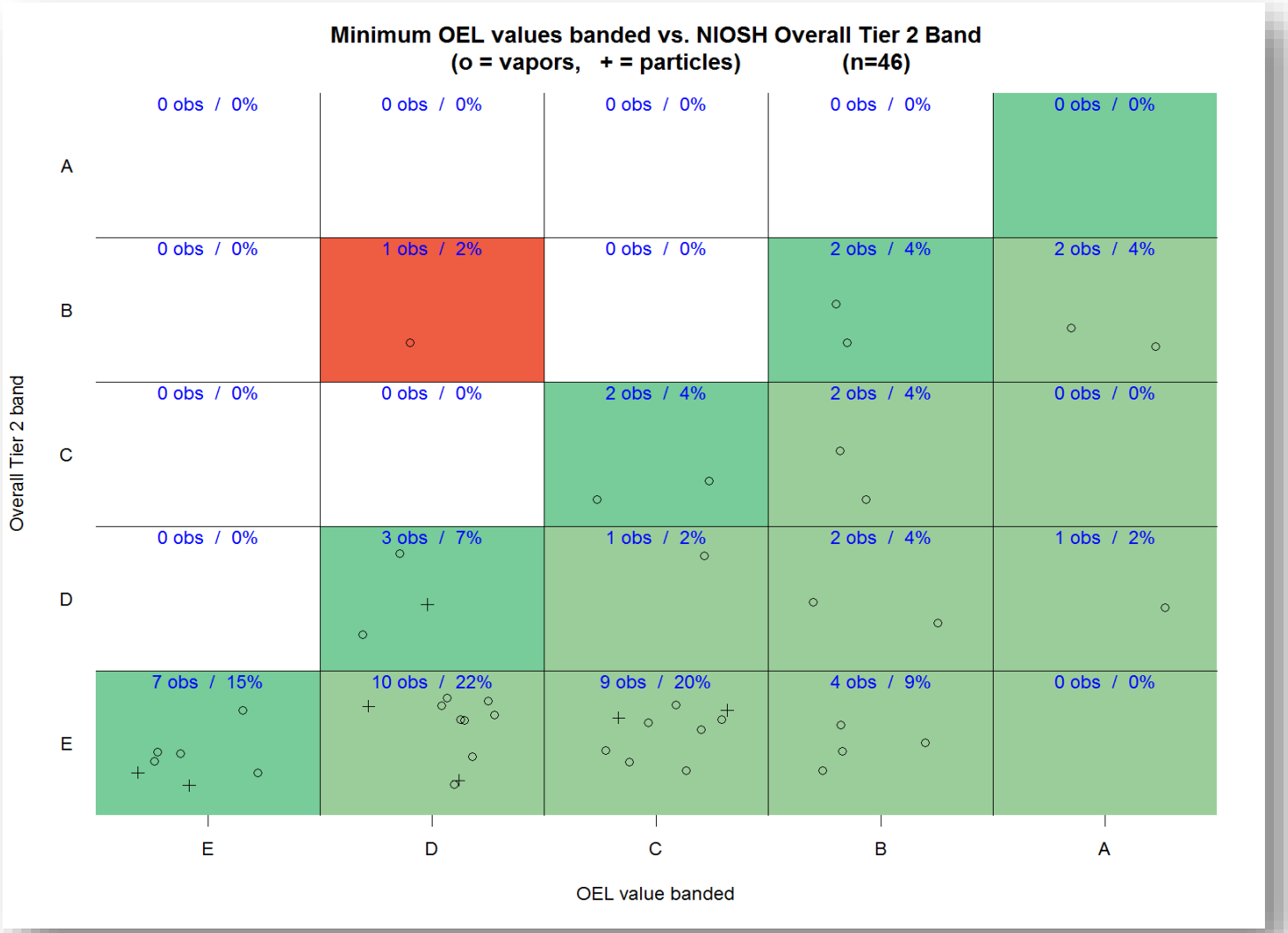
SUPPLEMENTARY SLIDES

THE FINDINGS AND CONCLUSIONS IN THIS PRESENTATION HAVE NOT BEEN FORMALLY DISSEMINATED BY THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY.

TIER 1 OVERVIEW



TIER 2 EVALUATION



EXPECTED PROJECT OUTPUTS

- NIOSH guidance document
- Sources of Information Summary
- Tools to facilitate finding and evaluating hazard data and assign chemicals to hazard bands
- Electronic tools to help users create OEB online