NIOSH Occupational Exposure Banding Initiative

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Overview

* Background and “big picture”
* Value of occupational exposure bands (OEB)
* NIOSH framework and decision logic
* OEB Tier 1 process
* OEB Tier 2 process
* Tier 2 Test with users
* Lessons Learned
* Next Steps

Question:

What are some challenges of our profession?

Do we always have the OELs we need?

Chemicals in Commerce

New Occupational Exposure Limits

- Approximately 1,000 chemicals with authoritative OELs
  - NIOSH RELs
  - OSHA PELs
  - California PELs
  - TLVs
  - WEELs
  - MAKs

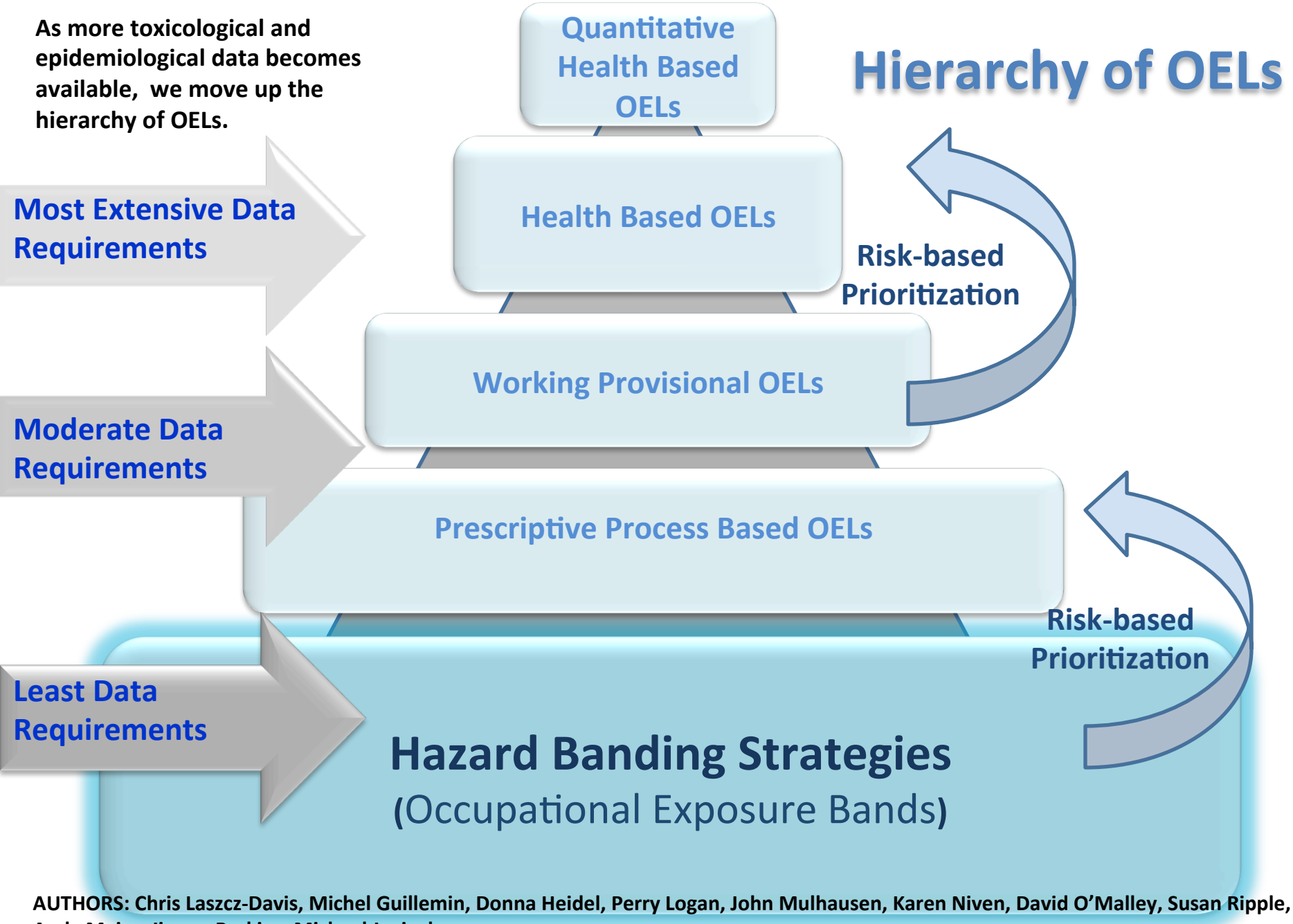
How do we handle all the new chemicals?

* Mechanism to quickly and accurately assign chemicals into “categories” or “bands” based on their health outcomes and potency considerations, is needed

* Occupational Exposure Bands (OEBs)

Tools for the Industrial Hygienist

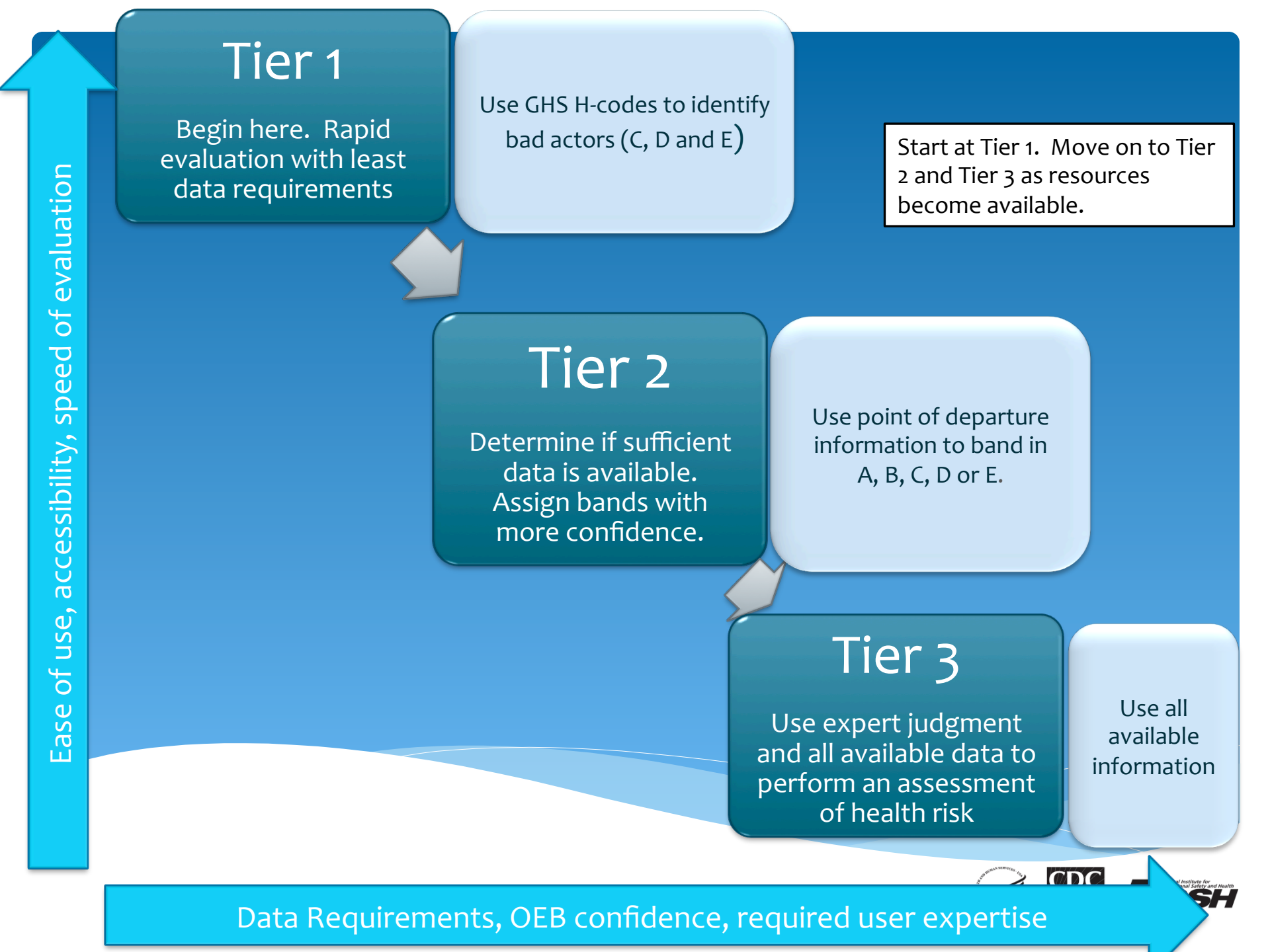
As more toxicological and epidemiological data becomes available, we move up the hierarchy of OELs.



AUTHORS: Chris Laszcz-Davis, Michel Guillemin, Donna Heidel, Perry Logan, John Mulhausen, Karen Niven, David O'Malley, Susan Ripple, Andy Maier, Jimmy Perkins, Michael Jayjock

OEB value

* 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


Tier 1
Begin here. Rapid evaluation with least data requirements
Use GHS H-codes to identify bad actors (C, D and E)
Start at Tier 1. Move on to Tier 2 and Tier 3 as resources become available.
Tier 2
Determine if sufficient data is available. Assign bands with more confidence.
Use point of departure information to band in A, B, C, D or E.
Tier 3
Use expert judgment and all available data to perform an assessment of health risk
Use all available information
Ease of use, accessibility, speed of evaluation
Data Requirements, OEB confidence, required user expertise

Tier 1 —Qualitative

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—Quantitative

User: Skilled occupational hygienist

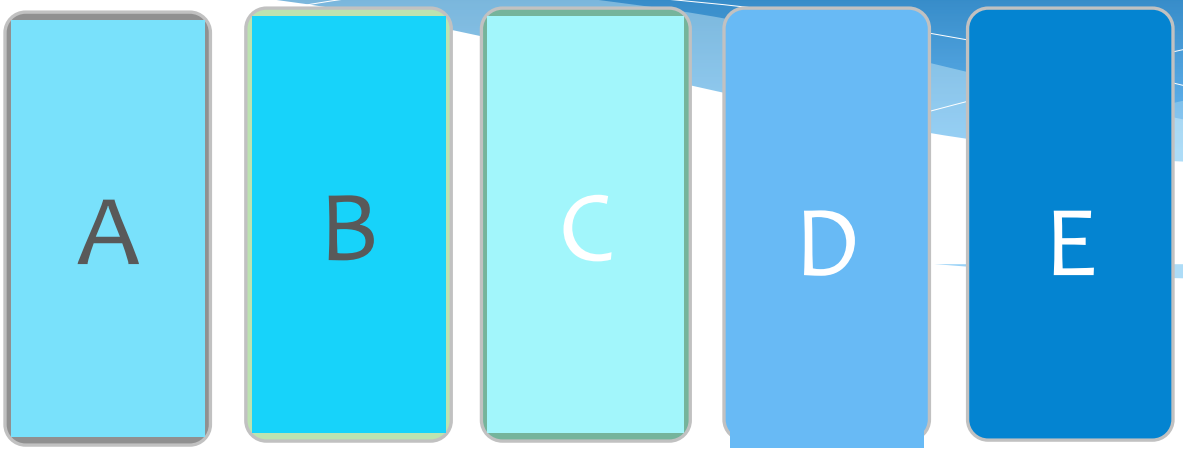
A Tier 2 evaluation produces a more refined OEB, based on point of departure data from reliable sources. Data availability and quality are considered.

Tier 3—Weight of Evidence

User: Toxicologist or experienced occupational hygienist

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

Overview of tier approach to OEBs



Less Hazardous *More Hazardous*

Tier 1 —Qualitative

Use GHS Hazard Statements to identify chemicals with potential for irreversible health effects at relatively low doses (Bands D or E) or reversible health effects (Band C). Use GHS Hazard Categories to assign chemicals into Bands C, D *or* E.

Tier 2—Quantitative

Determine point of departure, factoring data availability, hierarchy, and quality to support assigning chemicals into alternate bands.

Tier 3—Weight of Evidence

Involves integration of all available data and determining the degree of conviction of the outcome.

Health Hazards

Hazard Class	Hazard Category			
Acute Toxicity	1	2	3	4
Skin Corrosion/Irritation	1A	1B	1C	2
Serious Eye Damage/ Eye Irritation	1	2A	2B	
Respiratory or Skin Sensitization	1			
Germ Cell Mutagenicity	1A	1B	2	
Carcinogenicity	1A	1B	2	
Reproductive Toxicity	1A	1B	2	Lactation
STOT – Repeated Exposure	1	2		

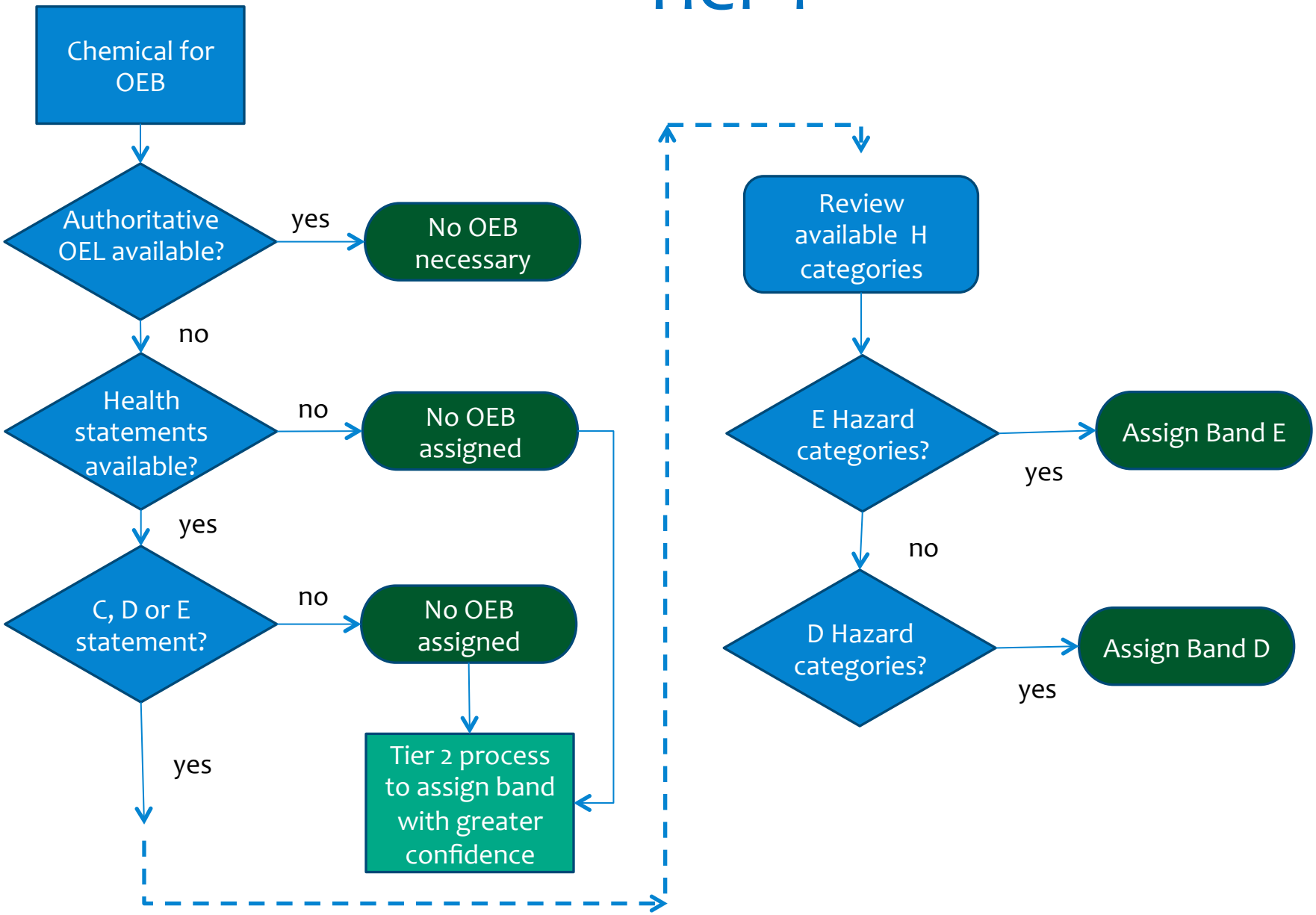
* Slide courtesy of OSHA

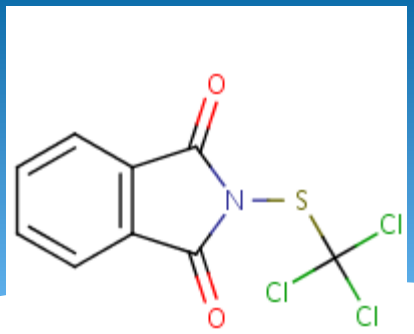
Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m^3	> 0.01 ≤ 0.1 mg/m^3	≤ 0.01 mg/m^3
	Vapors	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
Acute Toxicity	GHS Hazard Category	3, 4	2	1
	GHS Hazard Statements	Harmful if swallowed. Harmful if inhaled. Harmful in contact with skin Toxic if swallowed. Toxic if inhaled. Toxic in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.
	"H" Codes	H301, H302, H[illegible] H332, H311, H[illegible]2	[illegible]00, H330, H310	H300, H330, H310
Skin Corrosion/ Irritation	GHS Hazard Category	2		1A, 1B, 1C
	Skin corrosion / irritation GHS H[illegible] statemen[illegible]	Caus[illegible] skin irritation.		Causes severe skin burns and eye damage.
	Skin corrosio[illegible] irritation "H" Co[illegible]	H315		H314
Serious Eye Damage/ Eye Irritation	GHS Hazard Category	2A, 2B		1
	GHS Serious Eye Damage/Eye Irritation Hazard statement	Causes eye irritation Causes serious eye irritation		Causes serious eye damage
	Serious Eye Damage/ Eye Irritation "H" Codes	H319		H318

Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m^3	> 0.01 ≤ 0.1 mg/m^3	≤ 0.01 mg/m^3
	Vapors	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
Respiratory and Skin Sensitization	GHS Hazard Category	1B (skin)	1B (resp.) 1A (skin)	1A (resp.)
	GHS Respiratory and Skin Sensitization Hazard Statements	May cause an allergic skin reaction	May cause allergy or asthma symptoms or breathing difficulties if inhaled May cause an allergic skin reaction	May cause allergy or asthma symptoms or breathing difficulties if inhaled
	Respiratory and Skin Sensitization "H" Codes	H317	H334 H317	H334
Germ Cell Mutagenicity	GHS Hazard Category	2	1B	1A
	GHS Germ Cell Mutagenicity Hazard Statement	Suspected of causing genetic defects	May cause genetic defects	May cause genetic defects
	GHS Germ Cell Mutagenicity "H" Codes	H341	H340	H340
Carcinogenicity	GHS Hazard Category			2 1B 1A
	GHS Carcinogenicity Hazard statement			Suspected of causing cancer May cause cancer May cause cancer
	Carcinogenicity "H" Codes			H351, H350

Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m^3	> 0.01 ≤ 0.1 mg/m^3	≤ 0.01 mg/m^3
	Vapors	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
Toxic to Reproduction	GHS Hazard Category	2	1B	1A
	GHS Reproduction Hazard Statement	Suspected human reproductive toxicant	Known human reproductive toxicant Presumed human. reproductive toxicant	Known human reproductive toxicant.
	Reproduction "H" Codes*	"Suspected of damaging fertility or the unborn child" H361f, H361d, or H361fd	"May damage fertility or the unborn child" H360f, H360d, or H360fd	"May damage fertility or the unborn child"—H360f, H360d, or H360fd
Specific Target Organ Toxicity (Single Exposure)	GHS Hazard Category	2 (H3 3 (H335 and H336		1
	GHS Hazard Statement	May cause damage to organs May cause respiratory irritation or may cause drowsiness or dizziness		Causes damage to organs
	"H" Codes	H371, H335, H336		H370
Specific Target Organ Toxicity (Repeated Exposure)	GHS Hazard Category	2		1
	GHS Hazard Statement	May cause damage to organs <...> through prolonged or repeated exposure <<...>>		Causes damage to organs <...> through prolonged or repeated exposure <<...>
	"H" Codes	H373		H372

Tier 1


Chemical for OEB
Authoritative OEL available?
yes
No OEB necessary
no
Health statements available?
no
No OEB assigned
yes
C, D or E statement?
no
No OEB assigned
yes
Tier 2 process to assign band with greater confidence
Review available H categories
E Hazard categories?
yes
Assign Band E
no
D Hazard categories?
yes
Assign Band D



Example #1

* Folpet
  * White crystal, powder, or granule
  * Used as a fungicide for deciduous fruit, vegetables, and ornamental plants
  * No OEL exists, but serious potential health effects

  * Search GESTIS for Folpet to find Hazard codes, statements, and classifications

Tier 1 Example: Folpet

* Can be formulated into liquid, wettable powder, and solid forms
* Applied by dipping, soaking, or spraying
* Also used as a paint additive, wood surface treatment, and high volume spray
* Has been known to cause irritation to eyes, skin, respiratory tract
* Workers involved in mixing, loading and applying folpet may be occupationally exposed
* Some qualitative and quantitative data exist, but…
* **No OEL exists**

Examples of Data

SDS

MATERIAL SAFETY DATA SHEET
FOLPAN® 80WDG
Page 1 of 4

1. IDENTIFICATION

Product name:	**FOLPAN® 80WDG (PCP Registration No. 27733)**
Chemical name of active ingredient(s):	N-(Trichloromethylthio)phthalimide
Manufacturer/Registrant:	Makhteshim Agan of North America, Inc. 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604 Phone: 919-256-9300
For fire, spill, and/or leak emergencies, contact Infotrac:	Phone: 1-800-535-5053
For medical emergencies and health and safety inquiries, contact Prosar:	Phone: 1-877-250-9291

2. COMPOSITION/INFORMATION ON INGREDIENTS

COMMON NAME	CAS NO.	%	OSHA PEL	ACIGH TLV	OTHER	NTP/IARC/OSHA (CARCINOGEN)
Folpet	133-07-3	80	NA	NA	NA	NA

NA=Not applicable

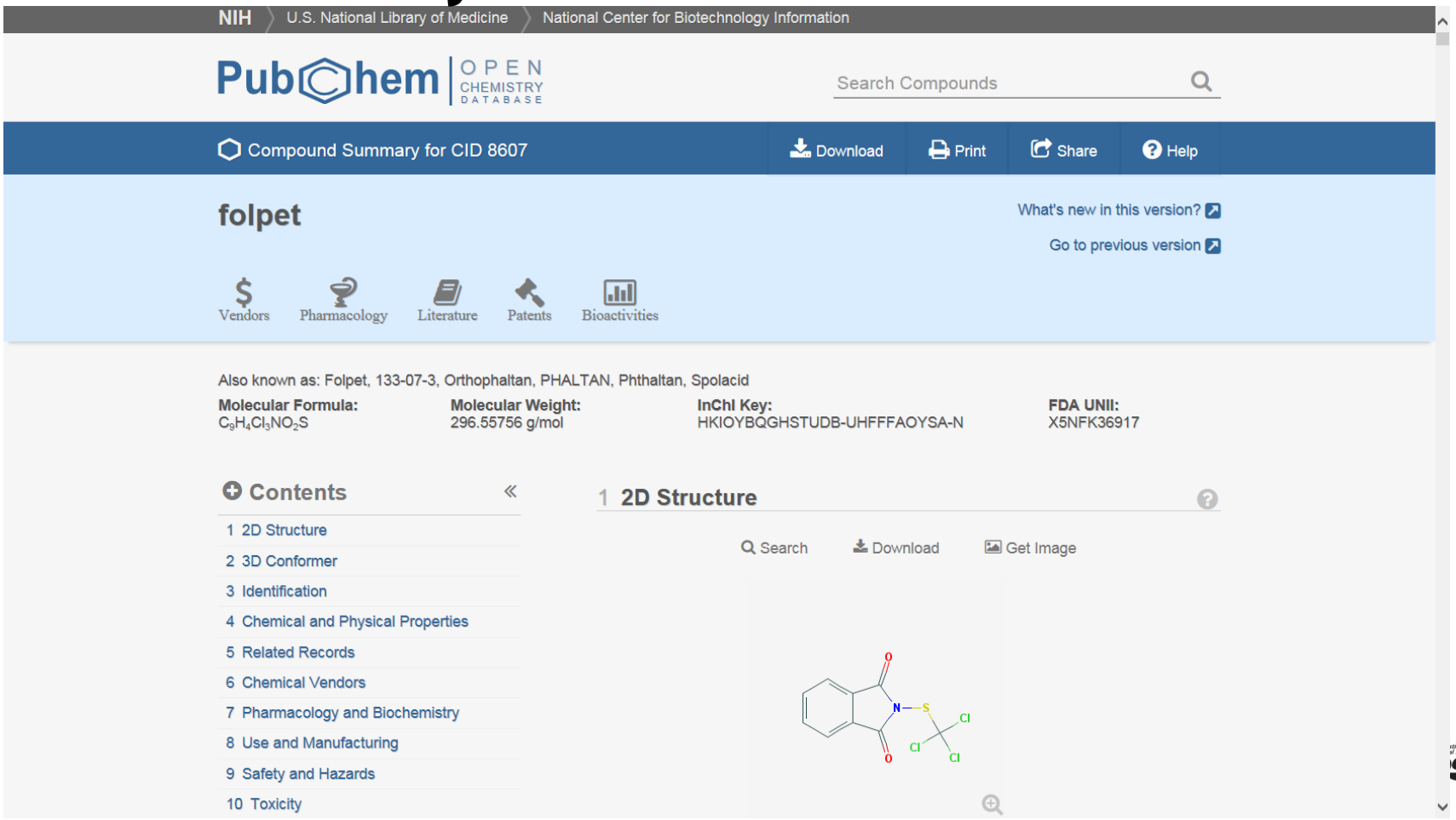
3. HAZARDS IDENTIFICATIONS

PHYSICAL PROPERTIES:

Appearance: Off-white granule
Odor: Faint odour (characteristic)

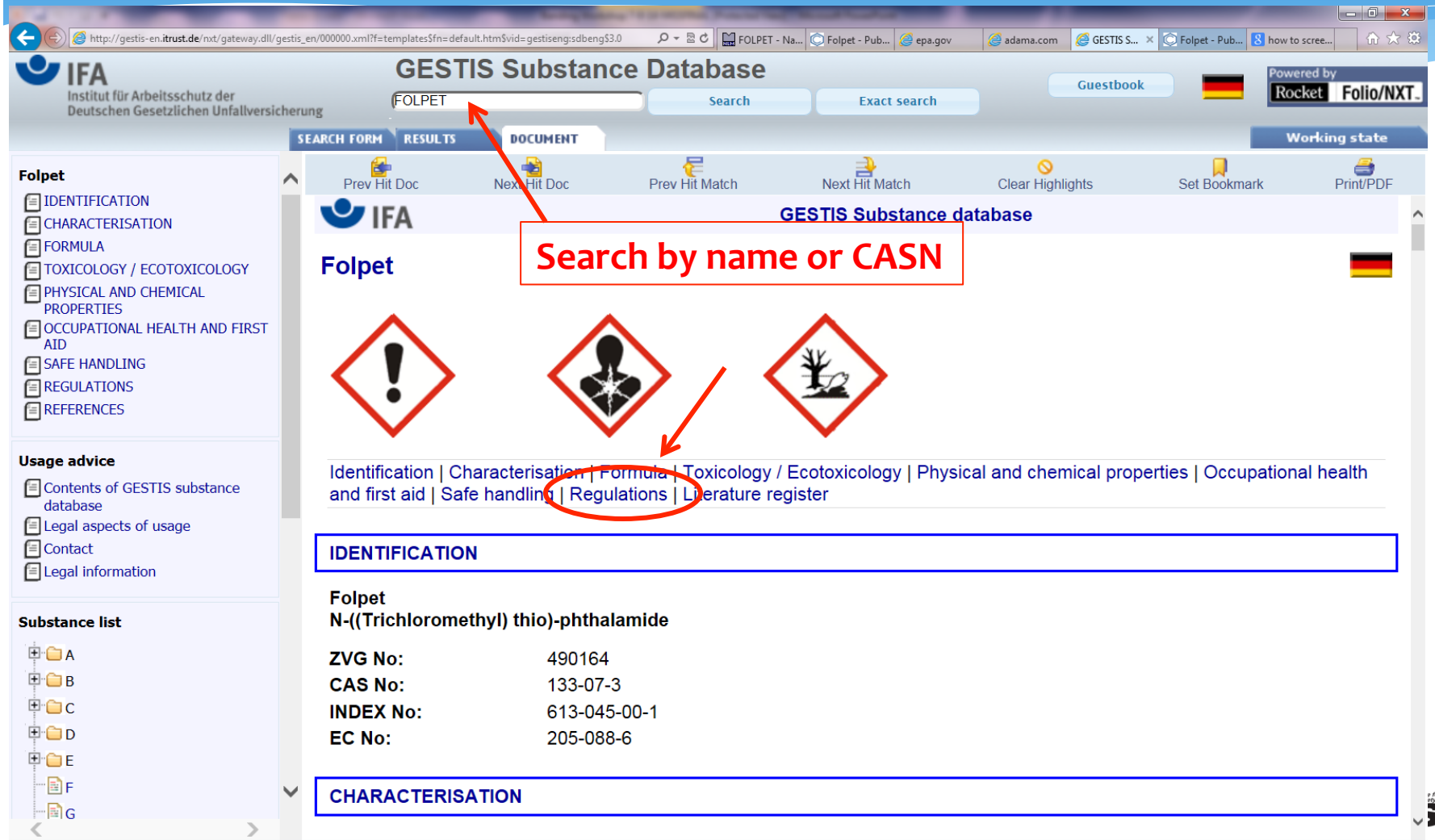
Examples of Data

National Library of Medicine



Tier 1 Example: Folpet

Step 1: Locate GHS H-codes and categories from recommended databases



Tier 1 Example: Folpet

Step 1: Locate GHS H-codes and categories from recommended databases

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COTOXICOLOGY
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HEALTH AND FIRST

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usage

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REGULATIONS

GHS Classification/Labelling | Old Classification | Workplace labelling | Water hazard class | Air quality control | Transport Regulations | Hazard Inci
Ordinance | Further regulations | Medical check-ups

Classification:
Acute toxicity, Category 4, inhalation; H332
Skin sensitisation, Category 1; H317
Eye irritation, Category 2; H319
Carcinogenicity, Category 2; H351
Hazardous to the aquatic environment, Acute Category 1; H400



Signal Word: "Warning"

Hazard Statement - H-phrases:
H332: Harmful if inhaled.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H351: Suspected of causing cancer.
H400: Very toxic to aquatic life.

Precautionary Statement - P-phrases:
P273: Avoid release to the environment.
P280: Wear protective gloves.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Manufacturer's specification by Sigma-Aldrich Group

Reference: 01221

Tier 1 Example: Folpet

Step 1 : Locate GHS H-codes and categories from recommended databases

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	**H332**	**4**	GESTIS	
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	**H319**	**2**	GESTIS	
Respiratory and Skin Sensitization	**H317**	**1**	GESTIS	
Germ Cell Mutagenicity				
Carcinogenicity	**H351**	**2**	GESTIS	
Toxic to Reproduction				
Specific Target Organ Toxicity				

Tier 1 Example: Folpet

Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart

Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m³	> 0.01 ≤ 0.1 mg/m³	≤ 0.01 mg/m³
	Vapors	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
Acute Toxicity	GHS Hazard Category	3, 4	2	1
	GHS Hazard Statements	Harmful if swallowed. Harmful if inhaled. Harmful in contact with skin Toxic if swallowed. Toxic if inhaled. Toxic in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.
	"H" Codes	H301, H302, H331, H332, H311, H312	H300, H330, H310	H300, H330, H310
Skin Corrosion/ Irritation	GHS Hazard Category	2		1A, 1B, 1C
	Skin corrosion / irritation GHS Hazard statement	Causes skin irritation.		Causes severe skin burns and eye damage.
	Skin corrosion / irritation "H" Code	H315		H314

Tier 1 Example: Folpet

Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	C
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	
Respiratory and Skin Sensitization	H317	1	GESTIS	
Germ Cell Mutagenicity				
Carcinogenicity	H351	2	GESTIS	
Toxic to Reproduction				
Specific Target Organ Toxicity				

Tier 1 Example: Folpet

Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart

Folpet CAS: 133-07-3				
Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	**H332**	**4**	GESTIS	**C**
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	**H319**	**2**	GESTIS	**C**
Respiratory and Skin Sensitization	**H317**	**1**	GESTIS	**D**
Germ Cell Mutagenicity				
Carcinogenicity	**H351**	**2**	GESTIS	**E**
Toxic to Reproduction				
Specific Target Organ Toxicity				

Tier 1 Example: Folpet

Step 3: Select the most conservative band as the Tier 1 OEB

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	C
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	C
Respiratory and Skin Sensitization	H317	1	GESTIS	D
Germ Cell Mutagenicity				
Carcinogenicity	**H351**	**2**	GESTIS	**E**
Toxic to Reproduction				
Specific Target Organ Toxicity				

Most conservative band: Band E

Based upon the Tier 1 banding process, the chemical should be in Band E

Tier 2 should now be completed.

Banding Chemicals in Tier 2

Tier 2

* Tier 2 - Semi-Quantitative
  * Skilled industrial hygienist
  * 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 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

What is Tier 2?

Tier 2 is 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

Acute Toxicity Technical Criteria

Band	A	B	C	D	E
Oral Toxicity LD_{50} (mg/kg bodyweight)	>2000	>300 and ≤ 2000	>50 and ≤ 300	>5 and ≤ 50	≤ 5
Dermal Toxicity LD_{50} (mg/kg bodyweight)	> 2000	>1000 and ≤ 2000	>200 and ≤ 1000	>50 and ≤ 200	≤ 5
Inhalation Gases (ppmV/4h) LC_{50}	> 20000	>2500 and ≤ 20000	>500 and ≤ 2500	>100 and ≤ 500	≤ 100
Inhalation Vapors (mg/liter/4h) LC_{50}	> 20.0	>10.0 and ≤ 20.0	>2.0 and ≤ 10.0	>0.5 and ≤ 2.0	≤ 0.5
Inhalation Dusts and Mists (mg/liter/4h) LC_{50}	> 5.0	>1.0 and ≤ 5.0	>0.5 and ≤ 1.0	>0.05 and ≤ 0.5	≤ 0.05

What is Tier 2?

* Some of the endpoints draw on categorical health outcomes (mild, moderate, severe)

* Others are based on quantitative toxicity information and/or potency data (LD50s, LC50s, NOAELs)

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)

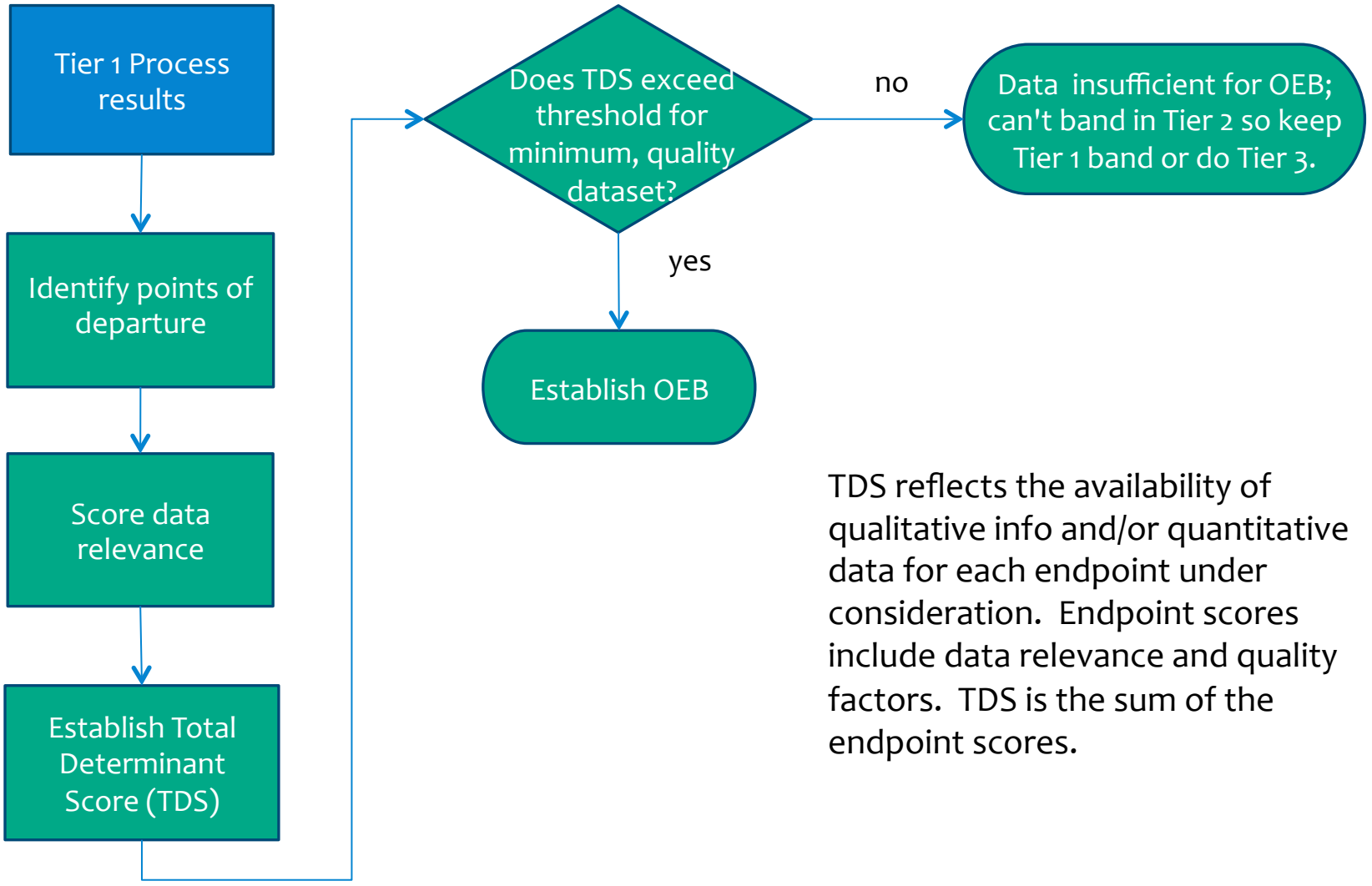
Total Determinant Score

* Total determinant score (TDS) = weighted average indicating the presence/absence of data for a specific health endpoint.

* Example: a cancer inhalation unit risk value tells us a lot about the hazardous nature of a chemical, so the presence of that information corresponds to a TDS of 30. However, an LD50 value is only weighted as a TDS of 5.

* The sum of all health endpoint TDSs must be at least 30 for a chemical to be banded in Tier 2.

Tier 2



TDS reflects the availability of qualitative info and/or quantitative data for each endpoint under consideration. Endpoint scores include data relevance and quality factors. TDS is the sum of the endpoint scores.

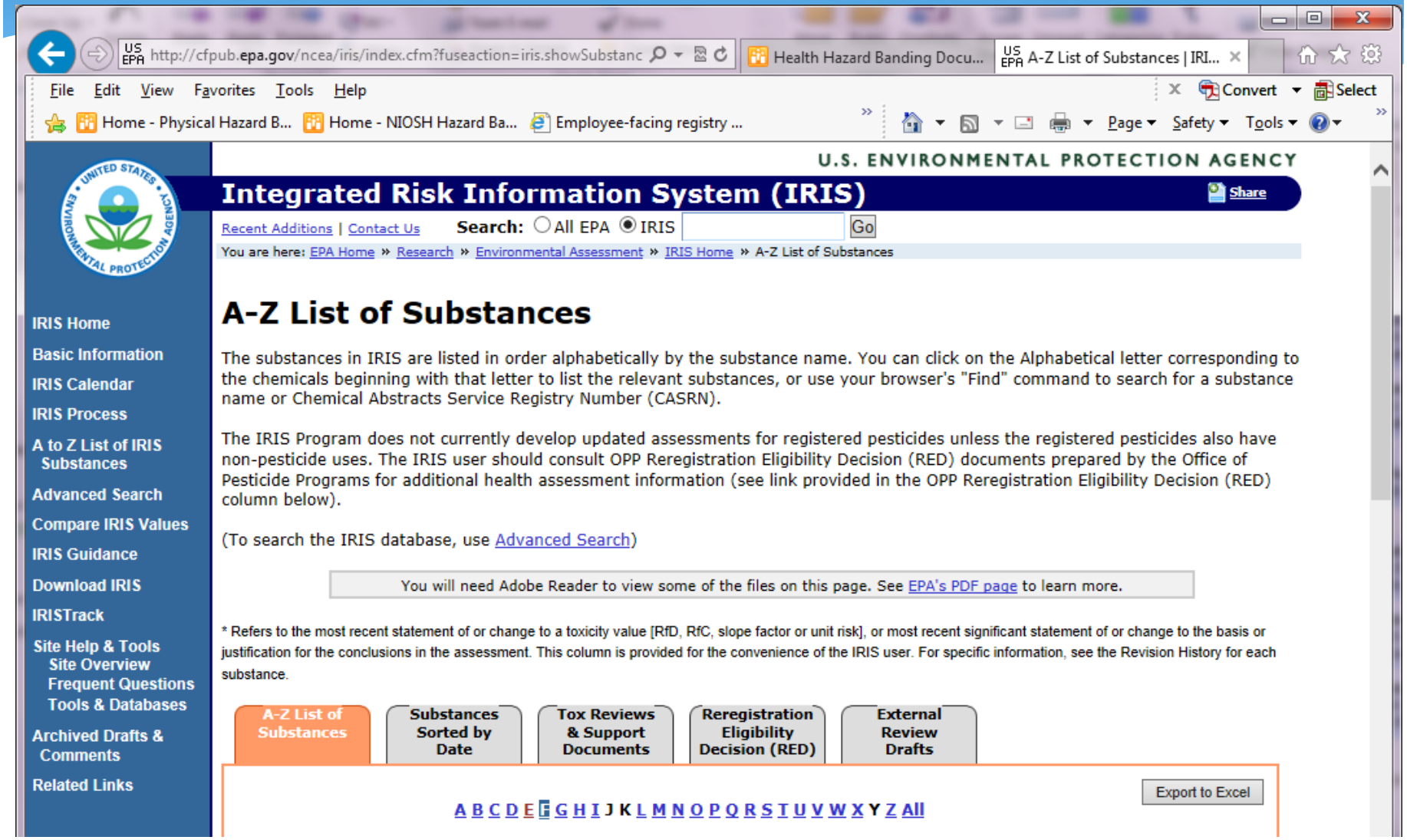
Tier 2: Step 1

Check Key Sources for Data Availability

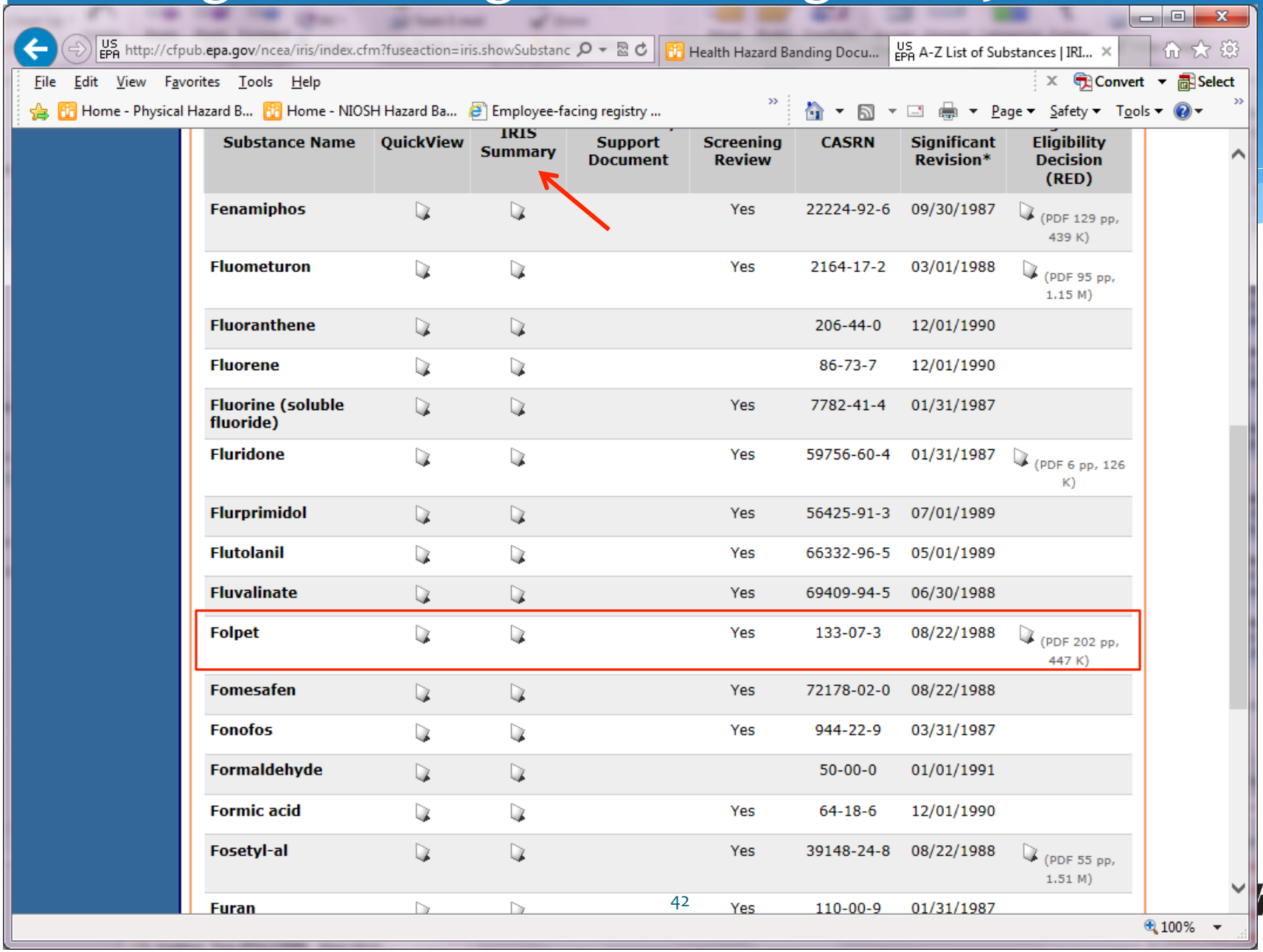
Rank	Source	Y/N	Strategy
1. Sources of toxicity benchmarks for banding according to systemic toxicity (RE) (layer 1)	EPA/IRIS		If Y: Document the animal-specific NOAELs for each toxicity benchmark (layer 1). Precludes searching for other resources in Rank 2 sources. If N: Search for other toxicity benchmarks in Rank 2 sources (layer 2).
	ATSDR		
	Health Canada		
	CalEPA		
2. Potential sources of acute toxicity, incidence information, and benchmarks for systemic toxicity (layer 2)	HSDB		List all available findings in the worksheet according to the rules for each endpoint.
	IPCS		
	IUCLID		
	REACH		
3. Sources for median lethal doses/ concentrations (only)	ChemID		List all available values in the worksheet according to the rules
	Lewis		

Step 2: Collect data (source by source)

EPA IRIS Search for Folpet, Carcinogenicity Data



Banding According to Carcinogenicity



http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanc

Health Hazard Banding Docu... | A-Z List of Substances | IRI...

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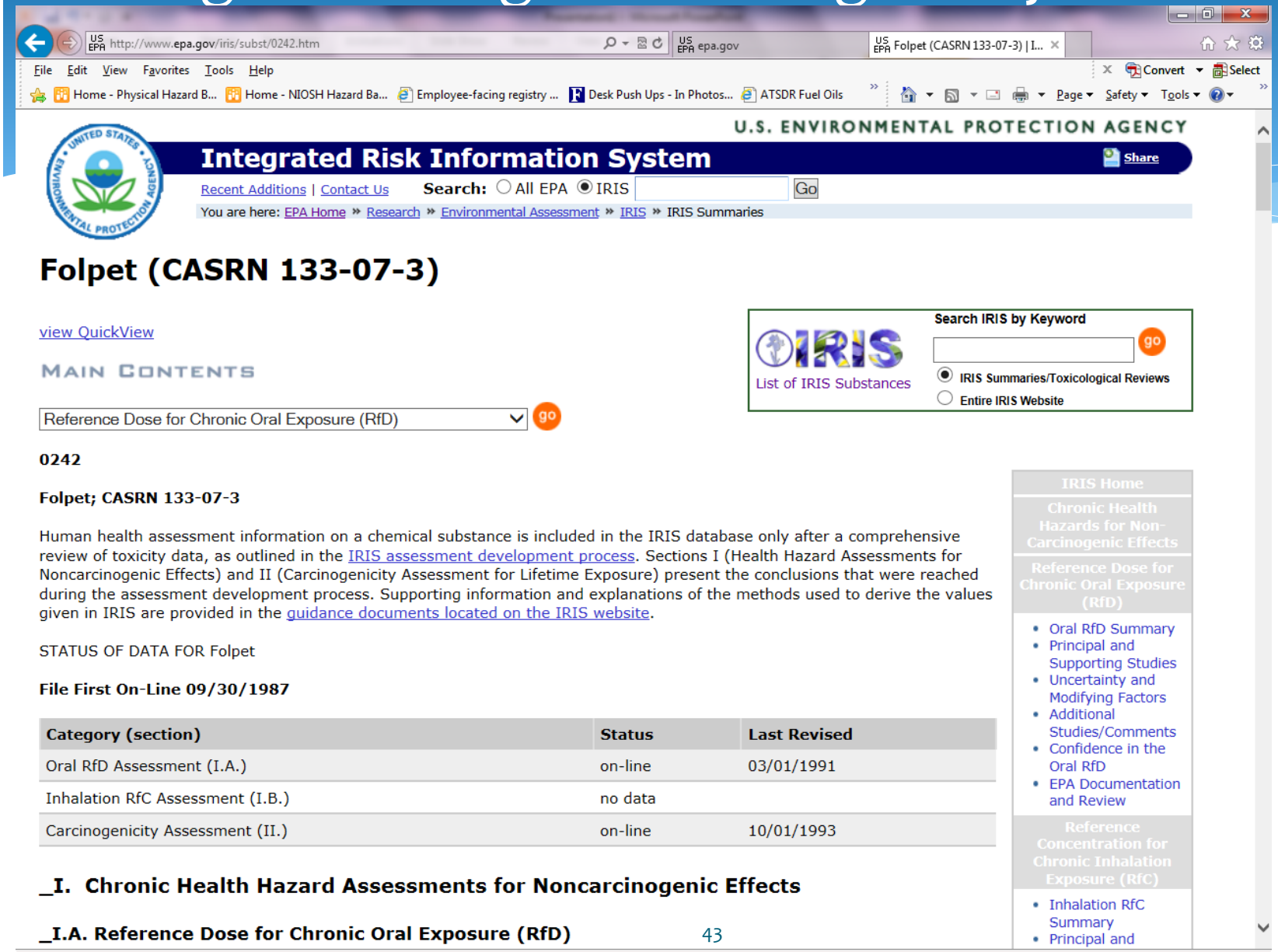
Home - Physical Hazard B... | Home - NIOSH Hazard Ba... | Employee-facing registry ...

Substance Name	QuickView	IRIS Summary	Support Document	Screening Review	CASRN	Significant Revision*	Eligibility Decision (RED)
Fenamiphos				Yes	22224-92-6	09/30/1987	(PDF 129 pp, 439 K)
Fluometuron				Yes	2164-17-2	03/01/1988	(PDF 95 pp, 1.15 M)
Fluoranthene					206-44-0	12/01/1990	
Fluorene					86-73-7	12/01/1990	
Fluorine (soluble fluoride)				Yes	7782-41-4	01/31/1987	
Fluridone				Yes	59756-60-4	01/31/1987	(PDF 6 pp, 126 K)
Flurprimidol				Yes	56425-91-3	07/01/1989	
Flutolanil				Yes	66332-96-5	05/01/1989	
Fluvalinate				Yes	69409-94-5	06/30/1988	
Folpet				Yes	133-07-3	08/22/1988	(PDF 202 pp, 447 K)
Fomesafen				Yes	72178-02-0	08/22/1988	
Fonofos				Yes	944-22-9	03/31/1987	
Formaldehyde					50-00-0	01/01/1991	
Formic acid				Yes	64-18-6	12/01/1990	
Fosetyl-al				Yes	39148-24-8	08/22/1988	(PDF 55 pp, 1.51 M)
Furan				Yes	110-00-9	01/31/1987	

100%

Banding According to Carcinogenicity



U.S. ENVIRONMENTAL PROTECTION AGENCY

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Folpet (CASRN 133-07-3)

view QuickView

MAIN CONTENTS

Reference Dose for Chronic Oral Exposure (RfD) go

List of IRIS Substances

Search IRIS by Keyword go

IRIS Summaries/Toxicological Reviews

Entire IRIS Website

0242

Folpet; CASRN 133-07-3

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the IRIS assessment development process. Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the guidance documents located on the IRIS website.

STATUS OF DATA FOR Folpet

File First On-Line 09/30/1987

Category (section)	Status	Last Revised
Oral RfD Assessment (I.A.)	on-line	03/01/1991
Inhalation RfC Assessment (I.B.)	no data	
Carcinogenicity Assessment (II.)	on-line	10/01/1993

IRIS Home

Chronic Health Hazards for Non-Carcinogenic Effects

Reference Dose for Chronic Oral Exposure (RfD)

- Oral RfD Summary
- Principal and Supporting Studies
- Uncertainty and Modifying Factors
- Additional Studies/Comments
- Confidence in the Oral RfD
- EPA Documentation and Review

Reference Concentration for Chronic Inhalation Exposure (RfC)

- Inhalation RfC Summary
- Principal and

_I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

_I.A. Reference Dose for Chronic Oral Exposure (RfD)

Banding According to Carcinogenicity

II.B.1. Summary of Risk Estimates

Oral Slope Factor — 3.5E-3/mg/kg/day

Drinking Water Unit Risk — 1.0E-7/ug/L

Extrapolation Method — linearized multistage procedure, extra risk

Drinking Water Concentrations at Specified Risk Levels:

Risk Level	Concentration
E-4 (1 in 10,000)	
E-5 (1 in 100,000)	
E-6 (1 in 1,000,000)	

Slope Factors $(mg/kg\text{-}day)^{-1}$	Assigned Band
≥ 10	E
<10 but ≥ 0.01	D
< 0.01	C

Putting it all together

* Each endpoint subscore is summed to find the Total Determinant Score (TDS).
* Banding is only valid if there is a TDS of 30 or greater.
* UNLESS, if any individual valid endpoint band corresponds to band E, the overall band is determined to be band E, regardless of the TDS. This can only be modified by a Tier 3 assessment.
* The Tier 2 worksheet will calculate all of this for you

Banding According to Carcinogenicity

Carcinogenicity (30 points possible)					
	Band A	Band B	Band C	Band D	Band E
EPA IRIS Weight Of Evidence					
EPA IRIS Slope Factor			X		
EPA IRIS Inhalation Unit Risk					
Health Canada TD05					
Health Canada TC05					
California Slope Factor					
California Inhalation Unit Risk					
Other cancer (Layer 2)					

Information manually entered into worksheet is electronically matched to NIOSH technical criteria and populated into final worksheet

Banding According to Carcinogenicity

Chemical:	Folpet							
CAS Number:	133-07-3							
Endpoint/Toxicity parameter		Most conservative band represented by the data					Determinant Score	Endpoint-specific band selection
(Score for the presence of data)		A	B	C	D	E		
Cancer potential	WOE (U.S. EPA)						0	
(20 for qualitative info, 30 for quantitative)	SF (U.S. EPA)			C			30	C
	IUR (U.S. EPA)						0	
	TD_{05} (Health Canada)						0	
	TC_{05} (Health Canada)						0	
	California Slope Factor						0	
	California Inhalation Unit Risk						0	
							30	
Reproductive (30							0	
Target organ tox	city (repeat exposure)						0	
	(Layer 1)[a]						0	
	(30)						0	
							0	
							0	
Target organ tox	city (repe						0	
	(Layer 2)[b]						0	
	(30)						0	
							0	
Mutagenicity (in	vivo) (10)						0	
Mutagenicity (in vitro) (5)							0	
Respiratory sensitization (10)							0	
Skin sensitization (5)							0	
Acute Toxicity (5)	LD_{50} (oral)						0	
	LD_{50} (dermal)						0	
	LC_{50} (gases)						0	
	LC_{50} (vapors)						0	
	LC_{50} (dusts/mists)						0	
						Determinant sub-score (acute toxicity)	0	
Skin irritation/corrosion (5)							0	
Eye irritation/corrosion (5)							0	
						TDS (Threshold for sufficient data = 30)	30	Yes, assign Tier 2 band
						Tier 2 Band selection		C

As additional data for other endpoints is entered, the Tier 2 band selection adjusts based on the most conservative band.

Final Band Selection

Chemical:	Folpet							
CAS Number:	133-07-3							
Endpoint/Toxicity parameter		**Most conservative band represented by the data**					**Determinant Score**	**Endpoint-specific band selection**
(Score for the presence of data)		**A**	**B**	**C**	**D**	**E**		
Cancer potential	WOE (U.S. EPA)						0	
(20 for qualitative info, 30 for quantitative)	SF (U.S. EPA)			C			30	C
	IUR (U.S. EPA)						0	
	TD_{05} (Health Canada)						0	
	TC_{05} (Health Canada)						0	
	California Slope Factor						0	
	California Inhalation Unit Risk						0	
						Determinant sub-score (cancer)	**30**	
Reproductive (30)			C				**30**	C
Target organ toxicity (repeat exposure)	RfD (U.S. EPA)				D		30	D
(Layer 1)[a]	RfC (U.S. EPA)						0	
(30)	MRL (ATSDR)						0	
	TDI (Health Canada)						0	
	TC (Health Canada)						0	
Target organ toxicity (repeat exposure)	Data on reproductive and developmental toxicity						0	
(Layer 2)[b]	Other DNELs						0	
(30)	Other DNELs (inhale)						0	
						Determinant sub-score (systemic toxicity)	**30**	
Mutagenicity (in vivo) (10)					D		**10**	D
Mutagenicity (in vitro) (5)				C			**5**	C
Respiratory sensitization (10)							**0**	
Skin sensitization (5)				C			**5**	C
Acute Toxicity (5)	LD_{50} (oral)		B				5	B
	LD_{50} (dermal)						0	
	LC_{50} (gases)						0	
	LC_{50} (vapors)						0	
	LC_{50} (dusts/mists)						0	
						Determinant sub-score (acute toxicity)	**5**	
Skin irritation/corrosion (5)			B				**5**	B
Eye irritation/corrosion (5)			B				**5**	B
						TDS (Threshold for sufficient data = 30)	**125**	Yes, assign Tier 2 band
						Tier 2 Band selection		**D**

Final Tier 2 Band: Band D

Tier 2 Band

* After a Tier 2 evaluation, the chemical is assigned **Band D.**
* Tier 1 uses a very conservative approach, due to fewer data requirements.
* By performing a Tier 2 evaluation, the user can incorporate quantitative data and refine the band assignment.
* Following Tier 2, an additional level of evaluation can be performed if the necessary data and user expertise are available.

Tier 3

* Tier 3 -
  * Toxicologist or experienced industrial hygienist
  * Determine the critical study from which a scientifically sound point of departure (POD) can be determined
  * Quantitative risk assessment to determine OEB/OEL

Tier 2 User Check

* Approximately 115 chemicals were selected:
  - EPA IRIS database
  - The TLV "Under Study" List
  - MAK list of "Substances for which no MAK value can be established at present"
  - Health Canada

* Validation Exercise:
  * Divided into 2 groups (New Users and Experts)
  * Completed significant training in Tier 2 OEB process
  * Assigned chemicals randomly
  * Provided draft guidance document, paper submittal sheets and Electronic Tool
  * Compared the banding results from multiple users for seven health endpoints

Issues identified in Tier 2 Evaluations

* Inappropriate conversion of units
* Confusion of respiratory irritation with respiratory sensitization
* Trawling for information in sources other than those specified in the methodology

Lessons Learned

* Improvements in training class to explain terminology
* Needed explanations on some endpoints
* Hardcopy resource guide needed
* Wish list for electronic tool

Next Steps

* Evaluate how validation staff conducted reviews and identify where confusion occurred in the details
* Improve criteria and guidance document
* Peer review and Public Comment
* Computer tools

Expected project outputs

* NIOSH guidance
* Overall process, including the decision logic
* Tools to facilitate finding and evaluating hazard data and assign chemicals to hazard bands
* Electronic tools to help users create OEB online
* Education materials for H&S professionals, managers, emergency responders and workers

Seeking bandits? Yes, we are!

NIOSH is looking for volunteers to test our OEB decision logic. If interested, please give me a business card today or email:

LMcKernan@cdc.gov

Thank you!

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