

Executive Summary:

CRITERIA FOR A RECOMMENDED STANDARD

Occupational Exposure to Diacetyl and 2,3-Pentanedione

Exposure Assessment Summary

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Overview of Presentation

- Organization of Criteria Document
- Process and Scope
- Rationale of Criteria Document
- Exposure Assessment Summary

Scope

- Review of scientific information related to diacetyl and 2,3-pentanedione
 - Overview of Exposure Assessment
 - Health Effects of Exposure to Workers
 - Toxicology Effects of Exposure
 - Quantitative Risk Assessment for Workers
 - Quantitative Risk Assessment for Animals
 - Basis of Recommended Standards

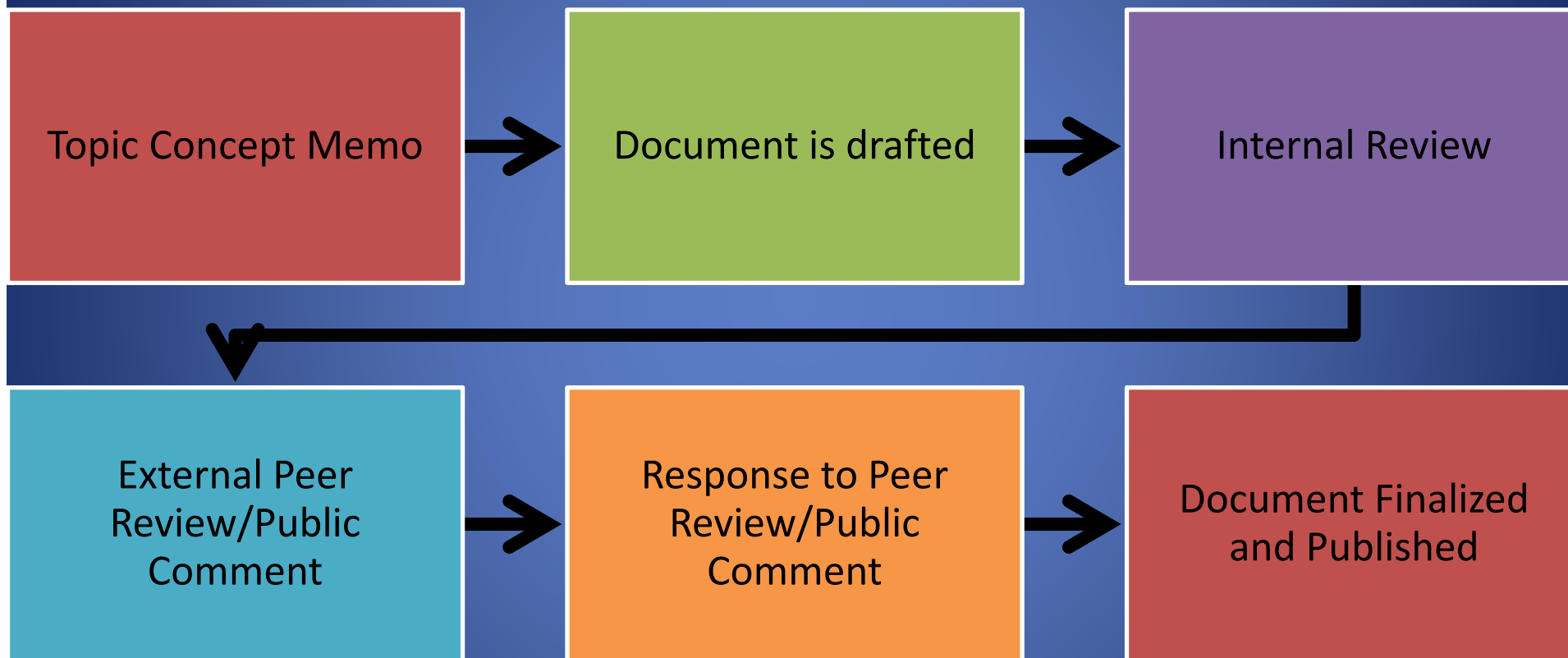


Scope - 2

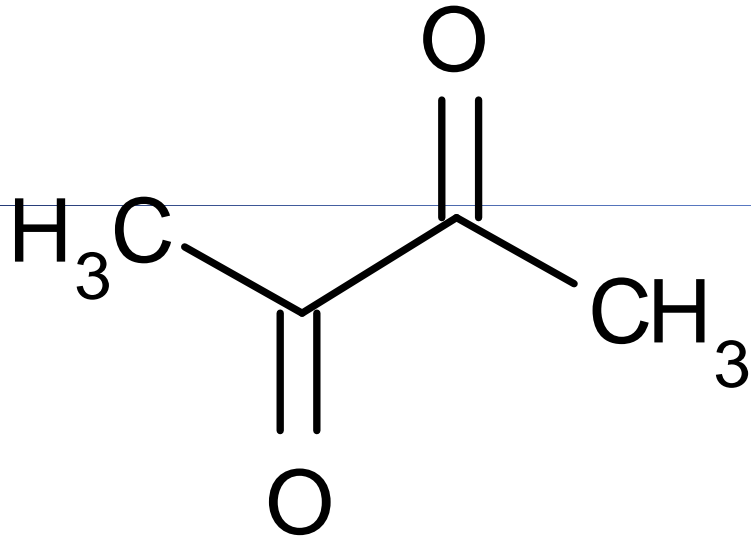
- Guidance
 - Hazard Prevention and Control
 - Engineering Controls
 - Work Practices
 - Personal Protective Equipment
 - Medical Monitoring and Surveillance
 - Exposure Monitoring



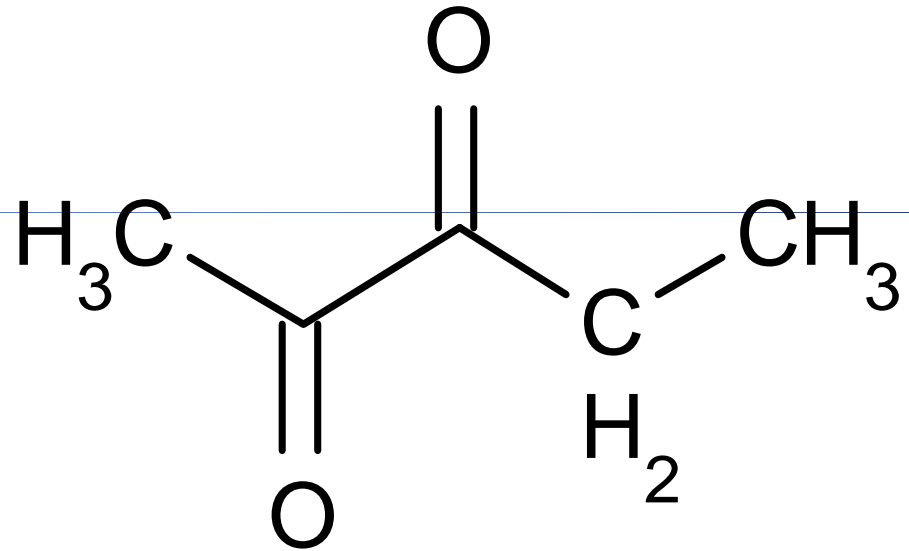
Criteria Document Process



Background



diacetyl



2,3-pentanedione

Background

- Occupational exposure to diacetyl associated with severe obstructive lung disease, bronchiolitis obliterans and decreased lung function
- 2,3-pentanedione used as substitute

History

- 1985: 2 cases in a plant manufacturing flavorings for baking industry
- 2000: Index Plant: 8 former workers in microwave popcorn plant with severe disease, 4 additional plants had workers with clinical bronchiolitis obliterans
- 2004-6: 2 cases in two CA flavoring plants resulted in industry-wide surveillance

Diacetyl

- NIOSH recommends that exposure to diacetyl be kept below a concentration of 5 parts per billion (ppb) as a time-weighted average (TWA) during a 40-hour work week
- NIOSH recommends a short-term exposure limit (STEL) for diacetyl of 25 ppb for a 15-minute time period.
- NIOSH recommends an Action Level of approximately one half the REL (2.6 ppb).

2,3-pentanedione

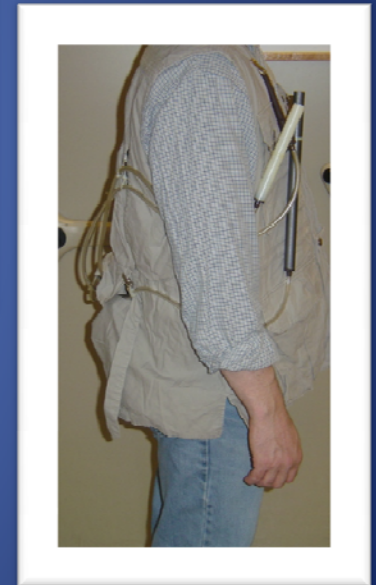
- 2,3-pentanedione and other substances are being used to substitute for diacetyl
- Structurally similar
- Published reports suggest that in rats 2,3-pentanedione causes airway epithelial damage similar to diacetyl

2,3-pentanedione

- NIOSH recommends that exposure to 2,3-pentanedione be kept below a concentration of 9.3 ppb in a TWA during a 40-hour work week.
- NIOSH also recommends a STEL for 2,3-pentanedione of 31 ppb during a 15-minute period.
- Because the REL is established at the reliable quantification limit, no action level is recommended for 2,3-pentanedione.

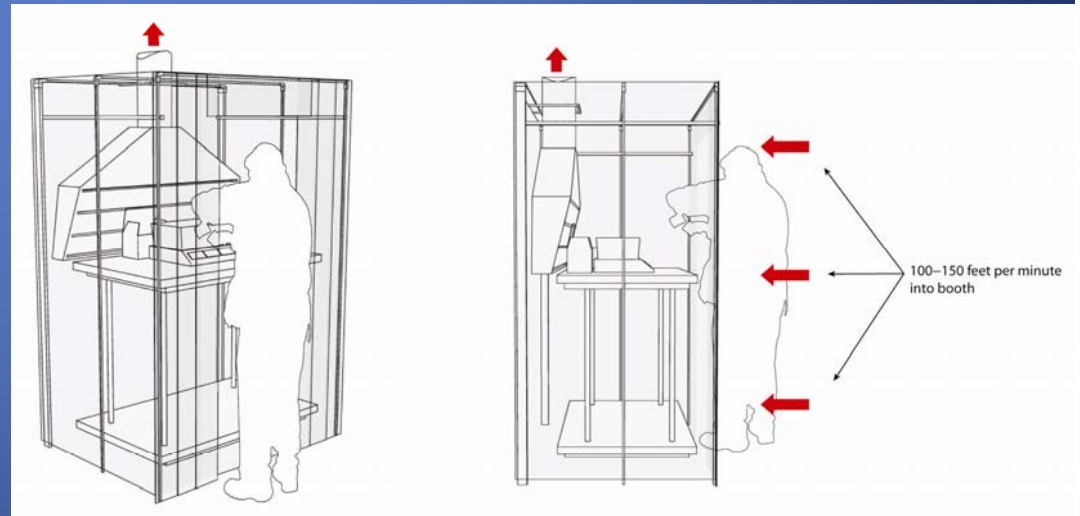
Achievability and Analytical Feasibility

- Engineering Controls
- Analytical Methods
 - OSHA Method 1012
 - OSHA Method 1013
 - OSHA Method 1016



Comprehensive occupational safety and health programs

- Exposure monitoring
- Medical monitoring
- Implementation and assessment of engineering controls
- Facilitate selection of appropriate PPE



Other Substitutes

- NIOSH has concern about other flavoring substitutes with structural similarities to diacetyl
- NIOSH recommends that such exposures also be considered and controlled to as low as reasonably achievable.

EXPOSURE ASSESSMENT SUMMARY

Potential for Exposure

- EPA Non-Confidential Inventory Updating Report, diacetyl had an aggregate production volume between 10,000 and 500,000 pounds
- NAICS category 311: 1.5 million workers food manufacturing
- FEMA: 6,520 employees work directly in the flavor manufacturing or laboratory activities

Measurement of diacetyl and 2,3-pentanedione

- Identify hazards
- Guide corrective actions such as engineering controls
- Identify improved work practices
- Select appropriate PPE

Table 1: Multiple Investigations of flavoring and food production industries

Study	Method	Location	Diacetyl concentration in ppm (Sample Type)		
			Arithmetic Mean	Geometric Mean	Range
Microwave Popcorn Plants					
Company G (NIOSH 2006)	NMAM 2557 (corrected)	Mixing room Packaging area QC lab Maintenance Other areas	57.2 (full shift TWA) 2.8 (full shift TWA) 0.8 (full shift TWA) 0.9 (full shift TWA) >0.15 (full shift TWA)		
Six companies (Kanwal 2006)	NMAM 2557 (corrected)	Packaging areas (area samples) Packaging areas (personal samples) Mixing rooms/areas (area samples) Mixing rooms/areas (personal samples)	0.019 – 3.0 0.023 – 1.16 0.63 – 57.2 0.035 – 1.33		
(White et al. 2010)	NMAM 2557	Mixers Non-mixers	0.057 – 0.860 (full shift) 0.014 – 0.074 (full shift)	0.029 – 0.231 (full shift) 0.001 – 0.018 (full shift)	0.004 – 3.90 (full shift) 0.004 – 1.00 (full shift)

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Study	Method	Location	Diacetyl concentration in ppm (Sample Type)		
			Arithmetic Mean	Geometric Mean	Range
Flavoring Production Plants					
Company B, (NIOSH 2007)	NMAM 2557 (corrected)	Powdered flavoring production area	2.73 (full shift TWA) 25.9 (partial shift)		204 (real-time peak)
Company C (NIOSH 2008)	NMAM 2557, OSHA PV2118	Liquid flavoring production area Powdered flavoring production area Task-based (pouring diacetyl)	0.46 (full shift TWA) 0.34 (full shift TWA)		11 (10 minute peak)
Company H (NIOSH 2008)	OSHA PV2118	Liquid production room Powder production	0.26 (full shift TWA) 0.07 (full shift TWA)		
	NMAM 2557	Liquid production (personal samples) Powder production (personal samples)	0.10 0.05		

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Flavoring Production Plants					
Company D (NIOSH 2009)	OSHA PV2118	Starter distillate room Starter distillate room (personal samples) Spray dry room Spray dry room (personal samples) Flavors room Flavors room (personal samples) Spray dry room, task-based (moving diacetyl between containers) Spray dry room, task-based (cleaning barrel with hose)	1.06 (full shift TWA) 1.78 (full shift TWA) 1.07 (full shift TWA) 0.756 (full shift TWA) 0.171 (full shift TWA) 0.329 (full shift TWA)		90 (real-time peak) 18 (real-time peak)
Company I (NIOSH 2011)	NMAM 2557	Spray drying Spray drying (personal samples) Other production areas Other production areas (personal samples)		0.169 (full shift TWA) 0.123 (full shift TWA) 0.375 (full shift TWA) 0.762 (full shift TWA)	
	OSHA PV2118	Spray drying Spray drying (personal samples) Coffee and tea area Liquid compounding area (personal samples)		0.167 (full shift TWA) 0.182 (full shift TWA) 0.076 (full shift TWA) 1.90 (full shift TWA)	
(Martynty et al. 2008)	NMAM 2557	All areas (personal samples)	2.48 (1–3 hours)		0.01 – 60 (1–3 hours)

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			Arithmetic Mean	Geometric Mean	Range
Diacetyl Production					
(van Rooy 2007)		Task specific			0.6 – 83 (real-time peaks)
Food Production					
Company M (NIOSH 2007)	NMAM 2557 NMAM 2549	All areas Directly above heated popping oil	No diacetyl detected		0.14 (real-time peak)
Company E (NIOSH 2009)	OSHA PV2118, OSHA 1013	All areas	No diacetyl detected		
Company F (NIOSH 2008)	OSHA PV2118	All areas	Below limit of detection (>0.02)		