Exposure Assessment First Steps:

Basic Characterization and Information Gathering

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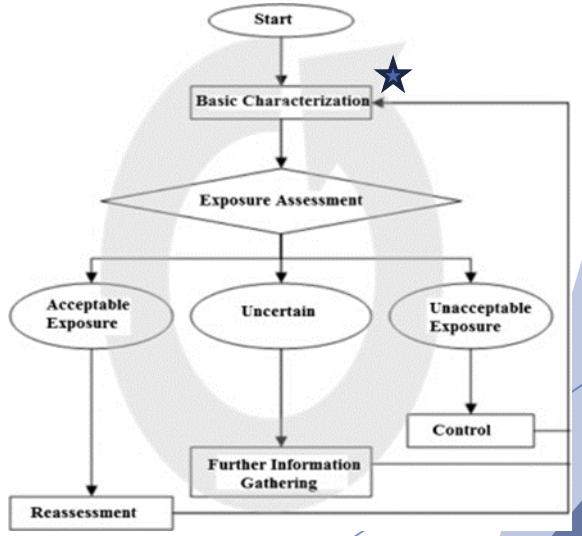
Basic Characterization and Information Gathering

- Objectives
  - Why is this needed?
  - What is a Basic Characterization
  - Questions that need Answering before exposure assessment
  - What are the sources of information
  - Workplace Information Needed
  - Workforce Information Needed
  - Environmental Agent Information Needed

Basic Characterization and Information Gathering

- Why is this Important?
  - Understand where, when, and how exposures occur in the workplace
  - Inform the next step in the process – Exposure Assessment
  - Avoid Unnecessary Sampling
    - Examples



Basic Characterization and Information Gathering

- What is it?
  - Information needed before applying qualitative and quantitative exposure assessment tools.
    - Builds on walk-through surveys
  - The information obtained is the foundation for exposure assessment
  - The information will be used to support professional judgment, priority setting, and development of controls.
  - It creates the context for assessment

Basic Characterization of Workplace

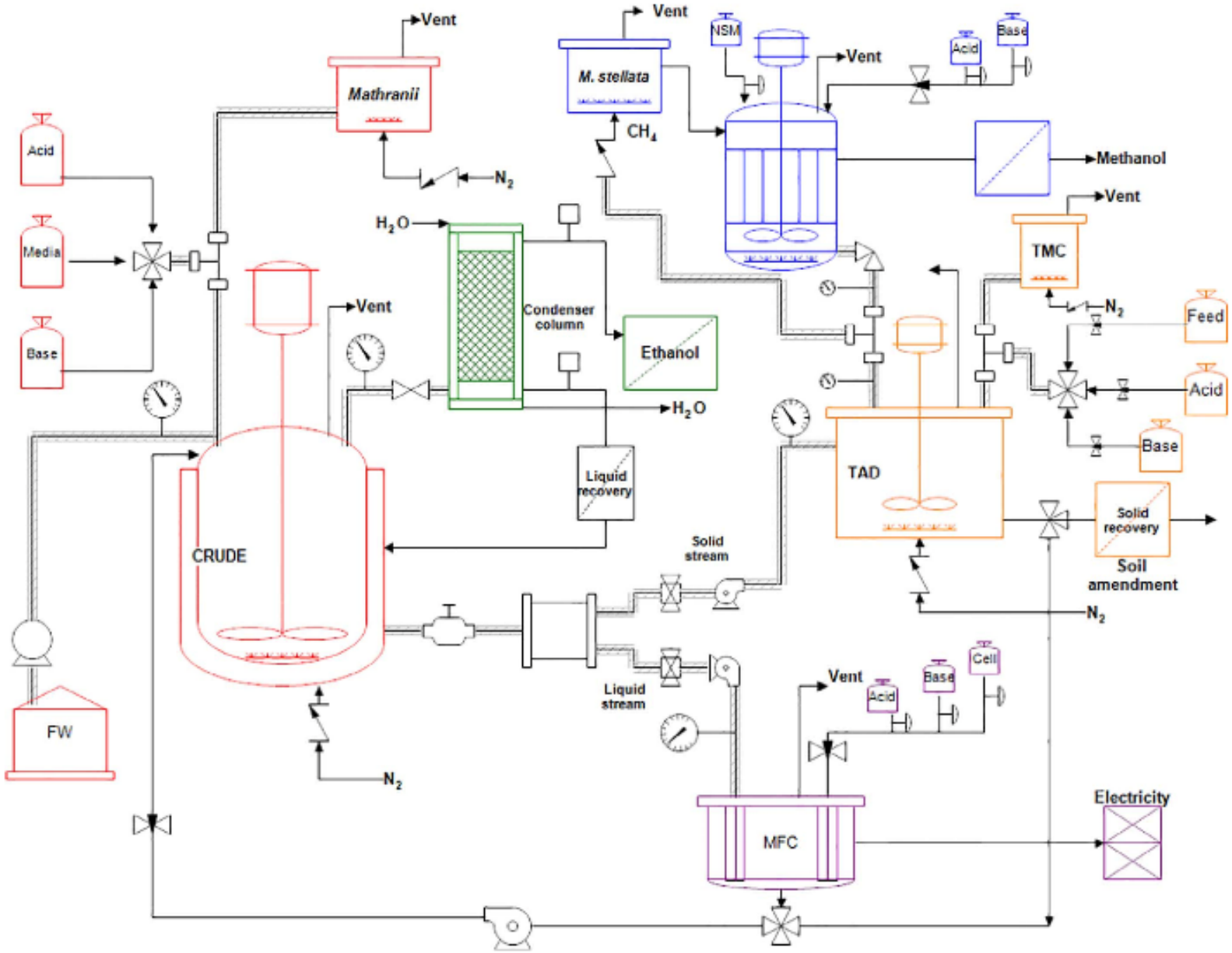
- Questions to Ask:
  - What are the hazardous agents? In what quantities?
  - What are the health effects?
  - What are the OELs
  - What are significant sources of exposure and how do workers interact with them?
  - What processes, operations, tasks, and work practices pose significant sources of exposure?
  - What are the process conditions? Temperature? Operating speed? Transfer points?
  - What controls are in place?

Basic Characterization of Workplace

- First Step in Exposure Assessment: Gather Information
  - Goal: Collect Information on workplace, workforce, and agents.
  - Sources of Information
    - Walk-around Surveys
    - Interviews with Workers, Managers, and Engineers
    - Interviews with medical and safety staff
    - Records – drawings P&ID, medical, employment, maintenance, previous monitoring
    - Literature search
    - OELs
    - Others?

Basic Characterization and Information Gathering

- Gathering Workplace Information
  - Know and understand the process!
  - PSM Data - PHAs
  - Preventative Maintenance Programs
  - P&ID
  - Process Flow Diagrams
  - Ventilation and PPE
  - Dermal Exposure - Hoysekeeping
  - Don’t forget about Cleaning and Maintenance activities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Condenser column
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Solid stream
Liquid stream
Vent
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CH_4
NSM
Vent
Acid
Base
Methanol
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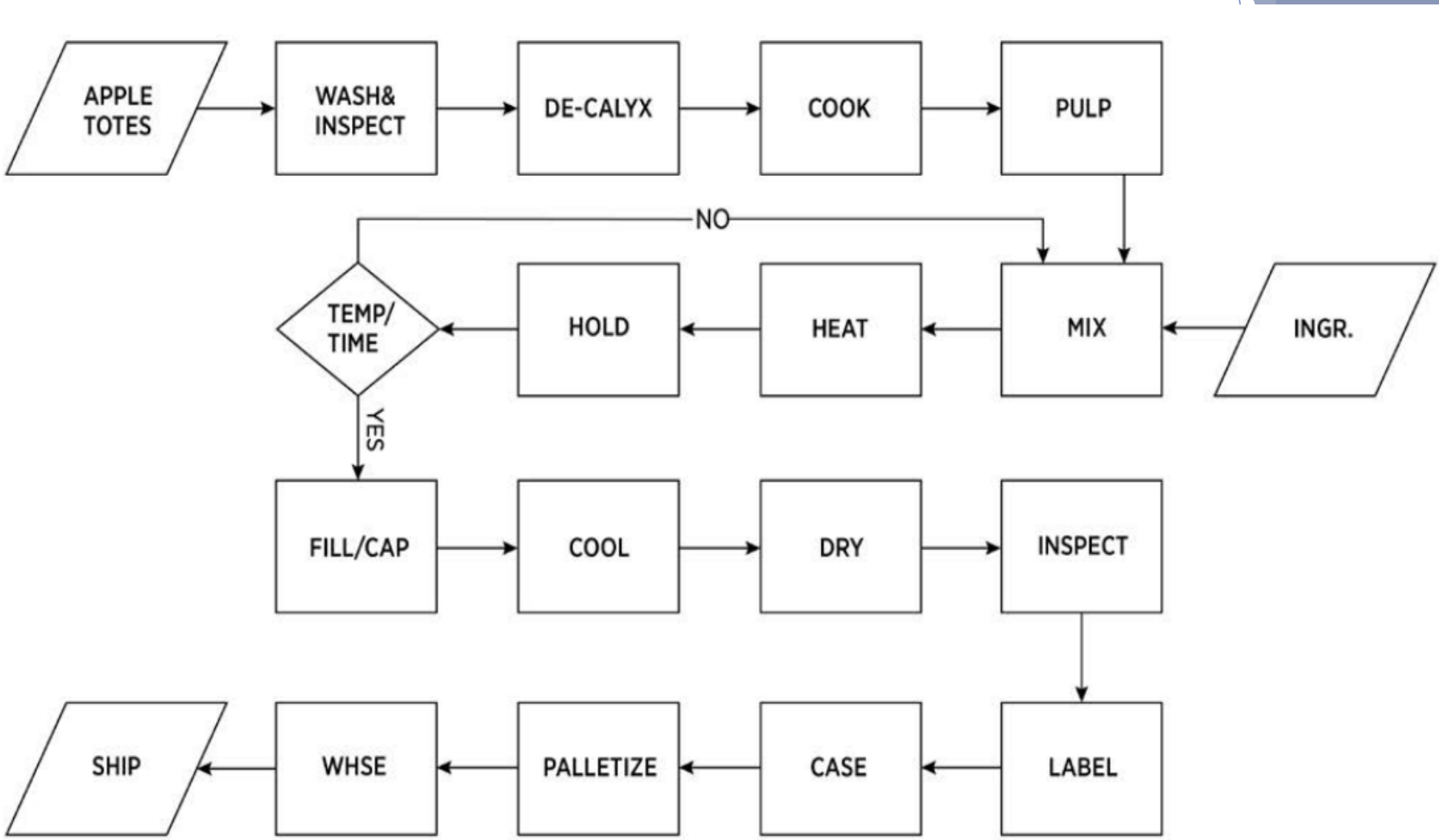
APPLE TOTES
WASH& INSPECT
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TEMP/ TIME
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YES
FILL/CAP
COOL
DRY
INSPECT
SHIP
WHSE
PALLETIZE
CASE
LABEL

Basic Characterization and Information Gathering

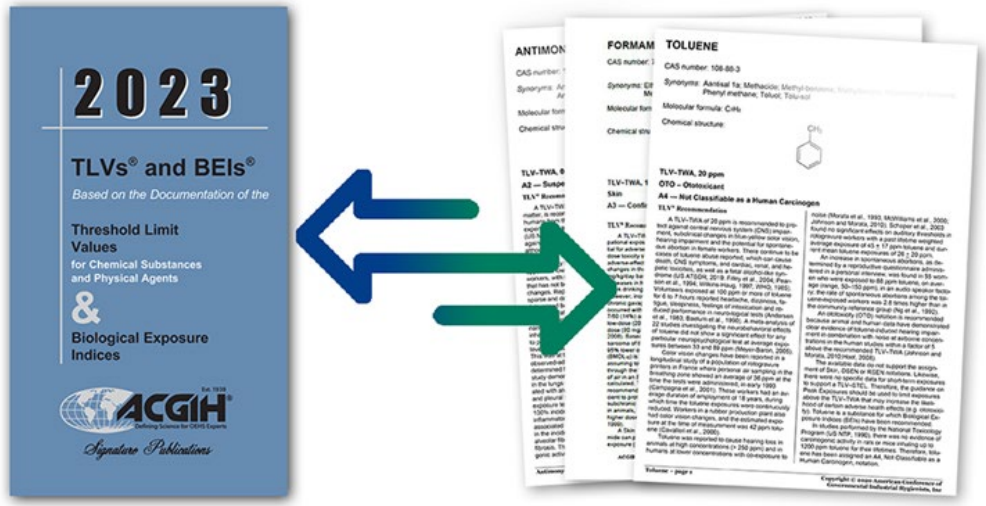
- Gathering Workforce Information
  - Routine and Non-routine
  - Work Schedules
  - Job descriptions – outline of work duties and tasks
  - Time spent on tasks, frequency of task
  - Previous exposure assessments
  - Observations of work practices
  - Work as Imagined vs. Work as done

Basic Characterization and Information Gathering

- Gathering Information on Environmental Agents
  - Chemical, Physical, and Biological Agents
  - Physical Properties (i.e. VP) / State
  - Quantities Used
  - Routes of Exposure
  - Potential Health Effects
  - SDSs
  - Raw Materials, Intermediates, Final Product, By Products, Wastes
  - OELs

Basic Characterization and Information Gathering

- Health Based OELs
  - Regulatory – OSHA/MIOSHA
  - Authoritative – ACGIH, NIOSH
  - Internal or Provisional
  - Working OEL / Hazard Banding



Basic Characterization and Information Gathering

- Health Based OELS
  - Working OEL / Hazard Banding

Figure 1. Typical potency classification system for pharmaceutical actives (5 band system). OEB is occupational exposure banding; OEL is occupational exposure limit; PPE is personal protection equipment.

OEB	1	2	3	4	5
OEL (µg/m³)	≥100	10 - 100	1 - 10	0.1 - 1	<0.1
Potential effects of exposure	None to minor	Minor to moderate	Moderate to serious	Serious	Serious
Handling	GMP/PPE	GMP/PPE	Containment	Containment	Containment/ robotics

Basic Characterization and Information Gathering

- Considerations for Using OELs
  - Why was the level set where it is?
  - How good is the health effect data
  - Are effects reversible, target organs, cancer, immediate death, etc.
  - Warning Properties
  - Can it be adjusted for different work schedules
  - Concurrent Exposures
  - One study TLVs - 1 in 7 not protected

Basic Characterization and Information Gathering

- Summary
  - The information gathered should provide an understanding of:
    - The process
    - Tasks - Time
    - Chemical, Biological, and Physical Agents
    - How and When Workers are exposed
    - Controls Present
    - Quantities Used
    - Chemical and Physical Properties
    - Potential health effects

Questions?

Reference

Jahn SD, Bullock W, Ignacio JS. *A Strategy for Assessing and Managing Occupational Exposures*. Vol 4th edition. AIHA; 2015.