Kenvue	*Pallet Management*	*Global Standard Operating Procedure*

1. OVERVIEW

In accordance with the Kenvue Quality requirements, each Kenvue Business and Functional Unit must establish and maintain or operate under processes that ensure Pallets and Wood Packaging Materials comply with ISPM-15 International Phytosanitary Regulations, and that Pallets and Wood Packaging Materials are controlled in a manner which reduces the risk for unintentional consequences.

1.1. Background

1.1.1. Special care should be taken to minimize the potential for mold, pests, and other contamination for wood Pallets and Wood Packaging Materials. Mold is a common potential issue with wood Pallets, especially those made from “white” (new) wood that are heat treated. Heat treated hardwood Pallets and Wood Packaging Materials are more prone to the development of mold than heat treated softwood Pallets and Wood Packaging Materials.

1.1.2. Treatments to prevent mold and pests may be applied to lumber, Pallet components, or to the finished Pallet/Wood Packaging Material. Non-chemical treatments are preferred. Heat treating wood Pallets and Wood Packaging Materials eliminates live pests in the wood. However, heat treatment does not prevent reinfestation, and does not protect against mold. Reducing moisture content in wood prevents mold growth, however it does not provide protection against pests. Exposure to a humid environment, for example as exists in tropical climates, reintroduces the potential for mold growth. As such, a combination of treatments may be necessary to protect against both mold and pests, and proper storage conditions are important to further reduce contamination risk. Pallets should be of a resilient and low-shedding material to prevent particulate contamination.

1.1.3. Chemical compounds can impart an undesirable musty/moldy odor to materials, components, finished products, and GxP supplies that come in contact with, or are exposed to the treated wood. For example, in the presence of halogenated phenolic compounds used to treat wood, such as tribromophenol (TBP), methylation can occur to form halogenated anisole compounds such as tribromoanisole (TBA). For this to occur, the chemical reaction requires the presence of a halogenated phenolic compound, time, moisture, and heat energy.

1.1.4. Non-wood Pallets are typically made from metal, molded plastics, or reinforced resins, which are not treated with fungicides. When considering the use of plastic or flammable composite Pallets, fire safety is a concern. A flame retardant chemical treatment is sometimes needed, which must comply with applicable requirements in this Standard Operating Procedure (SOP). In areas where

flammable vapors may be present, Pallets that contain plastics may present a risk due to the potential for an electrostatic brush discharge.

2. PURPOSE

This purpose of this Standard Operating Procedure (SOP) is to define the Kenvue requirements for the design, procurement, storage, and management of wood Pallets, non-wood Pallets, and Wood Packaging Materials to ensure patient, facility, product, and supply risks are minimized. Compliance to the requirements of this SOP is mandatory. Where required, additional actions must be taken to adhere to applicable local laws and regulations.

3. SCOPE

This SOP is applicable to every Kenvue Business and Functional Unit that manages or operates under a Quality System or bears a company name, trade name or trademark belonging to Kenvue and is responsible for establishing and maintaining processes for Pallet Management.

When the roles and responsibilities for performing quality system requirements reside outside of Kenvue, for example suppliers and external manufacturers, quality agreements or other formal purchase agreements must be documented and approved to ensure requirements are met.

All materials, components, finished goods, and GxP supplies for R&D, Clinical and Commercial are in scope. Non-GxP supplies are out of scope, for example general office supplies, food items, record archives, provided that associated Pallets and Wood Packaging Materials are segregated from Pallets and Wood Packaging Materials which are in scope of this SOP.

4. DEFINITIONS

Refer to the Kenvue Global Glossary of Terms (FRM-0009808) for commonly used terms.

4.1. Commodities: A Commodity is an engineered product not classified as a cosmetic, nor a drug, nor a medical device or combination product. Products constructed of solid materials, which could include (but not limited to) polymers and other resins (including adhesives), composites, natural and synthetic fibers including binders/finishes, metals (such as brass or stainless steel), electronics, pulp products (paper) and finishes/additives or printed surfaces.

4.2. Formulated Products: Solid or liquid product constructed of selected, processed and combined ingredients.

4.3. GMP Production Areas: Areas where products are manufactured (including assembly and packaging), or repacked/relabeled. Excludes Production Support Areas.

4.4. Food products: Substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans, and not classified as Nutritional.

4.5. Nutritional products: A broad umbrella term that is used to describe any product which exhibit physiological or health benefits in addition to the basic nutritional value found in foods, or is

intended to supplement the diet and provide essential nutrients, such as vitamins, minerals, proteins, amino acids, fatty acids, probiotics, and other substances.

4.6. Drugs: Any product containing a substance that is recognized by the Health Authority of the country it is marketed in as a Drug or Active Pharmaceutical Ingredient.

4.7. Phytosanitary Regulation: Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact or regulated non-quarantine pests.

4.8. Production Support Areas: Warehouse type locations in a manufacturing plant where materials, components, supplies, and/or work in process materials are stored.

4.9. Wood Packaging Materials: Wood or wood products (excluding paper products) used in supporting, protecting, or carrying materials, components, finished goods or GxP supplies (includes dunnage).

5. RESPONSIBILITIES

Quality Management is responsible for:

- Establishing procedures that meet the requirements of this SOP as well as applicable local laws and regulatory requirements.

Kenvue Environmental Health and Safety is responsible for:

- Approving risk assessments that meet the requirements of this SOP.

6. REQUIREMENTS

6.1. General Requirements – All Pallets and Wood Packaging Materials

6.1.1. Kenvue business units, as well as affiliates of Kenvue, logistics providers, and external manufacturers, must maintain an inspection process for Pallets and Wood Packaging Materials:

6.1.1.1. At incoming receipt, with or without materials, components, finished products, or GxP supplies on them: inspection process must include requirements for markings, color, configuration, contamination, and damage, as applicable.

6.1.1.2. At point of utilization in warehousing, logistics, manufacturing, and distribution: Inspection process must include an assessment for damage. If Pallets and Wood Packaging Materials are not stored in a Production Support Area or GMP Production Area, then the inspection must also include an assessment for contamination.

6.1.1.3. The inspection process must include requirements for segregation, investigation and disposition of nonconforming Pallets and Wood Packaging Materials, along with associated materials, components, finished products, and GxP supplies.

6.1.1.4. Refer to Supporting information in appendix 1 for Guidance for Inspections of Pallets and Wood Packaging Materials.

6.1.2. Pallets and Wood Packaging Materials must be stored and transported in an environment that minimizes risk of exposure to moisture, pests, and other potential contamination.

6.1.3. Pallets and Wood Packaging Materials must meet the requirements from 6.1.1 and 6.1.2 to be reused.

6.1.4. Additional actions must be taken to adhere to local laws and regulations, as applicable.

6.1.5. Pallets and Wood Packaging Materials which are in scope of this SOP must be segregated from Pallets and Wood Packaging Materials that are not in scope of this SOP. Controls must be established to prevent contamination and to prevent the use of non-compliant Pallets and Wood Packaging Materials.

6.1.6. Kenvue Business Units must include requirements from this SOP in formal purchase agreements for Pallets, Wood Packaging Materials, materials, components, finished products, GxP supplies, and services, as applicable, using at least one of the following documents: specifications, quality agreements, supply agreements, quality requirements, or purchase orders.

6.2. Wood Pallets and Wood Packaging Materials

6.2.1. The following chemical treatments are prohibited:

6.2.1.1. 2,4,6-tribromophenol (TBP), and

6.2.1.2. Any other form of phenol-based fungicide treatment, and

6.2.1.3. Methyl Bromide treatment. (Due to environmental concerns).

6.2.2. The following treatments are acceptable:

6.2.2.1. Pest prevention:

- Heat Treatment
- Sulfuryl Fluoride

6.2.2.2. Mold prevention:

- Air drying
- Kiln drying
- Sinesto B
- Sinesto AS-5
- Cutrol 375

6.2.2.3. Under no circumstance should Kenvue employees be directly involved with the physical application of these treatments to Pallets or Wood Packaging Materials.

6.2.3. All wood Pallets and Wood Packaging Materials used at Kenvue manufacturing locations and external manufacturers that are 1) located in Puerto Rico or Latin America, and 2) produce Drug, Nutritional and Food Products must be treated for mold prevention.

6.2.4. Where local usage of another Pallet or Wood Packaging Materials treatment is needed, a comprehensive risk assessment must be completed as indicated in 6.4.3, and approved by Kenvue Corporate Environmental Health and Safety, Chief Quality Officer, and Supply Chain Head. Delegation of approval is not permitted.

6.2.5. Shipments to a country or region that requires conformance to ISPM-15 must comply to ISPM-15, see website of the International Plant Protection Convention: https://www.ippc.int.

6.2.6. Shipments of materials, components, and GxP supplies to Kenvue and External Manufacturers must comply to ISPM-15, regardless of whether the receiving country or region requires adherence to ISPM-15.

6.2.6.1. Where local usage of Pallets and Wood Packaging Materials that do not comply with ISPM-15 is needed for shipments of materials, components, or GxP supplies, and the receiving country or region does not require conformance to ISPM-15:

- A comprehensive risk assessment shall be completed as indicated in 6.4.3, and approved by Kenvue Corporate Environmental Health and Safety, Chief Quality Officer, and Supply Chain Head. Delegation of approval is not permitted.
- Authorization for use of Pallets and Wood Packaging Materials that do not comply with ISPM-15 shall be included in formal purchase agreements for the specific materials, components, or GxP supplies, as applicable, using at least one of the following documents: specifications, quality agreements, supply agreements, quality requirements, or purchase orders.

6.2.7. Wood Pallets and Wood Packaging Materials that need to comply with ISPM-15 requirements must adhere to section 6.2.1 and 6.2.3 of this SOP, be Heat Treated to achieve a minimum temperature of 56°C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including its core), and display a Heat Treatment mark in accordance with ISPM-15.

6.2.8. Wood Pallets and Wood Packaging Materials that do not need to comply with ISPM-15 must adhere to section 6.2.1 and 6.2.3 of this SOP, and must be identified with a specific marking, color, or configuration.

6.2.9. Suppliers of Pallets and Wood Packaging Materials, as well as suppliers of materials, components, finished products, and GxP supplies using Pallets or Wood Packaging Materials, must provide documented evidence of compliance and traceability of treatments upon request.

6.2.10. Refer to Supporting Information is reported in Appendix for Example Specification for Empty Wood Pallets, as well as Pallet Types, Wood Types, Wood Packaging Materials and Wood Treatments.

6.3. Non-wood Pallets

6.3.1. Pallets that contain plastics must be free of polybrominated diphenyl ethers (PBDEs) flame-retardants - specifically penta-, octa-, and deca-brominated diphenyl ethers (BDEs).

6.3.1.1. Suppliers of Pallets, as well as suppliers of materials, components, finished products, and GxP supplies using Pallets, must provide documented evidence of compliance upon request.

6.3.2. Pallets that contain plastics must not be used in areas where flammable vapors may be present, designated as Class 1, Div 2, or ATEX Zone 1. For details refer to “Recognizing and Controlling Static Electricity Hazards”, NG-TRU-GDL-01489

6.3.3. Metal Pallets, as well as plastics Pallets in compliance with 6.3.1 and 6.3.2, are acceptable for supply of all materials, components, finished products, and GxP supplies.

6.3.4. The use of other Pallet materials, for example reinforced resin materials, single use slip sheets, corrugated cardboard Pallets, and processed pressed wood Pallets, must be documented in segment or local procedures. A comprehensive risk assessment must be completed prior to use as indicated in 6.4.3, approved by Kenvue Corporate Environmental Health and Safety Chief Quality Officer, and Supply Chain Head. Delegation of approval is not permitted.

6.4. Use of Pallets and Wood Packaging Materials in Warehousing, Logistics, Manufacturing, and Distribution

6.4.1. Metal Pallets, as well as plastics Pallets in compliance with 6.3.1 and 6.3.2, are acceptable for use everywhere.

6.4.2. Wood Pallets and Wood Packaging Materials, in compliance with 6.2, are acceptable in the following situations:

6.4.2.1. Within medical device, drug or combination products GMP Production Areas in manufacturing locations: for secondary packaging and for placing finished packaged product onto Pallets, provided that primary packaging is complete and facility & environmental segregation is in place between the primary packaging area and the area where the Pallet is used.

6.4.2.2. Within non-medical device, drug or combination products GMP Production Areas in manufacturing locations:

- Commodities for external use: All GMP Production Areas
- Cosmetic and Commodities for internal use: All GMP packaging production areas, provided that contamination protection is in place between the non-packaged products and the area where the Pallet or Wood Packaging Material is used.

6.4.2.3. Outside GMP Production Areas (Manufacturing Warehouses, Logistic Centers and Distribution Centers): for all materials, components, finished products, and GxP supplies, as well as for repack/relabel of finished products for outbound storage/shipment.

6.4.3. Pallet and Wood Packaging Material usage other than what is described in 6.4.1 and 6.4.2 must have a documented risk assessment completed prior to use, and approved by Kenvue Corporate Environmental Health and Safety, Chief Quality Officer, and Supply Chain Head. Delegation of approval is not permitted. The risk assessment must include the following:

6.4.3.1. Patient safety, product quality, occupational health, environment, fire safety, facilities, and regulatory impact.

6.4.3.2. Controls to prevent injury to personnel and damage to products due to poorly constructed or damaged Pallets and Wood Packaging Materials.

6.4.3.3. Controls to prevent chemical, microbial, pest, native particle, and foreign matter contamination.

6.4.3.4. Finished product types and associated regulatory/risk classifications.

6.4.3.5. Alternative Pallet types and materials, for example reinforced resin materials, single use slip sheets, corrugated cardboard Pallets, processed press wood Pallets.

6.4.3.6. Chemically treated Pallets as required by local customers, laws, regulations, or phytosanitary needs. Never allowed: 2,4,6- tribromophenol (TBP) or any other form of phenol-based fungicide treatment, Methyl Bromide, as well as polybrominated diphenyl ethers (PBDEs) flame-retardants. Allowed: Sulfuryl Fluoride, Sinesto B, Sinesto AS-5, and Cutrol 375.

6.4.3.7. Potential for high Pallet and Wood Packaging Material contamination risk based on country or region environmental exposure, for example tropical climate, as well as risk related to wood sources.

7. REFERENCES

7.1. Kenvue Global Glossary of Terms (FRM-0009808)

7.2. International Standards for Phytosanitary Measures Publication No. 15, 2018 version (ISPM 15) – Regulation of Wood Packaging Material in International Trade.

7.3. A listing of countries and regions that require adherence to ISPM-15 can be found on the website of the International Plant Protection Convention: https://www.ippc.int

8. APPENDICES

Appendix 1: Supporting information for Pallet Management

Appendix 1: Supporting information for Pallet Management

SECTION I – Guidance for Inspections of Pallets and Wood Packaging Materials

1. General Guidance for Pallet and Wood Packaging Material Inspection

All Pallets and Wood Packaging Materials, both with or without materials, components, finished products, or GxP supplies on them, should be inspected at receiving, prior to moving into a manufacturing area, and prior to storing in a warehouse environment. The inspection activity should be documented per local guidelines. Documentation may be in the form of a check list, or as part of the inbound receiving procedure with a statement that any documented reception means those controls were compliant, and any detected defect managed appropriately. Nonconforming Pallets and Wood Packaging Materials, as well as the associated materials, components, finished products, and GxP supplies should be segregated, investigated, and dispositioned.

2. Inspection Considerations

Pallets and Wood Packaging Materials should be properly constructed, properly marked, generally sound, safe to handle, and free from any contamination.

3. For all Pallets and Wood Packaging Materials

- The Pallet and Wood Packaging Material should be marked, colored, or configured as applicable, for example Heat Treatment stamp or supplier mark.
- There should not be any noticeable or objectionable odors.

For the controls below, it is recognized that those can only be executed within the limits of what is visible for Pallets and Wood Packaging Materials with materials, components, finished products, or GxP supplies on or in them.

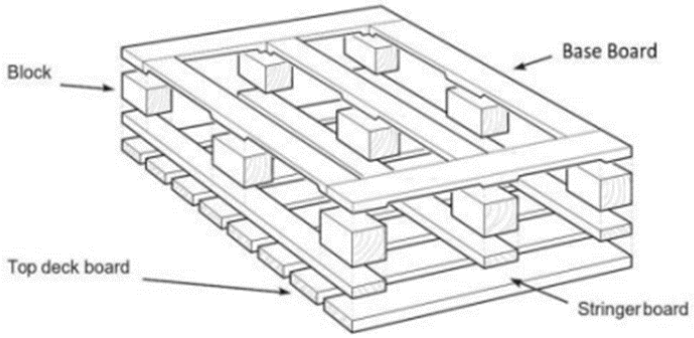
- There should be no obvious damages (for example splits, exposed nails, broken boards)
- The Pallet and Wood Packaging Material should be clean and free from contamination, for example chemical, microbial (fungi, mold), pests, native particles (sawdust, fibers, splinters), water damage, and/or foreign matter.

4. Additional for Empty Pallets

- Every base board should be properly fastened at each end and be the correct length to properly support a shipment with adequate edge distance remaining.
- Top deck boards, stringer boards, and base boards should be of consistent thickness and width.
- Base boards should not be split at their fastened end.
- There should not be any loose joints permitting racking out of square (diamonding).
- Verification level might be adjusted, especially in case of receiving brand new Pallets.

5. Terminology

This illustration is an example of typical wood Pallet construction for terminology reference. *Block Pallet facing upside down.*



6. Markings

This illustration is an example of typical ISPM15 Heat Treatment Pallet marking for reference.

SECTION II – Pallet Types, Wood Types, Wood Packaging Materials, and Wood Treatments

1. Pallet Types

As a portable platform for handling, storing, or moving goods, Pallets come in different sizes, formats, and materials which for the most part are easily distinguished in the context of this SOP. However, the differences between plastic Pallets and reinforced resin Pallets are less easily observed, and benefit from clarification:

- Reinforced resin Pallets are typically deployed for heavy loads, using fibers or rods to provide additional strength.
- These Pallets are significantly heavier, more durable, and more expensive than typical plastic Pallets.
- The weight difference compared to the same size plastic Pallet is a good indicator.
- Because of the composite structure, they are more difficult to recycle.

2. Wood Types
    - Hard Wood: originates from a tree which loses its leaves annually, for example oak.
    - Soft Wood: originates from conifer trees which are evergreen, for example pine.

3. ISPM-15 Regulated Wood Packaging Materials
   All forms of Wood Packaging Material that may serve as a pathway for pests posing a pest risk mainly to living trees, for example crates, boxes, packing cases, dunnage, Pallets, cable drums, spools/reels.

4. Exemptions to ISPM-15 Regulated Wood Packaging Materials
   The following articles are of sufficiently low risk to be exempted from the provisions of ISPM-15, however other requirements from this SOP may apply.
    - Wood Packaging Material made entirely from thin wood (6 mm or less in thickness).
    - Wood Packaging made wholly of processed wood material, such as plywood, particle board, oriented strand board or veneer that has been created using glue, heat or pressure, or a combination thereof.
    - Barrels for wine and spirit that have been heated during manufacture.
    - Gift boxes for wine, cigars and other commodities made from wood that has been processed and/or manufactured in a way that renders it free of pests.
    - Sawdust, wood shavings and wood wool.
    - Wood components permanently attached to freight vehicles and containers.

5. Wood Treatments
   Heat treatment:
        - Eliminates pests when exposing the entire profile of the wood, including its core, to a minimum temperature of 56°C for a minimum duration of 30 continuous minutes. Simply exposing the exterior of the wood to the desired temperature and duration (or to higher temperature and duration) is not sufficient to eliminate pests.
        - Typically occurs in a kiln (oven) and uses either a validated process, or temperature probes should be inserted in the core of the wood throughout the chamber. Heat treatment is often combined with Kiln drying, however kiln drying alone does not guarantee successful heat treatment. Proof of validated process, or proof of temperature probe results should be documented, and wood should be certified with the ISPM-15 heat treatment mark.
        - Heat treatment may be executed on the finished Pallets, on Pallet components, and/or on raw lumber. ISPM-15 contains detailed requirements for heat treatment, as well as for reuse and repair of heattreated wood Pallets and wood packaging materials.

Drying:

- Prevents mold growth by reducing moisture content in the wood below viable growth conditions.
  - As a general guideline, moisture content should remain below 19% to prevent mold growth.
- Typically occurs by air exposure or in a kiln.
  - Air drying: drying of timber by exposing it to the air.
  - Kiln drying: process of artificial or 'oven' drying by introducing heat.
- Drying does not eliminates pests unless combined with heat treatment.

Chemical treatment:

- Exposing the wood to chemicals by spraying or pressure impregnation, using for example Sinesto B, Sinesto AS-5, or Cutrol 375 for mold prevention, or sulfuryl fluoride for pest prevention.

SECTION III – Example Specification for Empty Wood Pallets

Instructions:

1. Items in blue are optional depending on the use of the Pallets as described in this standard.
2. Remove text in orange and remove any requirements in blue that are not applicable.

1.0 Material Requirements

Wood pallets must be free from:

. 2,4,6-tribromophenol (TBP), and

. Any other form of phenol-based fungicide treatment, and

. Methyl Bromide treatment.

Pallets, pallet components and/or lumber must be Heat Treated to achieve a minimum temperature of 56 C (132.8 Fahrenheit) for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including its core) and display a heat treatment mark in accordance with ISPM-15.
Pallets must be treated for mold prevention using one of the following methods:
• Air drying
• Kiln drying
• Sinesto B
• Sinesto AS-5

• Cutrol 375

Pallets must be identified with a unique marking, color, or configuration {define marking, color, or configuration}

The following treatments are acceptable. Any other treatments are not acceptable. Treatments may be applied to lumber, pallet components, or to the finished pallet.

2.0 Pest Prevention

- Heat Treatment
- Sulfuryl Fluoride

3.0 Mold Prevention

- Air drying
- Kiln drying
- Sinesto B
- Sinesto AS-5
- Cutrol 375

4.0 Quality Requirements

- Pallets must be properly constructed, properly marked, generally sound, safe to handle
- There must not be any noticeable or objectionable odors
- There must be no obvious damages (for example splits, exposed nails, broken boards)
- The Pallet must be clean and free from contamination, for example chemical, microbial (fungi, mold), pests, native particles (sawdust, fibers, splinters), water damage, and/or foreign matter
- Every base board must be properly fastened at each end, and be the correct length to properly support a shipment with adequate edge distance remaining
- Top deck boards, stringer boards, and base boards must be of consistent thickness and width
- Base boards must not be split at their fastened end
- There must not be any loose joints permitting racking out of square (diamonding)

*****END OF DOCUMENT*****

Document Revision History				
Revision Number	**Section**	**Description of Change**	**Reason for Change**	**Document Initiator/Owner**
1	N/A	New Standard Operating Procedure	Original Issue	Purbierta Nandy

Approver Name	Role	Date/Time
Wong Bee Lay	Quality Approver	Apr 23, 2024 05:54:58 PM
MORONI SERENA	Process Owner	Apr 24, 2024 07:59:47 AM
Horta Bryant	Global Procedure Specialist	Apr 24, 2024 01:14:42 PM

Impacted Site(s)

BL-Global.