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Harlan Laboratories

# Bedding Packaging for Biomedical Research Applications

## All Animal Bedding Materials Are Not Created Equally

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# Bedding Materials for the Biomedical Research Community

All products sold directly to commercial end-users, on an international basis.

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# *Defining The Market*

The International Biomedical Research Community

Customers such as:

- Government Institutions (NIH, FDA, USDA, CDC, EPA, DOD)
- Pharmaceutical Firms (Merck, Pfizer, Schering, Wyeth)
- Contract Toxicology Labs (Covance, Battelle, Wil Research)
- Medical Schools (Johns Hopkins, Harvard, Wash U.)
- Biotech Firms (Amgen, MedImmune, Genentech)
- Large Commercial Breeders (Harlan, Charles River, Jackson)

# THE MARKET: Part 2

**THE CUSTOMERS IN THIS SEGMENT ARE:**

> **LARGE USERS** Most often buying full pallets
>
> Some by in Bulk, Some buy full trucks
>
> Mechanized MaterialsHandling
>
> Some use robotics technology
>
> “Flowability” is vitally important

> **VERY DEMANDING** Rigid Specs for Product Quality

> **HIGHLY REGULATED** NIH, USDA, AAALAC, GLP’s

# *Harlan, as a part of this Industry*

1. is a Manufacturer of both Diets and some Beddings (***not*** cobs)
2. sells manufactured items (diets & some beddings) and re-sells other manufacturer's bedding items direct to commercial end users
3. is also one of the largest Commercial End Users
4. sells, re-sells and purchases on an International basis
5. products are ***not*** sold in retail stores

Therefore, we come to you with both from a manufacturer's viewpoint, as well as from a ***customer/end-user perspective***.

# *"All Bedding Materials are not created equally"*

***Wide Variety of Materials & Characteristics***

- ***Wood Chips*** ***(cubes of wood from saw cuts)***
- ***Corncobs*** ***(granular, 1/4" or 1/8" particles)***
- ***Paper*** ***(Loose Pulp)***
- ***Paper "chips"*** ***(diced, rigid squares of alpha cellulose)***
- ***Paper Pellets***
- ***Cob Pellets***
- ***Wood Pellets***
- ***Wood Shavings (not commonly used in research – variables)***

(NOTE: The vast majority of these items are still packaged & sold by weight)

# *CHARACTERISTICS:*

- VERY DRY: (typically 6 to 10% moisture or less)
  - Maximize Absorbency
  - Minimize Mold/Contaminants
  - NIH Specifications
  - Regulated & Controlled Indoor Storage Requirements

    (USDA, NIH Guidebook, AAALAC, FDA GLP's)

  ***MOISTURE:** Is a very bad thing, and is not tolerated. *Low* Moisture is critical for proper product performance, and to meet client specifications & expectations

  (This is not mulch, peat moss or top soil)

  * Some materials are compressible, but most are not

# The Issue

In meetings with NIST leaders, it was discovered that the spirit and intent of the current statute was to control packaging of materials such as mulch, peat moss & top soil. These materials, when packed by weight, can vary widely in terms of weight. Significant moisture loss can occur during shipment & storage. Such products can also be “spiked” with moisture to increase weight.

Animal Bedding is not plant bedding or soil, and as demonstrated earlier, in this particular market segment, moisture is an undesirable characteristic that is very tightly controlled & regulated. Most beddings used by clients in this segment are also not compressible, due mainly to the need for “flowability” in high-throughput facilities.

Further, for most bedding materials, raw materials & other input costs are purchased & calculated in terms of weight, freight is calculated in terms of weight, and so selling price is determined using weight. For value comparison purposes, clients either request or require pricing on bids & contracts in terms of weight.

# *NIH SPECIFICATIONS*

## *(NIH Spec: NIH-13-119)*

3.2 Processing: …. When delivered, corn cob bedding shall contain at least 8% but not more than 10% moisture…

3.3 Form: Specifications on particle distribution, dust content or fines, and bulk density minimums & maximums. (US Standard Sieve Tests/specs are also given here)

5.1 Packaging: Bedding shall be packaged in 40 Lb. bags (+/- 1 lb.)

The NIH Bid specifications also require that all bedding items be bid by weight, in terms of pounds, to allow for proper value comparison

# Accuracy in Filling Bags

***(NON-Compressible Materials)***

## By Weight

- Precise
- Alarmed/controlled
- Easily Verifiable (both by manufacturer and client)
- Complies with NIH Bid Specifications
- Preferred by most clients in large bids/Industry Standard

## By Volume

- Estimated by flow rates for filling bulk totes (or weight?)
- Less precise than weight, involves estimations
- Not as readily verifiable (especially larger packages)
- Does not comply with NIH bid requirements and strays from Industry Standards

# FACTORS IN DETERMINING HOW MUCH BEDDING MATERIAL TO PUT INTO A CAGE ("*Enough*")

First thing that must be done, per application, is determine the proper amount of material, by weight, to put into a cage. Absorbency is calculated in terms of a % of weight (Example: "Absorbs 130% of its weight in liquids")

Determined by:

> Type of Caging: IVC, Static, Enclosed Isolator, Other

> Species & Population of Cage

> Temp., Humidity & Air Changes: At cage level & at room level

> Desired Interval Between Cage Changes

> Weight, or "Amount of Absorbent Material", is the final determining factor, *not Volume* *(Rice Krispies vs. Grape Nuts)*

These and other factors will often be different within a given facility

# BULK TOTES: A Customer's Perspective

## When is this full?

## How would I verify?

# Accurate Weight is Required for Shipping

## Domestic Haulers

- An accurate weight per truckload or container must be calculated for every shipment, truck or rail
- Packing by weight makes calculations easy for the shipper, and is easily verified by the hauler

## Overseas Containers

- Same hold true for overseas containers, and clients prefer packaging by weight, which allows for more rapid/accurate verification
- Carriers must have the weight on Bill of Lading to comply with maximum weight laws

# *Summary:*

- Most bedding materials used in this industry are not compressible, and have therefore historically been packaged & sold by weight
- Moisture loss during storage, and risk of moisture “spiking” are not issues due to the low starting moisture
- Low moisture is vital to proper product performance, and is also tightly controlled & regulated by both the NIH, the USDA, and through bid specifications of many other larger end users
- Research Standards require strict and controlled indoor storage conditions to maintain the integrity of bedding products prior to use
- Packing by weight is more precise and much more easily verifiable, both by the manufacturer, and by the customer
- Packing by weight is specified by most government bids, and is preferred by most Purchasing Agents for ease & accuracy of value comparison

# Summary (continued)

- In terms of shipping, weight, not volume is required for calculating accurate weights for billing of freight (which is traditionally billed “per ton”), and in meeting legal truck and highway federal weight requirements. Weight is also required on all Bills of Lading
- For a Manufacturer: Verification by volume is less precise and more difficult when it comes to larger packages (such as bulk totes)
- For an End User: Verification by volume is not as easy for smaller packages, and nearly impossible (and labor-intensive) on larger packages that hold from 500 to 1000 lbs. of material
- Non-consumer provisions already existfor many other commodities regulated by the NIST and Weights & Measures Divisions. Non-compressible bedding materials for the biomedical research industry (which is clearly non-retail) should be covered by one of these non-consumer provisions.

# *Thank You!*