Shelf Life Recommendations for Inotiv Teklad Standard Natural Ingredient Diets

The purpose of this document is to communicate information about a change in the labeling of Teklad Standard diets to **include an expiration date of nine (9) or (12) months from the date of manufacture** on product packaging for the North American market.

The expiration date will be included along with the date of manufacture, either on the applied label or bag closure tape.

Historical recommendations in North America have been to use these types of diets within six (6) months after the date of manufacture *(Guide for the Care and Use of Laboratory Animals, 8th edition, 2011, National Academies Press)* and to maintain the products under proper storage conditions.

The *Guide* (pg. 66) recognizes, however, that the appropriate food storage time should take into account manufacturer's recommendations. As described further below, Inotiv has demonstrated that its Teklad Standard diets are suitable for use for at least 9 or 12 months after the date of manufacture, depending on whether the product is irradiated.

Shelf life is the period of time that a product is suitable for the intended purpose. The purpose of standard natural ingredient diets fed to laboratory animals is to deliver appropriate nutrient levels which support species life stage, result in good health, and aid research by being consistent over the course of feeding.

The guidelines, by product type, are shown in the table below:

Product Type	**Shelf Life Assurance**
Conventional – pelleted and extruded - All diets - Includes Non-human Primate & Guinea Pig (use Stabilized Vitamin C)	9 months
Irradiated – pelleted and extruded - Most diets	12 months
Exceptions - 2914 Irradiated Global Rodent Maintenance Diet - 2940 & 2941 Irradiated Global Guinea Pig Diets	 9 months 9 months

Shelf life is evaluated by monitoring changes in quality relative to some standard. The primary shelf life considerations for laboratory animal diets are vitamin stability and microbiological quality.

The diet shelf life practices in this document are based on consideration of the following:

- Data from studies designed to measure shelf life indicators like vitamin content, water activity, microbiology, and anisidine levels (indicator of fat oxidation) across time.
- Vitamin levels in standard natural ingredient diets are generous relative to estimated requirements.
- The manufacturing practices used to produce the products that result in diets with controlled moisture content and water activity below levels required to support microbiological growth.
- Other testing of vitamins at various times from post-manufacturing to two years.
- Use of published and internal resources to estimate vitamin degradation from manufacturing, irradiation, and storage over time, followed by a comparison to estimated nutrient requirements or accepted standards for lab animal species.
- Effect of packaging and irradiation on product stability.
- Comparison to shelf life practices in countries where these same Teklad standard diets are fed for 9 or 12 months (India, UK, Europe, Singapore, Australia, and New Zealand).
- Appropriate storage conditions (listed below) within Inotiv distribution centers and customer locations.
    - Temperature at or below 70^{0}F (minor excursions acceptable)*
    - Relative humidity (RH) at or below 65%
    - Clean and free of pests, in original packaging or in a container that prevents continuous exposure to light and minimal exposure to air

When stored properly, Inotiv is confident that Teklad Standard, Natural Ingredient diets are safe and suitable for purpose for the time frames (9 or 12 months) outlined in the table.

We understand that the policies and protocols of particular institutions may take precedence over this assessment. In those cases and to the extent possible, we will work to accommodate your specific diet age requirements.

To interact with our technical services team regarding these recommendations, email askanutritionist@Inotiv.com or Teklad@Inotiv.com.

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* It is not possible to definitively quantify what constitutes a minor excursion in temperature or relative humidity. More risk is likely when deviations are of greater magnitude and duration. With respect to risk for vitamin degradation due to temperature increases, temperatures would need to rise beyond the typical 5 -10^{0} F (up to 5^{0}C) range expected in facilities that have adequate temperature and humidity control. Small changes that could occur in several months can be obscured by measurement error. Packaging can minimize changes due to fluctuations of RH. It would be best practice for RH to not exceed 70% on a regular basis so that conventional diet in the 2-3 ply paper packaging does not experience appreciable increases in water activity.