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Standard Guide for Selection of Time-Temperature Indicators[1]

This standard is issued under the fixed designation F 1416; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide covers information on the selection of commercially available time-temperature indicators (TTIs) for noninvasive external package use on perishable products, such as food and pharmaceuticals. When attached to the package of a perishable product, TTIs are used to measure the combined time and temperature history of the product in order to predict the remaining shelf life of the product or to signal the end of its usable shelf life. It is the responsibility of the processor of the perishable product to determine the shelf life of a product at the appropriate temperatures and to consult with the indicator manufacturer to select the available indicator which most closely matches the quality of the product as a function of time and temperature.

NOTE 1—Besides time-temperature indicator, TTI is also an abbreviation for time-temperature monitor and time-temperature integrator.

1.2 Time-temperature indicators may be integrated into a Hazard Analysis and Critical Control Point (HACCP) plan. Appropriate instructions should be established for handling products for which either the indicator has signaled the end of usable shelf life or the shelf life of the product at its normal storage temperature has been reached.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Terminology

2.1 *Definitions:*

2.1.1 *activation energy*—the quantity commonly used to describe the dependence of the shelf life of a product (or the rate of a reaction) on temperature, as given by the Arrhenius relationship.

2.1.1.1 *Discussion*—The higher the activation energy, the more the shelf life of a product changes with temperature. If the shelf life of a product is known at two temperatures, the activation energy is given by the following formula:

$$E_a = \frac{ln(LIFE_1/LIFE_2)}{\frac{1}{T_1} - \frac{1}{T_2}} \times R \quad (1)$$

where $LIFE_1$ and $LIFE_2$= shelf lives at temperatures T_1 and T_2.

2.1.2 *all-temperature time-temperature indicator*—a TTI that continues to change at some rate at all temperatures.

2.1.3 *Arrhenius plot*—a plot of the logarithm of the shelf life of a product versus the reciprocal of temperature ($1\backslash T$).

2.1.3.1 *Discussion*—If the shelf life of a product exhibits Arrhenius behavior, then an Arrhenius plot of the shelf life will be a straight line. The activation energy of the shelf life is equal to the slope of the line times *R* (see 2.1.1.1). It is more accurate to use a regression analysis to determine the slope based on the data from at least three temperatures than to use only two points as in the previous equation. A blank Arrhenius plot is shown in Fig. 1. The plot axes are the $\log_{10}$ of the shelf life and the reciprocal of temperature. For ease of use, the Fahrenheit and Celsius temperatures are shown on the graph instead of the inverse temperature.

2.1.4 *Arrhenius relationship*—a relationship that describes the dependence of the rate of a chemical reaction on temperature as follows:

$$k = A_0 e - \left(\frac{E_a}{RT}\right) \quad (2)$$

where:

k = rate constant,
A_0 = constant with the same time units as k,
T = temperature, K (°C + 273), and
R = universal gas constant.

When R = 0.001987 kcal/(mol · deg), the activation energy, E_a, is given in units of kcal/mol.

When R = 0.00831 kJ/(mol · deg), the activation energy, E_a, is given in units of kJ/mol.

2.1.4.1 *Discussion*—This relationship also describes the dependence of the shelf life of many TTIs and perishable products on the effective average temperature to which they are exposed. Since the shelf life is the time for the reaction to proceed to a specific extent, the Arrhenius relationship for shelf life is given by the following formula:

$$LIFE = Be\left(\frac{E_a}{RT}\right) \quad (3)$$

where B = constant with the same time units as *LIFE*.

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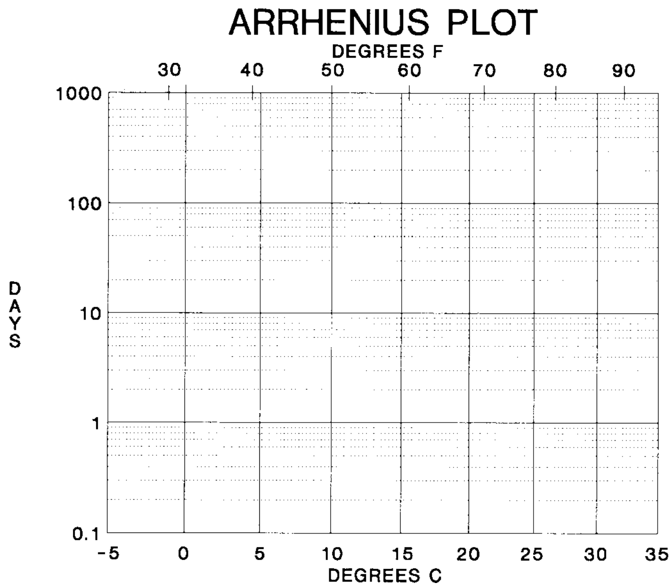

NOTE 1—This blank graph may be used to determine if the shelf life of a product exhibits standard Arrhenius behavior. The plot axes are the log_{10} of the shelf life and the reciprocal of temperature. Note that the *X*-axis of this plot is marked in Celsius degrees instead of inverse Kelvin degrees, so that the spacing between degrees is not uniform. For ease of use, the Fahrenheit and Celsius temperatures are shown on the graph instead of the inverse temperature. To use, plot the shelf life of the product at temperatures for which it is known. If the shelf life follows the Arrhenius relationship, the points can be connected with a straight line. The activation energy may be calculated by the equation in 2.1.1.1.

FIG. 1 Blank Arrhenius Plot

2.1.5 *dual function time-temperature indicator*— a TTI that combines both all-temperature and threshold-temperature responses, overlaid in a single indicator in order to modify the total time-temperature response.

2.1.6 *effective average temperature*—the single constant temperature that would have the same effect on the shelf life of a product as the actual temperature profile has for the same time period.

2.1.7 *hazard analysis and critical control points (HACCP)*—a method to control food quality and safety by identifying and controlling those processing and distribution steps where a food safety hazard may be prevented, eliminated, or reduced to acceptable levels.

2.1.8 *shelf life*—the time required for various changes to a product to accumulate to the point where the product no longer meets predetermined criteria and is no longer considered suitable for its original purpose.

2.1.8.1 *Discussion*—In some cases, such as where pathogenic microbial growth is involved, there may be a serious health risk in using a product past its shelf life. In such cases, the shelf life to be monitored should be conservative enough so that its expiration is signaled well before a health concern develops. It may be desirable to indicate even short occurrences of undesirably high temperatures. Other changes may also occur, such as in color, texture, or rancidity, which render a product unacceptable for its original use. For most perishable products, the shelf life decreases with increasing temperature.

2.1.9 *threshold-temperature time-temperature indicator*—a TTI that only changes at temperatures above a specific threshold.

2.1.10 *time-temperature indicator (TTI)*—a device that can be affixed to the package of a perishable product and that exhibits a change in a physically measurable or visually measurable property as a combined function of both time and temperature. For example, properties that change include color, light reflectance, or a moving boundary between two colors.

2.1.11 *time-temperature integrator*—see *time-temperature indicator*.

2.1.11.1 *Discussion*—This term emphasizes the fact that the indicator's response is an integration of the effects of both time and temperature.

2.1.12 *time-temperature monitor*—see *time-temperature indicator*.

2.2 *Definitions of Terms Specific to This Standard:*

2.2.1 *activation method*—the method by which an inactive TTI is changed to an active state.

2.2.1.1 *Discussion*—This may include a physical activation method, such as removing or breaking a barrier, or may require raising the temperature to the normal operating range of the TTI.

2.2.2 *inactive state*—the state in which a TTI does not respond to changes in temperature over time.

2.2.2.1 *Discussion*—Some types of indicators are active when manufactured and kept essentially inactive by storage at low temperatures.

2.2.3 *slackened-out product*—a product that is stored frozen for an indeterminate time and then thawed (slackened out) for the final part of its distribution and use.

3. Significance and Use

3.1 Expiration dates are often marked on the packages of perishable products to indicate the presumed end of their shelf lives. Since the shelf lives of most perishable products are temperature dependent, the expiration date is determined by assuming the product will be kept within a prescribed temperature range for its entire life. A problem with this method is that there is no way to determine if the shelf life of a product has been shortened by exposure to a higher temperature. A time-temperature indicator solves this problem when attached to the package because it reaches its end point sooner when exposed to a higher temperature.

3.2 In order to directly indicate the end of the shelf life, the time-temperature indicator characteristics should be matched as closely as possible to the quality characteristics of the product. When kept at the standard storage temperature for the product, the indicator should reach its end point at the same time as the product's shelf life. In addition, to determine the accuracy of the match at other temperatures, the change of shelf life with temperature should be known for both the product and the indicator. The Arrhenius relationship is a common and convenient method of describing the change of shelf life with temperature. In cases where it is not applicable, individual time-temperature points for the product may be established and an approximate correlation with the TTI obtained.

3.3 When attached to the package of a perishable product, a time-temperature indicator may supplement, or in some cases