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

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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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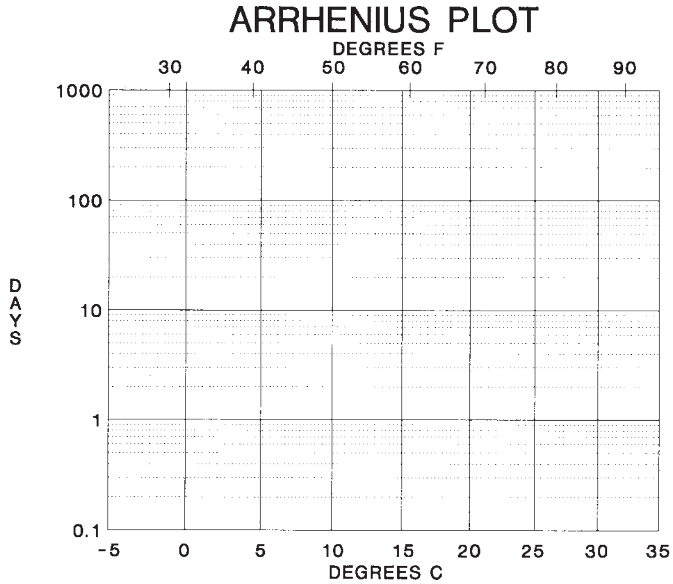

NOTE 1—This blank graph may be used to determine if the shelf life of a product exhibits standard Arrhenius behavior. The plot axes are the $\log_{10}$ of the shelf life and the reciprocal of temperature. Note that the *X*-axis of this plot is marked in Celsius degrees instead of inverse Kelvin degrees, 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 replace, the expiration date code. The addition of a TTI provides a greater level of confidence that the perishable product is within its shelf life because it responds to the actual temperature conditions to which the product has been exposed.

3.4 In the case of minimally processed refrigerated foods, the rapid growth of pathogenic bacteria at elevated temperatures may pose a serious health hazard even before the deterioration of the quality of the product becomes apparent to the consumer. In this case, an expiration date may be used for storage at the standard temperature, while a threshold-temperature TTI is used to indicate the exposure to temperatures at which growth becomes measurable. It is also possible to use a dual-function TTI, in which case the standard TTI would indicate the shelf life at the correct storage temperature while the threshold-temperature part would indicate the exposure to higher temperatures.

4. Methods of Classification

4.1 *Temperature Response*:

4.1.1 *All Temperature*— Active at all temperatures. These indicators are most applicable for products that have an Arrhenius shelf life versus temperature relationship, such as many fresh and processed foods.

4.1.2 *Threshold Temperature*—Active at temperatures above a threshold. These indicators are most applicable for slackened-out products, in order to respond only during the time when the product is not frozen. They are also useful for minimally processed refrigerated foods to indicate that a product has been exposed to abusive temperatures.

4.1.3 *Dual Function*— A combination of the previous types. This type of indicator may be used to respond slowly when the product is in the frozen state and to jump to a much faster response curve in the temperature range where the product is thawed. For minimally processed refrigerated foods, this type of indicator can be used to indicate the remaining shelf life when the product has been kept at the proper storage temperature and to signal the end of shelf life more rapidly at abusive temperatures.

4.2 *Reading Method*:

4.2.1 *Instrument Readable*—Intended to be scanned instrumentally. A computer (normally hand held) calculates the remaining shelf life of a product based on the state of the indicator. The shelf life history of the product may be maintained in a database file in the computer's memory.

4.2.2 *Visually Readable*—Intended to be interpreted visually. This type of indicator may be constructed either to show just the end point of the shelf life or to show a few levels of progression to the end point.

4.3 *Form*—All forms of TTIs should be produced with a means of attaching to a perishable product's package.

4.3.1 *Bar Code*—Instrument readable TTI in which both the indicator and auxiliary information are printed in bar coded form. The remaining shelf life of the product is calculated by a hand-held computer.

4.3.2 *Bull's-Eye*—Visually readable TTI in which the end of the shelf life is indicated when the printed center dot is the same color as an outer reference ring or in which the state of the product is determined by comparing the indicator color to multiple colors surrounding the center dot.

4.3.3 *Window-in-Pouch*— Visually readable TTI in which the state of the product is determined by comparing the color of an indicator liquid behind a window to the reference color or colors on the plastic pouch containing the liquid.

4.3.4 *Sandwiched Rectangular Wick*—Visually readable TTI in which the state of the product is determined by a moving color boundary. The boundary is viewed and measured through multiple holes in the outer layer.

4.3.5 *Special Graphics*— Printable, visually readable TTIs produced in alternate forms containing specific logos and graphics.

4.3.6 *Other Forms*— TTIs that use a physical property other than color to indicate the status of the shelf life.

5. Selection Criteria

5.1 *Product Shelf-Life Characterization*—It is the responsibility of the processor of the perishable product to determine the relevant time-temperature dependent characteristics of the product to be correlated with the indicator characteristics. In order to specify the appropriate time-temperature indicator for a product, information is needed on the shelf life of the product. Where a perishable product may pose a health risk after its shelf life has expired, the indicator's shelf life prediction must be conservative enough to ensure that the indicator will predict the end point well before a risk develops. The following information is required:

5.1.1 *Product Storage Conditions*—The product may be frozen, refrigerated, stored at ambient temperature, or slackened-out.

5.1.2 *Standard Storage Time and Temperature*—The shelf life of the product at the temperature at which it is intended to be stored and used.

5.1.3 *Additional Time and Temperature Parameters*—The shelf life shall be known for at least one other temperature if it is to be treated as an Arrhenius response, and it is desirable to know the shelf life for at least three temperatures to verify that the behavior is Arrhenius. It is also sufficient to specify one temperature point and the activation energy. For products that have non-Arrhenius behavior, specify additional temperature points. For products for which the storage time is much longer (or not important) below a threshold temperature, specify the threshold temperature and shelf life parameters above and below the threshold.

5.1.4 *Ambient Light Levels*—Some types of TTIs are affected by exposure to outside or fluorescent lighting. If the product is to be subjected to strong ambient light for a period of time which would affect the indicators, they shall be prepared with suitable light-blocking colored filters.

5.2 *Matching Indicator to Product*—Not all types of TTIs are manufactured by each processor. Choose TTIs from the manufacturer's standard specifications or by special order after consultation with the manufacturer.

5.2.1 *Instrument-Readable Indicators*—For instrument-readable indicators, it is not necessary that all shelf-life parameters of the indicator conform to those of the product.

The same indicator may be used for a wide range of products by just accessing the appropriate shelf life parameters stored in the computer.

5.2.2 *Visually Readable Indicators*—To properly indicate the end of shelf life of a product, a visually readable indicator should reach its end point before the shelf life at all temperatures within the reasonable and abusive storage ranges. If the indicator is designed to signal temperature abuse only, then either the indicator should reach its end point or a "use-by" date should be reached before the actual shelf life expires at all temperatures.

5.3 *Accuracy and Reliability*—Based on the shelf life parameters supplied by the processor of the perishable product, the indicator manufacturer should supply, upon request, information about the behavior of the indicator at the specified temperature points, along with the expected reading uncertainty and standard deviation of the lot. Indicator manufacturers should clearly indicate any limitations of the indicators with respect to possible environmental problems such as humidity, sunlight, and so forth.

5.4 *Application Method*—Indicators may be designed to be applied by hand or by high-speed automatic applicators.

6. Storage and Use

6.1 *Storage*—Store TTIs prior to use in accordance with the manufacturer's specifications.

6.2 *Activation*—Activate TTIs at the start of the attached product's shelf life. For some indicators, this implies equilibrating at the intended storage temperature. For others, this implies additional mechanical steps, such as applying pressure or removing a barrier. This is either included into a bar code printed upon activation or is stored in the computer memory by scanning the indicator upon application to the product. Also, record the initial state and time of application for machine-readable indicators.