Food Safety Management in the cold chain through "expiration dating"

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Abstract:

An open expiration date (eg use by XXXX) may be a useful means to ensure that a refrigerated food will not be consumed past a date at which it will become unsafe while in distribution in the cold chain. This assumes that the date is the management tool and can be calculated using various pathogen growth kinetics programs based on log normal or logistic functions using data for growth at constant temperature. This assumption is wrought with three problems that could result in an adulterated and unsafe food being consumed before the food reaches the expiration date: (1) it assumes microbial growth models based on measurable lag and log phase kinetics, but we also need to know the initial level of the pathogen and knowledge of the growth rate at below detection levels, i.e. time to detect; (2) It assumes that distribution is at constant temperature while in the real world it will vary; (3) It assumes that if temperature changes, growth kinetics will immediately follow the predicted rate at the new temperature (no history effect). This paper will review the principles of growth kinetics using examples for *Listeria*, as well as other organisms. The use of both chemical and RFID (radio frequency identity) time temperature integrator tags (TTI) placed on food packages to essentially integrate the time-temperature history and indicate actual shelf life left will be evaluated with respect to cold chain management. Such a tag would be used to make a conservative estimate of time to detect for cold chain management . Thus the time to end of shelf life based on safety criteria would be solved by labeling with the expiration date along with a statement such as "use by the date indicated unless the tag turns red". Shipping based on least shelf life left will reduce loss and potential injury due to pathogens.

Introduction:

An open date on a food package implies something about the shelf-life or safety of the food to a consumer (Szybist and Labuza 1999). They note that in several studies including a Prevention magazine survey in 1998, 61% of consumers felt the sell by date was the last date to safely sell a food while the use by date to 34% was that date beyond which the food was unsafe. This was reiterated in the National Enquirer (a consumer hot news magazine) with a warning not to use products past their use by date. To food producers the date they use on a food generally represents the time at which the loss of desired quality occurs based on the percentage of consumers they are willing to displease for a given distribution. To the food retailer the date represents a tool by which they exercise practices regarding how fast to move the product to get it into the consumer's home before it spoils. The date also implies that for products that enter the "cold chain" which include many ready to eat foods (luncheon meats, hot dogs, cut salads, produce, cheese etc.), the temperature in the refrigerated cabinet should be maintained at 4°C or less to insure that pathogens will not grow and multiply causing illness. Of course with Listeria, this is a problem as it can grow to -1 C. Thus if the temperature is not maintained properly and/or the food is contaminated with a pathogen, the food may spoil before the date leading to a disgruntled consumer or more importantly to a food poisoning incident. If no date is present, consumers may sort for those packages that are dated to find the youngest one with the false hope that that product has the best quality (Sherlock and Labuza 1992) .

The presence or absence of an open date on a food package has legal implications, with respect to either being misleading thus misbranded. In the United States, as stated in Section 201(n) of the Federal Food, Drug and Cosmetic Act (FFDCA) , the definition of misbranding says: ***If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling …*** This implies

that if a date is on the product, and especially if it is in conjunction with open dating of the food for consumer use, processors would need to have the relevant data to back up the statement, i.e. shelf life tests indicating how that date was set. Setting a date thus becomes a problem if the food product is temperature sensitive as are all refrigerated foods. Does one set the end date time for the optimal temperature in distribution, for an effective temperature for the distribution or for an abuse temperature which could lead to significant waste, i.e. throwing good food out? A food if not held at proper temperature distribution conditions to meet the legality of that date, i.e. if abused by improper transportation and storage temperatures, would become both misbranded (the date is a lie) and potentially adulterated if the distribution is such that pathogens not able to grow can now reproduce so as to reach a health concern level by becoming adulterated. Thus the food processor must design proper tests to assure that the date set is defendable in terms of quality and safety.

The choice of the type of expiration date is also a problem. There are no set standards and one finds many types of dating practices which have only partial usefulness (Szybist and Labuza 1999) . These include:

a. no date except for a recall code date identifying the plant and time it was made

b. born on date which is the date of manufacture which identifies how old the food it but without knowledge of shelf life is meaningless.

b. "sell by date"- useful for stock rotation especially at store but not of much value to the consumer in terms of home storage

c. better if used by - better is never defined but this is similar to d in terms of a quality standard that creates the brand image but perhaps a lower standard than best

d." best if used by" - a date of high quality implying it can be consumed after the date indicated but that it will not meet the manufactures high quality standard - this is similar to the date of "minimum durability" as used in the European Union (EU).

e. "use by" date which implies that the product is no longer edible, i.e. it has expired, and perhaps has become unsafe on that date. This is mostly used on perishable and ready to eat (RTE) refrigerated foods. In the latter case the date could be based on time to detect a pathogen or its toxin in a standard serving generally 1 CFU/25 g. This was the basis of the work by Baker and Genigeorgis (1990) on the shelf life of CAP/MAP fish.

f. " freeze by date" - popular on refrigerated chicken parts and assumes some refrigerated shelf

life left but if you want to keep it longer than freeze it first and thaw when needed. Given all these dating systems, an expiration date based on the effect of the temperature variation in the distribution chain would be the only logical way to create a true expiration date but one would need the ability to integrate the time temperature effect of the distribution itself.

Besides misbranding, Sec 402(a)(1) of the Federal Food Drug and Cosmetic Act states that a food is adulterated if it contains any poisonous or deleterious substance that renders the food injurious to health. This has been interpreted to such the mere detection of a pathogen is adulterative given the broad sensitivities of the young and those that are immuno-compromised such as AIDS or cancer patients and the elderly. This section of the law has been upheld in a number of court cases. Since it is well documented that temperature abuse occurs in distribution this becomes a critical issue in expiration dating and shelf life because of the potential for growth of pathogens above 4 °C. (Anon 1998; Szybist and Labuza 1999). As seen from an Audits International study (Table 1 Anon 1998), significant abuse occurs at retail because of improper refrigerated storage temperature especially with deli RTE meats

TABLE 1 Temperature data from retail studies (Anon. 1998)

Temp type	Avg. Value °F	Cheese	Lunch meat	Deli meat	Pre-pack Deli	Fish	Fresh meat
Mean °F	41.7	40.9	43.3	44.8	42.3	40	39.2
SD	5.88	4.99	6.14	5.91	5.54	6.05	5.06
Min	14	22	24	24	20	14	19
Max	70	68	66	64	66	70	58
%>41 F	47	39	60	71	54	34	27
% > 45	22	13	34	42	24	15	9
% < 50	6	3	11	14	6	3	1

In addition Szybist and Labuza (2001) showed such improper temperature control in the home (Figure 1). Taoukis et al has found similar results of temperature abuse for both retail and home storage in Greece.(Taoukis et al 1998) Thus if temperature abuse occurs as shown, a open shelf life date on the food based on some average temperature gives a false sense of security and if pathogens grow would constitute a substantial hazard. As noted by Keener

(2003), temperature monitoring of most food shipments in the US is generally poor and no-one can answer the question of whether abuse presents a food safety issue. He estimates that the loss to industry is around $2 billion per year but that includes health care costs. In a study of supermarket shrinkage ($ loss due to unsaleable goods), the Joint Industry Unsaleables Group estimated that the cost to industry was $2.6 billion (Lightburn 2003). About 58% of the loss was due to damaged goods. For foods, refrigerated products including produce had the greatest losses while frozen was the least. In an independent survey of 8924 stores by the National Supermarket Research Group, they found that shrinkage (damaged, returned or missing goods) was about 2.32% of sales while profits are only ~0.7 to 1% (Anon 2003) . Shrink includes cashier errors (35%), employees stealing (20%),shoplifting (20%), back door disappearance (11%) and damage (5%). It was noted that perishables accounted for 56% of shrink or about $6 billion of sales. What the loss is during distribution or at home is unknown except for a report by the Agricultural Research Service of the USDA which noted overall total food loss in the U.S. was about 26% including plate waste (Kantor et al 1997)

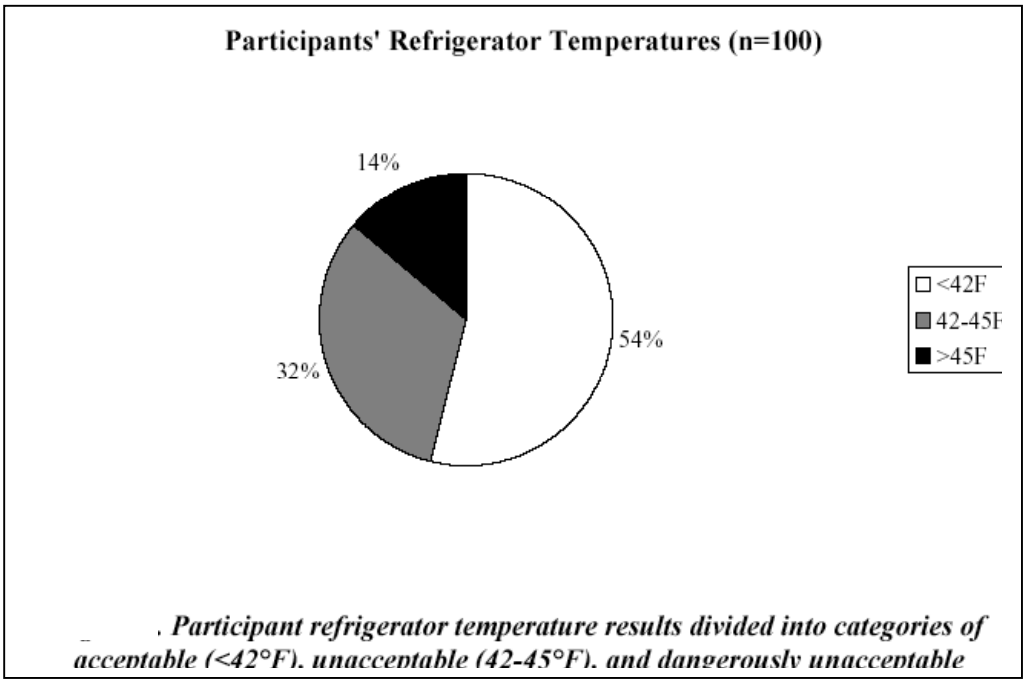


Figure 1 Home refrigerated temperature abuse (Szybist and Labuza 2001)

It has been obvious to regulatory agencies that industry and consumers were not doing a good job of temperature management. In 1996 (Federal Register 1996), the US Food and

Drug Administration along with the US Dept. of Agriculture (USDA) and the Department of Transportation (DOT) published a proposed rule making regarding temperature monitoring during transport and distribution in the cold chain especially for hazardous foods such as eggs and egg products, fish, meat, poultry and some dairy products. A set of alternative proposals were made including: (1) temperature performance standards; (2) shipper record keeping; (3) Mandatory HACCP-type systems such as temperature recording devices; (4) voluntary standards such as done by the Frozen Food Roundtable and the International Dairy Foods Assoc.; (5) a combination of approaches and lastly (6) No Federal Initiative. Essentially very little was done about this, perhaps because of the 9-11 incident and the threat of food bio-terrorism which has occupied the relevant agencies. FDA did institute the fish HACCP requirements which have some refrigeration requirements and in 2000 the FDA mandated that shell eggs be maintained at 45 °F (7.2 °C) or less in distribution and retail display (Federal Register 2000). This action on eggs was because of the problem of growth of salmonellae enteriditis in shell eggs.

An solution to this problem of spoilage and waste is to have a device (TTI) on the pallet, case or individual package that integrates the time temperature exposure in the cold chain with the same temperature response as the spoilage rate of the food or the growth rate of the pathogenic organism. Thus if properly designed, the TTI would indicate visually to distributors, retailers and consumers depending on the type of tag used, the extent of degradation that has occurred. This TTI tag would need to show a sharp color change just before or at end of shelf life (expiration date) when the spoilage level or pathogen number reaches some critical value that could lead to a consumer or regulatory risk, eg. the time to be able to detect, TTD, a pathogen in a serving of food. To be on the conservative side, this indicator change should occur at some time (hours, days ?) before the actual risk is present.

Microbial Shelf Life

Shelf life prediction is an essential feature in marketing refrigerated and Ready to Eat (RTE) products (Bogh-Sorenson and Olsson 1990; Anon 1992b). In shelf life testing of these products, there are at least three quality parameters that need to be evaluated at various temperatures during the test period: microbial safety, spoilage leading to off odors, discoloration, slime, visual microbial colonies and overall consumer sensory

organoleptic changes (Baker and Genigorgis 1990). When microbial hazards are minimal, tests for spoilage and organoleptic changes usually take precedence in shelf life determination.

Where a product may pose a health risk before sensory expiration such as a low oxygen pressure minimally heat treated meal (eg fish in a sauce), the shelf life prediction must be conservative enough to ensure that the determined sensory end point occurs before any risk develops. Skinner and Larkin (1998) addressed this issue with respect to *Clostridium botulinum* toxin production and illustrated a conservative approach applicable to use of TTIs. Kraft General Foods, Inc. eg., in light of the fact that much needed data was missing, used a safety margin of between 1/3 to 1/4 of the product's organoleptic shelf life as their printed shelf life expiration date on such foods, i.e. the date was set at 75% of the time to reach the actual expiration date they estimated. (Harris, 1989).

To model pathogen growth needed for the design of a TTI tag, because of the complexity of microbial growth, the following is needed (Labuza and Fu 1992, Labuza et al 1992):

a. an estimate of the initial microbial load which technically should be below the level of detection

b. time to detection of the pathogen (generally 1 CFU/25 g) or its toxin (TTD) as a function temperature (or other factors)

c. lag time and log phase growth kinetics as a function of temperature

d. a level of organisms (**X** CFU/25 g) which is above the 1 CFU/25 g at time to detect and represents the regulatory action level

e. a measure of the potential for a history effect where prior thermal exposure changes the expected growth rate at a new temperature and complicates modeling

f. the final microbial load that the safety shelf life time is based on which could be the time to detect, TTD or some higher value.

Note here that, given that the TTD for a pathogen can be predicted, modeling shelf life beyond that time is only a regulatory exercise, since the food would be considered adulterated at that point, i.e. the law in the US technically doesn't care that the infectious dose is higher than one organism per serving. Consumer knowledge that a

TTI allows for use beyond the TTD might have a negative marketing effect. However given that over 350 billion servings of RTE foods are consumed in the US and *Listeria* incidence is less than 5000 cases with about 500 deaths, this suggests that some resistance to levels above the detection limit is the norm. Despite this, one cannot predict who will eat a particular food so there is a dilemma as to what is the logical microbial load end point.

There many models used to predict the growth curve and it's temperature dependence (eg Ratkowski et al 1982). Fu et al. 1991, have shown that the simple straight line for lag time and Monod model for doubling time in the log growth phase adequately describes growth kinetics at constant temperature in these periods as illustrated in Figure 2.

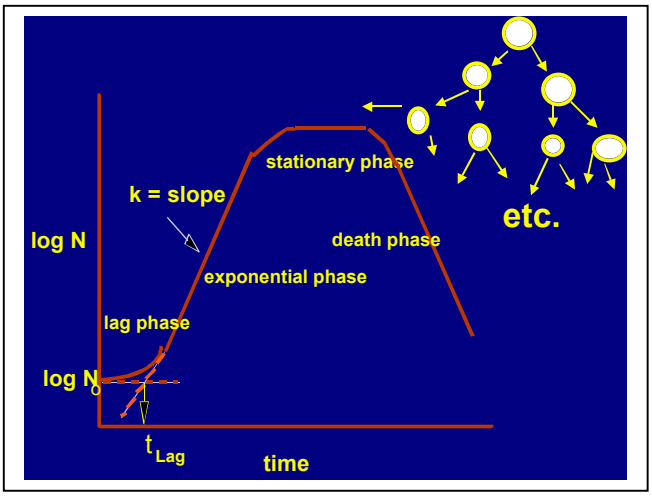


Figure 2 Representative growth curve above the time to detect.

Figure 3 shows actual data for *Listeria monocytogenes* strain 7776 (Bil Mar outbrake strain) indicating excellent fit to this simple model. Despite early acceptance for more complex statistical models, most have converted back to these simple KISS (Keep It Simple Scientist) models.

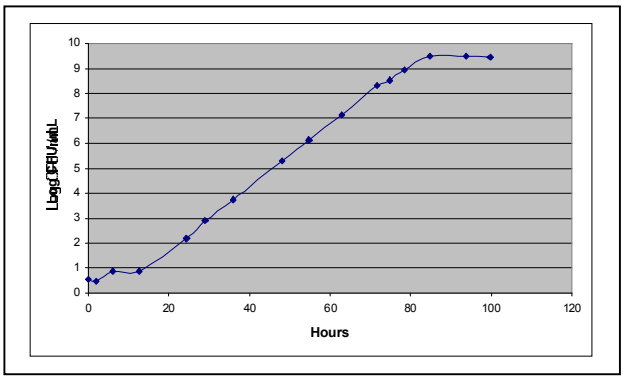
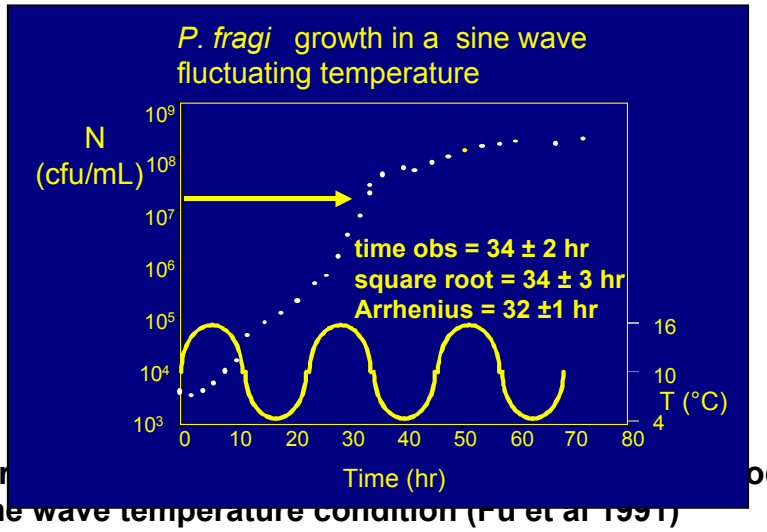


Figure 3 Growth Curve of Listeria monocytogenes @ 16 C

With respect to temperature dependence, Fu et al. 1991, have also shown that the Arrhenius model (log k vs 1/T ° K for log phase and log (lag time)^-1 vs 1/T °K for lag phase), the shelf life model (Log k vs T °C for both lag and log phase) and the square root model ($k^{-1/2}$ vs T °C) works very well for evaluating temperature dependence of growth in both the lag and log phase. Other proposed growth models (Gompertz, Logistic etc.) have not been tested well for either temperature dependence or variable temperature history because of their complexity.

Most growth models have ignored the influence of prior temperature history, i.e. history effect, on the growth rate at future temperatures (McMeekin and Olley 1986). With respect to temperature fluctuations in storage, Fu et al. 1991, used both the Arrhenius model and the square root model for the temperature dependence of Pseudomonas fragi and have predicted spoilage time to within ±2 hours for milk stored in a ±4 °C sine wave temperature regime as shown in Figure 4.



Figur odel to predict growth under a sine wave temperature condition (Fu et al 1991)

The main pathogens of concern in refrigerated RTE foods are listeria, *Clostridium botulinum, Salmonellae* species and *Campylobacter*. Our work has focused on *Listeria monocytogenes* strain 7776, the organism implicated in a listeria out break with luncheon meats and hot dogs. This is an important organism because it can grow down to about -1 C and as high as 40 °C with a maximum in the 30 to 35 °C range depending on the food. We have been obtaining kinetic data for growth in the lag and log phase in broth, on agar and on hot dogs which were directly packaged or treated under high

pressure (450 MPa for 15 min) in the final package. Figures 5a and 5b indicate the excellent adherence to the Arrhenius function for both lag and log phases. Both plots

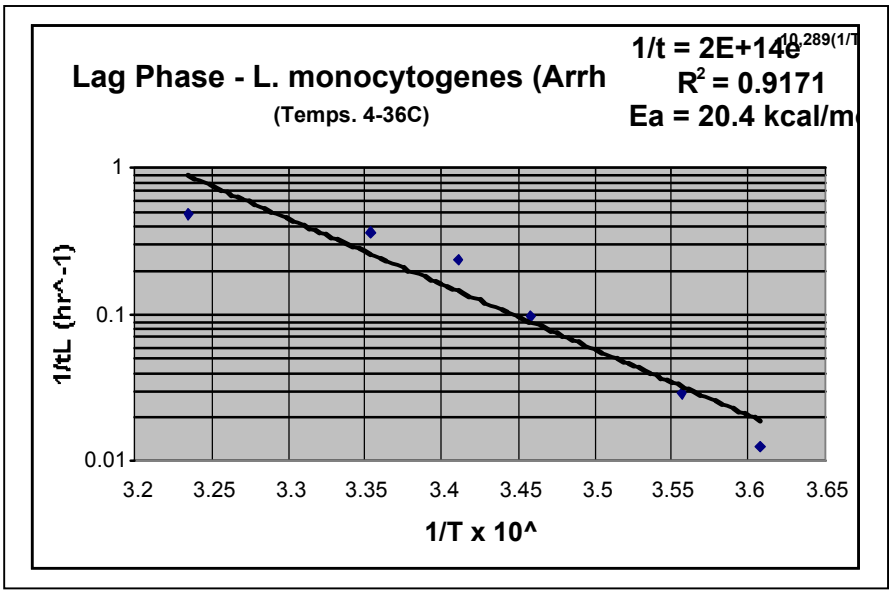


Figure 5 a. Arrhenius plot of temperature dependence of lag time and growth rate of *Listeria monocytogenes* strain 7776 grown in broth.

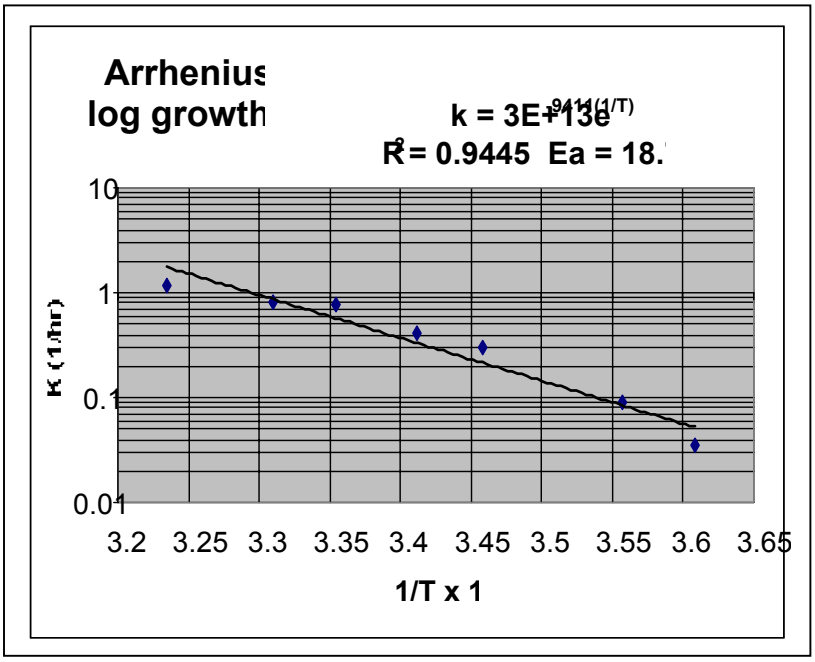


Figure 5 b. Arrhenius plot of temperature dependence of lag time and growth rate of *Listeria monocytogenes* strain 7776 grown in broth.

show a high R^2 and give the respective the activation energy (slope = Ea/R where R is the gas constant) which is a measure of the temperature sensitivity of the lag or growth rate. A higher E_a indicates a greater increase in growth with increased temperature. These values of 18.7 (log phase) to 20.4 (lag phase) Kcal/mole (~77 to 86 Kj/mole) are within the typical ranges for growth as shown in a literature evaluation by Fu et al (1991) and by Shimoni and Labuza specifically for meat and poultry (1998)

A history effect is one in which the growth rate of the microbe when shifted to a new temperature (eg moving from A @ 20 °C in Figure 6 to point B @ 4 °C) would occur at a different rate, either faster (line C) or slower (line D) than if the organism were always at the second temperature.

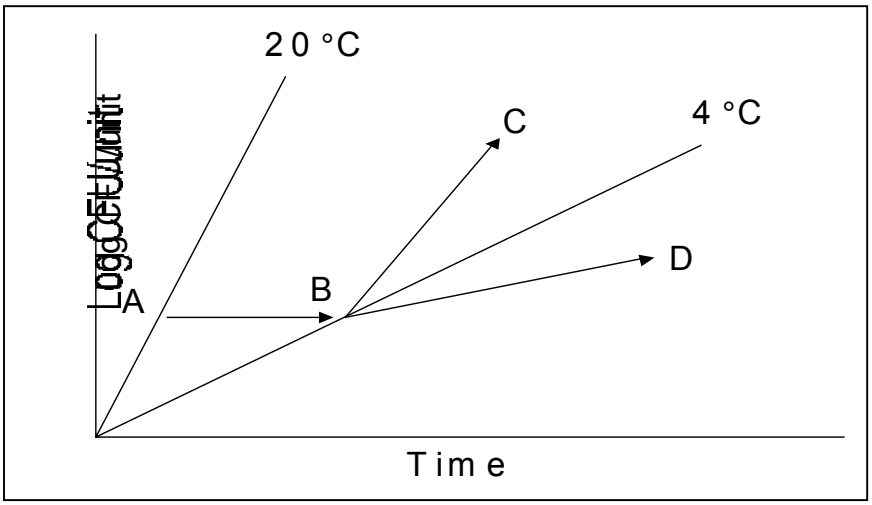


Figure 6 Example of a kinetic history effect

Figure 7 shows an example of a temperature shift experiment. In this case the growth rates at the 2nd and third temperature were within the 95% CL of the constant temperature growth rate, indicating no history effect. Table 2 and 3 summarize the results of single and multiple temperature shifts on the growth rate in order to evaluate if a history effect occurs. For a single shift there was no history effect with Listeria (Table 2) while for multiple shifts, the growth rate for the temperature regime at the last time shift was less than for constant temperature growth (Table 3). It is not known if this would be the case in the below detection limit growth phase or lag phase. In the cases where the growth was less at the new temperature, using the original rate for that temperature would over predict growth, thus being on the conservative side. Further

experiments are need on solid media like hot dogs to verify this but it lends credence to being able to model growth in fluctuating temperature conditions with a TTI.

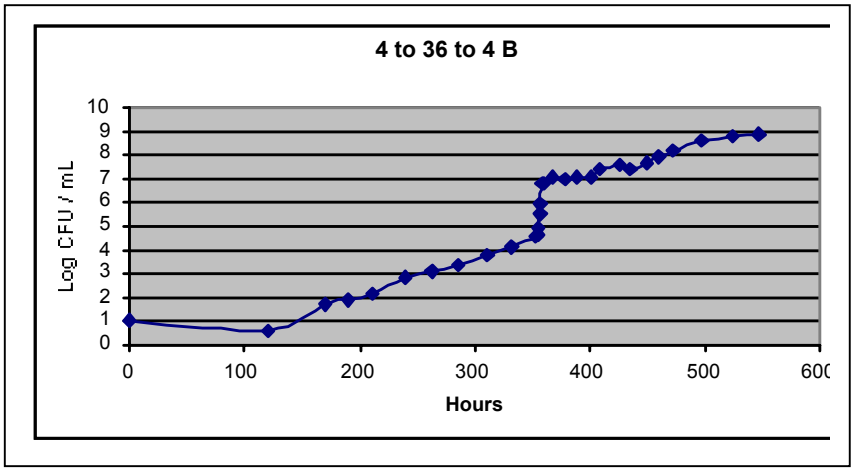


Figure 7 Example of a temperature shift experiment

Table 2
Log phase growth of Listeria in broth as compared to constant temperature growth rate for a single temperate shift from 4 °C to the indicated temperature

T (°C)	k) observed (hr^-1)	k constant (hr^-1)
8	0.09821± 0.031	0.0889± 0.0063 N SD
16	0.308 ± 0.023	0.293± 0.005 NSD
30	0.826± 0.038	0.819± 0.034 NSD
36	1.16 ± 0.0596	1.184 ± 0.043 NSD

Table 3 Influence of consecutive temperate shifts on growth of Listeria in log phase as compared to constant temperature growth rate done in broth

T °C	k observed hr^{-1}	k constant hr^{-1}	significance
4	**0.0374±0.0013**	**0.0354±0.001**	**NSD**
36	**0.756±0.084**	**1.184±0.043**	**NSD**
4	**0.041±0.286**	**0.0354±0.001**	**NSD**
36	**0.952±0.286**	**1.184±0.043**	**SD**

As noted earlier the most important parameter which needs to be determined is the rate growth as determined by the time to detect below the detection limit (eg at <1 CFU/25 g). The assumption to do this is similar to that used for evaluation of the lag phase, i.e. the reciprocal of the time to detect is the rate constant at that temperature, and if multiple temperatures fit an Arrhenius or a shelf life plot, this justifies the assumption. Recently we accomplished this for the same Listeria strain as above. The broth was inoculated at below detection limits incubated at seven temperatures and then representative samples were taken over time until detection occurred. Figure 8a and 8b show the Arrhenius plot (log 1/TTD vs 1/T in °K) and shelf life plot (log TTD vs T °C) for this.

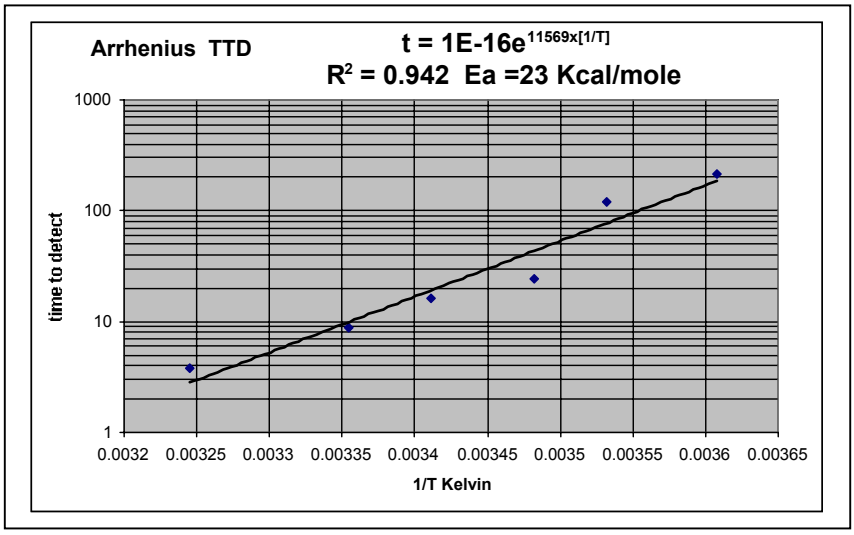


Figure 8a Arrhenius plot of TTD *Listeria monocytogenes* strain 7776r

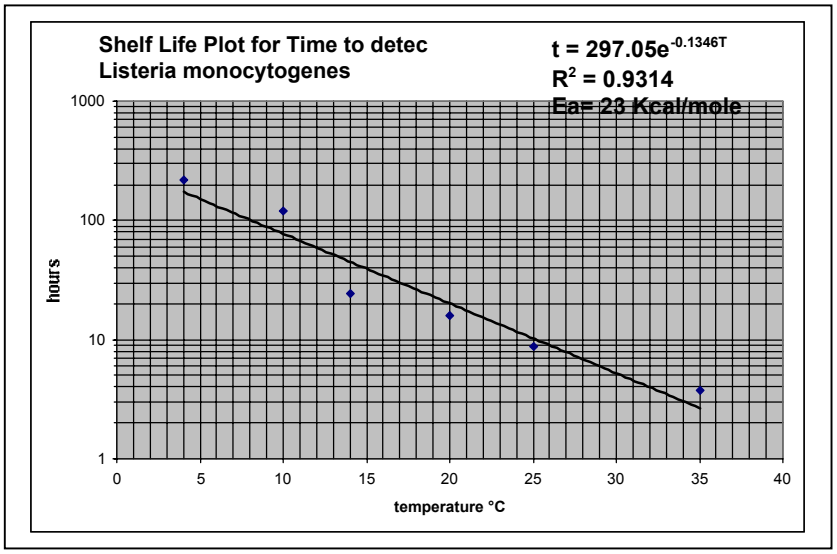


Figure 8b Shelf life plot of TTD *Listeria monocytogenes* strain 7776

Both gave good straight lines which was expected as found by Fu et al (1991) for *Psuedomnas fragi* and thus results in some of the criteria that is required in TTI tag design. One can see that at the extremes the data fall off the straight line. At least at the higher temperature this indicates that it was already above the growth rate maximum. A similar experiment was done on agar cubes and the shelf life plot is shown in Figure 9.

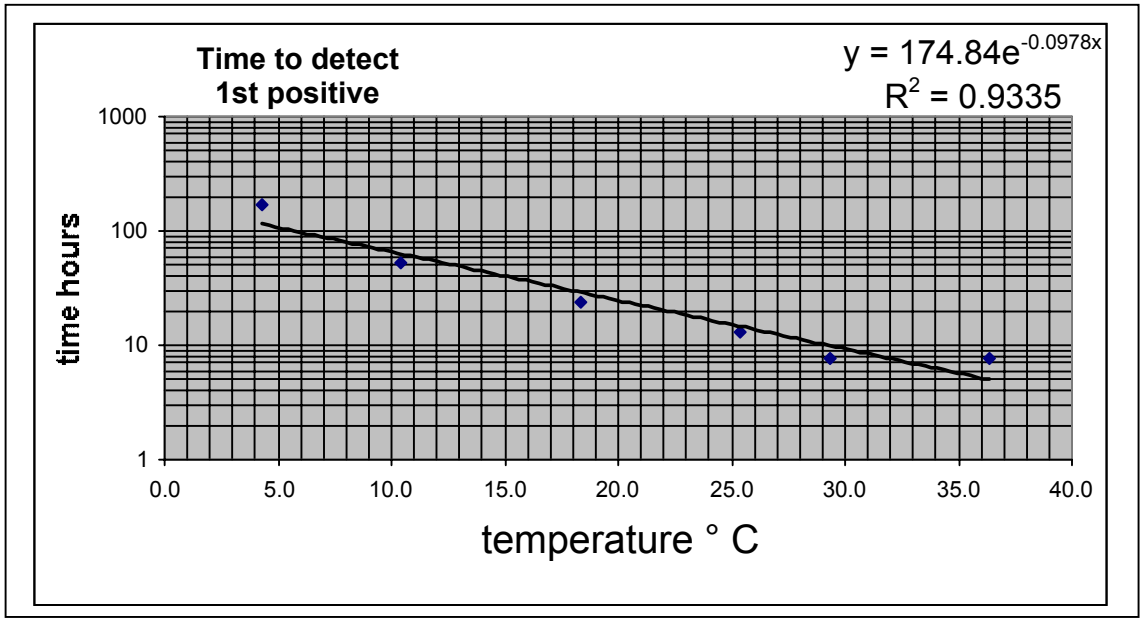


Figure 9 Shelf life plot of TTD *Listeria monocytogenes* strain 7776 on agar cubes

Note that the time to detect on the agar cubes at 25 °C was about 18 hours. Finally Figure 10 shows similar results for hotdogs that were HPP pasteurized before being inoculated with listeria at below the detection level. As seen the organism grew better on the hot dogs with a TTD of 8 hours at 25 C as compared to the broth and the agar cubes. All three are compared on the same graph. Table 4 indicates that there was no significant difference in the activation energy for the three media. They ranged from 15.6 to 23 Kcal/mole (65 to 97 Kj/mole). Despite using 7 temperatures for the study, the natural biological variation caused the fairly big range but was not significantly different. These results suggest that a TTI could be designed to indicate end of shelf life of hotdogs much in the same way we evaluated the data of Baker and Genigeorgis (1990) with respect to botulinum toxin production for CAP packed fish as shown in Figure 11.

The lower line in the figure indicates a safety margin which would be used for the TTI design. Note that at 25 °C , toxin is detected in one day, while the safety line is set at 4 hours. Also note that the activation energy for toxin falls within the range for listeria growth. It should be noted that in the Skinner and Larkin (1998) paper, they used an empirical polynomial equation to represent the safety curve, while in this shelf life plot transformation of the Arrhenius relation we use a proven mathematical relation.

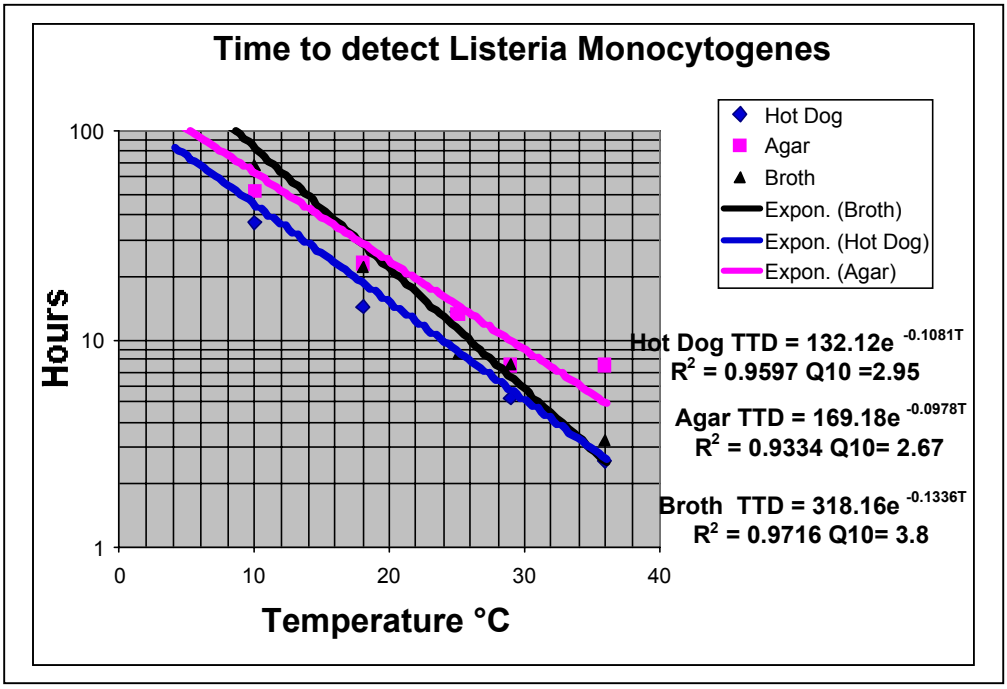


Figure 10 Shelf life plot of TTD *Listeria monocytogenes*Bstrain 7776 on hot dogs as compared to broth and agar cubes.

Table 4 Comparison of Activation energies

- **Broth**
  - **Lag period** E_a **= 20.4 ± 8.6 Kcal/mole**
  - **Growth period** E_a **= 18.7 ± 5.2 Kcal/mole**
  - **TTD period** E_a **= 23 ± 8 Kcal/mole**
  - **TTD Repeat** E_a **= 15.61 ± 5 Kcal/mole**
- **Agar TTD period** E_a **= 16.76 ± 5.51 Kcal/mole**
- **Hot dog TTD period** E_a **= 18.38 ± 5.16 Kcal/mole**

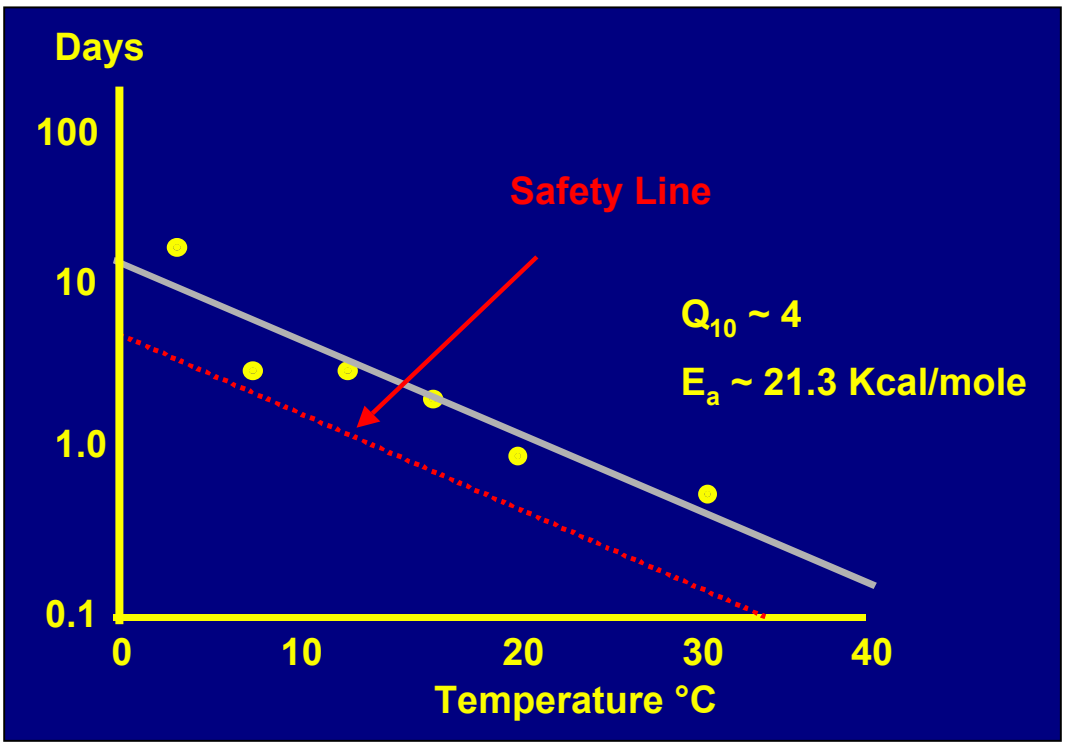


Figure 11 Shelf life plot of TTD bot toxin in fish (Baker and Genigeorgis 1990)

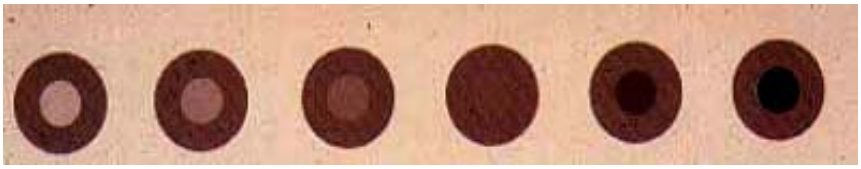
Time-Temperature Integrators (TTI)

Time-temperature integrators (TTI) are small, physical devices that are placed on the food package to measure the temperature history of a product and indicate a definitive change at the end of shelf-life through “integration” of the time temperature exposure, eg "Use food by July 30, 2004 unless dot turns red".(Rice 1989; Anon 1989; Anon 1992a; Sherlock and Labuza 1992) TTIs are reliable indicators of end of shelf-life for food products if they have similar temperature sensitivities (E_a) as for the food deterioration mechanism (Taoukis et al., 1991). The devices can used on individual consumer packages, so they establish a control system because not all products will receive uniform handling, distribution and time-temperature effects (Labuza,et. al., 1991). As a result, TTIs can increase the effectiveness of quality control in distribution, stock rotation practices of perishable foods in grocery stores, and efficiency in measuring freshness by the consumer as we noted earlier. (Sherlock, 1991; Wells and Singh 1989a, 1989b). Taoukis and Labuza (1982 a, b) showed that for the most part, the commercially available TTIs are both reliable and applicable for use in combination

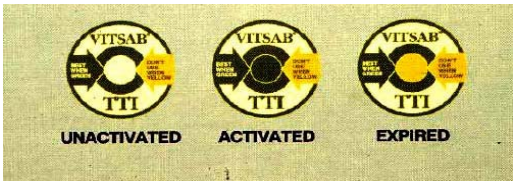
with open dating of refrigerated foods including RTE products. Malcata (1990), in addition, showed that although the tags respond more quickly to temperature abuse then the actual food because they are on the surface of the package, thus the response is on the conservative side of safety, i.e. the tag shows an endpoint before the food is spoiled. The Campden Food and Drink Association in the United Kingdom has developed technical standards for the evaluation of chemical TTIs (George and Shaw 1992). The three major manufacturers of chemical TTIs are 3M (Manske 1983), Lifelines (Fields and Prusik 1986; Prusik 1990) , and VITSAB (Blixt 1983) and are shown in Figure 12.

Figure 12: Three Commercial Types of chemical TTIs

a. a. 3M Monitor Mark WLF diffusion showing change in color as the product ages



b. Lifeline polymerization TTI showing change in color as the product ages



c. VITSAB enzyme based TTI showing change in color as the product ages

TTIs can play a critical role in food safety (Brackett 1992). There are potential dangers with controlled atmosphere packaged (CAP/MAP) refrigerated RTE meals and temperature abuse. Improper conditions can lead to the growth of harmful pathogens or botulinum toxin especially under anaerobic conditions (Notermans et al 1990; Conner et. al. 1989). FSIS has recommended monitoring the temperature of meat in the processing room during the entire grinding process of meats as established in the "Guidance for Beef Grinders to Better Protect Public Health" (Guidance for Minimizing Impact Associated with a Food Safety Hazard in Raw Ground Meat and Other FSIS Regulated Products). The document specifically mentions the use of TTIs on packages as an indicator of adequate temperatures of the meat during storage, distribution, and display of the products in grocery and other retail establishments. In addition FDA in the U.S. has recommended use of TTI for processed refrigerated RTE fish products in a section of the processed fish HACCP guidelines. If not used then the processor must use exacting processing methods (FDA 2001). As they note " In reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of nonproteolytic *C. botulinum* and the spores have not been destroyed (e.g. vacuum packaged raw fish, unpasteurized crayfish meat), the temperature must be maintained at 38°F (3.3°C) or below from packing to consumption. Ordinarily processors can ensure that temperatures are maintained at or below 38°F (3.3°C) while the product is in their control. However, current distribution channels do not ensure the maintenance of these temperatures after the product leaves their control. The use of time temperature integrators on each consumer package may be an appropriate means of enabling temperature control throughout distribution".

Most importantly the research in Europe and in Greece especially led by one of the TTI research pioneers, Dr. Petros Taoukis, has shown that use of TTI not only can reduce costs in food distribution but also reduce potential cases of food poisoning (Taoukis et al 1998; Giannakourou et al 2000, Koutsoumanis et al 2000). Some of their results are shown in Figure 13, indicating that shipping based on a Least Shelf Life Left First Out (LSFO) system vs the traditional First In First Out (FIFO) can create significant cost savings. As they note " It can be seen that in products with high activation energies the distribution of quality at consumption time is much wider as

temperature variation affects more intensely the rates of quality loss. Application of the LSFO system reduces the percentage of unacceptable products to less than 5% compared to 22% with the FIFO approach." This work has led to a seven laboratory EU project (#QLK1-2002-02545) entitled "Development and Application of a TTI based Safety Monitoring and Assurance System " (SMAS).

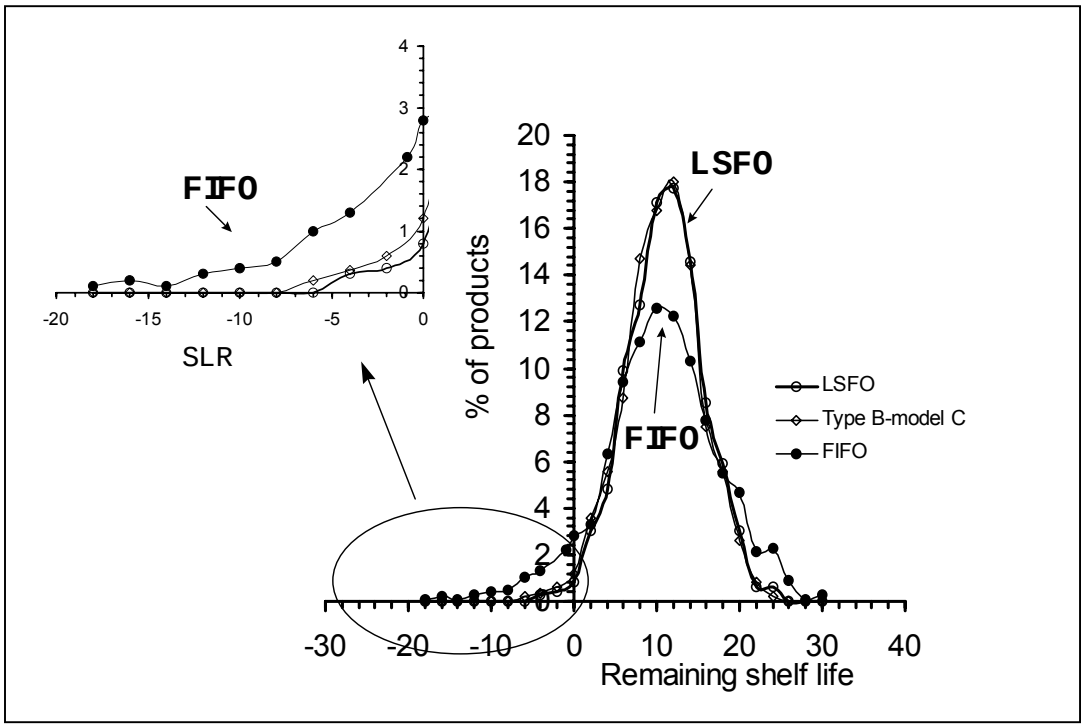


Figure 13. Distribution of quality of Russian salad products after 60 days distribution, retail and domestic storage. (Taoukis et al 1998)

As Taoukis notes above, it may not be possible to exactly match the activation energy of the TTI to the food deterioration kinetics. This could be a problem when used for predicting safety (Fu and Labuza 1992, Fu et al 1991; Labuza and Fu 1992; Taoukis 2001; Taoukis and Labuza 1999; Taoukis and Labuza 2003). The key elements in designing a chemical TTI that need attention are:

a. The activation energy (E_a) for the chemical reaction of the tag must be close to that of the pathogen, at least within ± 20 Kj/mole. There is an additional problem since the E_a can vary with stage of growth, i.e. the TTD, lag and log phases. Our work with listeria shows 23, 20.4 and 18.7 Kcal/mole respectively for these three stages based on seven storage temperatures. These were not different amongst

each other statistically at the 95% level, and the total difference of 18 Kj/mole may not pose a problem. In this case the tag chemistry would be designed to match the TTD line but reach end point at a shorter time as shown in Figure 14. Because of the chemistry, long development times may be needed to create a useable tag with any of the three chemistries shown . Both accuracy and reliability are critical.

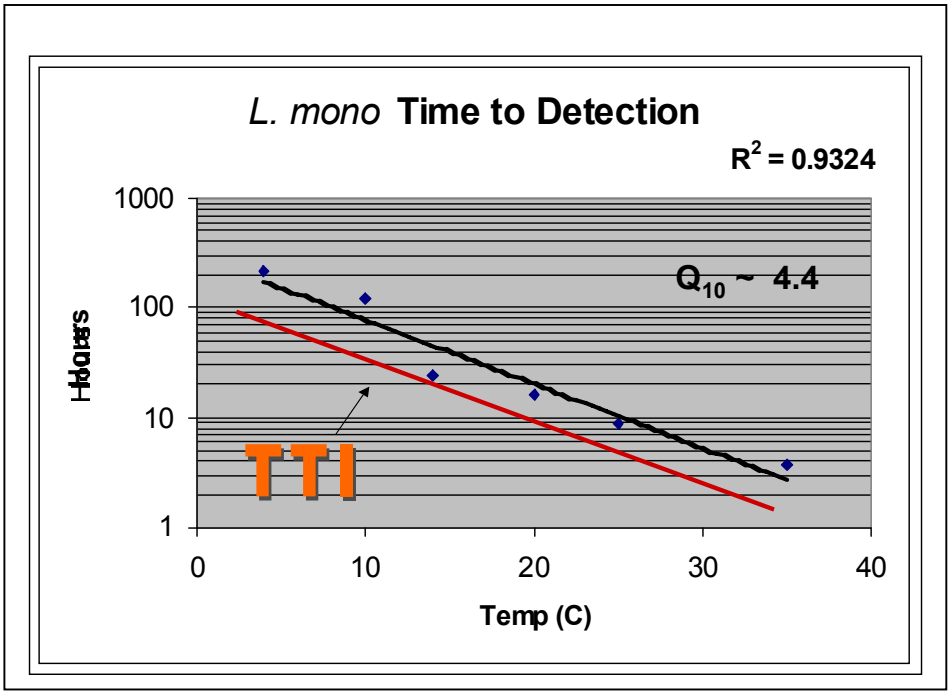


Figure 14 Shelf life plot of TTD indicating required chemistry of the TTI RFID tags.

b. The run out time varies with each growth phase creating the same problem as in a. This cannot be accounted for in a chemical tag while it could be in an electronic tag.

c. The end point for the consumer must be all or none (i.e. a sharp end point as in b) otherwise this will increase sorting. Sherlock and Labuza (1992) pointed out that about 65% of consumers sort dated foods looking for the youngest food even though it might have been temperature abused.

It should be pointed out that these tags have been successfully used for food quality, For example they are used on MREs by the military, on polio vaccine vials by

WHO and by the Monoprix chain in France for all their deli items. In addition Shimoni et al 2001) have tested them for use on milk and found them to be reliable within several hours . Shimoni et al (2000) also recognized their value for shelf life of refrigerated CAP/MAP meat and poultry products. However at this point in time there is no large acceptability of TTI tags. Part of this is the fear of the use of them for safety based shelf life. By employing them it puts the processor at greater liability if they don't work properly (Taoukis and Labuza 2003). A second is the cost. Prices for chemical tags need to come down to less than one cent to be viable but at that level it is a question of whether the tag manufacturer can make a profit. One driving force is that with a new generation of RFID labels, the TTI principle can be incorporated and adapted in the electronic tag format.

RFID tags

Since 1998 there has been a revolution in new materials and processes that have driven costs for memory chips, batteries and circuitry down dramatically. This has lead to the Radio Frequency Identification (RFID) or so called Smart Label revolution (Das and Harroup 2000) with predictions that such tags will replace the UPC code in two to three years. There are several companies developing two way RFID temperature sensor tags that record temperature which can be download at various receiver ports along the way for abuse analysis. Several others are taking the temperature monitoring one further step i.e. integration as is done in the chemical tag using the microbial kinetic parameters in an on board memory chip. The advantage is that such tags can integrate over all three stages of growth and can have an exact good/no good indicator (light) to eliminate sorting. In addition these tags will store the whole temperature time sequence of exposure thus allowing the processor to determine where abuse occurred. With RFID, by downloading of the data at various points in the chain, product close to being unsafe can be removed before the last stage, thus ensuring a safe food supply. As noted earlier, Koutsoumanis et al (2003) has shown that using a least shelf life left delivery system based on TTIs can save on the cost of distribution and reduce the probability of a Listeria outbreak. The current price for the t-T recording tags is around $2 making them viable only for cases or pallets but the price should be under 5¢ by 2005, driving this technology. As Wal-Mart has now declared that all there suppliers will

have to use RFID identity tags by 2006 (the largest 100 suppliers by 2005), this may force the market for an RFID-TTI ((Anon b 2003, Anon c 2003). Most likely this will start with pallet or case RFID tags. It should be noted that there are several companies with electronic data loggers (eg Sensitech, Massachusetts; Alien, California), one company with a flat card RFID time-temperature data logger for pallets (KSW Germany), and one with a RFID time-temperature integrator (Infratab, California). One would expect this market to grow in the next few years.

Metabolite Sensors

With revolutions in nano-technology, electronics, microbial genetics and chemistry, we also now have the ability to build sensors that can directly detect a specific pathogen strain using an antibody-antigen (AB-AG) sensor that detects a specific microbe surface protein. These have led to new pathogen detection techniques which have shaved off days in the ability to detect. Several universities and organizations have given presentations and press releases on their success in building an in-package sensor for pathogens. This seems to be the ultimate way to build in an end of shelf life on-package tag as it detects the real thing. Other sensors in development have relied on detection of microbial metabolic products using as an endpoint, a certain level. However there are some critical questions that must be addressed.

a. Topology: to sense the organism by AB-AG, it has to be directly under the sensor or the sensor has to touch the whole food surface. This assumes that contamination will be isotropic-homogeneous for which there is no proof, rather a non-homogeneous distribution is likely and in hamburger it can be inside at the center. No data exists for the rate of travel for a microbe in or on solid foods. Assuming 1 length per sec (1 μm/sec) it will travel 2.8 cm per hour. If the probe were a surface of 1 cm x 1cm exactly 1 cm away as a band on the radius, and the microbe took a straight line run toward it, the chances of hitting are less than 1 in 200 million. If a Monte Carlo approach is assumed, the chances would be > 1 in 10 billion.

b. metabolite sensor: These sensors assume that any chosen detectable metabolite is only produced by that particular pathogen and there is a direct correlation with growth level. This is an area of needed research most likely will not be

successful. Some have assumed they can use volatile metabolites but reaction, internal volume of headspace, scalping and diffusion out of the package will all occur make any prediction wrought with error. A more general approach would be to measure surface pH or conductance ((Gibson 1985) but this would not be pathogen specific.

c. Given a and b the cost of these sensors is unknown and probably high because of power requirements.

d. Electronic and chemical TTIs can be on the outside of a package while metabolite sensors need to contact the surface of the food. This creates problems of migration of compounds from the tag not allowed to contact food.

Conclusions

The question we addressed is whether an expiration date on a food can be set based on a food safety parameter, growth of a pathogen. Unfortunately such a date becomes meaningless if the product is temperature abused. We are close to the time when the use of on package (or case or pallet) sensors for shelf life and safety will become a reality. As seen in this review, both chemical and electronic RFID-TTI time-temperature integrators can integarte this abuse and relate it to shelf life expiration. To create these tags there is a need for collection of data on time to detect (TTD) and growth kinetics for each pathogen on each type of food. This data is sorely lacking especially TTD. But once collected ,we can set an expiration date based on some level of risk, i.e. the time to detect the pathogen or some higher regulatory action level. This information can then be used to design a time-temperature integrator device , TTI, that chemically or electronically integrates the stage the pathogen or the level its toxin is at and indicate distinctly the end point set as the "expiration date". Thus the device can be used as a HACCP monitor to evaluate in real time the extent to which temperature abuse during distribution and holding at retail and in the home affects the safety of the product. Thus products can be labeled "use by XXX unless indicator shows …. Where the later would depend on the TTI design. The chief drawback to the use of such a TTI will be in ensuring against sorting at retail if it is an on-package tag (note not a problem if pallet or case tag), getting the price low enough (which will depend on pallet vs case vs individual package) and overcoming the liability factor for the manufacturer by indemnifying them for temperature abuse in distribution as long as they collect the data and have an action plan (HACCP) to act on the

abuse before product reaches the consumer. It is envisioned that the RFID revolution will force TTIs in that direction and that use will start on pallets or cases.

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