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Shelf-life prediction: A comparison of methods

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The shelf-life assessment of a product is essential to ensuring its safety and integrity. Shelf life is the period of time during which the product retains its required quality level under well-defined storage conditions. To assess the stability of a generic product, a stability test is required: the product is kept under different storage conditions and the performance of characteristics used to assess the quality of the product is monitored. Data collected through stability tests are then used to predict the product's shelf life under further storage conditions a applying the calculated degradation rate. Kinetic models, such as the Arrhenius equation, are usually applied for this purpose. Since humidity can accelerate product degradation, it may be of interest to consider methods which quantify the effect of humidity. This paper proposes a comparison of several methods used to predict shelf life: the Bracket method, Eyring method, Peck method, Klinger method and Q-rule. An artificial case study is shown to compare the performance of the applied methods.

keywords: Shelf life, stability, degradation rate, acceleration factor.

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1 Introduction

Shelf life is defined as the number of days a product remains stable under the recommended storage conditions (Magari, 2003), or equally as the period of time during which the product retains its required quality level under well-defined storage conditions (Nicoli, 2012). In order to evaluate the shelf life of a certain product, it is necessary to conduct a stability test and examine the collected data using kinetic models. These types of studies are conducted in various fields, such as:

- the food sector – the importance of conducting stability tests is twofold: to ensure product safety and avoid health risks; to ensure product quality and guarantee nutritional value (Andrewes, 2021).
- the biotechnology and pharmaceutical sector - it is important to ensure that safe and effective pharmaceutical products are administered to patients therefore it is necessary to identify optimal storage and shipment conditions. For example, the World Health Organization (WHO) identifies temperature as one of the key factors affecting stability of vaccines, and stability data can help manage the cold chain required to avoid waste (Campa et al., 2021).
- the packaging sector - here both storage conditions and packaging type influence shelf life (Wang et al., 2022b). Shelf-life predictions can be made by considering different types of packaging to determine which combination of storage conditions and packaging maximize shelf life. Other packaging studies have looked at estimating the shelf life of paper, and the key factors are storage temperature and humidity level - higher temperatures and relative humidity cause a deterioration in the strength of paper (Małachowska et al., 2021).

When carrying out a stability test, the studied product is stored under differing storage conditions, allowing the collection of stability data. Kuzman et al. state that stability data are crucial to many important decisions, and are fundamental when it comes to setting a product's shelf life. (Kuzman et al., 2021).

Stability testing can be carried out in two ways: real-time stability testing or accelerated stability testing (Magari, 2003). In the first case, the product is stored under actual storage conditions. In the second, stress conditions, such as high temperature, are applied. Clearly accelerated stability testing avoids wasting time and reduces cost during data collection (Naveršnik et al., 2016). Of course, the resulting predictions should align with the real time long data (Legrand et al., 2021). The data collected through accelerated stability testing will be used to evaluate the kinetic model parameters. One of the most common kinetic models used in literature for shelf-life predictions is the Arrhenius equation. Once the Arrhenius equation, or more generally the equation of the chosen kinetic model, has been applied, it is possible to extend the relationship between degradation rate and time to temperature conditions other than the one used to collect the data (Kuzman et al., 2021).

One of the most important problems in shelf-life prediction is the fact that humidity is sometimes ignored. This is because, as an acceleration factor, it is complex to manage

(Magari, 2003). Nonetheless, the importance of humidity as a factor that can influence degradation rate is recognized in the literature. For example, P. Andrewes (Andrewes, 2021) states that humidity is an acceleration factor, although he doesn't discuss about it in his paper; E. Malachowska et al. (Małachowska et al., 2021) simply consider two different scenarios, one dry and one wet. Indeed, many methods which quantify the effect of humidity are described in the literature.

This article focuses on finding the best model from those most commonly used in the literature to predict the shelf life of a product stored in a warehouse with a particular temperature and humidity level. One of the product's key parameters is used to evaluate the quality of the product and its stability is assessed by checking the maximum acceptable value of the key parameter. Some studies combine linear regression models and kinetic models to evaluate the shelf life of a product stored under certain conditions, however these conditions relate to an accelerated stability test: the aim is to find a way to move quickly from prediction under accelerated conditions to prediction under other conditions. The quickest way to do this is to introduce the computation of an acceleration factor as a ratio between degradation rates under different storage conditions (Magari, 2003).

The paper is structured as follows: in section 2 we describe the methodologies considered to accurately estimate shelf life; in section 3 an artificial case study is used to compare methods. In conclusion, the strengths and weaknesses of the methods are reported in the last section.

2 Methodologies to predict shelf life

In the literature we found several methodologies for the estimation of shelf life. Some of them consider the effect of both temperature and humidity while others quantify only the effect of temperature.

Above all, the methodologies are required to identify the variable that should be taken into account when assessing the quality of the stored product. In our case study we use the key variable 'weight loss', as did Hartono et al. (Hartono et al., 2019). However, there is no reason why other variables cannot be considered and indeed we would also like to investigate equations which can model diffusion and solubility coefficients, such as the Arrhenius equation (McKeen, 2016). Of course, there are some limitations: the Arrhenius model is unable to describe the rate of the overall chemical reaction if there is more than one chemical reaction with different activation energies (Escobar and Meeker, 2006).

In our case, weight loss represents a decrease in moisture content due to the diffusion phenomena of the product. Sonawane et al. (Sonawane et al., 2021) focused their stability study on observing the lycopene content of tomato sauce: lycopene content is important for consumer acceptability and decreases as temperature increases during the product's drying process. Naversnik et al. (Naveršnik et al., 2016) observed the vitamin content in a pharmaceutical product while Campa et. al focused on the degradation of the O-acetylation content in a vaccine (Campa et al., 2021). In short, all variables that can be affected by diffusion and solubility phenomena can be considered for a degradation rate study.

Whichever method we apply (Bracket, Eyring, Peck, Klinger or Q-rule), in our case we must firstly measure weight loss (W) as it is the variable that determines the quality of the product under different storage conditions, i.e. different temperatures (T) and humidity levels (RH). For each condition of temperature (and humidity if the model includes this aspect) a degradation rate constant k can be estimated using the following equation (which is simply a linear regression model between weight loss and time of observation):

$$W_t = C_0 + k \cdot t \tag{1}$$

where, W_t is the weight loss as a %, C_0 is the model intercept, k is the slope corresponding to the degradation rate and t is the time at which the observation of the weight loss is made.

2.1 Bracket method

The first method we are going to look at is the Bracket method. It is based on the application of the Arrhenius equation (Magari, 2003) which is usually taken into consideration in the literature to evaluate the shelf life of a product (Wang et al., 2022a) (Wang et al., 2022b) (Van Boekel, 2021) (Campa et al., 2021) (Kaseke et al., 2021):

$$k = A \cdot e^{-\frac{E_a}{R \cdot T}} \tag{2}$$

In literature usually stability studies are based on Arrhenius equation which allows us to describe the kinetics of degradation of a product. As Naveršnik (Naveršnik et al., 2016) stated "Arrhenius equation is the base for extrapolation of stability data from elevated temperature to the actual storage condition." In the following paragraph we will see how to do that.

Using the achieved degradation rates from the linear regression model (see Equation (1)), the key parameters A and E_a can be estimated. To do this, the Arrhenius equation is considered in the following formulation:

$$\ln k = \ln A - \frac{E_a}{R \cdot T} \tag{3}$$

where k is the degradation rate, E_a is the activation energy, R is the universal gas constant equals to 8.314 $[J/(mol \cdot K)]$ and T is the temperature expressed in Kelvin. Especially, we will consider different experimental conditions, for each one we will apply the Equation (1) to achieve the degradation rates. These degradation rates at different storage conditions will be used to estimate the unknown parameters A and E_a (Equation (3)). To do that we define the linear regression model:

$$\tilde{y} = \tilde{a} + \tilde{b} \cdot \frac{1}{T} + \epsilon \tag{4}$$

where $\tilde{y} = \ln k$, $\tilde{a} = \ln A$, $\tilde{b} = \frac{-E_a}{R}$ and ϵ is an error term. After estimating $\tilde{a}$ and $\tilde{b}$, A and E_a are computed.

This first stage follows the standard two-stage model described by Naveršnik (Naveršnik et al., 2016).

The second stage consists in using the Arrhenius equation to estimate the degradation rate under a new condition of temperature, T_S:

$$k_S = A \cdot e^{-\frac{E_a}{R \cdot T_S}} \tag{5}$$

Knowing k_E and k_S, where k_E refers to the initial accelerated conditions of temperature, the ratio between them is called the acceleration factor (Magari, 2003):

$$\lambda = \frac{k_E}{k_S} = \exp\left[\frac{E_a}{R} \cdot \left(\frac{1}{T_S} - \frac{1}{T_E}\right)\right] \tag{6}$$

At the end of this approach, it is possible to estimate shelf life under condition T_S, knowing the shelf life t_E under T_E:

$$t_S = \lambda \cdot t_E \tag{7}$$

Naveršnik et al. propose a confidence interval calculation (Naveršnik et al., 2016). The shelf-life prediction t_S is calculated considering a 95% confidence interval (CI):

$$CI = [\lambda_{LOW} \cdot t_E, \lambda_{UPP} \cdot t_E] \tag{8}$$

where $\lambda_{LOW} = \dfrac{k_E}{{k_S}^{UPP}}$ and $\lambda_{UPP} = \dfrac{k_E}{{k_S}^{LOW}}$

The confidence interval (CI) is calculated by applying the equation 7 and considering a lower bound and an upper bound for the acceleration rate, respectively λ_{LOW} and λ_{UPP}. Essentially $[\lambda_{LOW}, \lambda_{UPP}]$ is an estimated CI for the acceleration rate λ, where, ${k_S}^{LOW}$ and ${k_S}^{UPP}$ are the lower and upper bounds of the confidence interval for the degradation rate k_S predicted by the equation 5, while k_E is the average degradation rate at accelerated conditions.

2.2 Eyring method

In order to consider both temperature and humidity as accelerating factors, the relationship between degradation rate and conditions of storage is expressed by the humidity-corrected Arrhenius equation. As said before in Section 2.1, Arrhenius equation is a useful tool to describe the kinetics of degradation of a product. Since humidity is recognised as an important accelerating factor, in literaure the Arrhenius equation was extend in order to consider also this aspect (Naveršnik et al., 2016). Once again by applying the humidity-corrected Arrhenius equation we face an extrapolation problem which allows us to move from accelerated stability data to actual storage conditions.

$$k = A \cdot e^{-\frac{E_a}{R \cdot T} + B \cdot RH} \tag{9}$$

Escobar and Meeker (Escobar and Meeker, 2006) proposed the degradation model in Equation (9). The estimation of the parameters A, E_a and B is similar to the estimation described in the Bracket method. See Park et al. (Park et al., 2013) and Equation (1).

Using the humidity-corrected Arrhenius equation to compute the degradation rates under accelerated conditions T_E and RH_E, and under the storage conditions of interest T_S and RH_S, the acceleration factor is obtained following the step described above (see Equation (6)):

$$\lambda = \frac{k_E}{k_S} = \exp\left[\frac{E_a}{R} \cdot \left(\frac{1}{T_S} - \frac{1}{T_E}\right) + B \cdot (RH_E - RH_S)\right] \tag{10}$$

Now the shelf life t_S under T_S and RH_S will be estimated using the known shelf life t_E under accelerated conditions T_E and RH_E: the formulation is the same as before (see Equation (7)), the only difference being the computation of the degradation rate in the evaluation of the acceleration factor.

Also in this case, the shelf-life prediction can be associated with a confidence interval (see Equation (8)).

2.3 Peck method

Peck (Peck, 1986) proposes another model to evaluate shelf life considering the effect of both temperature and humidity. In this case the degradation rate is expressed as follows:

$$k = A \cdot e^{-\frac{E_a}{R \cdot T}} \cdot (RH)^n \tag{11}$$

where E_a is the activation energy, R is the universal gas constant, and A and n are constants. The estimation of these parameters is explained by Park et al. (Park et al., 2013) and is very similar to the estimation of parameters in the previous methodologies (see also Equation (1)).

Once again, to predict shelf life we use an acceleration factor obtained from the ratio between the accelerated degradation rate and the degradation rate under a desired storage condition. We evaluate the shelf life, knowing the accelerated shelf life, using Equation (7). Also in this case, the shelf-life prediction can be associated with a confidence interval (see Equation (8)).

2.4 Klinger method

Klinger proposes another way to quantify the effect of humidity on the degradation rate (Klinger, 1991). In particular, the degradation rate is expressed as follows (Escobar and Meeker, 2006):

$$k = A \cdot e^{-\frac{E_a}{R \cdot T}} \cdot \left(\frac{RH}{1 - RH} \right)^n \tag{12}$$

As with the Bracket, Eyring and Peck methods, through the linearization and achieved degradation rates from Equation (1), it is possible to estimate the value of parameters E_a, A and n. An acceleration factor can then be computed as a ratio between degradation rate at accelerated storage conditions and desired storage conditions. Knowing the shelf life under accelerated storage conditions, the shelf life can be evaluated as before (see Equation (7)). Estimation of the shelf life can be associated with a confidence interval (see equation (8)).

2.5 Q-rule

Q-rule is the last method considered to evaluate shelf life. This method is somewhat different to those described above.

For Q-rule the degradation rate of a certain product is proportional to a factor which depends on temperature, especially on differences among temperatures expressed in Celsius and divided by 10^{o}C: due to the fact that usually the temperature 10^{o}C is taken as a reference, we denoted it as Q_{10} (Magari, 2003).

Knowing the shelf life under accelerated conditions of storage t_E, the prediction of shelf life t_S under a desired storage condition T_S is expressed as follows:

$$t_S = t_E \cdot Q_{10}^{\frac{T_E - T_S}{10}} \tag{13}$$

In other words, we can define the factor Q_{10} as:

$$Q_{10} = \left(\frac{t_S}{t_E} \right)^{\left(\frac{10}{T_E - T_S} \right)} \tag{14}$$

Let us suppose that $W_{T'_E}(t)$ and $W_{T'_S}(t)$ are the weight losses at time t and temperature T'_E and T'_S respectively. We look for the time points t'_E and t'_S so that:

$$W_{T'_E}(t'_E) = W_{T'_S}(t'_S) \tag{15}$$

Setting $t_E = t'_E$, $t_S = t'_S$, $T_E = T'_E$, and $T_S = T'_S$ in Equation (14) we can therefore compute the value of Q_{10}. It is possible to estimate the shelf life under different storage conditions following Equation (13).

The Q-rule method only considers the effect of temperature on shelf life estimation.

R.T. Magari (Magari, 2003), S.K. Niazi (Niazi, 2019) and R.K. Dinkov et al. (Dinkov et al., 2015) provide a description of this methodology.

3 Artificial case study

The aim of this toy example is to compare models that allows us to predict the shelf life of a product. The variable used to observe the conservation status of the product is weight loss: weight loss no higher than 2% is considered acceptable. The Bracket, Eyring, Peck and Klinger methods and Q-rule were applied to predict the shelf life of a generic product. This can be useful to determine the optimal storage conditions for a particular type of product or to predict the shelf life under actual storage conditions.

We assume that a unit of product was stored under different general conditions of temperature and humidity identified in Table 1.

Table 1: Storage conditions

Temperature	**Humidity**
25^oC	15%
25^oC	50%
40^oC	15%
40^oC	25%
40^oC	50%

Every week, for an observation period of 12 weeks, the weight of each unit of product was recorded and calculated as a % of weight loss with respect to its initial weight.

3.1 Data analytics

The collected data were analyzed after 12 weeks of observations using the Bracket, Eyring, Peck and Klinger methods and Q-rule.

3.1.1 Data analytics: descriptive statistics

Figure 1 shows the trend of the observed weight loss as a % for each condition of temperature and humidity. As Figure 1 shows, at a constant temperature, weight loss increases as humidity decreases, while at a constant humidity, weight loss increases as temperature increases. This happens frequently and support the conjecture that weight loss depends on both temperature and humidity, so it is important to consider both factors in the analysis if we want a more precise estimation of shelf life.

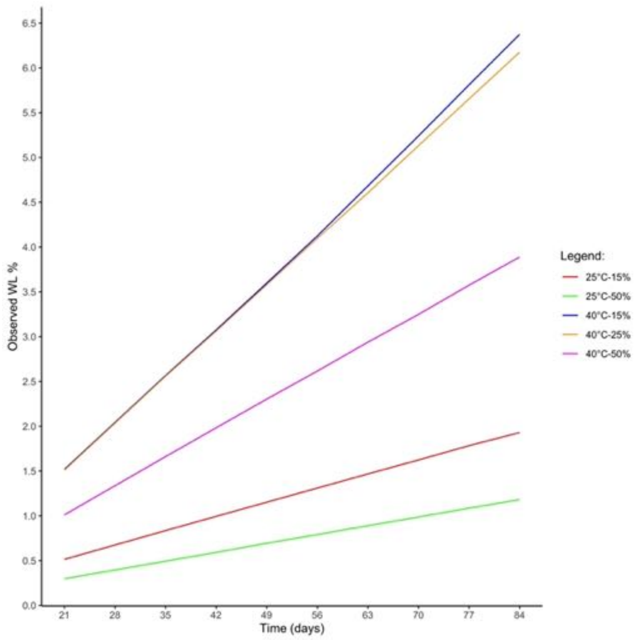

Figure 1: Descriptive statistic of Weight loss vs Time: each line represents the observed trend over time of weight loss for each storage condition.

3.1.2 Data analytics: Bracket method, Eyring method, Peck method, Klinger method and Q-rule

Taking 40^{o}C and 15% as the reference accelerated condition, the trend of the predicted weight loss with respect to time is represented in Figure 2 (see Equation (1)). The three lines represented in Figure 2 refer to the average, upper and lower predicted weight losses taking into account a confidence interval of 95%. In this case study the maximum permitted weight loss is 2% so the shelf life under the accelerated condition of 40^{o}C and 15% is 22.1 days.

Knowing t_E, we applied all the methods to predict the shelf life under different storage conditions and represent its trend. With the Eyring, Peck and Klinger methods, because shelf-life prediction depends both on temperature and humidity, either temperature or humidity must be fixed to represent the evolution of the shelf life in a bi-dimensional graph. For example, in Figures 3, 4 and 5 humidity is set at 60%.

With the Bracket method and Q-rule, because the estimation of shelf life depends only on the storage temperature, we can easily represent the shelf-life trend by varying temperature (Figure 6 and Figure 7).

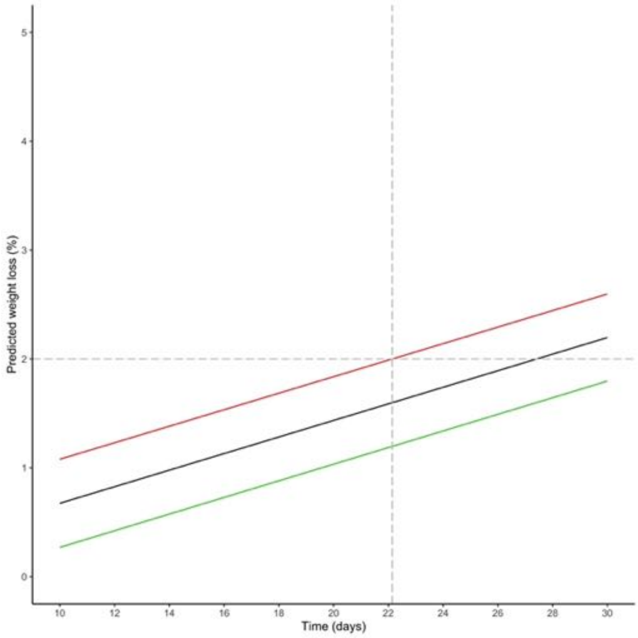

Figure 2: Predicted weight loss: the three lines represent the trend of the predicted weight loss with respect to time considering a confidence level of 95% and an accelerated condition of 40^oC and 15%. The black line is the average predicted weight loss, the red line is the upper predicted weight loss and the green line is the lower predicted weight loss.

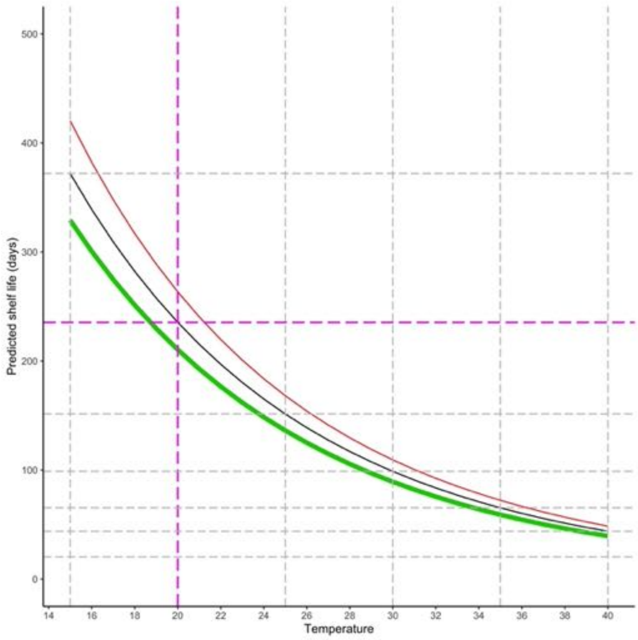

Figure 3: Trends of the predicted shelf life applying Eyring method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 60%.

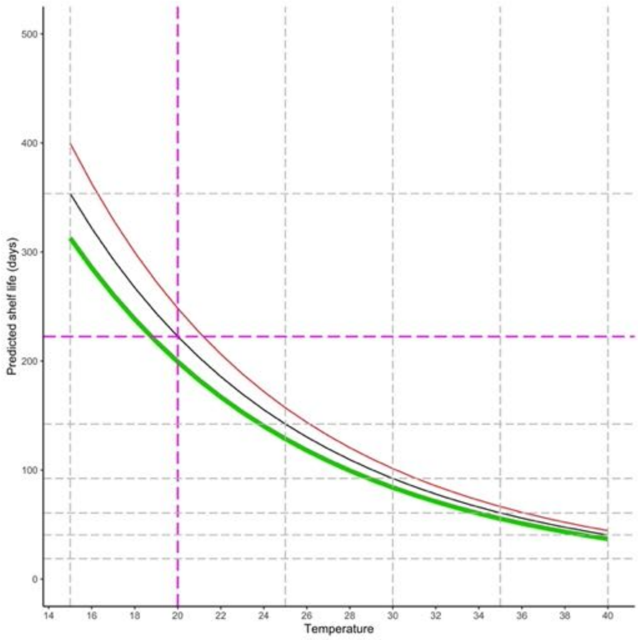

Figure 4: Trends of the predicted shelf life applying Peck method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 60%.

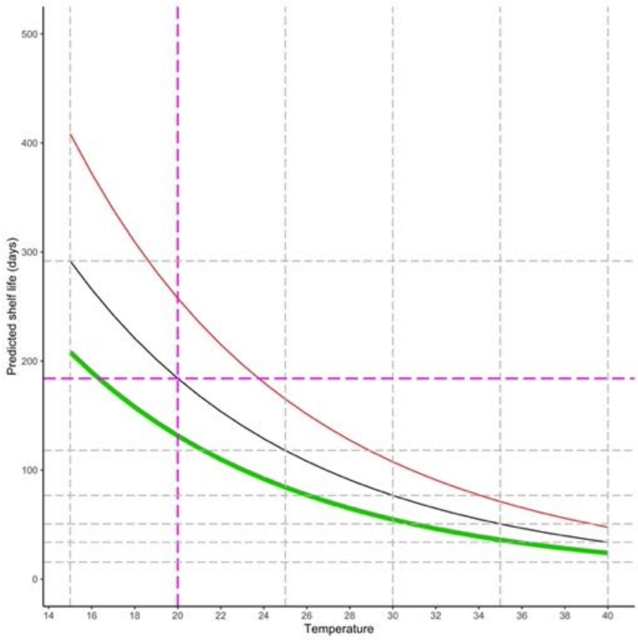

Figure 5: Trends of the predicted shelf life applying Klinger method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 60%.

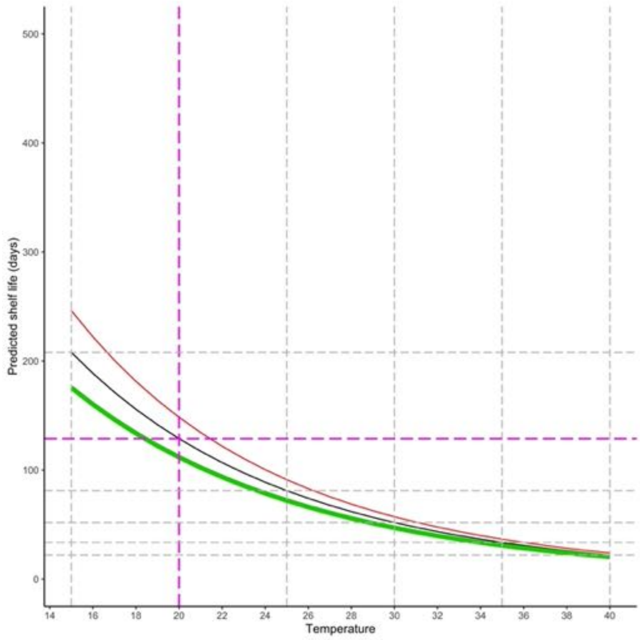

Figure 6: Trends of the predicted shelf life applying Bracket method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C.

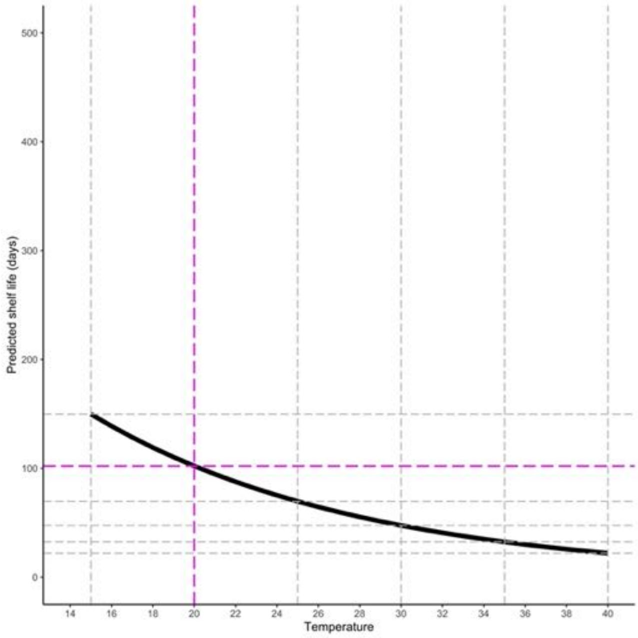

Figure 7: Trends of the predicted shelf life applying Q-rule method. It is highlighted the storage condition of interest of 20^{o}C and 60%.

These graphs can be useful to evaluate the predicted shelf life of a product under a certain storage condition of interest. For example, in Table 2 we summarize the predicted shelf life at 20^{o}C.

Table 2: Example of prediction with temperature 20^{o}C and humidity 60%.

Bracket method	Eyring method	Peck method	Klinger method	Q-rule
129 days	235.5 days	222.5 days	184 days	102 days
4.3 months	7.9 months	7.4 months	6.1 months	3.4 months

For the sake of completeness, we can observe what happens if we consider other humidity storage conditions, for example we will evaluate the shelf life of a product stored at 20^{o}C and two different levels of humidity: 40% and 80%. In Figures 8, 9 and 10 we represent the evolution of the shelf life in a bi-dimensional graph fixing humidity firstly at 40% and in Figures 11, 12 and 13 the same at 80%. Once again, in Table 3 we summarize the predicted shelf life at 20^{o}C and humidity at 40% or 80% (when humidity is considered).

Table 3: Example of prediction with temperature 20^{o}C and humidity 40% or 80%.

		Humidity 40%		
Bracket method	Eyring method	Peck method	Klinger method	Q-rule
129 days	174 days	186.5 days	162.6 days	102 days
4.3 months	5.8 months	6.2 months	5.4 months	3.4 months
		Humidity 80%		
129 days	319 days	252 days	201 days	102 days
4.3 months	10.6 months	8.4 months	6.7 months	3.4 months

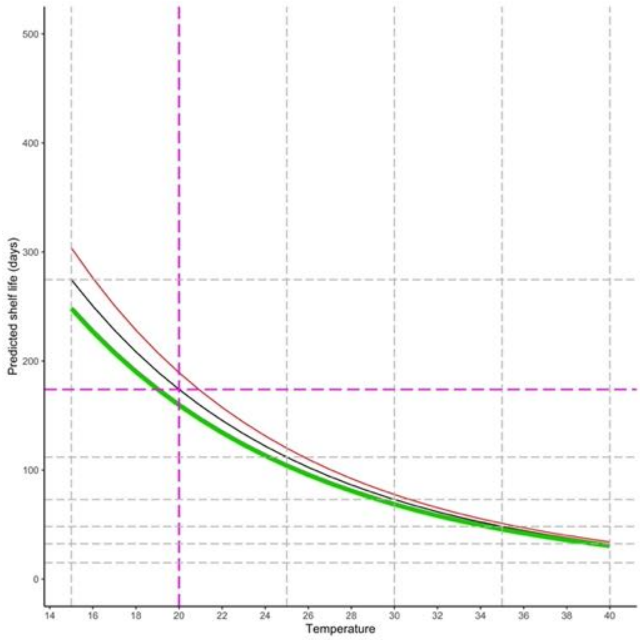

Figure 8: Trends of the predicted shelf life applying Eyring method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 40%.

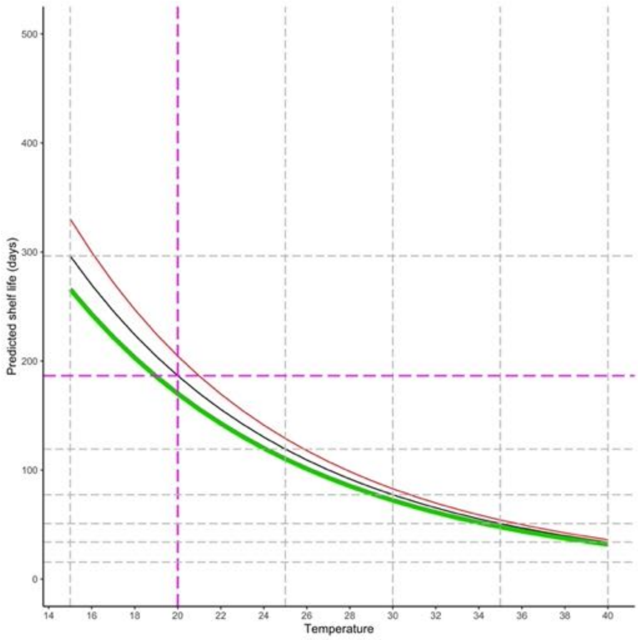

Figure 9: Trends of the predicted shelf life applying Peck method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 40%.

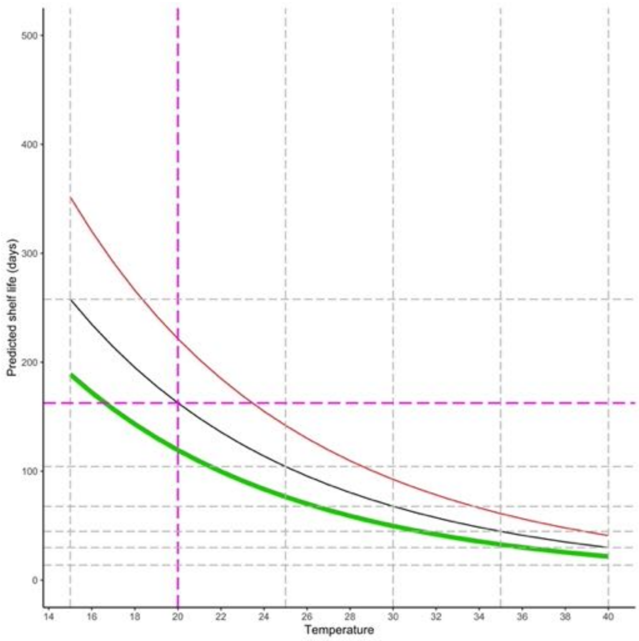

Figure 10: Trends of the predicted shelf life applying Klinger method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 40%.

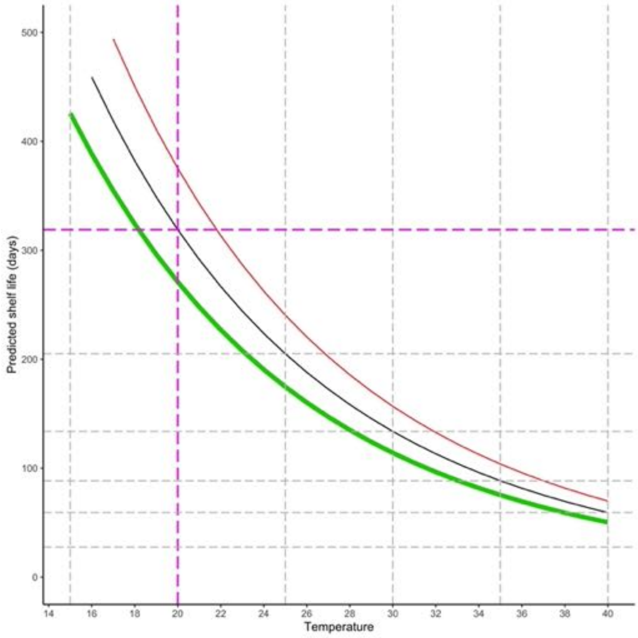

Figure 11: Trends of the predicted shelf life applying Eyring method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 80%.

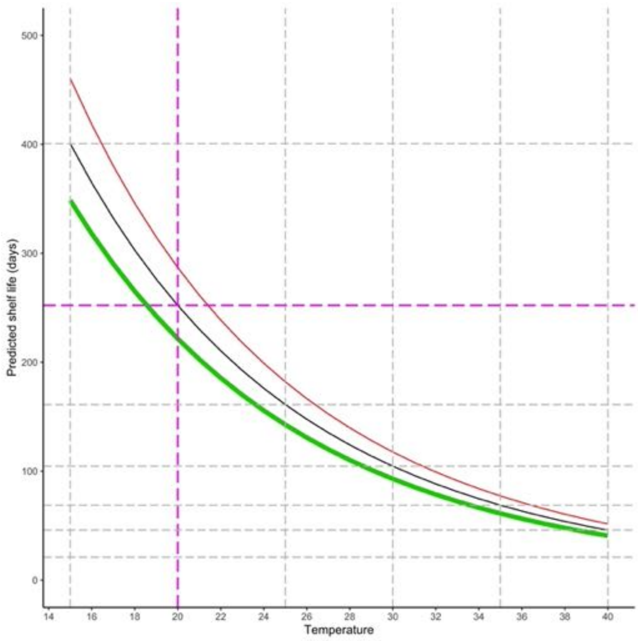

Figure 12: Trends of the predicted shelf life applying Peck method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 80%.

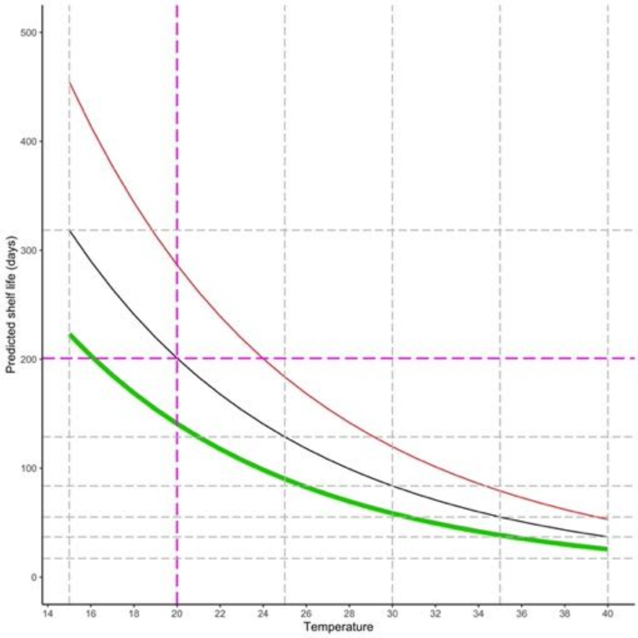

Figure 13: Trends of the predicted shelf life applying Klinger method: considering a confidence level of 95%, the black line represents the average prediction, the red line represents the upper prediction and the green line represents the lower prediction. It is highlighted the storage condition of interest of 20^{o}C and 80%.

3.1.3 A comparison of the approaches

In the previous case study the collected data was analyzed using five different approaches: three of them consider the effect of both temperature and humidity while the other two consider only the effect of temperature.

Table 4 shows the observed artificial data and the corresponding predicted values (the mean value is represented by the black line in Figure 3, Figure 4, Figure 5 and Figure 6).

Table 4: Comparison between observed shelf life and predicted shelf life obtained applying all five approaches and four storage conditions.

Store condition	**Observed**	**Bracket**	**Eyring**	**Peck**	**Klinger**	**Q-rule**
20^oC - 35%	142 days	128.5 days	161 days	175.5 days	156 days	102 days
25^oC - 15%	86.5 days	81 days	76.5 days	77.5 days	77 days	70 days
25^oC - 50%	142 days	81 days	130 days	131 days	111 days	70 days
30^oC - 65%	110 days	52 days	106 days	95.5 days	78.5 days	47.5 days

The performances of different methods considering the mean absolute percentage error (MAPE) are reported in Table 5.

Table 5: Mean absolute percentage error of the methods

Bracket method	Eyring method	Peck method	Klinger method	Q-rule
27.9%	9.3%	13.7%	17.8%	38.7%

In general, the methods which most accurately predict shelf life are the ones that consider the effect of both temperature and humidity.

4 Conclusion and discussion

This paper sets out a description and application of methods to evaluate the shelf life of a generic product from the food sector, biological/pharmaceutical sector or packaging sector, or more generally sectors in which the evaluation of shelf life is of fundamental importance. We decided to investigate methods present in the literature, three of which consider the effect of storage temperature and humidity on degradation rate, while two consider only the effect of storage temperature.

To assess the effectiveness of these methods, we considered an artificial case study. By comparing observed data under storage conditions of interest with predictions made for the same storage conditions using the methods mentioned above (Bracket, Eyring, Peck, Klinger and Q-rule), the methods that considered the effect of both humidity and temperature performed better than the others.

This study allowed us to demonstrate the importance of taking the effect of humidity into account for the estimation of shelf life.

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