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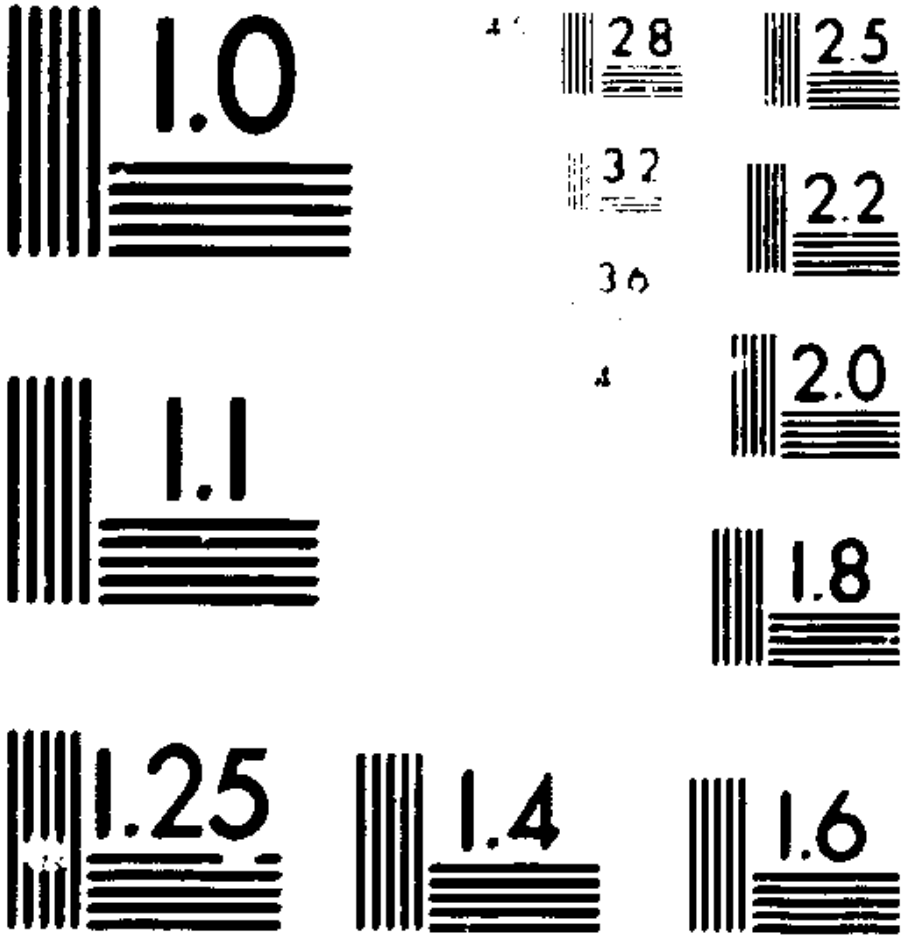

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CONSOLIDATION OF CAPACITY OF INSTITUTE OF FOOD TECHNOLOGY THROUGH CREATION OF A NATIONAL FOOD PACKAGING CENTRE

DP/BRA/82/030

BRAZIL

Technical report: Food Processing and Packaging*

Prepared for the Government of Brazil
by the United Nations Industrial Development Organization
acting as executing agency for the United Nations Development Programme

Based on the work of Chaim Mannheim
Expert in Food Processing and Packaging

United Nations Industrial Development Organization
Vienna

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During the month of July 1984 the expert was at the Centro de Tecnologia de Embalagem de Alimentos (CETEA) as a consultant on Food Processing and Packaging. During this mission a short internal course was given to about 25 participants from ITAL.

The past and present work program of the New Processing Technologies and Packaging Systems group was thoroughly reviewed. Proposals for future work of this group were discussed in detail as outlined in this report.

Limited discussions were also held with the metals, plastic and analytic groups and some suggestions were offered.

During this mission a few pilot plant and laboratory experimentals, concerning heat processing of flexible pouches, were initiated and programs for continuation were outlined.

Several industries were visited.

A list of additional equipment and supplies was drawn up and is given in this report. It is recommended to continue efforts of training staff externally and internally by bringing in experts and carrying out long term applied research projects.

INTRODUCTION

A. Project Background

The Food Packaging Center (CETEA) is part of the Instituto de Tecnologia de Alimentos - ITAL situated in Campinas in the State of São Paulo, Brasil. ITAL was started in 1963 and employs today about 350 persons including 13 Ph.D, 40 M.Sc., 40 graduates, 52 administrative staff and the rest general supporting staff. The physical plant in Campinas includes about 23000m^2 of buildings located on an area of about 100.000m^2.

The packaging area was established as a separate section early in the creation of ITAL and received further priority in 1969. Its foundation and development was aided by several National and International agencies including UNIDO since the beginning. The present UNIDO Project (BRA/82/030) enabled the establishment of the Food Packaging Center - Centro de Tecnologia de Embalagem de Alimentos - (CETEA), with the aim to up-scale the support to the rapidely expanding packaging and food industry in Brasil. Furthermore, it is intended that CETEA serve as a national as well as international training center in the important field of packaging. The Project for the creation of the Packaging Center (CETEA) is sponsored by the Government of the State of São Paulo, the Federal Brazilian Government via FINEP and EMBRAPA and the United Nation Development Programme (UNDP) through the United Nations Industrial Development Organization (UNIDO).

Packaging demand in Brasil is growing very fast in general and in the food field in particular. In 1979 about 65% of all metal packages, 60% of plastics, 40% of paper and paper board and 75% of glass were used for packaging of foods. Besides the increasing consumption of packaging materials up to-date knowledge about the technological aspects involved in the processing - packaging and storage systems become more important in Brasil. These is a great need for new, better and more efficient packaging systems as well as trained personnel and research and development facilities. It is one of CETEA's aims to fulfill this need.

At present CETEA has four experienced engineers with M.Sc. eleven graduates with B.Sc. degrees, 12 technicians one secretary and 5 other support staff. The Center is divided into four sections:

a) Plastics and paper

b) Metal and glass

c) Analytical

d) New processing technologies and packaging systems.

The UN/Brasil Food Packaging Center Project (BRA/82/030) was initiated in 1982 for a duration of 5 years. The investment in this project includes $1.512 million plus 476.835 million cruzeiros contributed by the Brazilian Covernment via EMBRAPA and the Interame rican Development Bank Cooperation Program. The project's aims are to up grade physical plant facilities, equipment and human resources needed to improve service to the Food Packaging industry.

B. Objectives of Mission

The objectives of this mission were discussed in writing several months ago and finalized after arrival in discussion with Mr. Luis Fernando Ceribelli Madi, the Project Coordinator and with Mr. Sylvio Alves Ortiz, head of the new Processing Technologies and Packaging Systems Group. The main objectives were:

1) Give a short internal short Course on "Processing and Packaging of Foods - Evaluation of different technologies;

2. Review and appraise the work program of the New Processing Technologies and Packaging Systems Group;

3. Plan new long term studies with above group;

4. Assist personnel of Center in processing of different products and solve processing and packaging problems;

5. Visit industries with aim to identify problems related to food packaging;

6. Review requirements for additional equipment needed.

7. Prepare report summerizing findings and make recommendations for future action.

DESCRIPTION OF WORK

A - GENERAL

This was the expert's third visit to the Packaging Group in ITAL and most certainly great improvements could be noted from the previous missions in 1975 and 1976. The Packaging Center is now located in a modern building of its own. It is well equipped in all areas related to primary packaging of foods including paper, plastics and laminates, metals, glass and has a good analytical laboratory suitable for carrying out necessary analyses as well as permeation and migration studies. Some of the facilities, like storage chambers, needed for shelf-life studies are incomplete but are planned to be finished in the near future. The center has a good and dedicated staff including four M.Sc. and 11 B.Sc. graduates and makes great effort to train this staff locally as well as abroad in up to-date techniques in the packaging field. One of the objectives of this mission was also to add to the training of the staff and up-date their know-how in problems related to Food Preservation and Packaging.

B - SHORT COURSE

A short course of about 22 hours entitled

"Processing and Packaging of Foods - Evaluation of different Technologies".

was given during this mission. The course was attended by 25 participants from ITAL as well as a few outsiders. (See Annex I) During the lectures discussion was encouraged and active participation of the participants took place.

The outline of the course was as follows:

1. Introduction - Objectives of course. Activities in Food Engineering and Biotechnology at Technion in Haifa, Israel.

2. Preservation of Foods by Heat - Basic principles of heat transfer, calculation of Thermal Death Times and Process Times by several methods. A partial summary of this part is given in Annex II.

3) Sterilizing Equipment - existing new and potential future methods.

4) Aseptic Packaging of Foods - A critical review of aseptic systems and their potential applications their advantages and disadvantages. Methods for sterilizng packaging materials system for processing of liquid products. A potential system for aseptically packaging particular products was described. The need for a dependable quality control program was stressed.

5) The use of Flexible Packaging Materials for preservation of foods - The current status of the Retort Pouch in the wold was reviewed as well as reasons for its sucess in Japan and its failure in other parts of the world.
Methods of preparation, filling, air removal, and thermal processing were given. Different methods of heating were analysed. All quality control aspects relating to packaging materials as well as filling, sealing and processing were thouroughly discussed.

6) Modified atmosphere packaging systems - The basic principles of controlled and modified atmosphere to extend storage life of perishable (not processed) foods were given. The application of modified atmosphere packaging systems for fresh fruits and vegetables as well as fresh meats and fish were discussed.

7) Other Packaging Systems - These include the Bag in Box systems, carton packages, composite cans, etc.

8) Shelf-life of Foods - A brief analysis how to approach the evaluation of shelf-life of various foods was offered.

C. REVIEW OF PAST AND PRESENT WORK PROGRAMS OF NEW PROCESSING SYSTEMS GROUP

The work of the New Processing Technologies and Packaging System's Group was discussed in several meetings with the entire group as well as with individuals. The majority of this group is working at ITAL for only a short time (1 - 2 years).

One of the main projects in this group has been, and still is, the project of Flexible Packages for Heat Processed Foods usually called the Retort Pouch Project.

The project was supported in the past by several agencies including OAS, UNIDO, EMBRAPA, FINEP and CNTP. The main object of this project was to set up the infrastructure needed to carry out work in this area and train personnell in all the details related to processing foods in pouches and carrying out the necessary quality control.

The main accomplished in this field were:

a) A review of the State of the art of this system in the world including a study of all the advantages and disadvantages as well as problems to over-come before this packaging systems can be introduced to Brasil. One of the main obstacles seems to be the lack of a suitable local packaging material. Therefore at present materials for sterilizing foods must still be imported, but materials for processing at 100°C or less are already available locally. These materials are presently evaluated and suggestions were made for appropriate tests.

b) The physical plant was built and equipment needed for processing was ordered and installed. This includeddesigning and building locally a retort for sterilizing pouches. The retort was installed and tested and is functioning properly. In addition filling, sealing, vacuum sealing equipment was ordered and installed. Furthemore quality control equipment was obtained and staff is now trained to operate all equipment, carry out heat penetration studies and calculate process times to obtain safe products. Tests for defects including leak test and BIO TEST were set up.
At the same time samples of products were prepared and formulations suitable for pouches were obtained.

c) Shelf-life studies with traditional foods like tomato products, as well as with typical Brasilian products like beans with or without meat were carried out. The bean product was succesful and this is a product which requires a lot of heating in the home, it seems to have good market potential. The tomato products were less succesfull and shelf-life was shorter than in cans.
Shelf-life of acid products with other materials like metallized PET/PE, Nylon/PE, and PET/PE was evaluated and found to be short (about 2 months) at ambient temperatures.

In addition to the Retort Pouch project several other small projects are being carried out in the group including:

a) Evaluation of Aluminium Tray Packs

These are semi rigid heat sealable trays suitable for thermal processing.

Initially optimum conditions (time, temperature and pressure) for sealing were studied. Method for measuring heat penetration with Ellab termocouples was learned.

The objective of this study is to evaluate these types of packages made from local materials for:

1) Meals for airlines in non sealed containers cooked and kept refrigerated untill use.

2) Prepare acid food in these packages.

3) Prepare low acid sterilized foods in these packages.

At present only imported trays are used but it is hoped that in the near future a local firm will prepare samples for evaluation as regards integrity of internal coating and sealability.

b) Seal perfomance of polyethylene coated aluminium foil to polystyrene cups. This is one example of several routinequality control and testing projects carried out for industry.

Based on above analyses the writer feels that the group is now well trained to carry out a variety of Projects in the field of Flexible and Semi Rigid packages for preserving foods. The group has at its disposal most of the equipment needed to carry out projects in this field. It is therefore recommended to use this capacity for some long term in depth studies related to new processing system as will be outlined in more detail further on.

In addition to above several discussion were also held with the Metals Group and Plastics Group. Suggestions for improvements were made which included: Use of whole cans, rather than small 2cm^2 disks, for corrosion - polarization studies.

Use of electrochemical measurements for external corrosion studies.

Use of flexible films for modified atmosphere packaging of fresh produce as well as meat or fish.

D - ASSISTENCE IN PROCESSING OF DIFFERENT PRODUCTS

During this mission several small projects were carried out.

a) Packaging green olives in transparent flexible packages. A study was initiated using two different filling - processing methods and suggestions for quality evaluation during storage weve given. These included following color changes by measuring extent of browning spectrophotometrically and trying to evaluate texture by means of a compression test used for corrugated cardboard.

b) Processing sausages in retort pouches.

Sausages were vacuum packed into retort pouches and processed in racks in autoclave. Heat penetration curves and Fo sterilization values were obtained by ELLAB SYSTEM. The Fo values were also checked by calculations. Since Ellab Systems Fo values only integrate from 110ºC these values were found lower than calculated values which take into account also the 100º to 110ºC range. It was suggested to order a part for the Ellab to enable integration beginning from 100ºC.

c) Use of different types of thermocouples.

Ellao thermocouples are reliable but very expensive. Therefore thermocouples made from 30 and 24 gauge copper constantan wire were tried. The main problem is the insertion of the wire into the packages and the positioning in the center. Several ways were locked into and further study in thus line is recommended. Special 30 gauge wire should be ordered soon.

E - VISIT TO INDUSTRIES

During this mission relatively few industries were visited due to the short time and in order to enable more effort on training and long term planning. Industries visited were:

1. CITROSUCO PAULISTA S.A.
   Caixa Postal 1, 15990, Matão, S.P.
   Phone (0162) 82 1711, 821866
   Telex 166433 - CPEX - BR.
   Person contacted: Mrs. Elizabeth S. Steger, Manager, Technical Research Division.

This plant is one of the biggest, if not the biggest orange concentrate producer in the world. They process abou 2,250.000 tons of oranges annually. Their main product is frozen concentrated orange juice (FCOJ) with orange oil and dried peel pellets as by products. Main shipping system is bulk tank farms, trucks, boat and receiving tank farms on other side of ocean. Part of production (about 30%) is still in polyethylene lined steel drums . Thus they have no packaging problems at this time.

2) ITAP S.A. Embalagens, Division of Flexible
   Avenida Marechal Mario Guedes 77
   CEP 05348 - São Paulo
   Phone (011) 268 2122 - Telex 24808
   Person contacted: Edelcio Krobath, Technical Manager.

This is a large very modern manufacturer of a large variety of plastic films and laminates.

Most films are based on local materials including adhesives, which create occaisionally quality problems. They produce films by lamination, coextrusion and also have vaccum metallizing facilities. Plant also prints films and produces pouches. A reasonable quality control laboratory exists carrying out routine tests. They seemed to be very interested in cooperating in applying new film structures for a wide range of applications.

3) SADIA - Frigobras, Companhia Brasileira de Friogíficos
Rua Fortunato Ferraz 365, Caixa Postal 6558
05093 - São Paulo, S.P. - Brasil
Phone (011) 831 2244 - Telex 1122370 FCBF Br
Persons Contacted: Eduardo D'Avilla, Gustavo Godoy Pereira Silho
Clovis Peissahk Manczyk

This is a very large producers of meat and large variety of meat products. Preservation methods include freezing, smoking, chilling, etc. The plant is very modern with up-to-date equipment and seems to have very high quality standards. They are very interested in new developments in the packaging field and willing to cooperate in trials.

F - FUTURE WORK PLANS

As mentioneed before the staff of CETEA is well trained and has good facilities and at its disposal to carry out many research projects related to food preservation. In order to optimize the use of the facilities and strengthen the capabilities of the staff it is strongly recommended to engage immediately in long term in depth applied research studies. This should be done, and can be done, whithout neglecting short term service projects and routine quality control contracts.

The nature of these studies should be true applied research projects rather than mere routine tests. It is felt that this will broaden the knowledge of the staff and give it a better understanding of their work as well as provide it with continued interest in it.

Furthermore, the efforts spent in trainning staff locally as well as abroad in non-degree as well as degree courses should be continued. In due time several people should be given the opportunity to study towards Doctorate degrees so that they can assume leadership roles in the organization. In the meantime experts from outside should be invited for periodiv review of programs, as well as for in-house training.

The proposed long term projects are:

1. Effect of different processing modes on heat transfer process times and quality of Flexible pouched foods in retail and institutional sizes;

2) Aseptic Packaging of Food Products;

3) Use of flexible packaging materials for modified atmosphere storage of non processes foods;

4) Effect of handling during processing and marketing on perfomance of flexible packages;

5) Evaluation of locally produced materials for flexible as well as semiflexible packages;

6) Shelf-life studies - kinetics of deterioration reations.

1) Heat transfer study of flexible pouches.

Objectives:- Study heat transfer , calculate process times and the effect on quality of foods packed in pouches.

Parameters of Study:

- 2 pouch sizes - retail and 1kg or larger institutional size
- different fill in weights;
- different methods of air removal, i.e. vacuum, steam, streching of pouches;
- sterilizing media - water-air, steam-air, still retort and rotating retort;
- different thermocouples to measure heat penetration;
- different pouch racks as regards space and flow of heating media over pouches;
- different foods- low viscosity, hight viscosity, solids (sausages), solids in liquid.

Tests

a) On packaging materials
   Burst strenght, Flex crack, Bio test, expansion of bags, internal pressure during heating, etc.

b) On product

Color, texture, browning, degradation of specific component like Vit in fruits, or Vitamini B_1, in low acid products or model solutions.

Part of this study could also be used to test different products or develop new formulation for products for the army, etc.

Note: Due to the fact that, except for Japan, the retail size Retort Pouch has not found market acceptability, it is this writers opinion that future efforts should involve larger size pouches for institutional applications. This market is expanding rapidely every where and is easier to penetrate than the retail trade. For example, at present products like tomato catchup are being hot-filled into 20 liter pouches for the fast-food market in the U.S.. Other examples exist. Therefore, some of the efforts should be given for obtaining data on hot-filling and cooling systems for pouches and obtain cooling methods i.e water dip, sprays and agitation during cooling.

2) Aseptic Packaging

This processing technology has achieved great importance for a variety of products in the U.S.A. as well as in Europe. Its further application to a wide range of products, both acid and low acid can be expected in the future. So far this method is limited to essentially liquid, i.e pumpable products. Several companies are working on equipments to process aseptically products with particles. One such systems was described in the short course. It is therefore this expert's opinion that the Special Systems Group should acquaint itself with this method and set up the proper procedures for its use. Several pieces of equipment will be needed for its application most of them available locally.

Objective: To set up infrastructure for aseptically packaging foods and use it for studies on several products.

Study Stages:

a) Study present state-of-the-art from scientific and comercial literature.

b) Set up equipment for trials including:

- aseptic laminar flow cabinet
- build tubular heat exchanger for in-line heating and cooling

c) Study various methods to sterilize packaging materials including:

- saturated steam, super heated steam and clorine or iodoform; solutions for sterilizing rigid containers like metal, and glass;
- hydrogen peroxide at different concentrations;
- ultra violet radiation;

In all cases tests should include different times, temperatures, concentrations and combinations of these.

After completion of preliminary tests, a test microorganism like Bacillus utilis shouls be used. In all cases tests must be carried out for microbiol sterility as well as possible adverse effects on packaging materials.

d) Carry out tests with food products, and/or model solutions, using glass or cans as controls. Shelf-life studies using at least three temperatures (15º, 25º and 35ºC) should be carried out.

Initially all foods in these studies should be acid foods. At a much later stage, the heat processing equipment of the "Martin-Dole" aseptic system existing in ITAL could be used to fill aseptically low acid liquid products.

Furthermore, applications for this system to large pouches (bag in box) in Brasil should be evaluated.

3) Modified Atmosphere Packaging

There is an increasing consumer demand for "fresh" i.e unprocessed products with reasonable shelf-life. There products include fresh produce, meat and fish as well as a variety of prepared products like salads, ready to heat and eat dishes etc. One method of extending shelf-life of foods, without using chemical preservatives, is throught the use of gases like carbon dioxide or nitrogen usually coupled with refrigeratio The application of this method requires use of special perm selective plastic films, i.e films which have specially needed permabilities to CO_2, N_2 as well as water vapor. Furthermore good knowledge about physiolocical changes taking place in "fresh" products is needed.

In general it can be said that this method can double shelf-life at same temperature as compared to storage life of same product with out modified atmosphere.

One potential application discussed during this mission was to slow down spoilage of fresh meat by a combination of sanitizing treatments and packaging so as to prevent spoilage during 24 - 48 hours even at ambient temperatures. Since meat is an expensive product it certainly can bear the extra cost of packaging materials especially if these also reduce loss of weight.

Objective: Evaluate feasibility of using flexible films for modified atmosphere packaging of fresh products.

Test Stages

a) Study present state of the art in this field and look for potential applications in Brasil;

b) Test permeabilities to CO_2, N_2 and WVTR of a variety of local and imported films;

c) Carry out shelf-life studies with fresh produce at refrigerated (3ºC) as well a higher temperatures (15º and 25ºC).

4) Effect of handling on perfomance of flexible packages

In the past most efforts were given to setting up processing and quality control procedures for filling, sealing and sterilizing pouches. As a continuation of these studies it is now recommended to evaluate perfomance of pouches to simulated transportation and marketing conditions.

Objectives: Study performance of packaging materials of thermally processed foods subjected of simulated marketing conditions.

Test stages

a) Select and characterize three different packaging materials. It is recommended that locally manufactured as well as imported materials be chosen.
Standard methods of evaluation including thickness, lamination strength, heat sealing conditions, burst strenght etc. will be used.

b) Prepare and process pouches with culture media.

c) Subject pouches to simulatedtransport abuse using drop test and vibration tests according to ASTM.

d) Evaluate package integrity using. Bio test, changes in permeability of whole package as well as by quantifying visual defects, like flex cracks, etc.

5) Evaluation of locally produced materials

The policy of Brasil is to minimize imports as much as possible and increase production of locally produced materials. This is a justified policy, but must be accompanied by suitable quality control procedures to arsure performance and safety of packaging materials. For example improper application of adhesives or printing solvents can have adverse effects on packed products.

Objective: Evaluate characteristics and performance of locally produced packaging materials.

Test stages

a) Characterize different packaging materials as regards strenght, lamination bonds, permeability properties, migration of monomers, adhesive or solvents and compare results to those obtained with similar imported materials: Nylon/PE; PET/PE; laminates with aluminium for acid products (resistant to 100ºC), semi rigid aluminium trays should be included in this study.
b) Prepare model solutions and check for off-tastes or off-odors using taste tests as well as "HOT JAR" method.

c) Make shelf-life studies of flexible pouches with different acid products including tomato products and olives, using hot-fill (if needed) and in-package cooling.

d) Set up procedures for packaging foods in semi rigid aluminum packs and test packs with different products.

6) Shelf-life studies

Quality assurance of new processing and packaging systems must include predictions of shelf-life in commercial marketing channels. In order to enable these predictions data on changes during storage must be available. The collection of these data involve studies of the kinetics of deterioration under varying storage conditions and obtaining rate constants of the relevant deteriorative reactions. While literature values are available it is very important to set up proper procedures to obtain data locally for products and under conditions existing in Brasil. Availability of such data will enable future shelf-life prediction based on accelerated tests and thus shorten the time needed to obtain the prediction.

Objectives:

Obtain data to predict shelf-life of locally produced products.

Study stages

a) Select a range of products and determine the critical parameter or parameters which govern their shelf-life.

b) Evaluate changes of above parameters at at least 3 - 5 temperatures.

c) Obtain reaction rates, Q_{10} values, as well as energies of activation, so as to define the permissable range of accelerated temperature conditions.

G. Requirements for additional equipment

The facilities of CETEA are well organized, all equipment is in good working condition and staff is well acquainted with its operation. A few additional pieces of equipment and supplies are strongly recommended to be acquired as soon as possible.

1. A laminar flow hood for aseptic work. The hood should be big enough so as to enable filling as well as sealing operations to be carriet out under it.

Potential supplies available in Brasil in Campinas
Cost estimate $ 2000 - $ 3000

2) Pouch filling machine for liquid products

Single Piston filler with adjustable range from 100 to 250 ml
Potential supplier. Simple Filler Corp, 3490 Investment Blud
Hayward, CA 94545, U.S.A.
Cost estimate $ 5000 - $ 10,000

3) Positive sanitary pump with variable speed drive
Mono or Waukesha type
Capacity 200 to 1000 ml/min
Suppliers Netch Germany or Moyno U.S.A.
Cost estimate $ 1000

4) Tubular heat exchanger

4 tubes (1,5 m length each) and shell
Design sketch for local manufacrure was given

5) Polystyrene cup heat sealer
Made locally
Cost estimate $ 1000

6) Apparatus to test flex resistance of flexible
Packaging materials:
Supplier Test Machines Inc.
400 Bayview Ave
Amity Ville, New York 11701
U.S.A.
Cost estimate $ 4000 - $ 5000

7) Thermocouple wire - Copper Constantan
30 gauge - At least - 100 ft
Supplier Omega Engineering Inc., Box 4047
Stamford, Conn. 06907, U.S.A.
Cost estimate $ 100

8) Change part for Ellab recorder to enable process time integration from 100°C.
Supplier Ellab, Copenhagen, Denmark
Cost estimate $ 100

In addition it is recommended to adapt retort for work with steam and air mixtures. This change may require some new acessories.

Furthermore it is recommended to install as soon as possible the rotating autoclave situated in the Unit Operations pilot plant.

RECOMMENDATIONS

1. Continue assistence to industry as concerns quality evaluation and control of packaging materials, trouble shooting and carry out special projects on a contract basis.

2. Continue efforts in training staff at all levels locally and abroad. Encourage staff to obtain advanced degrees in different areas and in different places.

3. Start as soon as possible long term applied research project with the aim to deepen knowledge in new fields. New projects recommended are:

   a) Heat transfer studies into flexible pouches in different sizes using different heating methods.

   b) Aseptic packaging of foods including study of methods of sterilizing packaging materials.

   c) Modified atmosphere packaging of fresh produce and meat.

   d) Effect of handling on integrity of flexible pouches.

   e) Shelf-life studies - kinetics of deteriorative reactions.

4. Obtain additional equipment and supplies as detailed in report.

5) Arrange for periodic review by external experts of work program.

ANNEX 1

Participants in shorl course on "Processamento e Embalagem de Alimentos - Avaliação de Diferentes Tecnologias"

Claire Isabel Grígoli de Luca Sarantópoulos
Léa Mariza de Oliveira
Assis Eurébio Garcia
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Gislene Capovilla
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Gina Maria Bueno Quirino
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Sidney Zanelli Junior
Paulo César Simel
Pilar de Massanguer
Ioanis A. Sarantópoulos
Nilson Monteiro Silvestre
Denise Calil P. Jardim

ANNEX II

PRESERVATION OF FOODS BY HEAT
DEFINITION OF TERMS AND METHODS FOR CALCULATING PROCESS TIMES

An understanding of the language, terminology, and symbolism is necessary to differentiate the many facets of microbiology, statistics, and engineering in the sterilization area. It is also necessary to understand the mathematical relationships that form the basis for an analytical treatment of the sterilization process. Mathematical relationships are used both in developing concepts and later in analytically determining the sterilizing value or in designing sterilization cycles for the production of sterile products. Mathematical relationships often help to clarify this otherwise rather complicated and involved area of science.

Much of the progress in the sterilization of food and drug products using heat and other forms of energy has been brought about by an understanding of the process in mathematical terms which in turn has made possible the analytical design and evaluation of sterilization processes.

Terminology and equations important in the thermal destruction of microorganisms and in heat penetration analysis are described below. An additional list of terms and definitions used in the environmental and sterilization microbiology area are at the end of Section 20.

Temperature

Thermal destruction of microorganisms deals with temperature effects, consequently, temperature is important; the symbol $\overline{T}$ will be used throughout to indicate temperature. Subscripts applied to the $\overline{T}$ are used to denote specific temperature conditions such as:

T is temperature that is changing with time (degrees F or C),
T_o is the initial temperature (degrees F or C),
T_1 is heating medium temperature (degrees F or C),
T_2 is cooling medium temperature (degrees F or C).

A more complete list of temperature terms is shown in Table I.

Table I

Symbols and Definitions of Temperature Terms

Symbol	Term	Definition
T	Temperature	T is a continuous temperature variable. To identify specific temperatures, subscripts are added. Unsubscripted it refers to product or container temperature.
T_o	Initial product temperature	The temperature of the product at the beginning of the process. It is usually measured in the slowest heating zone of the container. In heat penetration calculations, T_o is measured when $t_h = 0$. Ideally, the temperature of the product should be uniform throughout the container at $t_h = 0$, since a temperature variation may affect the j-value.
T_1	Heating medium temperature	The temperature of the medium in which the containers are heated.
T_2	Cooling medium temperature	The temperature of the medium in which the containers are cooled.
T_a	Intercept of fitted straight line to first heating curve	The intercept at $t_B = 0$ of the extension of the line fitted to the log-linear portion of the heating curve.
T_B	Steam-off product temperature	The temperature of the product at $t = t_B$.
T_{Ba}	Intercept of straight line fitted to cooling curve	The temperature intercept value at $t = t_B$ of the extension of the line fitted to the log-linear portion of the cooling curve.

Time

Time is the second important element in heat resistance studies. Time is usually measured in minutes. We shall be dealing with time both on a practical or clock basis and time on a theoretical basis. The symbol (t) will be used to indicate time that can be measured with a clock. Appropriate subscripts will be used with the symbol (t) to indicate particular time measurements. The symbol (t_h) will be used to denote the total heating time of a heat destruction test; the total heating time is measured starting from the time the container or unit is placed in the heating medium and is exposed to the heating temperature, be it retort or autoclave, and ending at the end of the heating period when the container or unit contacts the cooling medium.

Other time terms are shown in Table 2. Time relationships during a steam sterilization process are shown in Figure 1.

The Survivor Curve

The microbial survivor curve relates the microbial population and heating time. The symbol N is used to indicate microbial population in numbers of organisms. Specific terms used are:

N_c, the initial population in number of organisms per tube, vial, can, or other unit and

N_U, the population in number of organisms per tube, vial, can, or other unit after heating time U.

The heating time U_T that is used with the number of organisms to locate a point on the survivor curve is the equivalent time that the organism was subject to the heating medium temperature. The slope of the survivor curve is an important unit; the D-value is a measure of the slope and is defined as:

D_T, the thermal resistance value in minutes at temperature T, the time to reduce a microbial population by 90% at T.

For example:

$D_{250°F}$ = the thermal resistance value in minutes at 250°F, the time to reduce a microbial population by 90% at 250°F.

The number of organisms, N, per tube, vial, can, or other unit after heating time U_T, can be calculated using the equation:

$$\log N_U = -U_T/D_T + \log N_o \quad \text{or} \quad D_T = \frac{U_T}{\log N_c - \log N_U}$$

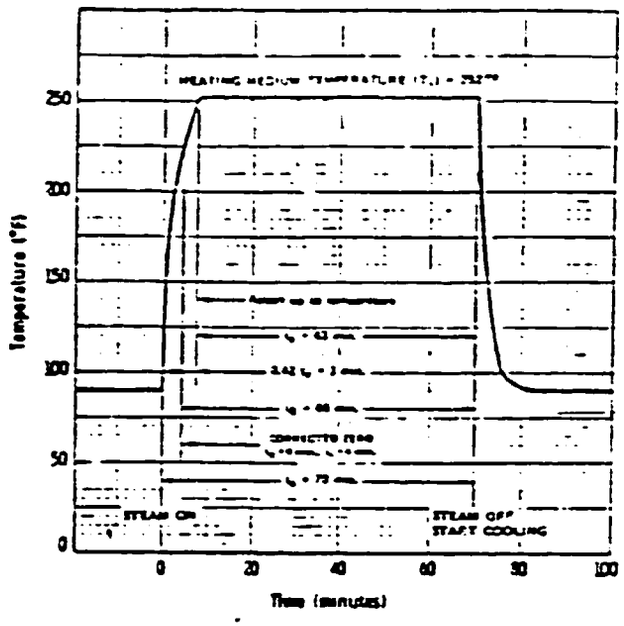


Figure 1: Time-Temperature Relationships in the Retort or Autoclave During a Steam Sterilization Process.

Table 2

Symbols and Definitions for Time Measured by the Clock

Symbol	Term	Definition
t	Time	Represents real time generally in minutes
t_B	Ball heating time	Heating time used in calculating sterilization processes by the method of Ball (1923)
t_c	Come-up time of the retort or autoclave	Time measured from steam-on ($t_h = 0$) until the retort or autoclave reaches the design operating temperature
t_h	Total heating time	The time measured from steam-on ($t_h = 0$) to steam-off
t_p	Process time	The process time, sometimes called dwell time, is measured starting when the retort or autoclave reaches the operating temperature ($t_p = 0$) to steam-off
t_{bh}	Heating curve intersection time	The time measured from Ball heating time zero ($t_B = 0$) to the intersection of the first and second straight lines of the broken heating curves
t_l	Lag correction factor	A convenient factor used in heat resistance studies to correct for the lag in heating and cooling ($t_l =$

Ecuivalent Time

In studies of thermal resistance and in sterilization process design and evaluation, we will be using an equivalent time value referenced to a particular temperature. In dealing with the heat destruction of microorganisms in real systems or sterilization processes there will always be measurable heating and cooling lags. The equivalent time at a reference temperature is determined mathematically. The temperature history of the heat treatment of an object includes a heating and cooling period and usually a holding period at temperature T_1; the analytical treatment evaluates the heating and cooling period usually in terms of the holding temperature. The result is the time that, as far as heat affect is concerned, the object under test was at the temperature indicated by the subscript of the term. Various names are used to designate this time: theoretical time, integrated time, or equivalent time. The following symbols are all units of equivalent time: U_T, D_T, and F_T; these terms will each be defined in the following discussion and are shown in Table 3.

Table 3

Sterilization Microbiology and Sterilization Process Terms

Symbol	Term	Definition
D(T)	Index of microbial destruction, measured as time	The time required at a temperature, T, to reduce a specific microbial population by 90 percent. It is the negative reciprocal of the slope of the line fitted to the graph of the logarithm of the number of survivors vs. time. For the D-value to be meaningful, the semilogarithmic survivor curve must approximate a straight line.
F(T,z)	Sterilization process equivalent time	The equivalent time at temperature, T_1, delivered to a container or unit of product for the purpose of sterilization, calculated using a specific value of z.
F_o	Sterilization process equivalent time	The number of equivalent minutes at T = 250°F delivered to a container or unit of product calculated using a z-value of 18°F (or at T = 121.1°C with a z-value of 10°C).
F_z	Sterilization process equivalent time at 120°C, z of 10°C	As we move to metric notation, it is suggested that 120°C be the reference temperature. The sterilization value calculated with 120°C as the reference temperature and with a z of 10°C would be indicated by the symbol, F_z.
IR	Survivor curve intercept ratio	The ratio of the logarithm of the y-intercept of the regression line for the survivor data divided by the logarithm of the initial number of microorganisms in the unheated control: IR = log N_{y_o}/log N_o
$L(T,z,T_{ref})$	Lethal rate	The lethal rate is the rate of destruction at temperature, T, expressed in terms of the reference temperature, T_{ref}. The actual units of the lethal rate, L, are: minutes at the reference temperature per minutes at temperature, T.
N_o	Initial number of microorganisms per unit	The initial number of viable microorganisms per unit. This is sometimes called the bioburden.
N_U, N_F	Number of microorganisms per unit after stress	The number of viable microorganisms per unit that survive a heat process of U min. at T_1 or of F min. at temperature, T.
N_{y_o}	Semilogarithmic graph regression line y-intercept	The zero-time intercept of the regression line fitted to survivor data in a semilogarithmic survivor curve format.
$U(T_1,z)$	Equivalent time at heating medium temperature	The equivalent time at the heating medium temperature, T_1, provided by the heat process calculated using a specified z-value.
Y_n	Spore log reduction	The number of log cycles of spore destruction in a sterilization process. Y_n = log N_o - log N_F.
z	Temperature dependence factor, measured in degrees	Temperature coefficient of microbial destruction (z). The number of degrees of temperature change necessary to cause the F, S, or D-value to change by a factor of ten.

Heating Curve Terminology

The heating curve is normally developed by plotting the logarithm of the difference between the heating medium temperature and the product or object temperature vs. time. The logarithm of the temperature difference function is plotted on the y-axis and time on the x-axis. When either heating or cooling data for conduction heating or cooling objects are plotted in this manner, it should be possible to draw a straight line asymptote to the heating curve. The equation for this straight line asymptote is:

$$\log (T_I - T) = \frac{-t_a}{f_h} + \log j\,(T_I - T_o).$$

We have previously discussed the fact that T refers to temperature and that t refers to time. The term, f_h, is a measure of the slope of the heating curve; it is the time for the temperature difference to decrease by 90 percent. Graphically, it is the time for the heating or cooling curve to traverse one log cycle. The value j, the lag factor, in the equation is the intercept function and is calculated using T_o, T_I, and the straight-line zero-time intercept value, T_a, in the equation:

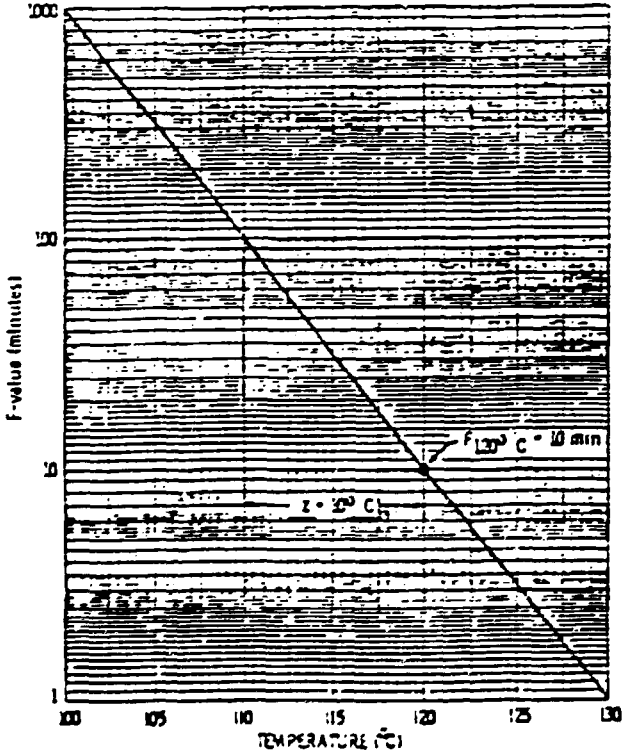
$$j_h = \frac{T_I - T_a}{T_I - T_o}.$$

SIMILARITIES IN THE TREATMENT OF EXPONENTIAL RELATIONSHIPS IN THE HEAT STERILIZATION AREA

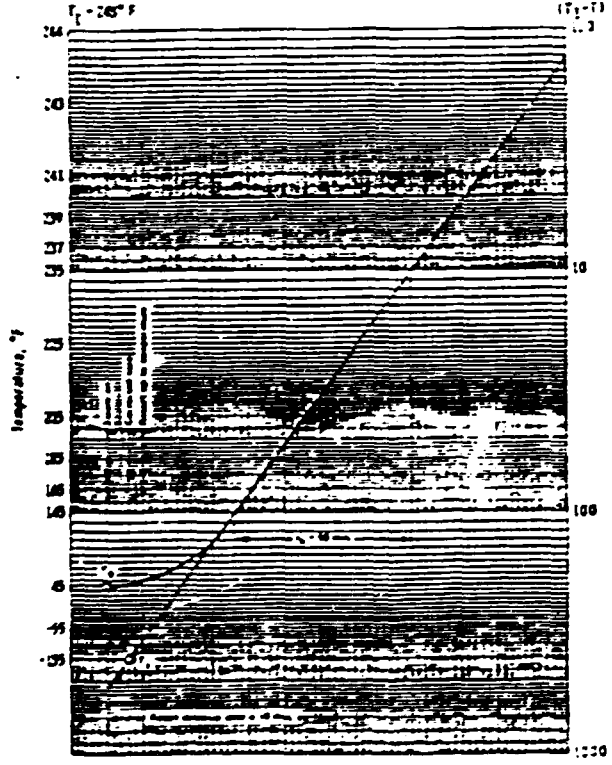
In learning, understanding, and remembering new information, the ability to associate the new information with information that the individual already knows increases the rate of learning. It is easier to understand, accept, and remember new knowledge if this information fits into an already established thought pattern.

In the microbiology and engineering of sterilization processes area, we deal with three exponential functions that we describe graphically as: the semilogarithmic microbial survivor curve, the semilogarithmic z-value or temperature coefficient curve, and the semilogarithmic heating or cooling curve. In treating these three phenomena we are consistent in that we will use parameters that are similar in definition for similar measures of all three exponential functions, and secondly, in the transient heat transfer area we will arrange the graph on the page so as temperature increases with time the curve moves in an upward direction and when cooling takes place where the temperature decreases with time the curve will move downward. These three exponential functions are illustrated on page 29.

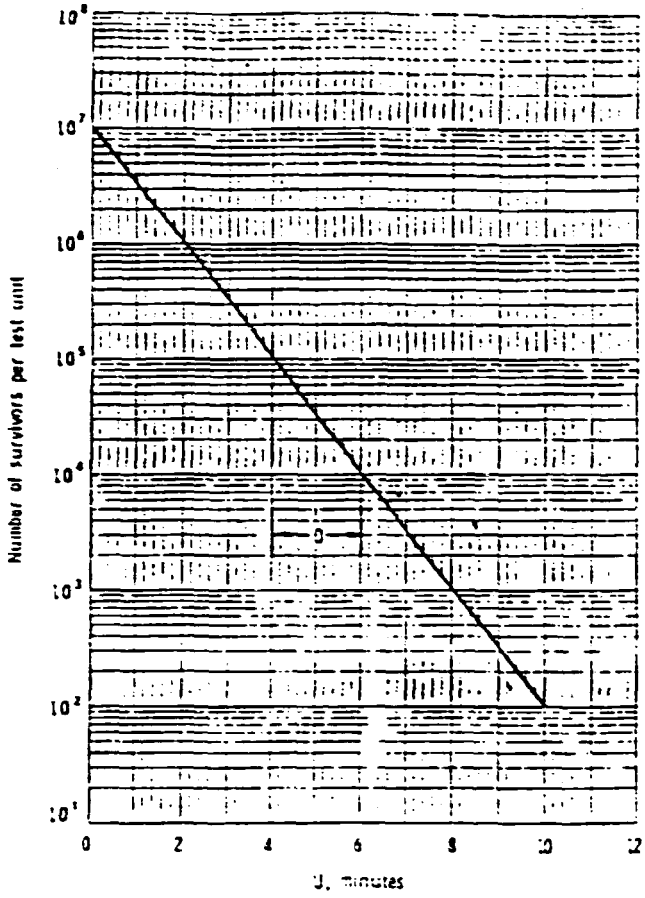
The mathematician who is at home with numbers, as we are with our laboratory organisms, wants purity of numbers and fundamental relationships. The movement of the line on the graph has no physical meaning to the mathematician - only the change in numerical basis; therefore, he may view our procedures as being unorthodox mathematically even though they contain no inaccuracies. We believe that having graphs where the flow of the graph is in the same direction as the flow of the variable is more comfortable to the microbiologist or engineer than having the line on the graph move in a direction opposite to the way we would normally perceive the variable to change. In the second place, the use of a Δx-value, the change in the x-axis variable for the line on the graph to traverse one log cycle on the y-axis, gives the microbiologist or engineer a feel for this variable since a Δx-value for a one log cycle change has real physical meaning.



thermal death time curve with z value



heating curve with f_h value



A. Survivor curve with the D-value indicated

TREATMENT OF EXPONENTIAL RELATIONSHIPS IN THE HEAT STERILIZATION AREA

In the quantitative analytical treatment of the heat sterilization area we use three exponential relationships. 1) Change in the number of surviving microorganisms with increased heat stress, a survivor or D-value curve, 2) temperature coefficient factor, a change in the D- and F-value with temperature, the thermal resistance, thermal death time, or z-value curve, and 3) the unsteady-state heat transfer relationship where the unaccomplished temperature difference is a function of time, the f-value curve. Typical graphs for each of these functions are shown on this page: the D-value curve in Figure A, the z-value curve in Figure B, and the f-value curve in Figure C. In each case the important parameter, D, z, or f, is the x-axis units necessary for the straight line semilogarithmic curve to traverse one log cycle. These curves are meant for practical use in that the user can visualize what is happening to the variable if there is a change in the D-value, if there is a change in the z-value, or if there is a change in the f-value. Consistency in treating survivor data, temperature coefficient considerations, and heating characteristics should make it easier for the new student to understand terminology and concepts of the sterilization area.

DEVELOPMENT OF THE RAHN SEMILOGARITHMIC SURVIVOR CURVE MODEL

We will develop a simple expression for the death of microorganisms using the mass action laws.

We are interested in killing microorganisms and in the number that die but we are more interested in the number of microorganisms that survive. We will use the symbol, N, to indicate the number of viable (surviving) organisms in our sample.

Consider that as a starting point we have a large number (of the order of 10^{25}) bacterial spores per test unit. The death of each spore will occur when a single molecule in the spore degrades or becomes inactivated. There is only one of these molecules per spore and it is the same molecule in each spore. Degrading of the single molecule results in death (the inability to outgrow and reproduce) of the spore.

The degradation reaction of this molecule follows the laws of chemical kinetics. The change in the number of viable spores with time is a function of the number of viable spores present and can be written in mathematical terms as follows.

$$\frac{dN}{dt} = -KN$$

Once having expressed the number of survivors in equation form, we can rearrange the equation into differential equation form and integrate the differential equation.

$$\frac{dN}{dt} = -KN$$

$$\int \frac{dN}{N} = -K \int dt$$

$$\ln N = -Kt + C$$

We can now evaluate the constant in the equation above using the boundary conditions which are: at time zero the microbial spore population is N_o or since we have the equation in logarithmic form we will let our constant equal the natural log of N_o ($\ln N_o$). We can now insert this value and develop the final equation.

$$\ln N = -Kt + C$$

$$at \quad t = 0, \; N = N_o$$

$$\therefore C = \ln N_o$$

$$\ln N = -Kt + \ln N_o$$

$$\frac{N}{N_o} = e^{-Kt}$$

We now have developed an equation which says that the number of survivors will decrease in an exponential manner. If we plot on a graph Ln N vs. Time, we would end up with a straight line. We have a graph of a log function vs. an arithmetic function. This is called a semi-logarithmic graph and our model is called the semilogarithmic survivor curve model.

ANALYTICAL TREATMENT OF MICROBIAL DESTRUCTION DATA USING
RAHN'S LOGARITHMIC ORDER OF DEATH MODEL

A practical system for treating microbial destruction data must be relatively simple in concept and in use. Natural logarithmics (logarithms to the base e) are readily understood by the mathematician; however, decimal logarithms or logaritnms to the base 10 are easier for the nonmathematician to understand and use. Therefore, we will convert the Rahn semilogarithmic survivor curve model that we have previously developed from logarithms to the base e to logarithms to the base 10. To simplify the operation we will redefine k to be k/2.303.

$$\ln N = -Kt + \ln N_o$$

$$\log N = -2.303Kt + \log N_o$$

$$k = 2.303K$$

$$\log N = -kt + \log N_o$$

$$\frac{N}{N_o} = 10^{-kt}$$

We will make a further simplification by replacing the reaction rate constant, k, with the D-value.

$$\log N = -kt + \log N_o$$

$$k = 1/D_T, \text{ (D function of temp)}$$

We will now replace the "t" in the equation with "U" which we define specifically as the equivalent time at test temperature and this will give us the final model we will be using throughout our discussion of microbial destruction.

$$\log N = -U/D_T + \log N_o$$

DEFINITIONS OF "STERILE" AND "STERILIZE" AND PRACTICAL IMPLICATIONS

Sterile. Free of living organisms. Sterilize. Any process, physical or chemical, which will destroy all forms of life, applied especially to microorganisms, including bacterial and mold spores, and the inactivation of viruses. The terms "sterile," "sterilize," and "sterilization" in a bacteriological sense mean the absence or destruction of all viable microorganisms. These terms are not relative - they are absolute; an item or unit is either sterile or it is not sterile!

The death of organisms of a microbial population subjected to heat, radiation, or chemicals usually proceeds as a geometric progression. Therefore, it is only with an infinite treatment that one can be absolutely sure that all microorganisms have been killed and therefore all units are sterile.

Increasing the sterilization process usually results in reduced product quality, also added expense. Therefore, it is suggested that for control purposes the product be accepted as being sterile when the probability of a nonsterile unit is sufficiently low and that the nonsterile hazard is not larger than other existing hazards associated with the use of this product or in everyday living.

A Working Approach to Specifications for Sterilization Processes

In the pharmaceutical industry, to call an item sterile, we should be able to certify that on a statistical basis, based on processing conditions, fewer than one unit in one million units is not sterile. The probability of a nonsterile unit (PNSU) therefore should be less than 10^{-6}.

For nonpathogenic contamination of canned foods, the same PNSU level of less than 10^{-6} appears realistic.

Where the pathogen Clostridium botulinum is a hazard, the sterilization process should be designed so fewer than one container in one billion containers will have a viable Clostridium botulinum organism after the containers have received the design sterilization process. This is a probability of a nonsterile unit (PNSU) of less than 10^{-9}.

DISCUSSION OF A PRODUCT UNIT AS THE BASIS FOR CALCULATING THE DESIGN F-VALUE

In our definition of the terms "sterile," "sterilize," or "sterilization," we agree that these terms are not relative but are absolute. An item or unit is either sterile or it is not sterile. Since the death of a microbial population subjected to heat, radiation, or chemicals proceeds as a type of geometric progression, only an infinite treatment will produce the absolute condition of sterility.

We reconcile these two divergent conditions by saying that we will accept for commercial use a product that is sterile if the probability of the unit being nonsterile is very low. It is generally agreed that for pharmaceutical products terminally sterilized as part of the manufacturing process there should be fewer than one nonsterile unit in one million units (the probability of a nonsterile unit, PNSU, should be less than 10^{-6}). In the food industry, for the pathogen Clostridium botulinum, there should be fewer than one unit containing Clostridium botulinum spores per 10^{9} units (PNSU < 10^{-9}).

In this discussion we have already alluded to our point of view, which is to sterilize products so that the final probability of microbial survival is on the basis of a unit of product.

Making the sterilization probability (PNSU) applicable to a unit of product means that we consider the initial microbial load of a unit of product and reduce it to a probability of 10^{-6} in the case of drug products. The same probability will exist whether we talk about a one-ml ampule of product or a one-liter bottle of product.

Using a rather improbable analysis, we can show the variation in this approach to sterilization process design: let us assume that an individual consumes two liters of a product that is available in both one-ml ampules and in one-liter bottles. If all the product, both in one-ml ampules and one-liter bottles, has a probability of a nonsterile unit (PNSU) of exactly 10^{-6}, then in consuming 2,000 ml obtained from two one-liter bottles of product there will be a probability of two in 10^{6} of obtaining a contaminated or nonsterile product. If, on the other hand, the individual consumed or utilized the contents of 2,000 one-ml ampules, he would have

2,000 units with each unit having a PNSU of 10^{-6}. The resulting overall probability of obtaining a contaminated or nonsterile unit will be two in 1,000.

Another approach is to assume that the final product should have a probability of nonsterile of one in one million (10^{-6}) on the basis of each ml of product. This is ideal for one-ml ampules where the probability of a nonsterile unit is one in one million. However, in a 1,000 ml bottle of product we will have 1,000 mls, each ml with a probability of nonsterile of 10^{-6}, which yields a PNSU of 10^{-3} for the 1,000 ml bottle of product. This line of thinking and procedure would be acceptable for the small unit but it would not be acceptable for the large unit.

Setting the standards on the basis of the large unit, for example, stating that the probability will be that you can have only one nonsterile (liter of bottle of product) in one million liters, will mean that the microbial concentration can be only one organism in one million liters. This is equivalent to one organism in 10^{9} ml or 10^{-9} organisms per ml. This would mean that the probability that would be used for the one-ml ampule would be 10^{-9}, compared to 10^{-6} for the one-liter bottle.

How should we resolve this problem? Any system that is going to be usable must be sufficiently simple to be workable! It seems to me that we will be better off using a single probability (PNSU < 10^{-6}) on the basis of the unit of product than to try to use a probability on the basis of survivors per weight or volume of product. To use a probability level on the basis of a unit of weight or volume requires some thought and decision as to whether we design on the basis of the largest-sized containers and have a constant rate, which will put a larger sterilization factor on the small volumes, or possibly using some type of sliding scale. The use of a sliding scale again gets us involved in the size of a consumption unit. I have also eliminated the idea that we can design on the basis of the smallest container volume because this will give a higher probability of a contaminated unit in the larger volumes, which will probably be unacceptable. A fixed sterilization cycle, such as the use of 12D or some other similar amount, will give a variation in the final probability of a nonsterile, depending upon the size of the container.

If we start with the premise that the probability of any one consumer of a sterilized product receiving a nonsterile unit should be less than

10^{-6} (one nonsterile unit when consuming one million units) and that the relative usage rate is the unit (the size of the container is proportional to the relative usage rate), then we can rationalize that sterilization processes should be designed on the basis of the unit of product and that the probability of a nonsterile unit (PNSU) should be 10^{-6}. This approach does not solve all problems; however, it will provide uniform reliability on the unit basis, which I believe is desirable and practical for the manufacturer, the regulatory agents, and also for the consumer.

TEMPERATURE COEFFICIENT MODELS

In our previous discussion of the semilogarithmic survivor curve it was pointed out that microbial destruction tests are carried out at a specific temperature. The data that are generated, including the D-value, are all specific for the particular test temperature. To use microbial destruction data effectively we must be able to adjust D-values from the test temperature to other temperatures of interest.

There are a number of reasons why we need a temperature coefficient model to be able to convert D-values or F-values at one temperature to D- or F-values at another temperature. Some of the important reasons are: 1) it is desirable and efficient to take advantage of the sterilization value that accrues as a product approaches heating medium temperature, i.e., to be able to integrate sterilization values over a range of temperatures, 2) in practical terms we are always in need of D- or F-values at other temperatures than the one that happened to be studied in the laboratory, and 3) many times, the heating system is such that it is easier to test at a temperature close to the desired level rather than trying to be exactly at the desired temperature.

In the heat sterilization area the Bigelow temperature coefficient model is widely used and, in my opinion, affords the necessary accuracy along with superb convenience. The Bigelow model is empirical in nature, but we should not let that distract from its utility. We will discuss the Bigelow model at some length and will use it extensively. We will also discuss the Arrhenius model.

Thermal Resistance Curve

The thermal resistance curve for a microorganism is the curve that relates the D-value at several temperatures. Thermal resistance curves are usually assumed to be straight lines over narrow temperature ranges; the straight line thermal resistance curve is described by the equation:

$$\log D_T = \frac{1}{z}(T_{ref} - T) + \log D_{T_{ref}} \quad \text{or}$$

$$z = \frac{T_{ref} - T}{\log D_T - \log D_{T_{ref}}}$$

z is the temperature change necessary for D(T, z) or F(T, z) to change by a factor of ten.

Thermal Death Time Curve

The thermal death time curve differs from the thermal resistance curve in that a thermal resistance curve is, by definition, the time at a range of temperatures to destroy 90% of the organisms, whereas the thermal death time curve is the time at a range of temperatures to produce some given level of sterilization effect. The terms D(T, z) and F(T, z) are related in that $F(T, z) = Y_n D(T, z)$, where Y_n is selected to provide a given degree of destruction or preservation. The term, Y_n, is the number of logs of reduction of the bacterial population and is sometimes referred to as the spore log reduction (Y_n is the spore log reduction (SLR); $Y_n = \log N_o - \log N$). The selection of Y_n is somewhat academic since the value of F(T, z) is usually based on prior processing experience.

The equation of the thermal death time curve is:

$$\log F_T = \frac{1}{z} (T_{ref} - T) + \log F_{ref}.$$

The equation of the thermal death time curve in exponential form (lethal rate arrangement) is:

$$\frac{F (T_{ref} Z)}{F(T, Z)} = 10^{(T - T_{ref})/z}$$

If T_{ref} is 250°F and z is 18°F, the equation is:

$$\frac{F_o}{F(T, 18°F)} = 10^{(T - 250°F)/18°F}.$$

F_o is the agreed-on symbol to represent a sterilization value at 250°F with a z-value of 18°F.

The Arrhenius Model

The Arrhenius model relates the reaction rate, k, from the basic thermal destruction equation,

$$\ln N = -kt + \ln N_o,$$

with temperature; however, in the Arrhenius equation, the reaction rate, k, is related to absolute temperature.

The basic Arrhenius model is shown as follows.

$$k = Ae^{\frac{-\Delta E}{RT}}$$

The integrated form of the model is:

$$\log k_1 - \log k = \frac{T_1 - T}{(2.303R\ T_1\ T)/E}$$

where

k = the specific reaction time (time^{-1});

A = a constant known as the frequency factor (time^{-1});

e = 2.71828 and is the Naperian natural logarithm base;

E = activation energy (calorie);

R = gas constant, 1.9865 Cal/(°C mole); and

T = absolute temperature °K.

(E, R, and T must be in self-consistent units.)

An Arrhenius graph is prepared by plotting the logarithm of the reaction rate, k, which is the reciprocal of D, vs. the reciprocal of the absolute temperature. First order reaction rate data will produce a straight line; the slope of this line is E/R.

DETERMINING z-VALUES

I. J. Pflug and Theron E. Odlaug

The calculation of the z-value is based on experimental data that may come from either of two types of experiments: 1) experiments carried out to determine thermal death times (TDT) at different temperatures or 2) experiments carried out to determine D-values at different temperatures. Below, we will briefly discuss how z-values are determined from data developed in these two ways.

z-Value from End-Point Data

The z-value is determined directly from TDT data. The TDT data are obtained by testing a minimum of five replicate units at five or six F-values, each at three or four temperatures. A large number of replicate units, homogeneous regarding inoculum and product, are required. The microbial inoculum can be either the natural product microflora or laboratory-produced spores. The F-values are selected so that growth in some of the replicates is certain at the shortest F-value with no growth at the largest F-value.

After the product is processed it is incubated and those containers positive for growth identified. The resulting data can now be plotted as points of growth and no growth on a semilogarithmic graph of log F vs. temperature. Two F-values are recorded: the largest F-value where at least one replicate unit was positive and the shortest F-value where all replicates were negative for growth. These "survival and destruction" F-values are gathered at a minimum of three heating temperatures.

After the data are collected the survival and destruction times are plotted on the log scale on the ordinate vs. heating temperature on the abscissa. A straight TDT line is now fitted to the data. Townsend, Esty, and Baselt (1938) offer the following suggestions for drawing this line:

1) A survival point is considered as positive data and the curve must be above every survival point.

2) Destruction points are indicative but not positive owing to the phenomenon of "skips." In general, however, a thermal death time curve should lie beneath as many destruction points as possible and still be above all survival points.
The slope of the TDT curve should be parallel to the general trend of the survival and destruction points.

There have been no additional rules developed as to how a "best" TDT line could be drawn. A straight line is usually fitted by eye to experimental data following the three rules just given.

z-Value from D-Value Data

The second way of estimating a z-value is from D-values determined at different heating temperatures. When D-value data at several different temperatures are available, the z-value can be determined by plotting the data on semilogarithmic graph paper. The D-value is plotted on the log scale on the ordinate vs. temperature on the abscissa. Conventionally, a straight line is drawn through the data points and the z-value is the degrees of temperature for the D-value to change by a factor of ten.

It is more accurate to fit a simple, least squares line to the data, log vs. temperature. The z-value estimate is the negative reciprocal of the slope of the fitted line. The units of the z-value are degrees of temperature; it is important to always include the temperature scale identification as °C or °F when using or reporting a z-value.

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BIGELOW MODEL

Bigelow (1921) observed that if the logarithm of the destruction time was plotted vs. temperature on an arithmetic scale the result over the range of temperatures studied was a straight line. This method of plotting thermal resistance and thermal death time data must be judged to be empirical. The simplicity of this type of analysis and the ready adaption of the analysis to analytical manipulation has encouraged the use of this method. The lack of a theory as to why thermal destruction data should respond to form straight lines when plotted in this manner has caused many researchers to pursue an unending search for a theory that could be used to reinforce this method of analysis or to locate or develop another method of analysis that was more amenable to a temperature coefficient theory. The Arrhenius type plot where the reaction rate is plotted as a function of absolute temperature has been used by many as a sophisticated tool for treating thermal resistance data to obtain activation energies.

General equation of the Bigelow model:

$$\log F_T = (T_{ref} - T)/z + \log F_{T_{ref}}$$

The Bigelow model in exponential form:

$$\frac{F_T}{F_{T_{ref}}} = 10^{(T_{ref} - T)/z}$$

Bigelow, W. D. 1921. The logarithmic nature of thermal death time curves. J. Infect. Dis. 29:528-536.

Q_{10}

The temperature coefficient of a process is the change in the rate of the process with a change in temperature. The Q_{10}-value is widely used by the scientific community as a measure of the temperature coefficient of chemical and biological reactions. Q_{10} is defined as the change in the reaction rate constant, k, for a change in temperature of 10°C. In equation form:

$$Q_{10} = \frac{k_{(T + 10°C)}}{k_T}$$

The Q_{10}-value of many chemical and biological reactions is 2; however, Q_{10}-values for the heat destruction of bacteria are larger, ranging from 2.2 to 4.6 for dry heat and 8 to 20 for wet heat.

The z-value is related to Q_{10} by the following equations:

$$z°C = \frac{10}{\log Q_{10}}; \quad Q_{10} = 10^{10/z°C}$$

$$z°F = \frac{18}{\log Q_{10}}; \quad Q_{10} = 10^{18/z°F}$$

THE GENERAL METHOD OF HEAT STERILIZATION PROCESS EVALUATION.

INTRODUCTION

This section will be devoted to developing the general method of process calculation including the lethal rate concept. The general method of sterilization process calculation will be demonstrated both by graphical and numerical methods.

A thermal death time curve with a D(120°C) of ten minutes and a z-value of 10°C is shown in Figure II.1. As an introduction to the general method Table II.1 is to be completed using data from Figure II.1.

Table II.1

Kill Times, Kill Times Relative to 120°C, and Lethal Rates Relative to 120°C for the z-Value Curve Data in Figure II.1, F(120°C) of Ten Minutes and a z-Value of 10°C

(1) T, °C	(2) (Kill Time) F_T, Min.	(3) (Relative Kill Time) F_T/F_{120}	(4) (Lethal Rate) F_{120}/F_T
120	10	1	1
110	100	10	0.1
130	1	0.1	10
100	1000	100	0.01
118	12.2	1.22	0.819
115	31	3.1	0.322
112	78	7.8	0.128

The sterilization value (F) of a heat process is customarily the equivalent time at a base or reference temperature. In the food processing industry it is usually equivalent minutes at 250°F. If a z-value of 18°F is used, the sterilization value at 250°F is called the F_o-value. The subscript (o) indicates that the temperature is 250°F and the z-value is 18°F. Since the United States' scientific community is committed to move to the metric system, the development and some of the examples in this section are using all metric units. In parts of this section we are using as our reference base the temperature of 120°C and identifying the sterilization value for this reference base as F_c. (When unspecified, z = 10°C.)

During the last fifty years many scientists have worked to develop improved methods of calculating the lethality of heat processes. Methods developed include: the "General Method" graphically (Bigelow et al., 1920) and numerically (Patashnik, 1953); "Formula Methods" (Ball, 1923, 1928; Ball and Olson, 1957); "Nomogram Method" (Olson and Stevens, 1939); and "Computer Method" (Sasseen, 1969). The "General Method," in its original graphical-use form, was laborious; hence, the development of other methods. In these developments accuracy of the method and ease and efficiency in application have been the objectives and it was usually not possible to satisfy both requirements. The advent of the digital computer makes possible wider use of the "General Method."

DEVELOPMENT OF THE LETHAL RATE CONCEPT

Determining the sterilization value of a heat process in terms of the equivalent time at a reference temperature, for example 120°C, means adding up the sterilization value at each temperature. The use of the lethal rate concept makes it possible to do this in a direct way.

The summing up of the lethal effects at different temperatures requires a temperature coefficient model. We will use the model of Bigelow et al. (1920). It is shown in general equation form below:

$$\log F(T) = 1/z\ (T_{ref} - T) + \log F(T_{ref})$$

and in its more useful arrangement below:

$$F(T)/F(T_{ref}) = 10^{(T_{ref} - T)/z}$$

The Bigelow model is shown in graphical form for an F(120°C) reference value of ten minutes and a z-value of 10°C in Figure II.1.

The graph in Figure II.1 relates the sterilizing value, F, with temperature. By definition, the time-temperature conditions of all points on the line produce the same microbial kill, although the F-value will vary widely with temperature as shown in Column 1 of Table II.1. All points on the line are equivalent to an F_c-value (T = 120°C, z = 10°C) of ten minutes. All points on the line are therefore F minutes at T°C, equivalent to an F-value of ten minutes at 120°C.

The next part of this development will be carried out on a general basis with symbols rather than with actual temperature conditions.

> The z-value graph relates time and temperature for an equal microbial kill.
> The "kill time" (Column 2, Table II.1) is F(T); units are "minutes at T."

The thermal death time or thermal resistance curve is a straight line when log F is plotted vs. temperature. The line is established by specifying the slope and a point on the line. The z-value is used as the slope function, $z = \frac{-1}{\text{slope}}$, and an F-value at a reference temperature, $F(T_{ref})$, as the point on the line.

> Sterilization processes are based on the "kill time" at a specified reference temperature (T_{ref}).
> The "kill time" at the reference temperature is $F(T_{ref})$.

In Column 3 of Table II.1 are listed the relative kill times corresponding to the temperatures in Column 1. These are determined by dividing the kill times at test temperature, F(T) (in Column 2), by the kill time at the reference temperature, $F(T_{ref})$.

> The kill time, F(T), at temperature T is determined from the z-value graph.
> Next, we determine the relative kill time:
> $\frac{F(T)}{F(T_{ref})}$, stated in units, $\frac{\text{minutes at } T}{\text{minutes at } T_{ref}}$.

The values of relative kill time are a function only of the z-value of the thermal death time (F-value) or thermal resistance (D-value) curve. Curves that have the same z-value will have the same relative kill time values.

The procedure of going from "kill time" to "relative kill time" has the effect of shifting the z-value curve to where it passes through the point $F(T_{ref}) = 1.0$.

The units of relative kill time are (minutes at T)/(minutes at T_{ref}). We can observe at this point that the reciprocal of the relative kill time will have units of (minutes at T_{ref})/(minutes at T); this is a rate expressed in terms of the chosen reference temperature.

Relative kill time is $\frac{F(T)}{F(T_{ref})}$.

The reciprocal of the relative kill time is the rate of microbial kill at any temperature (T) expressed in terms of T_{ref}.

$$\frac{F(T_{ref}),\ \text{min at } T_{ref}}{F(T),\ \text{min at } T}.$$

The reciprocal of the relative kill time which is the rate that is used in all sterilization process calculations is called the lethal rate and is identified by the symbol "L."

The rate of microbial kill is $\frac{F(T_{ref})}{F(T)}$ and is called the lethal rate (L). ←

The z-value equation is:

$$L = \frac{F(T_{ref})}{F(T)} = 10^{(T - T_{ref})/z}$$

Hence, the lethal rate, L, is $10^{(T - T_{ref})/z}$

The lethal rate is unique in that although we developed it using F-values, the lethal rate is a function only of 1) the difference between the product temperature (T) and the reference temperature (T_{ref}) and 2) the z-value. The product of the lethal rate and the time at temperature T is the kill time (equivalent minutes) at the reference temperature.

The kill time at the reference temperature is obtained by multiplying the reference temperature-based rate by the effective time.

$$\frac{F(T_{ref})}{F(T)} \times \Delta T = F(T_{ref}).$$

$$\frac{\text{min at } T_{ref}}{\text{min at } T} \times \text{min at } T = \text{min at } T_{ref}.$$

We have now shown in a general way how we can calculate the kill time at the reference temperature that is equivalent to process times at other temperatures. We will now go from the general solution to using specific reference temperatures and z-values. The generally agreed-on reference temperatures for the English system of units is 250°F, z = 18°F and for the metric system of units, 120°C and 10°C.

We can now insert reference temperatures and z-values into our general equations.

Metric System of Units

T_{ref} = 120°C, z = 10°C.

Therefore, $F(T_{ref}) = F_c$.

$$\frac{F(120°C)}{F(T)} = \frac{F_c}{F(T)} = 10^{(T - 120°C)/10°C}$$

Lethal rate, $L = 10^{(T - 120°C)/10°C}$

English System of Units

T_{ref} = 250°F, z = 18°F.

Therefore, $F(T_{ref}) = F_o$.

$$\frac{F(250°F)}{F(T)} = \frac{F_o}{F(T)} = 10^{(T - 250°F)/18°F}.$$

Lethal rate, $L = 10^{(T - 250°F)/18°F}$.

Since lethal rates for any specific reference temperature (T_{ref}) are a function only of the z-value and the product temperature, tables of lethal rates for a specific z-value for a range of product temperatures can be prepared. Three lethal rate tables are included in this section; for the English system a lethal rate table with a reference temperature of 250°F and a z-value of 18°F is shown in Table 11.2. For metric system use, a table of lethal rates with a reference temperature of 121.11°C with a z-value of 10°C is shown in Table 11.3

In using the general method we are interested in the overall effect where the product is at more than one temperature during the process. These can be summed up through appropriate procedures.

Table II.3

Table of Lethal Rates (L) for a Reference Temperature of 121.11°C and a z-Value of 10°C. L = Minutes at 121.11°C per Minute at T°C.

TEMP. DEG C	0	.1	.2	.3	.4	.5	.6	.7	.8	.9
90	.001	.001	.001	.001	.001	.001	.001	.001	.001	.001
91	.001	.001	.001	.001	.001	.001	.001	.001	.001	.001
92	.001	.001	.001	.001	.001	.001	.001	.001	.001	.002
93	.002	.002	.002	.002	.002	.002	.002	.002	.002	.002
94	.002	.002	.002	.002	.002	.002	.002	.002	.002	.002
95	.002	.003	.003	.003	.003	.003	.003	.003	.003	.003
96	.003	.003	.003	.003	.003	.003	.004	.004	.004	.004
97	.004	.004	.004	.004	.004	.004	.004	.005	.005	.005
98	.005	.005	.005	.005	.005	.005	.006	.006	.006	.006
99	.006	.006	.006	.007	.007	.007	.007	.007	.007	.008
100	.008	.008	.008	.008	.008	.009	.009	.009	.009	.010
101	.010	.010	.010	.010	.011	.011	.011	.011	.012	.012
102	.012	.012	.013	.013	.013	.014	.014	.014	.015	.015
103	.015	.016	.016	.017	.017	.017	.018	.018	.019	.019
104	.019	.020	.020	.021	.021	.022	.022	.023	.023	.024
105	.024	.025	.026	.026	.027	.027	.028	.029	.029	.030
106	.031	.032	.032	.033	.034	.035	.035	.036	.037	.038
107	.039	.040	.041	.042	.043	.044	.045	.046	.047	.048
108	.049	.050	.051	.052	.054	.055	.056	.057	.059	.060
109	.062	.063	.064	.066	.067	.069	.071	.072	.074	.076
110	.077	.079	.081	.083	.085	.087	.089	.091	.093	.095
111	.097	.100	.102	.104	.107	.109	.112	.115	.117	.120
112	.123	.126	.128	.131	.135	.138	.141	.144	.148	.151
113	.154	.158	.162	.166	.169	.173	.177	.182	.186	.190
114	.194	.199	.204	.208	.213	.218	.223	.229	.234	.239
115	.245	.251	.256	.262	.268	.275	.281	.288	.294	.301
116	.308	.315	.323	.330	.338	.346	.354	.362	.371	.379
117	.388	.397	.406	.416	.426	.435	.446	.456	.467	.477
118	.488	.500	.512	.523	.536	.548	.561	.574	.587	.601
119	.615	.629	.644	.659	.674	.690	.706	.723	.739	.757
120	.774	.792	.811	.830	.849	.868	.889	.910	.931	.953
121	.975	.997	1.021	1.044	1.069	1.094	1.119	1.145	1.172	1.199
122	1.227	1.256	1.285	1.315	1.346	1.377	1.409	1.442	1.475	1.510
123	1.545	1.581	1.618	1.655	1.694	1.733	1.774	1.815	1.857	1.901
124	1.945	1.990	2.037	2.084	2.133	2.182	2.233	2.285	2.338	2.393
125	2.448	2.506	2.564	2.624	2.685	2.747	2.811	2.877	2.944	3.012
126	3.082	3.154	3.228	3.303	3.380	3.459	3.539	3.622	3.706	3.792
127	3.881	3.971	4.063	4.158	4.255	4.354	4.456	4.559	4.666	4.774
128	4.885	4.999	5.116	5.235	5.357	5.482	5.609	5.740	5.874	6.010
129	6.150	6.294	6.440	6.590	6.744	6.901	7.062	7.226	7.394	7.567
130	7.743	7.923	8.108	8.297	8.490	8.688	8.890	9.097	9.308	9.525

To calculate the F_o-value that results when a product is at T_1°F for t_1 min + T_2°F for t_2 min and T_3°F for t_3 min:

$$\left[L(T_1) \times t_1\right] + \left[L(T_2) \times t_2\right] + \left[L(T_3) \times t_3\right] = F_o.$$

Ball and Olson (1957), on pp. 184-189, verify analytically the additive properties of partial sterility conditions at different temperatures. The student is directed to this reference for a more complete treatment of this subject.

DETERMINING THE F-VALUE OF A STERILIZATION PROCESS

Time-temperature data must be made available as a prerequisite to the analytical evaluation of a heat sterilization process. Once these data are available, the F-value of the sterilization process can be determined regardless of the heating pattern of the container.

Conventionally we are interested in the sterilization value at the slowest heating zone of the container, i.e., that zone in the container that receives the smallest F-value. The slowest heating zone must be located before the time-temperature data gathering process can begin.

Temperatures must be measured at small time intervals so that a clear picture of the heating and cooling pattern is available. The frequency at which temperature measurements are made during a test to gather time-temperature data depends on the rate of the heating of the product in the container which, in turn, is a function of container size and the viscosity of the product in the container. The temperature measurement interval will vary with the heating rate and should be selected so that an adequate number of time-temperature measurements are collected. Probably 20 data points are the minimum necessary to adequately describe the heating and cooling pattern and to calculate the F-value of the sterilization process.

THE GENERAL METHOD GRAPHICALLY

In this procedure the sterilizing value (F) of the heat process is obtained using a graphical integration technique to solve the general equation:

$$F(T_{ref}, z) = L\int dt.$$

In our example problem we will use 120°C as the reference temperature. The procedure is as follows: lethal rates are plotted on the y axis of 10 x 10 or 20 x 20 lines-per-inch graph paper as a function of time in minutes on the x axis. Since the lethal rate, L, is minutes at 120°C per minute at T plotted vs. time in minutes at T, the area under the curve is minutes at 120°C. The area under the curve is measured in square inches using a planimeter. To convert the square inch area under the curve to minutes at 120°C an area conversion factor is developed by determining the F_c of an area of one square inch of the graph. The square inch adjacent to the coordinate zero is the simplest area to work with; the product of the lethal rate one inch up the y axis and time one inch to the right on the x axis is minutes at 120°C per square inch of graph; the product of this factor and the area under the curve in square inches is minutes at 120°C.

The general method lethal rate graph illustrates at a glance the relative microbial kill power of the different portions of the heat process. It dramatically points out the importance of the last minutes before cooling starts and the ineffectiveness of the first few minutes after steam on.

In Table 11.6 are listed the time-temperature heating data for the slowest heating zone in a container of product. These data, along with the corresponding lethal rates, are shown in Table 11.6. The lethal rates were obtained from Table 11.4. In Figure 11.2 are shown the lethal rate data in Table 11.6 plotted to make a lethal rate graph; the area, measured using a planimeter, is 11.0 square inches. The area conversion factor of the graph is 1.0 (min at 120°C)/(square inch); the minutes at 120°C are 11.0 x 1.0 = 11.0 minutes.

Table 11.6

Calculating the Lethality of a Heat Sterilization Process Using the Method of Patashnik

Time (Min.)	Temperature (°C)	Lethal Rate (Min. at 120/Min. at T)
4	83.3	0.000
5	93.3	0.002
6	101.1	0.013
7	106.7	0.047
8	110.6	0.115
9	113.3	0.214
10	115.3	0.339
11	116.9	0.490
12	118.1	0.646
13	118.9	0.776
14	119.4	0.871
15	120.0	1.000
16	120.3	1.072
17	120.6	1.148
18	120.7	1.175
19	120.8	1.202
20	120.9	1.230
21	118.3	0.676
22	96.7	0.005
23	76.7	0.000

Sum of lethal rates = 11.021,

$F(120°C, 10°C) = \Delta t \times (\Sigma \text{ of lethal rates}) = 1 \times 11.021,$

= 11.0 Min.

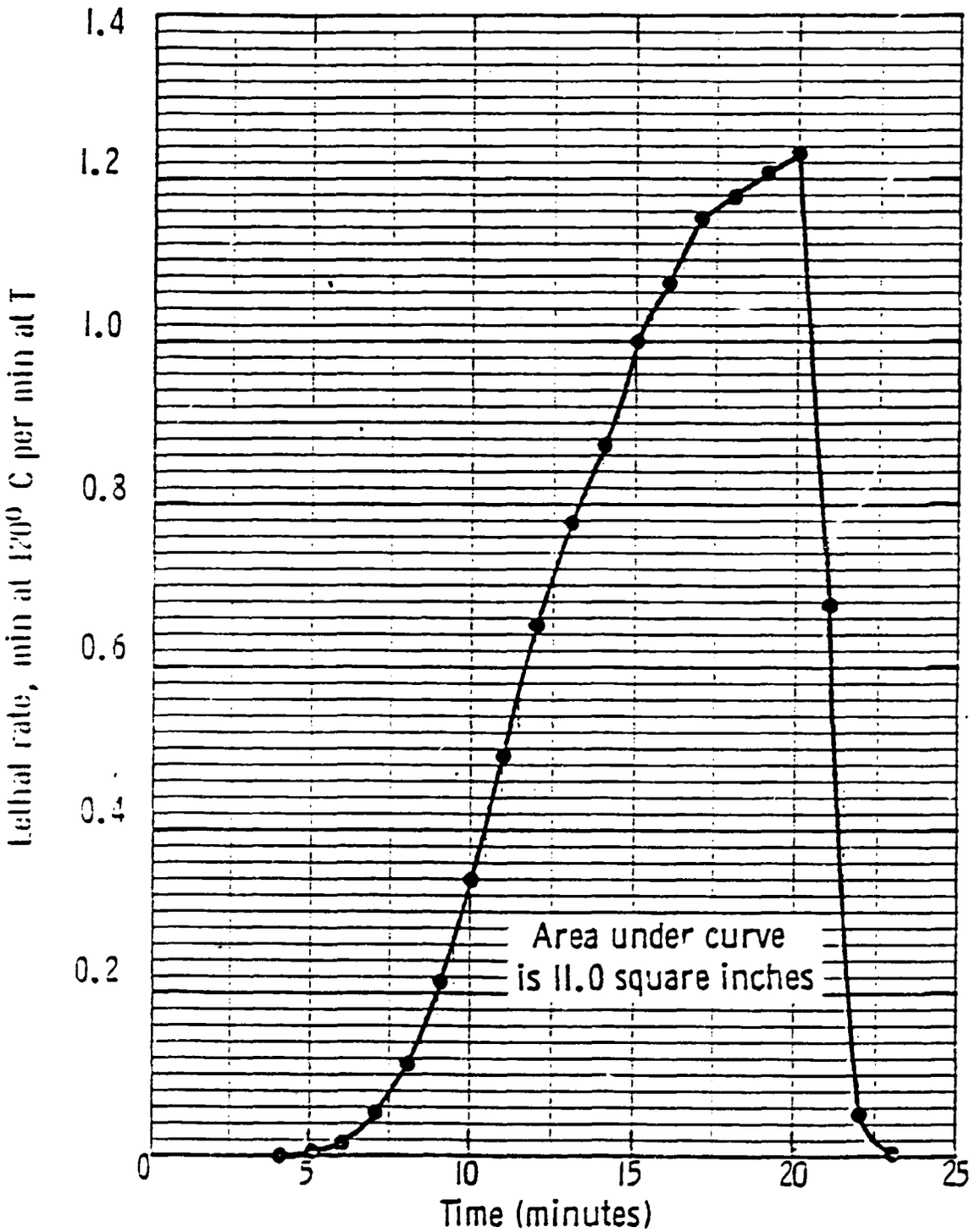

Figure 11.2: Lethal Rate Data from Table 11.6 Plotted to Make a Lethal Rate Graph.

THE GENERAL METHOD NUMERICALLY (NONMECHANIZED)

The principles of the general method outlined above are the same regardless of the computational procedure. The numerical computational procedure eliminates plotting the lethal rate graph and measuring the area under the curve.

Mathematicians have developed several methods for finding the area of an irregular geometric figure; two methods, the Trapezoidal Rule and Simpson's Rule, will be described here as possible methods for evaluating the area under the lethal rate curve. In both of these procedures it is necessary to divide the area under evaluation by equally-spaced parallel cords; the length of the cords are Y_0, Y_1, Y_2, . . . Y_n.

Burington (1940) states that, in general, Simpson's Rule is more accurate than the Trapezoidal Rule; however, lethal rate graphs are relatively simple geometric figures that usually can be made to start and end at zero and have a straight line base, so the difference in results using one or the other of the two methods is not great. Simpson's Rule for an odd number of Y values is written mathematically as:

$$\text{Area} = \tau/3(Y_0+4Y_1+2Y_2+4Y_3+\ldots+2Y_{n-2}+4Y_{n-1}+Y_n).$$

The Trapezoidal Rule for determining area is written mathematically as:

$$\text{Area} = \tau[(Y_0+Y_n)/2+Y_1+Y_2+\ldots+Y_{n-1}].$$

Patashnik (1953) describes the evaluation of thermal processes by the Trapezoidal Rule. In determining the F-value of a sterilization process the length of the cord is the lethal rate (L), and the distance between cords will be the time, d, between successive temperature measurements. The area under the curve is equivalent minutes at the reference temperature used in determining the lethal rates. Patashnik points out that in evaluating the usual heat process the data included in the analysis may be selected so the values of the first and last points, Y_0 and Y_n, are zero, simplifying the Trapezoidal Rule equation to:

$$\text{Area} = d(Y_1+Y_2+\ldots+Y_{n-1}).$$

In terms of lethal rates the Patashnik method simplifies to:

$$F(T_{ref}) = d[L(T_1)+L(T_2)+L(T_3)+\ldots].$$

The results of evaluating the heating data in Table II.5 numerically using the Trapezoidal Rule are shown in Table II.6. In this example, d = 1.0 min; therefore, the F(120°C, 10°C)-value is one times the sum of the lethal rates.

If the Patashnik method is to be used to determine the sterilization value of a portion of a sterilization process, for example, the initial 15 minutes of the process analyzed in Table 11.7, then we must use the basic Trapezoid Rule equation as shown below:

$$F(T_{ref}) = d\left[\frac{L(T_o)}{2} + L(T_1) + L(T_2) + L(T_3) \ldots L(T_{n-1}) + \frac{L(T_n)}{2}\right]$$

The 15-minute temperature would be T_n; therefore, only half of the $L(T_n)$ value will be added. The F(120°C, 10°C) for the first 15 minutes (Example Table 11.7) is calculated below:

Sum L(T) from 4 through 14 minutes = 3.513.

L(T) for 15 minutes = 1.00, $\frac{L(T)}{2}$ = 0.500.

Sum of the lethal rate = 4.013.

F(120°C, 10°C) = d x Σ of lethal rate = 1 x 4.013 = 4.0 minutes.

THE GENERAL METHOD BY COMPUTER OR PROGRAMMABLE CALCULATOR

Both the digital computer and programmable calculator are ideally suited for carrying out sterilization value calculations. Their ability to quickly calculate lethal rates and to sum the lethal rates using either the trapezoidal or Simpson's rule makes the process direct and efficient.

Available at the University of Minnesota is an interactive computer program written in Fortran that will calculate the equivalent sterilizing value (F at the desired base temperature and z-value) of a heat sterilization process. Sterilization values for several z-values can be obtained at the same time. This program is called FVALRHK and is listed in Table 11.8.

We have calculated the F_c-value for the data in Table 11.5 using the FVALRHK program. The result is an F_c-value of 11.0 minutes which is in agreement with our earlier calculated values. The interactive computer printout, including data input and data output, is shown in Table 11.9.