The influence on food safety of technological developments in the commercial manufacture of shelf-stable and refrigerator-stable heat-processed foods

by

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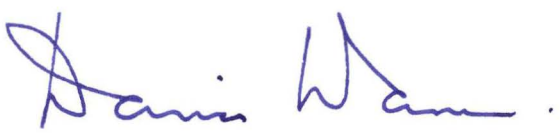

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Abstract

Several techniques were adopted to evaluate the influence on food safety of technological developments in the commercial manufacture of shelf-stable and refrigerator-stable heat-processed foods and these were as follows:

1. Development and assessment of a predictive model (known as DWC's Method) for calculating process lethality across a range of processing conditions. After analysis of data from 15 different heat penetration trials conducted in commercial manufacturing plants it was found that DWC's Method computed F values with errors of between -6 and +4% of the theoretical values calculated with an internationally accredited reference model (FMC's NumeriCal), whereas the model that is used extensively by manufacturers and regulators in Australia and New Zealand produced average errors of between -27 and -40% of the theoretical values calculated with NumeriCal.

2. Determination of the adequacy of thermal processes in commercially manufactured refrigerator-stable heat-processed foods (known as refrigerated pasteurised foods of extended durability or REPFEDs) and comparison of F_p values received in these processes with those recommended in Good Manufacturing Practice (GMP) guidelines. Of 16 thermal processes that were considered 11 (69%) satisfied GMP while, in five instances (31%), the thermal processes failed to deliver minimum F_p requirements and, in three of these cases, safety would have been compromised.

3. Evaluation of the adequacy of thermal processes used in commercially manufactured shelf-stable foods and comparison of F_o values received in these processes with those recommended in GMP guidelines. Of 32 thermal processes reviewed, 25 (78%) had F_o values $\geq$ 2.4 min which satisfied GMP, while in seven instances (22%) the F_o values were $<$ 2.4 min and were insufficient for safety.

4. Development and evaluation of microbiological challenge techniques (known as Biotests) to assess the ability of hermetic seals to prevent post-process leaker contamination (PPLC) in metal cans, glass containers and barrier plastic trays and pouches used in commercial manufacture of shelf-stable foods.

5. Development of a software package (known as DWC Analyser) to evaluate data gathered during heat distribution studies in retorting systems.

6. Evaluation of the performance of 16 commercial retorting systems in terms of compliance with GMP guidelines issued by international processing and regulatory authorities. It was found that three systems (19%) complied with the United States Food and Drug Administration requirements (Anon., 2002), which were the strictest of all the guidelines considered; five (31%) complied with guidelines recommended by May (1997a), Smout and May (1997) and the writer, and eight (50%) of the retorts failed to comply with any recognised GMP guidelines.

Acknowledgments

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Also, I wish to acknowledge and record my appreciation of the programming skills provided by Mr Michael Mobley of M2-Data Management who was responsible for converting the equations and various tables that are necessary for thermal process calculations into a user-friendly format that underpins DWC's Method of calculation and also DWC Analyser's method of temperature distribution analysis and presentation. My thanks also are extended to Ms. Sally Jones, the Executive Assistant to the Director of the Australian Food Safety Centre of Excellence, for her generous assistance in preparation and in printing the thesis.

Glossary

B	Adjusted thermal process time (B) = P_t + 0.4 X C.U.T.
C.U.T.	Retort come-up time
D	Constant time required at constant temperature required to bring about a logarithmic order of death (or a 90% kill) of a pure microbial culture
ΔP	The pressure differential that is caused by the difference between retort pressure (P_r) and internal container pressure (P_c), so that $\Delta P = P_c - P_r$
f_h	Time in minutes for the straight line portion of the semi-log plot of the heating curve to traverse one log cycle
f_c	Time in minutes for the straight line portion of the semi-log plot of the cooling curve to traverse one log cycle
F_o	A measure of the severity of a thermal process, with respect to micro-organisms with a z value of 10 Celsius degrees, expressed as being equivalent in sterilising effect to the time (duration) of heating in minutes at a reference temperature of 121.1 °C
F_p	A measure of the severity of a thermal process, other than for a conventional low-acid canned foods sterilisation process in which by definition the z value is 10 Celsius degrees and the reference temperature is 121.1 °C. For example with REPFEDs, an F_p value would be applicable to microorganisms with a z value of 9 Celsius degrees and a reference temperature of 90.0 °C.
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
j_h	The lag factor during heating
j_c	The lag factor during cooling
L	Lethal Rate of thermal destruction of microorganisms which is taken to be unity (1) at 121.1 °C for microorganisms of significance in the manufacture of low-acid heat processed foods. For REPFEDs the lethal rate is unity at 90 °C.
Low-acid food	Any food, other than beverages, where any component has a pH value greater than 4.6 and a water activity greater than 0.85
P_c	Internal pressure generated in a sealed container
PPLC	Post-process-leaker-contamination
P_r	Pressure in the retort

P_t	Process hold time, or the retort operators processing time, or the scheduled hold time
REPFED	Refrigerated pasteurised foods of extended durability
SHP	Slowest heating point
t	Elapsed time, in minutes, including the come-up time correction
T_o	Initial product temperature at the SHP. With Gillespy's, Board and Steele's and DWC's Methods of calculation, this is the initial product temperature at the "corrected" process time zero, i.e. 0.4 of the come-up time before the start of the scheduled hold phase, or 0.6 of the come-up time after steam-on.
T_r	Reference temperature
T_{Ret}	Retort temperature
T_{SHP}	Temperature at the SHP of the product
z	The number of Celsius degrees required to bring about a tenfold change either in the *D* value for a particular microorganism or in the rate of thermal destruction of that microorganism

Introduction

This work is the product of investigations that have been carried out by the writer in commercial food manufacturing facilities in Australia and internationally. In the main these studies involved evaluation of each or all of the following:

- Process adequacy for shelf-stable low-acid and acid foods.
- Process adequacy for low-acid and acid refrigerated pasteurised foods of extended durability (so called REPFEDs).
- Temperature distribution analysis in retorts.
- The adequacy of hermetic seals in various packaging media.

It was in the early stages of these investigations that deficiencies were recognised in the traditional approaches (at least in Australia and New Zealand) to modelling thermal processing calculations and evaluating retort performance. These deficiencies had become apparent and more pronounced as the food industry adopted higher processing temperatures at which, the then, conventional methods introduced large errors in F value determination. It was the inaccuracies inherent in the traditional approaches to these studies that provided the impetus to develop DWC Analyser and DWC's Method of thermal process calculation reported herein.

1 LITERATURE REVIEW

1.1 Microbial spoilage mechanisms in heat-processed packaged foods

The safety of heat-processed, hermetically sealed, packaged foods depends upon the prevention of each of the following three discrete types of microbial spoilage:

1. Pre-process (incipient) spoilage caused by microbial action prior to delivery of the thermal process.

2. Under-processing spoilage caused by an inadequate thermal process.

3. Spoilage caused by post-process leaker contamination (PPLC) of product that has received its scheduled thermal process, but which has been re-contaminated as a result of failure of the hermetic seal and/or because of poor hygiene and sanitation and/or container damage.

While no responsible manufacturer is likely to wittingly ignore the risk that these spoilage types may endanger the profitability of their operations, if not the health of their consumers, there is evidence of inadequate risk management arising through the adoption of poor manufacturing techniques.

1.1.1 Pre-process spoilage

Pre-process spoilage of heat-processed packaged foods tends to be overlooked as a potential cause of food poisoning, and yet it is likely to represent an increasingly significant health-risk given the growth in demand for convenient "as fresh" long shelf-life refrigerated foods. In this context Food Science Australia and Warne (2002) note "...there is little doubt that the risks of food poisoning from staphylococcal toxins will be increased with the adoption of minimal heat treatments for manufacture of refrigerator-stable foods." These foods are variously described as sous-vide foods, minimally processed foods, or refrigerated pasteurised foods of extended durability, "REPFEDs" (Mossel and Struijk, 1991). In response to the evolving demand for these products, there has been a commensurate growth of more "accessible" manufacturing techniques which utilise basic equipment and require little attention to, or understanding of, food hygiene princi-

ples. In some cases, the apparent ease of manufacture and the relatively low capital costs that are required to establish a rudimentary production facility have been incentives to those who, unlike their counterparts from the traditional canning industry, lack relevant technical expertise and/or who lack an awareness of the health risks involved.

Pre-process spoilage is typically associated with those categories of products that contain high counts of viable vegetative bacteria and spores at the time of processing. One such example was observed (by the writer) with pet foods containing offal and other by-products which, although unlikely to represent a human health risk may, nevertheless, yield un-saleable finished products because of loss of sensory quality. Another example involved a commercial manufacturer of low-acid (pH > 4.6) chilled sauces containing fresh cultured mushrooms. In this instance, diagnosis of spoilage revealed that the mushrooms were contaminated with heat resistant spores that had been heat-shocked during routine preparatory processing stages and subsequently held at temperatures favourable to their germination and outgrowth prior to delivery of the scheduled thermal process. Pre-process spoilage also has been observed (by the writer) in raw veal containing fresh parsley as a filling for shelf-stable lasagne meals. In this case, spoilage was attributed to the activity of the vegetative cells that contaminated the raw materials, as there was no preliminary heat treatment that would have destroyed these microorganisms and simultaneously activated spores that may have been present.

Another, less obvious, category of pre-process spoilage includes the use of materials containing pre-formed toxins. One such example caused the United States Food and Drug Administration (USFDA) to issue an Import Alert notice in March 1999 following detection of staphylococcal enterotoxin in canned mushrooms from the Peoples Republic of China (Anon., 1999). In this particular case there were four incidents affecting over 100 people following consumption of canned product from three different manufacturing sites. Further investigations carried out by the USFDA and the Canadian government demonstrated the presence of toxin in product from an additional eight manufacturers. Other similar notices were issued by the USFDA after the detection of staphylococcal enterotoxin in canned mushrooms from Korea in 1990 (Anon., 1990), Taiwan in 1992 (Anon., 1992) and Thailand in 1993 (Anon., 1993). In instances such as these, the risk of food poisoning arises from the possible ingestion of the heat-stable staphylococ-

cal enterotoxin rather than the microorganisms themselves. *Staphylococcus aureus* typically exhibits a D_{60} value of 1 to 2.5 min in phosphate buffer, whereas in low-acid foods the toxin has been shown to survive F_o values of between 3 and 8 min (Bennett and Berry, 1987). This means that the presence of the toxin is not necessarily due to poor handling by the manufacturer at the time of canning; it may be because of use of raw materials that have been handled under unsanitary conditions or have been subjected to temperature abuse at some stage during harvesting, transportation and processing.

Given that the detection of pre-formed staphylococcal enterotoxin has led to recalls of shelf-stable canned mushrooms for which Good Manufacturing Practice (GMP) requires that the target F_o values will be ≥ 2.8 min; (although in practice the F_o values are likely to be ≥ 10 min), there is little doubt that the risks of food poisoning will take on heightened significance with the adoption of minimal heat treatments for mushrooms and other raw materials that may be contaminated with the enterotoxin. The dangers arise because the majority of minimal heat treatments given REPFEDs are no more than mild heat treatments or pasteurisation processes, which target psychrotrophic, relatively heat sensitive microorganisms and their spores as well as vegetative cells of mesophilic and thermophilic bacteria (Mossel and Struijk, 1991; Gorris and Peck, 1998 and Del Torre *et al.*, 2004). This means that minimal processes will not be sufficient to denature staphylococcal toxins should they be present because of poor hygiene and sanitation during handling. In cases such as these, safety with respect to survival of proteolytic *Clostridium botulinum* relies upon chilled storage at less than the minimum growth temperature (i.e. < 10°C) to prevent growth, as pasteurisation processes will be ineffective against the spores that may have contaminated the raw material.

1.1.2 Under-processing spoilage

The health risks associated with under-processing spoilage of shelf-stable low-acid canned foods most frequently relate to the survival of proteolytic *Clostridium botulinum* spores, whereas with refrigerator stable minimally processed low-acid foods, the focus of attention frequently (but not exclusively) becomes survival and growth of the more heat sensitive non-proteolytic *Clostridium botulinum* spores. In the former case, the objective of the thermal process is to reduce the probability of survival of a single *Clostridium botulinum* spore by a factor of a million million (Hersom and Hulland, 1980). This means that the probability that one spore

of proteolytic *Clostridium botulinum* will survive the thermal process is one in 10^{12}. This approach has given rise to the so-called 12*D* concept (Stumbo, 1973) which, conservatively, assumes an initial contamination level of one spore/g of product located at the slowest heating point (SHP) of the container. Strictly speaking, the probability of *Clostridium botulinum* spore survival in the container at points other than the SHP will be less than one in 10^{12}. However, irrespective of whether consideration is for the entire container or a single gram of product at the SHP, there is little practical distinction between the two viewpoints in terms of risks to consumer health.

The prevention of under-processing spoilage by pathogens other than mesophilic *Clostridium botulinum* is not considered an issue when designing thermal processes for low-acid shelf-stable foods. The reason for this is that the minimum process must achieve, at least, a 12-logarithmic reduction in survivors specifically for mesophilic *Clostridium botulinum,* which has a $D_{121.1}$ value of 0.23 min (Hazzard and Murrell, 1989) and which is considered the most heat resistant pathogen likely to be found in foods. This means that a so-called 12D process also will be sufficient to bring about satisfactory reduction in the probability of survival of other, less heat resistant, pathogens. Therefore, the only circumstances in which other pathogenic microorganisms may lead to under-processing spoilage would be when there had been gross under-processing, such as might occur had the product not been retorted at all.

With refrigerator-stable low-acid foods, or REPFEDs, the thermal process is based on destruction of target microorganisms different from those in shelf-stable foods. As noted, this, typically, includes spore-forming, non-proteolytic *Clostridium botulinum,* however, the non-spore-forming *Listeria monocytogenes* and/or the spore-forming *Bacillus cereus* may also need to be considered. For this class of product, GMP requires that the thermal process will be at least equivalent to a 6*D* process with respect to the target microorganism. Hence, it was with respect to the thermal destruction of non-proteolytic *Clostridium botulinum* that the Advisory Committee on the Microbiological Safety of Food (ACMSF, 1992), Betts (1996), the European Chilled Foods Federation (ECFF, 1996) and the Australian Quarantine and Inspection Service (AQIS, 1992) all issued guidelines recommending that the minimum thermal processes should at least be equivalent to 10 min at 90°C. This "guideline" heat treatment was based on research by Gaze and Brown (1990) at the Campden Food and Drink Association that was quoted by

the Advisory Committee on the Microbiological Safety of Food (ACMSF, 1992). Gaze and Brown (1991) found that the D_{90} value for non-proteolytic *Clostridium botulinum* was 1.1 min, so that a 6*D* process would be equivalent to 7 min at 90 °C. However, in order to incorporate a safety margin ACMSF (1992) recommended that the *6D* process for psychrotrophic *Clostridium botulinum* should be equivalent to 10 min at 90 °C. The inclusion of the "safety margin" therefore implied the possibility of an actual D_{90} value for non-proteolytic *Clostridium botulinum* of 1.7 min at 90°C.

A thermal process equivalent to 10 min at 90°C will be more than sufficient to bring about the required degree of destruction for *Listeria monocytogenes* which does not form spores and which has relatively low D_{70} values of less than 0.3 min in various media including chicken, beef, carrot and reconstituted dried milks (El-Shenawy *et al*, 1989; Mackey *et al*, 1990; Gaze *et* al, 1989 and Boyle *et al* 1990).

Processes equivalent to 10 min at 90°C have come to be regarded as the benchmark for REPFEDs (ACMSF, 1992; AQIS, 1992; Betts, 1996; ECFF, 1996 and FAIR Concerted Action 1999) in which the storage temperature shall be below the minimum required for growth of proteolytic *Clostridium botulinum.* While the severity of the heat treatment in these processes is quantified (i.e. 10 min at 90°C, or its equivalent), the meaning of the phrase "extended durability" is less precise. For instance, although ACMSF (1992) and ECFF (1996) each differentiate between shelf-lives of less than 10 days and more than 10 days, neither specifies an upper limit to shelf-life. As a guide to commercial practice in Australia use-by dates of six to ten weeks from the date of production are likely to be the maximum recommended for refrigerated storage at ≤ 4°C. Some manufacturers of REPFEDs find that an upper limit of 10 weeks refrigerated shelf-life is insufficient for distribution and storage of their value-added perishable products, particularly when these are destined for export markets. Examples of products falling into this category include whole abalone, whole-shell mussels, whole salmon and salmon portions, and selected cheeses. It has been found in commercial trials (Warne, *unpublished.* See Section 3.3.1) that through use of strictly controlled heating and cooling profiles, processes sufficient to deliver 12-log reductions (rather than the recommended 6-log reductions) in the probability of survival of non-proteolytic *Clostridium botulinum* can be adopted and, so-called, "as fresh" quality can be maintained. Each of these processes is tailored to suit particular retort temperatures, fill weights, pack dimensions and initial product temperatures

and they (together with the associated technical support systems) are now subject to commercial licensing arrangements using DWC FoodTech's F_p-Hermetica™ (DWC FoodTech Pty. Ltd. Melbourne, Australia) thermal processing technology. The benefit of using a 12*D* cycle for REPFEDs, rather than the conventional 6*D* cycle, is that with respect to the target microorganism (i.e. non-proteolytic *Clostridium botulinum*) the thermal process is analogous to its shelf-stable counterpart (in which the target microorganism is proteolytic *Clostridium botulinum*). At probabilities of survival of the respective target microorganisms of ≤ 1 in 10^{12}, both REPFED and shelf-stable of products can be regarded as being "commercially sterile", provided the storage temperature of the former is at less than 10°C and the latter is less than approximately 45°C (to preclude germination and growth of thermophilic spore-formers that may have survived the thermal process). Under these circumstances the limit to the shelf- life of REPFEDs is no longer dictated by the risk of growth of non-proteolytic *Clostridium botulinum*. Rather, the determinant of shelf life is more likely to be the sensitivity of the product to quality changes during prolonged refrigerated storage and, in many instances, this is affected by the vacuum in the container (and therefore the oxygen content) at the time of sealing and/or the oxygen permeability of the packaging material.

The pathogenic spore-former *Bacillus cereus* is widely distributed in nature (ICMSF, 1996) and therefore it too should be considered a possible contaminant in refrigerator-stable and shelf-stable foods when the formulations include milk, rice, cereal products, vegetables, herbs, spices and other dried products. However, "its presence and incidence in/on fish is not well established" (ICMSF, 1996). This means that the thermal processes given REPFEDs may need to cope with the destruction of spores of psychrotrophic *Bacillus cereus* that are more heat resistant than those of non-proteolytic *Clostridium botulinum*. For instance, Gaillard *et al* (1998) showed that at a pH of 6.5 and an a_w of 1.00, in a citrate/phosphate buffer *Bacillus cereus* spores exhibited *D* values of 0.15, 2.39 and 63.39 min at temperatures of 105, 95 and 85°C, respectively. For comparative purposes, it has been shown (page 5) that a conservative (i.e. safe) reference D_{90} value for non-proteolytic *Clostridium botulinum* can be taken as 1.7 min at 90°C which approximately corresponds to a D_{95} value of 0.54 min for this microorganism. This means that *Bacillus cereus* spores with a D_{95} value of 2.39 min may have, of the order of, four or more (i.e. 2.39/0.54 or 4.4) times the heat resistance of non-proteolytic *Clostridium botulinum* spores. Therefore, it follows that a ther-

mal process designed to target spores of *Bacillus cereus* will need to be significantly more severe than one designed to bring about a comparable reduction in the population of non-proteolytic *Clostridium botulinum* spores. For instance with respect to non-proteolytic *Clostridium botulinum,* these data show that a 12*D* process (i.e. equivalent to 20 min at 90 °C) will bring about only 2 to 3 log reductions in the survivors of *Bacillus cereus* spores; whereas the *6D* process (i.e. equivalent to 10 min at 90°C) for REPFEDs which is recommended by ACMSF, (1992), AQIS (1992), Betts (1996), ECFF (1996) and FAIR Concerted Action (1999) will achieve little more than a single log reduction in the spore counts of *Bacillus cereus.*

Although caution suggests that it is appropriate to quantify the probability of survival of heat resistant *Bacillus cereus* spores, various authors (Carlin *et al.*, 2000; ICMSF, 1996 and Tatini, 2000) have noted that heat resistance, spore germination and the ability to produce toxin are all decreased at refrigeration temperatures. Carlin *et al* (2000) quote a range of D_{90} values for *Bacillus cereus* spores ranging from 0.8 to 1.5, 0.8 to 3.2 and 0.9 to 5.9 min for isolates with minimum growth temperatures of < 5, 5 to 10, and > 10°C, respectively. Extrapolation of these data highlights the importance of refrigeration temperatures for REPFEDs. For instance, in cases where storage temperatures were between 5 and 10°C, a process sufficient to effect a 6*D* reduction in *Bacillus cereus* spores would need to be equivalent to 19.2 (6 x 3.2) min at 90°C. However, if it were possible to maintain temperatures at less than 5°C, a process equivalent to 9 (6 x 1.5) min at 90°C would suffice. This means that a 6*D* process that targets non-proteolytic *Clostridium botulinum* (target F_p = 10 min) may also be appropriate for one targeting *Bacillus cereus* (target F_p = 9 min).

Whilst refrigerated storage temperatures are recommended and integral to the safety of REPFEDs, it may not be realistic to expect that they will be maintained throughout the chilled distribution chain. For this reason it is prudent to consider the impact of temperature abuse on the heat resistance of *Bacillus cereus* spores that may be present. Based on the heat resistances quoted by Carlin *et al* (2000) spores isolated following growth at > 10°C may be expected to have D_{90} values of up to 5.9 min, and this means that the corresponding 6*D* cycle would need to be equivalent to 35.4 min at 90°C which, in turn, is equivalent to around a 21*D* (35.4/1.7) cycle with respect to destruction of non-proteolytic *Clostridium botulinum.* Were a 12*D* cycle for this strain of *Bacillus cereus* desired, the proc-

ess would need to be equivalent to 70.8 min at 90°C. Processes of this magnitude can be considered extreme as they treat *Bacillus cereus* on a par with *Clostridium botulinum* as far as a potential health risk arising from under-processing is concerned, nonetheless they have been evaluated in development trials (Warne, *unpublished*) with DWC FoodTech's F_p-Hermetica™ system which holds an Australian Provisional Patent Application Number (2005903090). Despite the severity of these processes the sensory attributes of the finished products have been found consistent with "as fresh" quality and superior to that of their shelf-stable counterparts.

When establishing minimal heat processes it is important not to overlook instances where certain authors report maximum *D* values that are significantly higher than those observed by others. For instance, the *D* values quoted by Gaillard *et al* (1998) and Carlin *et al* (2000), (see pages 6 and 7, respectively) are less than the maximum values quoted by Dufrenne *et al* (1995). The latter authors quote *D* values for *Bacillus cereus* strains ranging from 2.8 min to 100 min, and from 4.6 min to 200 min for psychrotrophic and mesophilic strains, respectively. In these instances the lower *D* value are not the issue as they will not form the basis for specification of the minimum acceptable F_p values. Of potential concern though are D_{90} values of between 100 and 200 min, particularly the latter should the efficacy of chilled storage be questionable. Therefore, in order to ensure that the *D* values used for process selection are realistic and applicable to commercial situations, it is preferable to determine the heat resistance and the growth characteristics of isolates in the foods in question, rather than in laboratory media that, although easier to work with, may distort the results.

It is for reasons such as these that, when reviewing thermal processes for REPFEDs in which *Bacillus cereus* spores may be present, Carlin *et al* (2000) carried out a microbial risk assessment which included hazard identification and characterisation, exposure assessment and challenge testing in various food systems. Studies such as these should be regarded as a pivotal component of R&D programmes leading to the commercial manufacture and release of REPFEDs. One of the objectives of these exercises is to determine whether spores that might survive the thermal process are capable of germination *in vivo* and thereafter whether cell growth and toxin production can occur under the projected storage conditions. However, cell growth alone does not necessarily represent a

health risk for as noted by Gorris and Peck (1998) "high numbers of cells of *Bacillus cereus* are needed to pose a genuine safety hazard".

Commercial manufacturers of low-acid canned foods are satisfied if there is a sufficiently remote probability of pathogenic spore survival for there to be no significant associated public health risk arising from under-processing and an acceptable, albeit low, risk (that is, a commercial risk) of there being some non-pathogenic spoilage. The actual spoilage rate that constitutes an acceptable level of non-pathogenic spoilage is not clearly defined and, instead, reflects commercial experience. For instance, May and Archer (1998) indicate "levels of spoilage below one container in 50,000 are considered to be the minimum goal, if the spoilage is not due to a process deviation." In this instance, "spoilage" can be considered as arising from the "chance" survival of microorganisms, i.e. from under-processing. The likely reason for not tolerating spoilage at levels of one, or more, container(s) in 50,000 (other than from a process deviation) is that non-pathogenic spoilage rates of this magnitude at ambient temperatures would not be commercially viable. In this context, "spoilage" refers to non-pathogenic microbial activity arising from the survival of microorganisms following delivery of a standard process. It does not include spoilage due to post-process leaker contamination (PPLC), which may or may not be caused by pathogens.

In practice, Australian manufacturers of shelf-stable heat-processed foods typically aim to achieve levels of non-pathogenic microbial spoilage due to under-processing of no more than one to two containers in 100,000 units, and in most instances, levels of less than one to two per 1,000,000 containers would be the norm (M. Philp, *pers. comm.* and N. Highfield, *pers. comm. 2002*). While performance figures for under-processing spoilage levels with refrigerator stable heat-processed foods are difficult to obtain, there appears to be no sound reason why they should be tolerated at any higher frequencies than for their shelf-stable counterparts. In practice the obverse is more likely to be the case as one hurdle upon which microbial stability depends, i.e. chilled storage, is frequently compromised by poor control in distribution, display and in the home.

Irrespective of which target microorganisms may have been considered when designing a minimal thermal process for REPFEDs, a 6-log reduction in contamination levels will not be sufficient, unless the product is stored at temperatures of less than 10 °C in order to prevent growth of heat resistant strains of proteolytic *Clostridium botulinum.* Evidence indicates that, despite the health risks arising

from temperature abuse, correct storage temperatures are not always achieved. For instance, Doyle (1998) notes, "Temperature control in refrigeration units of retail outlets and home...is frequently unacceptable for perishable foods that rely solely or largely on refrigeration temperature to control food borne pathogens." Richardson (1999) states "Published and unpublished data obtained from surveys in Australia and overseas consistently show the retail cabinet as a weak link in the cold chain. This is particularly the case for chilled foods." This view is reinforced by Carlin *et al.,* (2000) who record that a survey of retail outlets in France found that for foods intended for storage below 8°C the mean temperature was 6.9 ± 3.5°C; whereas those foods intended for storage below 4 °C had a mean temperature of 5.7 ± 3.3°C. These authors also quote figures showing that in a survey of domestic refrigerator temperatures in the United Kingdom and France temperatures ≥ 8°C were recorded in 25% and 50% of cases, respectively. Further evidence of poor temperature control is provided by the Australian New Zealand Food Authority (ANZFA, 2001) who report the results of a survey in which the storage temperatures at the point of sale of 93 samples of commercial chilled noodles were measured. The data show that 78% of the samples were stored at less than the 5 °C (as recommended), while 19% and 2% were stored at between 6 and 8°C, and above 9°C, respectively. Projecting a realistic worst-case scenario therefore, it can be seen that based on these data, 2% of the samples were held at temperatures which were sufficient to support the growth of proteolytic *Clostridium botulinum* even though the thermal process would have had no effect on the spore population of this contaminant had it been present. The ANZFA survey also revealed that the Standard Plate Counts (SPCs) were between 10^6 and 10^8 cfu/g, between 10^8 and 10^9 cfu/g, and greater than 10^9 cfu/g, with 28%, 43% and 7% of the samples, respectively. Amongst the likely causes for the high counts were listed, inadequate cooking (i.e. under-processing), post-process contamination and inadequate control of storage temperature. Clearly, these articles underscore the importance of storage temperature in prevention of under-processing spoilage with REPFEDs.

The risks of botulism due to poor temperature control of a minimally processed product were illustrated in the United States in 1994 when the header in one trade journal noted "Two sickened by chowder botulism; maker recalls all lot codes" (Anon., 1994a). A more sanguine representation of the same incident recorded "Refrigerated soup recalled for re-labelling after case of botulism" (Anon.,

1994b). What re-labelling might do for the safety of the product was not made clear.

The difficulties that conscientious manufacturers and retailers face when supplying the REPFEDs food chain were exemplified by a California State Department of Health Services spokesman involved in this incident when he commented: "But you could put 'keep refrigerated' and 'perishable' labels on chowder or chicken or anything, and if someone takes it home, stores it in a cupboard for three weeks, notices that it smells and tastes bad, and still eats it - I don't know what kind of label is going to prevent that" (Anon., 1994a).

In this case, the manufacturer appeared to have taken reasonable care while developing the product, for it was noted (Anon., 1994a) that:

- The product had been coded for a 70 day refrigerated shelf-life and had been shelf-life tested for 170 days under refrigeration.
- The product was labelled "keep refrigerated", but there was no warning that the product (clam chowder) was perishable.

1.1.3 Spoilage caused by post-process leaker contamination (PPLC)

1.1.3.1 The incidence of PPLC

Contemporary data relating to the overall incidence of spoilage caused by PPLC of commercially heat-processed shelf-stable foods are rarely published, however, there are numerous reports which, despite having been written 20 to 30 years ago, are of more than historical interest. This reference material is particularly relevant when comparing the performance of hermetic seals on metal cans (which rely on well proven and robust technology) with those of their more vulnerable counterparts of glass and flexible containers (some of which rely on relatively new, more demanding, technology). For instance, Put *et al.*, (1972) cite details of individual "cases of food poisoning (which) are associated in the literature with post-process re-infection of canned foods, and these...include typhoid and staphylococcal food poisoning and intoxication due to *Clostridium botulinum*". These authors note, "In practice reinfection is frequently reported in apparently well constructed cans with high quality double seams and side seams which cannot be shown to leak by any of the traditional test methods." Therefore, given that PPLC has been shown to occur in metal cans that appear to be of "commercial"

quality, it can be expected that the less robust hermetic seals on glass and flexible containers will more vulnerable to PPLC arising from one or more or poor application, mechanical damage and or poor post-process hygiene and sanitation.

Odlaug and Pflug (1978) completed an industry survey of retort cooling water in 17 canneries in the US and found that approximately 1% of commercial cans had constant leaks through the double seams. These authors had adopted the terminology that had been used by Put *et al.,* (1972) which defined "leaks" as "hermetic seal failures that permitted the escape of 0.01 mL of air at normal temperature and pressure (NTP) in 15 s." Furthermore, Odlaug and Pflug (1978) made clear the distinction between the estimated 1% of cans that leak and the frequency of microbial spoilage caused by PPLC. It was estimated that the combination of 1% leaking cans (as defined) and retort cooling water contamination levels of one anaerobic spore/mL and one anaerobic spore/10mL would produce spoilage rates of 0.2 and 0.02 cans/100,000 respectively. It was concluded that if it can be "assumed that only a fraction of the anaerobic spores are *Clostridium botulinum,* the probability of leaking in a *Clostridium botulinum* spore would be less than 2×10^{-6} to 2×10^{-7}."

On this basis therefore Odlaug and Pflug (1978) estimated that the probability of detection of a single spore of *Clostridium botulinum* in a commercially manufactured low-acid canned food product would be, of the order of 5×10^{3} to 5×10^{4} times that of the probability of a single spore surviving a thermal process in which the product had received a 12*D* process. This comparative analysis suggests that, notwithstanding the efforts to ensure that the probability of *Clostridium botulinum* surviving a thermal process remains commercially acceptable (i.e. $\leq 1/10^{12}$), a far greater health risk arises due to PPLC.

In their discussion of spoilage caused by leakage, Odlaug and Pflug (1978) refer to Davidson *et al.,* (1977) who had found that the average incidence of swollen cans detected at the supermarket level was around 20 per 100,000. Of these 85% were estimated to be swollen because of microbial spoilage, which translates to an overall spoilage rate caused by PPLC of around 17 cans/100,000. This figure is in general agreement with that arrived at by Odlaug and Pflug (1978) who estimate that spoilage rates of around 20 cans/100,000 would arise when commercial cans (with a base leakage rate of 1%) were cooled in water containing 100 vegetative cells/mL. Microbial contamination levels of this order are not inconsistent with current GMP which requires that retort cooling water be

chlorinated, or otherwise treated, so that total counts will be < 100 cfu/mL (Codex Alimentarius, 1995).

Interest in the incidence of PPLC through can double seams increased following botulism outbreaks in 1978 and 1982 in which six people were affected and three died after consumption of canned Alaskan salmon. In response to their concerns, the USFDA convened a technical meeting between industry representatives, regulators and academia to review the potential health risks arising from use of "defective containers". The group report (NFPA/CMI, 1984) concluded that on the evidence gained from review of data relating to botulism outbreaks and the presence of *Clostridium botulinum* or its toxin in commercially canned foods over a 42 year period, the "vast majority of the problems have been due to underprocessing rather than to container leakage." Interestingly, NFPA/CMI's final report records Odlaug and Pflug (1978) as concluding, "the likelihood of post-process leakage (contamination) from *Clostridium botulinum* in canned foods is between 10^{-7} and 10^{-10}, based on probability considerations." It is unclear how NFPA/CMI arrived at probabilities of post-process leakage from *Clostridium botulinum* which were, at their "best", one thousand times lower than those estimated by Odlaug and Pflug (and quoted in the preceding paragraphs). Nevertheless, the NFPA/CMI (1984) document extrapolates further and factors in a 1% probability that consumers would eat spoiled food and by these means they were able to conclude, "the probability of human botulism from leakage increases to approximately 10^{-9} to 10^{-10}."

Verifiable Australian data relating to the incidence of PPLC in canned foods are not available from packaging materials suppliers, or food manufacturers, or from any central recording agency and for this reason most of the information that can be gathered is anecdotal. This does not appear to be due to over-zealous commercial-in-confidence practices but, rather, a reflection of the difficulty in setting up and monitoring reliable surveillance networks to gather and interpret data. Also, the absence of relevant data is partially attributable to the *ad hoc* nature of data collection by individual manufacturers and/or the manner in which suspect spoiled cans frequently are returned from the trade for diagnosis only after they have been opened and exposed to re-contamination. Under these circumstances, there is no reason to believe that the Australian experience with the incidence of leaking cans would not mirror that found in the United States. For instance C. Sabie (*Pers. comm.* 2002) reports "If...the US canning industry have

one...(leaking can)...in 10,000 (cans of sound product)...we feel comfortable with our operation". Therefore, it is likely that when Murrell (1986) in his review of the microbiological safety of food observed that there had been no incidence of (canned) food poisoning recorded in Australia, he would not have been implying that no cans had leaked over the period to which he referred. On the contrary, Murrell's concern regarding the implications of seam leakage on the safety of canned food was highlighted when he noted the inability to relate the results of traditional leak test procedures (dye tests, vacuum tests, pressures tests and helium detection test) with those of challenge tests (Biotests).

Although time-consuming (and therefore inapplicable as in-line test procedures) Biotests can be used to evaluate hermetic seals in most forms of packaging used for heat-processed foods (i.e. cans, glass, flexibles and semi-flexibles). The common objective of these tests is to challenge the integrity of the seal while it is exposed to high levels (10^6 to 10^8 cfu/mL) of pure cultures of contaminants, often with simultaneous mechanical abuse to the seal area. These testing regimes are therefore more severe than might reasonably be expected "in the trade" and in practice they produce leaker spoilage rates that would never be tolerated with commercial product. Nonetheless, it shall be shown (see Section 3.4) that Biotests may be developed which allow differentiation between leakage rates in cans, and glass sealed with Trivac, twist and push-on twist-off (PT) caps and various forms of heat seals on barrier trays and form-fill-seal (FFS) pouches. It is for this reason that Biotests may be of value when developing new packaging systems and/or processing conditions, or investigating incidences of PPLC amongst commercial stock in which there is no obvious reason for hermetic seal failure.

Hazzard and Murrell (1989) drew attention to the safety implications of post-process leaker contamination (pin-hole leakage) while referring to the botulism incidents with canned salmon and unpublished data linking four cases of botulism in Australia with leakage through seams of Taiwanese mushrooms. Evidence from the retail trade of poor seam quality was gathered by Warne *et al.,* (1985) when they examined 84 cans of mushrooms from the same Taiwanese manufacturer whose products had been incriminated in the botulism incident in canned mushrooms. These authors found that 22% of the seams at the can maker's end and 14% of those at the canner's end failed to comply with the, then, Draft Australian Standard (Anon., 1984) for minimum recommended overlap; it was found

also that 26% of the juncture ratings at the canner's end were below the recommended minimum value and 8% of the samples failed a leak test. While these data did not prove that the outbreak in question had been caused by PPLC, there was sufficient circumstantial evidence for the Victorian Health Department to request that stocks be removed from all retail outlets throughout the State. As an adjunct to the survey of imported canned mushrooms, Warne and Brown (1985) carried out similar analyses of seam quality on 280 locally produced canned food items. These data showed that failure to comply with the draft standard for various seam attributes ranged from zero to 7% at the canner's end and from zero to 5% at the can maker's end. Among the conclusions drawn from these surveys of samples collected from the retail trade, Warne and Brown (1985) noted, "some retailers either disregard or are unaware of the dangers in selling blown or damaged cans." The distinction has previously been made between leakage and spoilage and there is evidence that not all leaking cans will spoil. The incidence of spoilage will be less in cans from production lines which have been engineered to minimise opportunities to damage seams and on which sound post-process hygiene and sanitation procedures are practiced, than it will be in cans from those lines where there is no such care. Again, verifiable data relating to the actual spoilage rates (as distinct from "benign" leakage rates) are difficult to obtain, although the absence of any spoiled cans (assessed by the absence of vacuum, flippers or swollen cans) in 100,000 to 1,000,000 units is not unusual for some Australian manufacturers.

Survey data and publications aside, it is known (M. Philp, *pers comm.*; N. Highfield, *pers comm.* 2002) that technical personnel in the canned food and the packaging industries would find intolerable microbial spoilage levels at 1% of production.

In the years since Put *et al.,* (1972) published their treatise, metal cans with soldered side seams have given way to metal cans in which the side seams are welded and/or to composite cans with plastic bodies and metal or heat sealed ends. Glass and heat sealable flexible materials have also captured market share from cans with soldered side seams. With soldered side seams the juncture was regarded as "a critical area of the double seam, due to the two additional thicknesses of metal at that point" whereas with "welded side seam cans, the thickness of the weld is only slightly greater than the thickness of the body metal" (Gavin and Weddig, 1995). This has meant that the juncture of the side seam and

the double seam on welded cans is less vulnerable to PPLC than it formerly was on the older style soldered cans. Despite these advances in can making technology, many industry sources (C. Sabie, *pers. comm.*; K. Richardson, *pers. comm.* and N. Highfield, *pers. comm.* 2002) maintain that trade spoilage of commercially canned products caused by PPLC remains more prevalent than pre-processing spoilage, or spoilage caused by under-processing. This view is supported by May (2000) who contends that failure from commercial processes "will include failure due to under processing, incorrect storage conditions and container failure (the last probably being the main cause of spoilage)". Ito (*Pers. comm.* 2002) believes that, notwithstanding the absence of reliable data, the experience of the National Food Processing Authority (NFPA) is that the development of the two piece metal can has been responsible for a reduction in the incidence of post-process leaker contamination. NFPA's view with respect to the loss of hermetic seals with plastic containers is that it is "not so much failure of the heat seal as physical damage of containers as the main cause of problems (PPLC)." (K. Ito, *pers. comm.* 2002).

1.1.3.2 Factors affecting the incidence PPLC in plastic and glass packaging materials

The difficulties experienced with data collection and analysis with metal cans are even more pronounced when attempting to estimate the incidence of PPLC (and spoilage) of products packed in glass and flexible and semi-flexible pouches and trays. However, several factors suggest that these systems are more prone to hermetic seal failure than are traditional double seams on two-piece cans and three-piece welded cans.

1. Closure systems for glass lack the mechanical strength that is provided by the double seam on metal cans. For instance, as noted by Food Science Australia and Warne (2002) the hermetic seal on, so-called, twist caps and PT closures that are widely used with pasteurised and sterilised products packed in glass rely on maintenance, at all times, of a positive pressure differential across the seal. This means that at all stages throughout the thermal process, after completion of cooling and throughout distribution and storage, the pressure inside the sealed container must be less than that in the surrounding environment. In practice this relationship is maintained by a combination of hot filling and/or vacuum sealing, followed by over-pressure retorting for those products that are heat treated at temperatures above 100 °C. For those products that are pasteurised, heat treat-

ments with or without over-pressure are sufficient. No matter which processing regime is adopted, the barrier to PPLC in hermetically sealed glass containers remains the interface between the plastisol sealing compound and the glass sealing surface. Such a system, relying as it does on a positive pressure differential to maintain the hermetic seal, lacks the mechanical strength that is provided by the interlocking double seam formed by the body hook and the cover hook on metal cans.

2. The hermetic seal with flexible and semi-flexible packaging materials relies on fusion of two interfacing polymer layers and, not unlike their glass counterparts, GMP requires that these systems rely on maintenance of a positive pressure differential across the seal. Although it has been shown that there are instances when heat seals will not fail despite the pack containing a higher internal pressure than the surrounding environment, this is not a sound practice and it should be avoided. At the worst, lack of attention to the pressure differentials will cause immediate pack failure (i.e. the pack will burst); however, also invidious are those instances where the seal is compromised so that micro-leaks occur without there being overt signs of seal failure.

3. Flexible and semi-flexible packaging materials are more prone to mechanical damage and puncturing through mishandling than are metal cans.

4. When sealing plastics and foils care must be exercised to prevent contamination of the sealing surface, as it is known that food particles and/or entrapped fats and moisture can compromise seal integrity. To avoid these seal imperfections some food manufacturers install high-speed cameras to detect irregular images of the seal that are caused by foreign matter contamination. However, at between Aus$30,000 and Aus$100,000/lane these systems tend to be prohibitively expensive for some smaller operators who, having installed a simple processing line at, relatively, little capital cost, do not understand and/or underestimate the need to protect the integrity of the hermetic seal. While "vision systems" are effective, common disincentives to their continued use are that they require frequent tuning and that trained operators need to understand the reason for the rejection of individual containers. The combination of poorly maintained equipment and poorly trained operators is likely to lead to the machine being turned off.

Recognising the propensity for, and health risks associated with, heat seal contamination, other non-destructive tests have been developed to detect these critical defects. For example, one such system utilising ultrasonic imaging has proved effective in limited trials (with 30 samples) for the detection of channel defects between 9.5 and 15 μm diameter and strand inclusions measuring from 20 to 60 μm in diameter (Ozguler *et al.,* 1998). However, because of the sensitivity of the equipment and the precision required to scan the critical area of test samples, it is unlikely that in its present form this technique realistically can be transferred to commercial applications across the food industry.

Because of the inherent risks in relying on inspection to cull packs with unsatisfactory seals from production lines, and the expense of rejecting more packs than is necessary (due to the over-sensitivity of detection devices) some manufacturers choose instead to concentrate their efforts on process improvement. The rationale in these instances is to prevent the formation of faulty seals, rather than install equipment that will remove them. The usual approach in these circumstances is to work with filling equipment to ensure that filling is clean and heat seal areas do not become contaminated.

Therefore, given that packaging systems other than metal cans are being used with increasing frequency, in the shelf-stable and the minimally processed food sectors, it can be expected that there will be increased risks of spoilage caused by PPLC.

1.1.3.3 The use of over-pressure for retorting products in glass, flexible and semi-flexible packaging materials

Because glass, flexible and semi-flexible packaging materials are more prone to PPLC than metal cans, the conventional guidelines of GMP that were applicable to retorting techniques in metal cans are no longer sufficient for safety. For this reason GMP has evolved so that it now incorporates procedures for control, throughout the entire retort cycle, of pressure differentials across the relatively vulnerable alternate forms of hermetic seals. For instance, May (2001) advises that typical over-pressures for plastic trays, pouches and plastic cans should be between 10 to 20 kPa, 10 to 30 kPa and 40 to 50 kPa, respectively. In all cases, the pressures cited imply that the pressure in the retort will exceed the pressure in the sealed container by the amounts shown. By contrast, control of pressure differentials in metal cans (other than in the early stages of cooling product in

steam-fed retorts) had previously been a relatively minor issue. The reason for this is that metal cans tolerate substantial internal pressures without damaging ("peaking") their ends. For instance, one Australian manufacturer of food and beverage cans advises that conventional 73 mm diameter food cans typically will tolerate internal pressures that are of the order 200 to 240 kPa (2.0 to 2.4 bar) higher than the external pressure, before peaking (N. Highfield, *pers. comm.* 2002). However, should internal container pressures exceed external pressures by comparable amounts while processing glass, flexible and semi-flexible systems, the hermetic seal will immediately fail and the conduit for PPLC will be established.

In response to these circumstances, prudent manufacturers are aware of, and treat as critical, those factors affecting the internal pressure within heated sealed containers. For those manufacturers using glass, flexible and semi-flexible packaging, and who are aware of the risks of PPLC this has not been an issue. For such companies (represented by Heinz Wattie's, Campbell's Soup, Golden Circle, Simplot Australia, Nestlé and others) it is now common practice to incorporate in their HACCP plans, or other food safety plans, procedures which regulate each, or all, of fill temperature, vacuum at sealing and headspace.

Appropriate HACCP plans will therefore implement procedures which ensure that pressure differentials (ΔP) between the inside of the hermetically sealed container and the processing vessel will be kept to a minimum (e.g. from 10 to 50 kPa, depending on the packaging system) so that at all times the internal pressure in the container will be less than the external pressure in the retort. Although maximum recommended pressure differentials are rarely, if ever, provided by the packing material suppliers, glass closure systems with excessive external pressure will cause, so-called, compound cut-through (Food Science Australia and Warne, 2002). This is the condition in glass containers when excessive retort pressure causes the glass finish to totally penetrate the plastisol gasket so that bare metal is in contact with the top of the glass sealing surface. While the pressure differentials giving rise to compound cut-through on glass closures are analogous to those causing "panelling" or crushing of the sidewall of cans, they are, however, far more likely to cause loss of the hermetic seal and PPLC than they will when applied to cans. Conversely, closure ejection (when the closure is forced from the finish of the jar by excessive internal pressure in the container) has the same causes as can peaking (distortion of the can end, particularly

around the double seam, caused by excessive internal pressure). Closure ejection is potentially dangerous because the hermetic seal can be lost (even temporarily) without producing other overt signs of seal failure.

May (1997a) notes that protection of hermetic seals through control of pressure differentials is important to minimise opportunities for spoilage arising from PPLC, however, it is also recognised (Codex Alimentarius, 1995; Hersom and Hulland, 1980; Put *et al.*, 1972) that manufacturers need to control the following aspects of production;

- the microbiological quality of the cooling water,
- the manner in which wet containers are handled after their removal from the retort or other cooking vessel, and
- the hygienic status of the processing lines,

It is for these reasons that GMP guidelines and related codes of practice require that retort (and other) cooling water and water that contacts containers after delivery of a shelf-stable process is of an acceptable microbiological quality. The USFDA's Guide to Inspections of Low Acid Canned Food Manufacturers Part 2 (Anon., 1997) states "cooling water should be chlorinated or otherwise adequately treated to kill organisms which may be found in the water so that if water leaks through the seam it will not carry any organisms into the can." As noted previously, Codex Alimentarius (1995) recommend that retort cooling water be chlorinated, or otherwise treated, so that total counts will be < 100 cfu/mL.

The Codex Alimentarius (1995) recommendations apply specifically to shelf-stable foods, however there is no reason why they ought not be extended to include REPFEDs. This is particularly so in those cases where the shelf life and/or the storage temperature of the refrigerated product is, or may be, sufficient for the growth of psychrotrophic microorganisms that gain entry to the pack as a results of PPLC. Hence, in the many texts and documents relating to minimal processing, the omission of any reference to the need for microbiologically sound cooling water appears an oversight. Therefore, the case for specification and control of the microbiological quality of cooling water ought be reinforced by the knowledge that some pathogens are able to grow and produce toxin within the recommended refrigerated shelf life of many REPFEDs.

For instance, *Listeria monocytogenes* has been reported to grow to 10^6cfu/g in two weeks at 3 °C which is well within the recommended shelf-life of many REPFEDs (Mossel and Struijk, 1991). Peck (1997) reported the time required to produce toxin in various foods inoculated with 1 to 100 spores/g of non-proteolytic *Clostridium botulinum.* At temperatures of 4, 8, and 12°C toxin was detected in 18, 8 and 6 days, respectively, in cod; in salmon, toxin was detected in 21, 6 and 3 days, respectively, while in turkey no toxin was detected after storage at 4°C but at 8 and 12°C toxin was detected after 8 and 5 days, respectively. Peck (1997) also records the risks of recontamination and toxin production in "a wide range" of cooked vegetables. For instance, "toxin production from cooked cauliflower inoculated with 10^3 spores/g of non-proteolytic *Clostridium botulinum* was detected after 21 d at 5°C, after 15 d at 8°C and after 4 d at 16°C." Following inoculation at 10 cfu/mL production of *Bacillus cereus* diarrhoeal toxin has been reported in minced meat and lasagna within 24, 12 and 2 d when storage was at 4, 7 and 17 °C, respectively (van Netten *et al*, 1990). These data indicate that it is realistic to acknowledge that in cases where PPLC occurs with refrigerated minimally heat-processed products, the risks of spoilage and toxin production by pathogenic microorganisms ought not be ignored. Therefore, as with shelf-stable foods, the safety of REPFEDs depends on the integrity of the hermetic seals that act as barriers to PPLC.

The foregoing discussion has reviewed the mechanisms of three modes of food spoilage of heat-processed shelf-stable and refrigerator-stable foods. This establishes a reference framework against which other factors affecting the safety of thermally processed products can be considered and these shall be considered as follows:

- Section 1.2 includes a review of the heat resistance characteristics of the target microorganisms with particular reference to *Clostridium botulinum.*
- Section 1.3 reviews techniques for validation of temperature distribution and process evaluation in retorts and other processing vessels.
- Section 1.4 compares two methods of calculating process F values.
- Section 1.5 discusses procedures for selecting and specifying minimum target F_p values.

- Section 1.6 considers evidence of non-compliance with Good Manufacturing Practice in manufacture of heat processed foods.

1.2 The heat resistance of target microorganisms and the influence of inactivation kinetics on calculation of F values

Despite non-linear inactivation kinetics being reported by Esty and Meyer (1922) in their original work that led to the establishment of the minimum process requirements for the destruction of proteolytic *Clostridium botulinum* spores in low-acid canned foods, the traditional means that are widely used to calculate target F values for thermal processes assume linear first-order reactions. The reasons for maintaining this approach (in the face of evidence to the contrary) reflects both its practicality (as thermal processing history shows that the assumptions have not lead to botulism caused by under-processing) and its simplicity. The simplicity derives from the use of the following expression to calculate target F values:

$$F = D(\log N_o - \log N_S)$$

In this equation the constant decimal reduction time *D* is obtained from the linear semi-log plot of the survivor curve, the initial spore load is designated N_o and the spore load of survivors after exposure to heat at constant temperature is designated N_S.

When sterilising low-acid canned foods the reference temperature, by convention, is 121.1°C and the *Z* value is 10 C° and, in these instances, the F value that is calculated is referred to as an F_o value. However, not all heat treatments are based on these reference values. For instance, in acid products, the heat resistance of the target microorganisms tends to be lower than in low-acid products and therefore the reference temperatures are usually quoted at temperatures of less than 121.1°C. In such circumstances, the reference temperatures and *Z* values are likely to be 100°C and 9 C°, 93.3°C and 8.3 C°, or 80.0°C and 9 C°, respectively, whereas with REPFEDs the reference temperature is 90°C and the *Z* value is between 7 and 10 C°. (AQIS, 1992; Food Science Australia and Warne, 2002; ~~NFPA Gaze, 19921968~~).

The assumption that the thermal destruction of bacterial contaminants can be accurately described by first-order kinetics means that equal proportions of surviving cells die in consecutive constant intervals of time, and this in turn provides

the basis for calculating the 12*D* process or the "botulinum cook". GMP assumes that initial loads (N_o) will be of the order of 1 spore/g, final loads (N_S) will be no more than one spore in 10^{12} g (i.e. one spore in a million tonnes of product), and that the $D_{121.1}$ value for the most heat resistant spores of proteolytic *Clostridium botulinum* is 0.23 min (Hazzard and Murrell, 1989). Therefore, the minimum time (F) required to achieve commercial sterility (i.e. the so-called 12*D* process) can be calculated as;

$$F = 0.23 (\log 1 - \log 10^{-12})$$

$$= 0.23 \times 12$$

$$= 2.8 \text{ min.}$$

Stumbo (1973) and Hersom and Hulland, (1980) quote $D_{121.1}$ values of 0.2 min and 0.21 min, respectively for spores of proteolytic *Clostridium botulinum*, and this means that the corresponding 12*D* processes would be 2.4 min and 2.5 min. Showing extra caution, May and Archer (1998) round the minimum target F_o value for low-acid canned foods preserved by heat to 3 min.

Russell (1982) considers that the concept of a linear semi-logarithmic survival curve for *Clostridium botulinum* (and other microorganisms) is an over-simplification and this view is supported by Peleg and Cole (1998). These authors believe that it is more accurate to consider the actual relationship describing the plot of survival numbers against time of exposure to lethal heat as exhibiting a non-linear (or "slightly curved") order of death. One implication of not maintaining a linear semi-logarithmic order of death is that the decimal reduction time (the *D* value) changes as thermal destruction of the target population (of a pure culture) proceeds. In cases where the curve slopes down (i.e. is convex) the heat resistance of the surviving population decreases as destruction proceeds; whereas should the curve slope up (i.e. is concave) then heat resistance increases. Peleg and Cole (1998), and Russell (1982) consider that it is incorrect to ascribe differences in heat resistance solely to characteristics of the substrate in which the culture was grown (such as pH, water activity, the presence of modified atmospheres and the presence or absence of nutritional and inhibitory substances), or to the age of the culture, or to other experimental artefacts. The alternate view is that the characteristics of the survival curve reflect a distribution of heat resistances across different microorganisms in the population, i.e. some microorgan-

isms are killed before others. In this manner, Peleg and Cole (1998) propose "the survival curve is the cumulative form of a temporal distribution of lethal events".

In a practical sense, there are several implications of non-linear (rather than linear) semi logarithmic survival curves presenting a more accurate description of bacterial resistance to heat.

1. Regulations, and much of the elementary theory underpinning basic thermal process calculations, do not reflect the evidence that some bacteria under test conditions exhibit non-linear, semi-logarithmic survival curves. This means there are contradictions in maintaining a view that all microorganisms exhibit linear survival curves while simultaneously mandating that thermal processes must be delivered as a continuum because F values from separate thermal processes are not cumulative. The notion of non-cumulative F values implies, for instance, that a 12*D* cycle for *Clostridium botulinum* may only be delivered as a single cycle; it cannot be delivered as, say, two separate 6*D* cycles, or one 4*D* cycle followed by a separate 8*D* cycle. It is regarded as GMP that manufacturers deliver their entire target F values in a single continuous process.

In certain circumstances, exceptions have been made by some regulatory authorities (e.g. USFDA, AQIS and the New Zealand Food Safety Authority) to the prohibition (for regulatory purposes) of all non-continuous processes and this is a consequence of there now being recognised mathematical procedures for determining F values in cases of short-term interruptions (or deviations) to scheduled processes. However, while the mathematical procedures involved in calculating the sterilising effect of various component parts of an interrupted process are, relatively, straightforward for the end-user (largely as a result of computer analysis) none of these approaches take into account the possibility that sub-lethal heat treatments may alter the underlying heat resistance of the target microorganisms. This is because the calculations concentrate solely on processing parameters (retort temperature, processing time, initial product temperature, come-up-time etc.) and the product's heating parameters (thermal diffusivity, and f and j values) which are specific to the product and the containers in which they are being processed, while ignoring changes that may occur to the inherent heat resistance of the target microorganisms at sub-lethal temperatures. Appleyard and Gaze (1993) describe sub-lethal processes as being those caused by slow heating of product in large vessels, or by extended heating and holding times. Etoa and Michiels (1998) cite an example of a sub-lethal process of 63 °C for 60 min

which increased the $D_{121.1}$ value of spores of *Bacillus stearothermophilus* from 4.31 to 6.50 min. In this instance a 50% increase in heat resistance resulted from a delay, which could well be replicated by the commercial operating conditions in many food processing establishments.

The distinction between short-term and long-term interruptions is not defined clearly and usually relies on sound (but cautious) judgement based on experience. As a guide, it is suggested short-term interruptions should be those in which the process can be considered continuous and therefore the F values in each part of the process cumulative. Short-term interruptions might therefore be characterised as those events in which the core product temperatures at the SHP of the containers do not fall below those at which the lethal rate of destruction is less than $1/100^{th}$ or $1/1000^{th}$ of that at the particular reference temperature used for calculating the F value of the process. This corresponds to a lowering of the core temperature by two to three times the Z value below the reference temperature. According to this approach the core temperature in a low-acid canned food during a short-term interruption should not fall below 101.1°C for a fall in temperature equivalent to two Z values (i.e. [121.1 - 2 x 10] C°, where Z = 10 C° and the reference temperature = 121.1°C) or 91.1°C for a fall in temperature equivalent to three Z values. At these temperatures the lethal rate (i.e. the rate of thermal destruction of microorganisms relative to that at a specified reference temperature at which is taken to be unity) would be 0.01 and 0.001, respectively. In cases where the core temperature falls by more than three Z values, it is suggested that the interruption should be considered long-term and the entire process recommenced. Also to be remembered in cases of interrupted processes are the potential effects on the heating rates caused by changes in the nature of the product, as for example might occur when products thicken as a result of starch gelatinization.

In Australia and New Zealand, the mathematical procedures used to calculate F values in deviant processes include Board and Steele's (1978) version of the original Gillespy Method (1951) and more recently FMC FoodTech's NumeriCal Method© (FMC Technologies Inc., Madera, California) and DWC FoodTech's Method (DWC FoodTech Pty. Ltd. Melbourne, Australia. See section 2.1.2). Each of these methods can be used to estimate the actual F values delivered by "deviant cycles" or non-scheduled processes (NSPs) and they all rely on established mathematics and modelling techniques that are derived from primary heat pene-

tration data. The common objective of these methods is to project accurately product temperatures at the slowest heating point (SHP) in the container whilst it is being heated (and in some instances cooled). Once product temperatures are known, lethality (L) can be calculated via the equation shown below which describes the relationship between temperature and the relative rate of destruction of target microorganisms.

$$L = \text{Log}^{-1} (T - T_r)/Z$$

$$= 10^{(T - Tr)/z}$$

where T = product temperature

T_r = reference temperature

z = number of degrees required to bring about a tenfold change in the decimal reduction time (D)

Therefore, while the mathematical basis for calculating lethality in deviant processes may be sound, there are some inconsistencies in use of the heat resistance data upon which F values are determined and the magnitude of bacterial destruction brought about by thermal processes is calculated. Only linear (and overly simplistic) interpretations of semi-logarithmic survival curves (which yield constant *D* values) can be used to predicate the concept that, when interruptions are short-term, F values are cumulative. However, given evidence that thermal destruction is characterised by non-linear semi-logarithmic survival curves (in which the *D* values for the target microorganisms are not constant) thermal processes in which there are short-term interruptions ought not to be considered cumulative.

The relationship between the temperature and the method of heating also affects calculation of *D* values. The usual procedure for determining the *D* values of target microorganisms is to subject pure cultures to an isothermal treatment (i.e. constant temperature) in a specified heating medium. Once the *D* value has been determined, the heat resistance at other temperatures can then be computed using the lethality equation shown above, and this in turn enables calculation of the process F value using the following equation;

$$F = \Delta t \sum 10^{(T - Tr)/z}$$

$$= \Delta t \sum L$$

where,

Δt = is the time interval between measurements

T = is the product temperature at time t

T_r = is the reference temperature, which for low-acid canned foods is 121.1°C and for REPFEDS is 90°C

Z = which for low-acid canned foods is 10 C° and for REPFEDS is, typically, between 7 and 10 C°. Therefore, the value of Z that is selected will affect the value of F

In a commercial environment however, such as when heating packaged food placed on tray dividers in a retort, there are heating lags at the slowest heating point of the container. This means that the heating conditions are non-isothermal and in these situations, it is possible "to determine the inactivation parameters under dynamic conditions" (Carlin *et al.*, 2000). There are several advantages associated with this mode of heating and these include the ability to gain more information in a single experiment (because of the ease of replication during a single trial); lag times are accounted for as all temperatures are recorded at the slowest heating point and labour costs are reduced (Carlin *et al.,* 2000).

Carlin *et al.,* (2000) also report that the differences between *D* values determined via isothermal and non-isothermal procedures are not significantly different. However, these authors point out that regression analysis of data from non-isothermal trials can introduce errors when the survival curve deviates from linearity because of shoulders at the start, or tails at the completion, of the heating process. Some of these difficulties are overcome when interpreting the data in the manner described by Peleg and Cole (1998) according to which "the survival curve is the cumulative form of a temporal distribution of lethal events....Because there is a spectrum of heat resistances in the population – some organisms are destroyed sooner, or later, than others – the shape of the survival curve is deter-

mined by its distribution properties." In this manner the representation of the distribution of the thermal resistance, can be described as a cumulative form of the Weibull distribution. Because the Weibull model more accurately reflects published data on the lethal effect of heat than those methods which assume that all cells or spores in a population have identical heat resistance, it provides a superior means of predicting survivors (of a heat treatment). It is for this reason that the Weibull model can be used to provide data for quantitative microbial risk assessment.

2. Whereas GMP requires that shelf-stable, low-acid canned foods will receive at least a 12*D* process with respect to the destruction of proteolytic *Clostridium botulinum*, it is conceivable that there will be fewer decimal reductions in instances where the semi-logarithmic survival curve is convex. For instance, Anderson *et al.,* (1996) conclude that their work "predicts that the actual log reduction of *Clostridium botulinum* after heating at 121°C for 3 min would be closer to 7 logs." Notwithstanding that the reference temperature quoted by these authors was 121°C rather than 121.1°C, it follows that a "botulinum cook" will deliver a probability of proteolytic *Clostridium botulinum* spore survival of one in 10 million (or one in 10^7) rather than the target of one in one million million (or one in 10^{12}). This means that the errors flowing from an assumption of a linear semi-logarithmic survival curve might cause an increase in the probability of *Clostridium botulinum* spore survival by a factor of 100,000.

It is because of projections such as these that the relation between the theory and practice of thermal process calculation warrants review. This is not to say that the 12*D* model is unsafe - the absence of botulism in the trade caused by under-processing suggests otherwise. Rather it suggests that not only are twelve decimal reductions of *Clostridium botulinum* not attainable (unless minimum target F_o values are increased beyond the GMP guideline values of 2.4 to 2.8 min), but also they are not necessary.

3. Another issue arising from adherence to a linear semi-logarithmic survival curve interpretation of heat resistance is that in the case of *Clostridium botulinum* it has not been shown (nor is it ever likely to be shown) to apply over 12 consecutive logarithmic cycles. Peleg and Cole (1998*)* point out that thermal destruction data rarely covers more than five or six orders of magnitude. They therefore question the validity of projecting constant thermal destruction rates over a further

six or seven orders of magnitude as is necessary to achieve a, so-called, 12*D* cycle.

4. Given that "there is a growing number of published observations that...(the thermal destruction curve)...is a non-linear relationship" (Peleg and Cole, 1998) the common approach of nominating a single value for the decimal reduction time (*D*) that should be used in the following equation to determine target F values, becomes questionable

$$F = D(\log N_o - \log N_S)$$

Because of the variation that will occur with *D* values, it is appropriate to recognise that there may be a range of target F values, rather than a single F value, when specifying a thermal process. In commercial practice, most manufacturers make allowances for these variations by selecting *D* values that, they feel, represent worst-case conditions for each of the target microorganisms, i.e. they choose the highest *D* values.

What is less justifiable however is the misplaced confidence with which some processors base calculations of target F values when using *D* values that are quoted to the second (and sometimes third) decimal places. Given the manner in which *D* values are determined; the different media in which the microorganisms are cultured, heated and recovered after heat treatment; the errors in enumeration of survivors, and the non-linearity of the thermal destruction curves, it is unrealistic to quote *D* values (and more importantly the associated F values) beyond the first decimal place.

The tendency to be over-specific (when quoting *D* values for calculation of target F values) portrays a misunderstanding of the natural variability that is involved when heating biological materials in different food systems and/or an overly simplistic understanding of what the term "F value" means. As examples of the variable heat resistance that has been found, consider Russell (1982) who quotes D_{110} values for *Clostridium botulinum* type A as ranging from 0.95 to 1.55 min in tomato juice and from 1.36 to 2.8 min in a buffer at pH of 7. Variability is also demonstrated by Bradshaw *et al* (1975) when quoting $D_{115.6}$ values for *Bacillus cereus* in 0.067 M phosphate buffer at pH 7 of between 0.13 and 11.3 min and $D_{121.1}$ values in the same medium of between 0.03 to 2.35 min. Similarly, Jenson and Moir (1997) quote $D_{95.5}$ values for *Bacillus cereus* of between 1.5 and 36.2

min in distilled water; between 1.8 and 19.1 min in milk and a single $D_{121.1}$ value of 30 min in soybean oil. Further evidence of the variability of the heat resistance of *Bacillus cereus* spores is presented by Carlin *et al.,* (2000) who quote a range of D_{90} values between 0.8 and 5.9 min for cultures isolated from cooked chilled foods containing vegetables. Stumbo (1973) quotes $D_{121.1}$ values for spores of proteolytic *Clostridium botulinum* of between 0.10 and 0.20 min, whereas Hazzard and Murrell (1989) quote a single value of 0.232 min. In the latter example, the significance of quoting a *D* value to the third decimal place can be questioned. Casadei and Jewell (2001) express the notion of variability in a more general sense when they say "As microorganisms vary in size, age and most other properties, it would be surprising if they did not also vary in tolerance." These authors elect to use the term "tolerance" rather than the more usual term "resistance," as the latter tends to have special meaning in relation to microbial inactivation kinetics, whereas their emphasis is to choose a term that is consistent with survival statistics. It is for this reason that Casadei and Jewell's (2001) preference is for "tolerance" which they defined as "the time for which an organism tolerates the conditions before dying."

In cases where it was found that the *D* values for *Clostridium botulinum*, for instance, range by a factor of two, the minimum target F value would also range by the same amount. In more extreme cases as with, say, *Bacillus cereus, D* values ranging by a factor of 10 imply a tenfold range of target F values. It is for these reasons that, unless data which are highly specific to the particular food system, are available, heat processors should presume worst-case (i.e. the maximum) *D* values that will yield correspondingly high target F values sufficient to accommodate the most heat resistant target microorganisms. Simultaneously, these manufacturers should not quote actual or target F values beyond the first decimal place.

The assumption of linear rather than non-linear semi log survival curves is not the only issue of concern when calculating and specifying thermal processes. In addition there are at least three sources of experimental error that should be considered.

- First, errors will arise through use of a constant Z value for estimation of the rates of bacterial destruction other than at the reference temperature of 121.1°C for shelf-stable low-acid canned foods for which the Z value is traditionally taken as 10 C°, or when Z = 9 C° for REPFEDs.

- Secondly, errors will arise when using the General Method (Bigelow *et al.*, 1920), also known as the Reference Method, for calculating the area under the time *versus* lethal rate heating curve for the slowest heating point of the test container. It is in recognition of these shortcomings that Tucker (2001) considers, "Process values (i.e. F values) calculated using the General Method should not be considered exact values...but as estimates and therefore quoted to one decimal place."

- Thirdly, errors in temperature reading (from the temperature sensor and the logger) also should be considered - though usually they are not. Navankasattusas and Lund (1978) indicated that errors in thermocouples are in the range of ± 0.1 - 1°C, which in turn can lead to an error in lethality of between 2.3 and 26%. More recent guidelines and reviews (May 1997a, 1997b, 2000; Smout and May 1997; IFTPS 1992, 2004, 2005) discuss the source of errors in process calculation and indicate that errors of between ± 0.30 and ± 0. 5°C in temperature readings are typical for many of the thermocouple systems used in process evaluation work. Applying an error of ± 0.5°C to a product in which the SHP was held, say, at 121.1 °C for 15 min, the range in calculated F_o values accumulated only during the hold phase of the process would be 13.4 to 16.8 min. Therefore in these circumstances an error of ± 0.5°C in reading temperature translates to an error in F_o value of -10.9% (i.e. an underestimation of the F_o value) to +12.2% overestimation. Robertson and Miller (1984) reported similar errors following experiments in which seven replicate cans that had been prepared identically and filled with the same product (a 5% bentonite slurry) were processed three consecutive times for 90 min at 121 °C. These authors found that the F_h values (i.e. the F value accumulated in heating) within each run "varied from 3.4 to 7.1 min, or from 13 - 26%." This means that the errors reported by Robertson and Miller (1984), but which were not attributed to any particular cause, were of the same order as those that would arise from errors in temperature readings of ± 0.5°C.

As has been noted, the effect of substrates on the heat resistance of target microorganisms should be considered when establishing thermal processes. Also, it is important to acknowledge that a fundamental issue affecting public health risks arising from survival of *Clostridium botulinum* is the ability of the microorganism

to grow in the food under consideration. For instance, it is known (C. Sabie, *pers. comm.* 2001) that the USFDA has approved processes for pumpkin purée in which the target F_o value is less than 2.8 min, which is the generally accepted absolute minimum for low-acid canned foods. In this case, despite the product being low-acid, extensive challenge studies were able to confirm that the medium did not support the growth of *Clostridium botulinum.*

Fernandez and Peck (1999) note also the effect of the growth medium on the apparent heat resistance of microorganisms. These authors record that "the measured heat resistance of spores of non-proteolytic *Clostridium botulinum* is increased by perhaps 2 orders of magnitude by the presence of hen egg white lysozyme and other factors (e.g. egg yolk emulsion, fruit and vegetable extracts, or other enzymes) in the medium used for enumeration of survivors." They also concluded that, because of the increase of the *D* value of non-proteolytic *Clostridium botulinum* spores, under some circumstances, the minimal processes that had been included in guidelines issued by the Advisory Committee on the Microbiological safety of Foods (ACMSF, 1992) and the European Chilled Food Federation (ECFF, 1996) did not deliver a 6*D* process for the target microorganisms.

The influence of the recovery medium on the apparent *D* values of non-proteolytic *Clostridium botulinum* is shown in Table 1.1 (from Food Science Australia and Warne, 2002). In this case, the *D* values at various temperatures are compared for two strains of lysozyme-permeable spores of non-proteolytic *Clostridium botulinum.* These data are particularly relevant in relation to the various guidelines for minimally processed low-acid foods (REPFEDs), which state that such products should be given, at least, a 6*D* heat treatment.

The D_{90} values shown in Table 1.1 indicate that the target 6*D* processes would not be achieved by heating for 10 min at 90°C for either the 17B or the Beluga strain. In the case of the 17B strain, the recommended process would be equivalent to little more than a 0.5*D* process (i.e. 10/18.7), whereas with the Beluga strain, the recommended process would bring about, approximately, a 0.8*D* (i.e. 10/11.8) reduction of the target *Clostridium botulinum* spores. This means that in cases where the lysozyme enzyme may be present in the recovery medium, the recommended process would be insufficient to effect a 6*D* reduction in the numbers of surviving non-proteolytic *Clostridium botulinum* spores.

It is also important to establish the influence of changing temperature on the heat resistance of microorganisms. The term characterising this relationship is the Z value, which is defined as the number of degrees required to bring about a ten-fold change either in the *D* value for a particular microorganism or, more generally, in the rate of thermal destruction. For low-acid canned foods the *Z* value is normally taken to be 10 C° for the bacterial spores of significance. However, for minimally processed refrigerator-stable foods, the *Z* values frequently quoted range is from 7 to 10 C°. For instance, ACMSF (1992) and AQIS (1992) recommend a *Z* value of 9 C°; ECFF (1996*)* recommend a *Z* value 7 C° for temperatures less than 90°C; and the French Ministry of Agriculture (1988) recommends a *Z* value of 10 C°. More recently, as part of the European Commission's Harmony project, the FAIR Concerted Action (1999) recommends that, based on the reference process of 10 min at 90°C, the *Z* value should be 7 C° for temperatures of less than 90°C, whilst for temperatures above 90°C the *Z* value should be 10 C°. For acid foods (e.g. fruits, including tomatoes and other products that may contain butyric anaerobes), which typically are given a relatively mild pasteurisation process, the *Z* value quoted by the NFPA (1968) is 8.3 C°.

It has been found that *Z* values do not necessarily hold across wide temperature ranges and for this reason a three to four *Z* range is generally considered the limit across which the logarithmic relationship between *Z* and *D* will hold.

It is because of the uncertainties involved in accounting for all of those factors influencing the selection and delivery of a thermal process that a simplified "worst case" approach has become the norm across the food industry. While there is no doubt that this conservative approach is safe, it suffers because there is no consideration given to quoting the confidence intervals with which F values may be calculated. This is because "there has been no attempt to assess the error in measurement...and (therefore) generalised safety margins are unscientifically added to the process" (May, 2000). As a consequence some processes are more severe than they need be for safety and for commercial sterility, and this may adversely affect productivity and sensory quality of the end products.

May (2000) hypothesises that given sufficient research expenditure a more scientific approach may lead to use of statistical methods for quantifying errors when calculating processes that will deliver commercial sterility, and possibly improve product quality and productivity. While attractive in theory, May (2000) nevertheless anticipates the following three scenarios that might discourage industry ex-

penditure on resolving the differences between a "worst case" and a statistical approach to process specification.

- First, there is the case when a statistical approach indicates that an existing process does not deliver the desired probability of survival of the various target microorganisms. Under these circumstances it is likely that most manufacturers will resist increasing their processes unless the proposed change can be seen as a way of reducing an unacceptable and recurring level of spoilage. However, as seen in Section 1.1.2, there is little evidence that there are significant levels of under processing spoilage in the trade. Therefore, given the lack of an apparent need for change, R&D expenditure on new statistical approaches is likely to be limited.

- Secondly, despite the expenditure, statistically based methodologies may not lead to any change in an existing process, in which case there is no return on the investment.

- Thirdly, through adopting a more scientific statistically based approach to error estimation, the process may be reduced. However beneficial such an option may be, it is likely to face resistance because of the perception that the proposed changes may lead to an increase in trade spoilage.

Table 1.1 D_T values and corresponding[1] D_{90} values for lysozyme-permeable spores of non-proteolytic *Clostridium botulinum* determined on medium with lysozyme and for reference[2] non-proteolytic *Clostridium botulinum* (without lysozyme) for which the D_{90} value is 1.7 min and estimation of decimal reductions achieved by recommended[3] 10 min at 90°C process for minimally low-acid foods containing *Clostridium botulinum* spores with similar heat resistance. (Modified from Lund and Peck, 1994 and quoted in Food Science Australia and Warne, 2002)

Strain	Temperature T (°C)	D_T value[4] (min)	D_{90} value[5] (min)	Decimal reductions achieved by recommended 10 min @ 90°C, or equivalent, process
17B	85	100.0	19.3	10/19.3 = 0.5*D*
"	90	18.7	18.7	10/18.7 = 0.5*D*
"	95	4.4	13.9	10/13.9 = 0.7*D*
Beluga (E)	85	45.6	8.8	10/8.8 = 1.1*D*
"	90	11.8	11.8	10/11.8 = 0.8*D*
"	95	2.8	8.8	10/8.8 = 1.1*D*
Reference	70	1223.5	1.7	10/1.7 = 5.9*D*
"	75	236.2	1.7	10/1.7 = 5.9*D*
"	80	45.6	1.7	10/1.7 = 5.9*D*
"	85	8.8	1.7	10/1.7 = 5.9*D*
"	90	1.7	1.7	10/1.7 = 5.9*D*

1. For calculation of D_{90} values corresponding to D_T values, assume z = 7 C° for temperatures below 90°C and Z = 10 C° for temperatures above 90°C. (FAIR Concerted Action, 1999).
2. Reference non-proteolytic *Clostridium botulinum* for which the D_{90} value is 1.7 min.
3. 6*D* process for non-proteolytic *Clostridium botulinum* as recommended by Betts (1996) ACMSF (1992), ECFF (1996) and AQIS (1992).
4. D_T values experimentally determined for 17B and Beluga strains and extrapolated for Reference strain.
5. D_{90} values extrapolated from experimental data for 17B and Beluga strains.

1.3 Validation of heat processing equipment and process adequacy

1.3.1 The distinction between temperature distribution and process evaluation trials

As noted in previous sections, the safety and microbiological stability of heat-processed foods depends, in part, on the prevention of under-processing spoilage. In this context, the objective of heat processing is to deliver an F value that will reduce to acceptable levels the probabilities of survival of various target microorganisms. With shelf-stable low-acid packaged foods, the minimum requirement is that the F_0 value will be ≥ 2.8 min (assuming a $D_{121.1}$ value of 0.23 min for proteolytic *Clostridium botulinum).* With REPFEDs, the thermal process should be at least equivalent to 10 min at 90 °C (i.e. equivalent to a 6*D* cycle for non-proteolytic *Clostridium botulinum)* after which storage must be at < 10°C to prevent the growth of proteolytic *Clostridium botulinum.*

It is customary to define the requirements of process adequacy of low-acid foods in terms of minimum F values or, with acid-foods, the minimum core temperatures that must be achieved at the SHP of the container. In either case, this procedure provides a clear and quantifiable objective for the thermal process. In practice, manufacturers will confirm the adequacy of their heat processes via heat penetration (also known as process evaluation) studies involving replicate packs under worst-case conditions that anticipate the range of processing parameters most likely to retard heat penetration to the SHP of the container. Smout and May (1997) define these heat penetration tests as "(tests) conducted to determine the heating and cooling characteristics in the coldest point (point of lowest lethality) of a given product, in a given container, under specified process conditions, usually in the coldest zone (lowest lethality zone) of the retort."

What also is critical, but frequently overlooked, is the need to validate routinely the performance of the thermal processing equipment. Equipment validation is distinct from validation of the severity (i.e. the F value) of the process that is "delivered". Equipment performance is investigated in temperature distribution (also known as heat distribution) studies, which reflect not only the capabilities of the equipment (e.g. retorts, pasteurisers, heat exchangers, ovens and kettles) but also, in some cases, the heating characteristics due to the dimensions of the

packaging that is being used and the product that is being processed. Temperature distribution studies are defined by Smout and May (1997) as "tests performed to study the uniformity in lethality throughout the retort with particular emphasis on the identification of the position in the retort that potentially results in lowest lethality."

As noted, the correct operation of the retort is affected by factors other than the retort itself. For example, Food Science Australia and Warne (2002) record that the heat transfer rates (and therefore the heat absorption rates) of convection heating products (e.g. water or single-strength filtered fruit juices) packed in cans are more rapid than in conduction heating products (e.g. viscous liquids and solids in identically sized containers). Consequently the steam requirements will be greater in the former cases. In relation to the importance of product related characteristics, the United States' Institute for Thermal Processing Specialists (IFTPS, 2005) note that for retorts in which convection heating products are processed, the fastest heating product should be selected, whereas in retorts that are used for products that heat by conduction, the containers should be filled with the slowest heating of the products to be processed. IFTPS (2005) further make the point that "water may also be used, but the come-up-times will be somewhat longer than will occur with product".

The duration of the retort come-up-time is also an important factor that should be considered. When the come-up-time is short (as may occur when the steam supply is plentiful because there is little steam demand from elsewhere in the plant) the temperatures throughout the vessel at the start of the scheduled hold time are likely to be less uniform than they would be had the come-up-time been extended (say, because of steam shortages). For instance, it can be expected that full-immersion, re-circulating water retorts in which the come-up-times (CUTs) are relatively short, will produce greater temperature differentials between the side and the centre of test baskets at the end of the CUT than will the same retorts when the CUTs are extended. This means that a worst-case scenario with respect to uniformity of temperatures is one in which the come-up-time is short. For this reason it is preferable that short retort come-up-times are replicated during temperature distribution trials.

As part of temperature distribution studies, care must be taken to validate performance under worst-case conditions that include consideration of not only the product's heating characteristics but also the container design. In some circum-

stances, small rectangular rigid containers will favour a close-packing arrangement that is able to retard a uniform temperature distribution in steam-fed retorts. However, in Barriquand's cascading water-water retorts (Barriquand Steriflow, Paris, France), Lagarde's water-shower (Lagarde, Montelimar Cedex, France) retorts or FMC's water-spray over-pressure (FMC Technologies Inc., Madera, California) retorts, poor temperature distribution can arise when the relatively large surface areas of, say, retortable pouches interferes with recirculation of process water through the retort. For these reasons it is essential in retort validation studies that the system is loaded with containers that not only are most likely to impede the circulation of the heating medium, but also the containers should be filled with the most "convective" heating product.

A further consideration when investigating the temperature distribution throughout a retort is the nature of the heating medium for, as noted by Smout and May (1997) and Tucker (2001), uniform temperatures do not necessarily equate to uniform heating rates at the SHP of the container. Tucker (2001) recorded that the reason for this "is because of less favourable heat transfer coefficients with...(systems using water, and steam and air)...when compared with condensing steam and also the reduced quantity of heat available in, for example, a raining (recirculating) water system."

It is in recognition of the importance of, and the need to differentiate between, temperature distribution and process evaluation studies that Smout and May (1997) made the point that "both heat distribution and heat penetration studies form part of process design and are also important in HACCP, since the sterilisation process forms a critical control point for thermally processed foods." While these authors clearly understand the need for routine retort (and other equipment) validation as part of a HACCP program, this viewpoint is not shared by all manufacturers of heat-processed food, nor is it shared by all equipment suppliers. It is because of the significance of retort validation in ensuring product safety that groups such as IFTPS have issued guidelines for the conduct of temperature distribution studies in still steam retorts (IFTPS, 1992), water immersion retorts (IFTPS, 2004) and water-cascade and water-spray retorts (IFTPS, 2005). In Australia and New Zealand there are no such guidelines nor are there local industry groups or professional associations where these matters are considered.

It is partially in response to the lack of standard protocols within Australia and New Zealand for conduct of, and analysis of data from, retort temperature distri-

bution studies that development and validation of a data-logging software package was included as an objective of this thesis. As shall be seen in Sections 3.1 and 3.2 the software enables standardised analysis of data and assessment of retort performance according to various criteria for which the parameters may be set by the operator. A definition of the terms and the testing criteria used by DWC Analyser for temperature distribution and process evaluation studies is contained in Section 2.5.2 and the capabilities of the software are demonstrated in Sections 3.1 to 3.3.

In summary, the means by which HACCP compliance can be achieved is through a two-step validation sequence that first assesses the performance of the heat processing equipment (via temperature distribution trials) and secondly assesses the adequacy of thermal processes (via process evaluation trials).

1.3.2 Objectives of temperature distribution trials

The objectives of temperature distribution validation trials are as follows:

- To monitor the uniformity of temperatures throughout the processing vessel. This includes an assessment of the temperature differentials between the sides and the centres of filled baskets containing the packaged foods.

- To identify the cold spots (the points of lowest lethality) in the processing vessel.

- To evaluate the ability of the controller to regulate the temperature in the processing vessel so that it complies with standards and guidelines for compliance.

- To ensure that the thermograph (or other permanent record) provides an accurate history of the temperatures that were experienced in the processing vessel throughout the thermal process.

It can be seen that temperature distribution studies such as these indicate little if anything about the rate of heat transfer through the product. That is, they provide no direct information about the thermal characteristics of the product, i.e. the f and the j values (which are dependent on the container in which the product is packed), or α (the thermal diffusivity) which is product specific and independent of packaging. Therefore, other than in extreme cases where the processing ves-

sel obviously is not performing satisfactorily, temperature distribution studies do not provide, directly or indirectly, any information upon which the adequacy of the process can be assessed. This means temperature distribution studies are unable to provide any indication of the F values at the SHPs of test containers. Other than via direct microbiological challenge tests, which enable the rates and/or the extent of destruction of selected target microorganisms to be determined via enumeration of survivors following a designated thermal process, the only way that the F value of a process can be established is through process evaluation studies.

1.3.3 Guidelines for the conduct of temperature distribution trials

When new equipment is installed it is usual to conduct temperature distribution trials as part of the supplier's commissioning process. Thereafter, it is good practice to ensure that follow-up trials are completed on a routine basis to ensure that performance does not deteriorate as it may do, for instance, when impellers on re-circulation pumps wear, or steam, air or water feed lines and distributors become blocked. However, unlike the essential requirement that reference thermometers or other temperature measuring devices will be calibrated at least annually or "more frequently if necessary to ensure their accuracy" (Anon., 2002) the conduct of temperature distribution trials is not mandated. At best, temperature distribution trials are recommended in voluntary guidelines prepared by industry associations (IFTPS 1992, 1995, 2004 and 2005) or by other authorities expert in the field (May 1997a; Smout and May 1997). For instance, in a document, relating specifically to temperature distribution trials in full water immersion retorts, including agitating systems operated in a still mode, IFTPS (2004) recommend "a minimum of three (3) leads should be used, each located in different layers or otherwise separated in each basket/crate/rack; leads should be placed so that measuring junctions are not in direct contact with containers or other internal material surfaces".

That guidelines such as these lack mandatory status appears an oversight which, in some cases, may predispose manufacturers to have unwarranted confidence in the ability of their retorts (or other heating systems) to establish and maintain uniform temperatures.

While the accuracy of correctly calibrated thermometers ought not be an issue, their placement is occasionally such that they do not truly reflect the temperature

at the cold-spot of the processing vessel. Of even greater concern though is the tendency in some recirculating water systems to overlook installation of any reference thermometer (or other means) with which to monitor cold-spot temperatures.

The importance of identifying the location of the cold-spot in a retort will be seen in Section 3.3.2 Cases 10-12 and Section 3.5 Case 1, which investigate possible causes of under-processing in commercial shelf-stable canned foods. Cold-spot identification is particularly important in cases where there are likely to be temperature gradients across the retort baskets, so that the temperatures around the sides exceed those at the centre of the baskets. In such cases temperature differentials may be exacerbated by the close-packing nature of the containers (e.g. small diameter cans and jars) and/or the method of the heating. For example, full water immersion retorts in which the heating medium (i.e. hot water) is recirculated via an external pump are more likely to create heating lags at the centres of the baskets than are conventional steam or water-spray retorts (such as those manufactured by FMC and Lagarde) or cascading water-shower retorts (such as those manufactured by Barriquand) in which the heating medium is able to penetrate between containers to the centres of the basket.

Failure to identify the location and magnitude of temperature differentials at the cold-spot in retorts represents an unacceptable risk of under-processing spoilage and possible food poisoning. Risks of this nature are likely to be detected (and avoided) by those manufacturers who are prepared to go beyond annual calibration of their reference thermometers and include, as well, temperature distribution analysis. Detailed analyses of retort performance is recommended by May (1997a), Smout and May (1997), Tucker (2001), IFTPS (1992, 1995, 2002, 2004, 2005) and Food Science Australia and Warne (2002). The occasions on which these authors advocate that heat distribution trials be conducted include the following;

- On installation of the system.
- Once a year, thereafter.
- On installation of additional retorts that use the same steam supply.
- On those occasions that a retort is re-located.

- When the supply of major services to the retort (e.g. steam, air or water) has changed significantly.

- When there are any changes to the controller, the temperature control sensor, water-level indicators (if these could affect the temperature distribution about the containers whilst they are being processed).

- When there are any changes to the control valves affecting steam supply, air supply, water supply or automatic drain valves.

- When there are changes to the steam injection points, the bleeders and/or vents (in steam air systems), water re-circulation pumps, heat exchangers (in those systems using indirect heating).

- When there are changes to container dimensions and profiles that might affect heat distribution throughout the retort.

- When there are changes to the retort basket dimensions, the perforations in baskets, or the dividers that are placed between layers of containers.

- When there are changes to container stacking patterns that could affect heat distribution throughout the retort baskets.

In all cases, these temperature distribution trials should be conducted under "worst-case" conditions. This means the trials should be regulated so that the selection of the settings for each variable under consideration will favour a reduction in the uniformity of temperatures throughout the retort.

1.3.4 Objectives of process evaluation trials

The objectives of process evaluation studies confirming the adequacy of thermal processes are as follows:

- To determine under worst-case conditions the primary heating characteristics of the product (i.e. the f_h, j and α values) in replicate test containers,

- To determine under worst-case conditions the cumulative lethal effect (i.e. the F value) of the entire process (including come-up, hold and cooling) at the SHP of replicate test containers when they are located in the "cold spot" in the retort or heating vessel.

Techniques used to gather and interpret the primary heating characteristics of packaged foods in order to calculate process F values, vary. However, the common feature they share is their reliance on generation of replicate sets of the time-temperature data from the SHPs of containers which are representative of worst-case conditions.

Australian regulators (AQIS, 2002) specify that at least six sets of time-temperature data are required from thermocouple probes mounted in a minimum of six containers (with an accompanying probe representing the temperature in the retort). AQIS (2002) also advise "where possible trials should be conducted to determine the colder spots in the retort, however if this is not practical the probed units should be randomly dispersed within the retort including suspect colder locations." While recognising the importance of cold-spot determination, the conditional nature of the AQIS directive is surprisingly casual, considering public health risks may be involved.

More stringent (than those advocated by AQIS) are the approaches to data collection in process evaluation trials recommended by IFTPS (1995) and May (1997b, 2000). IFTPS (1995) recommend that 10 data sets should be generated from at least two test runs, or replicate runs should be completed until data from 10 probes are available. IFTPS (1995) state that after determination of the retort's cold-spot, "at least two full replications of each test are recommended" and they add, "should results from these tests show variation, a minimum of a third test is recommended."

May (1997b and 2000) and Smout and May (1997) indicate that, as in the United States, processing authorities in the United Kingdom also are more rigorous than their Australian counterparts. In the United Kingdom data are required from three runs each with at least three containers. May (1997b) adds that "this level of testing combined with the worst-case methodology and a minimum botulinum cook has a proven record for establishing safe processes."

Selection of appropriate procedures that ensure the accuracy and the reproducibility of heat penetration data are therefore of paramount importance as experimental errors will expose manufacturers to unacceptable risks of under-processing spoilage and consumers to unacceptable risks of food poisoning caused by the survival of heat resistant bacteria.

1.4 Comparison of two methods for calculation of process F values

In most instances throughout Australia and New Zealand, food manufacturers and regulators use one of two methods for calculation of process F values. The first method (known as the General or Reference Method) relies on analysis of time-temperature data to determine actual F values. The second method, which is a derivative of the method developed by Gillespy (1951), has predictive capabilities but lacks the accuracy of the General Method.

1.4.1 The General (or Reference) Method

The General Method (Bigelow *et al.*, 1920), of calculating process F values is the reference method against which all other methods should be compared. The reason for its accuracy is that the severity (or F value) of the process being evaluated is based solely on actual time-temperature data that have been collected during heat penetration trials. Once temperature at the SHP is known, the corresponding lethal rate of the thermal destruction of the target microorganisms can be calculated using the equation (shown on page 25)

$$L = \text{Log}^{-1} (T - T_r) / Z$$

after which the F value can then be calculated using the equation (shown on page 26)

$$F = \Delta t \sum 10^{(T - Tr) / Z}$$

where T = is the product temperature at the SHP of the container at time t

T_r = is the reference temperature (which for low-acid canned foods is 121.1°C)

Z = 10 C° (for target microorganisms in low-acid canned foods)

The lethal rate equation, shown above, can be transformed so that

$$L = 10^{(T - Tr) / z}$$

And by substituting $10^{(T - Tr)/z}$ for L, it can be seen that

$$F = \Delta t \sum L$$

In summary, these equations show that the F value of a process is the product of the lethal rates and the time over which they were acting.

The General Method is a simplified mathematical procedure that is based on the relationship linking the change in the rate of destruction of target microorganisms with the changes in temperature at which they are heated. Replicate sets of time-temperature data (gathered during heat penetration trials) are used to determine the changes in the rates of microbial destruction at the SHPs of containers during heating and cooling. In this manner a conventional time-temperature plot in which temperature is drawn on the Y-axis and time on the X-axis simultaneously can be regarded as a lethal rate-time plot in which lethal rate is drawn on the Y-axis and time on the X-axis. Therefore, in order to generate a continuous plot of the change in lethal rate over time it is sufficient to plot temperature against time using scales which reflect the inter-relation between product temperature and the lethal rate of microbial destruction of the target microorganisms.

As has been noted, when sterilising low-acid canned foods the F value that is calculated is referred to as an F_o value, whereas with other processes (such as with acid products and REPFEDs) the F value is frequently designated as an F_p value, in which case the subscript "p" can be regarded as indicating a pasteurisation process.

Similarly, with REPFEDs, which are held under refrigeration after processing, the most heat resistant pathogenic target microorganism is non-proteolytic *Clostridium botulinum,* for which the lower limit for growth is 3°C (Graham *et al*, 1996). However, unlike proteolytic *Clostridium botulinum* spores, which are highly resistant and which require high temperatures (e.g. >110°C) for their thermal destruction, non-proteolytic *Clostridium botulinum* spores have D_{90} values of between 0.4 and 1.1 min (Gaze and Brown, 1990). For this reason the reference temperature for expressing the F value of "minimal processes" for REPFEDs is 90°C while the *Z* value is 9 C°.

Selection of the most appropriate reference temperature and *Z* value therefore reflects the heat resistance of the target microorganisms and the sensitivity of

heat resistance to change in temperatures. However, once the selection is made, it is a simple matter to determine the lethal rate (L) at any temperature using the lethal rate equation shown on page 44. This equation was used to generate Table 2.1 in Section 2.1.1 on page 61, and in this case the reference temperature was 121.1°C and the *Z* value was 10 C°.

When F values other than F_o values are to be calculated (i.e. when the reference temperature and the *Z* value are not 121.1°C and 10 C°, respectively), the zero subscript is replaced with an alternate identifier. For instance, for minimal processes with low-acid foods, or with pasteurisation of acid products, the F value is frequently referred to as an F_p value, and in these instances, the reference temperature and the *Z* value are also quoted.

Key features of the General Method include the following;

1. The method most frequently is used to determine the actual F value delivered by a thermal process during which appropriate time-temperature data for replicate packs representing worst-case conditions have been gathered.

2. When used to calculate actual F values, the method is accurate and makes no assumptions about the uniformity of the heating, or the cooling characteristics of the product, or the heating lags that may occur, or the uniformity of the retort temperature.

3. The accuracy of the method is not affected by fluctuations in retort temperature.

4. Compared with the method developed by Gillespy (1951), (which subsequently underwent minor modification by Board and Steele [1978]), the General Method offers little predictive capability. Therefore the General Method is most suitable for data sets gathered under "actual" (rather than hypothetical) conditions in which all relevant processing and product variables are defined, controlled and measured. (The modifications that Board and Steele (1978) applied to the Gillespy Method were introduced in order to better estimate the contribution of the cooling component to the total process lethality. However because of its close links with Gillespy's original technique, the method of calculation adopted by Board and Steele is frequently referred to as Gillespy's Method.)

5. The method is not suitable for calculation of the effect on F value of alteration to processing conditions (i.e. retort temperature, retort come-up-time , processing time, cooling water flow rates, cooling water temperature or other factors which may affect the heating or cooling rates achieved in the retort). This limitation does not apply in cases where the product temperature at the SHP has reached retort temperature and the amount by which it is proposed to alter the process hold time does not affect the temperature at the SHP. In these circumstances, the change in processing time will bring about a calculable change (addition or reduction) to the F value.

6. The method is not suitable for calculation of the effect on F value of alteration to initial product temperatures.

7. The method is not suitable for calculation of the processing time required to deliver a nominated target F value. This limitation does not apply in cases where the product temperature at the SHP has reached retort temperature and the amount by which it is proposed to alter the process hold time in order to achieve the desired target F value does not affect the temperature at the slowest heating point. In these circumstances, the change in processing time will bring about a calculable change (addition or reduction) to the F value.

8. The method allows calculation of the contribution to total process lethality (i.e. the total F value) of the heating and the cooling components of a process.

9. The method may be applied to complex (broken) heating curves for products that undergo a change in their thermal diffusivity during the process (e.g. for products which thicken, and therefore heat or cool more slowly, during the process; or conversely for products that degrade and heat or cool faster during processing).

1.4.2 The Gillespy Mathematical Method for calculation of F value and processing time

One of the major shortcomings with the General (or Reference) Method for calculation of F value is that, with few exceptions, the values that are obtained with one product under one set of filling and processing conditions do not enable calculation of the F value under another set of conditions. It is for this reason that

the General Method typically is used for validation of commercial processes (where there are few, if any, variables), rather than in R&D exercises in which a range of critical attributes affecting the heating characteristics of a product may be subject to alteration.

The Gillespy Method (as modified by Board and Steele [1978]) overcomes some of the limitations of the General Method, but it is generally recognised to be at the cost of accuracy. The inaccuracies arise for the following reasons;

1. The method relies on prediction of the product temperature at the SHP of the container, whereas with the General Method, the actual temperature is measured directly.

2. The means of predicting the core temperature assumes that the rate of change in the difference between the retort temperature and the temperature at the SHP is constant throughout the process. This is not always the case as the heat transfer properties of some products alter as temperatures increase. For instance, starch solutions gel and become more viscous, while some heat-sensitive gels break down and become less viscous.

3. The contribution to the total F that is accumulated as the container cools (i.e. after steam-off) is estimated through use of a single constant. The need for inclusion of a constant was recognised by Board and Steele (1978) who noted that "Gillespy's Method sometimes overestimated the contribution of the cooling phase to the F_o of the process because under circumstances often encountered in cannery practice products which heat by conduction may cool more rapidly than assumed in Gillespy's Method by a combination of convection and conduction."

Over-estimation of the F value accumulated during cooling is potentially dangerous as it may give the false impression that the total F value for the process was sufficient for safety, whereas in marginal processes this may not be the case. The dangers arising from over-estimation of the cooling contribution to the total F value was a consequence of Gillespy incorrectly assuming that the rate of cooling (expressed via the f_c value) in containers was comparable to the rate of heating (expressed via the f_h value). The f_h or f_c value of a packaged product is the time in minutes for the straight-line portion of the semi-log plot of the time-temperature heating curve or cooling curve, respectively, to traverse one log cycle. The f_h

value is function of the thermal diffusivity (α) of the product and the dimensions of container in which it is packed so that the higher the f_h value the slower the heating rate. This meant that in instances when heating was slow (i.e. for products with relatively high f_h values) Gillespy had incorrectly assumed that the rate of cooling (expressed via f_c) also would be slow. Gillespy's error in assuming the equality of f_h and f_c values meant that in those cases when products had high f_h values it would follow that, after steam-off, the core temperatures would remain high (or even increase temporarily) and this would result in the apparent accumulation during cooling of a significant portion of the total F value. Therefore, when a product actually cooled faster than the Gillespy Method had assumed (i.e. when f_c was less than f_h, rather than equal to f_h), the total F value that was delivered by a process would be overestimated, or alternately an insufficient process hold time required to deliver a target F value would be calculated.

In order to compensate for incidences when the rate of cooling was faster than the rate of heating (i.e. when f_c was less than f_h), Board and Steele (1978) included a constant, empirically derived, factor of 0.08 in the various equations used in the original Gillespy Method. When the modification was applied by Board and Steele (1978) they found that "this factor gives an estimate which is appropriate for cans which heat by conduction but cool by a faster process as a result of short periods of ebullition during the early part of cooling." At the time that the correction factor was applied, it was recognised that the value of 0.08 would lead to an under-estimation of total F_o for products that cooled by conduction. However, Board and Steele (1978) commented that it was "difficult to predict the mechanism of heat transfer during cooling in a particular can so it is recommended that the factor, although conservative, be adopted for general use."

In 1978, when Board and Steele's paper was published, the errors in their modification of Gillespy Method were tolerated because generally they were not large. However, the development of more sophisticated computer controlled retorts capable of operating at higher processing temperatures (e.g. 125 to 135°C rather than at ≤ 121°C) has rendered this generalisation invalid. The reason for this is that at the higher processing temperatures, the errors that occur become so pronounced that to ignore them will lead to significant over-processing with a commensurate loss of quality and unnecessary expense. This means that Board and Steele's Method, when applied to high processing temperatures, resulted in over-processing which was the opposite of the original problem with Gillespy's Method

which was under-processing. In this regard, Food Science Australia and Warne (2002) have shown that total F_o values (calculated via the modified Gillespy Method) may be underestimated by between 40 and 100% and that the errors tend to be larger at high temperatures. Food Science Australia and Warne (2002) also concluded that when using Board and Steele's (1978) modification of the Gillespy Method of F value calculation:

- Conduction heating products in containers with relatively low surface area:volume ratios with high f_h values, demonstrated large (> 42%) under-estimation of the actual total F value (determined by the General Method).

- Large discrepancies between the F values calculated by the General and Gillespy Methods can be attributed to the high lethality of core temperatures in the early stages of cooling. In the period when Board and Steele (1978) published their work, retort processing temperatures were typically at 121.1°C or less, at which values the corresponding lethal rate of destruction of the target microorganisms was unity or less. However, most of the over-pressure retorts now available are rated to pressures of four or five bar and at these pressures retort temperatures of 125 to 135°C are achievable. Although product core temperatures are unlikely to reach these high retort temperatures (due in part to the fact that shorter process times are required) often they will exceed 121.1°C and this will mean that the lethal rate will be greater than at 121.1°C. For instance, at 125°C and 135°C, the lethal rates are 2.45 and 24.55 times, respectively, those at 121.1°C. Therefore, one effect of processing at higher retort temperatures is that the contribution to the total F value that is achieved in cooling (i.e. after steam-off) will be significantly higher than it would have been had the retort temperature not exceeded 121.1°C.

- For the cases that were considered by Food Science Australia and Warne (2002), reliance on the Gillespy Method of F calculation would not risk product safety; however, it may lead to over processing.

It is in response to the shortcomings of the Gillespy Method that one of the research objectives of this thesis was to develop and validate an "improved" mathematical method which although based on Board and Steele's modified form of Gillespy's Method, includes the facility to correct for errors in calculation of the F value delivered in cooling. This Method is referred to as DWC's method of F

value calculation, and it has been included as part of the DWC Analyser software package that has been described in Sections 1.3.1 (page 38-39) and 3.1. (pages 114-119).

1.5 Selection and specification of minimum target F_p values for REPFEDs and development of F_p-Hermetica™ processing technology

The rationale behind the development of DWC's F_p-Hermetica™ processing technology (see Section 1.1.2 page 6) was to deliver a product in which the shelf-life at ≤ 5°C exceeded the six to 10 weeks that is frequently quoted for REPFED products. The reason for seeking a shelf-life extension (for up to one year in some cases) was to enable manufacturers to supply their value-added products to local and export markets that would otherwise be unavailable because of expiry of the shelf-life while the product moved through the distribution and storage chains.

ICMSF (1998) identified (on the basis of epidemiological data, their incidence and characteristics of the individual microorganisms) the bacterial pathogenic microorganisms in seafoods, dairy products, meats and related items, vegetables and poultry as being one or more of the following;

- *Vibrio spp*
- *Salmonella spp*
- *Campylobacter jejuni*
- *Escherichia coli*
- *Yersinia enterocolitica*
- *Shigella*
- *Staphylococcus aureus*
- Proteolytic *Clostridium botulinum*
- Non-proteolytic *Clostridium botulinum*
- *Bacillus cereus*
- *Clostridium. perfringens*
- *Listeria monocytogenes*
- Group A and C *Streptococci*
- *Yersinia enterocolitica*
- *Brucella abortus*
- *Mycobacterium bovis*
- *Pseudomonas aeruginosa*
- *Coxiella burnetii*
- *Aeromonas hydrophila*

Of the microorganisms cited by ICMSF (1998), the spores of proteolytic *Clostridium botulinum* are the most heat resistant. However, in the context of the public health risk in REPFEDs the distinction between proteolytic and non-proteolytic *Clostridium botulinum* is important.

Not only do proteolytic and non-proteolytic *Clostridium botulinum* have different minimum growth temperatures (10 and 3°C, respectively), they also share another important distinction and this relates to their heat resistance. While the $D_{121.1}$ value for the former is 0.23 min, the D_{90} value for the latter is 1.7 min (see page 5). As an approximation, this translates to a heat resistance for non-proteolytic *Clostridium botulinum* that is of the order of one 175th (i.e. 1/175) of that of proteolytic *Clostridium botulinum*. Therefore, it is because of the relative heat sensitivity of non-proteolytic *Clostridium botulinum* that the minimal processes for REPFEDs need not be as severe as the sterilisation processes that are used for shelf-stable low-acid products.

As discussed in Section 1.1.2 (page 4) GMP for minimally processed refrigerated low-acid foods requires the "elimination" (or reduction to commercially acceptable levels) of spores of non-proteolytic *Clostridium botulinum* and this is achieved by bringing about a 6*D* reduction in their numbers (or probability of survival). Such processes equate to a heat treatment (after the products have been hermetically sealed in their containers) that is equivalent in sterilising effect to 10 min at 90°C (i.e. F_p = 10 min; T_{ref} = 90°C and Z = 9 C°) at the SHP of the container. The often-quoted disadvantage with these processes is, however, that the products have insufficient refrigerated shelf-life to allow for national distribution and marketing, let alone export. F_p-Hermetica's™ processing technology addresses these shortcomings while providing finished products that match expectations of quality and safety.

Food safety risks with REPFEDs in hermetically sealed containers are not confined to those arising as a result of survival of non-proteolytic *Clostridium botulinum* because of under-processing, or the growth of proteolytic *Clostridium botulinum* because of poor control of chilled temperatures. (It is to be expected that spores of the latter will not have suffered any significant destruction at the processing temperatures and processing times typically used in minimal processing.) As noted on pages 6 to 8, *Bacillus cereus* spores may be more heat resistant than those of non-proteolytic *Clostridium botulinum* and this means that they

also should be considered as potential pathogenic survivors of minimal processes that have been designed solely to be equivalent to the 10 min at 90°C which is recommended by ACMSF, (1992), AQIS (1992), Betts (1996), ECFF (1996) and FAIR Concerted Action (1999). It is for this reason that F_p-Hermetica™ processes also target psychrotrophic *Bacillus* spores that may be present in the raw materials and which survive minimal heat treatments that are adequate for the elimination of non-proteolytic *Clostridium botulinum.*

The REPFEDs that are processed using F_p-Hermetica™ processing technology have an extended shelf-life (e.g. up to one year, depending on the barrier properties of the packaging material) at between 3°C and less than 10°C (although the labels recommend storage at ≤ 5°C). This means that the products will be stored at, respectively, above the minimum growth temperature for non-proteolytic *Clostridium botulinum* and below the minimum growth temperature for proteolytic *Clostridium botulinum.* The F_p values that have been selected for commercial processes are at least equivalent to 12*D* cycles for non-proteolytic *Clostridium botulinum* and this equates to minimum F_p values ≥ 20 min. In these instances the actual target F_p values reflect the nature of the foodstuff, the refrigerated shelf-life that is required and the barrier properties of the packaging material.

As a guide as to what is achievable, some commercial seafood manufacturers using F_p-Hermetica™ have received regulatory approval for production and export of items for which a refrigerated shelf-life of one year is declared, provided that other components forming part of the technology are satisfied. These components include microbiological challenge studies to demonstrate freedom from, or absence of growth of, psychrotrophic pathogens that are, under certain circumstances, more heat resistant than non-proteolytic *Clostridium botulinum* (for instance *B. cereus*) and also implementation of appropriate process monitoring and testing regimes to demonstrate maintenance of hermetic seals.

1.6 Evidence of non-compliance with Good Manufacturing Practice in production of shelf-stable foods and REPFEDs

Two aspects of non-compliance are to be considered: those relating to the severity of the thermal process (i.e. the extent of under-processing or over-processing that may occur) and those relating to PPLC. Pre-process spoilage is excluded from this discussion because, other than for the possible presence of heat-stable pre-formed toxins due to use of infected raw materials and/or poor preparatory

practices, it is less important with respect to food safety and food quality. The reason for this is that (with the exception of pre-formed toxins) typical indicators of pre-processing microbial spoilage are likely to be overt and therefore detectable before affected products are released to the trade or consumed.

1.6.1 Non-compliance relating to the severity of the thermal process

As has been discussed (in Section 1.1), incidents of spoilage caused by under-processing rarely are reported. Primarily, this is a reflection of their infrequency; however, it is also to be expected (and reasonable) that manufacturers would choose not to divulge information of this nature unless safety and/or commercial interests are involved. Under these circumstances, the usual means of obtaining data is through in-house investigative exercises that have been implemented to understand and resolve the issues concerned. Typically, this means that any data gathered will be treated as commercial-in-confidence and therefore unlikely to be made available to third parties.

Also to be considered in relation to non-compliance with GMP is the distinction between under-processing and under-processing spoilage. Those manufacturers who are aware of the health and the commercial risks arising from survival of microorganisms, also are likely to be aware that not all under-processing leads to spoilage. For these companies, the issue therefore becomes one of delineating between unacceptable health risks and acceptable commercial risks.

With respect to the survival of *Clostridium botulinum* spores, under-processing spoilage is more likely with REPFEDs than it is with shelf-stable foods. With the latter, GMP prescribes at least a 12*D* process with a minimum F_o value of ≥ 2.8 min (i.e. 12 times a $D_{121.1}$ value of 0.23 min), for safety from survival of proteolytic *Clostridium botulinum* spores. Whereas with REPFEDs the minimum recommended F_p value is for a 6*D* process and this will be equivalent to 10 min at 90°C (ACMSF, 1992; AQIS, 1992; Betts, 1996; ECFF, 1996 and FAIR Concerted Action 1999). In practice with shelf-stable products other than abalone, for which the minimum F_o values are frequently 2.4 min (i.e. 12 times a $D_{121.1}$ value of 0.20 min as quoted by Stumbo [1973] rather than 12 times a $D_{121.1}$ value of 0.23 min as quoted by Hazzard and Murrell, [1989]), typical F_o values are likely to be three to four times the allowable minimum. This is because typical shelf-stable processes are designed to reduce, to satisfactory levels, the probability of survival of mesophilic and thermophilic spores that are more heat resistant than spores of *Clos-*

tridium botulinum. Therefore, short of gross under-processing, it is unlikely that mesophilic spores will survive a shelf-stable process, while those thermophilic spores that may survive will be unable to germinate at the temperatures of storage.

The picture is less clear when assessing the risks of under-processing spoilage with REPFEDs and this is for a variety of reasons including the following;

- The target F_p value requires only a 6*D* cycle with respect to the thermal destruction of the target non-proteolytic *Clostridium botulinum*. Such a process would not achieve a 6*D* cycle for bacterial spores that are more heat resistant, such as some strains of psychrotrophic *Bacillus cereus* (see page 6).

- Compared with their counterparts in the long-established shelf-stable heat processed food sector, some REPFED manufacturers are less aware of the causes and risks of under-processing spoilage.

- Because of the filling temperatures (e.g. 85 °C) that have been chosen some REPFED processes, which rely on hot filling and cooling, never will be able to achieve heat treatments after filling and sealing that are equivalent to a 6*D* cycle with respect to the thermal destruction of the target non-proteolytic *Clostridium botulinum.*

- The inclusion of refrigeration as a means of preventing or retarding germination and growth of spore-forming survivors means that inadequacies in the cold chain will expose the products to risks of spoilage.

Examples of under-processing demonstrated by a failure to comply with minimum target F values in commercial manufacture of REPFEDs and shelf-stable foods are considered in Section 3.3.1 and 3.3.2, respectively.

While there are no health risks associated with over-processing, there is evidence (seen in Section 3.3.2) that some low-acid canned food manufacturers select target F_o values that are not only in excess of minimum safety requirements, but also are well beyond what is normally considered sufficient to destroy thermophilic heat resistant spores. In some cases, the manufacturer's justification for these excessive processes is that they seek "extra safety" for their products. The rationale for this is difficult to comprehend (and might be viewed as fanciful) as

target F_o values in the mid-20s, hypothetically, will reduce the probability of survival of proteolytic *Clostridium botulinum* to less than one in 10^{100}. This is not to deny that some manufacturers select high F_o values (in excess of minimum safety requirements) in order to achieve desirable sensory quality for their products, or to limit the risks of thermophilic spoilage in cases where their raw materials are heavily contaminated with thermophilic spores, or their cooling systems are inadequate, or it can be expected that their finished products will be exposed to temperatures favourable to thermophilic growth.

Given that REPFEDs are promoted to evoke connotations of foods that are "as fresh," "minimally processed" or "un-processed", it is not likely that these products will be grossly over-processed. Rather, those manufacturers who are aware of health risks associated with under-processing will select processing regimes that will deliver minimum F_p values that are appropriate, but generally not as extreme as their counterparts producing for the shelf-stable market. While these minimal processes will be sufficient to bring about at least a 6*D* reduction in the spore population of non-proteolytic *Clostridium botulinum,* they definitely will not provide adequate protection against spores of proteolytic *Clostridium botulinum.* It is for this reason that storage temperatures must be maintained at less than 10°C and the recommended shelf-life frequently is less than 10 weeks.

1.6.2 Non-compliance relating to post-process leaker contamination (PPLC)

As discussed in Section 1.1.3, nationally and internationally, shelf-stable low-acid heat processed canned foods have established a sound record with respect to the incidence of PPLC and for this reason two-piece welded cans continue to set the standard against which the performance of the hermetic seals on all other packaging systems must be compared. Recent Australian experience demonstrates that alternate systems using flexible and semi-flexible packaging for heat processed shelf-stable foods and REPFEDs are gaining market share. Furthermore, although the evidence is more likely to be anecdotal than scientifically based, this success appears to be achieved without experiencing unacceptable rates of PPLC despite the relative vulnerability of their hermetic seals when compared with metal cans. The same trends are apparent in the United States, notwithstanding Ito's view (*Pers. comm.* 2002) that physical damage to the container rather than seal failure is the main cause of PPLC.

Nonetheless in Australia, a potential source of PPLC remains with those products from manufacturing environments in which there is a lack of awareness of the need for hermetic seals. For instance as noted by Warne (1995), "The state of the art (of evaluating hermetic seals) cannot be said to be so well developed (as in the manufacture of shelf-stable heat processed foods), nor is the experience so extensive, for manufacturers of long shelf-life refrigerated foods using flexible packaging systems." Examples of this category of product can be found in Australian retail outlets where REPFEDs in package formats that, by design, cannot be hermetically sealed. Also, commercial products are available in which heat seal areas are contaminated, and/or the heat seals are discontinuous, are poorly formed or are otherwise compromised. Manufacturers of these products demonstrate insufficient concern as to the adequacy of the hermetic seals on their products and in many instances this attitude is reinforced by a lack of any seal testing regime such as would be expected in an appropriate HACCP plan. Unlike their counterparts in the shelf-stable heat processed food sector, some manufacturers of REPFEDs appear not to recognise the health risks arising from PPLC despite their products being held at temperatures for periods sufficient to allow pathogens (including proteolytic *Clostridium botulinum*) and other spoilage microorganisms to reproduce.

2 EXPERIMENTAL METHOD

2.1 Procedures for using Gillespy's and DWC's Methods of thermal process calculation

2.1.1 Gillespy's Method of calculation

The procedures and the equations for F value calculation using the Gillespy Method are described by Board and Steele (1978). These authors explain that "the method with minor modifications of the part dealing with the cooling phase of the process has been used by these laboratories (the then CSIRO Division of Food Research) for evaluating heat sterilising processes for some years and recently the method was used as a basis for calculation by programmable calculator and computer." Board and Steele's paper (1978) "describes the simplified version of Gillespy's Method and how it has been adapted for automatic calculation." The version of the Gillespy Method referred to by Board and Steele is the model that is widely used throughout Australia and New Zealand and which is taught in the, so called, Approved Persons Courses that have been accredited by authorities in each of these countries.

When expressed in a simplified form the accumulated lethality of a process (i.e. the F value) is equivalent to the integrated sum of the lethalities over the duration of the heating cycle. This relation may be expressed as follows:

$$F = \Delta t \sum 10^{(T - Tr)/z} \qquad (1)$$

where,

Δt = is the time interval between temperature measurements

T = is the product temperature at time t

T_r = is the reference temperature, which for low-acid canned foods is 121.1°C and for REPFEDs is 90°C

z = 10 C°C for shelf-stable low-acid foods and between 7 and 10 C°C for REPFEDs

However, as shown on Page 24

$$L = \text{Log}^{-1} (T - T_r) / z$$

$$\therefore \quad L = 10^{(T - Tr) / z}$$

Substituting $10^{(T - Tr) / z}$ in equation (1) gives

$$F = \Delta t \sum L \qquad (2)$$

Equation (2) also forms the basis for the General Method of F value calculation. However in order to solve equation (2) it is necessary to know the temperature of the product at the SHP (T_{SHP}) at any time (t) during the heating process and this can be determined through the following equation in which T_{SHP} is the same as T in equation (1), the temperature of the heating vessel is T_{Ret}, and the product's heating parameters are j and f

$$T_{SHP} = T_{Ret} - j (T_{Ret} - T_o) 10^{-t/f}$$

When calculating process lethalities with the version of the Gillespy Method adopted by Board and Steele (1978), reference is made to two tables. The first is the lethal rate table (Table 2.1), which can be derived for any range of temperatures once the reference temperature T_r and the *Z* value are known, and which uses the equation

$$L = \text{Log}^{-1} (T - T_r)/Z$$

The second table (Table 2.2) derived by Board and Steele (1978) relates the adjusted thermal process time B, the variables v and u shown in equations (3) and (6) and their respective re-arranged forms, in the manner shown below.

$$v = B/f_h - \log [j (T_{Ret} - T_o) / z] + 0.08 \qquad (3)$$

which can be re-arranged so that

$$B = f_h \{v + \log [j (T_{Ret} - T_o) / z] - 0.08\} \qquad (4)$$

$$B = f_h \{v + m\} \qquad (5)$$

where $m = \log [j (T_{Ret} - T_o) / z] - 0.08$

Once v is known, the term u can be interpolated from Table 2.2 and, once u is known, the F value for the process can be calculated using the equation

$$F = u \times f_h \times L \quad (6)$$

which can be re-arranged so that

$$u = F / (f_h \times L) \quad (7)$$

As an example of the use of Table 2.2, consider that the value of v was required in order to determine an adjusted thermal process time B, for a process for shelf-stable foods in which the F value was 13.8 min, the processing temperature (T_{Ret}) was 118.5°C (at which temperature Table 2.1 shows that L is equal to 0.550), the f_h value was 43 min, the j value was 1.6 and the initial product temperature (T_o) was 25°C. Using equation 7, the value of u can be calculated as

$$u = 13.8 / (43 \times 0.550)$$

$$= 0.584$$

Table 2.2 shows, by interpolation between values of u of 0.580 and 0.588, that v is equal to 1.125. Once v is determined, the value of B can be calculated using equation 4, so that

$$B = f_h \{v + \log [j (T_{Ret} - T_o) / z] - 0.08\}$$

$$= 43 \{1.125 + \log [1.6 (118.5 - 25) / 10] - 0.08\}$$

$$= 95.4 \text{ min}$$

When using Table 2.2 to find the value of v, in cases when u >2. 8, v may be calculated from the equation

$$v = u + 0.613 \quad (8)$$

When correcting for the retort come-up time (C.U.T.) the following equation is used to calculate Operator Process Time P_t (which is frequently known as the scheduled retort hold time or the scheduled process hold time).

$$B = P_t + 0.4 \times \text{C.U.T.} \quad (9)$$

For example, consider in the case above (when B equals 95.4 min) that the retort come-up time (C.U.T.) was 10 min. Therefore, the Operator Process Time (P_t) can be calculated as follows:

$$B = P_t + 0.4 \times C.U.T. \quad (9)$$

$$\therefore \quad P_t = 95.4 - 0.4 \times 10$$

$$= 91.4 \text{ min}$$

Table 2.1. Values of Lethal Rate (L)[1] for temperatures (T) ranging from 90°C to 134.9°C in 0.1°C intervals, when *Z* is equal to 10°C and the reference temperature (T_r) is 121 .1°C

C	0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
90	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
91	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
92	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.002
93	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
94	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
95	0.002	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
96	0.003	0.003	0.003	0.003	0.003	0.003	0.004	0.004	0.004	0.004
97	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.005	0.005	0.005
98	0.005	0.005	0.005	0.005	0.005	0.005	0.006	0.006	0.006	0.006
99	0.006	0.006	0.006	0.007	0.007	0.007	0.007	0.007	0.007	0.008
100	0.008	0.008	0.008	0.008	0.009	0.009	0.009	0.009	0.009	0.010
101	0.010	0.010	0.010	0.010	0.011	0.011	0.011	0.011	0.012	0.012
102	0.012	0.013	0.013	0.013	0.013	0.014	0.014	0.014	0.015	0.015
103	0.015	0.016	0.016	0.017	0.017	0.017	0.018	0.018	0.019	0.019
104	0.019	0.020	0.020	0.021	0.021	0.022	0.022	0.023	0.023	0.024
105	0.025	0.025	0.026	0.026	0.027	0.028	0.028	0.029	0.030	0.030
106	0.031	0.032	0.032	0.033	0.034	0.035	0.035	0.036	0.037	0.038
107	0.039	0.040	0.041	0.042	0.043	0.044	0.045	0.046	0.047	0.048
108	0.049	0.050	0.051	0.052	0.054	0.055	0.056	0.058	0.059	0.060
109	0.062	0.063	0.065	0.066	0.068	0.069	0.071	0.072	0.074	0.076
110	0.078	0.079	0.081	0.083	0.085	0.087	0.089	0.091	0.093	0.095
111	0.098	0.100	0.102	0.105	0.107	0.110	0.112	0.115	0.117	0.120
112	0.123	0.126	0.129	0.132	0.135	0.138	0.141	0.145	0.148	0.151
113	0.155	0.158	0.162	0.166	0.170	0.174	0.178	0.182	0.186	0.191
114	0.195	0.200	0.204	0.209	0.214	0.219	0.224	0.229	0.234	0.240
115	0.245	0.251	0.257	0.263	0.269	0.275	0.282	0.288	0.295	0.302
116	0.309	0.316	0.324	0.331	0.339	0.347	0.355	0.363	0.372	0.380
117	0.389	0.398	0.407	0.417	0.427	0.437	0.447	0.457	0.468	0.479
118	0.490	0.501	0.513	0.525	0.537	**0.550**	0.562	0.575	0.589	0.603
119	0.617	0.631	0.646	0.661	0.676	0.692	0.708	0.724	0.741	0.759
120	0.776	0.794	0.813	0.832	0.851	0.871	0.891	0.912	0.933	0.955
121	0.977	1.000	1.023	1.047	1.072	1.096	1.122	1.148	1.175	1.202
122	1.230	1.259	1.288	1.318	1.349	1.380	1.413	1.445	1.479	1.514
123	1.549	1.585	1.622	1.660	1.698	1.738	1.778	1.820	1.862	1.905
124	1.950	1.995	2.042	2.089	2.138	2.188	2.239	2.291	2.344	2.399
125	2.455	2.512	2.570	2.630	2.692	2.754	2.818	2.884	2.951	3.020
126	3.090	3.162	3.236	3.311	3.388	3.467	3.548	3.631	3.715	3.802
127	3.890	3.981	4.074	4.169	4.266	4.365	4.467	4.571	4.677	4.786
128	4.898	5.012	5.129	5.248	5.370	5.495	5.623	5.754	5.888	6.026
129	6.166	6.310	6.457	6.607	6.761	6.918	7.079	7.244	7.413	7.586
130	7.762	7.943	8.128	8.318	8.511	8.710	8.913	9.120	9.333	9.550
131	9.772	10.000	10.233	10.471	10.715	10.965	11.220	11.482	11.749	12.023
132	12.303	12.589	12.882	13.183	13.490	13.804	14.125	14.454	14.791	15.136
133	15.488	15.849	16.218	16.596	16.982	17.378	17.783	18.197	18.621	19.055
134	19.498	19.953	20.417	20.893	21.380	21.878	22.387	22.909	23.442	23.988

1. As shown in Section 1.4.1 page 43, lethal rate (L) may be calculated using the equation $L = Log^{-1} (T - T_r) / z$. The highlighted example shows that at 118.5°C the lethal rate (L) is equal to 0.550.
2. Selection of appropriate values for T_r and Z is discussed on pages 44 and 45.

Table 2.2. Values of u for v ranging from - 0.2 to 3.49 (from Board and Steele, 1978)

v	0.00	0.01.	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
- 0.2	0.003	0.003	0.003	0.003	0.004	0.004	0.005	0.005	0.005	0.006
- 0.1	0.006	0.007	0.008	0.008	0.009	0.010	0.010	0.011	0.012	0.013
0.0	0.014	0.015	0.016	0.017	0.019	0.020	0.021	0.022	0.024	0.025
0.1	0.027	0.029	0.030	0.032	0.034	0.036	0.038	0.040	0.042	0.044
0.2	0.047	0.049	0.051	0.054	0.057	0.059	0.062	0.065	0.068	0.071
0.3	0.074	0.077	0.080	0.084	0.087	0.091	0.094	0.098	0.102	0.106
0.4	0.110	0.114	0.118	0.122	0.126	0.131	0.135	0.140	0.144	0.149
0.5	0.154	0.159	0.164	0.169	0.174	0.179	0.184	0.190	0.195	0.201
0.6	0.206	0.212	0.218	0.223	0.229	0.235	0.241	0.247	0.253	0.260
0.7	0.266	0.272	0.279	0.285	0.292	0.298	0.305	0.312	0.318	0.325
0.8	0.332	0.339	0.346	0.353	0.360	0.368	0.375	0.382	0.390	0.397
0.9	0.404	0.412	0.419	0.427	0.435	0.442	0.450	0.458	0.466	0.474
1.0	0.482	0.490	0.498	0.506	0.514	0.522	0.530	0.538	0.546	0.555
1.1	0.563	0.571	**0.580**	**0.588**[1]	0.597	0.605	0.614	0.622	0.631	0.639
1.2	0.648	0.657	0.665	0.674	0.683	0.692	0.700	0.709	0.718	0.727
1.3	0.736	0.745	0.754	0.763	0.772	0.781	0.790	0.799	0.808	0.817
1.4	0.826	0.835	0.844	0.853	0.863	0.872	0.881	0.890	0.900	0.909
1.5	0.918	0.927	0.937	0.946	0.955	0.965	0.974	0.984	0.993	1.002
1.6	1.012	1.021	1.031	1.040	1.050	1.059	1.069	1.078	1.088	1.097
1.7	1.107	1.116	1.126	1.136	1.145	1.155	1.164	1.174	1.184	1.193
1.8	1.203	1.212	1.222	1.232	1.241	1.251	1.261	1.270	1.280	1.290
1.9	1.300	1.309	1.319	1.329	1.339	1.348	1.358	1.368	1.378	1.387
2.0	1.397	1.407	1.417	1.426	1.436	1.446	1.456	1.466	1.475	1.485
2.1	1.495	1.505	1.515	1.524	1.534	1.544	1.554	1.564	1.574	1.584
2.2	1.593	1.603	1.613	1.623	1.633	1.643	1.653	1.662	1.672	1.682
2.3	1.692	1.702	1.712	1.722	1.732	1.742	1.751	1.761	1.771	1.781
2.4	1.791	1.801	1.811	1.821	1.831	1.841	1.851	1.860	1.870	1.880
2.5	1.890	1.900	1.910	1.920	1.930	1.940	1.950	1.960	1.970	1.980
2.6	1.990	2.000	2.009	2.019	2.029	2.039	2.049	2.059	2.069	2.079
2.7	2.089	2.099	2.109	2.119	2.129	2.139	2.149	2.159	2.169	2.179
2.8	2.189	2.199	2.209	2.219	2.229	2.239	2.248	2.258	2.268	2.278
2.9	2.288	2.298	2.308	2.318	2.328	2.338	2.348	2.358	2.368	2.378
3.0	2.388	2.398	2.408	2.418	2.428	2.438	2.448	2.458	2.468	2.478
3.1	2.488	2.498	2.508	2.518	2.528	2.538	2.548	2.558	2.568	2.578
3.2	2.588	2.598	2.608	2.618	2.628	2.638	2.648	2.658	2.668	2.678
3.3	2.688	2.698	2.708	2.718	2.728	2.738	2.748	2.758	2.768	2.778
3.4	2.788	2.797	2.807	2.817	2.827	2.837	2.847	2.857	2.867	2.877

1. Interpolation of the data when u is equal to 0.584 shows that v is equal to 1.125

As shown by Board and Steele (1978) the equations used in the Gillespy Method calculations could be incorporated into automated calculations and for these purposes a model was required to generate the values of u and v, which are shown in Table 2.2. When describing the model that he had developed Steele (*pers comm.*, 1983) noted "A desirable feature of the model is that the same coefficients be used to calculate v from u or u from v. A suitable model is to fit the data to a series of second order polynomials. We have been able to reduce the data from the table (Table 2.2) to six polynomials, five with a second order component and one linear. The table of coefficients for the polynomials and their appropriate ranges are described (in Table 2.3). The polynomials fit the data to within 0.001, which is sufficiently accurate for all process conditions."

Table 2.3. Coefficients for the polynomials of the form $u = a\,v^2 + b\,v + c$ (From Board and Steele 1978)

	Coefficient			Range			
				v		u	
Polynomial number	a	b	c	From	To	From	To
1	0.2500	0.1050	0.0140	- 0.2	0	0.003	0.014
2	0.4000	0.0800	0.0140	0	0.8	0.014	0.330
3	0.1750	0.4475	- 0.1405	0.8	1.3	0.330	0.740
4	0.0500	0.7850	- 0.3720	1.3	2.07	0.740	1.500
5	0.0062	0.9605	- 0.5500	2.07	3.40	1.500	2.800
6	0.0000	1.0000	- 0 0613	3.40	∞	2.800	∞

2.1.2 Derivation of DWC's Method for calculation of F value and processing time

As discussed in Section 1.4.2, in its original form the Gillespy Method over-estimated the F values achieved by a given process, or under-estimated the processing times required to deliver a target F value. When this error was "corrected," by Board and Steele (1978), by inclusion by the "constant" 0.08 in equations 3 and 4 (on page 58), the modified method was found to yield reasonable results at the relatively low retort temperatures in use at that time (typically, at less than 121°C). However, it tended to significantly under-estimate actual F values, or over-estimate processing times, at higher retort temperatures (e.g. 122 to 135°C). It was these inaccuracies (which are described on pages 48 to 50) which prompted the derivation of DWC's Method as a means of addressing the errors in estimation of that part of the total F value that was accumulated during cooling.

For this reason one of the research objectives of this thesis was to develop and validate an "improved" predictive model for calculating processing times (P_t) and/or F values. Henceforth this method of calculation will be referred to as DWC's Method. (DWC's Method is contained in the DWC Analyser software package referred to on pages 39 and 107-112.)

DWC's Method enables the, so-called, 0.08 cooling constant to be adjusted so that the F value contribution that was delivered after steam-off was comparable to that indicated by the General Method. This is achieved by providing a simple mechanism for correcting the 0.08 cooling constant until the F values in cooling matched those determined via the General Method.

Like the methods of Gillespy (1951) and Board and Steele (1978), DWC's Method is based on solution of the equation below, which expresses the accumulated lethality of a process (i.e. the F value) as the integrated sum of the lethalities over the duration of the heating cycle.

$$F = \Delta t \sum L$$

As has been shown (Section 1.4.1) this equation also forms the basis for the General Method of F calculation. However, unlike the General Method (in which actual time-temperature data are available) neither DWC's Method, nor Gillespy's (1951) original method nor the method of Board and Steele (1978) require knowl-

edge of product core temperatures continuously throughout a thermal process. Rather, the predictive nature of the latter three methods make it possible to solve for F, once the f_h value and the core temperature (T_{SHP}) of the product at the SHP at any time (t) during the heating process are known. In each case, the core temperature can be calculated (rather than being measured) through the equation

$$T_{SHP} = T_{Ret} - j\,(T_{Ret} - T_o)\,10^{-t/f}$$

Where T_{Ret} = the temperature of the retort

j = the heating lag factor

T_o = the initial product temperature

2.2 Comparison of F values determined with Gillespy's and DWC's Methods of calculation

The objectives of the trials described in this section were as follows;

1. Working with primary heat penetration data gathered from trials in commercial canneries in Australia, New Zealand and the United Arab Emirates (UAE), to compare the accuracy of Board and Steele's (1978) modification of Gillespy's Method, DWC's Method and FMC's NumeriCal© for calculation of F values with results determined when using the General (or Reference) Method.

2. Using the heating parameters that have been derived from analysis of primary data, to compare the accuracy of Gillespy's and DWC's Methods for prediction of F values with the results obtained when using FMC's NumeriCal© under a range of processing conditions likely to be encountered in commercial practice.

FMC's NumeriCAL© is a commercial software package that is available in an off-line form for approximately Aus$25,000. FMC's validation of NumeriCAL has led to its approval by the United States' Food and Drug Administration (USFDA) and

the United States' Department of Agriculture (USDA) and its widespread use throughout the North American and European heat processing industries.

The feature of NumeriCal that accounts for its accuracy is that it uses primary heat penetration data to compute the heating parameters (j_h and f_h) and the cooling parameters (j_c and f_c) and this enables derivation of theoretical heating and cooling curves which match the actual curves. Once these derived curves are established calculation of F values is a simple procedure.

NumeriCal's adoption by the Australasian food processing industry has been slow and confined to abalone and paua processors for whom the risks of inadequate processes are relatively high because of their preference for thermal processes which deliver minimum target F_o values of 2.4 min, and little more.

The procedures used to calibrate thermocouples and gather heat penetration data for the comparative analyses described above were similar to those described in Section 2.3.

2.3 Evaluation of process adequacy via heat penetration studies

The objective of the trials described in this section was to evaluate the adequacy of thermal processes (F_p or F_o values) with respect to their compliance with the generally recognised target F values and GMP for minimally processed foods (REPFEDs) and shelf-stable foods. In the former cases, the products included acid and low-acid chilled soups and sauces, rice, noodles, vegetables, dairy products and seafoods, manufactured commercially, in various sites in Australia and New Zealand. Process evaluation for shelf-stable products included vegetables, dairy products, infant foods, sauces, meats and seafood products manufactured commercially, in Australia, New Zealand, Thailand and United Arab Emirates (UAE).

Shown in Tables 2.5 and 2.6, respectively, are the REPFEDs and shelf-stable products for which F_p or F_o values were determined for comparison with Good Manufacturing Practice (GMP) values. Also shown in these tables are the processing conditions where these are relevant to the F_o and F_p values obtained, and the number of replicate packs in each heat penetration trial.

Table 2.5. Summary of REPFEDs and thermal processing conditions for which process F_p values were determined for comparison with GMP values

Food category	Location of manufacturer	Container	Number of replicates	Process[1] (°C)	Process[1] (min)
Acid soups & sauces	Australia	250 g pouch	15	85.0	40
	New Zealand	175 g pouch	Continuous[2]	≥ 78.0	Cool[3]
	"	300 g tub	"	≥ 78.0	Cool
Low-acid soups & sauces	Australia	250 g pouch	15	85.0	40
	New Zealand	175 g pouch	Continuous	≥ 78.0	Cool
	"	300 g tub	"	≥ 78.0	Cool
Seafoods	Australia	225 g cup	6	105.0	40
	"	240 g cup	6	105.0	23
	New Zealand	1 kg pouch	6	105.0	20
Rice	Australia	200 g tub	20	100.0	15
	"	1.5 kg pouch	8	100.0	30
Noodles	Australia	200 g tub	16	100.0	10
Vegetables	Australia	1.5 kg pouch	3 & 4	100.0	25
Dairy products	Australia	125 g tub	7	~~0~~113.0	~~11~~335

1. Process signifies the temperature and the duration of the heat treatment.
2. "Continuous" indicates filling temperatures were monitored in the filling hopper continuously.
3. "Cool" represents a hot fill (at ≥ 78 °C) and cool process without any prescribed intermediate hold phase prior to the start of cooling.

Table 2.6. Summary of shelf-stable foods and thermal processing conditions for which process F_o values were determined for comparison with GMP values

Food category	Location of producer	Container	Replicates	Process [1] (min)	Process [1] (°C)
Vegetables	Australia	150 g can	5	8	122.0
	"	210 g can	8	45	121.0
	"	340 g can	10	12	120.0
	"	340 g can	10	26	116.0
	"	420 g can	10	23	116.0
	"	420 g can	5	85	116.0
	"	2950 g can	5	30	116.0
	New Zealand	Twin-pack pouch	10	30	120.0
	"	1 kg pouch	2	23	120.0
CIC[2]	Australia	150 g can (O)[3]	10	20	122.5
	"	(A)[4]	9	33[5]	120.0
	"	150 g can (O)	5	7[5]	118.0
	"	(A)	24	9	117.0
	"	250 g can (O)	24	50	117.0
	"	(A)	10	45[5]	117.0
Sauces	Australia	375 g jar	6	65	119.0
	Thailand	375 g jar	5	50	119.0
CIC[6]	Australia	170 g jar	5	20	102.2
	"	170 g jar	6	25	124.4
	"	170 g jar	4	55	118.9
Meats	Australia	340 g can	6	48	110.0
	"	450 g can	5	48	110.0
	"	905 g can	6	90	110.0
	UAE	415 g can	6	95	115.0
	"	850 g can	6	100	115.0
Seafoods	Australia	375 g jar	9	75	121.1
Molluscs	Australia	410 g can	3	45	113.7
	"	Unit pouch	12	64	114.0
	New Zealand	410 g can	18	36	116.0
	"	Unit pouch	7	36	113.3
	"	"	7	40	113.3
	"	"	7	46	113.3

1. Process signifies the temperature and the duration of the heat treatment.
2. "CIC" signifies identity of low-acid product classified as Commercial-in-Confidence.
3. "O" signifies original process, before processing conditions were altered.
4. "A" signifies amended process, after processing conditions were altered to increase F_o value.
5. Processes included a temperature over-shoot for retort equilibration prior to stabilising hold phase on set value.
6. "CIC" signifies identity of acid product (processed at 102.2 °C) and two low-acid products classified as Commercial-in-Confidence.

Data acquisition during process evaluation trials was with copper-constantan Type T thermocouple probes and an Ellab CMC 821 digital recorder (Ellab A/S, Krondalvej 9, DK-2610 Roedovre, Denmark) or a DWC M16F Data Logger (DWC FoodTech Pty. Ltd., Melbourne, Australia). Prior to each trial, all thermocouples were calibrated against the reference thermometer that was attached to the retort, or to the heating vessel, in which the respective products were being processed. When calibrating the probes, they first were gathered and bound in a cluster, so that their tips were adjacent to one another, after which the cluster was placed adjacent to the measuring point of the reference thermometer inside the processing vessel. In Plates 2.1 and 2.2 can be seen the arrangement for positioning thermocouples for calibration in an FMC water-spray retort. In this example, the tips of the probes are located adjacent to the end of the stem of the reference MIG (mercury in glass) thermometer.

In order to gather heat penetration data in replicate test packs, the tips of thermocouple probes were positioned at the slowest heating points (SHPs) of filled containers which were located at the cold-spot of the processing vessel. Examples of these arrangements are shown in Plates 2.3, 2.4 and 2.5. In Plate 2.4 can be seen the manner in which the tip of the thermocouples were located at the SHP of the products (in this instance whole shell mussels in pouches). In Plate 2.5 can be seen an external view of the arrangement for introducing the thermocouple through the side of the vacuum sealed retort pouch and the method by which free probes are attached to measure the retort temperature adjacent to the sealed package. In Plate 2.6 can be seen six replicate pouches on a single retort tray with thermocouples attached and in Plate 2.7 is the arrangement showing 11 layers of trays that make up a single retort trolley. Similar techniques to those shown in Plates 2.1 to 2.7 were used throughout the process evaluation trials described in this section. In those instances when retorts were operating with rotation the thermocouples were passed into the retort through a slip-ring assembly.

Unless otherwise specified, filling and processing conditions were selected to replicate, so-called, worst-case conditions. In this manner variables such as fill temperatures, fill weights of solids and/or liquid components, particle or portion size, product viscosity, container headspace (in cases of products that were processed with rotation), retort come-up time, processing temperature and processing time were all selected in order to minimize heating at the slowest heating point. Under these circumstances, the F_o or the F_p values that were obtained

would represent the "least values" likely to be experienced with commercial operating conditions.

The data were automatically collected on file for analysis using DWC Analyser (DWC FoodTech Pty. Ltd., Melbourne, Australia) a software package that had been developed as part of this thesis and refined during the period of these evaluations. DWC Analyser automatically generates the semi-log heating plots from the time-temperature data at the SHPs for each of the test packs containing thermocouples and then calculates the respective heating parameters f_h and j. For each data set DWC Analyser simultaneously calculates the corresponding F_o and F_p values by means of the General Method of calculation.

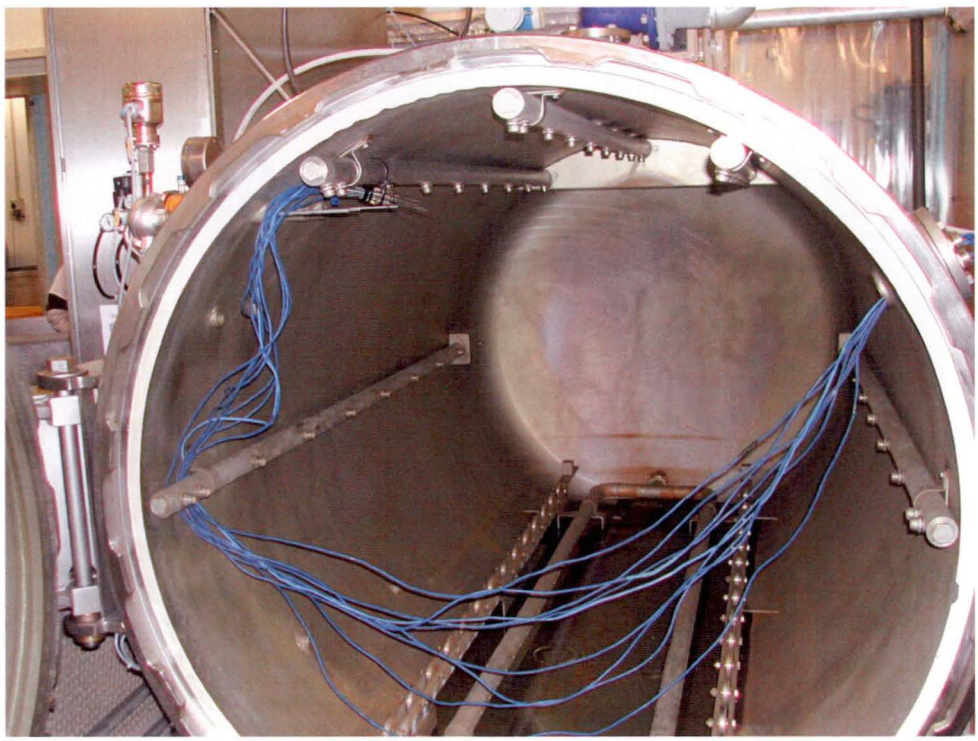

Plate 2.1. Location of thermocouples adjacent to the end of the stem of the reference thermometer for calibration in two-basket FMC water-spray retort.

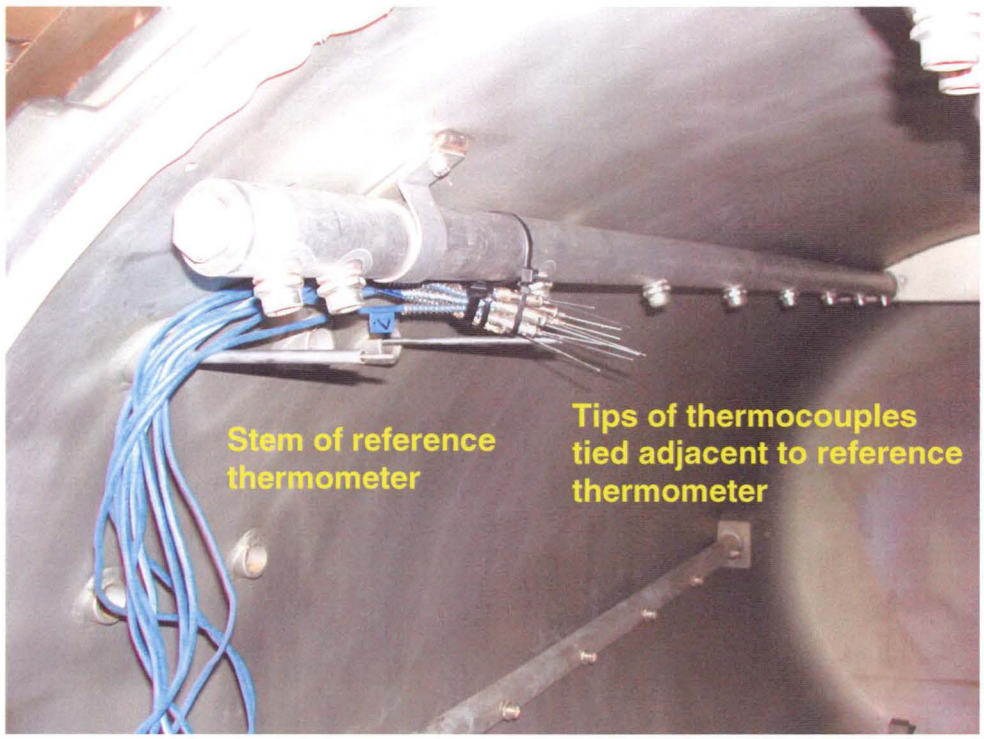

Plate 2.2. Location of thermocouples adjacent to the end of the stem of the reference thermometer.

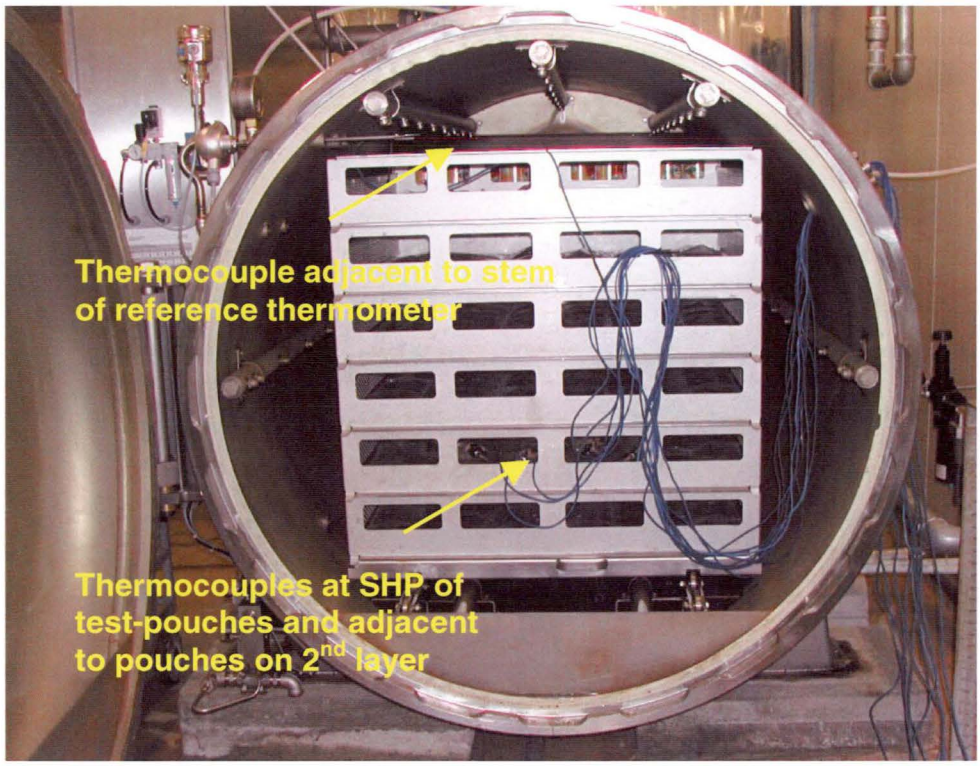

Plate 2.3. End-on view of test basket with six layers of tray dividers for processing retort pouches. The thermocouples located at the SHPs in test-pouches, and a single thermocouple recording the temperature of the retort at the external surface of the pouches, are located on the second of six layers, which was found to be the "cold spot" in the vessel. Also shown, is a single thermocouple for recording the temperature at the reference thermometer throughout the process.

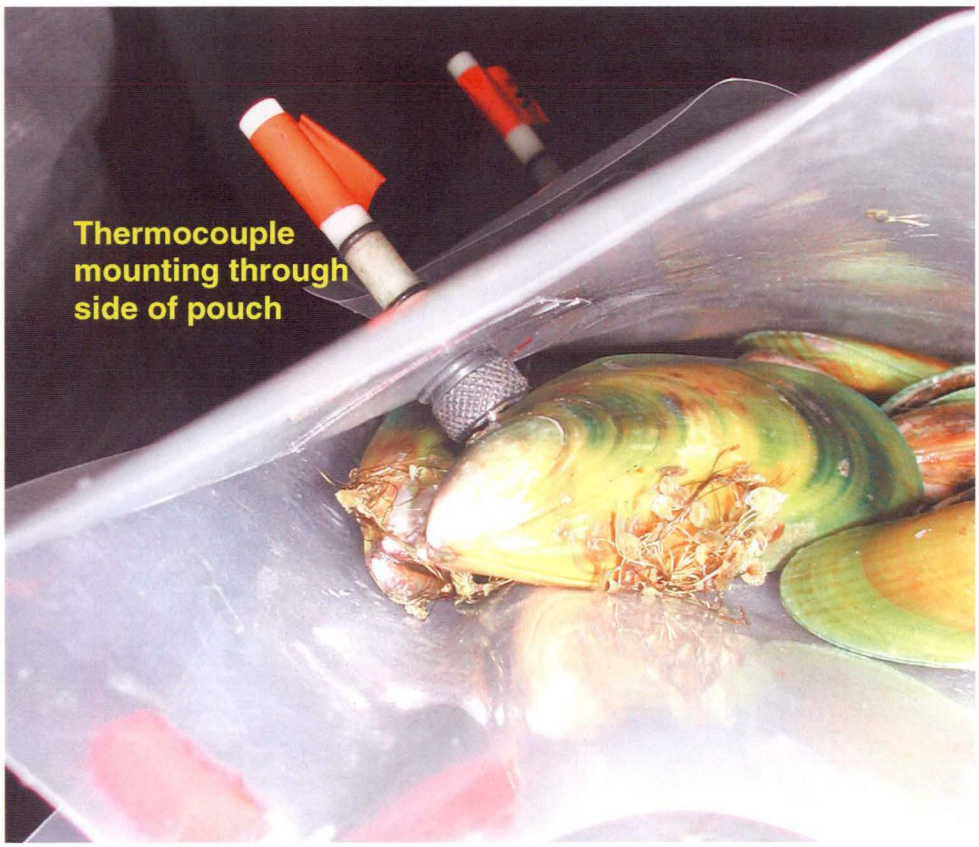

Plate 2.4. Packing gland arrangement for mounting thermocouple through the side of the pouch into the slowest heating point of the flesh of the whole-shell mussel.

Plate 2.5. Thermocouple mounted through packing gland. Also shown is the tip of the "Free" probe used to monitor retort temperature adjacent to the test packs.

Plate 2.6. Arrangement showing six replicate pouches on a single retort tray with thermocouples attached and in two cases the “free” probes used to monitor retort temperature.

Plate 2.7. Stacking arrangement for 11 layers of trays. In this example the pouches with thermocouples attached to the SHPs are on the 2nd layer while the bottom layer was left empty.

2.4 Evaluation of Biotests to assess the adequacy of hermetic seals

In order to investigate the propensity for post-process leaker contamination (PPLC) in several commercial packaging systems, and with systems that were under development prior to their commercial release, a microbiological challenge test (Biotest) was developed. In all cases the packaging system under investigation had been designed (by the manufacturer) to provide hermetic seals that would withstand the rigors of thermal processing and thereafter provide protection from PPLC during transit along the manufacturer's packaging line, throughout the storage and delivery chains and during routine handling by the end-user.

The Biotest procedure was used to evaluate the hermetic seals in the following four packaging systems;

- Glass containers sealed with Trivac closures (ACI Metal Closures, Spotswood, Victoria), local and imported twist-style metal caps, and PT (Push-On Twist-Off) closures.
- Three-piece metal cans sealed with standard sanitary can ends and with Full-Panel Easy-Open (FPEO) metal ends.
- Barrier plastic trays sealed with laminated heat sealable aluminium foil.
- Barrier plastic heat-sealable pouches.

The rationale for the Biotest is that it challenges the adequacy of hermetic seals, in particular their ability to prevent post-process leaker contamination, under simulated worst-case conditions. For this reason the effect on seal performance of the following variables is often considered;

- The composition and/or supplier of the packaging material
- Sealing temperature, pressure and sealing time with heat seal applications
- The profile of the sealing heads with heat seal applications

- The profile of the sealing surface and its relation to the compound or sealing gasket in glass closure systems
- The formation of the double-seam in metal cans
- Vacuum where applicable
- Fill weights and/or headspace
- Processing temperature, time and over-pressure
- Fill temperatures

Hermetic seals were visually inspected prior to subjecting the containers to the Biotest in order to ensure that only those seals that appeared to be of commercial quality were tested. Hermetic seals that contained obvious defects that might be expected to affect performance were not necessarily excluded from the Biotest, however they were not included in the test result, as they were not representative of commercial quality finished product.

The common procedure that was adopted was to challenge the integrity of hermetic seals in packs that had been sterilised (in the case of low-acid products) or pasteurised (with medium and high-acid products and/or minimally processed low-acid products). Following their respective heat treatment, test packs and controls which had been filled with product, or a suitable growth medium, and then sealed were manually removed from the retort (or the heating vessel) and submerged in a water bath containing approximately 10^5 to 10^6 *Enterobacter aerogenes*/mL in a 0.1% peptone solution at ambient temperature. After immersion for 15 to 20 minutes, the test packs were removed from the broth and subjected to a standard mechanical impact about the seal area. In those cases where impact was not feasible, as with flexible pouches or heat-sealed plastic trays, the containers were aspirated by hand (for approximately 20 s) immediately prior to their removal from the test solution. Following aspiration or impact, the test packs were transferred to an incubator at 30°C for up to 21 days. The balance of the test packs (acting as controls) was removed from the solution and placed directly in an incubator at 30°C for up to 21 days.

The objective of the Biotests was to induce detectable levels of spoilage in tests containers and in control containers. In all cases, a positive result (indicative of

PPLC) was considered one in which the test container and/or the control produced gas and was swollen because of bacterial action inside the container. The contamination level (10^5 to 10^6 *Enterobacter aerogenes*/mL) in the immersion bath was selected as it represents between 10 and 100 times that considered acceptable for the microbiological quality of cooling water in can double seams after cooling has been completed. This level of contamination represents an extreme condition as many of the newer style over-pressure retorts (introduced in Australia in the last 15 to 20 years and manufactured by FMC [FMC Technologies Inc., Madera, California], Barriquand [Barriquand Steriflow, Paris, France] or Lagarde's water-shower [Lagarde, Montelimar Cedex, France]) operate with, so-called, closed-circuit cooling water systems. This means that, having been exposed to the entire heating phases of the process, the water that recirculates through the system and comes into direct contact with the containers has been indirectly cooled via a heat exchanger. Therefore, because of the heat treatment that it has received (by the time that cooling commences), the cooling water is sterile (or at least records a not-detectable Viable Count). It is for this reason that, unlike the cooling water in conventional steam retorts, the cooling water in FMC, Barriquand and Lagarde retorts is not chlorinated. Under these circumstances, the Biotest immersion medium is likely to have contamination levels that are of the order of 10^5 to 10^6 times that of the retort cooling water in, so called, closed circuit systems.

Not only is the Biotest an evaluation of seal performance under worst-case conditions but also it is, by design, sufficiently severe to induce detectable levels of PPLC in commercial packaging systems acting as controls. As cans and glass jars of various capacities have established a sound track record over four to five decades, and more, it is reasonable that systems such as these should provide the benchmark against which alternate packaging systems can be compared.

That control packs may fail the Biotest, while nevertheless performing satisfactorily in the trade, demonstrates the magnitude of the worst-case conditions that have been re-produced. Furthermore, results that show failure rates in test containers that do not exceed those obtained with a commercial packaging system (acting as a control) will provide evidence of the acceptability of the system under evaluation.

2.4.1 Glass containers sealed with Trivac closures, local and imported twist-style metal caps, and PT (Push-On Twist-Off) closures

In this series of Biotests, Trivac closures applied to the microwaveable glass jars were the test variable under examination, while local (Australian) and imported (French) twist caps and local PT closures were included as controls. The objective of the Biotest was to determine whether the Trivac closure would provide a sufficiently robust hermetic seal to withstand retorting and post-process handling. Previously, the experience in Australia with Trivac closures had been confined to non-retorting applications (such as with jams and spreads) in which the seals were not exposed to temperatures above ambient or over-pressure. Also, in these circumstances because of the nature of the products, had the Trivac closures failed, there were no associated health risks. This was in contrast with the proposed new application in which the closures were to be applied to glass jars containing acid and low-acid products and in the latter case seal failure might lead to PPLC and unacceptable health risks. A total of 1,241 containers were tested, of which 645 were sealed with Trivac closures and 596 were sealed with control closures.

Commercially prepared product that had been filled, vacuum-sealed with Trivac closures, and heat processed in 370 g prototype jars manufactured by ACI Glass Packaging, were supplied by the manufacturer of an established Australian brand of shelf-stable foods for whom the trials were being conducted. All jars had been filled with one of three different product formulations. Of these, two products were classified as low-acid (chilli con carne and macaroni cheese with their pH values > 4.6) and were retorted (by the food manufacturer) in order to achieve a target F_o value ≥ 2.8 min. The remaining product (macaroni napolitan with a pH value ≤ 4.6) was classified as acid and was hot filled, sealed and cooled without retorting.

The Australian made control twist caps were applied to 375 g jars that had been filled with commercially prepared blends of fettuccini alfredo and spaghetti carbonara and processed (by the food manufacturer) to achieve an F_o value ≥ 2.8 min. In addition, two further sets of controls were prepared, one of which used imported twist caps applied to 375 g jars that had been filled with lactose broth (Oxoid Media) and processed in a Barriquand retort according to the test cycle shown in Table 2.7. The other control used commercially purchased infant-formula egg custard that had been filled in 125 g jars, sealed with aluminium PT closures and processed to achieve an F_o value ≥ 2.8 min.

All processed glass containers were equilibrated at ambient temperatures prior to their immersion for 15 to 20 min in an ambient temperature water bath containing approximately 10^5 *Enterobacter aerogenes*/mL.

Following their immersion, control (non-impacted) containers were removed from the bath and placed in an incubator at 30°C for up to 21 days. Those containers that were impact abused were removed from the bath, placed in a test rig, and supported from behind in the manner shown in Plates 2.8 and 2.9. While in this position, the closures were struck on the circumference about their maximum diameter, with the head of a 0.6 kg metal pendulum having an impact velocity of 76 $cm.sec^{-1}$. In addition, in order to evaluate the relative abuse resistance of the hermetic seals under extreme conditions, around 30 jars of each variety of product in microwaveable jars sealed with Trivac closures, and around 30 jars of egg custard sealed with PT caps, were subjected to an impact in which the impact velocity was 165 $cm.sec^{-1}$. In Plates 2.10 and 2.11 are side and elevated views, respectively, showing the extent of the damage suffered by PT caps following impact to jars of egg custard with the pendulum having an impact velocity 165 $cm.sec^{-1}$. Following impact, all test containers were placed in an incubator at 30°C for up to 21 days during which time they were regularly inspected and those that showed obvious signs of spoilage (i.e. gas production and/or leakage) were removed from the incubator. In Table 2.8 can be seen a summary of the various closure and product combinations, their respective codes and the numbers of each that were tested.

Table 2.7. Barriquand over-pressure retort cycle with a 10 min come-up time and 15 min hold time at 121.1°C, used for processing jars of lactose broth sealed with imported twist closures

Phase	Medium	Time (min)	Temperature (°C)	Pressure (kPa)
1	Steam	5.0	80.0	30
2	Steam	5.0	121.1	130
3	Steam	15.0	121.1	200
4	Water	3.0	103.0	120
5	Water	4.0	70.0	50
6	Water	5.0	35.0	0
7	Forced	10.0	-	-
8	End	-	-	-

Table 2.8. Closure and product combinations, codes and numbers tested in Biotest of glass container closure systems

Closure	Product	Code	Variable or control	Number tested
Trivac	Chilli con carne	CCC	Variable	240
Trivac	Macaroni cheese	MC	"	191
Trivac	Macaroni napolitan	MN	"	214
Twist (Local[1])	Fettuccini alfredo	FA	Control	108
Twist (Local[1])	Spaghetti carbonara	SC	"	104
Twist (Imported[2])	Lactose broth	LB	"	196
PT	Egg custard	EC	"	188

1. Closure manufactured in Australia
2. Closure manufactured in France

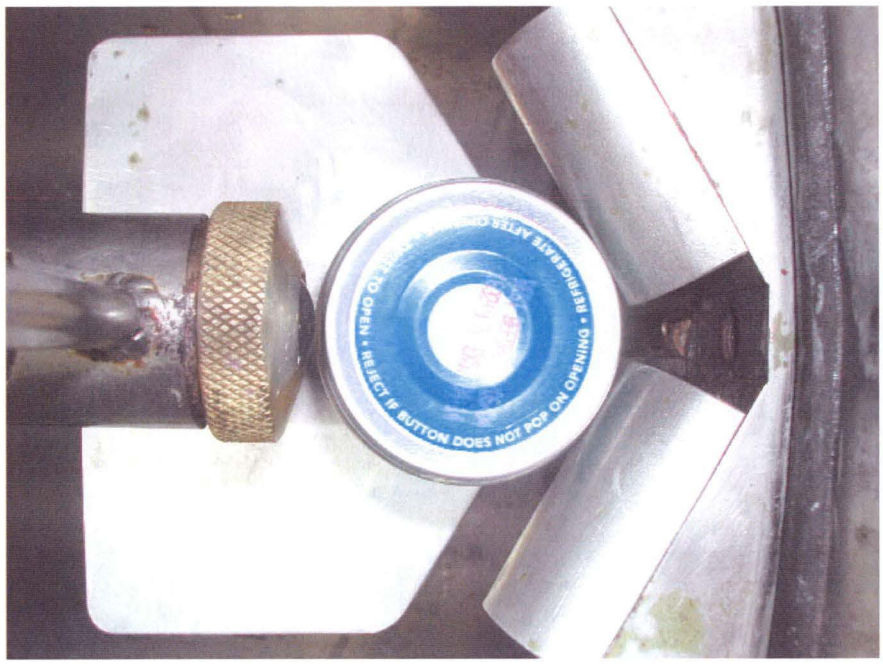

Plate 2.8. Pendulum head at moment of impact with test container

Plate 2.9. Rear view of pendulum head at moment of impact with test container

Plate 2.10. Side view of PT closure following impact with 0.6 kg pendulum head at 165 cm.sec.$^{-1}$.

Plate 2.11. Elevated view of PT closure following impact with 0.6 kg pendulum head at 165 cm.sec.$^{-1}$.

2.4.2 Three-piece metal cans sealed with standard sanitary can ends and with Full-Panel Easy-Open (FPEO) metal ends

The Biotest described in this section was initiated in response to the detection of blown cans prior to the release of commercial stocks (held in the manufacturer's warehouse) of low-acid soups (pH > 4.6) packed in 74 x 112.5 mm (nominally 420 g) cans fitted with Full-Panel-Easy-Open (FPEO) can ends. Although the incidence of spoilage had not been determined, it had been reported that six of 13 varieties of low-acid soups were affected and that spoilage was first detected within four to five days of commercial production, whereas there was no spoilage amongst any tomato based soups (pH 4.1 - 4.3) that had been produced over the same period.

Preliminary microbial analysis of affected stocks had revealed the presence of pure cultures of mesophilic, anaerobic, spore-forming organisms that were typical of *Clostridium* species. Also detected in other containers were various mixed cultures containing clostridia and cocci. The presence of mixed cultures is generally regarded as being indicative of PPLC, whereas the detection of pure cultures of spore-forming microorganisms is typically associated with spoilage caused by under-processing. However, in this instance, examination of electronic and hard-copies of the manufacturer's processing records and examination of the thermochromic (heat sensitive) ink codes printed on the ends of processed cans, established beyond doubt that under-processing could be excluded as the cause of spoilage. Under these circumstances, it was inferred that spoilage had been caused by PPLC and that the reason for the detection of a pure culture of spore forming microorganisms was likely to be the result of the preferential destruction of vegetative non spore-forming bacteria in the chlorinated retort cooling water.

Concurrently with the preliminary and direct evidence from microbial analysis implicating post-process leaker contamination as the cause of spoilage, independent examination by the packaging material supplier indicated that neither the score line on the FPEO can end, nor the rivet used for removing the end, was at fault. For these reasons it was concluded that the most likely path for leakage was via the can's double seam. Provisional double seam analyses indicated that, with the possible exception of the tightness of the double seam at the can makers ends (CMEs), all other double seam attributes at the CMEs and the canners ends (CEs) were adequate and in compliance with GMP. With respect to the marginal

aspects of the tightness of the double seam, it had been found that seam tightness at the CME of spoiled cans was in the range of 65 - 70%, whereas the minimum value recommended in the, then, Australian standard was 70% tightness.

It was in order to establish whether double seam tightness at the CME (i.e. the end which contained the full-panel easy-open feature) of cans was a contributing factor leading to PPLC that the Biotest was conducted. It was against this background and because of the commercial implications arising from forced delays to the scheduled launch of the affected product lines, that it was decided that the challenge tests should be conducted on the following four categories and numbers of cans;

- Two thousand and two (2,002) suspect cans in which the tightness rating at the CMEs was 65 - 70% (coded as EOO, signifying easy-open original seam tightness).

- Two thousand and fifty four (2,054) cans that had been manufactured to have their tightness rating at the CMEs at > 90% (coded as EOT, signifying tightened easy-open ends).

- One hundred (100) suspect cans in which the second action roll was repeated to increase seam tightness at the CME (coded as EORT, signifying repeat easy-open ends).

- One thousand nine hundred and fourty four (1,944) control cans fitted with standard sanitary ends at the CMEs (coded as CON, signifying control cans).

All containers (with the easy-open ends in place at the CME) were hot filled (≥ 80°C) with a blend of an egg custard medium enriched with sugar. The filled cans were sealed with standard sanitary ends (at the CEs), retorted in order to achieve an F_o value > 2.8 min., cooled in the retort and equilibrated at ambient temperatures prior to their immersion for 15 to 20 min in an ambient temperature water bath containing approximately 10^5 *Enterobacter aerogenes*/mL. The entire filling, sealing, retorting and cooling operations were carried out on the food manufacturer's commercial production line.

On their removal from the immersion bath, approximately half of the original easy-open cans (coded EOO), half of the tightened easy-open cans (coded EOT), and one third of the control containers (coded CON) were placed directly in an incubator at 30 °C without being subjected to any impact.

The balance of the containers (i.e. approximately half of the cans coded EOO and EOT, and 2/3^{rds} of those coded CON, plus all of the cans coded EORT) were transferred to the test rig for immediate impact testing. Of these, all the cans coded EOO, EOT, EORT and half of the cans coded CON were struck a standard blow at the lap on the CME (i.e. at the end containing the easy-open feature). The balance of the control cans (coded CON) were struck a standard blow at the lap (i.e. the point of intersection between the side-seam and the rolled double seam) on the CEs.

Those containers that were impact abused were placed in the test rig and struck a standard blow with the head of a 0.6 kg metal pendulum having an impact velocity of 165 cm.sec^{-1}. The magnitude of damage caused by striking cans in the test rig can be seen in Plates 2.12 and 2.13. Following impact, all damaged cans also were placed in the incubator at 30°C.

All incubated containers were inspected after four days and 10 days storage at which times any blown cans were removed and counted. The incubation test was terminated after 10 days storage and any cans that had blown were considered to have failed the Biotest. A summary of the various categories of cans included in the Biotest can be seen in Table 2.9.

Table 2.9. Summary and distribution of various categories of 74 x 112.5 mm cans subjected to Biotests following detection of blown cans fitted with Full-Panel-Easy-Open (FPEO) can ends amongst commercial stocks of low-acid soups

Can codes and description	Total cans tested	Number with no impact	Number impact tested
EOO – Easy open end with original seam tightness	2,022	1,015	1,007
EOT – Easy open end with original seam tightened	2,054	1,035	1,019
EORT – Easy open end with original seam re-tightened	100	0	100
CON – Control cans with standard sanitary ends at canners end (CE)	648	0	648
CON - Control cans with standard sanitary ends at can makers end (CME)	648	0	648
CON – Control can with standard sanitary ends at CE and CME	648	648	0

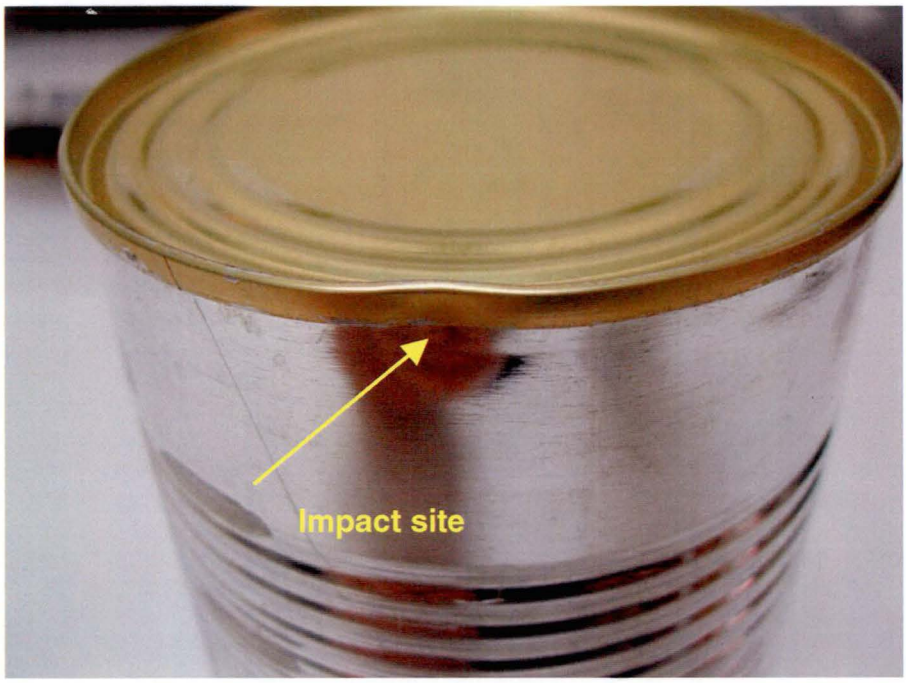

Plate 2.12. Side view of 74 mm can end following impact with 0.6 kg pendulum head at 165 cm.sec.$^{-1}$.

Plate 2.13. Top view of 74 mm can end following impact with 0.6 kg pendulum head at 165 cm.sec.$^{-1}$.

2.4.3 Barrier plastic trays heat sealed with laminated aluminium foil

The two Biotests described in this section were completed as part of a packaging development exercise to evaluate the performance, under challenge conditions, of heat-sealed barrier trays. The 220 g trays and the foil top-web in the study were subjected to testing during the commissioning process of a new high-barrier plastic tray packaging line that had been installed for manufacture and supply of commercial shelf-stable meals into the Australian and New Zealand markets. At the time of the trials, no shelf-stable meals in barrier trays had been produced commercially in Australia.

Although the trays used in each of the Biotests were of identical design and had identical performance requirements, those used in the first Biotest were imported, whereas those used in the second test had been produced by an Australian manufacturer. Prior to production of the trays for use in the second trial, no similar barrier-containers suitable for retort applications had been locally manufactured. Notwithstanding this, the heat processing aspects of the trials were no more than an extension of existing practices used for the manufacture of low-acid foods packed in cans and glass. There was, however, a lack of commercial experience with use of each of the imported sealing machine, the barrier trays, and the foil top web that were to be used in this application.

Neither the supplier of the barrier trays nor the supplier of the aluminium top web provided instructions as to the recommended conditions for heat-sealing the trays. Similarly, the sealing machine supplier was able to provide only general information relating to the preferred settings for use of their machine. In the absence of explicit machine set-up procedures, and finished pack testing criteria that normally would be used when evaluating can double-seams and/or glass container closures, the quality of the heat seals was first assessed in terms of appearance and performance in simple mechanical tests. These assessments included visual inspection for the absence of obvious seal defects such as blisters, creases or folds in the seal area, and burst pressure and seal strength tests. Thereafter, those packs that were assessed as commercial were subjected to the Biotest evaluations.

Because of the vulnerability of semi-rigid packaging systems to mechanical damage during handling, it was decided to incorporate an actual and a simulated

transport test in each of the Biotests. In the first instance (Biotest 1) the filled and sealed containers packed in cartons were placed on a test-rig that simulated a, so-called, "generic road profile test" prior to Biotesting and incubation. In the second test (Biotest 2), following their immersion and aspiration but prior to incubation, the containers (also in cartons) were transported by road from metropolitan Melbourne to country Victoria for storage at 30°C. After incubation was completed, these containers were than returned by road transport to the manufacturing plant in Melbourne for inspection.

Biotest 1 – imported trays with simulated transport.

Twelve hundred imported trays were hot filled (70°C) with a starch slurry which had been shown in preliminary studies to support the growth of the *Enterobacter aerogenes* test culture accompanied by voluminous gas production. After filling, the barrier trays were heat-sealed and individually inspected prior to being manually placed inverted on retort trays. The purpose of the inspection was to cull from the test, those packs that appeared to have unsatisfactory heat seals. After loading, the trays were placed on two retort trolleys and positioned into a two-basket Barriquand retort for processing according to the test cycle shown in Table 2.10 in order to achieve an F_o value > 10 min.

Table 2.10. Barriquand over-pressure retort cycle with a 35 min come-up time and 28 min hold time at 122.0°C, used for processing barrier trays heat-sealed with aluminium foil

Phase	Medium	Time (min)	Temperature (°C)	Pressure (kPa)
1	Steam	15.0	90.0	50
2	Steam	20.0	122.0	160
3	Steam	3.0	122.0	180
4	Steam	25.0	122.0	180
5	Water	8.0	70.0	120
6	Water	5.0	60.0	70
7	Water	6.0	50.0	50
8	Forced	6.0	35.0	0
9	End	-	-	-

After cooling, the containers were removed from the retort and equilibrated at ambient temperatures. Nine hundred (of the 1200) trays were then packed into individual cardboard sleeves, which were then packed 24 per carton for transport to Victoria University of Technology's Packaging Laboratory for simulated transport tests.

In each of the simulated transport tests, cartons (containing 24 trays) were stacked four high and clamped on a test rig with a 30 kg weight placed on top of the uppermost carton. Each of nine sets of four cartons (i.e. 9 x 4 x 24 = 864 trays) was tested in this manner and subjected to Victoria University of Technology's generic road profile (Random Profile No. 2) testing sequence for 30 min., while the table acceleration was set at 0.7 $m.s^{-2}$. After completion of the simulated transport test, all cartons were returned to the processing plant for Biotesting.

Eight hundred and sixty four trays were immersed (24 at a time) for 15 to 20 min in an ambient temperature water bath containing between 2.7×10^5 and 4.7×10^5 *Enterobacter aerogenes*/mL. The containers were aspirated by hand while in the immersion bath after which they were removed and allowed to dry in air. Once dry, all containers were hand-packed into single sleeves and then re-packed into cartons (24 sleeves/carton) and incubated at 30°C for 21 days, during which time they were regularly examined and any swollen containers removed and counted. One hundred and ninety two control packs, which had not been subjected to the simulated transport test were also soaked, aspirated and then incubated in the manner described.

Biotest 2 – local trays with road transport.

One thousand ~~eleven~~ one hundred and eighty seven locally manufactured trays were hot filled (70 °C) with a starch slurry which had been shown in preliminary studies to support the growth of the *Enterobacter aerogenes* test culture accompanied by voluminous gas production. After filling, the barrier trays were heat-sealed and individually inspected prior to being placed inverted on retort racks. As with the previous Biotest in this series of trials (i.e. Biotest 1) the purpose of the inspection was to cull from the test those packs that appeared to have unsatisfactory heat seals. In this manner, 1,140 sealed packs were prepared for Biotesting. After loading, the racks were placed on two retort trolleys and positioned

into a two-basket Barriquand retort for processing according to the test cycle shown in Table 2.10 in order to achieve an F_o value > 10 min.

After cooling, the containers were removed from the retort and equilibrated at ambient temperatures prior to their immersion for 20 to 25 min in an ambient temperature water bath containing between 3.9 x 10^6 and 9.1 x 10^6 *Enterobacter aerogenes*/mL. The containers were aspirated by hand while in the immersion bath after which they were removed, allowed to dry in air and hand-packed into cartons (24 units/carton). All cartons were then transferred by road transport to country Victoria and placed in an incubator at 30°C for 14 days. Following incubation, the cartons were returned to the processing plant and examined for evidence of blown packs and/or leakage.

2.4.4 Barrier plastic heat-sealable pouches

The Biotests described in this section were completed in the early stages of a packaging development program in order to evaluate the performance, under challenge conditions, of heat-sealed pouches manufactured on a form-fill-seal (FFS) machine. At the time of the trial, the Australian experience with FFS technology for pouch manufacture was confined to acid food products (in which the pH was ≤ 4.6) and other commodities in which there was considered to be no public health implications associated with seal failure.

Two pouch sizes (1 kg and ~~2~~ 3 kg) were under evaluation and each was being considered by a multinational food manufacturer for supply of acid and low-acid soups and sauces to the food service sector. Two different roll-stock materials for the pouches were supplied by Hosokawa (Japan). The roll-stock for the 1 kg pouches was identified as VASNR-80 and had a nominal thickness of 122µm. This laminate comprised the following structure (outside to inside) 12µm PET-aluminium oxide/15µm PVDC/15µm nylon/80µm random polypropylene copolymer. The roll-stock for the 3 kg pouches was identified as VASNK-100 and had a nominal thickness of 142µm. This laminate comprised the following structure (outside to inside) 12µm PET-aluminium oxide/15µm PVDC/15µm nylon/100µm block polypropylene copolymer.

Five hundred 1 kg pouches and 420 3 kg pouches were formed in-line and filled (at approximately 60°C) with an egg custard that had been shown in preliminary studies to support the growth of the *Enterobacter aerogenes* test culture accom-

panied by voluminous gas production. After filling, the pouches were heat-sealed in-line and individually inspected prior to being manually placed flat on retort trays. The purpose of the inspection was to cull from the test, those packs that appeared to have unsatisfactory heat seals. Once loaded, the pouches were placed on two retort trolleys and placed in a two-basket Barriquand retort for processing according to the test cycle shown in Table 2.11 in order to achieve an F_o value > 10 min.

Table 2.11. Barriquand over-pressure retort cycle with a 16 min come-up time and either a 40, or a 60 min, hold time at 121.0 °C, used for processing 1 kg and ~~2~~ 3 kg, respectively, form-fill-seal pouches.

Phase	Medium	Time (min)	Temperature (°C)	Pressure (kPa)
1	Steam	8.0	90.0	30
2	Steam	8.0	121.0	180
3	Steam	40.0/60.0	121.0	200
4	Water	3.0	100.0	180
5	Water	3.0	90.0	150
6	Water	6.0	70.0	100
7	Water	6.0	40.0	70
8	Water	5.0	30.0	20
9	End			

At the completion of the cycle, the pouches were removed from the retort and equilibrated at ambient temperatures prior to immersion for 15 to 20 min in an ambient temperature water bath containing between 1.5 x 10^6 and 1.6 x 10^6 *Enterobacter aerogenes*/mL. The containers were aspirated ~~(aspirated by hand-~~ manually massaged) while in the immersion bath after which they were removed and allowed to dry in air. Once dry, all containers were placed in an incubator at 37°C for 10 days during which time they were regularly inspected for signs of leakage and/or gas production.

2.5 Evaluation of heat processing equipment through temperature distribution trials

The objectives of the trials described in this section were as follows;

1. Working with primary temperature distribution data gathered from trials in processing establishments in Australia, New Zealand, the Peoples Republic of China and the United Arab Emirates, to assess the performance of various styles of commercial retorts in terms of their compliance with GMP guidelines and regulatory requirements.

2. To demonstrate DWC Analyser as a tool for analysis of retort temperature distribution data using internally derived criteria and other performance parameters that have been specified in GMP guidelines and by regulatory authorities.

2.5.1 Distribution of thermocouples in the retorts and conduct of the trials

Prior to the commencement of the trials, the tips of thermocouples were gathered in a cluster and located adjacent to the reference thermometer of the retort in which the temperature distribution was to be evaluated. (See Plates 2.1 and 2.2; on pages 71 and 72, respectively.) Following their calibration against the reference thermometer at, or close to, the temperature at which the validation study was to be conducted, the thermocouples were positioned between containers that had been filled with product, or water, and sealed. In this manner, thermocouple probes were dispersed over several layers from top to bottom throughout the "test bin" as shown schematically in Figure 2.5. Throughout the trials the retort(s) was (were) operating under "full load" conditions and the "test bin" in which the thermocouples were located was fully packed with containers. The "test bin" was then sequentially located in each of the available positions in the retort, while those bins occupying the remaining positions were also filled with containers, as shown in Figure 2.6.

In those cases where the temperature distribution was evaluated in more than one retort, the test bin containing the thermocouple probes was transferred to the next unit, and the process of moving the bin sequentially through the retort was repeated.

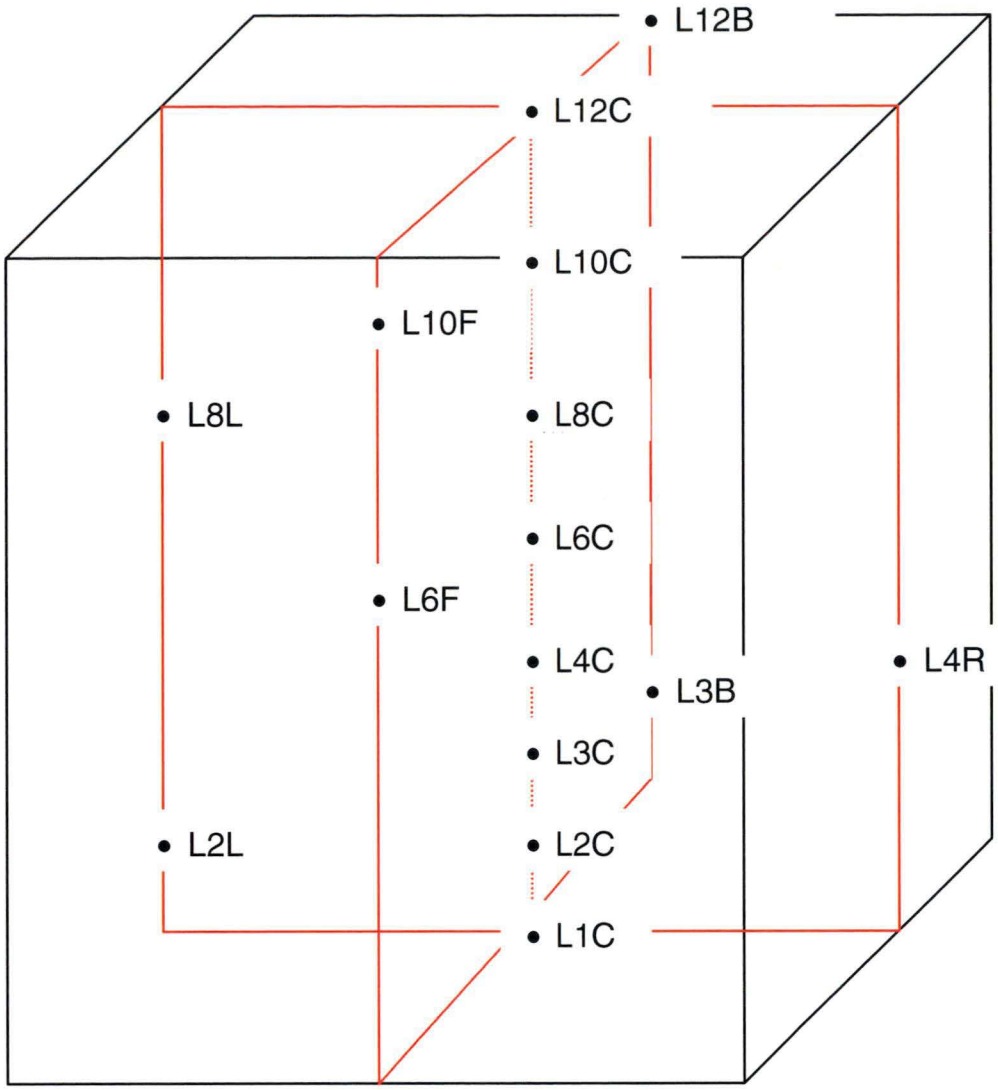

Fig 2.5 Schematic of test bin showing location of probes during temperature distribution trials. Throughout the Tables, probe location is designated so that "L1C" indicates that the probe was on layer 1 (L1) on the central axis, "L2L" indicates that the probe was on layer 2 (L2) on the left side axis (viewed from the front of the retort), "L3B" indicates that the probe was on layer 3 (L3) on the rear side axis (viewed from the front of the retort), and "L4R" indicates that the probe was on layer 4 (L4) on the right side axis (viewed from the front of the retort).

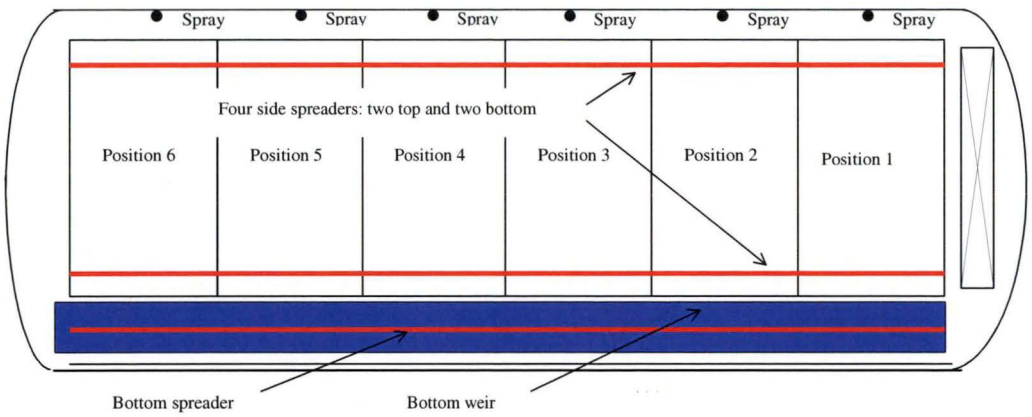

Figure 2.6. Example of designation used for location of "test basket" while measuring heating rates during temperature distribution trials in six-basket (Lagarde) retort.

Throughout each temperature distribution trial, the temperatures were continuously monitored and recorded at 30 sec intervals using an Ellab CMC 821 digital recorder (Ellab A/S, Krondalvej 9, DK-2610 Roedovre, Denmark) or a DWC M16F Data Logger (DWC FoodTech Pty. Ltd., Melbourne, Australia). Prior to each trial, all thermocouples were calibrated against the reference thermometer that was attached to the retort following the same method that has been described in Section 2.3. The data were automatically collected on file for analysis using DWC Analyser's performance criteria that were developed specifically for validation of heat processing equipment and which are described, in full, in Section 2.5.2.

In each series of trials at a particular manufacturing site, whether evaluating the temperature distribution in one or more retorts, a common test cycle was developed.

Shown in Plate 2.14 is an end-on view of a test basket set up for temperature distribution studies in a two-basket FMC water-shower retort used for processing cans and in Plate 2.15 can be seen a side-on view of the same unit.

Shown in Plate 2.16 is an end-on view of a test basket set up for temperature distribution studies in a six-basket FMC water-shower retort used for processing glass bottles and in Plate 2.17 can be seen a side-on view of the same unit.

Shown in Plate 2.18 is a test basket set up for temperature distribution studies in a three-basket Barriquand cascading-water retort used for processing metal cans and plastic cups and pouches, and in Plate 2.19 can be seen the distribution of five thermocouples across the bottom layer of the test basket in the same unit.

In Plate 2.20 can be seen the arrangement for locating thermocouple probes adjacent to cans so that the tip of the thermocouple is insulated from direct contact with the surface of the container.

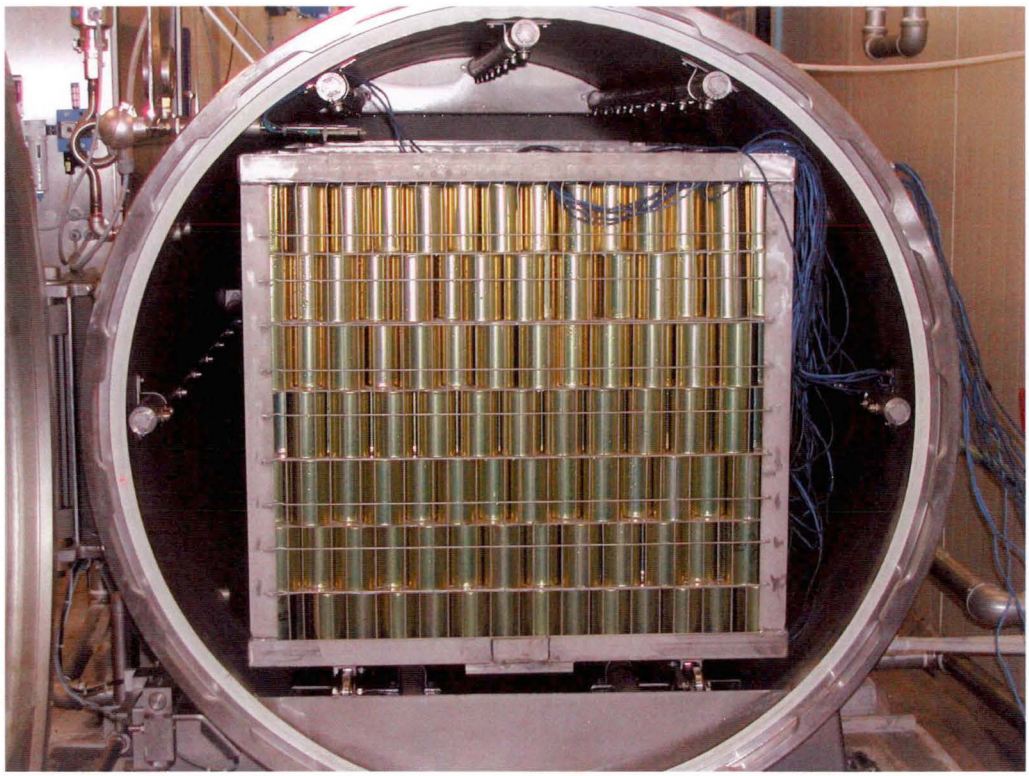

Plate 2.14. End-on view of test-basket showing entry of thermocouple probes through side of vessel and their distribution between cans for temperature distribution study in a two-basket FMC water-spray retort

Plate 2.15. Side-on view of two-basket FMC water-spray retort for processing cans, retort pouches and plastic tubs.

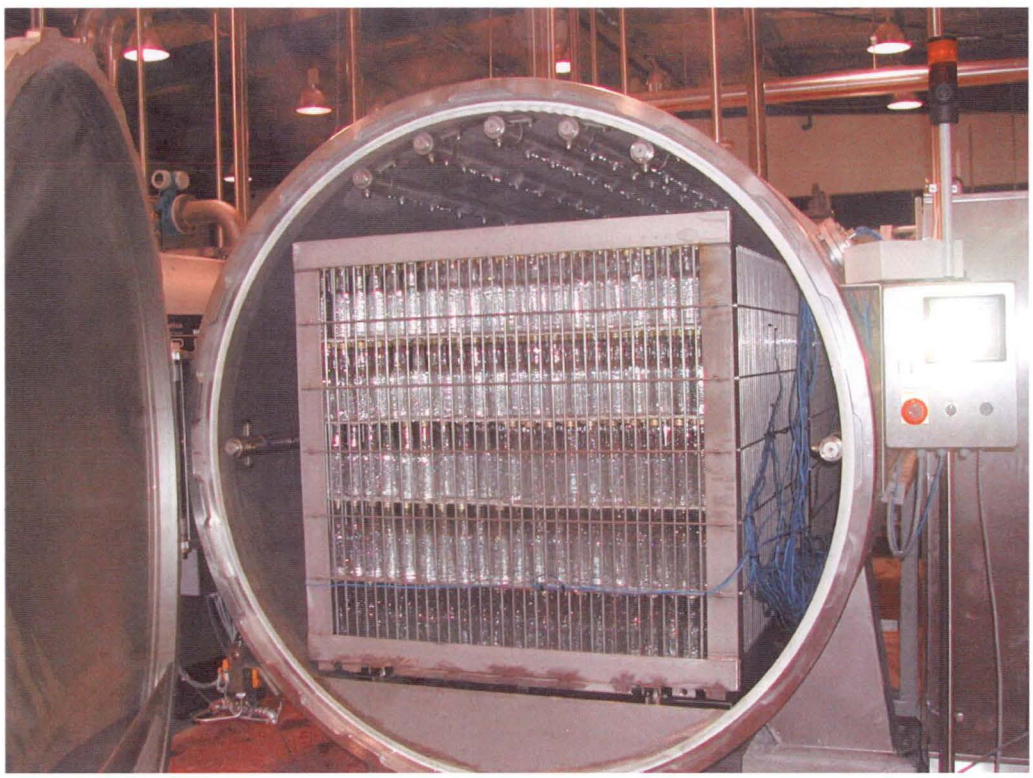

Plate 2.16. End-on view of test-basket showing entry of thermocouple probes through side of vessel and their distribution between glass bottles for temperature distribution study in a six-basket FMC water-spray retort.

Plate 2.17. Side-on view of six-basket FMC water-spray retort used for processing glass bottles.

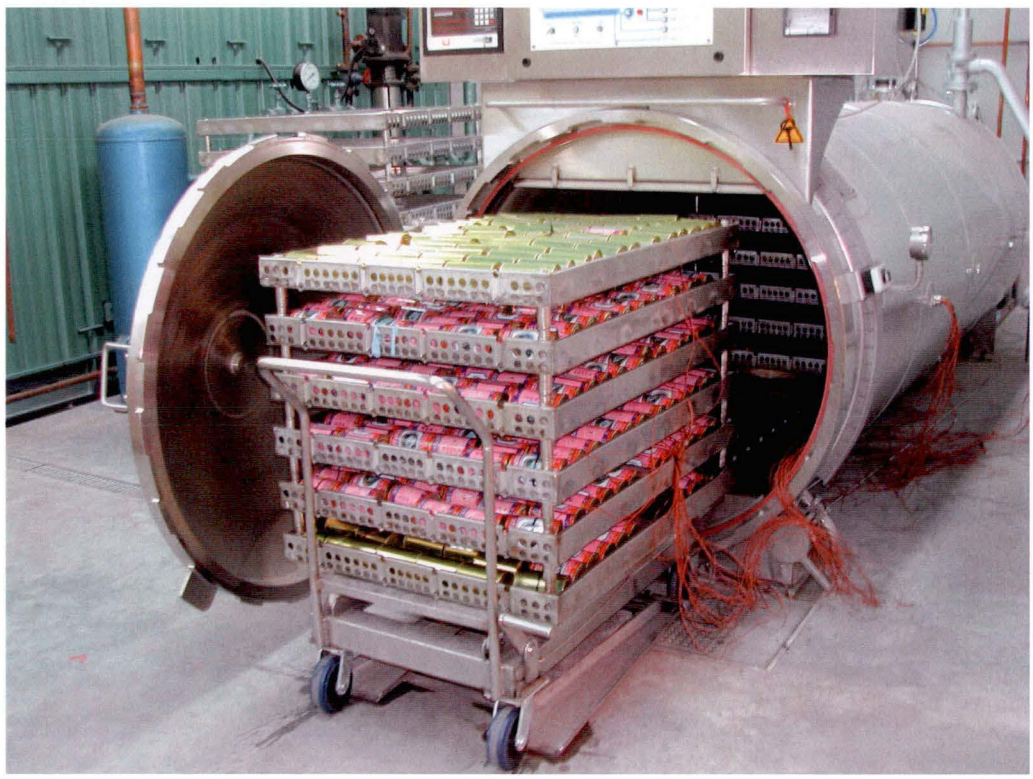

Plate 2.18. View of test-basket showing location of thermocouple probes through side of vessel and their distribution between cans for temperature distribution study in a three-basket Barriquand cascading-water retort.

Plate 2.19. Distribution of five thermocouples across bottom layer of retort basket for temperature distribution studies in a three-basket Barriquand cascading-water retort.

Plate 2.20. Arrangement for locating thermocouple probe adjacent to can, amongst rows of six 73 x 118.5 mm cans. Note that the tip of the thermocouple is insulated from direct contact with the surface of the container.

2.5.2 Performance criteria for evaluation of heat processing equipment

As discussed in Sections 1.3.1 to 1.3.3, there are numerous approaches used for temperature distribution studies. However, notwithstanding the credentials of many of the "processing authorities" that work in this field, there is in Australia and elsewhere no generally recognised procedure for data analysis by means of which retort performance can be objectively assessed. This is regarded as a procedural lapse that may cause difficulties in cases where demonstration of "adequate temperature" distribution forms part of validation procedures during commissioning, and prior to acceptance, of new plant. Similarly, standard testing protocols ought to form a key component of HACCP validation exercises, without which a food manufacturer may not only fail to satisfy regulatory requirements but also may be found deficient in the exercise of demonstrating due care.

In order to address the need for a standardised protocol for data analysis, performance criteria were developed as part of DWC Analyser's software. Description of these criteria and the rationale for their use is included below. Concurrently, the software also was developed to enable data analysis and data presentation in a standard format in terms of compliance with the criteria that had been proposed in GMP guidelines.

The performance criteria that were adopted for validation of heat processing equipment are presented below. Throughout discussion of these performance criteria it will be noticed that the term F is used exclusively rather than F_o or, for instance, F_p. By definition, the term F_o applies to cases involving low-acid canned foods in which the reference temperature for quantification of process severity is 121.1°C and the Z value is 10 C°~~C~~. In other cases (such as with for REPFEDs or with acid foods) the reference temperatures and the *Z* values are different and in these circumstances the F has a different subscript as in F_p.

- The F value at the completion of the come-up time, i.e. at start of hold time (min). This attribute was recorded as *F value start of hold (min).*
- The F value at the completion of the hold phase, i.e. at steam-off. This attribute was recorded as *F value steam-off (min).*
- The F value at the completion of cooling. This attribute was recorded as *Final F value (min).*

- The target F value at steam-off. This attribute indicates the theoretical F value that would be achieved in those cases that the retort was at the scheduled hold temperature (i.e. the process set-value) for the entire scheduled hold time. The target F value ignores the contribution to the F that may be achieved during the come-up time and during cooling. For instance in instances where the sterilisation phase was 10 min at 119.5 °C, the target F would be 6.9 (6.918) min (i.e. 10 x 0.6918, where the lethal rate at 119.5 °C = 0.6918).

  This attribute was recorded as *Target F value at steam-off.*

- The Compliance Coefficient. This attribute expresses the actual F value achieved during the sterilisation (or hold) phase as a proportion of the target F value of this phase. In this manner, compliance values of less than unity indicate that the actual F value was less than the target F value for this phase and this in turn indicates that the retort was at temperatures that were less than the set-value during the hold phase. Conversely, compliance values of greater than unity indicate that the total F value was greater than the target F value of this phase and this indicates that the retort was at temperatures that were above the set-value during the hold phase. Compliance values of unity indicate that the total lethality (i.e. the F value) of the scheduled hold phase was exactly equivalent to having held the retort at the scheduled process temperature for exactly the scheduled hold time.

  This attribute was recorded as *Compliance Coefficient.*

  Compliance Coefficients ideally should be ≥ 1 however in this series of trials coefficients of ≥ 0.9 were considered adequate.

- The range in F values across all probes. This attribute was recorded as *Range F value (min).*

- The elapsed time from the start of the cycle until the temperature is within X°C of the set-value (SV), i.e. the time for the temperature at the point of measurement to reach SV – X. For instance, after the elapsed time represented by the term SV – 1, the temperature would comply with the Australian Standard for steam-fed retorts

(Anon.,1981), which requires that the temperature during the hold phase shall be within ± 1°C of the set value.

Study of various guidelines indicate that there is a range in what might be considered acceptable for this (and other) attributes. For instance, Smout and May (1997) in their *Guidelines for batch retort systems – Full water-immersion - Raining/Spray Water - Steam/Air,* indicate that the retort temperature should be held to within - 0.5 °C to +1°C of the scheduled hold temperature. However Smout and May (1997) also record that the United States' National Food Processors Association (NFPA, 1985) "indicate that all points in the retort should be at or above the desired process temperature within one minute after the retort reaches the process temperature and the holding phase starts. In addition, all thermocouple readings after the first minute should have a maximum range of 3 F° (1.7 C°) and should be within 1.5 F° (0.8 C°) of the reference temperature device". In this context, the United States Food and Drug Administration (Anon., 2002) and Codex Alimentarius (1995) say no more than "each retort shall be equipped with an "automatic" (included by USFDA but not Codex Alimentarius) steam controller to maintain the retort temperature". However, the USFDA's attitude to temperature control is that any deviation of retort temperature below the filed processing temperature shall be regarded as a non-scheduled process (NSP), whereas Codex does not specify operating limits. In these circumstances, when assessing performance against the USFDA's requirements, in the term SV – X, the value of X would be assigned zero. A more lenient interpretation would allow X to be equal to 1 °C, or more.

In order to accommodate these options DWC Analyser enables the value of "X" to be selected manually.

This attribute is recorded as *SV – X °C (min).*

- The elapsed time from the start of the actual programmed hold time until the temperature at the point of measurement reached the set-value (SV) – X °C. In this manner, a negative lag time (for example shown as "-1.5") indicates that the temperature at the point of measurement reached SV – X °C, 1.5 min prior to the start of the pro-

grammed hold time. Conversely, a positive lag time (for example shown as "+2.2") indicates that the temperature at the point of measurement was at SV – X °C, 2.2 min after the start of the programmed hold time.

Throughout these studies, heating lags of more than "+2.0 min" were considered unacceptable. In cases where the retort at the point of measurement failed to reach the set-value, the result was recorded in the respective tables as "***".

This attribute was recorded as *Lag time (min).*

- The temperature recorded by each probe at the completion of the nominal programmed (or scheduled) come-up time. Therefore, in cases where there was a positive lag time the temperature recorded would be less than the set value SV, whereas in those cases where there was a zero lag, or a negative lag, the temperature would be identical to, or more than, SV respectively.

  This attribute was recorded as *Temp at end of CUT (°C).*

- The temperature fluctuation that was recorded during that part of the hold phase after which the temperature at the point of measurement had reached SV – X °C. This therefore provides measure of the ability of the retort to control temperature after having reached the temperature corresponding to SV – X °C.

  This attribute was recorded as *Temp range during hold (°C).*

  Preferably, the temperature range at each point of measurement during hold should be within a prescribed range of the set-value. In cases of temperature overshoot this criterion may be exceeded without there being any implications with respect to product safety.

- The minimum temperature that was recorded during that part of the hold phase after which the temperature at the point of measurement had reached the temperature corresponding to SV – X °C.

  This attribute was recorded as *Min. temp during hold (°C).*

In many commercial operations, the minimum temperature during hold is considered adequate provided that it is no more than one degree above, or one half a degree (C) below, the set-value. However some, the USFDA for example, are more stringent and insist that the temperature during hold shall not fall below the set value.

- The temperature recorded by each of the probes throughout the test basket at a nominated time after the end of the scheduled come-up-time, or the start of the scheduled hold (sterilisation) phase. Typically, the elapsed time after which these temperatures are measured will be between one and five minutes.

  DWC Analyser allows the elapsed time to be selected, and in these trials five minutes was chosen.

  This attribute was recorded as *Temp at 5 min.*

- The temperature range throughout the test basket at the start of the scheduled hold (sterilisation) phase.

  Guidelines for performance vary. As noted, the relevant parts of the Australian Standard (Anon., 1981) specify that the steam supply in retorts heated with saturated steam shall be sufficient to maintain a temperature within ± 1°C of scheduled retort operating temperature throughout the hold phase of the process. The standard makes no reference to the degree of temperature control that is required for retorts that are heated via steam-air, water-spray or water-shower systems.

  The National Food Processors Association (NFPA's) recommendation (1985) for condensing steam retorts states that the temperature should be at or above the Set Value within one minute of the start of the hold phase and after the first minute, the range should be ≤ 1.7°C. The NFPA guideline also requires that all thermocouples should be within 0.8°C after the first minute of the hold phase.

  Smout and May (1997) *Guidelines for Batch Retort Systems – Full Water-immersion –Raining/Spray Water –Steam/Air* indicate that the retort should hold the scheduled process temperature to + 1°C to -

0.5°C, however no reference is made to the allowed time over which compliance with this guideline is required.

In a series of trials in one basket in a four-basket 100 mm diameter Barriquand retort Adams and Hardt-English (1990) found a range of 2.2°C during the first minute, 1.0°C by the third minute and 0.8°C by the fifth minute, which Smout and May (1997) "considered as excellent". On this basis, throughout these trials temperature ranges of ≤ 1 °C across the basket after five minutes were considered commercially acceptable, although smaller ranges were preferable.

This attribute was recorded as *Temp range at 5 min.*

2.5.3 Summary of retort styles included in temperature distribution studies

Shown in Table 2.12 is a summary of the various styles of retorts that were included in temperature distribution studies. A detailed description of the retort types that were evaluated is given by May (1997a). Also shown are the types of containers used in the evaluation, the product categories and the location of the manufacturing plant. The food manufacturer has not been disclosed, however for discussion purposes they have been identified by case. The results and discussion of the temperature distribution studies are contained in Section 3.4.

Table 2.12. Retort styles included in temperature distribution studies

Case	Type of retort	Container	Product	Location
1	Water-immersion	Cans	CIC	Australia
2	"	Plastic tubs	Rice	"
3	"	Cans	Meats	UAE
4	"	"	Beverages	PRC
5	Steam	"	Vegetables	Australia
6	"	"	"	"
7	"	"	Seafood	New Zealand
8	Steam-air	"	CIC	Australia
9	"	Plastic tubs	Fruits	"
10	Water-shower[1]	Cans	Vegetables	"
11	Cascading-water[1]	Trays	Pet foods	Australia
12	"	Cans	Molluscs	"
13	"	Pouches	Vegetables	New Zealand
14	Water-spray[2]	Glass	Dairy	New Zealand
15	"	Cans	Vegetables	Australia
16	"	Pouches	Molluscs	"

1. Water shower retorts are a New Zealand adaptation of a Barriquand cascading water retort, the major difference is that in the former the shower above the retort baskets falls from an open trough, whereas with the Barriquand retort the shower is contained in a sealed unit which acts as top distributor.
2. Water spray retorts are manufactured by Lagarde and FMC and in these systems the water enters the vessel through a series of uniformly spaced spray nozzles running along spreaders at the sides and the tops of the pressure chamber.

3 RESULTS AND DISCUSSION

3.1 Features of DWC Analyser and DWC's Method of process calculation

DWC's Method was developed as a component of this thesis in order to correct the errors arising from use of a single cooling constant (0.08) in Board and Steele's modification of Gillespy's Method. For this reason DWC's Method can be considered as the means of correcting the shortcomings of Board and Steele's model for process calculation. Although DWC's Method incorporates Steele's polynomial solutions (shown in Table 2.3) of the Gillespy Method calculations, it is different to Board and Steele's modified method as it includes the option to manually select values for the so-called cooling constant.

DWC Analyser (the software package in which DWC's Method is contained) has the following features:

- As can be seen in Fig 3.1, DWC Analyser enables calculation of F values via the General Method (shown as the Reference Trapezoidal Method in Figs 3.1 to 3.3) from primary heat penetration data. This means that "actual" and "predicted" F values can be calculated simultaneously via the General Method and DWC's Method, respectively, (the latter is accessible through the "Mathematical method" drop-down menu button shown in Figs 3.1 to 3.3). For these calculations DWC's Method utilises the equations and tables (shown in Section 2.1.1 on pages 57 to 63) that were adopted by Board and Steele.

- DWC's Method is an improvement over Board and Steele's Method as it enables manual adjustment of the value of the cooling constant (which is fixed at 0.08 in Board and Steele's Method) in order to match the F values achieved in cooling with those calculated via the General (or Reference) Method. This means that the product's cooling characteristics (and therefore the lethality achieved during cooling) are more accurately reflected than is possible when using Board and Steele's Method. This unique aspect of DWC's Method removes the errors in F value calculation which arise with Board and Steele's Method, and which may lead to over or under-processing.

- In the example shown in Fig 3.2 the value of "0.08" is retained and the F_o value achieved in cooling is 2.0 (1.99) min. In Fig 3.3 the cooling constant has been increased (manually) to 0.298 as a result of which the F_o value achieved in cooling has increased to 8.3 min and this agrees exactly with that calculated with the General Method calculation shown in Fig 3.1.

  In this manner DWC's Method enables "fine tuning" of the F values contributed in cooling and provides a more accurate estimation of the total F value of a process than was possible when using Gillespy's (1951) original method or the "improved" method of Board and Steele (1978).

- As shown in Fig 3.4, DWC Analyser uses raw data from process evaluation trials to plot semi-log time-temperature graphs and calculate f_h and j values.

- DWC's Method may be used for prediction of processing temperatures and processing times required to deliver nominated target F values over the range of processing temperatures (including those at ≥121.1°C), retort come-up times, filling temperatures and product heating parameters (f_h and j) that are used in commercial practice.

- DWC's Method may be used for prediction of the F values achieved over the range of processing temperatures (including those at ≥121.1°C) and processing times, retort come-up times, filling temperatures and product heating parameters that are used in commercial practice.

- DWC's Method may be used for estimation of the actual F values delivered by non-scheduled processes. That is, in cases for processes in which the actual processing and/or filling conditions and/or product heating parameters do not match those against which the scheduled process was validated.

The data required to solve the equations used in DWC's Method and Board and Steele's (1978) modified Gillespy Method and the sequences for completing the calculations are summarised in Table 3.1.

Table 3.1. Summary of data required and sequence for calculating F value delivered by a thermal process or process time required to deliver a target F value using DWC's Method and Board and Steele's version of the Gillespy Method. (Adapted from Food Science Australia and Warne, 2002).

To calculate F value	To calculate processing time
Require	*Require*
Initial product temp (T_o)	Initial product temp (T_o)
Temperature of processing (T_r)	Temperature of processing (T_r)
f_h value	f_h value
Lag factor (j)	Lag factor (j)
Retort come-up-time (C.U.T.)	Retort come-up-time (C.U.T.)
Process time	Target F value
Then Solve DWC's Method equations using corrected cooling constant, or Solve Gillespy Method equations	*Then* Determine lethal rate L at processing temperature
Determine lethal rate L at processing temperature	Solve DWC's Method equations using corrected cooling constant, or Solve Gillespy Method equations
Solve for F	Solve for process time

To simplify the use of DWC's Method the software was programmed to display separate single screens that enabled a direct comparison of the F values contributed in cooling when calculated by each of the General Method and DWC's Method as the value of the "0.08" cooling constant was manually adjusted. Examples of these displays are illustrated as follows:

- Fig 3.1 shows the F values calculated at steam off and during cooling, via the General Method (or Reference Trapezoidal Method).
- Fig 3.2 shows the F values calculated at steam off and during cooling, via DWC's Method but without correcting the value of the cooling constant (which is shown as 0.08).
- Fig 3.3 shows the F values calculated at steam off and during cooling, via DWC's Method after correcting the value of the cooling constant from 0.08 to 0.298.

- Fig 3.4 shows the semi-log plot of the heating curve for the data represented in Figs 3.1 to 3.3. This plot indicates that the heating parameters f_h and j had values of 27.22 min and 1.38, respectively. The product was a conductive heating item packed in a 130 g jar in which initial product temperature was 23.4°C. The retort come-up time was 16.5 min and the process was 45 min at 122.4°C, after which cooling commenced.

Although the alternate values that might be used to replace the 0.08 are not restricted, the user is only required to adjust the constant so that the F contribution in cooling determined by the DWC's Method matches that determined by the General Method. When using DWC's method the changes to the value of the, so-called, constant (i.e. the value of "0.08") that have been incorporated in the automated calculations will have no effect on the F value achieved during the heating phase of the process.

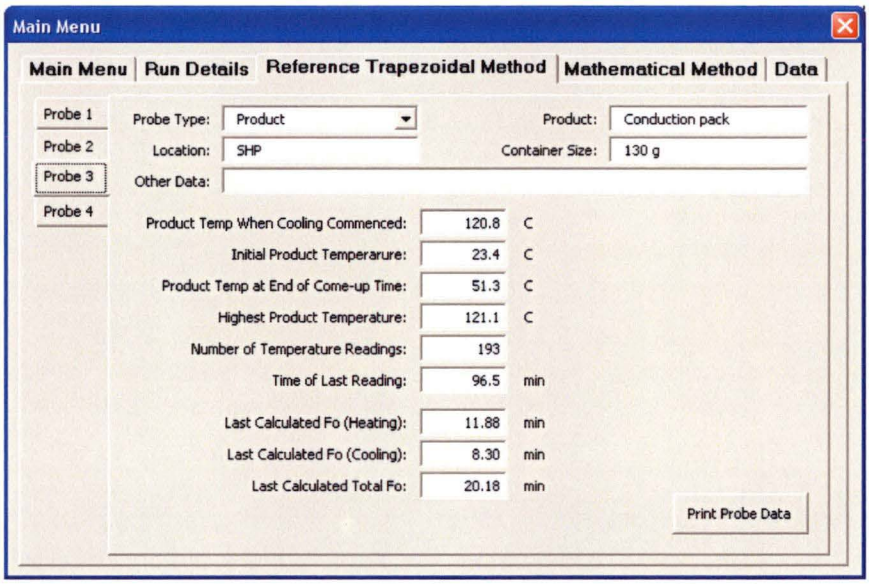

Fig 3.1. Screen showing the F value calculated via the General Method. In this example the F value calculated in heating (i.e. at steam-off) was 11.9 (11.88) min, that accumulated in cooling (i.e. after steam-off was 8.3 (8.30) min, and the Total F value was 20.2 (20.18) min.

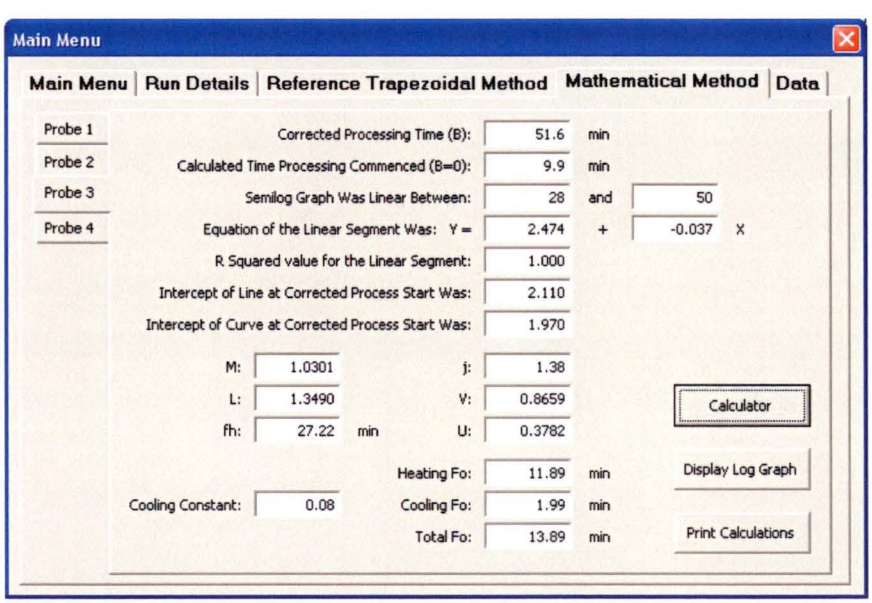

Fig 3.2. Screen showing F value calculated via DWC's Method but without correcting the value of the cooling constant (0.08). In this example the F value calculated in heating (i.e. at steam-off) was 11.9 (11.89) min, which agrees with the General Method calculation shown in Fig 3.1 and that accumulated in cooling (i.e. after steam-off) was 2.0 (1.99) min. Therefore in this example the Total F value was 13.9 (13.89) min. which is significantly less than the 20.2 min determined via the General Method.

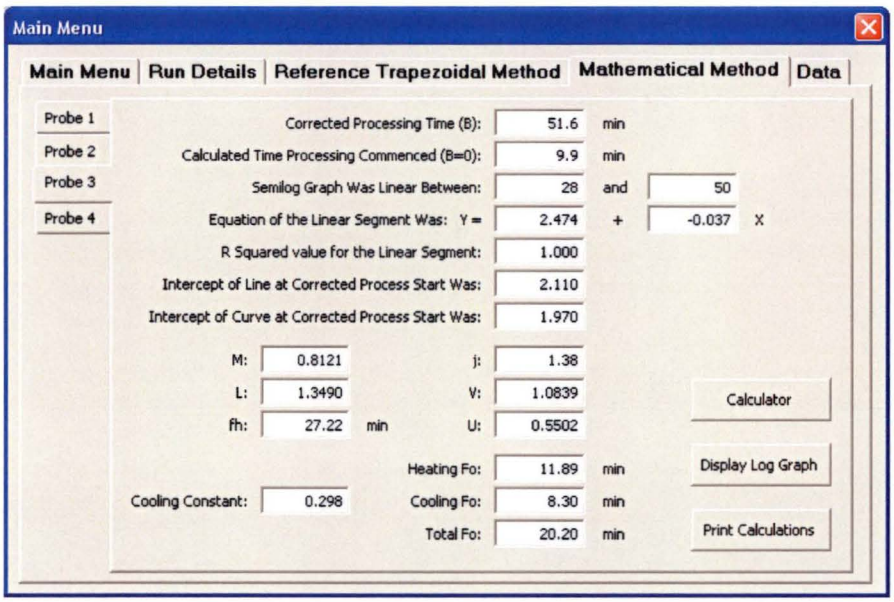

Fig 3.3. Screen showing F value calculated via DWC's Method after correcting the cooling constant to 0.298. In this example the F value calculated in heating (i.e. at steam-off) was 11.9 (11.89) min, which agrees with the General Method calculation shown in Fig 3.1 and that shown in Fig 3.2, however the F value accumulated in cooling (i.e. after steam-off) was 8.3 (8.30) min. Therefore in this example the Total F value was 20.2 (20.20) min which agrees with that determined via the General Method.

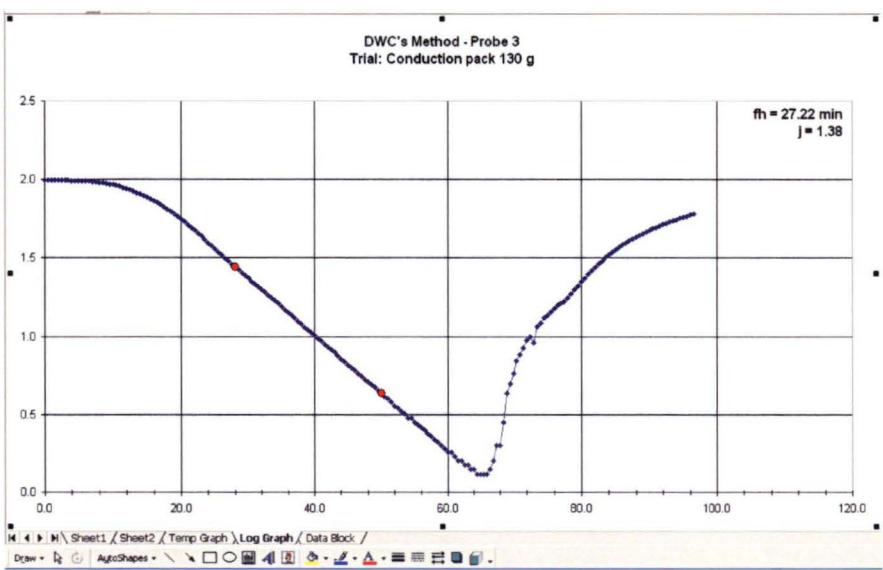

Fig 3.4. Semi-log plot of heating curve (for data represented in Figs 3.1 to 3.3, showing f_h value of 27.22 min and j value of 1.38.

3.2 Comparison of F values determined with Gillespy's and DWC's Methods of calculation

Shown in Tables 3.2 to 3.16 are the results of F value calculations using the General (or Reference) Method, Gillespy's Method, DWC's Method and FMC's NumeriCal. As the General Method uses actual time-temperature data and makes no assumptions about uniformity of the temperature of the heating medium, or the thermal characteristics of the product, the major source of error in the calculation (after excluding errors relating to the accuracy of the temperature measuring device and/or the data logger) arises from use of overly large time intervals between recording core product temperatures. It was to minimise errors of this nature, that the temperatures across all thermocouples were scanned at 30s intervals throughout all trials. It is because of its high level of accuracy that the General Method is regarded as the standard against which all other methods are compared. By contrast, each of the other three methods uses modelling techniques to estimate core product temperatures (and hence lethal values) as they change throughout the heating and cooling processes and it is on this basis that the corresponding F values of the thermal processes are calculated.

In the tables the classification of the F value at "Steam-off" and "Final" enables demarcation of the cumulative process lethality at the time the steam to the retort is turned off (which is taken to be the time that cooling commences) and at the completion of cooling.

In the body of each of the tables the first two columns in the first row of data (shown in bold) correspond to the actual (i.e. measured) initial product temperature at the start of the respective processes or the actual process temperature of the retort during the hold phase, and the corresponding process (hold) time. It was under these conditions that the raw data were gathered for calculation of F values with the General Method and calculation of the heating parameters f_h and j that are required to calculate F values using Gillespy's and DWC's Methods, and the heating parameters f_h and j_h, and f_c and j_c that are required for calculation with NumeriCal. Once the heating parameters were determined they were then used to calculate the projected (or theoretical) F values when the initial product temperature, the process temperature or the corresponding process time were altered. Also shown in bold in the first row are the F values calculated by each of the four methods when using the primary data.

In total, across the eight sets of processing variations that were considered in each of Tables 3.2 to 3.16 (i.e. a total of 120 [or 8 x 15] processing options), final F values were calculated by Gillespy's Method, DWC's Method and NumeriCal.

Shown in the footnotes to each of Tables 3.2 to 3.16 are the j and f_h values that were derived from the primary data and which were used to determine the F values with Gillespy's and DWC's methods of calculation. Also shown in the footnotes are the values for the corrected cooling constants that have been used to generate the F values when using DWC's Method of calculation, whereas, with Gillespy's Method the cooling constant remained fixed at 0.08 for all calculations.

3.2.1 Comparison of F values using primary data

Comparison of the actual F values shown in Tables 3.2 to 3.16 (when calculated by General Method analysis of the primary heat penetration data) and those F values calculated by each of the three mathematical models using the same data, indicates the following:

1. In 11 of 15 instances (shown in Tables 3.2 - 3.6, 3.8 - 3.11, 3.13 and 3.16) there was no difference between the F values generated in heating (i.e. at steam-off) when calculated by each of the four methods. It is inevitable that, for the heating component of the process, the F values determined by Gillespy's Method and DWC's Method will agree as the latter seeks only to correct the contribution during cooling which the Gillespy's Method frequently underestimates. Nevertheless, the exact agreement of the F values at steam-off in 12 of 15 cases re-affirms the validity of the basic heating parameters, f_h and j, upon which both DWC's and Gillespy's Methods rely.

2. In all four of the instances (shown in Tables 3.7, 3.12, 3.14 and 3.15) in which there were differences between the F values at steam-off, those calculated by DWC's Method (and therefore Gillespy's Method) underestimated the actual values, whereas the NumeriCal values agreed with the General Method calculations. This indicates that DWC's Method and Gillespy's Method of calculation erred on the side of caution in each of these cases. In the four examples referred to the under-estimation of the F values was 3, 4, 7 and 7%, respectively, of the General Method values.

It is not unusual during thermal process evaluation trials that ranges of this magnitude are experienced amongst data sets generated from replicate (and supposedly identical) cans in the same trial, and for this reason the observed under-estimation of up to 7% is not considered extreme. For instance May (1997b) consider that "small run-to-run and sample variations in measured lethality, e.g. <10% difference, would indicate a straightforward process evaluation."

3. While in all but four cases there was agreement between the actual (i.e. General) F values calculated at steam-off and those calculated by the Gillespy and DWC's Methods, in each of the 15 examples there were large discrepancies between the final F values calculated by the Gillespy Method and those calculated by the General Method. Significantly though, these discrepancies were not evident when using DWC's Method of calculation. The data in Tables 3.2 to 3.16 indicate that in every case the final F value calculated via the Gillespy Method underestimated the actual, or General Method, value. It can be calculated that the under-estimation errors ranged from a minimum 10% (Table 3.7 in which the Final Gillespy F value was 9.3 min and the General Method Final F value was 10.3 min) to a maximum of 64% (Table 3.15 in which the Final Gillespy F value was 29.2 min and the General Method Final F value was 80.1 min), and that the mean under-estimation error with the Gillespy Method of calculation was 29%. These errors are of the same order of magnitude as those quoted by Food Science Australia and Warne (2002) who reported under-estimations of "between 40 and 100% and that the errors tend to be larger at high temperatures."

4. Further analysis of the data reveals that the errors that were evident when using the Gillespy Method's final F values were all reduced, if not removed, when final F values were determined with DWC's Method of calculation. In 11 of the 15 cases, the final F values calculated by DWC's Method and the General Method were identical, and in the four instances (shown in Tables 3.7, 3.12, 3.14 and 3.15) where there were differences the discrepancies were minor. In the cases referred to, the final General Method F values were 10.3, 49.4, 43.1 and 80.1 min., while the corresponding values determined by DWC's Method were 10.1, 48.3, 43.0 and 79.0 min, respectively. These data indicate that the under-estimation error due to DWC's method of calculation were, respectively, 2, 2, 0(0.2) and 0(0.1)%. This means that in the four

cases that there were underestimation errors, the average underestimation was only 1% of the actual value.

5. The final F values calculated using NumeriCal agreed with the General Method values in 11 of the 15 cases. This means that overall, when based on the analysis of primary heat penetration data, NumeriCal (which it will be recalled is USFDA endorsed as an approved method) performed no better than DWC's Method. In the four cases when there was disparity in the results, the General Method final F values were 2.5, 3.0, 43.1 and 80.1 min, in Tables 3.2, 3.11, 3.14 and 3.15, respectively, while the corresponding values determined by NumeriCal were 2.4, 2.9, 43.0 and 80.0 min. This equates to underestimation errors with NumeriCal of 4, 3, 0(0.2) and 0(0.1)%, respectively; whereas the corresponding errors with DWC's Method were 2, 2, 0(0.2) and 0(0.1)%.

6. That there was strong agreement between General Method final F values and those calculated by DWC's Method and NumeriCal is not surprising, for each of these models incorporate the facility to "match" their respective values to those calculated by the General Method. As has been discussed in Section 2.2 DWC's Method is different to Gillespy's Method in that it provides the option to adjust the cooling constant so that the F values accumulated in cooling agree with those calculated by the General Method. DWC's Method does not however enable any adjustment to the F values that are calculated in heating (i.e. at steam-off) other than those produced as a consequence of finding the line of best fit for the semi-log plot of the time *versus* product temperature heating curve which is required to determine the heating parameters f_h and j. However, once settled upon, f_h and j can be regarded as constants throughout all calculations using DWC's Method.

   NumeriCal, on the other hand, enables adjustment of the heating parameters (j_h and f_h) as well as the cooling parameters (j_c and f_c), so that a theoretically derived heating and cooling curve, from which the final F value can be calculated, matches the actual heating and cooling curve that is generated from the primary data; and from which, in turn, the actual F value also can be calculated by integration of lethalities. This feature of NumeriCal means that the heating and cooling parameters j_h and f_h, and j_c and f_c, respectively, are derived from the curve that best approximates the actual heating and cooling curve.

In summary, therefore, the results in Tables 3.2 to 3.16 show that with respect to the accuracy of the calculation of final F values from primary time-temperature data, there is little to differentiate between DWC's Method and NumeriCal. In each case, the models have calculated theoretically derived final F values that are identical to, or within an acceptable range of, actual values that have been calculated with the General Method. Gillespy's Method by contrast shows average underestimation errors of almost 1/3rd of the total F value calculated by the General Method.

The relative merits of Gillespy's Method, DWC's Method and NumeriCal will now be assessed, in Sections 3.2.2 to 3.2.6, in terms of their ability to predict accurately F values in cases where the processing parameters (e.g. initial product temperatures, process hold times and process temperatures) may change.

In order to establish a benchmark for comparison of these three calculation methods, the F values determined by NumeriCal will be accepted as (the most) accurate and for this reason it is in comparison with F values determined by NumeriCal that DWC's and Gillespy's Methods will be assessed. To provide a means of differentiating between acceptable and unacceptable performance, the following bands have been used;

- Those results in which an error (or deviation from NumeriCal) is ≥ -10.0% will be classified as unacceptable; i.e. errors of -10.0% or -10.1% or more are unacceptable.

- Those results in which an error (or deviation from NumeriCal) is < -10.0% and ≤ 10.0% will be classified as acceptable; i.e. errors of between -9.9% and 10% are acceptable.

- Those results in which an error (or deviation from NumeriCal) is > 10% will be classified as unacceptable; i.e. errors of more than 10.0% are unacceptable.

In order to understand the rationale behind selecting the three bands described above, it is useful to recall discussion of the errors that might occur with temperature readings. In Section 1.2 it was noted that errors in temperature readings may be between ± 0.5°C and that this could account for errors in calculation of F_o values of -10.9% to +12.2%. Given that not all temperature monitoring and recording systems reliably will have errors of less than ± 0.5°C, it follows that errors of up to ± 10% in calculation of F_o values also may be expected.

It is against this background that the proposed demarcation between acceptable and unacceptable performance of Gillespy's and DWC's Methods has been established at ± 10% of the NumeriCal value.

3.2.2 Comparison of F values with changes to process hold times

Examination of the data in Tables 3.2 to 3.16 and the summary in Table 3.17, indicates that ~~are~~ there were large errors through use of Gillespy's Method when comparing the projected final F values determined by each of Gillespy's Method, DWC's Method and NumeriCal, for cases in which the only changes to the "original" processing conditions relate to extensions or reductions in process hold times.

Analysis of the projected F values in those cases in which the processing hold times were either reduced or extended (while all other conditions were as in the original heat penetration trials) indicates that the average error with the Gillespy Method of calculation was -37%, whereas with DWC's Method it was 2%. Furthermore, of the 30 cases considered, 29 (or 97%) had errors of ≥ -10.0% when using Gillespy's Method, whereas the corresponding figure when using DWC's Method was 2 of 30 (or 7%).

These data demonstrate the shortcomings of Gillespy's Method as a model for projecting the F values delivered in cases where processing hold times have been altered in error (for example as in the case of non-scheduled processes) or when they are altered intentionally to reduce, or increase, the final F values of a process. The data also show that, because of its substantially greater agreement with NumeriCal (i.e. 93% acceptable for DWC's Method compared with 3% acceptable for Gillespy's Method), DWC's Method is far more likely than Gillespy's Method to give a realistic estimation of the change in F values brought about by a scheduled, or non-scheduled, change in processing hold times.

3.2.3 Comparison of F values with decreases in initial product temperatures and with changes to process hold times

In this series of comparisons (of data in Tables 3.2, 3.4 - 3.5, 3.7 - 3.16 and 3.17) the accuracy of Gillespy's Method and DWC's Method relative to NumeriCal was assessed when decreasing the initial product temperatures while processing with a range of hold times.

Analysis of the projected F values indicates that, not only did Gillespy's Method produce a far higher frequency of errors (relative to NumeriCal) than did DWC's Method, but also the errors were larger with Gillespy's Method than they were with DWC's Method. The data show that the average error when using Gillespy's Method of calculation was -40% whereas with DWC's Method it was -6%. This means that, on average, Gillespy's Method underestimated the values calculated with NumeriCal by over six (6.7) times the underestimation found when using DWC's Method. Also, whereas 97% (or 38/39) of the results using the Gillespy Method had errors (relative to NumeriCal) of ≥ -10.0%, only 15% (or 6/39) of values determined by DWC's Method differed from NumeriCal values by -10% or more.

The data indicate that although the differences between the performance of the two methods were not as pronounced when decreasing initial temperatures as they were when calculating the effect on final F values of changing processing hold times, there is ample evidence that DWC's Method has greater agreement with NumeriCal. These figures show that 85% of the final F values calculated by DWC's Method could be classified as acceptable (i.e. the errors relative to NumeriCal values were < -10.0% and ≤ 10.0%). This means that DWC's Method is far more likely than Gillespy's Method to give a realistic estimation of the change in F values brought about by decreasing the initial product temperature.

The mathematics used in calculation of F values at steam off is identical in Gillespy's and DWC's Methods and therefore the values obtained are the same. The data show that each of these methods computes F values at steam off which are less than those determined with the NumeriCal model. However, the correction that was applied with DWC's Method tends to produce an F value in cooling that is closer to the NumeriCal value (in cooling) than the value that is calculated with the Gillespy Method. It is for this reason that the total F values calculated with DWC's Method after initial temperatures have been reduced are closer to the NumeriCal

values that those estimated with Gillespy's Method. This reasoning also accounts for the observation that at low initial temperatures (for example with 5 °C as shown in Table 3.14) DWC's Method yields final F values that exhibit relatively large under estimations of the NumeriCal values.

The magnitude of the under estimation of the final values (and the inability for DWC's Method to calculate a value that better agrees with NumeriCal) is a consequence of the steam-off values with each of Gillespy's and DWC's Methods being lower than the NumeriCal equivalents. For instance, analysis of the data in Table 3.14 reveals that with the 5°C initial temperatures the proportions of the final F values (calculated by DWC's Method and NumeriCal) that were accumulated in cooling were comparable at 81 and 78%, 100 and 90% and 67 and 64%, for the 23, 15 and 30 min process times, respectively. However, the F values at steam off (calculated by DWC's Method) were only 66% (5.7/8.7), 0% (0/0.3) and 75% (39.7/52.9) of the NumeriCal values, for the 23, 15 and 30 min process times, respectively. This indicates that had there been no under estimation (depression) of the steam off F values arising through use of the identical mathematical model underlying DWC's and Gillespy's Method calculations at steam off, there would have been much closer agreement between the final F values calculated by DWC's Method and NumeriCal.

Overall, these data therefore highlight the extremely conservative nature of Gillespy's Method. The comparisons also demonstrate why those manufacturers who rely on Gillespy's Method to calculate the F values of their processes, or the processing times required to deliver target F values, risk over processing their products.

An example that illustrates the potential commercial significance of the underestimations inherent in the Gillespy Method of final F value calculation can be seen in Table 3.2, which relates to canned abalone. Assuming worst-case heating parameters, the f_h and j values for these abalone were 28.0 min and 1.5, respectively, and the corrected cooling constant for use in DWC's Method of calculation was 0.31. The data in Table 3.2 show that when the hypothetical initial product temperature was 25°C, DWC's Method and NumeriCal both indicate that an F_o value of 2.6 min would be achieved with the scheduled process of 50 min at 113°C, whereas Gillespy's Method indicates that the final F_o value would be only 1.8 min. Based on the heating parameters that were derived in these trials, it can be calculated that, with Gillespy's Method of calculation, a scheduled 57 min process at 113°C would

be required to deliver an F_o of 2.6 min; however, with DWC's Method of calculation such a process would yield an F_o of 3.5 min.

To place these comparisons in a commercial context, processes of 50 min at 113°C are typical for 74 x 119 mm cans of abalone as they satisfy not only minimum F_o requirements for low-acid canned foods (i.e. that the F_o value should be at least 2.4 min) but also they satisfy the canners' preferences to maximise their drained weight yields. Manufacturers of canned abalone have long known about, and been sensitive to, the inverse relationship between the severity of their processes and the drained weights recovered from their products. As an example of the weight losses that may be expected Warne and Brown (1982) showed that average drained weight losses in cans of black-lip abalone (*Notohaliotis ruber*) ranged from 12.8 to 29.1% following scheduled processes of 40 min at 115.6°C and 60 min at 121.1°C, respectively. With current (2005) selling prices for Australian canned abalone at around US$750/case (of 24 cans with individual drained weights of approximately 212 g/can) or US$147/kg, it is little wonder that commercial manufacturers will do all possible to prevent overprocessing. At these selling prices, a sustained 5% increase in yield corresponds to an increase of around US$7.35/kg drained weight, which equates to an increase in the selling price/can of around US$0.31. This means that a manufacturer who produced around one million cans of abalone each year, while implementing a processing regime that maximised yields, could expect to earn US$300,000 a year more than a competitor who overprocessed their product and consequently suffered an additional 5% drained weight loss on retorting.

3.2.4 Comparison of F values with increases in initial product temperatures and with changes to process hold times

In this series of comparisons (of data in Tables 3.2, 3.4 - 3.5, 3.7 - 3.16 and 3.17) the effect on the accuracy of Gillespy's Method and DWC's Method relative to NumeriCal was determined when increasing the initial product temperatures while processing with a range of hold times.

Analysis of the projected F values when initial temperatures were increased (rather than decreased as in Section 3.2.3) indicates that Gillespy's Method once again produced a far higher frequency of unacceptable errors (relative to NumeriCal)

than did DWC's Method; also the errors were larger with Gillespy's Method than they were with DWC's Method. However, in these cases (with initial temperature increases) the extent and magnitude of the errors were less than when initial temperatures were decreased. Analysis of the data shows that when initial product temperatures were increased the average error when using Gillespy's Method of calculation was -27%, whereas with DWC's Method it was 4%. Therefore, as was observed with the comparisons made in Section 3.2.3, these data show that, on average, Gillespy's Method underestimated the values calculated with NumeriCal by a factor of over six times that found when using DWC's Method.

As a result of the proposed increases in the initial product temperature, 79% (i.e. in 31 of 39 cases) of the final F values that were determined with Gillespy's Method were unacceptable as they had errors of ≥ -10.0%, relative to NumeriCal values. By contrast, analysis of the final F values calculated with DWC's Method showed that in only 15% of cases (or in six of 39 instances) the errors were > 10%, or unacceptable. The figures show therefore that the proportion of unacceptable results with the Gillespy Method was marginally superior (by 18%) in cases where the initial temperatures were increased rather than decreased (as in Section 3.2.3); however the overall proportion of unacceptable results with DWC's Method was comparable (at 15%) in both sets of circumstances. Conversely, the proportion of "acceptable" errors with DWC's Method of calculation was comparable (at 85%) irrespective of whether initial product temperatures were increased or decreased.

Once again therefore the results show that Gillespy's Method is conservative and that as a result manufacturers who rely on it, in cases when their initial product temperatures increase, are likely to over process their products. Take for example the cous-cous (described in Table 3.9) that was processed in 58 x 98 mm glass jars for 55 min at 118.0°C and which received an actual F_o value (determined via each of the General Method, DWC's Method and NumeriCal) of 12.9 min. The heating parameters j and f_h that were derived for this product were 1.9 and 27.3 min., respectively, and the corrected cooling constant for use in DWC's Method was 0.32. Imagine also that the manufacturer wished to reduce the processing time so that daily output could be increased by at least 10% and it was with this objective in mind that the initial product temperature was increased from 43.4 to 60°C.

A standard Gillespy Method calculation indicates that in order to achieve the target F_o value of 12.9 min., the process hold time with the new (i.e. increased) initial product temperature would be 59 min, or over 7% or 4.0 min, longer. A more realis-

tic calculation of the new processing time can be made with DWC's Method, which incorporates a cooling constant of 0.32. Under these circumstances the amended process hold time would be 52 min and this corresponds to a saving in the scheduled hold time of around 5%. However, this saving falls short of the hypothetical saving required to increase overall productivity by 10%. Under the circumstances described the manufacturer would need to reduce the total cycle time, which can be estimated to be around 100 min and which typically would be made up of a 20 min retort come-up time, a 55 min hold time at 118.0°C and a 25 min cooling time.

In order to achieve a 10% increase in productivity the 100 min total cycle time would need to be reduced to a total of 90 min; however all of the reduction would need to be achieved by reducing the hold time (as the retort come-up time and the cooling time would not alter). This means the projected hold time would need to be of the order of 45 min (i.e. 55 min less the 10 min saving required). In order for the manufacturer to deliver a 10% increase in productivity, purely by increasing the initial product temperature, it is necessary to calculate the target initial temperature (at the start of the retort cycle) required to produce the target F_o value of 12.9 min using the standard Gillespy Method and also DWC's Method. Based on Gillespy Method calculations the initial temperature would need to be increased from 43.4 to 100°C, whereas using DWC's Method the initial temperature would need to increase to around 85°C. Under commercial operating conditions it would not be feasible for the manufacturer to fill glass so that the initial temperature at the start of the retort cycle had not dropped to less than 100°C as a result of unavoidable delays between filling and the initiation of the retort's cycle. However, filling temperatures of around 90 to 92°C are achievable and these could be expected to deliver initial product temperatures at the start of the cycle of 85°C or more.

This hypothetical analysis therefore demonstrates that because of its overly conservative nature, the Gillespy's Method indicates that the manufacturer could not achieve the desired 10% increase in efficiency by increasing fill temperatures. In contrast, DWC's Method predicts that an increase in initial temperature to around 85°C would mean that the desired increases in productivity are achievable.

3.2.5 Comparison of F values with increases in retort temperatures and with changes to process hold times

Three cases are presented in which the retort temperature was considered to have increased and the details of these can be seen in Tables 3.3, 3.6 and 3.17. In the example in Table 3.3 the effect on the accuracy of Gillespy's Method and DWC's Method relative to NumeriCal was determined when the retort temperature was increased from 113 to 116°C while the process hold time varied, and in Table 3.6 two sets of examples are considered when the retort hold temperature increased from 110°C to each of 116 and 120°C and the retort hold times varied.

As has been the seen with the examples considered in Sections 3.2.1 to 3.2.4, analysis of the projected F values shows that Gillespy's Method produced a far higher frequency of unacceptable errors (relative to NumeriCal) than did DWC's Method. Analysis of the data reveals that when retort temperatures were increased the average error with the Gillespy Method of calculation was -32%, whereas with DWC's Method the average error was -0.3% (shown as 0 in Table 3.17). In each (i.e.100%) of the nine scenarios examined the errors with Gillespy's Method calculations were unacceptable as the deviation from the F values calculated by NumeriCal were ≥ -10.0%. In contrast with the less conservative DWC's Method of calculation, 1/3rd (shown as 33% in Table 3.17) of the values were found unacceptable.

While the trends seen in this group of results are generally consistent with those in the previous sections, and indicate that DWC's Method of calculation yields results which are consistently closer to NumeriCal values than does Gillespy's Method, it is considered, nevertheless, that there are insufficient data on which to base further extrapolation.

3.2.6 Comparison of F values with decreases in retort temperatures and with changes to process hold times

In this series of comparisons analysis of the data in Tables 3.3 and 3.17 indicates that the F values projected by Gillespy's Method have greater errors (with respect to NumeriCal F values) than the corresponding values calculated via DWC's Method. As with the examples when the retort temperatures were increased, the data illustrate that the impact of lowering the retort temperature was to cause Gillespy's Method to underestimate the actual F values that would be delivered. In

this instance the average error with the F values calculated with Gillespy's Method was -30%, whereas with DWC's Method of calculation the error was 1.4%. Furthermore, 100% of the F values calculated with Gillespy's Method were judged unacceptable, while each of the F values calculated with DWC's Method was acceptable.

Therefore, on the limited analysis of the data in those cases when the retort temperature was decreased, Gillespy's Method was once again found to be conservative and to lack the accuracy of DWC's Method.

3.2.7 Summary of comparisons of F values with changes to process conditions and initial product temperatures

The data in Table 3.17 show the average errors (%) and the proportion of values outside the 10% limits for theoretical F values calculated by Gillespy's and DWC's Methods. The conclusions that can be drawn from these comparisons are as follows:

1. Errors with the theoretical final F values calculated by Gillespy's Method ranged from -27 to -40% of the theoretical values calculated via NumeriCal. These finding are in accord with the actual average underestimation of 46% due to the Gillespy's Method, which was quoted by Food Science Australia and Warne (2002).

2. DWC's Method produced theoretical final F values which ranged from -6 to 4% of the theoretical values calculated via NumeriCal and this shows that, as a predictive tool, DWC's Method was far more accurate than Gillespy's Method.

3. With four of the five classes of processing variations that were considered, the Gillespy Method had ≥ 97% of the theoretical F values outside the 10% limits that were used to distinguish between acceptable and unacceptable performance. In the set of variations in which the changes to processing conditions included an increase in initial product temperature (see Section 3.2.4) it was found that 79% of cases had theoretical final F values determined with Gillespy's Method that were outside the 10% limits.

4. The proportion of theoretical F values which were outside the 10% limits when using DWC's Method ranged from 0 to 33% across all processing variations.

5. Across the eight sets of processing variations that were considered in each of Tables 3.2 to 3.16 (i.e. a total of 120 processing conditions), there was not one case in which the theoretical final F value calculated via the Gillespy Method exceeded that calculated with NumeriCal.

6. The data in Table 3.17 (and also in Tables 3.2 to 3.16) show that the errors in Gillespy's Method are likely to lead to an underestimation of the F values delivered by a process, or an overestimation of the time required to deliver a nominated target F value.

Table 3.2. Comparison of F_o values using General Method, Gillespy's Method, DWC's Method, and FMC's NumeriCal for single abalone in brine packed in 74 x 119 mm metal cans with a retort come-up time of 12 min., a nominal process of 50 min at 113°C with an initial product temperature of 11.6°C, and alternate initial temperatures and process times at 113°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
11.6[2]	**50**	**1.4**	**2.5**	**1.4**	**1.7**	**1.4**	**2.5**	**1.4**	**2.4**
"	40	-	-	0.5	0.7	0.5	1.3	0.5	1.2
"	60	-	-	2.6	2.9	2.6	3.8	2.6	3.8
10.0	50	-	-	1.3	1.5	1.3	2.3	1.4	2.4
"	40	-	-	0.5	0.6	0.5	1.2	0.5	1.2
"	60	-	-	2.5	2.8	2.5	3.7	2.6	3.8
25.0	50	-	-	1.5	1.8	1.5	2.6	1.6	2.6
"	40	-	-	0.6	0.8	0.6	1.4	0.6	1.3
"	60	-	-	2.7	3.0	2.7	4.0	2.8	4.0

1. j and f_h values of 1.5 and 28.0 min., respectively and cooling constant for DWC's Method of 0.31.
2. Figures shown in bold are for the slowest heating of six replicate packs following a process of 50 min at 113°C and an initial product temperature of 11.6°C.

Table 3.3. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for single abalone in brine packed in 74 x 119 mm metal cans with a retort come-up time of 12 min., an initial product temperature of 22.3°C and alternate process temperatures and process times

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Process temp (°C)	Process time (min)	Steam-off (min)	Final (min)	Steam-off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
113[2]	**50**	**1.5**	**2.5**	**1.5**	**1.7**	**1.5**	**2.5**	**1.5**	**2.5**
"	40	-	-	0.6	0.7	0.6	1.3	0.6	1.2
"	60	-	-	2.7	3.0	2.7	3.9	2.7	3.9
116	50	-	-	2.8	3.3	2.8	4.9	2.8	4.5
"	40	-	-	1.1	1.4	1.1	2.5	1.1	2.3
"	60	-	-	5.2	5.8	5.2	7.6	5.1	7.3
111	50	-	-	0.9	1.1	0.9	1.6	0.9	1.6
"	40	-	-	0.4	0.5	0.4	0.8	0.4	0.8
"	60	-	-	1.7	1.9	1.7	2.5	1.7	2.4

1. j and f_h values of 1.6 and 28.5 min., respectively and cooling constant for DWC's Method of 0.30.
2. Figures shown in bold are for the slowest heating of six replicate packs following process of 50 min at 113°C and an initial product temperature of 22.3°C.

Table 3.4. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for paua in brine packed in 88/63 x 105 mm plastic cans with a retort come-up time of 14 min., a nominal process of 50 min at 113°C with an initial product temperature of 28.8°C, and alternate initial temperatures and process times at 113°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
28.8[2]	**50**	**2.0**	**2.8**	**2.0**	**2.3**	**2.0**	**2.8**	**2.0**	**2.8**
"	40	-	-	0.9	1.1	0.9	1.5	0.9	1.5
"	60	-	-	3.4	3.7	3.4	4.2	3.3	4.2
15	50	-	-	1.8	2.1	1.8	2.5	1.9	2.7
"	40	-	-	0.7	0.9	0.7	1.3	0.9	1.4
"	60	-	-	3.2	3.4	3.2	4.0	3.2	4.1
40	50	-	-	2.2	2.5	2.2	2.9	2.1	2.8
"	40	-	-	1.0	1.2	1.0	1.6	1.0	1.6
"	60	-	-	3.6	3.9	3.6	4.4	3.4	4.3

1. j and f_h values of 2.2 and 23.6 min., respectively and cooling constant for DWC's Method of 0.23.
2. Figures shown in bold are for the slowest heating of seven replicate packs following process of 50 min at 113°C and an initial product temperature of 28.8°C.

Table 3.5. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 950 g ham in 156 x 108 x 77.5 mm metal cans with a retort come-up time of 18 min., a nominal process of 90 min at 110°C with an initial product temperature of 8.9°C, and alternate initial temperatures and process times at 110°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
8.9[2]	**90**	**0.2**	**0.4**	**0.2**	**0.3**	**0.2**	**0.4**	**0.2**	**0.4**
"	70	-	-	0.0	0.0	0.0	0.1	0.0	0.1
"	110	-	-	0.7	1.0	0.7	1.2	0.8	1.2
5.0	90	-	-	0.2	0.3	0.2	0.4	0.2	0.4
"	70	-	-	0.0	0.0	0.0	0.1	0.0	0.1
"	110	-	-	0.7	0.9	0.7	1.1	0.7	1.1
20.0	90	-	-	0.2	0.4	0.2	0.5	0.3	0.5
"	70	-	-	0.0	0.1	0.0	0.1	0.0	0.1
"	110	-	-	0.9	1.1	0.9	1.3	0.9	1.3

1. j and f_h values of 2.0 and 68.0 min., respectively and cooling constant for DWC's Method of 0.15.
2. Figures shown in bold are for the slowest heating of four replicate packs following process of 90 min at 110°C and an initial product temperature of 8.9°C.

Table 3.6. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 950 g ham in 156 x 108 x 77.5 mm metal cans with a retort come-up time of 18 min., an initial product temperature of 8.9°C and alternate process temperatures and process times

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Process temp (°C)	Process time (min)	Steam-off (min)	Final (min)	Steam-off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
110.0[2]	**90**	**0.2**	**0.4**	**0.2**	**0.3**	**0.2**	**0.4**	**0.2**	**0.4**
"	70	-	-	0.0	0.0	0.0	0.1	0.0	0.1
"	110	-	-	0.7	0.9	0.7	1.1	0.6	1.0
116.0	90	-	-	0.6	0.9	0.6	1.3	0.6	1.3
"	70	-	-	0.1	0.1	0.1	0.2	0.1	0.3
"	110	-	-	2.4	3.1	2.4	3.9	2.2	3.6
120.0	90	-	-	1.4	2.0	1.4	3.1	1.3	2.9
"	70	-	-	0.2	0.3	0.2	0.5	0.1	0.6
"	110	-	-	5.7	7.5	5.7	9.3	5.2	8.4

1. j and f_h values of 2.0 and 68.0 min., respectively and cooling constant for DWC's Method of 0.15.
2. Figures shown in bold are for the slowest heating of four replicate packs following process of 90 min at 110°C and an initial product temperature of 8.9°C

Table 3.7. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 2.72 kg (6 lb) corned beef in 153 x 157 mm metal cans with a retort come-up time of 21.0 min., a nominal process of 240 min at 121.0°C with an initial product temperature of 38.6°C, and alternate initial temperatures and process times at 121.0°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
38.6[2]	**240**	**6.2**	**10.3**	**6.0**	**9.3**	**6.0**	**10.1**	**6.2**	**10.3**
"	210	-	-	2.1	3.6	2.1	4.0	2.2	4.3
"	270	-	-	13.6	18.9	13.6	20.1	13.6	20.2
30.0	240	-	-	4.7	7.5	4.7	8.1	4.9	8.4
"	210	-	-	1.5	2.8	1.5	3.1	1.6	3.3
"	270	-	-	11.2	16.0	11.2	17.1	11.4	17.3
50.0	240	-	-	8.6	12.7	8.6	13.7	8.6	13.5
"	210	-	-	3.3	5.7	3.3	6.0	3.4	6.1
"	270	-	-	17.9	24.0	17.9	25.3	17.4	25.0

1. j and f_h values of 1.9 and 186.8 min., respectively and cooling constant for DWC's Method of 0.096.
2. Figures shown in bold are for the slowest heating of six replicate packs following process of 240 min at 121.0°C and an initial product temperature of 38.6°C.

Table 3.8. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 1.36 kg (3 lb) corned beef in 153 x 84 mm metal cans with a retort come-up time of 22.5 min., a nominal process of 155 min at 121.0°C with an initial product temperature of 42.1°C, and alternate initial temperatures and process times at 121.0°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
42.1[2]	**155**	**9.2**	**16.2**	**9.2**	**12.7**	**9.2**	**16.2**	**9.2**	**16.2**
"	125	-	-	2.6	4.2	2.6	6.1	2.7	6.3
"	185	-	-	21.5	26.9	21.5	31.9	21.6	31.8
15.0	155	-	-	5.1	7.6	5.1	10.3	5.7	11.0
"	125	-	-	1.1	2.0	1.1	3.0	1.3	3.6
"	185	-	-	14.5	18.9	14.5	23.1	15.4	24.2
60.0	155	-	-	14.6	19.0	14.6	23.3	13.1	21.3
"	125	-	-	5.2	7.7	5.2	10.4	4.4	9.2
"	185	-	-	29.6	35.9	29.6	41.2	27.6	38.9

1. j and f_h values of 1.2 and 126.3 min., respectively and cooling constant for DWC's Method of 0.148.
2. Figures shown in bold are for the slowest heating of three replicate packs following process of 155 min at 121.0°C and an initial product temperature of 42.1°C.

Table 3.9. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 170 g chicken cous-cous in 58 x 98 mm glass jars with a retort come-up time of 20.0 min., a nominal process of 55 min at 118.0°C with an initial product temperature of 43.4°C, and alternate initial temperatures and process times at 118.0°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
43.4[2]	**55**	**8.8**	**12.9**	**8.8**	**9.7**	**8.8**	**12.9**	**8.8**	**12.9**
"	25	-	-	0.3	0.5	0.3	1.5	0.3	1.3
"	85	-	-	23.5	24.7	23.5	28.1	23.5	28.1
15.0	55	-	-	7.2	8.1	7.2	11.1	7.7	11.7
"	25	-	-	0.1	0.2	0.1	0.9	0.2	0.9
"	85	-	-	21.6	22.7	21.6	26.2	22.3	26.9
60.0	55	-	-	10.2	11.1	10.2	14.4	9.5	13.7
"	25	-	-	0.6	0.9	0.6	2.2	0.4	1.7
"	85	-	-	25.1	26.2	25.1	29.7	24.4	29.0

1. j and f_h values of 1.9 and 27.3 min., respectively and cooling constant for DWC's Method of 0.32.
2. Figures shown in bold are for the slowest heating of six replicate packs following process of 55 min at 118.0°C and an initial product temperature of 43.4°C.

Table 3.10. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 850 g chicken luncheon in 73 x 230 mm metal cans with a retort come-up time of 6.5 min., a nominal process of 100 min at 116.6°C with an initial product temperature of 52.2°C, and alternate initial temperatures and process times at 116.6°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
52.2[2]	**100**	**6.0**	**8.9**	**6.0**	**7.1**	**6.0**	**8.9**	**6.0**	**8.9**
"	80	-	-	2.2	2.9	2.2	4.2	2.3	4.2
"	120	-	-	11.2	12.6	11.2	14.8	11.1	14.6
40.0	100	-	-	5.0	6.0	5.0	7.7	5.1	7.8
"	80	-	-	1.7	2.3	1.7	3.4	1.8	3.4
"	120	-	-	9.9	11.3	9.9	13.4	9.9	13.4
65.0	100	-	-	7.3	8.5	7.3	10.5	7.2	10.3
"	80	-	-	3.1	3.9	3.1	5.4	3.1	5.3
"	120	-	-	12.9	14.4	12.9	16.6	12.5	16.1

1. j and f_h values of 1.6 and 59.4 min., respectively and cooling constant for DWC's Method of 0.20.
2. Figures shown in bold are for the slowest heating of six replicate packs following process of 100 min at 116.6°C and an initial product temperature of 52.2°C.

Table 3.11. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 425 g white sauce in 72 x 126 mm glass jars with a retort come-up time of 12.5 min., a nominal process of 62 min at 118.4°C with an initial product temperature of 27.3°C, and alternate initial temperatures and process times at 118.4°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
27.3[2]	**62**	**1.3**	**3.0**	**1.3**	**1.9**	**1.3**	**3.0**	**1.3**	**2.9**
"	52	-	-	0.4	0.7	0.4	1.2	0.4	1.3
"	72	-	-	3.2	4.1	3.2	5.6	3.2	5.6
10.0	62	-	-	0.9	1.4	0.9	2.3	1.0	2.3
"	52	-	-	0.2	0.4	0.2	0.8	0.2	0.9
"	72	-	-	2.5	3.3	2.5	4.7	2.5	4.7
45.0	62	-	-	2.1	2.9	2.1	4.1	1.9	3.7
"	52	-	-	0.7	1.2	0.7	1.9	0.6	1.7
"	72	-	-	4.4	5.5	4.4	7.2	4.0	6.7

1. j and f_h values of 1.8 and 48.0 min., respectively and cooling constant for DWC's Method of 0.19.
2. Figures shown in bold are for the slowest heating of three replicate packs following process of 65 min at 118.4°C and an initial product temperature of 27.3°C.

Table 3.12. Comparison of F_p values[1] using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 125 g long-life refrigerated cheese in 94/82 x 33 mm plastic tubs with a retort come-up time of 14.5 min., a nominal process of 35.5 min at 114.0°C with an initial product temperature of 19.4°C, and alternate initial temperatures and process times at 114.0°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
19.4[3]	**35.5**	**25.6**	**49.4**	**24.7**	**39.2**	**24.7**	**48.3**	**25.7**	**49.4**
"	25.5	-	-	3.2	6.4	3.2	9.1	3.5	9.7
"	45.5	-	-	92.2	122.8	92.2	139.9	90.7	139.8
10.0	35.5	-	-	19.1	31.2	19.1	39.0	21.5	42.4
"	25.5	-	-	0.0	4.4	0.0	6.3	2.7	7.7
"	45.5	-	-	78.4	106.5	78.4	122.4	80.8	127.0
30.0	35.5	-	-	33.5	51.1	33.5	61.7	31.5	58.1
"	25.5	-	-	4.9	10.0	4.9	13.6	4.9	12.6
"	45.5	-	-	111.3	145.0	111.3	163.6	103.6	156.3

1. F_p values when T_{ref} = 100 °C and Z = 10 °C
2. j and f_h values of 1.2 and 37.3 min., respectively and cooling constant for DWC's Method of 0.12.
3. Figures shown in bold are for the slowest heating of seven replicate packs following process of 34.5 min at 114.0°C and an initial product temperature of 19.4°C.

Table 3.13. Comparison of F_o values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 125 g meat pastes in 57 x 87 mm glass jars with a retort come-up time of 16.5 min., a nominal process of 45.0 min at 122.4°C with an initial product temperature of 23.4°C, and alternate initial temperatures and process times at 122.4°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
23.4[2]	**45.0**	**11.9**	**20.2**	**11.9**	**13.9**	**11.9**	**20.2**	**11.9**	**20.2**
"	30.0	-	-	2.0	2.9	2.0	6.2	2.0	5.8
"	60.0	-	-	28.2	30.9	28.2	38.4	28.3	38.5
10.0	45.0	-	-	9.9	11.9	9.9	17.8	11.2	19.3
"	30.0	-	-	1.3	2.0	1.3	4.9	1.7	5.2
"	60.0	-	-	25.6	28.1	25.6	35.6	27.2	37.5
40.0	45.0	-	-	13.2	15.4	13.2	21.9	13.0	21.5
"	30.0	-	-	2.6	3.6	2.6	7.3	2.5	6.6
"	60.0	-	-	30.0	32.7	30.0	40.3	29.6	40.0

1. j and f_h values of 1.4 and 27.2 min., respectively and cooling constant for DWC's Method of 0.30.
2. Figures shown in bold are for the slowest heating of three replicate packs following process of 45 min at 122.4°C and an initial product temperature of 23.4°C.

Table 3.14. Comparison of F_p values[1] using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for 10F2 abalone in brine packed in 78 x 115 mm plastic cans with a retort come-up time of 15 min., a nominal process of 23 min at 105.6°C and an initial product temperature of 11.0°C, and alternate initial temperatures and process times at 105.6°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
11.0[4]	**23**	**10.0**	**43.1**	**9.3**	**18.5**	**9.3**	**43.0**	**10.0**	**43.0**
"	15	-	-	0.0	0.0	0.0	4.9	0.3	3.7
"	30	-	-	54.9	83.4	54.9	147.5	57.3	153.1
5.0	23	-	-	5.7	11.6	5.7	30.5	8.7	39.1
"	15	-	-	0.0	0.0	0.0	3.0	0.3	3.1
"	30	-	-	39.7	62.9	39.7	118.4	52.9	144.4
25.0	23	-	-	13.4	24.2	13.4	54.6	13.5	53.6
"	15	-	-	0.0	0.0	0.0	6.6	0.6	5.5
"	30	-	-	68.6	100.9	68.6	171.6	69.3	175.8

1. F_p values when T_{ref} = 90°C and Z = 9 C°C
2. Cans packed as 10Fs i.e. 10 pieces of maximum weight for individual pieces of 30 g and net fill weight ≤ 240 g.
3. j and f_h values of 1.4 and 27.5 min., respectively and cooling constant for DWC's Method of 0.21.
4. Figures shown in bold are for the slowest heating of six replicate packs following process of 23 min at 105°C, an initial product temperature of 11.0°C.

Table 3.15. Comparison of F_p values[1] using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for single 1F2 abalone in brine packed in 78 x 115 mm plastic cans with a retort come-up time of 15.5 min., a nominal process of 40 min at 105.5°C with an initial product temperature of 5.2°C, and alternate process times and initial temperatures at 105.5°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
5.2[4]	**40**	**16.5**	**80.1**	**15.3**	**29.2**	**15.3**	**79.0**	**16.5**	**80.0**
"	30	-	-	0.0	0.0	0.0	13.0	1.0	12.7
"	50	-	-	87.1	129.4	87.1	248.3	90.4	255.2
3.0	40	-	-	12.7	25.2	12.7	70.3	15.5	77.0
"	30	-	-	0.0	0.0	0.0	10.8	0.9	11.9
"	50	-	-	77.7	117.4	77.7	230.8	87.2	248.9
15.0	40	-	-	20.5	35.8	20.4	94.4	21.4	95.3
"	30	-	-	0.0	0.0	0.0	17.6	1.6	16.8
"	50	-	-	103.4	150.0	103.4	277.7	106.4	285.6

1. F_p values when $T_{ref} = 90°C$ and $Z = 9$ C°C
2. Cans packed as 1Fs i.e. One piece with maximum weight of 225 g.
3. j and f_h values of 1.8 and 38.2 min., respectively and cooling constant for DWC's Method of 0.24.
4. Figures shown in bold are for the slowest heating of six replicate packs following process of 40 min at 105°C, an initial product temperature of 5.2°C.

Table 3.16. Comparison of Fo values using General Method, Gillespy's Method and DWC's Method, and FMC's NumeriCal for single 10F1 abalone in brine packed in 78 x 115 mm plastic cans with a retort come-up time of 15.5 min., a nominal process of 40 min at 116.°C with an product initial temperature of 16.3°C, and alternate process times and initial temperatures at 116.°C

Process variables		General Method F_o value		Gillespy's Method[1] F_o value		DWC's Method[1] F_o value		NumeriCal F_o value	
Initial temp (°C)	Process time (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)	Steam off (min)	Final (min)
16.3[3]	**40**	**1.6**	**2.6**	**1.6**	**2.0**	**1.6**	**2.6**	**1.6**	**2.6**
"	30	-	-	0.4	0.6	0.4	0.9	0.4	0.9
"	50	-	-	3.7	4.2	3.7	5.0	3.6	4.9
5.0	40	-	-	1.3	1.6	1.3	2.2	1.5	2.4
"	30	-	-	0.3	0.4	0.3	0.7	0.4	0.9
"	50	-	-	3.1	3.6	3.1	4.4	3.4	4.7
30.0	40	-	-	1.8	2.2	1.8	2.8	1.8	2.8
"	30	-	-	0.5	0.7	0.5	1.1	0.5	1.1
"	50	-	-	3.9	4.4	3.9	5.2	3.8	5.2

1. Cans packed as 10Fs i.e. 10 pieces of maximum weight for individual pieces of 30 g and net fill weight ≤ 240 g
2. j and f_h values of 1.2 and 28.8 min., respectively and cooling constant for DWC's Method of 0.18.
3. Figures shown in bold are for the slowest heating of nine replicate packs following process of 40 min at 116.0°C, an initial product temperature of 16.3°C.

Table 3.17. Effect of changing processing conditions on the average errors in calculation of F values when comparing Gillespy's and DWC's Methods against NumeriCal values and proportion of computed results in which the errors were ≥ -10 % and > 10% of the NumeriCal values.

Variations in processing conditions	Tables	Average error in final F value calculation (%)		Proportion values outside 10% limits (%)	
		Gillespy's Method	DWC's Method	Gillespy's Method	DWC's Method
Change hold times	3.2 - 3.16	-37	2	97	7
Decrease initial temperatures and change hold times	3.2, 3.4 - 3.5, 3.7 - 3.16	-40	-6	97	15
Increase initial temperatures and change hold times	3.2, 3.4 - 3.5, 3.7 - 3.16	-27	4	79	15
Increase retort temperatures and change hold times	3.3 & 3.6	-32	0[1]	100	33[2]
Decrease retort temperatures and change hold times	3.3	-30	1	100	0

1. Actual average value was -0.3 rounded to zero
2. In three of nine cases the values exceeded 10% limits

3.3 Evaluation of process adequacy via heat penetration studies

In order to set minimum F_p and F_o values against which the adequacy of commercial thermal processes can be assessed, it is necessary to identify the target pathogenic microorganisms which must be eliminated, or reduced to commercially acceptable probabilities of survival. Having satisfied these public safety criteria, manufacturers then decide what, if any, additional processing severity (F value) they may require in order to reduce the probabilities of spoilage by non-pathogenic microorganisms, some of which may be more heat resistant than the target pathogens. As has been discussed (Section 1.1.2 page 3) Good Manufacturing Practice requires that, with respect to the safety of low-acid heat processed foods, the target microorganisms which must be destroyed by the thermal processes are proteolytic and non-proteolytic *Clostridium botulinum.*

Under these circumstances, and as discussed previously (Section 1.1.2 page 4), REPFEDs will require a minimum F_p value of 10 min., when T_r = 90°C and Z = 9 C°C, as this can be shown to bring about six decimal reductions in the probability of survival of non-proteolytic *Clostridium botulinum.* Shelf-stable, low-acid foods require a process that will bring about 12 decimal reductions in the probability of survival of proteolytic *Clostridium botulinum* and, as shown in Section 1.2 page 22, this will be achieved with an F_o value of between 2.4 and 2.8 min., when T_r = 121.1°C and Z = 10 C°C.

Because most manufacturers see the need to provide protection against those contaminants which are more heat resistant than the spores of proteolytic and non-proteolytic *Clostridium botulinum* in shelf-stable and refrigerator stable foods, respectively, the target F values that are adopted commercially are frequently in excess of the minima quoted above. Notwithstanding the tendency for some manufacturers to "add F values" to their process, there are no published standards as to what minimum F values are recommended. Rather, provided safety from *Clostridium botulinum* is assured, most manufacturers will set their own target F values and these are likely to reflect any, or all, of the following:

- Caution
- Precedence
- The microbiological status of raw materials

- Reliability of equipment
- Adequacy of cooling after processing
- Integrity of the cold chain in the case of REPFEDs
- Temperatures of storage for shelf-stable foods
- The history of spoilage attributed to under-processing

With such a diversity of factors affecting their selections, it is little wonder that there are large disparities as to the target F values that manufacturers adopt.

The results of process evaluation trials which are presented in Sections 3.3.1 and 3.3.2 have been extracted from the commercial-in-confidence trials completed (by the writer) nationally and internationally with various food and beverage manufacturers and equipment suppliers (including Barriquand, FMC and Lagarde).

3.3.1 Process adequacy in REPFEDs

In Table 3.18 can be seen the product descriptions, the processing conditions and the corresponding F_p values that were found for the range of commercially manufactured REPFEDs (as presented in Table 2.5 on page 67) that were included in this study. Also shown in the table is the classification as to whether the F_p values that were calculated (or in some instances estimated) for the heating processes were sufficient to satisfy GMP guidelines for the various categories of products and processes.

Review of the results contained in Table 3.18 indicates the following:

1. Of the 16 thermal process and pack combinations that were considered 11 (69%) satisfied GMP requirements with respect to safety from under processing as they had F_p values ≥ 10.0 min. Of four products that had F_p values between 10 and 20 min., two had values estimated as at least 11 min., one at 10.7 min and one at 15.6 min. For the remaining seven, F_p values ranged from 29.9 min to 704.5 min. This means that each of these 11 products exhibited F_p values that complied with the recommendations of ACMSF (1992), Betts (1996), ECFF (1996) and AQIS (1992).

2. Of the five instances (i.e. 31%) in which the thermal processes failed to deliver minimum F_p requirements, three were associated with low-acid foods and, in these cases, public safety would have been compromised. With respect to these three cases it can be noted that:

   - In the "worst-case" example of the low-acid soup and sauce in a 250 mL pouch (case 3) the F_p value was classified as "none detectable" as it was found that the upper layers of the pouches were not submerged in the water-immersion pasteurisation tank in which they were being heat-treated. In these instances the temperatures on the outer surface of the pouches were observed to fluctuate between 57 and 85°C. The process had been designed and specified so that after filling and sealing at ≥ 85°C, the product would be held continuously at 85°C for at least 40 min. Calculation shows that under these circumstances the minimum target F_p value would be 11 min. However in cases when the core temperature fell below 75°C this would not have been achieved.

     Investigations established that the reason for an inadequate heat treatment being delivered was a failure to comply with written instructions (included in the company's HACCP Plan) that the water level in the immersion tank must be maintained above the uppermost layer of pouches. Also concerning was the observation that failure to comply with standard operating instructions was not detected directly during a routine review of records, but had only come to light after pouches intermittently were found to have relatively high (≥ 100,000cfu/g) Standard Plate Counts.

     Microbiological standards covering REPFEDs are not included in the Food Standards Australia New Zealand - Standard 1.6.1. (2004), and Hasell and Salter (2003) do not mention them in their report of the review by Food Standards Australia New Zealand (FSANZ) of Australia's and New Zealand's codes and regulations covering microbiological standards for foods. Therefore, although this product recorded SPCs of ≥ 100,000 cfu/g, there was no breach of any relevant standard. Nevertheless, the counts were considered to be unacceptably high for hermetically sealed heat processed products that were still early in their refrigerated shelf lives.

- In the one instance (case 4) with the low-acid 175 g pouches and 300 g tubs, the F_p values were classified "none detectable" as after filling at 78°C, there was no controlled holding stage prior to the start of cooling. It can be calculated that even had the product maintained its minimum filling temperature (78°C) it would have needed to hold this temperature for in excess of three and a half hours in order to achieve the recommended minimum F_p value of 10 min. This calculation assumes that the *Z* value is 9 C°C, as recommended by ACMSF (1992); however ECFF (1996) advocate a Z value of 7 C°C for temperatures less than 90°C, and on this basis the hold time required at 78 °C to achieve an F_p value of 10 min would be over eight and a half hours. These calculations demonstrate that that no matter which *Z* value is selected for determination of process lethality, the minimum target F_p of 10 min would not have been achieved. Therefore, it is reasonable to conclude that this manufacturer was supplying the retail trade with low-acid soups and sauces that failed to meet GMP guidelines with respect to minimum F_p values, despite the products' classification as "hazardous" because of its association as a potential growth medium for non-proteolytic *Clostridium botulinum*.

- The 1.5 kg pouch pack of vegetables (case 11) that were processed for 25 min at 100°C received an F_p value of 3.1 min., which is equivalent to less than two decimal reductions in spores of the target non-proteolytic *Clostridium botulinum*.

3. The three seafood products (cases 5 - 7) in which F_p values exceeded a 12*D* process for non-proteolytic *Clostridium botulinum*, were all examples of low-acid REPFEDs that had been manufactured according to F_p-Hermetica's thermal processing technology (which has been described in Section 1.1.2 page 5 and in Section 1.5 pages 51-52). One of the advantages of these processes, other than their ability to maximise sensory quality, is that yields are far higher than would be achieved had the products been made shelf-stable, as is the normal case. For instances in cases 5 and 6 the drained weight recoveries were in excess of 15% higher than normally experienced with their shelf-stable counterparts.

4. Of the two rice products, one (case 8) had an F_p value of 183.2 min which was far in excess of GMP requirements, however in this instance the relatively severe process was required to ensure that the raw product was ade-

quately cooked. In the second example (case 9 in which the F_p value was 10.7 min) the rice had been pre-cooked and this meant that the thermal process was required only to deliver the recommended 6*D* cycle for REPFEDs.

5. Like the rice in case 8, the noodles in case 9 required a relatively severe process (in which the F_p value was 123.8 min) in order to cook (soften) the product.

6. In the trials with vegetables (case 11) it can be seen that by extending the processing time from 25 to 30 min at 100 °C, the F_p value increased from an unsatisfactory 3.1 min to 29.9 min., which is more than sufficient.

7. The dairy product represented in case 12 is an example of the manufacturer adopting an incorrect thermal process schedule in the first instance. The F_p value of 704.5 min that was delivered by the 35 min process at 113°C was far in excess of that required for a refrigerated product. It can be calculated that an F_p of 704.5 min is approximately equivalent to an F_o of 0.4 min., and this means that it would have been sufficient to deliver a 2*D* process for proteolytic *Clostridium botulinum* which has heat resistance of around 175 times that of non-proteolytic *Clostridium botulinum* (See Section 1.5 page 51). In this case a 10 min reduction in processing time led to delivery of an F_p value that exceeded the 6*D* cycle required by GMP for REPFEDs and approached that of the 12*D* cycle proposed by F_p-Hermetica.

Table 3.18. Summary of products, packaging systems, process conditions and least F_p values[1] delivered commercially manufactured REPFEDs

Case	Container	Process conditions	F_p value (min)	GMP	Comments
	Acid soups & sauces				
1	250 mL pouch	Nominally 40 min at 85.0°C	≥ 11	Yes	Products hot filled at ≥ 85.0°C and then submerged in water bath for at least 40 min in order to deliver an F_p of at least 11 min
		Worst-case 40 min at ≤75.0°C	None detectable	No	Core temperatures sufficient to contribute F_p value of ≤ 0.2 min which is marginal for a refrigerated acidified product containing herbs and spices
2	175 g pouch and 300 g tub	Fill at ≥ 78.0°C then cool	"	"	No prescribed hot-holding time between filling and cooling, therefore process is marginal for refrigerated acidified product
	Low-acid soups & sauces				
3	250 mL pouch	Nominally 40 min at 85.0°C	≥ 11	Yes	Products hot filled at ≥ 85.0°C and then submerged in water bath for at least 40 min in order to deliver a minimum F_p of 11 min
		Worst-case 40 min at ≤75.0°C	None detectable	No	Core temperatures insufficient to deliver minimum target F_p for refrigerated low-acid product
4	175 g pouch and 300 g tub	Fill at ≥ 78.0°C then cool	"	"	No prescribed hot-holding time between filling and cooling, therefore process is inadequate for refrigerated low-acid product

Case	Container	Process conditions	F_p value (min)	GMP	Comments
	Seafoods				
5	225 g cup	40 min at 105.0°C	80.1	Yes	F_p value exceeds a 12*D* process; product has up to 12 months refrigerated shelf-life at ≤ 5.0°C
6	240 g cup	23 min at 105.0°C	43.1	"	"
7	1 kg pouch	20 min at 105.0°C	39.9	"	"
	Rice				
8	200 g tub	15 min at 100.0°C	183.2	"	F_p value exceeds requirement for 6*D* process
9	1.5 kg pouch	30 min at 100.0°C	10.7	"	F_p matches requirement for 6*D* process
	Noodles				
10	200 g tub	10 min at 100.0°C	123.8	"	F_p value exceeds requirement for 6*D* process
	Vegetables				
11	1.5 kg pouch	25 min at 100.0°C	3.1	No	Process insufficient to deliver minimum target F_p value
		30 min at 100.0°C	29.9	Yes	F_p value exceeds requirement for 6*D* process
	Dairy Products				
12	125 g tub	35 min at 113.0°C	704.5	"	F_p value exceeds requirement for 6*D* process
		25 min at 113.0°C	15.6	"	F_p value appropriate for 6*D* process

1. F_p values based on a Reference Temperature of 90 °C and a *Z* value of 9 C°.

3.3.2 Process adequacy in shelf-stable foods

In Table 3.19 can be seen the product descriptions, the processing conditions and the corresponding F_o values that were found for the range of commercially manufactured shelf-stable foods (as presented in Table 2.6 on page 68) that were included in this study. Also shown in the table is the classification as to whether the F_o values that were calculated for the heating processes were sufficient to satisfy GMP guidelines for the various categories of products and processes.

Review of the results contained in Table 3.19 indicates the following:

1. Thirty two thermal process and pack combinations were considered in this study and 25 (78%) of these had F_o values ≥ 2.4 min., which satisfied GMP requirements with respect to safety from under processing.

2. The seven instances (i.e. 22% of cases) that revealed F_o values < 2.4 min were made up of two each from vegetables and molluscs, and three that were classified as commercial-in-confidence (CIC) in order to maintain the manufacturer's anonymity. In relation to these seven cases of inadequate F_o values it can be added that:

    - The two vegetable processes (cases 8 and 9) had F_o values of 0.9 and 1.2 min for the twin pack cobs and the kernels, respectively. It was calculated that in order to achieve F_o values of 2.4 min these processes would need to be extended from 30 min to approximately 38 min at 120°C for the twin pack cobs, and from 23 to 35 min at 120°C for the kernels. However, with both products it was found that attempts to increase F_o values were detrimental to product quality and led to unacceptable darkening. Also of interest (because of the commercial risk that it presented) was the selection of a target F_o value that had little capacity to eliminate thermophilic spores that are known to contaminate vegetables, such as *Geobacillus stearothermophilus* (Jenson *et al*, 2001), and which could be transferred to the product via the flume water used to carry the cobs along the process line (ICMSF, 1998). *Geobacillus stearothermophilus* has a $D_{121.1}$ value of between three and six minutes (Jenson *et al*, 2001) and this means that even had F_o values of 2.4 min been achieved these processes would have delivered less than a single logarithmic reduction in thermophilic spore counts.

It was understandable that when faced with these options the manufacturer considered processing their products as REPFEDs, rather than shelf-stable commodities.

- The thermal processes in three cases (10 - 12) were immediately revised as soon as it was realised that the least F_o values were unsatisfactory. Whilst the speed with which appropriate corrective action was taken was commendable, less satisfactory was the sequence of events that allowed inadequate thermal processes to remain undetected in the first place. In cases 10 and 12 adequate F_o values were achieved when temperature overshoots were introduced prior to the start of the scheduled hold phase and in these two instances the minimum F_o values increased from 1.1 and 2.0 min to 3.7 and 3.6 min, respectively. In case 11 a two minute extension to the hold time (albeit at 117 rather than 118 °C) was sufficient to increase the least F_o value from 1.8 to 3.0 min.

- The two remaining instances in which the minimum F_o values failed to comply with GMP are shown as cases 24 and 26 in which the products were Australian abalone and New Zealand paua, respectively. In the first example (case 24) the least F_o value was only 0.7 min (rather than 2.4 min which is the value most frequently targeted by abalone and paua processors) and this means that the probability that spores of proteolytic *Clostridium botulinum* would survive the thermal process would be of the order of one hundred million (10^8) times that regarded as satisfactory. The reason why abalone (and paua) processors might be attracted to such low F_o values have been discussed previously (Section 3.2.3 page 126), however, there is no doubt that in this case the pursuit of higher yields was at the cost of consumer safety.

  In the second example shown in case 26, the final F_o was 2.3(4) min. This is considered to be more an instance of the final F_o failing (just) to satisfy GMP and regulatory requirements than it is an example of a demonstrably increased health risk caused by under processing. Like the example in case 24, this is another instance of a manufacturer attempting, albeit unsuccessfully, to fine-tune their process in order to maximise recoveries.

3. In seven of nine instances (cases 1 to 7) the processes for vegetables were more than required for safety and appropriate for protection from thermophilic spores that might contaminate raw materials. Given that F_o values ranged from 5.2 to 8.3 min it is likely that these processes would provide, at least, one to two decimal reduction in the number of thermophilic spores surviving the process, and in the absence of regular reports of thermophilic spoilage in the trade this is sufficient.

4. The thermal processes used by two manufacturers of low-acid pasta sauce were evaluated and in one instance (case 13) the minimum Fo was 3.0 min while in the other (case 14) it was 14.0 min. Although of different composition and physical characteristics, the products were marketed as similar and consumers regarded and used them as such. As far as the microbiological quality of the raw materials was concerned, there was no reason given why one product would require a thermal process which delivered an F_o value that was more than four times that of the other.

   Notwithstanding the differences in the severity of these two processes both were safe; however the protection offered to prevent thermophilic spoilage was greater in case 14 than it was in case 13.

5. The three examples shown in cases 15 to 17 all comply with GMP with respect to minimum F_o or F_p values. Case 15 was an acid product in which the pH was between 4.0 and 4.3 and on this basis the F_p value recommended by NFPA (1985) is 5 min. The other two products were low-acid (pH> 4.6) and in each case the processes were designed to provide protection against thermophilic spoilage. With case 16, however, there had been a history of thermophilic spoilage due to extremely heat resistant thermophiles and for this reason the high F_o of 32.6 min had been selected.

6. Cases 18 to 19 are all examples of processes that are adopted when preservatives are added to the formulation in order to reduce target F_o values below those required for low-acid foods preserved by heat alone. In these cases sodium nitrite and sodium erythorbate were added at dosing levels of 200 and 500 mg/kg, respectively and in addition 2.4% sodium chloride was also included. Because of the inclusion of these preservatives, the F_o values, which ranged from 0.1 to 1.2 min were sufficient for product safety.

The reduction of target F_o values when coupled with the use of preservatives is common within the Australian industry and also is in line with the Australian Defence Force Foods Specification (ADFFS, 1995) which states that thermal processes for cured canned meats containing not more than 120 mg/kg nitrite must achieve core temperatures of at least 100°C. In the process evaluations studies carried out for this manufacturer it was found that minimum core temperatures were 100.7, 108.6 and 104.1°C for the 340, 450 and 905 g cans, respectively. Furthermore, the data in Table 3.19 show that the ranking of the F_o values followed that of the cans' core temperatures.

7. Cases 21 and 22 represent two can sizes of a beef luncheon meat in which a low level of sodium nitrite was included to aid colour, but not to enable selection of an F_o value less than that required for traditionally heat processed shelf-stable foods. In this instance the nitrite level was less than 10 mg/kg and the minimum F_o values were 5.7 and 9.9 min., for the 415 and the 850 g cans, respectively. In addition to satisfying GMP guidelines with regard to safety, the final F_o values were intended to provide protection from the risks of thermophilic spoilage.

   However, when considering the adequacy of the processes shown in cases 21 and 22 it is important not to overlook the location of the cannery (in the United Arab Emirates) and the effect that this may have on the incidence of thermophilic spoilage. For four to five months of the year ambient temperatures in the UAR frequently exceed 40°C and for this reason greater protection than is possible with F_o values of less than 10 min may be required to prevent thermophilic spoilage. This is not so solely because warehouses will be at temperatures favourable for thermophilic growth, but also because of the difficulties that are experienced when attempting to cool hot cans after completion of sterilisation. For instance, data from these trials show that the core temperatures after 30 minutes cooling were still above 90 and 95°C, for the 450 and the 905 g cans, respectively. Consequently, core temperatures when cans were removed from the retorts frequently were above 40 °C (M. Aslam, *pers comm.* 2001) and this is higher than that which is generally recommended to minimise risks of thermophilic spoilage. Under these circumstances, because of the difficulties that this manufacturer had with securing adequate cooling water it was not surprising to learn that the incidence of

stack spoilage was higher in the summer than it was in winter (M. Aslam, *pers comm.* 2001).

8. Case 23 represents a conductive heating solid pack seafood product processed in glass for which the least F_o value was 5.7 min. This process was therefore sufficient for product safety and sufficient to provide moderate protection from thermophilic spoilage. Unlike cases 21 and 22, the cannery operated in a temperate climate and the temperature and availability of the cooling water was adequate.

9. Cases 27 to 29 are examples of New Zealand paua in which the manufacturer targeted F_o values that would be sufficient to match GMP values (i.e. ≥ 2.4 min) without overprocessing. These data reinforce the need for paua (and abalone) processors to control the weights of their fish, as it can be seen that the heavier the individual weights the longer the process that is required. It is for these reasons that most canners develop several thermal processes that are tailored to accommodate the weight ranges that they face in commercial practice.

Table 3.19. Summary of products, containers, process conditions, least F_o values and compliance with GMP for commercially manufactured shelf-stable foods included in process evaluation studies

Case	Container	Process conditions	F_o value (min)	GMP	Comments
	Vegetables				
1	150 g can	8 min at 122.0°C	5.6	Yes	Corn kernels. Process sufficient for safety and moderate protection from thermophilic spoilage
2	210 g can	45 min at 121.0°C	8.3	"	Mushrooms. Process sufficient for safety and moderate protection from thermophilic spoilage
3	340 g can	12 min at 120.0°C	5.7	"	Asparagus. Process sufficient for safety and moderate protection from thermophilic spoilage
4	"	26 min at 116.0°C	7.4	"	Asparagus. Process sufficient for safety and moderate protection from thermophilic spoilage
5	420 g can	23 min at 116.0°C	7.6	"	Green beans. Process sufficient for safety and moderate protection from thermophilic spoilage
6	"	85 min at 116.0°C	5.2	"	Creamed corn. Process sufficient for safety and moderate protection from thermophilic spoilage
7	2950 g can	30 min at 116.0°C	7.2	"	Asparagus. Process sufficient for safety and moderate protection from thermophilic spoilage
8	Twin-pack pouch	30 min at 120.0°C	0.9	No	Corn cobs. Process failed to deliver minimum F_o required by GMP for product safety
9	1 kg pouch	23 min at 120.0°C	1.2	"	Corn kernels. Process failed to deliver minimum F_o required by GMP for product safety

Case	Container	Process conditions	F_o value (min)	GMP	Comments
	CIC[1]				
10	150 g can	20 min at 122.5°C	1.1	No	Process failed to deliver minimum F_O required by GMP for product safety
		33 min at 120°C[2]	3.7	Yes	Revised process satisfied GMP
11	150 g can	7 min at 118.0°C	1.8	No	Process failed to deliver minimum F_O required by GMP for product safety
		9 min at 117.0°C	3.0	Yes	Revised process satisfied GMP
12	250 g can	50 min at 117.0°C	2.0	No	Process failed to deliver minimum F_O required by GMP for product safety
		45 min at 117.0°C[2]	3.6	Yes	Revised process satisfied GMP
	Sauces				
13	375 g jar	65 min at 119.0°C	3.0	Yes	Pasta sauce. Process sufficient for safety but little protection from thermophilic spoilage
14	"	50 min at 119.0°C	14.0	"	Pasta sauce. Process sufficient for safety and adequate protection from thermophilic spoilage
	CIC				
15	170 g jar	5 min at 102.2°C	0.0(2)	Yes	Acid product. The F_o of 0.0(2) corresponds to an F_p value of 10.7 min (based on Reference temp. of 93.3°C and *Z* of 8.3°C) which satisfies GMP
16	"	25 min at 124.4°C	32.6	"	Process sufficient for safety and for protection from spoilage by extremely heat resistant thermophiles
17	"	55 min at 118.9°C	14.1	"	Process sufficient for safety and adequate protection from thermophilic spoilage

Case	Container	Process conditions	F_o value (min)	GMP	Comments
	Leg ham				
18	340 g can	48 min at 110.0°C	0.1	Yes	In combination with nitrites and salt the final F_o values was sufficient to comply with GMP[3]
19	450 g can	48 min at 110.0°C	1.2	Yes	In combination with nitrites and salt the final F_o values was sufficient to comply with GMP[3]
20	905 g can	90 min at 110.0°C	0.4	"	"
	Beef luncheon				
21	415 g can	95 min at 115.0°C	5.7	"	Process sufficient for safety and moderate protection from thermophilic spoilage
22	850 g can	100 min at 115.0°C	9.9	"	"
	Seafoods				
23	375 g jar	75 min at 121.1°C	5.7	"	Tuna. Process sufficient for safety and moderate protection from thermophilic spoilage
	Molluscs				
24	410 g can[4]	45 min at 113.7°C	0.7	No	Australian abalone. Process failed to deliver minimum F_o required by GMP for product safety
25	Unit pouch. Fill weight 200 g	64 min at 114.0°C	2.8	Yes	Australian abalone. F_o values sufficient for safety
26	410 g can[4]	36 min at 116.0°C	2.3	No	New Zealand paua. Process failed to deliver minimum F_o required by GMP for product safety

Case	Container	Process conditions	F_o value (min)	GMP	Comments
	Molluscs (cont'd)				
27	Unit pouch. Fill weight 130-140g	36 min at 113.3°C	2.8	Yes	New Zealand paua. F_o values sufficient for safety
28	Unit pouch. Fill weight 160-170g	40 min at 113°C	2.7	"	New Zealand paua. F_o values sufficient for safety
29	Unit pouch. Fill weight >225g	46 min at 113°C	2.7	"	New Zealand paua. F_o values sufficient for safety

1. "CIC" signifies product identity classified as Commercial-in-Confidence
2. Processes included a temperature over-shoot for retort equilibration prior to stabilising hold phase on set value and this led to an increase in final F_o values in these instances.
3. F_o values comply with requirements of Australian Defence Force Foods Specification (ADFFS, 1995) for heat processed leg ham.
4. Total drained weight ≥ 205 g.

3.4 Evaluation of Biotests to assess the adequacy of hermetic seals

3.4.1 Glass containers sealed with Trivac closures, twist caps and PT caps

The objective of this Biotest was to evaluate the performance of a retortable Trivac closure as a reliable means of providing a hermetic seal to glass containers that were to be filled with acid and low-acid convenience meals. The food manufacturer proposed to launch a range of new products into the convenience food market and for this reason it was important to have a closure that could be applied to, so-called, wide-mouth microwaveable glass containers that would also serve as ramekins allowing consumption directly from the container. Use of PT closures (long regarded as the industry standard for abuse resistance, reliability and safety) was precluded on the basis of cost. Therefore, successful performance of a retortable Trivac closure was critical to the release of the proposed product range.

In Table 3.20 can be seen the results of the Biotests conducted on glass containers sealed with retortable Trivac closures, twist caps and PT (push-on twist-off) caps. For the various closure and product combinations are shown the frequencies and the proportion (%) of containers passing and failing when impacted at 76 $cm.sec^{-1}$ and/or 165 $cm.sec^{-1}$.

The data show that with all closure systems the controls (i.e. those containers that were immersed in the test medium but which were not impacted) had pass rates ranging from 92 to 100%. This result re-affirms the efficacy of these sealing systems, provided that the sealing surfaces were not disrupted by impact, even under conditions when the contamination levels in the Biotest immersion bath were two to three log scales higher than those permitted in the cooling water of conventional retorts. In these systems cooling water is added from an external source and GMP requires that the Total Count of the water entering the retort shall be < 100 cfu/mL (Codex Alimentarius, 1995). However, in the FMC, Barriquand and Lagarde styles of retorts the cooling water that comes into contact with the containers has been sterilised during the thermal process, and this means that the counts in the immersion suspension used in this Biotest would have been up to five log scales higher than those typically found in the cooling water.

Table 3.20. Frequency of failures following Biotests on glass containers sealed with Trivac closures, twist caps and PT caps

Closure/product	Control (no impact)		Impacted samples			
			76 cm. sec^{-1}		165 cm. sec^{-1}	
	Pass (No/%)	Fail (No/%)	Pass (No/%)	Fail (No/%)	Pass (No/%)	Fail (No/%)
Trivac/CCC	67/100	0/0	62/43	82/57	0/0	29/100
Trivac/MC	63/100	0/0	40/41	58/59	0/0	30/100
Trivac/MN	70/99	1/1	91/80	23/20	7/24	22/76
Twist (Local)/FA	33/92	3/8	11/15	61/85	-	-
Twist (Local)/SC	36/100	0/0	26/38	42/62	-	-
Twist (Imported)/LB	68/99	1/1	15/12	112/88	-	-
PT/(Egg custard)	64/100	0/0	93/100	0/0	24/77	7/23

In contrast with the excellent performance of all of the controls, following impact at 76 $cm.sec^{-1}$ the retortable Trivac closures and the twist closures did not attain the 100% pass rate found with the PT caps. The failure rates for the twist closures ranged from 62 to 88% and this was marginally inferior to that with the retortable Trivac closures for which failure rates ranged from 20 to 59%. The excellent result (with zero failures) for the PT cap accounts for the widespread commercial success of this system with acid and low-acid retorted foods, including the quality and safety sensitive infant food sector.

The retortable Trivac closures subjected to impact at 165 $cm.sec^{-1}$ experienced 100% failure rates when applied to retorted products (i.e. CCC and MC) and 76% failure rates when applied to the hot filled and cooled product (MN). The difference between the performance of retorted and non-retorted closures (at both impact velocities) is a reflection of the stresses applied to the hermetic seals during processing. In the former cases the sealed containers were subjected to the rigors of over-pressure retorting and this can cause compound softening and localised compound movement which may weaken the hermetic seals and render them susceptible to PPLC. Hot fill products by contrast were cooled under atmospheric conditions without over-pressure and this is a gentle operation that places little stress on the hermetic seal.

The PT closures after impact at 165 cm.sec^{-1} showed a 23% failure rate, which although an increase over that following impact at 76 cm.sec^{-1} (when there were no failures) was less than one quarter of that for the retorted Trivac closures.

These results demonstrate that the retortable Trivac closure that was being proposed for commercial release was less likely to fail under impact (and risk PPLC) than the local and imported twist caps, however their abuse resistance was inferior to that of PT closures. It was because of the disparity between the failure rates of retortable Trivac closures and PT closures (which provided the benchmark for acceptable performance) that the manufacturer chose to terminate the development program and not launch the product. The conclusion drawn from these Biotests was that release of shelf-stable low-acid foods using a closure system that had been shown to be far less reliable than PT closures represented an unacceptable health risk.

It can be seen that the Biotest procedure that was developed enabled differentiation in the abuse resistance and the vulnerability to PPLC of various closure systems, while providing the means of comparing performance of a proposed new glass container and closure system against that of a proven industry benchmark.

3.4.2 Three-piece metal cans with standard sanitary ends and FPEO metal ends

The purpose of this Biotest was to establish whether double seam tightness of the can ends containing the full panel easy open (FPEO) feature was responsible for the PPLC and spoilage that was detected in stocks of a range of low-acid foods awaiting commercial launch as a new product line.

All 6,120 cans that were subjected to the Biotest were first inspected after four days incubation at 30 °C cans and by this time 125 of the 148 cans that were to blow had blown. Thus the Biotest had simulated the four to five day lag period that was observed between production and detection of blown cans in commercially manufactured stocks. The frequency of spoilage that was detected following the Biotest is summarised in Table 3.21.

Table 3.21. Frequency of failures following Biotests of metal cans with standard and FPEO can ends

Can codes	No impact		Impact	
	Pass (No/%)	Fail (No/%)	Pass (No/%)	Fail (No/%)
EOO[1]	1,014/99.9	1/0.1	886/88.0	121/12.0
EOT[2]	1,035/100.0	0/0.0	1,014/99.5	5/0.5
EORT[3]	-	-	90/90.0	10/10.0
CON-CE[4]	-	-	637/98.3	11/1.7
CON-CME[5]	-	-	648/100.0	0/0.0
CON-CE & CME[6]	648/100.0	0/0.0	-	-

1. EOO signifies easy-open end with original seam tightness
2. EOT signifies tightened easy-open ends with overlaps at CME > 90%
3. EORT signifies cans with the 2nd action roll repeated on the easy-open ends
4. CON-CE signifies control cans with standard can ends and impact at canner's ends
5. CON-CME signifies control cans with standard can ends and impact at can maker's ends
6. CON-CE & CME signifies control cans with standard can ends and with no impact test

Analysis of the data in Table 3.21 reveals the following:

1. The 12% failure rate amongst the impacted FPEO cans with the original seam tightness (coded EOO) was the highest failure rate of all the cans tested. This suggests that the most likely cause of failure (caused by PPLC) in these test cans was impact at the FPEO end. The low (0.1%) failure rate of cans coded EOO when not impacted indicates that the hermetic seal formed by the double seam on the FPEO end, while adequate when not abused, was vulnerable to mechanical damage.

2. Whereas re-application of the 2nd action roll made little difference to failure rates after impact (cf. 12% and 10% failure with cans coded EOO and EORT, respectively), those cans that had the tightness rating on their FPEO ends increased to > 90% showed only 0.5 % failures compared with the 12% failures previously observed. This improvement in performance indicated that, in the first instance, manufacture of cans with a tightness rating of 90% would most likely provide double seams that were more resistant to mechanical damage

and subsequent PPLC (say, from routine handling on the filling and packing lines) than the FPEO cans as originally supplied by the can maker.

3. Two of the three control cans (CON-CME and CON-CE & CME) exhibited 100% pass rates while those coded CON-CE had failures at 1.7% after impact. The performance of the latter was considered satisfactory as the severity of the Biotest protocol is expected to induce low levels of failure in commercial quality containers.

4. The absence of failures in all but one of the 2,698 cans that were not impacted, compared with the overall failure of 147 cans of the 3,422 cans that were impacted, underscores the importance of avoiding mechanical damage on commercial filling and packing lines. The need to comply with this aspect of GMP is occasionally difficult to substantiate in some commercial environments, as not all impact damage leads to overt failure. However, the data in Table 3.21 demonstrate that while cans may appear robust, when they suffer mechanical abuse (for example, of the magnitude of that shown in Plates 2.12 and 2.13 on page 90) the likelihood of them losing their hermetic seals increases. Furthermore, as shown in this Biotest, when seal failure occurs the likelihood of PPLC leading to spoilage is increased in cases where post-process hygiene and sanitation is not controlled adequately.

In this instance, involving a case when several thousand cans of product were found to have spoiled prior to their commercial release, the Biotest procedure that was developed was sufficient to demonstrate the vulnerability of can double seams when subjected to mechanical damage. It was on the basis of the results obtained in this series of trials that the food manufacturer directed their can supplier to tighten the double seam on the FPEO end of their cans. For their part the food manufacturer undertook to increase surveillance of post-process hygiene and sanitation procedures and together these actions cleared the way to recommence commercial production and, in due course, successful release of product to the trade.

3.4.3 Barrier plastic trays heat sealed with laminated aluminium foil

This Biotest formed part of a process validation program to assess the performance of heat seals on barrier trays pending the launch of a new range of acid and low-acid meals into the Australian and New Zealand markets.

Provisional operating parameters of the heat-sealing machine (i.e. the temperature of the sealing heads, the heat sealing contact time and the seal head pressure) had been established as those that best delivered satisfactory seal appearance (i.e. freedom from visual defects, and smooth and continuous seals with an absence of blisters, channels and folds across the heat seal). However, the parameters that established satisfactory mechanical strength were more difficult to define because the relationship between these physical attributes and the ability of the heat seal to prevent PPLC had not been demonstrated. This was because, at the time, no other food manufacturer in Australia or New Zealand had direct experience with heat-sealing barrier plastic trays for production of shelf-stable heat processed foods. The requirement for shelf-stability had elevated the importance of maintaining hermetic seals beyond that required for refrigerated or frozen products to be equal to that required in canned foods. Consequently, minimum pass levels for mechanical characteristics that would correlate with the formation of satisfactory hermetic heat seals in commercial production were largely unknown. In the absence of standards specifying minimum performance standards and test criteria (as there were for example in, the then, Australian Standard AS 2730 for can double seams [Anon., 1984]) the only guideline values relating to mechanical strength were those "offered" (without guarantee) by various packaging materials suppliers. Under these circumstances it was decided to set tentative pass standards for burst pressure and peel strength and these were ≥ 420 kPa and > 2.0 kg/25 mm after retorting, respectively.

The maximum failure level that would be considered acceptable also had not been defined, however, in this instance it was based on experience with other Biotests with other packaging systems. It had been found (Warne, *unpublished*) that up to 2% of commercial quality metal cans could be induced to fail in similarly severe Biotests and on this basis it was decided that the same pass level would be required with barrier plastic trays.

Therefore, it was in order to determine whether the absence of visual defects and compliance with burst pressure and peel strength performance correlated with the formation of satisfactory hermetic seals that these two Biotest were completed. The results of each Biotest are shown in Table 3.22.

Table 3.22. Frequency of failures in Biotest of imported and locally manufactured heat-sealed and retorted barrier plastic trays following simulated transport and road transport

Biotest	Control		Transport test	
	Pass (No/%)	Fail (No/%)	Pass (No/%)	Fail (No/%)
Biotest 1 - imported trays				
Simulated transport[1]	-	-	860/99.5	4/0.5
No transport	192/100.0	0/0.0		
Biotest 2 - local trays				
Road transport[2]	-	-	1,131/99.2	9/0.8

1. Simulated transport testing, prior to immersion in the test suspension, using Victoria University of Technology's Random Profile No. 2 sequence for 30 min., with table acceleration set at $0.7 m.s^{-2}$.
2. Road transport to country Victoria, after immersion in the test suspension, followed by 14 days incubation at 30 °C and road transport return to Melbourne.

The results in Table 3.22 show that, after Biotesting 864 imported trays that were subjected to a simulated transport test and 1,140 locally made trays that were subjected to a road transport test, rates of failure were 0.5 and 0.8%, respectively. The data show also that there were no failures amongst the 192 imported containers that underwent neither simulated nor road transport, but which were immersed and ~~aspirated~~manually massaged in the test suspension.

As discussed, it is in the nature of Biotests that there is no absolute standard that may be referred to when setting pass levels, but based on experience which followed similar methodology and microbial loading of the test suspension to that used in this case (Warne, *unpublished*) a 2% level is considered reasonable. Therefore, the results with the imported and the locally manufactured trays were considered satisfactory. The low levels of failures in these trials were comparable with those in the Biotest of control metal cans described in Section 3.3.2 in which were found failure rates of 1.7% (11/684) and 0.0% (0/648) for cans coded CON-

CE and CON-CME, respectively. Also, in the series of trials with metal cans there were no failures amongst 648 controls (CON-CE & CME) and this too matches the results found for the controls in trials with barrier plastic trays.

It is appropriate to place the results of this Biotest (using a previously untried combination of packaging components) in a commercial context. As a result of the low (<2%) failure rates under Biotest conditions, it was concluded that the sealing parameters that had been adopted for heat sealing the barrier trays and the visual and mechanical testing procedures that had been developed to confirm seal adequacy, were sufficient to provide confidence that the hermetic seals on the trays would perform satisfactorily. On this basis the decision to proceed to full commercial production was taken, and this subsequently led to the manufacture of around five million containers over a two year period, without detection of a single incident from the trade of PPLC caused by failure of the hermetic seal (Warne, *unpublished*).

3.4.4 Barrier plastic heat-sealable pouches

The purpose of this Biotest was to evaluate the performance, under challenge conditions, of heat-sealed pouches manufactured on a form-fill-seal (FFS) machine. Because experience with FFS technology had been confined to shelf-stable acid foods, rather than acid and low-acid varieties, there was concern regarding the ability to achieve hermetic seals under circumstances in which seal failure and PPLC may have serious implications for public health. At the outset, therefore, the confidence that might be drawn from success with this trial, which was necessary to warrant progression to commercial production, was tempered by a degree of caution not typically associated with Biotests involving metal cans, glass or aluminium and plastic retortable pouches.

The results in Table 3.23 indicate that the 500 1kg and the 420 3 kg pouches that were subjected to the Biotest produced nine (1.8%) and eight (1.9%) pack failures, respectively. With an unproven packaging system and with foods that might present an unacceptable health risk should there be PPLC, failure rates of this magnitude were considered to be too close to the 2% maximum rate that had been adopted for these trials. It was for this reason that the development program leading to the launch of the new product line was aborted.

Table 3.23. Frequency of failures in Biotest of 1 kg and 3 kg FFS pouches

Pouch	Pass (No/%)	Fail (No/%)
1 kg pouch	491/98.2	9/1.8
3 kg pouch	412/98.1	8/1.9

3.5 Evaluation of heat processing equipment through temperature distribution trials

The results of the temperature distribution studies that were completed in 16 commercial retorting systems are summarised in Tables 3.24 - 3.40. The test criteria that have been used for analysis include selected features drawn from GMP guidelines and recommendations by NFPA (1985), Codex Alimentarius (1995), May (1997a, 1997b), Smout and May (1997), the United States Food and Drug Administration (Anon., 2002) and Warne (*unpublished*). In some circumstances, where for instance a manufacturer was seeking to gain USFDA approval for use of their retort(s) to produce for the US market, it was necessary to adopt a strict interpretation of the relevant USFDA guidelines. In other cases where USFDA registration was not required, evaluation has been based on compliance with other guidelines and recommendations. Data analysis was completed using DWC Analyser according to the various parameters that have been described in Section 2.5.2.

As with the results of process evaluation trials discussed in Section 3.3, the data in this section have been extracted from the commercial-in-confidence trials completed by Warne (*unpublished*) that have been conducted nationally and internationally with various food and beverage manufacturers and equipment suppliers (including Barriquand, FMC and Lagarde).

In each of the 16 cases that have been reviewed preference has been to use worst-case data gathered from replicate trials for analysis, as they represent the level of performance upon which the overall performance of the retort(s) must be evaluated. However, in cases where a single trial has been conducted, the available data have been used; or, in instances when replicate trials illustrate little dif-

ference in performance, just one of the replicates has been chosen. As described in Section 2.5, when replicate trials were conducted in retorts with more than one basket, the basket containing the thermocouples was moved sequentially along each of the systems, while those baskets containing ballast were placed in the other positions.

The following considerations influenced selection of which retorting systems and container and product combinations would be included in this review and the extent to which reasons for poor performance would be considered:

1. It was not feasible, nor was it necessary, to review all data from all processing establishments in which temperature distribution trials have been completed. Rather, the approach was to select a cross section that included all of the major types of retort, and a variety of container and product combinations. In this manner, representative examples have been selected from each establishment.

2. The purpose of this component of the program was to present an overview of performance of a variety of retorts, with an emphasis being placed on the safety of the finished goods. Wherever possible worst-case data have been presented, particularly in cases where this indicated that the retort had been operating outside recommended and/or mandatory guidelines that may have been applicable. Emphasis was placed on worst-case examples because these were most likely to highlight aspects of performance that had implications for the adequacy, and in extreme cases the safety, of the thermal processes.

3. The review also was to demonstrate the capabilities of DWC Analyser as a tool for conducting a standardised, rapid, analysis of heat distribution data gathered in commercial environments. As will be seen, in many instances this has involved multiple data sets (from up to 16 probes simultaneously) generated from temperature scans at 30 s intervals, for up to an hour at a time, in food manufacturing plants with several retorts, with up to six basket capacity. It has been found (Warne, *unpublished*) that, in such circumstances, there was need for a standardised methodology that enabled rapid data analysis and comparison of performance using pre-selected parameters.

4. The objective of this review has not been to explain, or to speculate about, the reasons why retort performance has, or has not, complied with Good

Manufacturing Practice guidelines. This is because the emphasis has been to evaluate DWC Analyser as a tool for monitoring retort performance rather than as a means of identifying the individual cause(s) of poor performance which can be numerous and which is(are) likely to include one or more of the following:

- Inadequate steam supply and poor quality (wet) steam.
- Blocked steam distribution inlets.
- Inadequate venting (particularly in steam retorts).
- Inadequate water circulation caused by poor pump performance in water recirculation systems.
- Blocked screens and water inlets in shower and spray systems, respectively.
- Poor calibration of temperature and/or pressure recording equipment.
- Poor calibration of steam, water and pressure controllers.
- Faulty operation of control valves.
- Failure to remove condensate.
- Blocked vents and bleeders.
- Over-packed retort baskets.

3.5.1 Full water immersion retorts

Case 1. Full water-immersion retort processing metal cans (See Table 3.24 and Fig 3.1)

In this instance the retort was a full water-immersion system, with water recirculation, used for commercial processing of a low-acid food in metal cans. The identity of the product and further description of the retort has been classified as commercial-in-confidence in order to protect the confidentiality of the manufacturer.

The process scheduled specified a 21 min CUT to 119°C, a two minute equilibration during which the retort temperature was allowed to fall to the set value of 118°C, a 10 min hold at 118°C, after which the retort was cooled. Throughout the entire process the retort baskets were rotated about their horizontal axes. The results shown in Table 3.23 represent worst-case data when the test basket was in the coldest position in the retort. In Figure 3.1 can be seen the temperature profile for the retort (Probe 7) and the temperature at the slowest heating point in the basket (Probe 4).

The performance of this retort failed to comply with GMP for the following reasons:

- Not one of the six probes in the test basket reached set value (SV), although the probe recording retort temperature (#7) showed that set value was reached after 20.5 min, which was 30 s prior to the end of the come-up-time. USFDA regard it as mandatory that all sections of a retort reach and maintain, at least, set value throughout the hold phase of the process. May's (1997a) recommendations are less stringent and require that the retort be not lower than 0.5 °C, or higher than 1 °C above, the scheduled hold temperature.

- For all six probes in the test basket, compliance coefficients were less than the minimum acceptable value of 0.9. The least compliance coefficient of 0.5 was recorded for by probe 4 and this was clearly below the USFDA requirement (which implies that compliance coefficients must be ≥ 1.0) and also below the minimum acceptable value of 0.9 that was adopted in these trials.

- The temperature profiles in Fig 3.1 show that at the end of the CUT the temperature difference between the slowest heating point in the basket and the

side of the retort was 9.4 °C. This means that while the temperature at the side of the retort at the end of the come-up-time was at the set value (119 °C) the temperature in the centre of the basket was, only, 109.6 °C. The implications of there being such a large gradation in retort temperatures are serious for product safety. The lethal rate at 109.6 °C is 0.07, whereas at 119 °C it is 0.62. It is at the latter value that the retort should have reached in order that the target F_o value could be achieved in the slowest heating point in the basket. Non-compliance issues of this nature are of particular concern when the retort process hold times are relatively short, as they were for the processes used by this manufacturer.

- Five minutes into the hold phase the temperature difference across all points of measurement was 3 °C, which also was unacceptable as it was outside the NFPA (1985) guideline which requires that all points in the retort must be at, or above, the set value within one minute of the end of the come-up-time. Performance also falls outside May's (1997a) guidelines and Smout and May's (1997) guidelines stating that the temperatures should be within -0.5 and + 1°C of the value throughout hold phase.

It was because of the failure to comply with several aspects of the United States Food and Drug Administration (Anon., 2002) requirements and the GMP guidelines recommended by May (1997a), Smout and May (1997) and Warne (*unpublished*) that the manufacturer immediately withdrew this retort from commercial production and instigated remedial action.

Case 2. Full water-immersion retort processing plastic tubs (See Table 3.25 and Fig 3.2)

This is the second full water-immersion retort evaluated in these trials and, as common with these systems, it too incorporated water recirculation to assist uniform temperature distribution throughout the processing chamber. In this instance the product was a rice-based REPFED packed in 200g plastic cups that was to be launched into the chilled food sector of the retail market. The trials were being conducted as part of commissioning the retorts.

The process scheduled specified a 1.5 min CUT to 100°C and a 10 min hold at 100°C prior to cooling. Throughout the process the retort baskets were rotated

about their horizontal axes. The results shown in Table 3.25 represent worst-case data when the test basket was in the coldest position in the retort. In Figure 3.2 can be seen the temperature profile monitored at the top of the top (7^{th}) layer in the retort basket (Probe 5) where heating was rapid, while the temperature at the slowest heating point in the basket (Probe 3) was in the centre of the 3^{rd} layer where it was insulated from the passage of hot recirculating water.

Analysis of retort performance in these temperature distribution trials revealed the following:

- Each of the four probes reached temperatures that were within 1°C of the set value (shown as Time to SV-1 in Table 3.25) although in all cases this was after the CUT had been completed. This means that, according to the criteria that have been described in Section 2.5.2, all points of measurement recorded positive lag values. The greatest lag (i.e. the slowest heating position) was found for probe 3, while the least lag (i.e. the fastest heating position) was for probe 5 at the top of the basket and in these cases the lag values were 6.0 and 3.0 min, respectively. This means that it was six minutes into the scheduled 10 min hold time before the slowest heating point in the basket was within 1°C of the set value.

  Therefore based on a maximum acceptable lag time of 2 min, these data show that this aspect of performance contravened GMP.

- Three of the four compliance coefficients were within GMP guidelines (i.e. ≥ 0.9) with the exception being that recorded at the slowest heating point in the basket (L3C) for which the compliance coefficient was an unacceptably low 0.6.

- The temperature profiles in Fig 3.2 show that at the end of the CUT the temperature difference between the slowest heating point in the basket and the top of the retort basket was 9.0 °C. As was noted in Case 1, non-compliance showing temperature differentials of this magnitude, coupled with extended heating lags, may have serious implications (with respect to the risks of under processing) when retort process hold times are relatively short.

- Five minutes into the hold phase the temperature difference across all points of measurement was 8.6 °C, which was unacceptable as it was outside the United States Food and Drug Administration (Anon., 2002), NFPA (1985) and

the GMP guidelines recommended by May (1997a), Smout and May (1997) and Warne (*unpublished)* for this aspect of performance.

This water-immersion retort was similar in design and operation to the one described in Case 1, and it too failed to comply with several aspects of the United States Food and Drug Administration (Anon., 2002) requirements and the GMP guidelines recommended by May (1997a), Smout and May (1997) and Warne (*unpublished).*

Case 3. Full water-immersion retort processing metal cans (See Table 3.26 and Fig 3.3)

This was the third full water-immersion retort evaluated in these trials and, although a different brand to those represented in Cases 1 and 2, its mode of operation was similar.

As in the previous two cases, the retort in Case 3 was operating under "full load" conditions and the "test bin" in which the thermocouples were located was fully loaded with six layers of 415 g metal cans that had been filled and sealed. The balance of the (two) baskets contained water-filled cans as ballast.

Analysis of retort performance in temperature distribution trials revealed the following:

- In no case did the compliance coefficient reach or exceed unity. The maximum value was 0.9 and this was recorded for probes 6, 10 and 11, which were located at the top of the basket (i.e. at positions 6C, 5S and 6S, respectively) where they were the first of the probes to be exposed to the hot water as it entered the processing vessel. In all other positions, the compliance coefficients were unacceptably low.

- The temperature profiles in Fig 3.3 show that at the end of the CUT the temperature difference between the slowest heating point in the basket and the top of the retort basket was 6.0 °C, which was outside GMP guidelines

- In six of the 10 locations, because of the uneven temperature distribution in this retort, the lag times exceeded the recommended maximum value of two minutes. As expected, because of the manner in which the hot water entered

at the top of the retort, the lag times were greatest at the bottom of the basket and least at the top of the basket. This characteristic was also observed in cases 1 and 2, and is typical of recirculating water full water-immersion retorts.

- The temperature range at 5 min into the sterilising phase was 2.3 °C, which exceeds the preferred maximum value of 1 °C.

- Based on their compliance coefficients, lag times, temperatures at the end of come-up-time, and temperatures 5 min into the hold phase, the "coldest" location in the basket was in the centres of the first and the second layers (i.e. at positions L1C and 2LC).

Overall, the performance of this retort was unacceptable as it did not comply with the United States Food and Drug Administration (Anon., 2002) requirements and those recommended by May (1997a), Smout and May (1997) and Warne (*unpublished)*. As with the previous two cases (both of which were full water-immersion systems) the failure to comply was largely because of the unacceptably low compliance coefficients and the inter-related high lag times.

In this instance, because the retort was being used for the commercial manufacture of low-acid products for export markets, it was temporarily de-commissioned pending the completion of further trials.

Case 4. Full water-immersion retort processing metal cans (See Table 3.27)

This retort was one of five horizontal four-basket water-immersion retorts used for the commercial manufacture of a fruit-based beverage in two-piece 350 mL metal cans. These trials were completed during production and while the retort was filled with cans of product. The thermocouples for monitoring temperature distribution were placed on the top (7^{th}) and the bottom (1^{st}) layers of cans in retort baskets positioned at each of the front, midway between the front and the centre, and the centre of the retort.

Analysis of retort performance revealed the following:

- Compliance coefficients were all acceptable and ranged from the minimum recommended value of 0.9, to 1.1. The least value was recorded by probes 1

and 3, which were on the bottom layers of the baskets in the front and mid-way between the front and the centre of the retort, respectively.

- Lag times were negative for each of the probes on the top of the baskets and this reflects the manner in which the hot water first enters through a top distributor running the length of the unit, and thereafter re-enters from the same distributor as recirculation proceeds. However, the lags across the base of the baskets were all positive and this change (from negative to positive) is because early in the heating phase the recirculating water loses heat to the cold containers as it passes through the baskets. Consequently, those locations that are the furthest removed from the points of entry of the hot water (i.e. at the bottom of the baskets) will be the last to reach set value. (This characteristic was also observed in the recirculating water retorts reviewed in Cases 1, 2 and 3.) The greatest lag was two minutes, which is the maximum acceptable value in this series of trials, but which would be unacceptable based on strict interpretation of the United States Food and Drug Administration (Anon., 2002) guidelines.

- In two test positions, minimum retort temperatures fell below the set value of 75 °C. The data indicate that these were only temporary fluctuations that were detected on a single temperature scan one minute after the start of the scheduled hold phase, and for this reason they were not considered serious and likely to affect the severity of the thermal process. Nevertheless, according to a strict interpretation of USFDA guidelines the performance of this unit would have led to its rejection.

- The temperature range at 5 min into the sterilising phase was 0.9°C, which demonstrates acceptable temperature control. However, three of the six values were below the set value (75°C), which would be unacceptable to the United States Food and Drug Administration guidelines but acceptable to May (1997a), Smout and May (1997) and Warne (*unpublished*).

Although, the performance of this retort would be found unacceptable according to USFDA guidelines, based on the test criteria that have been developed by others (May, 1997a; Smout and May, 1997 and Warne, *unpublished*) its performance could be classified as marginal.

3.5.2 Steam retorts

Case 5. Vertical steam retort processing metal cans (See Table 3.28)

This retort was a vertical three-basket steam retort used for the commercial manufacture of vegetables in brine. These trials were completed during production and while the retort was filled with 420 g cans of product. The thermocouples for monitoring temperature distribution were placed at the top and the bottom layers of each of the three-baskets that filled the retort.

Analysis of retort performance revealed the following:

- The temperatures at the end of the scheduled CUT were all at least 14°C above the 116°C set point and ranged from 130.8 to 135.1°C. Although not a product safety issue, this demonstrates an unacceptable level of automatic control throughout venting. It can be concluded also that the lack of temperature control extended beyond the end of the CUT, for had the retort been held at the set value (116°C) for the scheduled 15 min, the F_o values would have increased beyond those at the start of the hold time by approximately 4.7 min. The data show, however, that the F_o values accumulated during hold were all > 90 min.

- The target F_o value at steam-off for a 15 min process at 116°C is 4.6 min, however the data in Table 3.28 show that the actual F_o values were between 101.5 and 132.4 min.

- As a result of the unacceptably high temperatures throughout the retort, all compliance coefficients were over 20 times the recommended value (of 1). This indicates that the retort was "running hot", as a result of which it could be expected that there would be a loss of colour and texture, particularly with heat sensitive vegetables packed in brine.

- It was noted that the steam regulator valve became stuck in the fully open position as a result of interference between the recording pens and the set point indicators on the thermograph controller. Consequently the retort pressure rapidly exceeded the maximum set value which caused the retort safety valve to open fully, however this was not able to prevent the continued build up of pressure and temperature in the vessel.

Under these circumstances it was evident that the retort was out of control and posed an immediate health risk to the operators. Control was only established after the intervention of the retort operator who manually overrode the system and corrected the fault.

- Despite the high temperatures that were recorded at the end of the come-up-time, minimum temperatures during hold fell below the set-value and ranged from 108 to 114.7°C. Therefore this aspect of performance also failed to comply with GMP, as did the temperature ranges during hold, which were between 26.2 and 33.6°C.

Notwithstanding the inability to regulate the adequacy of the thermal process under commercial operating conditions, there was also an unacceptable risk of injury had the retort not been under the supervision of an experienced operator. For these reasons the retort was immediately withdrawn from service.

Case 6. Vertical steam retort processing metal cans (See Table 3.29)

This retort was one of six vertical three-basket steam retorts used for the commercial manufacture of vegetables in brine in 410 g metal cans. These trials were completed during production while the retort was filled with cans of product. Following their calibration, nine of the 12 thermocouples were positioned on the central vertical axis from top to bottom throughout three-baskets (each containing five layers of cans). The remaining three thermocouples were placed at the side of each of the baskets adjacent to the third layer of cans.

Analysis of retort performance revealed the following:

- In two of 12 locations compliance coefficients were all unacceptably low with values of 0.5 and 0.8 for probe 3 at the centre of the 5th layer and probe 6 at the centre of the 8th layer, respectively.

- In line with the unacceptable compliance coefficients, the lag times for probes 3 and 6 were 6.5 and 4 min, respectively, which also was excessive and not consistent with GMP. One of the remaining probes (#5 at L6C) recorded a lag time of 2.5 min, whereas all other locations had lags that were within guideline values (i.e. ≤ 2 min).

- In seven cases, minimum retort temperatures during hold were below the set value of 121°C and this too was unacceptable.

- The temperature range at 5 min into the sterilising phase was 4.0°C, which reinforces the view that this retort was not operating to a satisfactory standard.

The performance of this retort was found unacceptable according to the United States Food and Drug Administration (Anon., 2002) guidelines, and also with respect to the test criteria that have been developed by May (1997a), Smout and May (1997) and Warne (*unpublished*).

Case 7. Horizontal steam retort processing metal cans (See Table 3.30)

This retort was one of two horizontal three-basket steam retorts used for the commercial manufacture of seafoods in 95 g two-piece metal cans. The trials were completed during commissioning of a new cannery that was to supply local New Zealand and North American markets. Therefore, in order to satisfy the process filing requirements of the USFDA it was necessary to evaluate the system against more stringent performance standards than typically would be applied had all production been for local consumption. Thermocouples were distributed throughout 24 layers, each containing approximately 196 cans of 95 g cans. On this basis there were 4,704 cans/basket or 14,112 cans in a fully loaded retort. It was with this packing arrangement that all temperature distribution and process evaluation trials were conducted. All cans used in temperature distribution trials were filled with water and each layer of containers was separated by polypropylene dividers into which had been punched 14 mm diameter holes at 25 mm centres.

Analysis of retort performance revealed the following:

- On the basis of their compliance coefficients (all of which were ≥ 1.1) and the uniformity of temperatures above the set value throughout the hold phase, the performance of the retort was acceptable.

- All thermocouple probes recorded temperatures that were equal to or greater than the minimum set value (115 °C) during the hold (sterilisation) phase of the process. It will be recalled that the requirement to maintain all tempera-

tures at least at the set value throughout the hold phase was an essential pre-condition mandated by USFDA.

- The range of temperatures during the hold phase (all ≤ 1°C) was satisfactory and indicative of excellent temperature control.

- The ranges in temperature across the test basket five minutes into the hold phase were small (0.7°C) which re-affirmed the excellence of temperature control.

- Heating lags across all 15 probes were all negative (≤ -3.5), and therefore acceptable.

- The data show a high degree of uniformity across all probes and demonstrate that the probe at the centre of the 12th of 24 layers (designated L12C) reached the scheduled hold temperature after all other probes in the test basket. Therefore, on this basis the "cold spot" in the basket was in the centre of the 12th (middle layer).

All aspects of the performance of this retort was found to be satisfactory and in compliance with Good Manufacturing Practice and the requirements of the United States Food and Drug Administration (Anon., 2002).

3.5.3 Steam-air retorts

Case 8. Horizontal steam-air retort processing metal cans (See Table 3.31)

This retort was one of five that had been re-commissioned following their relocation and the purpose of the trials was to re-affirm their adequacy for the production of low-acid foods packed in cans. In all trials, the retorts were operating under "full load" conditions and the "test bin" throughout which the thermocouples had been distributed was fully loaded with 14 layers of water-filled 125 g cans. The balance of the (four) baskets also contained water-filled 125 g cans.

Following their calibration 12 thermocouples were positioned from top to bottom throughout the "test bin" which was sequentially located in each of five positions in the retort, while the other bins containing the cans occupied the remaining positions.

Analysis of retort performance revealed the following:

- In all instances compliance coefficients were ≥1.0 which was desirable and in line with Good Manufacturing Practice guidelines recommended by Warne (*unpublished*).

- The data show that in 11 of 12 cases the heating lags were negative and in one case it was zero. This means that at each of these locations the retort was within 1°C of the set value (121.1°C) at the start of the sterilisation phase. The exception was at the slowest heating point (represented by probe #5) and this was within 0.8°C of the set value at the end of the come-up-time

- The temperature range in the test bin throughout the entire sterilisation segment was, with two exceptions ≤ 0.6°C, which is indicative of excellent control. In the exceptional cases temperature ranges were 1.1 and 1.2 °C for probes 1 and 5, respectively.

- The temperature range throughout the test bin after five minutes of the sterilisation phase had elapsed was 0.7 °C and this also indicates excellent temperature control.

The data show that the overall performance of this retort was acceptable in terms guidelines by May (1997a), Smout and May (1997) and Warne (*unpublished*). However, because temperatures in position 1 and 5 fell by 0.2 and 0.8 °C, respectively, below the set value the retort would not satisfy the United States Food and Drug Administration (Anon., 2002) requirements. As a matter of caution and principle the USFDA regulations are rigorous, however, it is considered that temporary fluctuations of the magnitude observed in these trials would have no significant effect on total process lethality.

Case 9. Horizontal steam-air retort processing plastic tubs (See Table 3.32)

The data reviewed in these trials were generated while commissioning two six-basket steam-air retorts that were to be used for processing fruit products in 400 g heat sealed plastic tubs. Pre-calibrated thermocouple probes were positioned in the centre of each of seven layers throughout a single "test bin" that had been filled with 400 g tubs containing fruit in juice. An eighth probe was located on the side of

the "test bin" adjacent to the top layer of tubs. The five bins that were placed in the retort to make up the "full load" were filled with 825 g cans containing fruit.

Analysis of retort performance revealed the following:

- Compliance coefficients, with one exception, matched or exceeded the minimum recommended value of 0.9. The exception was for the probe at the centre of the top layer of cups and in this case the compliance coefficient was 0.8. The highest coefficient was 1.3 and this was found in the centre of the bottom layer of cups. The difference in values between the coefficient at the bottom of the basket and that at the top was not unexpected. With this style of steam-air retort the steam spreaders run along the base of the unit and as a result the bottom layer of the basket is first to heat; and, conversely, the layer at top is the last to heat.

- With the exception of the probe at the centre of the top layer, all lag times (required to reach set-value less one degree) were ≤ 0. Under circumstances in which the scheduled hold time was for 10 min, or more, this level of performance would not be a matter for great concern. However with this manufacture, the actual process hold time that was to be used in commercial production was extremely short at only 3.5 min, and this made it more important that the set value would be achieved throughout all parts of the retort.

- Minimum temperatures during hold ranged from 103.4 to 105°C, and only four probes recorded minimum temperatures that were within 0.5°C of the set-value as recommended by May (1997a) and Smout and May (1997).

- Minimum temperatures at 3 min into the hold phase (or 0.5 min prior the start of cooling) were all equal to, or higher than, the set value of 105°C. This indicated that the retort had continued to heat throughout that stage of the process that the temperature should have been stable (and at set value).

In summary, although the performance of this system was comparable with many other retorts, the areas of non-compliance with GMP that were observed were of heightened concern because of the short duration of the hold phase of the process. In cases where hold times are short it is imperative that the retort should quickly reach and maintain set temperature otherwise there will be unacceptable risks of under processing. (In this instance, however, the acidity of the fruit products was sufficiently low to prevent health risks arising from any spoilage that might occur.)

3.5.4 Water-shower retorts

Case 10. Horizontal water-shower retort processing metal cans (See Table 3.33)

The results presented in these trials were gathered during annual temperature distribution trials that were carried out on three horizontal, six-basket, water-shower retorts that are used for the manufacturer of a range of low-acid vegetable products in metal cans. Fifteen of 16 thermocouples were distributed throughout a test basket that was packed with 12 layers of 125 g metal cans that had been filled with water and sealed. The 16th probe had been tied adjacent to the bulb of the MIG reference thermometer. During all trials the retort was operating under "full load" conditions with five-baskets containing ballast (12 layers of filled 125 g metal cans) in addition to the "test basket" containing the thermocouples.

Analysis of retort performance revealed the following:

- The data reveal that with two exceptions (which recorded values of 0.9) compliance coefficients were between 1.0 and 1.1. This result demonstrates that there were highly uniform temperatures throughout the hold phase.

- All probes recorded negative lag values. This demonstrates that at all points of measurement temperatures were within 1 °C of the set value before the retort entered the hold phase.

- The minimum temperatures during the hold phase ranged from 117 °C (probe 4) to 120.6°C (probe 3). In the former case however the lower temperature was the result of a momentary fluctuation in the first 30 s of the hold phase, after which the minimum temperature was 120.6°C.

- The temperature range throughout the test basket 5 min into the hold phase was 0.4 °C, which is indicative of excellent temperature control.

In summary, based on the range of test criteria that have been established by Warne (*unpublished),* the overall performance of this retort was within guideline values. Performance however did not satisfy the United States Food and Drug Administration requirements (Anon., 2002).

3.5.5 Cascading-water retorts

Case 11. Horizontal Cascading-water retort processing aluminium trays (See Table 3.34)

The results presented in these trials were generated during replicate temperature distribution trials in one of two six-basket retorts processing 100 g aluminium trays of pet food. The thermocouples were distributed throughout 28 layers, each containing 64 100g containers that had been filled with pet food and sealed and placed on freestanding tray dividers.

Analysis of retort performance revealed the following:

- The compliance coefficients were, with one exception, acceptable and ranged from 0.9 (on the bottom layer twice, and the 5th and 7th layers once) to 1.1 on layers 11-14 and 16. The exceptional value of 0.8 was recorded at the MIG (reference thermometer) but this was because of a heating lag of the thermometer mounted in the external heat exchanger, rather than an indication of the temperature within the test basket in retort. Localised heating lags such as these frequently have been observed (Warne, *unpublished*) early in the hold phase with Cascading-water retorts and in these instances they were a reflection of the temperature of the recirculating process water immediately before it re-entered the heat exchanger. It is because of the location of the thermometer outside the chamber in which the retort baskets are placed that the apparent discrepancy between process water temperature and reference temperature occurs. Nevertheless, it is because of this characteristic that the retort did not satisfy USFDA' s requirements.

- With the exception of data for the MIG and the lag recorded for probe 4 on the centre of the 5th layer (i.e. for which the lag was zero) the lag times were all $\leq$ -0.5, which was indicative of uniform heating during the retort come-up-time.

- The temperatures at the end of the scheduled come-up-time (with the exception of that at the MIG) ranged from 125.1 (at the centre of the 5th layer) to 126.7 °C on layer 27 of the basket. The high temperatures across the upper layers early in the process were expected as, with Cascading-water systems, they are the first to be exposed to the heated water as it enters the retort through the top distributor and cascades over the basket below.

- Minimum temperatures throughout the basket during the hold phase ranged from 125.2 (probe 4 on layer 5) to 126.6°C (probe 16 on layer 16) also reflect the gradients that typically are experienced within baskets with Cascading-water systems.

- The temperature range 5 min into the hold phase was an exceptionally low 0.6 °C, which demonstrated satisfactory temperature control in this retort.

Overall, these data demonstrate that the performance of the retort was acceptable in terms of the guideline values that have been recommended by Warne (*unpublished*) for these types of systems. However, performance did not comply with USFDA's stricter guidelines, as these do not permit temperatures anywhere in the system (including at the MIG) being less than the set value at any stage during the hold phase.

Case 12. Horizontal water-shower retort processing metal cans (See Table 3.35)

The trials described in this case were conducted in order to gain USFDA process filing accreditation for a Cascading-water retort used for the manufacture of molluscs in 425 g metal cans. The retort was operating under a full load made up of four baskets each containing five layers of 100 (10 rows of 10) of cans. After their calibration fifteen thermocouples were distributed throughout a test basket containing cans that had been filled with water, closed and loaded into the test basket. A separate thermocouple (#16) was positioned in the process water return line leading to the heat exchanger.

In these trials the parameters for the operation of the retort were selected to satisfy USFDA's minimum performance standards which require that all temperatures throughout the retort are at, or above, the set value for the duration of the hold phase. As has been seen this standard is more stringent than the guidelines recommended by May (1997a), Smout and May (1997) and Warne (*unpublished*), and they are also harder to achieve and they do not necessarily produce significantly safer F_o values in finished products.

Analysis of retort performance revealed the following:

- On the basis of their compliance coefficients (all of which were between 1.1 and 1.2) and the uniformity of temperatures above the scheduled hold tem-

perature throughout the hold phase, the performance of the retort was acceptable in all locations throughout the test basket.

- At the end of the come-up-time, the minimum temperature in the test basket was 113.4°C, which exceeded the set value.
- All thermocouple probes recorded temperatures that were equal to or greater than the scheduled hold temperature (113 °C) throughout the entire hold phase.
- The range of temperatures during the hold phase was between 0.3 and 0.7°C, which was satisfactory and indicative of excellent temperature control.
- Heating lags across all 15 probes were between -1.5 and -3.5 min., which was acceptable.
- The temperature range across the test basket 5 min into the hold phase was an exceptionally low 0.5°C, which re-affirms that temperature control in this system was excellent.

In summary, these temperature distribution trials demonstrate that the unit was performing satisfactorily and in compliance with USFDA requirements for this style of system. There were no heating lags; compliance coefficients were all acceptable, and temperature ranges throughout the test basket during the scheduled hold phase of the test cycle were also acceptable and indicative of sound performance.

Case 13. Horizontal Cascading-water retort processing plastic pouches (See Table 3.36)

These trials were conducted to evaluate the temperature distribution throughout a single test bin in one of two Cascading-water retorts that was used for the manufacture of shelf-stable vegetables packed in retortable pouches. The retort was operated under "full load" conditions with the test bin in position 5 (adjacent to the door). The test bin and the four other bins were fully loaded with twelve layers of 40 pouches on each layer.

Analysis of retort performance revealed the following:

- The compliance coefficients ranged from 0.8 for probe 1 at the bottom of the basket (at L1S), to 1.2 on layer 12 (at L12S and L12C). This trend of diminishing compliance coefficients from top to bottom in the retort basket was typical of those found frequently with Cascading-water systems in which the recirculating water enters from the top of the retort and percolates through the basket to the bottom weir. However, the lower value of 0.8 nevertheless was outside GMP guidelines for this style of retort.

- A further indication of the relatively slow heating at the bottom layer of the bin were the lag times of nine minutes and three minutes, for probes 1 and 2 respectively. Lags of this magnitude were unacceptable as they erode the time that product exposed in these locations would have been heated by water at the scheduled retort temperature. Guideline values required that the lag times were no more than two minutes in any location in the test basket.

- Across all points of measurement the temperature at the end of the CUT were below the set value and in the worst position (probe 1 at the bottom of the basket) the temperature was only 107.5°C. This aspect of performance was unacceptable.

- Five minutes into the hold phase three of six positions still had not reached the retort's set value and in the worst case (probe 1) the temperature was 117.4°C. Given this method of operation there was an unacceptable risk that product would be under processed and not achieve its target F_o value.

These results showed that the performance of this retort was far from satisfactory and it was reasonable to conclude that product processed in such a manner would present an unacceptable risk to consumer health. It was concluded that the unsatisfactory heating rates at the side of the bottom layer (L1S) in the bin was caused by poor water recirculation at this point and that the most likely contributing factor was the over-packing of pouches on the retort trays.

3.5.6 Water-spray retorts

Case 14. Horizontal water-spray retort processing glass (See Table 3.37)

These trials were carried out in one of three six-basket water-shower retorts used to manufacture shelf-stable dairy based products packed in glass containers. Following their calibration 15 thermocouples (No's 1 to 15) were distributed throughout five layers of a test bin containing water-filled 270 mL bottles. A single thermocouple (#16) also was mounted adjacent to the tip of the reference thermometer (MIG).

Analysis of retort performance revealed the following:

- In six of 16 instances the compliance ~~coefficient~~ coefficients were all at the nominal target value of 1.0, while of the remaining cases eight had coefficients of 1.1 and two had coefficients of 1.2. Therefore the data show that at points of measurement the retort reached processing temperature in an appropriate time and maintained that temperature throughout the hold phase.

- The data show that compliance coefficients were uniformly distributed throughout all layers of the test bin. Whilst it is more usual to find lower compliance coefficients concentrated in the lower levels of the test bin, the fact that this was not obviously the case was not considered to be significant.

- Without exception, all of the thermocouples in the test bin and the single thermocouple at the MIG recorded lag values of ≤ -1.5 and all temperatures at the end of the CUT were $\geq 115°C$. This demonstrates adequate heating rates in all test positions throughout the basket.

- The range in temperatures during the hold phase were all $\leq 0.7°C$, which is an exceptionally good result showing excellent temperature control.

- Minimum temperatures during hold were all in excess of 114.6°C. This means that once the hold phase commenced the temperatures at all times were no more than 0.4°C below the set value. Although not acceptable to the United States Food and Drug Administration standards this result is within guidelines recommended by May (1997a), Smout and May (1997) and Warne (*unpublished*).

- Another indicator of the uniform heating were the temperatures throughout the retort five minutes into the hold phase. The data show that without exception all temperatures were $\geq 115°C$ five minutes into the hold phase and at this time the range of temperatures was 1°C.

The overall performance of the retort was superior to that found for the other two retorts. Without exception, the results demonstrate compliance with all appropriate guidelines other than those required by USFDA, which stipulates that no temperature shall fall below the set value at any stage during the hold phase.

Case 15. Horizontal water-spray retort processing cans (See Table 3.38)

These trials were carried out in one of four four-basket water spray retorts used for processing vegetables in metal cans. Following their calibration, the thermocouples were distributed throughout the "test bin" along the central axis, and around the sides, of 12 layers of water filled 125 g easy-open cans. The "test bin" was located sequentially in each of four positions in each of the retorts, and in each instance, the remaining three bins (also packed with cans that had been filled with water) occupied the remaining positions.

Analysis of retort performance revealed the following:

- The compliance coefficients were all unacceptably low and ranged from 0.5 (twice) to 0.8. In cases in which low-acid products, such as vegetables in brine, are processed at high temperatures (e.g. 126°C), the schedule hold time will be short. In these circumstances low compliance coefficients are of concern as they indicate that the cans will not have been exposed to the scheduled hold temperature for the prescribed hold time, and this represents an unacceptable risk of under processing.

- Lag times in all test positions were excessive and ranged from 3.5 to 9 min. This demonstrates that the cold spots in the test basket experienced unacceptably high heating lags. As expected, the least heating lags (see probes 5 and 6) were at the sides of the test bin where the cans, and the spaces between, were directly exposed to the water spray.

- In all but one case the temperatures recorded at the end of the come-up-time were 6.2°C or more, below the set value. The exceptional case was with the probe at the side of the 11th layer and in this instance the temperature was 4.9°C below the set value. Performance failures of this magnitude were clearly outside all GMP guidelines and represented unacceptable health

risks, particularly as this retort was used to sterilise low-acid products in brine at high temperatures.

- The range in temperatures across the bin after five minutes was 3.1°C and this too was outside GMP guidelines for all styles of retort.

- The "cold spot" (based on total accumulated F_o values) was on the 10th layer of the central axis on three occasions and on the 11th layer of the side axis once. Although these results are atypical, they have not been discarded as the individual heating profiles do not suggest abnormal probe function.

In overview the data demonstrate that performance of this retort was far from satisfactory as it failed to comply with any of the performance guidelines that had been established by the United States Food and Drug Administration (Anon., 2002), May (1997a), Smout and May (1997), NFPA (1985) and Warne (unpublished).

Case 16. Horizontal water-spray retort processing cans (See Table 3.39)

The trials described in this case were conducted in order to gain USFDA process filing accreditation for a water-spray retort used for the manufacture of molluscs in plastic pouches. The retort was operating under a full load made up of four baskets each containing nine layers of 12 pouches (four rows, each of three containers) or 108 pouches/basket and 432 pouches/full retort load. Trials were completed with 15 pre-calibrated thermocouples located throughout the test basket and a separate thermocouple (thermocouple #16) positioned adjacent to the bulb of the reference thermometer.

In these trials the parameters for the operation of the retort were selected to satisfy USFDA's minimum performance standards which require that all temperatures throughout the retort are at, or above, the set value for the duration of the hold phase. As has been seen this standard is more stringent than the guidelines recommended by May (1997a), Smout and May (1997) and Warne (*unpublished*), and they are also harder to achieve and they do not necessarily produce significantly safer F_o values in finished products.

Analysis of retort performance revealed the following:

- On the basis of their compliance coefficients (all of which were ≥ 1.1) the performance of the retort was acceptable in all locations throughout the test basket.

- The lag times ranged between -0.5 and -1.0 min. This means that, without exception, the retort had reached the scheduled hold temperature (113.0°C) by the completion of the come-up and this is indicative of adequate and uniform temperatures throughout the test basket.

- Throughout all locations in the test basket, and at all times at the reference thermometer, the temperatures at the end of the come-up were above the set value (i.e. > 113.0°C). At no stage during the scheduled hold phase did the temperature in the test basket or at the reference temperature fall below the set value. Such a degree of uniformity clearly demonstrated the adequacy of temperature control throughout the basket and was a pre-condition for complying with USFDA's requirements

- The lowest of the minimum temperature during the hold phase was 113.0°C.

- The temperature range across the test basket 5 min into the hold phase was 1.3°C, which although larger than the preferred range (< 0.8°C) was not considered important with respect to the adequacy of the processes that would be delivered in this retort.

In summary therefore, the temperature distribution trials demonstrated that the unit was performing satisfactorily and in compliance with guidelines of GMP and USFDA requirements for this style of retort. There were no heating lags; compliance coefficients were all acceptable, and temperature ranges throughout the test basket during the scheduled hold phase of the test cycle were also acceptable and indicative of sound performance.

3.5.7 Summary of performance of all retorts evaluated

The results that have been presented in Sections 3.5.1 to 3.5.6 have been based on temperature distribution studies that were conducted on commercial retorts in

the food industries in Australia, New Zealand, the UAR and the Peoples Republic of China. In those cases when the trials were carried out while commissioning new systems, or re-commissioning old ones (for instance following their relocation), modifications to the control programs or to the services and parts of the equipment may have been implemented in order to optimise performance. It was only after these modifications had been completed that the temperature distribution trials were completed.

The balance of the trials were completed *in situ* under commercial operating conditions and, in these cases, no attempt was made to improve performance prior to conducting the temperature distribution trials. The reason for adopting this approach reflects the objective of the trials which was to evaluate performance on systems under normal operating conditions. In some cases, where performance was found to be unsatisfactory, changes to the operation of the retorts were recommended and implemented in order to improve compliance with GMP guidelines; while in other cases changes were not made or were not possible.

The results of these trials are summarised in Table 3.40 using the following three criteria for classifying overall performance:

- Performance complied with the requirements of the United States Food and Drug Administration (Anon., 2002).
- Performance did not comply with the requirements of the United States Food and Drug Administration (Anon., 2002) but did comply with those of May (1997a), Smout and May (1997) and Warne (*unpublished*).
- Performance did not comply with the requirements of the United States Food and Drug Administration (Anon., 2002), May (1997a), Smout and May (1997) and Warne (*unpublished*).

The data in Table 3.40 show that of the 16 retorts in which temperature distribution trials were conducted only three (19%) were found to comply with the requirements of the United States Food and Drug Administration (Anon., 2002) which were the strictest of all the guidelines that have been considered.

Five (31%) of the retorts complied with the guidelines recommended by May (1997a), Smout and May (1997) and/or Warne (*unpublished*). It should be noted

that in none of these instances was the reason for not satisfying the strict interpretations of the USFDA guidelines sufficient to lead to manufacture of un-safe product. This was because the areas of non-compliance with USFDA's requirements were not considered to be of sufficient magnitude or duration to significantly affect heating rates at the slowest heating points of containers.

Of greatest concern was the finding that eight (50%) of the retorts failed to comply with any of the GMP guidelines that have been considered. In these instances there were examples where the poor performance would most likely lead to manufacture of products in which target F values would not be achieved, or more seriously manufacture of unsafe products.

Table 3.24. Case 1: Temperature distribution in full immersion retort with 21 min CUT to 119°C, 2 min equilibration and 10 min hold time at 118°C

Attribute/probe	1	2	3	4	5	6	7
Location	L2C	L4C	L5C	L6C	L8C	L10C	RTD side
F at start of hold time (min)	0.3	0.2	0.2	0.1	0.1	0.2	1.4
F at steam-off (min)	5.0	4.2	3.9	3.3	3.4	3.5	8.3
Final F (min)	5.7	5.0	4.7	4.2	4.2	4.2	8.5
Target F at steam-off (min)	5.9	5.9	5.9	5.9	5.9	5.9	5.9
Compliance coefficient	0.8	0.7	0.6	0.5	0.6	0.6	1.2
Range Final F value (min)	4.3						
Time to SV - 0C	...[1]	...	...	...	...	...	20.5
Lag time (min)	...	...	...	...	...	...	-0.5
Temp at end of CUT (C)	113.9	112.1	111.2	109.6	110.0	110.7	119.0
Temp range during hold (C)	...	...	...	...	...	...	3.1
Min. temp during hold (C)	...	...	...	...	...	...	117.4
Temp at 5 min into hold (C)	117.3	117.0	116.8	115.6	115.9	115.9	118.6
Temp range at 5 min into hold (C)	3.0						

1. The symbols "..." signify that at no stage was the set value temperature (shown as Time to SV - 0) reached. Therefore data for lag times, the temperature ranges during hold and the minimum temperatures during hold also were ignored.

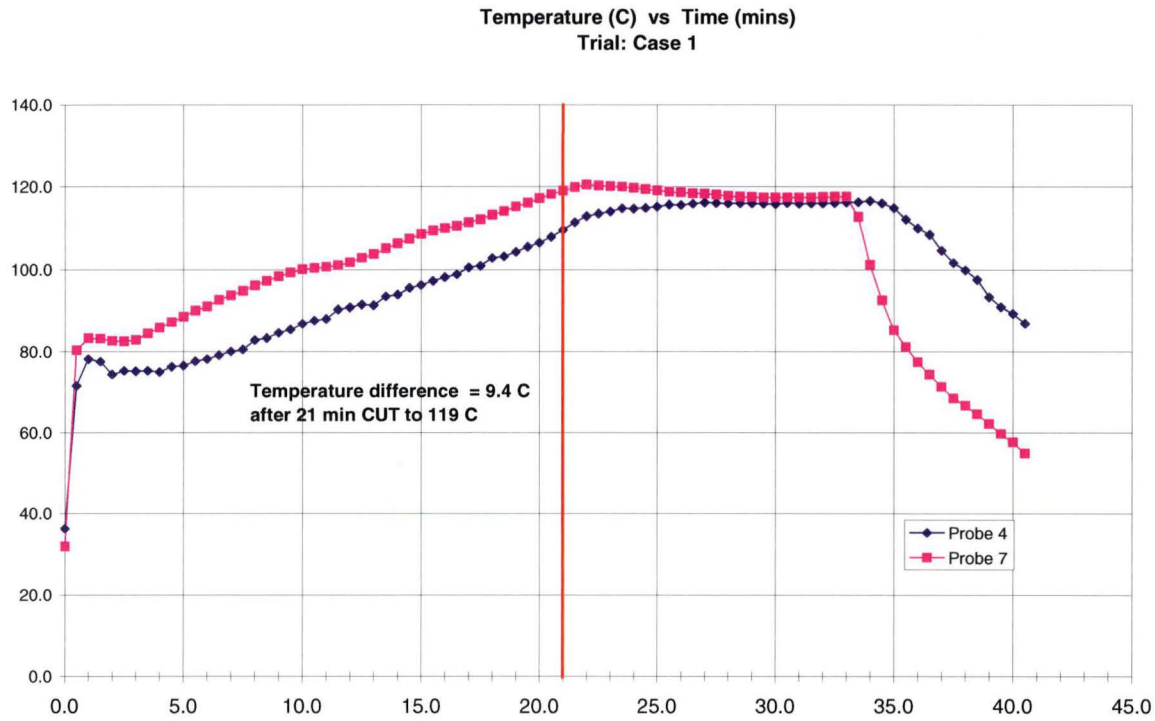

Figure 3.1. Case 1: Temperature profiles showing maximum temperature range at end of come-up-time. Probe 4 is at the slowest heating point in the basket and Probe 7 is the retort temperature measured at the side of the vessel.

Table 3.25. Case 2: Temperature distribution in full immersion retort with 1.5 min CUT to 100°C, and 10 min hold time at 100°C

Attribute/probe Location	1 L1C	3 L3C	4 L6C	5 L7C(Top of basket)
F at start of hold time (min)	1.2	0.0	2.5	2.0
F at steam-off (min)	130.1	74.2	119.3	169.5
Final F (min)	146.4	104.3	128.9	176.5
Target F at steam-off (min)	129.2	129.2	129.2	129.2
Compliance coefficient	1.0	0.6	0.9	1.3
Range Final F value (min)	72.3			
Time to SV - 1C	6.0	7.5	6.0	4.5
Lag time (min)	4.5	6.0	4.5	3.0
Temp at end of CUT (C)	88.4	81.2	89.2	90.2
Temp range during hold (C)	3.9	1.3	2.4	5.4
Min. temp during hold (C)	99.6	99.5	99.6	99.8
Temp at 5 min into hold (C)	100.6	96.6	101.0	105.2
Temp range at 5 min into hold (C)	8.6			

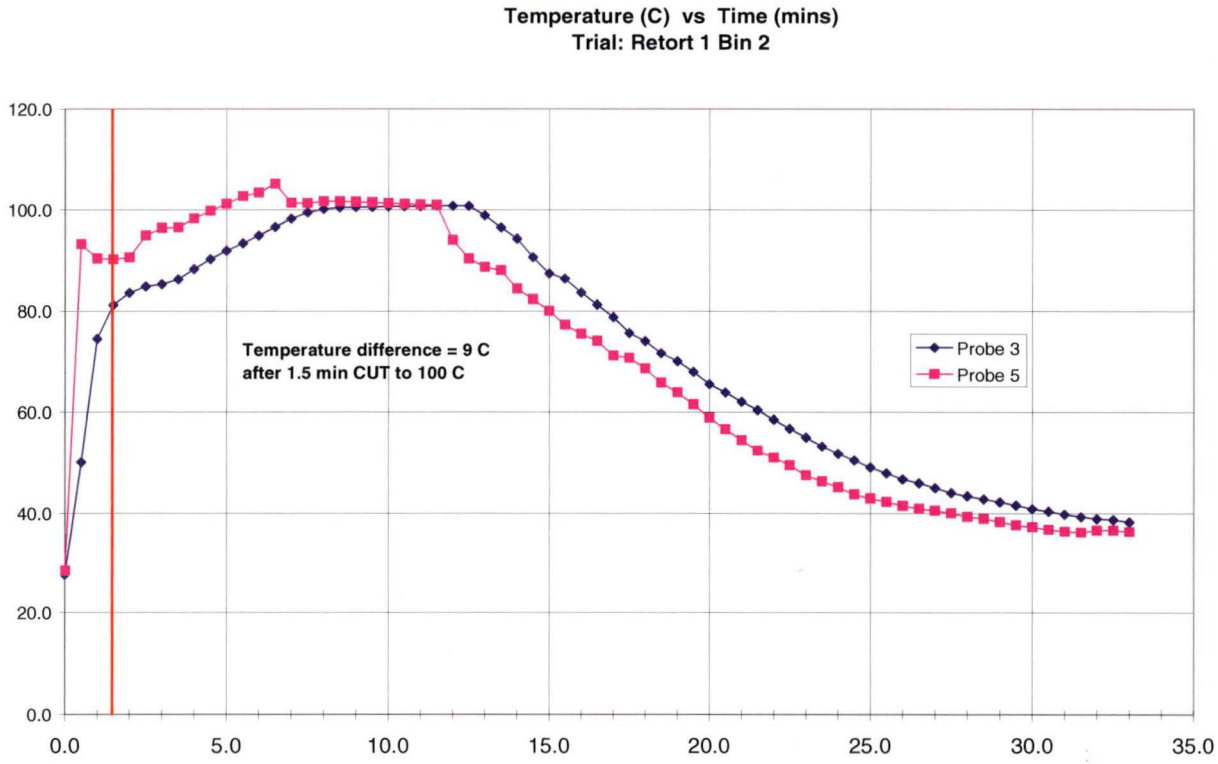

Figure 3.2. Case 2: Temperature profiles showing maximum temperature range at end of come-up-time. Probe 3 is at the slowest heating point in the basket and Probe 5 is the retort temperature measured at the top of basket immediately beneath the water inlet lines.

Table 3.26. Case 3: Temperature distribution in full immersion retort with 10 min CUT to 115°C, and 9 min hold time at 115°C

Attribute/probe Location	1 L1C	2 L2C	3 L3C	4 L4C	5 L5C	6 L6C	7 L1S	8 L3S	10 L5S	11 L6S
F at start of hold time (min)	0.0	0.0	0.1	0.1	0.2	0.3	0.1	0.3	0.3	0.3
F at steam-off (min)	1.2	1.1	1.3	1.7	2.0	2.2	1.5	2.1	2.3	2.4
Final F (min)	1.4	1.4	1.6	1.9	2.1	2.3	1.7	2.3	2.5	2.6
Target F at steam-off (min)	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2
Compliance coefficient	0.5	0.5	0.5	0.7	0.8	0.9	0.6	0.8	0.9	0.9
Range Final F value (min)	1.2									
Time to SV - 1C	18.0	18.0	17.5	14.5	12.5	10.5	17.5	11.0	10.5	10.5
Lag time (min)	8.0	8.0	7.5	4.5	2.5	0.5	7.5	1.0	0.5	0.5
Temp at end of CUT (C)	105.2	105.7	107.7	110.4	112.2	113.2	108.0	112.1	113.3	113.6
Temp range during hold (C)	0.1	0.1	0.1	1.3	2.1	3.1	0.2	2.7	2.6	3.1
Min. temp during hold (C)	114.2	114.0	114.1	113.6	113.3	113.1	114.4	113.0	113.2	113.2
Temp at 5 min into hold (C)	112.8	112.7	113.2	114.0	114.5	114.6	113.7	115.0	114.9	115.0
Temp range at 5 min into hold (C)	2.3									

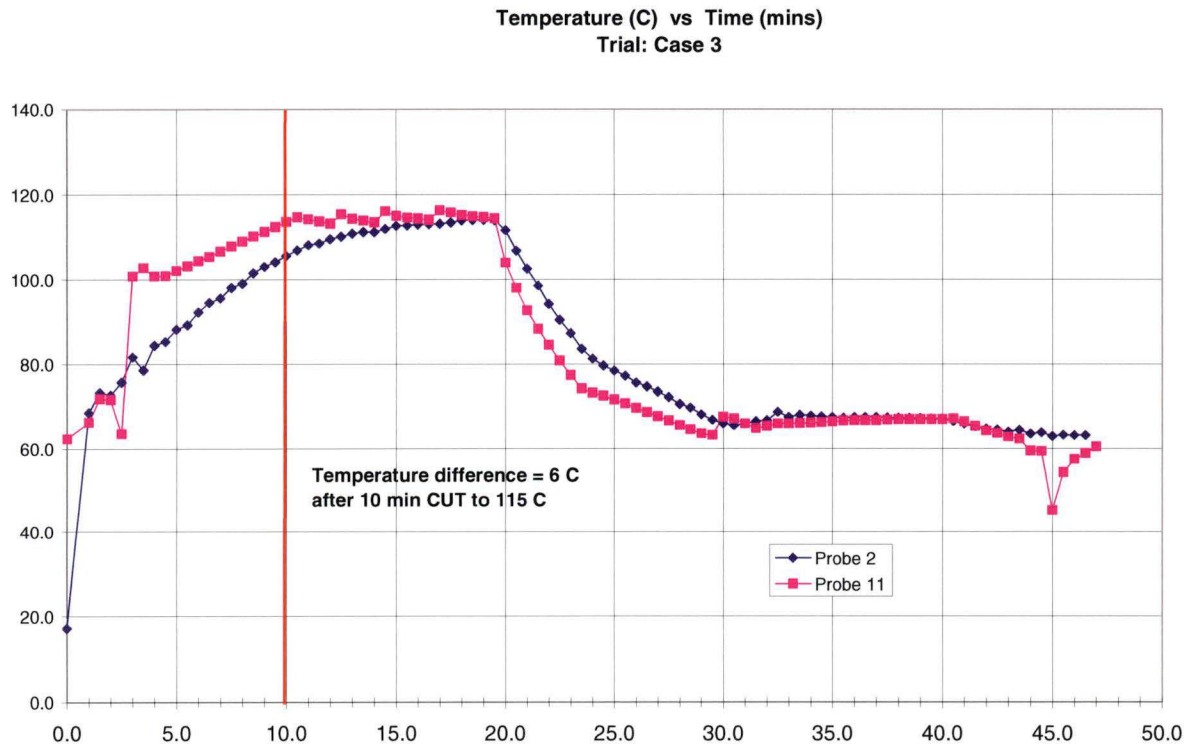

Figure 3.3. Case 3; Temperature profiles showing maximum temperature range at end of come-up-time. Probe 2 is at the slowest heating point in the basket and Probe 11 is the retort temperature measured at the top of basket immediately beneath the water inlet lines.

Table 3.27. Case 4: Temperature distribution in full immersion retort with 9 min CUT to 75°C, and 12 min hold time at 75°C

Attribute/probe Location	1 Front bottom	5 Front top	3 Mid bottom	2 Mid top	6 Centre bottom	4 Centre top
F at start of hold time (min)	1.9	5.4	2.6	10.8	3.4	10.6
F at steam-off (min)	12.9	16.9	13.8	22.4	16.0	22.7
Final F (min)	13.4	17.4	14.4	22.7	16.4	22.9
Target F at steam-off (min)	12.0	12.0	12.0	12.0	12.0	12.0
Compliance coefficient	0.9	1.0	0.9	1.0	1.1	1.0
Range Final F value (min)	9.5					
Time to SV - 1C	10.5	5.5	11.0	0.0	10.5	0.0
Lag time (min)	1.5	-3.5	2.0	-9.0	1.5	-9.0
Temp at end of CUT (C)	72.1	73.8	72.6	76.4	72.9	76.4
Temp range during hold (C)	1.3	2.6	0.7	10.6	1.4	10.0
Min. temp during hold (C)	74.0	72.9	74.7	66.1	74.4	66.4
Temp at 5 min into hold (C)	74.8	74.8	74.9	75.0	75.7	75.3
Temp range at 5 min into hold (C)	0.9					

Table 3.28. Case 5: Temperature distribution in vertical steam retort with 8 min CUT to 116°C, and 15 min hold time at 116°C

Attribute/probe	1	3	4	5	6	8
Location	Top top basket	Base top basket	Top centre basket	Base centre basket	Top bottom basket	Base bottom basket
F at start of hold time (min)	11.1	13.7	12.8	16.3	14.3	6.0
F at steam-off (min)	127.0	118.1	108.0	132.4	120.9	101.5
Final F (min)	143.1	120.1	109.6	132.8	131.2	103.1
Target F at steam-off (min)	4.6	4.6	4.6	4.6	4.6	4.6
Compliance coefficient	25.0	22.5	20.5	25.0	23.0	20.6
Range Final F value (min)	40.0					
Time to SV - 1C	5.5	6.0	5.5	5.0	5.0	5.5
Lag time (min)	-2.5	-2.0	-2.5	-3.0	-3.0	-2.5
Temp at end of CUT (C)	133.5	134.4	134.0	135.1	134.5	130.8
Temp range during hold (C)	26.8	30.0	28.6	33.6	26.2	26.8
Min. temp during hold (C)	113.3	110.9	112.0	108.0	114.7	113.9
Temp at 5 min into hold (C)	115.6	115.1	114.6	117.8	114.7	114.9
Temp range at 5 min into hold (C)	3.2					

Table 3.29. Case 6: Temperature distribution in vertical steam retort with 15 min CUT to 121°C, and 10 min hold time at 121°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12
Location	L1C	L3C	L5C	L3S	L6C	L8C	L10C	L8S	L11C	L13C	L15C	L13S
F at start of hold time (min)	1.0	1.0	0.3	1.2	0.0	0.0	1.2	0.9	0.9	0.9	1.0	0.9
F at steam-off (min)	12.2	10.8	5.3	13.4	8.8	7.9	14.3	14.5	13.6	13.7	14.0	12.7
Final F (min)	13.2	12.1	6.8	14.8	10.5	9.6	15.4	17.1	15.2	15.4	15.1	13.9
Target F at steam-off (min)	9.8	9.8	9.8	9.8	9.8	9.8	9.8	9.8	9.8	9.8	9.8	9.8
Compliance coefficient	1.1	1.0	0.5	1.2	0.9	0.8	1.3	1.4	1.3	1.3	1.3	1.2
Range Final F value (min)	10.3											
Time to SV - 1C	15.0	15.0	21.5	15.0	17.5	19.0	15.0	15.0	15.5	15.5	15.0	15.5
Lag time (min)	0.0	0.0	6.5	0.0	2.5	4.0	0.0	0.0	0.5	0.5	0.0	0.5
Temp at end of CUT (C)	120.1	120.3	105.0	120.6	64.1	61.7	121.5	120.1	119.8	119.9	120.3	119.9
Temp range during hold (C)	2.8	3.6	1.5	1.9	1.2	1.1	1.7	3.6	1.6	1.7	3.4	1.8
Min. temp during hold (C)	120.1	118.7	120.3	120.6	120.5	121.2	121.5	120.1	121.6	121.7	120.3	121.5
Temp at 5 min into hold (C)	121.1	119.8	118.5	121.7	121.3	121.7	122.1	122.5	122.3	122.2	122.1	121.7
Temp range at 5 min into hold (C)	4.0											

Table 3.30. Case 7: Temperature distribution in horizontal steam retort with 17 min CUT to 115°C, and 15 min hold time at 115°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Location	L4BL	L4BR	L4C	L4FL	L4FR	L12BL	L12BR	L12C	L12FL	L12FR	L20BL	L20BR	L20C	L20FL	L20FR	MIG
F at start of hold time (min)	2.6	2.5	2.2	2.3	2.2	2.1	2.3	1.3	2.4	2.3	2.1	2.1	1.8	1.9	2.0	2.0
F at steam-off (min)	7.5	7.2	6.9	6.7	6.5	6.4	7.0	5.7	7.2	6.9	6.3	6.1	6.0	5.9	6.0	6.1
Final F (min)	8.0	7.7	7.3	7.0	6.9	6.8	7.4	6.1	7.5	7.3	6.6	6.5	6.2	6.1	6.3	6.3
Target F at steam-off (min)	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7
Compliance coefficient	1.3	1.3	1.3	1.2	1.2	1.2	1.3	1.2	1.3	1.2	1.1	1.1	1.1	1.1	1.1	1.1
Range Final F value (min)	1.9															
Time to SV - 0C	16.0	16.0	16.5	16.0	16.5	16.5	16.0	17.5	16.0	16.0	16.5	16.5	17.0	16.5	16.5	16.5
Lag time (min)	-5.0	-5.0	-4.5	-5.0	-4.5	-4.5	-5.0	-3.5	-5.0	-5.0	-4.5	-4.5	-4.0	-4.5	-4.5	-4.5
Temp at end of CUT (C)	116.6	116.5	116.4	116.1	116.1	116.0	116.3	116.0	116.4	116.4	115.8	115.8	115.8	115.6	115.7	115.7
Temp range during hold (C)	0.8	0.8	0.8	0.7	0.8	0.7	0.7	0.7	0.7	1.0	0.6	0.7	0.6	0.5	0.6	0.6
Min. temp during hold (C)	115.8	115.7	115.6	115.4	115.3	115.3	115.6	115.3	115.7	115.4	115.2	115.1	115.2	115.1	115.1	115.1
Temp at 5 min into hold (C)	115.8	115.7	115.6	115.4	115.3	115.3	115.6	115.3	115.7	115.8	115.2	115.1	115.2	115.1	115.1	115.1
Temp range at 5 min into hold (C)	0.7															

Table 3.31. Case 8: Temperature distribution in horizontal steam-air retort with 21 min CUT to 121.1°C, and 10 min hold time at 121.1°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12
Location	L1S	L5S	L9S	L14S	L1C	L2C	L5C	L7C	L9C	L11C	L13C	L14C
F at start of hold time (min)	3.5	4.6	4.3	4.3	1.3	2.6	2.9	2.7	2.7	2.8	3.4	4.1
F at steam-off (min)	13.6	16.1	15.3	15.3	11.7	14.2	13.8	14.3	14.4	13.5	14.1	15.3
Final F (min)	15.5	17.8	16.9	16.6	12.9	15.5	14.8	15.6	15.6	14.5	15.1	16.4
Target F at steam-off (min)	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Compliance coefficient	1.0	1.1	1.1	1.1	1.0	1.2	1.1	1.2	1.2	1.1	1.1	1.1
Range Final F value (min)	4.9											
Time to SV - 1C	14.5	14.5	14.5	15.0	17.0	15.5	15.0	15.5	16.0	15.5	15.0	14.5
Lag time (min)	-2.5	-2.5	-2.5	-2.0	0.0	-1.5	-2.0	-1.5	-1.0	-1.5	-2.0	-2.5
Temp at end of CUT (C)	121.0	121.6	121.5	121.4	120.3	121.5	121.3	121.9	122.0	121.5	121.6	121.8
Temp range during hold (C)	1.1	0.5	0.5	0.5	1.2	0.5	0.4	0.5	0.4	0.5	0.6	0.4
Min. temp during hold (C)	120.9	121.5	121.3	121.3	120.3	121.5	121.3	121.6	121.6	121.2	121.2	121.5
Temp at 5 min into hold (C)	121.1	121.7	121.5	121.5	121.5	121.8	121.5	121.8	121.8	121.5	121.5	121.7
Temp range at 5 min into hold (C)	0.7											

Table 3.32. Case 9: Temperature distribution in horizontal steam-air retort with 14 min CUT to 105.0 °C, and 3.5 min hold time at 105.0°C

Attribute/probe	1	2	3	4	5	6	7	8
Location	L1C	L2C	L3C	L4C	L5C	L6C	L7C	L8S
F at start of hold time (min)	58.5	48.0	36.8	39.0	40.5	36.4	22.8	29.1
F at steam-off (min)	175.4	145.4	129.5	139.1	140.6	129.6	92.7	114.2
Final F (min)	204.2	168.8	152.1	162.4	163.3	150.8	110.0	143.0
Target F at steam-off (min)	89.9	89.9	89.9	89.9	89.9	89.9	89.9	89.9
Compliance coefficient	1.3	1.1	1.0	1.1	1.1	1.0	0.8	0.9
Range Final F value (min)	94.3							
Time to SV - 1C	13.0	13.5	14.0	14.0	13.5	14.0	14.5	14.0
Lag time (min)	-1.0	-0.5	0.0	0.0	-0.5	0.0	0.5	0.0
Temp at end of CUT (C)	105.9	105.3	104.3	104.7	104.7	104.3	103.6	104.2
Temp range during hold (C)	1.9	0.9	1.2	1.1	1.1	1.2	1.4	1.0
Min. temp during hold (C)	105.0	104.8	104.3	104.7	104.7	104.3	103.4	104.2
Temp at 3 min into hold (C)	105.3	105.0	105.0	105.5	105.8	105.5	104.8	105.0
Temp range at 3 min into hold (C)	1.0							

Table 3.33. Case 10: Temperature distribution in horizontal water-shower retort with 25.5 min CUT to 120.5°C, and 12 min hold time at 120.5°C

Attribute/probe Location	1 L1C	2 L2C	3 L2B	4 L3C	5 L3L	6 L4C	7 L4R	8 L6C	9 L6F	10 L8C	11 L8F	12 L10C	13 L10L	14 L12C	15 L12B	16 MIG
F at start of hold time (min)	3.6	3.7	3.7	3.0	3.5	2.7	3.4	2.5	2.1	2.7	2.3	2.9	-	3.3	3.4	3.3
F at steam-off (min)	14.5	14.7	14.8	13.7	14.4	13.4	14.4	12.9	11.9	12.5	12.8	13.4	-	13.8	13.7	13.7
Final F (min)	16.3	16.4	18.2	15.5	17.0	14.9	18.3	15.9	15.5	13.5	16.7	14.1	-	14.6	15.4	15.1
Target F at steam-off (min)	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	-	10.5	10.5	10.5
Compliance coefficient	1.0	1.1	1.1	1.0	1.0	1.0	1.1	1.0	0.9	0.9	1.0	1.0	-	1.0	1.0	1.0
Range Final F value (min)	4.8												-			
Time to SV - 1C	23.0	23.0	23.0	23.5	23.0	23.5	23.0	23.5	24.0	23.5	24.0	23.0	-	23.0	23.5	23.0
Lag time (min)	-2.5	-2.5	-2.5	-2.0	-2.5	-2.0	-2.5	-2.0	-1.5	-2.0	-1.5	-2.5	-	-2.5	-2.0	-2.5
Temp at end of CUT (C)	121.2	121.0	121.2	119.1	121.1	120.8	121.2	119.9	120.3	120.3	120.4	120.8	-	120.9	120.8	120.5
Temp range during hold (C)	0.7	0.5	0.6	4.0	0.6	0.3	0.7	0.7	0.2	1.5	0.3	0.7	-	0.6	0.7	0.3
Min. temp during hold (C)	120.5	120.5	120.6	117.0	120.5	120.5	120.5	119.9	120.1	119.1	120.4	120.3	-	120.4	120.2	120.3
Temp 5 min into hold (C)	120.6	120.6	120.6	120.7	120.6	120.6	120.7	120.5	120.3	120.5	120.5	120.5	-	120.5	120.3	120.5
Temp range 5 min into hold (C)	0.4															

Table 3.34. Case 11: Temperature distribution in Cascading-water retort with 21.5 min CUT to 126.0°C, and 10 min hold time at 126.0°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Location[1]	L1C	L1FRM	L1FRC	L5C	L7C	L7FLM	MIG	L10C	L10FLC	L10FRM	L14BLC	L14BLM	L14C	L15C	L20C	L27C
F at start of hold time (min)	10.3	8.2	13.0	7.8	8.1	10.3	8.4	9.4	9.7	13.2	12.2	14.3	10.8	13.2	11.8	17.3
F at steam-off (min)	39.1	36.9	42.4	36.6	37.1	40.3	34.6	39.4	41.7	45.4	44.9	47.5	43.7	45.7	43.3	51.1
Final F (min)	41.0	40.0	44.1	40.1	39.4	42.4	36.6	42.0	44.8	47.6	47.0	49.9	46.9	47.8	45.7	53.3
Target F at steam-off (min)	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9	30.9
Compliance coefficient	0.9	0.9	1.0	0.9	0.9	1.0	0.8	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.0	1.1
Range Final F value (min)	16.7															
Time to SV - 1C	20.0	21.0	19.0	21.5	21.0	20.0	25.0	20.5	20.5	19.5	19.5	19.0	20.0	19.0	19.5	18.0
Lag time (min)	-1.5	-0.5	-2.5	0.0	-0.5	-1.5	3.5	-1.0	-1.0	-2.0	-2.0	-2.5	-1.5	-2.5	-2.0	-3.5
Temp at end of CUT (C)	125.4	125.1	125.8	125.1	125.1	125.7	123.9	125.4	125.7	126.1	126.1	126.4	126.0	126.0	125.9	126.7
Temp range during hold (C)	0.6	0.8	0.3	1.0	0.8	0.3	0.3	0.5	0.7	0.3	0.3	0.2	0.6	0.3	0.4	0.2
Min. temp during hold (C)	125.5	125.3	125.8	125.2	125.4	125.9	125.9	125.7	125.9	126.2	126.3	126.4	126.1	126.3	126.1	126.6
Temp at 5 min into hold (C)	126.0	126.0	126.0	126.0	126.0	126.1	126.0	126.1	126.4	126.4	126.5	126.6	126.5	126.5	126.4	126.6
Temp range at 5 min into hold (C)	0.6															

1. Code for location of probes with R signifying right, L signifying left, F signifying front, B signifying back, M signifying mid (e.g. L1FRM means the Front Right Mid position on Layer 1), XXC signifying corner (e.g. L1FRC means the Front Right Centre position on Layer 1) and C signifying centre.

Table 3.35. Case 12: Temperature distribution in Cascading-water retort with 16.0 min CUT to 113.0°C, and 10 min hold time at 113.0°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Location	L1BL	L1BR	L1C	L1FL	L1FR	L2BL	L2BR	L2C	L2FL	L2FR	L3BL	L3BR	L3C	L4C	L5C	MIG
F at start of hold time (min)	0.5	0.7	0.9	0.9	0.9	0.7	0.7	1.0	1.1	0.9	0.7	0.9	1.0	1.1	1.1	1.0
F at steam-off (min)	2.2	2.4	2.6	2.6	2.6	2.5	2.4	2.7	2.9	2.7	2.4	2.6	2.8	2.9	3.0	2.8
Final F (min)	2.5	2.6	2.8	2.8	2.8	2.7	2.6	2.9	3.1	2.9	2.7	2.8	2.9	3.1	3.2	3.0
Target F at steam-off (min)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Compliance coefficient	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.1	1.1	1.1	1.1	1.2	1.2	1.1
Range Final F value (min)	0.7															
Time to SV - 0C	14.5	13.5	13.0	13.0	13.0	13.5	13.5	13.0	12.5	13.0	13.5	13.0	12.5	12.5	12.5	12.5
Lag time (min)	-1.5	-2.5	-3.0	-3.0	-3.0	-2.5	-2.5	-3.0	-3.5	-3.0	-2.5	-3.0	-3.5	-3.5	-3.5	-3.5
Temp at end of CUT (C)	113.4	113.6	113.8	113.9	113.8	113.8	113.7	113.9	114.0	114.0	113.7	113.9	113.9	114.2	114.3	113.8
Temp range during hold (C)	0.3	0.3	0.5	0.5	0.5	0.4	0.4	0.6	0.6	0.6	0.4	0.5	0.5	0.5	0.7	0.4
Min. temp during hold (C)	113.2	113.3	113.3	113.4	113.3	113.4	113.3	113.3	113.4	113.4	113.3	113.4	113.4	113.7	113.6	113.4
Temp at 5 min into hold (C)	113.4	113.4	113.4	113.4	113.3	113.5	113.4	113.4	113.6	113.5	113.4	113.5	113.5	113.8	113.7	113.6
Temp range at 5 min into hold (C)	0.5															

Table 3.36. Case 13: Temperature distribution in Cascading-water retort with 14.0 min CUT to 120.0°C, and 23 min hold time at 120.0°C

Attribute/probe Location	1 L1S	2 L1C	3 L6S	4 L6C	5 L12S	6 L12C
F at start of hold time (min)	0.0	0.3	0.3	0.4	0.7	0.8
F at steam-off (min)	13.8	18.9	19.4	19.7	21.5	21.9
Final F (min)	14.7	19.7	20.2	20.5	22.1	22.4
Target F at steam-off (min)	17.9	17.9	17.9	17.9	17.9	17.9
Compliance coefficient	0.8	1.0	1.1	1.1	1.2	1.2
Range Final F value (min)	7.7					
Time to SV - 1C	23.0	17.0	16.0	15.0	14.0	14.0
Lag time (min)	9.0	3.0	2.0	1.0	0.0	0.0
Temp at end of CUT (C)	107.5	115.5	115.2	117.0	119.1	119.6
Temp range during hold (C)	1.1	1.9	2.0	2.0	2.0	1.5
Min. temp during hold (C)	119.1	119.0	119.0	119.0	119.1	119.6
Temp at 5 min into hold (C)	117.4	119.8	119.9	120.1	120.6	120.7
Temp range at 5 min into hold (C)	3.3					

Table 3.37. Case 14: Temperature distribution in water-spray retort with 20.0 min CUT to 115.0°C, and 15 min hold time at 115.0°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Location	L1C	L2C	L2R	L2F	L2L	L2B	L3C	L3R	L3F	L3L	L3B	L4C	L4F	L5C	L5F	MIG
F at start of hold time (min)	0.9	0.8	0.9	0.9	0.9	1.1	1.0	1.0	1.0	1.0	1.3	1.1	1.0	1.1	1.3	0.8
F at steam-off (min)	4.5	4.5	4.7	4.7	4.6	5.2	5.1	5.3	5.2	5.1	5.8	5.0	4.7	5.0	5.7	4.8
Final F (min)	4.8	4.7	4.9	5.0	4.8	5.4	5.4	5.5	5.5	5.3	6.0	5.2	5.0	5.2	5.9	5.0
Target F at steam-off (min)	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.7
Compliance coefficient	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.2	1.1	1.0	1.1	1.2	1.1
Range Final F value (min)	1.3															
Time to SV - 1C	18.5	18.5	18.5	18.5	18.5	18.0	18.5	18.0	18.0	18.0	17.5	18.0	18.0	18.0	17.5	18.5
Lag time (min)	-1.5	-1.5	-1.5	-1.5	-1.5	-2.0	-1.5	-2.0	-2.0	-2.0	-2.5	-2.0	-2.0	-2.0	-2.5	-1.5
Temp at end of CUT (C)	115.0	115.1	115.2	115.3	115.2	115.9	115.7	115.7	115.7	115.6	116.3	115.7	115.4	115.5	116.3	115.7
Temp range during hold (C)	0.5	0.7	0.8	0.6	0.6	0.4	0.7	0.6	0.5	0.6	0.5	0.5	0.4	0.6	0.4	0.3
Min. temp during hold (C)	114.7	114.6	114.7	114.9	114.7	115.3	115.1	115.3	115.3	115.1	115.8	115.2	114.9	115.0	115.8	115.3
Temp at 5 min into hold (C)	115.1	115.1	115.3	115.3	115.2	115.6	115.7	115.8	115.7	115.6	116.1	115.5	115.3	115.4	116.0	115.5
Temp range at 5 min into hold (C)	1.0															

Table 3.38. Case 15: Temperature distribution in water-spray retort with 16.5 min CUT to 126.0°C, and 10 min hold time at 126.0°C

Attribute/probe Location	1 L2C	2 L4C	3 L7C	4 L10C	5 L1S	6 L11S
Fo at start of hold time (min)	0.7	0.2	0.7	0.4	0.8	1.1
Fo at steam-off (min)	20.1	15.9	23.4	15.5	24.0	26.8
Final Fo (min)	23.9	19.0	25.9	18.1	25.9	28.1
Target Fo at steam-off (min)	30.9	30.9	30.9	30.9	30.9	30.9
Compliance coefficient	0.6	0.5	0.7	0.5	0.7	0.8
Range Final Fo value (min)	10.0					
Time to SV - 1C	26.0	25.5	21.5	25.5	20.5	20.0
Lag time (min)	9.0	8.5	4.5	8.5	3.5	3.0
Temp at end of CUT (C)	119.2	114.4	119.2	116.6	119.8	121.1
Temp range during hold (C)	0.1	0.8	0.6	0.8	1.6	0.5
Min. temp during hold (C)	125.0	124.3	125.0	124.3	124.3	125.3
Temp at 5 min into hold (C)	124.2	123.4	125.1	122.4	125.4	125.5
Temp range at 5 min into hold (C)	3.1					

Table 3.39. Case 16: Temperature distribution in water-spray retort with 16.0 min CUT to 113.0°C, and 15.0 min hold time at 113.0°C

Attribute/probe	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Location	L1C	L2FR	L2FL	L2C	L2BL	L2BR	L3C	L4FR	L4FL	L4C	L4BL	L4BR	L5C	L7C	L9C	MIG
Fo at start of hold time (min)	0.5	0.4	0.4	0.4	0.5	0.5	0.4	0.5	0.7	0.7	0.6	0.7	0.6	0.6	0.6	0.7
Fo at steam-off (min)	3.0	3.0	3.0	3.0	3.2	3.3	3.2	3.4	3.5	3.6	3.7	3.9	3.8	3.9	4.0	3.6
Final Fo (min)	3.1	3.1	3.1	3.1	3.3	3.4	3.3	3.4	3.6	3.7	3.8	4.0	3.9	4.0	4.1	3.7
Target Fo at steam-off (min)	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
Compliance coefficient	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.4	1.4	1.4	1.5	1.3
Range Final Fo value (min)	1.0															
Time to SV - 0C	15.5	15.5	15.5	15.5	15.0	15.5	15.5	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0
Lag time (min)	-0.5	-0.5	-0.5	-0.5	-1.0	-0.5	-0.5	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0
Temp at end of CUT (C)	115.5	115.6	115.5	114.5	115.8	115.9	115.3	116.2	116.4	117.3	116.5	116.7	116.7	116.7	116.9	116.8
Temp range during hold (C)	2.0	2.2	2.0	1.8	2.1	2.2	2.1	2.2	2.8	3.4	2.3	2.3	2.3	2.2	2.3	2.9
Min. temp during hold (C)	113.0	113.0	113.1	113.1	113.2	113.3	113.4	113.4	113.2	113.4	113.7	113.9	113.9	114.1	114.1	113.3
Temp at 5 min into hold (C)	113.4	113.5	113.5	113.6	113.7	113.8	113.9	113.9	114.0	114.0	114.3	114.5	114.4	114.6	114.7	114.6
Temp range at 5 min into hold (C)	1.3															

Table 3.40. Summary of performance of commercial retorts in terms of compliance with various Good Manufacturing Practice guidelines

Type of retort	Number evaluated	Compliance with USFDA[1]	Compliance with CCFRA[2] and/or Warne[3]	Failed to comply
Full water- immersion	4		1	3
Steam	3	1		2
Steam-air	2		1	1
Water-shower	1		1	
Cascading-water	3	1	1	1
Water-shower	3	1	1	1

1. As specified by the United States Food and Drug Administration (Anon., 2002)
2. In Campden and Chorleywood Food Research Association's (CCFRA) publications edited by May (1997a) and Smout and May (1997)
3. As specified by Warne (*unpublished)*

4 SUMMARY AND CONCLUSIONS

Various techniques have been developed in the course of this work in order to study the influence on food safety of technological developments in the commercial manufacture of shelf-stable and refrigerator stable heat processed foods and these may be summarised as follows:

1. A software package (DWC Analyser) has been developed which incorporates a predictive model (using DWC's Method) for calculating process lethality (F values) over a range of processing conditions. The predictive model was found to have greater accuracy in terms of compliance with an internationally accredited model (FMC's NumeriCal), and also the General Method of calculation, than the conventional model that is widely used throughout Australia and New Zealand.

   The greater accuracy of DWC's Method of calculation, relative to the conventional model, is attributable to the manner in which the lethality accumulated in cooling is calculated. DWC's Method overcomes the shortcomings in the conventional model by enabling the predicted lethality in cooling (determined from one set of data) to be matched against the actual lethality in cooling (determined from the same set of data). Once the cooling characteristics of the product have been aligned in this way it was found, over 15 different heat penetration trials, that DWC's Method computed F values with errors averaging between -6 and 4% of the theoretical values calculated with NumeriCal, whereas the errors with the traditional model averaged between -27 and -40% of the NumeriCal values.

   Since its development and evaluation in commercial canneries, 19 copies of DWC Analyser have been sold to national and multi-national food manufacturers and research establishments throughout Australia, New Zealand, Thailand and Malaysia.

2. The adequacy of thermal processes in commercially manufactured refrigerator-stable heat-processed foods (REPFEDs) was evaluated in terms of compliance with GMP and found to be inadequate in five of 16 (31%) instances. In three of these cases (all of which were with low-acid foods) minimum target F_p values (≥ 10 min at 90°C) were not achieved as a result of which the safety of the product was compromised.

The reasons for non-compliance with GMP included the following:

- Failure to ensure adequate heat distribution around the packs
- Failure to achieve sufficiently high fill temperatures
- Failure to establish an adequate processing time

The two other cases in which target F_p values were not achieved were with acid products in which the safety of the product was not affected.

3. The adequacy of thermal processes in commercially manufactured shelf-stable heat-processed foods was evaluated in terms of compliance with GMP and found to be inadequate in seven of 32 (22%) instances. In each of these cases minimum target F_o values (≥ 2.4 min at 121.1°C) were not achieved as a result of which the safety of the product was compromised.

   The reasons for non-compliance with GMP included the following:

   - Failure to establish an adequate processing time and/or temperature
   - Failure to ensure adequate heat distribution around the packs

4. Biotest procedures were developed to assess the ability of hermetic seals to prevent post-process leaker contamination (PPLC) of sealed containers in commercial manufacture of shelf-stable foods. In three of the four examples that were studied the procedure was sufficient to demonstrate an unacceptable risk of hermetic seal failure on glass jars with Trivac closures, three piece cans with Full-Panel-Easy-Open (FPEO) ends and form-fill-seal (FFS) plastic pouches.

   In the fourth case that was studied the Biotest procedure indicated that the heat seals formed on barrier-plastic trays were sufficiently robust to tolerate commercial manufacture and handling during transport and storage. On this basis the decision to proceed to commercial production was taken, and this subsequently led to the manufacture of around five million containers over a two year period without detection of a single incident from the trade of PPLC caused hermetic seal failure.

5. DWC Analyser has been developed so that it not only includes the predictive model (described as DWC's Method) for calculating process lethality,

but also it incorporates a tool for standardised, rapid, analysis of retort temperature distribution data using internally derived criteria as well as other performance parameters that have been specified in various GMP guidelines and by regulatory authorities.

The temperature distribution data analysis function of DWC Analyser was evaluated in 16 commercial processing establishments in Australia, New Zealand, the Peoples Republic of China and the United Arab Emirates, in order to assess the performance of various styles of commercial retorts.

6. Based on the studies in the 16 commercial processing establishments in which DWC Analyser was used to evaluate retort performance it was found that:

   - Only three (19%) retorts were found to comply with the requirements of the United States Food and Drug Administration (Anon., 2002) which were the strictest of all the guidelines that have been considered.

   - Five (31%) of the retorts complied with the guidelines recommended by May (1997a), Smout and May (1997) and/or Warne (unpublished).

   - Eight (50%) of the retorts failed to comply with any of the GMP guidelines that have been considered. Under these circumstances it can be expected that target F values would not be achieved or, more seriously, the safety of the product would have been compromised.

7. The frequency of non-compliance with guidelines recommended by the United States Food and Drug Administration (Anon, 2002), May (1997a), Smout and May (1997) and Warne (unpublished) indicates that the adequacy of retort performance is not regarded by some manufacturers as being of sufficient importance to warrant regular review and corrective action. Given the critical nature of process delivery and the impact that this may have on product safety this is both surprising and unsatisfactory. In order to address these issues and to reinforce the importance of retort operation it is recommended that:

   - Australian food manufacturers and regulators are made aware through journals, presentations and seminars of the frequency with which non-

compliance is detected in thermal processing establishments and the impact that this may have on product safety.

- Australian food manufacturers and regulators receive specialised training that highlight the importance of, and means of assessing, retort performance in a standardised manner. (Work in this area has commenced, in conjunction with Food Science Australia with whom DWC FoodTech has a joint venture, in order to present the "Approved Persons Course" and specialist advanced training programs.)

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