PNADC-905

REPORTS PREPARED

BY

Mr. Thomas J. Ragusa

Thermal Process Technology, Inc.

Thermal Process Expert

March 25 - April 9, 2001

Compiled by Agriculture Led Export Businesses
12 Dokki Street, 6th Floor
Dokki, Cairo
TEL 02-338-1445
FAX 02-748-0729

USAID Project No. 263-0264

THOMAS J. RAGUSA

PRESIDENT
THERMAL PROCESS TECHNOLOGY, INC.

- Microbiology
  - Plant Sanitation Survey
  - Low-Acid food spoilage investigation
  - Commercial sterility testing
  - Thermal Death Time Studies
  - Inoculated Pack Studies
  - Biotesting of food containers for defects in seal integrity
  - Training and education

- Thermal Processing
  - Heat penetration studies
  - Temperature distribution studies
  - Thermal process design and evaluation
  - Thermal process deviation evaluation
  - Evaluation of food and beverage processing systems
  - System integration with datalogger and software
  - Training and education

- Software Distribution
  - Distributor of *WinCalc* a Windows™ based software package used in the evaluation of heat penetration and temperature distribution data. Process tables generated using Ball's Formula. Sophisticated database manager.

VITAE

Thomas J. Ragusa

SUMMARY OF EXPERIENCE:

Twenty-one years with major metal and plastic manufacturing packaging companies. Experience in packaging, microbiology, and foods and beverage processing used in analyzing and solving customer and manufacturing problems.

WORK EXPERIENCE:

Thermal Process Technology, Inc., October 1994 to present, President

American National Can Co., June 1990 to September 1994, Thermal Processing Coordinator

Continental Can Co., August 1978 to June 1990, Senior Scientist

PATENT:

U.S. Patent number: 4,473,591; 'Process for the Preservation of Green Color in Canned Vegetables, September 25, 1984

PUBLICATION:

W. P. Segner, T. J. Ragusa, C.L. Marcus, E. A. Soutter; Biological Evaluation of a Heat Transfer Simulation for Sterilizing Low-Acid Large Particulate Foods for Aseptic Packaging; Journal of Food Processing and Preservation 13 (1989) 257-274.

EDUCATION:

Illinois Benedictine College -Lisle	M.B.A. August 1992
University of Illinois-Champaign-Urbana	M.S. Food Science, July 1978
Illinois Benedictine College-Lisle	B.S. Biology December 1975

RETORT EVALUATIONS & UPGRADES

Assignment: Task 2, Mr. Tom Ragusa
Level of Effort: Minimum, 20 days in country, 2 travel days, plus 9 days in the United States
Time In-Country - March 22 - April 11, 2001 (approx.)

Desired Professional Qualifications: The consultant shall be an acknowledged as a recognized process authority by the United States Food & Drug Administration. He or she must have access to the tools to allow the consultant to conduct heat distribution and heat penetration studies. He or she shall also be able to determine and assist with filing processes for low-acid and acidified foods in hermetically sealed containers to assure compliance with the United States Food & Drug Administration's Low Acid Canned Food Regulations (LACF).

Education: A minimum of a B.S. degree in food science or a related discipline is preferred for all instructors. Proven practical experience in working with low-acid and acidified food processors is mandatory.

Language: There is no language requirement. A basic knowledge of Arabic would be useful, however.

Computer Literacy: Reporting requires a basic understanding of word processing and other programs. All reports are prepared in Microsoft Word 6.0 or higher.

Level of Effort and Duration of the Assignment: The assignment will consist of three in-country phases. Each will last 15-21 days, depending upon the availability of the consultant and amount of work in the individual processing operations. These will consist of;

1. Retort Surveys – Evaluate retort systems to assure compliance with LACF regulations. During this phase, the consultant will also assist interested processors in preparing forms to register their operation with the FDA.

2. Conduct Heat Distribution Studies – Following the retort surveys and satisfactory completion of all recommended upgrades to the system, the consultant shall return to conduct heat distribution studies in the retort systems. These studies will determine the cold spot in the system.

3. Heat Penetration Studies – Following the heat distribution studies, the consultant may need to conduct heat penetration studies on all products manufactured by the companies. This will allow the consultant to determine thermal processes for all products. The consultant will also assist the processor with process filing.

There will be additional time allocated for evaluating studies and preparing reports. The time required for these activities cannot be determined at this time, as the level of effort will depend upon the results of the different phases, but should not exceed three (3) days per trip.. There will also be up to six days allocated for preparation for each trip to Egypt.

Background of Work: The Agriculture-Led Export Businesses project has been developed to increase exports of processed foods from private sector Egyptian food processors. Over the three year life of the project, the goal is to increase exports by some $10,000,000US. This will be accomplished through concerted efforts to enhance marketing, business and technical practices by exporters and potential exporters. The project also seeks to build alliances, links and associations to expand export businesses and improve the health and viability of the Egyptian food processing industry.

To compete in the international market place, especially in Europe, the United States or Japan, processors of all foods for export must be able to manufacture high quality and safe products. One group of products that is traded internationally is low-acid canned foods. These products, due to the potential hazard from *Clostridium botulinum*, must be manufactured in facilities that have properly designed and set-up retorts. They must also be processed using thermal processes established by recognized process authorities to assure safety. Surveys of the industry have indicated that Egyptian processors of low-acid canned foods are deficient in these areas.

Work Activities: The objective of this project will be to upgrade the low-acid canned food operations throughout Egypt.

The specific role of the consultant shall be;

1. Proposal – The consultant shall prepare a proposal for work described in this Scope of Work.
2. Retort Surveys – The consultant shall examine all retort systems in target processor facilities using the Food & Drug Administration's (FDA) Low-Acid Canned Food Regulations found in 21 CFR Part 113 as a guideline.
3. Cannery Registration – The consultant shall assist interested processors in preparing forms and registering their processing operation with the FDA.
4. Heat Distribution Studies – The consultant shall conduct heat distribution studies in retorts to determine "cold spots". These studies shall be conducted after the processor has completed all recommendations highlighted in the retort survey conducted in Phase 1.
5. Heat Penetration Studies – The consultant may be required to conduct heat penetration studies on specific products as a prelude for determining processes for those products.
6. Process Filing – The consultant shall assist the processors in filing processes for their products with the Food and Drug Administration.
7. Industry Program – The consultant shall develop a ½ day program on process filing, record keeping and adherence to the Low-Acid Canned Food Regulations.
8. Reports – The consultant shall prepare reports for all processors including deficiencies, recommendations for improvement and next steps.

Reporting: All reports shall be submitted in hard copy and electronically to Mr. Stier. Reports shall be prepared using MICROSOFT Word 6.0 or above in an arial font in a 12 pitch on size A4 paper. Trip reports should be prepared while in-country and submitted prior to departure. The summary report shall be submitted within three weeks of the departure from Egypt.

Richard F. Stier
Director, Technical Services
Agricultural Led Export Business

Mr. Tarek Shata_____ Approved _____ Disapproved
CTO

Mr. Dennis Buda_____ Approved _____ Disapproved
COP

LACF-02.doc
August 24, 2000, RFS

C

REGISTRATION INFORMATION
RETORT PROCESSING

Name _____

Title _____

Company _____

Address _____

_____

TEL _____

FAX _____

Email _____

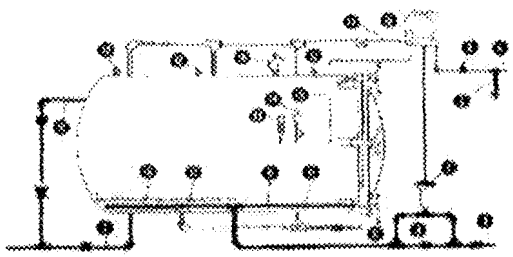
Attendees may register by calling in or faxing this registration to ALEB. They may also register at the door. EAGA members will receive a 25% discount.

Registration Fee: There will be an 80 LE fees for this program. Registrants will receive a course notebook, coffee breaks morning and afternoon and a certificate of participation following completion of evaluation forms.

For further details, contact:

Agriculture Led Export Businesses (ALEB)
12 Dokki Street
Dokki, Cairo, EGYPT
TEL 202-338-1445 (6 Lines)
FAX 202-748-0729

RETORT OPERATIONS AND PROCESS FILING



A WORKSHOP
SPONSORED
BY THE
AGRICULTURE LED EXPORT
BUSINESSES PROJECT (ALEB)
CAIRO, EGYPT

THE CENTER FOR ADVANCED FOOD
TECHNOLOGY
PISCATAWAY, NJ, USA

USAID Project No. 263-0264

April 8, 2001 at 9:30 at the
ALEB Offices,
Dokki, Cairo

RETORT OPERATIONS AND PROCESS FILING

INTRODUCTION

In the summer of 1971, two outbreaks of botulism in the United States resulted in the passage of new regulations to assure the safety of low-acid and acidified canned foods. Both incidents involved canned soup products. In one, botulinum toxin a can of vichyssoise resulted in one death and the demise of the company who manufactured the product.

These regulations were developed to assure that canned foods were safe and wholesome. Adherence to the regulations will help processors compete in not only the United States but in the work markets as they will assure buyers that your operations are "under control."

This program is designed to help Egyptian processors better understand the importance of controlling thermal process operations so that they can better compete in the world markets. The U.S. regulations are used as a guideline for operations.

COURSE OUTLINE

9:00 - Registration

9:30 – Welcome & Introduction - R. Stier

10:00 – Basics of Thermal Processing – R. Stier

10:30 – Plant & Retort Audits: System Setup to Assure Control – T. Ragusa

11:30 – Break

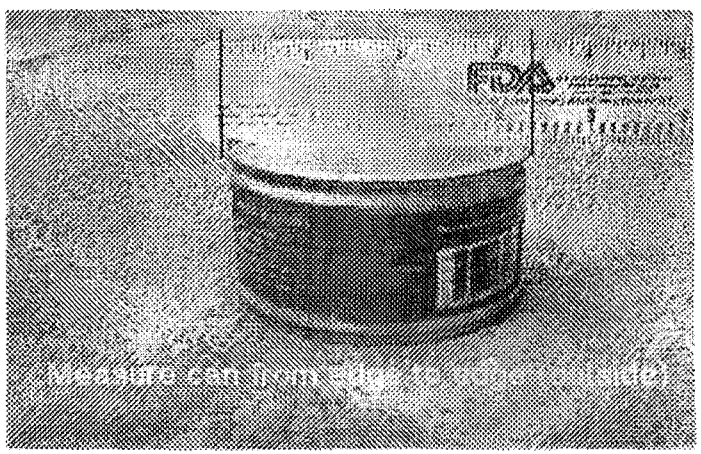
11:45 – Process Filing for Low Acid & Acidified Foods – T. Ragusa

1:15 – Lunch

2:30 – Records & Record Keeping: Retorts & Seams – T. Ragusa

3:30 – Recalls & Liability – T. Ragusa

4:30 – Question Period



FACULTY

Mr. Thomas Ragusa (Thermal Process Technology, Inc.)

Thomas Ragusa is the President of Thermal Process Technology, Inc., and consulting firm whose primary focus is thermal processing, thermal process technology, and process microbiology. Ragusa is a graduate of the University of Illinois and was employed by the Continental Can Company and the American National Can Company as a thermal processing authority prior to starting his own company. Thermal Process Technology is also a distributor for a software program used for evaluating heat penetration and temperature distribution data.

FOR FURTHER INFORMATION

Mr. Richard F. Stier
Director, Technical Services
Mr. Morad S. Ahmed
Co-Director, Technical Services
Agricultural Led-Export Businesses
12 Dokki Street, 6th Floor
Giza, Egypt
TEL 02-338-1445 (6 Lines)
FAX 02-748-0729
EMAIL morad@egyptonline.com
aleb@aleb.org

COURSE INFORMATION

Monday April 8, 2001 @ 9:30 at the ALEB Training Center, 5th Floor, 12 Dokki Street

ALEB Training Event Information

Course Name: **Retort Operation & Process Filling**

Start Date: **08-Apr-2001**

Instructor: Tom Ragusa

Dates:

Date	Start Time	End Time	Location
08-Apr-2001	9:30 am	5:00 pm	ALEB Office

Notes:

Attendees:

Name	Company	Paid	EAGA
Dr. Ateya El Makhzangy	Dr. Olivee Co. for Food Industries & Agriculture Investment S.A.E	☐	☐
Mr. Mohamed Emad El Din	Edfina Co. for Preserved Foods	☐	☐
Eng. Ibrahim Mohamed El Yamany	Edfina Co. for Preserved Foods	☐	☐
Eng. Ibrahim Mohamed El Yamany	Edfina Co. for Preserved Foods	☐	☐
Mr. Essam Arafat	El Misrieen - Misr October for Food Industries	☐	☐
Mr. Magdy Fahmy Mohamed	Enjoy - Nile Co. for Food Industries	☑	☑
Mr. Ali Ibrahim	ESAS - Egyptian Seed Association	☐	☐
Mr. Adel Niazi	ESAS - Egyptian Seed Association	☐	☐
Mr. Amr Ali	ESAS - Egyptian Seed Association	☐	☐
Mr. Osama Mohamed Abd El Maksoud	Harvest Foods	☑	☐
Mr. Mukhtar Barkat	Harvest Foods	☑	☐
Mr. Nader Iskander	Kamena Products Corporation	☑	☐
Mr. Mohamed Reda Mohamed	National Cooling & Freezing - CAFCO	☐	☐
Mr. El Kotb Mostafa Bakr	Super Foods - The Egyptian International Co. (Nagger Group)	☐	☐

Number of Attendees: 14

THERMAL PROCESS TECHNOLOGY, INC.

April 16, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

via email

Dear Rick:

The following is the summary of my activity during my visit to ALEB Cairo from March 23 to April 9, 2001.

Trip Highlights:

I visited 9 food-processing plants located in the areas around Cairo and Alexandria. Emphasis was on the thermal processing activities at the plants. Reviewed were the physical conditions of the processing and recording equipment, thermal process establishment, venting schedule development, adherence to schedule processes, records and record keeping. At several plant locations I helped the individual managers fill out the FDA form 2541 for plant registration and FDA form 2541a for process filing.

I presented a workshop on Retort Operations and Process Filing. ALEB and the Center for Advanced Food Technology at Rutgers University sponsored this workshop. The workshop was held on Sunday April 8, 2001, at the ALEB offices. Representatives of several processors of low-acid canned foods attended the workshop, as well as, a retort manufacturer. This was considered a successful workshop.

Every low-acid food processor that was visited had serious 21 CFR part 108, part 113, and part 114, violations. In fact, if the FDA inspected these plants, each would have been required to operate under the Emergency Permit Control previsions of the Act. None of the canning plants have scientifically established processes for their low-acid or acidified canned foods. None of the canning plants have temperature distribution data to support the retort operating procedures. These canning plants have inadequate records.

The older food processing plants that were at one time owned and operated under government control typically show the greatest problems and in my opinion, have the least chance of competing in a global environment. The newer plants, especially the ones that are owned by private investors are typically in much better shape.

Some of these plants want to ship processed canned foods to the European Union countries and especially to the US. Besides updating their manufacturing and process knowledge, these plants must decide what products to export. Importing raw materials from overseas, for example, dried chickpeas from Canada; to export back to Canada

2800 Springdale Circle
Telephone [illegible]

and US does not seem to make economic sense. The Egyptians need to determine what products give them a competitive advantage over their competitors. The agriculture department of Egypt should be able to help in this regard. The Egyptians may have to lobby the government for changes in the law to help their industry.

Education and training seemed to be lacking in these canning facilities. This lack of training not only concerns itself with the thermal processing activities but, as well as, the area of sanitation and good manufacturing practices. There appeared to be no understanding why thermal processes needed to be established using scientific methods. Thermal processes throughout Egypt were judged adequate if no swells developed during storage.

Most operating thermal processes appeared to be greater than what should be necessary to produce a commercially sterile product. During the visits I explained that if the processes were designed scientifically and delivered as scheduled, money would be saved with lower steam costs, increase productivity in the plant, no incubation requirement and better product quality.

In describing what kind of tests (temperature distribution and heat penetration) most managers wanted to know more. There is a definite need to educate these food processors in the basics of food microbiology, thermobacteriology, and thermal process determination. Some of this training and education can be done with 3-4 day workshops. For other serious students, a college level course(s) is required.

The food processors in Egypt need to work together for their common good. It is my understanding that the water buffalo producers in Egypt have formed an association to improve that industry. The Egyptian food processors need to form a similar association.

The following is the list of activity in Egypt:

Date	**Activity**
Mar-23-2001	Left Chicago for Cairo
Mar-24-2001	Arrived Cairo 8:00 PM
Mar-25-2001	Visited American Canning Co. 6th October City, 3rd Industrial Zone, Lot 38 Tel (002011) 3360 15-16 17, Fax (002011) 3360 13 Mr. Desouky Shehata, Operations Manager Mr. Mohammed Saleh, Quality Assurance Mr. Mohamed Mahmoud Dagher, Production Manager
Mar-26-2001	visited local food markets
Mar-27-2001	Visited El Mohandes National Meat Processing Co. BEEFY 6th October City, 1st Industrial Zone Tel (012) 3102356 Mr. Sammy Afifi
Mar-28-2001	Visited Galina, Nobareya - El Almerya (With Mr. Gupta and Stier)

	Mr. Samer Massoud Production Manager Mr. Amged Khalil Visited Kaha Co. for Preserved Foods - Tabiyah (near Alexandria) Tel (03) 5620242, Fax (03) 5611150 Dr. Mohamed Ibrahim, Director Quality Control, Tel (013) 600706 Eng. Hassam Sorour, sector director Eng. Tarhi Said, Mechanical Engineer Eng. Mohamed Afifi, plant manager
Mar-29-2001	Visited Kaha Co. for Preserved Foods Kilo 29-30 Cairo on the Alexandria agriculture road Tel (013) 600261 Dr. Mohamed Ibrahim, Director Quality Control, Tel (013) 600706 Kamel Ahmed Bade, plant manger Mr. Hosnoy Tantawy, plant director
Mar-30-2001	off
Mar-31-2001	visited local food markets prepared slides for presentation
April-1-2001	Visited Harvest Foods 6th of October City, Zone 3, lot 65 Tel (011) 3440528 - 33, Fax (011) 340531 Mr. Helmy Zeidy - owner Mr. Mokhtar Barakat - production manager Mr. Waddah Abdel - Hai - general manager Mr. Ossama M.Abdel-Maksoud, quality control engineer
April-2-2001 SAE	Visited Dr. Olivee For Food Industries & Agricultural Investment Factory: Zagazig, Manahiet Alsadat Tel (055) 373873; Fax (055) 303873 Cairo Office at 17 Al Ahram St. Hillepolice Tel (02) 4194723; Fax (02) 2915271 email: dr.olivee@egyptonline.com Mr. Ibrahim Ali Ibrahim - general manager Dr. Attia El.Mekhzangy; Assistant Prof. of Food Technology, Zagazig University, Institute of Efficient Productivity Mr. Essam Abdallah - quality manager
April-3-2001	Visited Vitrac Factory at Tersa, Kaha, Qalyobia Tel (013) 600648 - 600032 - 601942 - 601943; Fax (013) 620689 Mr. Said A. Hegazy, Research and Lab Manager Dr. Abd El-Rahman M. Khalaf Allah, who also is on the faculty of Food Science & Technology, Department, Cairo University
April-4-2001	Visited Egyptian Dairy & Foodstuff Co. (Edafco) Vive Brand 10th of Ramadan City Eng. Nabeel M. Ibrahim, production manager, Tel, (015) 410497

	Mr. Sherif A. Mohammed, quality control, Tel (015) 411335/6/7 Mr. Hussein Dawood, export manager, Tel (015) 410497 Mr. Mohamed Abu alla, technical manager Fax, (015) 410498 email edafcocompany@hotmail.com
April-5-2001	Visited Edfina Co. for Preserved Foods El Ras Elsoda, Alexandria Tel (03) 533400; Fax (203) 5349017 Eng. Zinab Ebada El Kashef, head of research development and quality Eng. Ibrahim M.E. Moustafa, R & D, & quality control manager
April-6-2001	off
April-7-2001	visited local food markets prepared slides for presentation
April-8-2001	Workshop at ALEB offices 'Retort Operations and Process Filing'
April-9-2001	Depart for Chicago

Thomas J Ragusa
Thermal Process Technology, Inc.
Consultant for ALEB

April 9, 2001

TEL011-336-15/016
FAX 011-336-013

Mr. Desoky Shehata
Americana/Egyptian Canning Company
3rd Industrial Zone, Lot 38
6th of October City

Dear Mr. Desoky:

On behalf of the ALEB project, we would like to thank you for taking the time to work with Mr. Tom Ragusa during his March 25 visit. Mr. Ragusa was very impressed with the operation, as you will see from his report to me. He did, however, note several areas where improvements could be made to assure compliance with the United States regulations for low-acid canned foods. These are summarized in his report and highlighted below. We also sent you a fax dated April 1 suggesting several changes that should be made when the Levati people are with you.

We have also enclosed a copy of the course manual from Mr. Ragusa's workshop and a copy of the Codex Alimentarius "*Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Products.*" There have been processors who have questioned our use of American regulations when their target markets are Europe or the Middle East. Take a look at the Section IV, Part D, 6 (a), Heat Processing on page 6 of 7. These guidelines support what we have been emphasizing in programs like the Better Process Control School. The bottom line is that if you can meet the U.S. regulations, you will easily meet the Codex guidelines, which are used as arbiters for international trade.

1. Perforations in Steam Spreader – Addressed in April 1 fax to your attention.

2. Bleeders – In a steam retort such as you have, bleeders should be installed. This issue was addressed in the April 1 fax.

3. Process Authority – The work with Levati should help you validate your processes. They should be the authority on the filing form. Process filings should include a vent schedule, that is, the time that each retort should be venting to achieve a certain temperature and to assure that there is no air remaining in the shell, process times and temperatures and any other factors that the process authority deems critical, such as fill weight.

4. Recording Thermometer – The recording thermometer was reading higher than the Mercury-in-Glass (MIG) thermometer. According to 113.40 (a) (2), "*The temperature chart shall be adjusted to agree as nearly as possible with,*

but no higher than, the known mercury-in-glass thermometer during the process time."

5. Temperature Chart – Mr. Ragusa observed that temperature tracing fell below the scheduled process temperature. This would be considered a process deviation and should be addressed as such.
6. Initial Temperatures – We talked about the necessity to take initial temperatures of cans as part of your process in both the Better Process Control School and during previous visits. This is something that you need to begin doing. The Levati technicians should be able to help you establish what temperature to use and develop a procedure to determining these values.

7. Forms – Mr. Ragusa promised to send you a copy of the FDA 2541A filing form as an EXCEL file. You will find that file, plus several others on the disk in the manual from his workshop. Other files on the disk are the Retort Record Form, the Retort Survey Form developed by PhF Specialists and a work file that contains a number of websites that contain information related to thermal processing. May we suggest that you take the retort record form on the disk and add descriptors in Arabic beneath the English one. This will allow your workers to easily understand and use the form. The English would fulfil the requirements for export to the United States.

Mr. Ragusa feels that once you get your systems set up properly, you should be able to operate in a more cost-effective manner. Improved venting and science-based processes may actually result in shorter cooks and reduced energy usage.

Finally, I contacted Mr. Dennis Spink, whom Mohamed Dagher met in Portland about canning corn from frozen product. His response is attached. He also sent me a second email in which he stated, "*But of course, canning varieties are the best.*" Good luck, and let us know if you have any questions with regards to this project.

Thank you again for your hospitality. Should you have any questions, or require any assistance, please do not hesitate to call either Eng. Morad Ahmed or myself.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: Files, M. Ahmed

March 26, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Dear Rick:

On Sunday March 25, 2001, we visited Americana Canning in the city of 6 October. We met with Mr. Desoky Shehata, Operations Manager, Mr. Mohamed Saleh, Quality, and Mr. Mohamed Mahmoud dagher, Production Manager.

The outside of the plant is very well maintained. The inside of the plant was also in very good condition. We saw no evidence of drip or condensate that could cause contamination. The floors, walls and ceiling were constructed to facilitate cleaning.

They had several questions about process filing forms (FDA form 2541a) so we reviewed the forms and discussed what values go in the various parts of the form. I suggested that they obtain a copy of NFPA's 26-L bulletin for suggestions for their bean processes if they process the same can size as listed in the bulletin. We explained the difference between the fill-in weight vs. drained weight. We went into some detail explaining what an F-value is what a F_o is and what types of sterilizing values are used for acidified foods.

We also discussed the mechanics of conducting temperature distribution test and heat penetration tests. Apparently there will be a firm from Italy in Americana Canning this week to conduct at least temperature distribution tests.

Finally we had a brief walk through the plant. The sanitation of the plant appeared to be satisfactory. The plant was manufacturing Beans in Brine in a retail size can. The dry beans are imported from all parts of the world. In the plant the beans are soaked for about 12-14 hours in cool water. After soaking the beans are flumed into a blancher at about 95°C. The beans are cooled, dewatered, inspected for defects, and sent to the pocket type filler. The beans are filled into the can followed by an overflow briner. The cans are closed on an Angelus double seamer, washed with cold water and placed in a retort crate with divider sheets in-between layers of cans. The crates are filled into 4 crate horizontal retorts and processed at about 121°C for about 65 minutes.

There are several items that need immediate attention. There is no established vent schedule at the plant. Currently the plant uses a 4-5 minute vent with no temperature requirement. I noticed that the retorts have 2 bottom steam

spreaders. However, the perforations are aimed at the retort shell. I mentioned that the retort would vent faster if the perforations were aimed at the retort crates.

A process authority did not review the suggested thermal processes.

Each retort had a mercury-in-glass (MIG) thermometer and temperature recorder. The MIG was difficult to read. The MIG should be replaced with ones that meet the regulation, which is no more that 17°F/inch readable to 1°F or (0.5°C).

The recording thermometer was reading higher than the MIG. Temperature tracings on the chart fell below the scheduled process temperature. This was not considered by plant personnel as serious. No initial temperatures were measured.

The plant does have a recall procedure. The plant has an incoming inspection program for of all incoming materials. Records and records review require some improvement. For products exported to the US, the records must be in English, signed by the person making the measurement or observation and signed by a representative from management. This is not always done.

The double seams are torn down regularly and the results are recorded. The plant uses the optical method. I thought is was quite interesting that the plant makes their own cans. They buy coated sheet stock from Japan, slit the plate into body blanks, and make welded three piece cans on a Soudronic welder. The ends are purchased from Europe. The plant makes the retail size cans and purchases the 603x700 cans.

The plant incubates 100% of their production for 2-weeks prior to labeling. This is a very good practice and it is not required by the regulations. I was not able to ascertain what happens when spoilage is found in the incubated lot.

I agreed to send Mr. Desoky Shehata a copy of FDA form 2541a as a that I have as an Excel spreadsheet.

In conclusion, I appreciate the warm hospitality that was shown to me and I believe that the visit was worthwhile for both Americana and for me. I look forward to working with the plant in the future.

Best regards,

Thomas J Ragusa
Thermal Process Technology, Inc.

Fax Cover Sheet

April 1, 2001

To:	Desouky Shehata
Company:	Egyptian Canning Company
CC:	M. Ahmed
Fax Number:	011-336-013
Phone Number:	011-336-015
From:	Rick Stier
No. of Pages:	1
Subject:	Retort Issues

Dear Mr. Desouky:

Thank you for taking the time to work with Tom Ragusa last week. He told me that you were, as always, courteous and helpful.

Mr. Ragusa also mentioned that the Levati people would be in shortly to do the retort upgrades and the heat distribution studies. He suggested that there were several changes that should be made before the work begins.

1. Steam Spreader – The holes on the steam spreaders are on the bottom of the steam spreader pipe pointing directly at the retort shell. The United States regulations state that the perforations should be along the top 90° of the pipe, that is, within 45° of the top center. {21 CFR Part 113.40 (a) (7).} The steam spreader pipes should be rotated so that you are in compliance with this part of the regulation. Mr. Ragusa feels that making this change will not only bring you into compliance with this part, but will also improve venting thereby saving energy in the long run.

2. Bleeders – The retorts should be plumbed so that can be installed {21 CFR Part 113.40 (a) (8).} These shall be 1/8 inch (0.32 cm) or larger. They should be installed within 30 cm of the ends of each retort and no more than 2.4 meters apart. The bleeders are designed to emit steam constantly during the process showing the operator that the system is operating properly.

If you follow the guidelines that we discussed during the Better Process Control School and have the Levati folks set up the retorts in that fashion, you will be in compliance with the US regulations.

Finally, Mr. Ragusa believes that you may be significantly over-processing your bean products. The work by Levati should help you develop processes based on sound science, which may be shorter than what you are using now. Shorter cooks will allow you to save energy and increase production as you may be able to do more retort loads during the course of a day.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

SECTION I - SCOPE

This code of hygienic practice applies to fruit and vegetable products which are packed in hermetically sealed containers and which are processed by heat either before or after being filled into the containers.

SECTION II - DEFINITIONS

A. ***Hermetically sealed*** means air-tight.

B. ***Container*** means any hermetic enclosure for food including, but not limited to, metal, glass or laminated plastics.

C. ***Heat processed*** means processed by heat to an extent which results in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation.

SECTION III - RAW MATERIAL REQUIREMENTS

A. Environmental Sanitation in Growing and Food Production Areas

(1) **Sanitary disposal of human and animal wastes**. Adequate precautions should be taken to insure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygienic hazard, and extreme care should be taken to protect all food products from contamination with these wastes.

(2) **Sanitary quality of irrigation water**. Water used for irrigation should not constitute a public health hazard to the consumer through the product.

(3) **Animal, plant pest and disease control**. Where control measures are undertaken, treatment with chemical, biological or physical agents should be done only in accordance with the recommendations of the appropriate official agency, by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of toxic residues being retained by the crop.

B. Sanitary Harvesting and Production of Raw Food Materials

(1) **Equipment and product containers**. Equipment and product containers should not constitute a hazard to health. Containers which are re-used should be of such material and construction as will facilitate thorough cleaning, and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Sanitary techniques**. Harvesting and production operations, methods and procedures should be clean and sanitary.

(3) **Removal of obviously unfit materials**. Unfit products should be segregated during harvesting and production to the fullest extent practicable and should be disposed of in such a place and in such a manner that they cannot result in contamination of the food and water supplies or other crops.

(4) **Protection of product from contamination**. Suitable precautions should be taken to protect the raw product from being contaminated by animals, insects, vermin, birds, chemical or microbiological contaminants or other objectionable substances during handling and storage. The nature of the product and the methods of harvesting will indicate the type and degree of protection required.

C. **Transportation**

(1) **Facilities**. Conveyance for transporting the harvested crop or raw product from the production area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Handling procedures**. All handling procedures should be such as will prevent the product from being contaminated. Extreme care should be taken in transporting perishable products to prevent spoilage or deterioration. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product, it should be of sanitary quality as required in Section IV - A - 2(c).

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. **Plant Construction and Layout**

(1) **Location, size and sanitary design**. The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; should be of sufficient size for the purpose intended without crowding of equipment or personnel; should be of sound construction and kept in good repair; should be of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and should be so designed as to permit easy and adequate cleaning.

(2) **Sanitary facilities and controls**

(a) ***Separation of processes***. Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) ***Water supply***. An ample supply of hot and cold water should be available. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the "International Standards for Drinking Water" World Heath Organization, 1971.

(c) *Ice*. Ice should be made from water of potable quality and should be manufactured, handled, stored and used, so as to protect it from contamination.

(d) ***Auxiliary water supply***. Where non-potable water is used - for such purposes as fire control -

it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) ***Plumbing and waste disposal.*** All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies. The plumbing and the manner of waste disposal should be approved by the official agency having jurisdiction.

(f) ***Removal of solid or semi-solid wastes*** from the product preparation and canning areas should be on a continuous or near continuous basis using water and/or appropriate equipment so that these areas are kept clean and there is no danger of contaminating the product. Also they should be disposed of in a way that they cannot be used for human food. Waste materials should be disposed of in a place and in such a manner that they cannot contaminate food and water supplies and cannot offer harbourages or breeding places for rodents, insects or other vermin.

(g) ***Lighting and ventilation***. Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, obnoxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fill into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage.

(h) ***Toilet-rooms and facilities***. Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet-rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(i) ***Hand-washing facilities***. Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be approved by the official agency having jurisdiction. The facilities should be kept in a sanitary condition at all times.

B. Equipment and Utensils

(1) **Materials**. All food contact surfaces should be smooth; free from pits, crevices and loose scale; non toxic; unaffected by food products; and capable of withstanding repeated exposure to normal cleaning; and non-absorbent unless the nature of a particular and otherwise acceptable process renders the use of a surface, such as wood, necessary.

(2) **Sanitary Design, construction and installation**. Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils**. Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products.

C. Hygienic Operating Requirements

While additional and more specific requirements may be established for certain products, the following should apply as minimal in all food production, handling, storage and distribution.

(1) **Sanitary maintenance of plant, facilities and premises.** The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(2) **Vermin control.** Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals.** Dogs, cats and other domestic animals, should be excluded from areas where food is processed or stored.

(4) **Personnel health.** Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms.

(5) **Toxic substances.** All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing including suitable headdress should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) ***Acceptance criteria***. The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) ***Storage***. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) ***Water***. Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting**. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation**. Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing**. Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

(5) **Packaging of finished product**

(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

(b) ***Techniques***. Packaging should be done under conditions that preclude the introduction of contamination into the product.

(6) **Preservation of the finished product**

(a) ***Heat processing***. Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

(b) ***Cooling of processed containers***. Where processed containers are cooled in water, the water should be of potable quality or suitably treated so as not to constitute a public health hazard. If cooling water is recirculated it should be effectively disinfected by chlorine or otherwise before use or each re-use.

(c) ***Decrating and handling of processed containers***. After processing and cooling, containers should be handled n such a manner as to avoid contamination of the product. Rough handling of processed cans, especially while they are still wet, should be avoided. Belts, runways and other processed can-conveying equipment should be maintained in good hygienic condition.

(d) ***Inspection of processing containers***. Containers should be inspected before labelling and casing and defective containers withdrawn.

(7) **Storage and transport of finished product**. The finished product should be stored and transported under such conditions as will preclude the contamination with, or development of pathogenic or toxigenic microorganisms or infestation and protect against deterioration of the product or of the container.

E. **Sanitation Control Programme**

It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

F. **Laboratory Control Procedures**

In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of products processed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all foods that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. For certain products it may also be desirable to check the process by incubation of samples.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and analysis or determination to meet the following specifications.

A. To the extent possible in good manufacturing practice the products should be free from objectionable matter.

B. The products should not contain any pathogenic microorganisms or any toxic substance originating from microorganisms.

C. The products should comply with the requirements set forth by the Codex Committees on Pesticide Residues and Food Additives as contained in permitted lists or Codex Commodity Standards.

D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

Subj: Effects on Quality of corn
Date: 04/09/2001 7:53:22 PM Egypt Standard Time
From: Osuspink@cs.com
To: Rickstier4

They can use frozen in canning. That is what the Egytian canning company is looking at starting. Regular sweet corn is a fair finish product. The color is the main concern. The juice can darken and be a problem but this can be corrected by pH control. The Japanese process alot of corn from frozen corn. I have not done enough work on super sweet corn to say for sure what would happen but I feel that it could be done with the result being a good product. They should thaw the corn fast and cook it as fast has their retorts can reach.

Subj: **RE: Thank you**
Date: 04/10/2001 4:35:56 PM Egypt Standard Time
From: tjragusa@worldnet.att.net (Thomas J. Ragusa)
To: desouky@mismet.com.eg ('User Desouky')
CC: rickstier4@aol.com ('rickstier4@aol.com')

File: 2541a.xls (37376 bytes)
DL Time (TCP/IP): < 1 minute

April 10, 2001

Dear Desouky:

I enjoyed my visit with you on March 25. You have a nice plant. With Levati, your plant processing records and retort should be in compliance with Codex and US regulations.

Attached is an Excel file with FDA form 2541a. There are no instructions with the file and it will take a little time to fill out the form for the first time. After that, it will be much faster.

Best regards,

Tom Ragusa
Thermal Process Technology.

-----Original Message-----
From: User Desouky [SMTP:desouky@mismet.com.eg]
Sent: Wednesday, April 04, 2001 4:43 AM
To: aleb@egyptonline.com
Cc: tjragusa@worldnet.att.net
Subject: Thank you

Dear All,

This is to thank you for your continuos help & support specially your great efforts in Thermal Processing Principles & Practices School

As well your visits To ECC-American Plant.

We have a confirmed date from Levati Italian Process Authority to comply the FDA requirements for our products which is April 23 ed -3 days

Mr. Rick please you may arrange a visit to our plant at that time if possible

Nice Regards
Desouky Shehata

---------- Headers ----------
Return-Path: <tjragusa@worldnet.att.net>

April 13, 2001

Mr. Samy Afifi
Beefy – El Mohandes National Meat Processing Company
1st Industrial Zone
6th of October City

Dear Mr. Samy:

On behalf of the Agriculture Led Export Business (ALEB) project, we would like to thank you and your colleagues for taking the time to work with Mr. Tom Ragusa during his March 27 visit. We have attached a copy of his report, which cites a number of significant problems; problems that can affect public health, your reputation and your business. Mr. Ragusa's recommendations include;

1. Establishing a Good Sanitation Program – It is imperative that Beefy take steps to upgrade its sanitation and hygiene programs. This includes the development and implementation of programs addressing cleaning and sanitizing, pest management, worker education and Good Manufacturing Practices (GMP's). For example, Mr. Ragusa mentioned that lighting in the factory is poor. This is one of the basic requirements in the GMP's.

2. Retort Upgrades – All retorts must have functioning mercury-in-glass thermometers and recording charts. There is no way to properly document processes and assure public safety without such instruments. We would also suggest that heat distribution studies by conducted on your systems. This is work that Stock, as the retort supplier, may be able to do for you. Consider contacting Mr. David Polvino, Vice-President at davep@stockamerica.com.

3. Damage to Systems – The present policy of not washing cans before they go into the retorts could clog the circulation system and damage the retort. You have an expensive piece of equipment, which is worth protecting.

4. Thermal Processes – Thermal processes based on good science need to be established. You also need to keep records of how the processes were established.

5. Can Coding – Changing can codes once a month is unacceptable and may even be illegal by Egyptian standards. Codes should be changed every shift, or at least once a day. This system helps protect your company and your reputation.

At ALEB, our mission is to help you and others increase exports. To do that, processors looking to export need to make an effort to comply with international, not Egyptian standards. We are using US guidelines for retort processing because we feel that their adoption will allow processors to meet both the Egyptian and international guidelines. You will find a copy of the "*Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Product*" attached to the report. Section IV, D, 6, entitled Heat Processing, may be seen below;.

> *Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.*

This is the guideline that all processors of canned food will need to follow in the future, hence our efforts to help you upgrade your operations.

Finally, we strongly suggest that Beefy turn to their sister companies, Egyptian Canning and Heinz Egypt, in the 6th of October to help in adoption of these recommendations. Both companies have worked extensively with ALEB and benefited from their association with us.

Thank you again for your hospitality. Should you have any questions or require any additional information, please feel free to contact Eng. Morad Ahmed or myself.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: Files, M. Ahmed

March 28, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On Tuesday March 27, 2001, we visited Beefy Canning in the city of 6 October. We met with Mr. Sammy Afifi, and the plant manager, but I was not able to comprehend his name.

The inside of the plant was not very well lit and was difficult evaluate the plant sanitation. GMP rules were not being followed. Dirty clothing was allowed in the production areas and there was no rule requiring hair restraints.

The retort room has a lot of room for improvement. There are 4 retorts. Two retorts were simple horizontal steam retorts. One retort was a conventional water immersion Stock Rotomat, and the other was a Stock Rotovap which is a water spray type of retort.

None of the retorts have a mercury-in-glass thermometer. The Stock recording charts were inoperable. The horizontal retorts were not operating during the visit. The horizontal steam retorts do not have a steam spreader or bleeders. The steam enters through the back of the retort. The vent pipe is located on top of the retort. The vent valve is closed when the temperature reaches 100°C. I asked to see some processing records; there were no records to review. The can code changes every month. I suggested that the code be changed at least once shift, but they said it was difficult and not necessary.

The Stock Rotomat baskets were filled without using divider sheets. When excess meat is attached to the outside of the cans, the divider sheets are not used because of the difficulty in cleaning the divider sheets after process. No mention was made about the meat clogging the circulatory system of the retort. Apparently, Stock originally suggested thermal processes for Beefy. I saw no process recommendations. Processes appear to be based upon experience.

Obviously, this plant is not ready and not even close to being ready to meet FDA/USDA canning regulations. According to plant management, there has not been a canning related problem since the plant has been in existence.

They are probably over-processing. Their attitude I believe is that over-processing will overcome any deficiency in sanitation and control. The retort operation in my opinion is dangerous.

Recommendations:

The retorts need calibrated mercury-in-glass thermometers and the recording charts need to be repaired. Temperature distribution tests are required for the two Stock retorts. The two horizontal retorts without steam spreaders I do not believe could be brought into compliance with the USDA/ FDA canning regulations.

The meat processes need to be based upon scientific heat penetration tests. A system of records and records keeping must be established at this plant. The can codes should be changed at least once a shift. After filling, the cans should be washed off, prior to being placed in the retort baskets. Meat chunks will clog the Stock water circulation system and may result in underprocessing.

A good sanitation program needs to be established in the plant along with following good manufacturing practices. Since this plant is owned by the same company that owns Americana Canning, perhaps the two plant managers can work together to improve Beefy.

Respectfully submitted,

Thomas J Ragusa
Thermal Process Technology, Inc.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

SECTION I - SCOPE

This code of hygienic practice applies to fruit and vegetable products which are packed in hermetically sealed containers and which are processed by heat either before or after being filled into the containers.

SECTION II - DEFINITIONS

A. ***Hermetically sealed*** means air-tight.

B. ***Container*** means any hermetic enclosure for food including, but not limited to, metal, glass or laminated plastics.

C. ***Heat processed*** means processed by heat to an extent which results in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation.

SECTION III - RAW MATERIAL REQUIREMENTS

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(1) **Sanitary disposal of human and animal wastes.** Adequate precautions should be taken to insure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygienic hazard, and extreme care should be taken to protect all food products from contamination with these wastes.

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(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) ***Acceptance criteria***. The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) ***Storage***. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) ***Water***. Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting**. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation**. Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing**. Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

(5) **Packaging of finished product**

(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

(b) ***Techniques***. Packaging should be done under conditions that preclude the introduction of contamination into the product.

(6) **Preservation of the finished product**

(a) ***Heat processing***. Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

(b) ***Cooling of processed containers***. Where processed containers are cooled in water, the water should be of potable quality or suitably treated so as not to constitute a public health hazard. If cooling water is recirculated it should be effectively disinfected by chlorine or otherwise before use or each re-use.

(c) ***Decrating and handling of processed containers***. After processing and cooling, containers should be handled n such a manner as to avoid contamination of the product. Rough handling of processed cans, especially while they are still wet, should be avoided. Belts, runways and other processed can-conveying equipment should be maintained in good hygienic condition.

(d) ***Inspection of processing containers***. Containers should be inspected before labelling and casing and defective containers withdrawn.

(7) **Storage and transport of finished product**. The finished product should be stored and transported under such conditions as will preclude the contamination with, or development of pathogenic or toxigenic microorganisms or infestation and protect against deterioration of the product or of the container.

E. Sanitation Control Programme

It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

F. Laboratory Control Procedures

In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of products processed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all foods that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. For certain products it may also be desirable to check the process by incubation of samples.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and analysis or determination to meet the following specifications.

A. To the extent possible in good manufacturing practice the products should be free from objectionable matter.

B. The products should not contain any pathogenic microorganisms or any toxic substance originating from microorganisms.

C. The products should comply with the requirements set forth by the Codex Committees on Pesticide Residues and Food Additives as contained in permitted lists or Codex Commodity Standards.

D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

April 13, 2001 TEL/FAX 03-583-0187

Mr. Ahmed Auf
Auf Group
Auf Building
509 Horreya Street
Boulkly, Alexandria

Dear Ahmed:

We would like to thank your staff for the hospitality shown to Mr. Tom Ragusa on his visit to the Tabia plant on March 28. Mr. Ragusa was very pleased with the cooperation that he received from the group, which included Hassam Sorour, Tarhi Sai and Mohamed Afifi. He was not, however, pleased with the condition of the plant and the apparent lack of understanding of thermal processing and the need to document processes. His report is enclosed and includes a number of recommendations related to sanitation and process operations. His suggestions are self-explanatory. In the interest of protecting and building your business and assuring public health, we strongly suggest that you take steps to address these issues.

We are fully aware that some of your staff feel that they are doing a good job in that they are meeting "*Egyptian Standards*," and also understand that they wonder why we continue to base audits and workshops on American standards and regulations. As you know, our mission is to help you and others increase exports. To do that, processors need to make an effort to comply with international, not Egyptian standards. We feel that if we can get processors to follow US guidelines, they will be able to meet both the Egyptian and international guidelines. You will find a copy of the "*Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Product*" attached to the report. Please note Section IV, D, 6, entitled Heat Processing. This will be the basis for evaluation of Egyptian processors involved in international trade in the near future. The guidelines emphasize that ***processes be based on the recommendations of technical specialists competent in canning technology,*** not experience.

Please feel free to contact us should you have any questions or require any additional information.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: Files, M. Ahmed, Eng. Mohamed Afifi (Kaha – Tabia)

March 29, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On Wednesday March 28, 2001, we visited Kaha Canning in Tabiyah near Alexandria. We met with Eng. Hassam Sorour the sector director, Eng. Tarhi Said Mechanical Engineer, Eng. Mohamed Afifi the plant manager and Dr. Mohamed Ibrahim the QC research director for Kaha Company. In the meeting was Mr. Ahmed Tarek, from Greena who does technical consulting for Kaha. He also helped with the translation. I thought the meeting was well worthwhile. I enjoyed the folks in the plant. They were very cordial and answered my questions.

The outside of the buildings had all kinds of vegetation growing next to the plant buildings. The inside of the plant was dark. Doors were wide open, no screens were seen. The plant was dirty. The paint was peeling. In short the plant was in need of a thorough cleaning and should be refurbished.

We discussed the need for scientifically designed thermal processes and vent schedules. I showed them what typical time/temperature data looks like. I showed Kaha how we plot the data. I believe Dr. Mohamed understood the importance of data. The others relied on process experience and the 'Egyptian Standard' that says foods must not contain Salmonella, Staphylococcus, etc. The plant has already applied for a FCE number but has not submitted any process filing forms. We discussed the process filing form and defined what is a F_o value.

The plant was not running production while I was there. Dr. Mohamed explained the process steps for the low-acid bean product. The beans are blanched in kettles, drained and hand filled into cans. The cans are then placed on a conveyer and filled with hot brine with an overflow type system. The cans then travel through an exhaust box for about 15-20 minutes. The reason for the exhaust box is to achieve a high vacuum in the cans. The double seamer is not equipped with steam flow. The exhaust box was deteriorated. The entrance and exit to the box has some sort of dirty strap frayed cloth material. Whatever bacteria are growing on this material inoculates every can entering and exiting.

There are two retorts used for processing low-acid foods. The Chaconsa retorts are Spanish made. The horizontal 4-basket retort has no glass thermometer, however it has a dial thermometer. The recording chart was inoperable. The retort has no bleeders. There was no clock. There is no vent schedule. The retorts are vented until the retort operator sees steam coming from the vent valve. No initial temperatures are measured.

At first the retorts looked like a Stock retort. The upper drum in this case holds cooling water. They did not operate the retort for me. I asked how they knew if the retort ever has a temperature drop. I was told that the retort operator always monitors the retort when it is processing. If a temperature drop occurs the retort operator stops the process timer, allows the temperature to achieve its process temperature and then resume the rest of the process. Of course no records are available to confirm any of this.

The retort operator's log recorded the number of baskets in the retort, the code, the scheduled time and temperature, and the seamer start and stop time. I suggested that they record the steam on and off time instead of the seamer start and stop. It was explained to me that the product loses too much temperature if the time from the first can to last can in the retort is more than an hour. So after one hour of doubleseaming the retort will be closed and the process started.

Recommendations:

The retort and the retort control system will take a lot of money and effort to bring them up to meet FDA regulations. Each of the retorts requires calibrated mercury-in-glass thermometers. The recording charts need to be repaired or replaced.

Temperature distribution tests are required for these retorts. These tests must be conducted with the smallest can size that will be processed in the retort. Bleeders must be installed in these steam retorts. Bleeders are used to help circulate the steam in the retort. Without circulation, cold spots may occur in the retort, which may result in underprocessing.

The exhaust box should be discarded. A simple steam flow device can be easily made to fit in the double seamer. A steam flow device will produce a vacuum in the can without the excess heating that occurs in the exhaust box.

The processes need to be based upon scientific heat penetration tests. All the low-acid food products and can sizes should have scientifically based processes. Fill-in weights must be measured with an accurate scale. Mechanical filling is preferable to the hand fill system. A system of records and records keeping must be established at this plant.

The vegetation around the plant should be removed or trimmed..

A good sanitation program needs to be established in the plant along with following good manufacturing practices. The whole plant is in need of a good thorough cleaning and sanitation program.

Respectfully submitted,

Thomas J Ragusa
Thermal Process Technology, Inc.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

SECTION I - SCOPE

This code of hygienic practice applies to fruit and vegetable products which are packed in hermetically sealed containers and which are processed by heat either before or after being filled into the containers.

SECTION II - DEFINITIONS

A. ***Hermetically sealed*** means air-tight.

B. ***Container*** means any hermetic enclosure for food including, but not limited to, metal, glass or laminated plastics.

C. ***Heat processed*** means processed by heat to an extent which results in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation.

SECTION III - RAW MATERIAL REQUIREMENTS

A. Environmental Sanitation in Growing and Food Production Areas

(1) **Sanitary disposal of human and animal wastes.** Adequate precautions should be taken to insure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygienic hazard, and extreme care should be taken to protect all food products from contamination with these wastes.

(2) **Sanitary quality of irrigation water.** Water used for irrigation should not constitute a public health hazard to the consumer through the product.

(3) **Animal, plant pest and disease control.** Where control measures are undertaken, treatment with chemical, biological or physical agents should be done only in accordance with the recommendations of the appropriate official agency, by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of toxic residues being retained by the crop.

B. Sanitary Harvesting and Production of Raw Food Materials

(1) **Equipment and product containers.** Equipment and product containers should not constitute a hazard to health. Containers which are re-used should be of such material and construction as will facilitate thorough cleaning, and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Sanitary techniques.** Harvesting and production operations, methods and procedures should be clean and sanitary.

(3) **Removal of obviously unfit materials**. Unfit products should be segregated during harvesting and production to the fullest extent practicable and should be disposed of in such a place and in such a manner that they cannot result in contamination of the food and water supplies or other crops.

(4) **Protection of product from contamination**. Suitable precautions should be taken to protect the raw product from being contaminated by animals, insects, vermin, birds, chemical or microbiological contaminants or other objectionable substances during handling and storage. The nature of the product and the methods of harvesting will indicate the type and degree of protection required.

C. **Transportation**

(1) **Facilities**. Conveyance for transporting the harvested crop or raw product from the production area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Handling procedures**. All handling procedures should be such as will prevent the product from being contaminated. Extreme care should be taken in transporting perishable products to prevent spoilage or deterioration. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product, it should be of sanitary quality as required in Section IV - A - 2(c).

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. **Plant Construction and Layout**

(1) **Location, size and sanitary design**. The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; should be of sufficient size for the purpose intended without crowding of equipment or personnel; should be of sound construction and kept in good repair; should be of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and should be so designed as to permit easy and adequate cleaning.

(2) **Sanitary facilities and controls**

(a) *Separation of processes*. Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) *Water supply*. An ample supply of hot and cold water should be available. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the "International Standards for Drinking Water" World Heath Organization, 1971.

(c) *Ice*. Ice should be made from water of potable quality and should be manufactured, handled, stored and used, so as to protect it from contamination.

(d) *Auxiliary water supply*. Where non-potable water is used - for such purposes as fire control -

it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) ***Plumbing and waste disposal.*** All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies. The plumbing and the manner of waste disposal should be approved by the official agency having jurisdiction.

(f) ***Removal of solid or semi-solid wastes*** from the product preparation and canning areas should be on a continuous or near continuous basis using water and/or appropriate equipment so that these areas are kept clean and there is no danger of contaminating the product. Also they should be disposed of in a way that they cannot be used for human food. Waste materials should be disposed of in a place and in such a manner that they cannot contaminate food and water supplies and cannot offer harbourages or breeding places for rodents, insects or other vermin.

(g) ***Lighting and ventilation.*** Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, obnoxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fill into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage.

(h) ***Toilet-rooms and facilities.*** Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet-rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(i) ***Hand-washing facilities.*** Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be approved by the official agency having jurisdiction. The facilities should be kept in a sanitary condition at all times.

B. Equipment and Utensils

(1) **Materials.** All food contact surfaces should be smooth; free from pits, crevices and loose scale; non toxic; unaffected by food products; and capable of withstanding repeated exposure to normal cleaning; and non-absorbent unless the nature of a particular and otherwise acceptable process renders the use of a surface, such as wood, necessary.

(2) **Sanitary Design, construction and installation.** Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils.** Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products.

C. Hygienic Operating Requirements

While additional and more specific requirements may be established for certain products, the following should apply as minimal in all food production, handling, storage and distribution.

(1) **Sanitary maintenance of plant, facilities and premises.** The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(2) **Vermin control.** Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals.** Dogs, cats and other domestic animals, should be excluded from areas where food is processed or stored.

(4) **Personnel health.** Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms.

(5) **Toxic substances.** All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing including suitable headdress should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) ***Acceptance criteria***. The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) ***Storage***. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) ***Water***. Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting**. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation**. Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing**. Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

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(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

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It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

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D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

April 13, 2001 TEL/FAX 03-583-0187

Mr. Ahmed Auf
Auf Group
Auf Building
509 Horreya Street
Boulkly, Alexandria

Dear Ahmed:

On behalf of the ALEB project, we would like to thank your staff for the hospitality shown to Mr. Tom Ragusa on his visit to the Kaha plant on March 29. During that visit, he met with Mr. kamel Ahmed Bade, Mr. Hosny Tantawy and Dr. Mohamed Ibrahim. The staff with whom he worked was cooperative and answered all his inquiries. A copy of Mr. Ragusa's report is attached to this letter. He is, unfortunately, not very complimentary with regards to the condition of the plant and the processing lines. He also told me when we chatted about the operation that he was very concerned about the safety of low-acid foods coming from the plant. His report cites a number of instances where the Kaha operation is in violation of the United States regulations governing the production of low-acid canned foods. These include;

- No mercury-in-glass thermometers
- An inoperable recording chart
- No bleeders on the retorts
- No clock for timing processes
- No vent schedules
- No taking of initial temperatures

The low-acid canned food regulations found in Title 21 part 113 (copy included) were developed to assure the safety of low acid canned foods. A failure to adhere to these regulations could compromise product safety and create a public health problem, so it is imperative efforts be made to upgrade the retort operations.

Mr. Ragusa's recommendations may be found in his report. These include several that we have made in the past, so we know that you are aware of our concerns and the problems in the plant, in particular the sanitation issues. We urge you to "*light a fire*" under management at the facility and get them working on cleaning up and instilling a sense of hygiene in the work force.

We also are aware that some of your staff feel that they are doing a good job in that they are meeting "*Egyptian Standards*," and also understand that they wonder why we continue to base audits and workshops on American standards and regulations. As you know, our mission is to help you and others increase exports. To do that, processors need to make an effort to comply with international, not Egyptian standards. We feel that if we can get processors to follow US guidelines, they will be able to meet both the Egyptian and international guidelines. You will find a copy of the "*Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Product*" attached to the report. Please note Section IV, D, 6, entitled Heat Processing. This will be the basis for evaluation of Egyptian processors

involved in international trade in the near future. The guidelines emphasize that ***processes be based on the recommendations of technical specialists competent in canning technology,*** not experience.

Please feel free to contact us should you have any questions or require any additional information.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: Flies, M. Ahmed, Kamel Ahmed Bade (Kaha – Kaha)

March 30, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On Thursday March 29, 2001, we visited Kaha Canning on the Alexandria Agricultural road near Cairo. We met with Kamel Ahmed Bade the plant manger, Mr. Hosnoy Tantawy the plant director, Dr. Mohamed Ibrahim the QC research director for Kaha Company.

This is a huge food manufacturing plant. This plant employs numerous types of food processing equipment and technologies from juice processing to tomato processing to low-acid canned foods. It is interesting to see all these technologies under one roof.

The outside of the buildings had all kinds of vegetation growing next to the plant buildings. The inside of the plant was dark. Doors were wide open, no screens were seen. The glass windows that are intact have not been cleaned in a long time. The walls, stairs, processing areas, floors are in need of cleaning and the ceiling is peeling either paint or mold. The birds are nesting in insect electrocution devices that no longer work. This particular situation is totally unacceptable for several reasons. The processing areas that I visited were very dark the lighting was poor. The floor felt like I was walking in mud. There are wooden pallets and cardboard strewn all over the plant.

This plant location has a FCE number. Number 07300 was issued in 1981. I asked if any process filing forms had been submitted, but due to a communication problem, that question was not answered.

The plant uses various packaging including metal cans, glass, and pouches.

The plant can process 1000 tons of tomatoes per day during the tomato pack. They were quite proud of their tomato processing line. They process acidified okra, green beans in brine, peas in brine, foul (dry soaked bean) in brine and frozen and acidified (canned) artichokes. The plant also processes juices in the plant. The plant has two Mespack 'aseptic' Spanish hot filled foil pouch filling lines. One was being used for apple juice during my visit. The other line was used for filling tomato paste.

The Mespack line looked new. However, the room the filler was in was filthy like the rest of the plant. Wet wood everywhere no ventilation in this area. The hot filled pouches travel to a dirty spray-cooling tunnel. The cooling water is non-treated well water. I do not know the quality of the water. After exiting the tunnel the wet pouches are placed in filthy dirty cartons and placed haphazardly on a pallet. I pointed out a crushed cartons on the bottom of the pallet. Dr. Mohamed had the workers fix the pallet. I told him that if that pallet were to end up at a port in the US, the customs agent would sent it back.

The plant was not running any low-acid canned food production while I was there. Dr. Mohamed explained the process steps for the low-acid bean product. The beans are blanched in kettles, drained and filled with a small pocket filler. The filler had trash in it when I looked into it. The cans are then placed on a conveyer and filled with hot brine with an overflow type system. The cans then travel through an exhaust box for about 15-20 minutes. The reason for the exhaust box is to achieve a high vacuum in the cans. The Angelus double seamer is not equipped with steam flow. The exhaust box was dilapidated. The entrance and exit to the box has some sort of dirty frayed cloth material. Whatever bacteria are growing on this material inoculates every can entering and exiting.

There are four retorts used for processing low-acid foods. These Danish retorts are similar to the Chaconsa retorts at the Alexandria plant location. The horizontal 4-basket retort has no glass thermometer, however it has a dial thermometer. The recording chart was inoperable. The retort has no bleeders. There was no clock. There is no vent schedule. The retorts are vented until the retort operator sees steam coming from the vent valve. No initial temperatures are measured.

In a similar fashion with its Alexandria sister plant, the processes and vent schedules are based upon experience.

I reviewed some double seaming records. From what I could understand, they do not measure a wrinkle rating. I asked how they measure for seam tightness, and I was told that a sample of cans is air pressure tested. If the cans pass the pressure test, the double seam tightness is OK.

Like the Alexandria plant, this plant also manufacturers their own cans. This plant has lacquer line and a litho line. From what I was able to see they did a great job with the lacquer line (they were manufacturing a white inside coating, this is difficult to do correctly); and 4 or 5 color pass litho for the outside.

They have two wire welded can lines. They were manufacturing a 202x306-juice can during my visit. They even make the 202 ring pull aluminum end. The plant makes 70, 100, 170, 250, 360, 550, 2000, and 3000 cm^3 cans. I told them for the process filing form FDA 2541a they need to present the can size in the diameter x height designation. I showed them how to make this measurement.

Even the can manufacturing area was a mess. The area looked like a junkyard with all the old and unused equipment all piled up.

The juice processing line was not much different from the rest of the plant. Even though the line was not running, the line was filthy. There was trash in the fruit conveyors; there was trash in the fruit scrubbers. The juice de-aeration system was inoperable. I was told that was an essential piece of equipment. I asked if they still produce juice without the unit working, and the answer was yes.

Perhaps Kaha can consolidate the entire can manufacturing at this location and send the food processing equipment to other Kaha locations.

Recommendations:

The retort and the retort control system will take a lot of money and effort to bring them up to meet FDA regulations. Each of the retorts requires calibrated mercury-in-glass thermometers. The recording charts need to be repaired or replaced.

Temperature distribution tests are required for these retorts. These tests must be conducted with the smallest can size that will be processed in the retort. Bleeders must be installed in these steam retorts. Bleeders are used to help circulate the steam in the retort. Without circulation, cold spots may occur in the retort, which may result in underprocessing.

The exhaust box should be discarded. A simple steam flow device can be easily made to fit in the double seamer. A steam flow device will produce a vacuum in the can without the excess heating that occurs in the exhaust box.

The processes need to be based upon scientific heat penetration tests. All the low-acid food products and can sizes should have scientifically based processes. Fill-in weights must be measured with an accurate scale. A system of records and records keeping must be established at this plant.

The vegetation around the plant should be removed or trimmed.

A good sanitation program needs to be established in the plant along with following good manufacturing practices. The whole plant is in need of a good thorough cleaning and sanitation program.

Respectfully submitted,

Thomas J Ragusa
Thermal Process Technology, Inc.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

SECTION I - SCOPE

This code of hygienic practice applies to fruit and vegetable products which are packed in hermetically sealed containers and which are processed by heat either before or after being filled into the containers.

SECTION II - DEFINITIONS

A. ***Hermetically sealed*** means air-tight.

B. ***Container*** means any hermetic enclosure for food including, but not limited to, metal, glass or laminated plastics.

C. ***Heat processed*** means processed by heat to an extent which results in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation.

SECTION III - RAW MATERIAL REQUIREMENTS

A. Environmental Sanitation in Growing and Food Production Areas

(1) **Sanitary disposal of human and animal wastes.** Adequate precautions should be taken to insure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygienic hazard, and extreme care should be taken to protect all food products from contamination with these wastes.

(2) **Sanitary quality of irrigation water.** Water used for irrigation should not constitute a public health hazard to the consumer through the product.

(3) **Animal, plant pest and disease control.** Where control measures are undertaken, treatment with chemical, biological or physical agents should be done only in accordance with the recommendations of the appropriate official agency, by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of toxic residues being retained by the crop.

B. Sanitary Harvesting and Production of Raw Food Materials

(1) **Equipment and product containers.** Equipment and product containers should not constitute a hazard to health. Containers which are re-used should be of such material and construction as will facilitate thorough cleaning, and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Sanitary techniques.** Harvesting and production operations, methods and procedures should be clean and sanitary.

(3) **Removal of obviously unfit materials**. Unfit products should be segregated during harvesting and production to the fullest extent practicable and should be disposed of in such a place and in such a manner that they cannot result in contamination of the food and water supplies or other crops.

(4) **Protection of product from contamination**. Suitable precautions should be taken to protect the raw product from being contaminated by animals, insects, vermin, birds, chemical or microbiological contaminants or other objectionable substances during handling and storage. The nature of the product and the methods of harvesting will indicate the type and degree of protection required.

C. **Transportation**

(1) **Facilities**. Conveyance for transporting the harvested crop or raw product from the production area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Handling procedures**. All handling procedures should be such as will prevent the product from being contaminated. Extreme care should be taken in transporting perishable products to prevent spoilage or deterioration. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product, it should be of sanitary quality as required in Section IV - A - 2(c).

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. **Plant Construction and Layout**

(1) **Location, size and sanitary design**. The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; should be of sufficient size for the purpose intended without crowding of equipment or personnel; should be of sound construction and kept in good repair; should be of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and should be so designed as to permit easy and adequate cleaning.

(2) **Sanitary facilities and controls**

(a) *Separation of processes*. Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) *Water supply*. An ample supply of hot and cold water should be available. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the "International Standards for Drinking Water" World Health Organization, 1971.

(c) *Ice*. Ice should be made from water of potable quality and should be manufactured, handled, stored and used, so as to protect it from contamination.

(d) *Auxiliary water supply*. Where non-potable water is used - for such purposes as fire control -

it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) ***Plumbing and waste disposal.*** All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies. The plumbing and the manner of waste disposal should be approved by the official agency having jurisdiction.

(f) ***Removal of solid or semi-solid wastes*** from the product preparation and canning areas should be on a continuous or near continuous basis using water and/or appropriate equipment so that these areas are kept clean and there is no danger of contaminating the product. Also they should be disposed of in a way that they cannot be used for human food. Waste materials should be disposed of in a place and in such a manner that they cannot contaminate food and water supplies and cannot offer harbourages or breeding places for rodents, insects or other vermin.

(g) ***Lighting and ventilation.*** Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, obnoxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fill into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage.

(h) ***Toilet-rooms and facilities.*** Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet-rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(i) ***Hand-washing facilities.*** Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be approved by the official agency having jurisdiction. The facilities should be kept in a sanitary condition at all times.

B. Equipment and Utensils

(1) **Materials.** All food contact surfaces should be smooth; free from pits, crevices and loose scale; non toxic; unaffected by food products; and capable of withstanding repeated exposure to normal cleaning; and non-absorbent unless the nature of a particular and otherwise acceptable process renders the use of a surface, such as wood, necessary.

(2) **Sanitary Design, construction and installation.** Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils.** Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products.

C. Hygienic Operating Requirements

While additional and more specific requirements may be established for certain products, the following should apply as minimal in all food production, handling, storage and distribution.

(1) **Sanitary maintenance of plant, facilities and premises.** The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(2) **Vermin control.** Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals.** Dogs, cats and other domestic animals, should be excluded from areas where food is processed or stored.

(4) **Personnel health.** Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms.

(5) **Toxic substances.** All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing including suitable headdress should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) ***Acceptance criteria***. The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) ***Storage***. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) ***Water***. Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting**. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation**. Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing**. Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

(5) **Packaging of finished product**

(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

(b) ***Techniques***. Packaging should be done under conditions that preclude the introduction of contamination into the product.

(6) **Preservation of the finished product**

(a) ***Heat processing***. Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

(b) ***Cooling of processed containers***. Where processed containers are cooled in water, the water should be of potable quality or suitably treated so as not to constitute a public health hazard. If cooling water is recirculated it should be effectively disinfected by chlorine or otherwise before use or each re-use.

(c) ***Decrating and handling of processed containers***. After processing and cooling, containers should be handled n such a manner as to avoid contamination of the product. Rough handling of processed cans, especially while they are still wet, should be avoided. Belts, runways and other processed can-conveying equipment should be maintained in good hygienic condition.

(d) ***Inspection of processing containers***. Containers should be inspected before labelling and casing and defective containers withdrawn.

(7) **Storage and transport of finished product**. The finished product should be stored and transported under such conditions as will preclude the contamination with, or development of pathogenic or toxigenic microorganisms or infestation and protect against deterioration of the product or of the container.

E. Sanitation Control Programme

It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

F. Laboratory Control Procedures

In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of products processed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all foods that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. For certain products it may also be desirable to check the process by incubation of samples.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and analysis or determination to meet the following specifications.

A. To the extent possible in good manufacturing practice the products should be free from objectionable matter.

B. The products should not contain any pathogenic microorganisms or any toxic substance originating from microorganisms.

C. The products should comply with the requirements set forth by the Codex Committees on Pesticide Residues and Food Additives as contained in permitted lists or Codex Commodity Standards.

D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

THERMAL PROCESSING REFERENCE SITES

GOVERNMENT	
AOAC Bacteriological Analytical Manual	http://www.cfsan.fda.gov/~ebam/bam-toc.html
California Cannery Inspection Program	http://www.dhs.cahwnet.gov/ps/fdb/HTML/Food/indexcan.htm
Canadian Food Inspection Agency	www.cfia-acia.agr.ca
European Union on Line	http://europa.eu.int
Food and Agriculture Organization	http://www.fao.org
National Center for Food Safety & Technology	http://www.iit.edu/~ncfst/
United States Food & Drug	www.fda.gov
US FDA - Thermal Processing Regulations	http://vm.cfsan.fda.gov/~acrobat/cfr113.pdf
US FDA - Acidified Food Regulations	http://vm.cfsan.fda.gov/~acrobat/cfr114pdf
US FDA - Instructions for Filing	http://vm.cfsan.fda.gov/~comm/lacf-s1.html
US FDA - Bad Bug Book	http://www.cfsan.fda.gov/~mow/intro.html
United States Department of Agriculture	http://www.usda.gov
ASSOCIATIONS & OTHER REFERENCES	
Campden & Chorleywood Food Research	www.campden.co.uk
Canning & Filling Magazine	www.canningandfilling.com
Central Tecnologie Nacional de la Conserves	www.ctnc.es
Food Processors Institute	www.fpi-food.org
Institute for Thermal Processing Specialists	http://www.iftps.org
National Food Processors Association	http://www.nfpa-food.org
Temperature Indicators	http://www.temperature-indicators.co.uk/retort.htm

SOURCE: 62 FR 2249, Jan. 15, 1997, unless otherwise noted.

§ 111.50 Packaging of iron-containing dietary supplements.

(a) The use of iron and iron salts as iron sources in dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, is safe and in accordance with current good manufacturing practice only when such supplements are packaged in unit-dose packaging. "Unit-dose packaging" means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term "dosage unit" means the individual physical unit of the product (e.g., tablets or capsules). Iron-containing dietary supplements that are subject to this regulation are also subject to child-resistant special packaging requirements in 16 CFR parts 1700, 1701, and 1702.

(b)(1) Dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, are exempt from the provisions of paragraph (a) of this section until January 15, 1998, if the sole source of iron in the dietary supplement is carbonyl iron that meets the specifications of § 184.1375 of this chapter.

(2) If the temporary exemption is not extended or made permanent, such dietary supplements shall be in compliance with the provisions of paragraph (a) of this section on or before July 15, 1998.

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Subpart A—General Provisions

Sec.

AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

SOURCE: 44 FR 16215, Mar. 16, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Aseptic processing and packaging* means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) *Bleeders* means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) *Come-up-time* means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) *Commercial processor* includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.

(t) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(u) *Vacuum-packed products* means those products that are sealed in a container under the vacuum specified in the scheduled process, the maintenance of which vacuum is critical to the adequacy of the scheduled process.

(v) *Vents* means openings through the retort shell, controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(w) *Water activity* (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 113.5 Current good manufacturing practice.

The criteria in §§ 113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.88, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 113.10 Personnel.

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.

Subpart B [Reserved]

Subpart C—Equipment

§ 113.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1 °F and whose temperature range does not exceed 17 °F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks that specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening and equipped with a ¼e-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2 °F within a range of 10 °F of the processing temperature. Each chart shall have a working scale

64

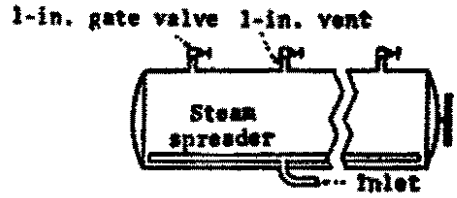
holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraph (a)(12)(i)(*a*) through (*d*) and (ii)(*a*) and (*b*) of this section.

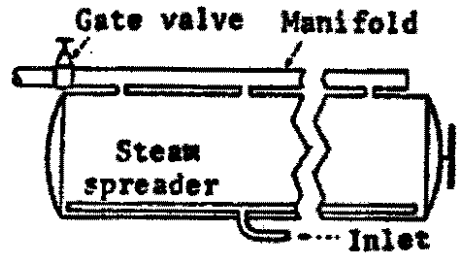
(i) *Venting horizontal retorts. (a)* Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere: end vents not more than 2½ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225 °F, or at least 7 minutes and to at least 220 °F.

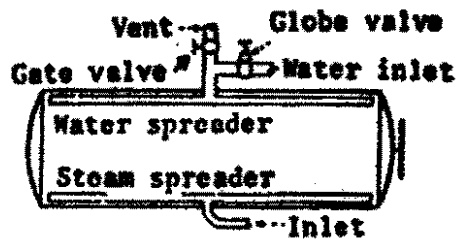
(*b*) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; and vents not over 2½ feet from ends of retort: Size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225 °F, or for at least 8 minutes and to at least 220 °F.

(*c*) Venting through water spreaders.



frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(b) *Equipment and procedures for pressure processing in water in still retorts—*(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1 °F and whose temperature range does not exceed 17 °F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date when it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2 °F within a range of 10 °F of the processing temperature. Each chart shall have a working scale of not more than 55 °F per inch within a range of 20 °F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording-thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer, except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts, the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts, the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the control bulb. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

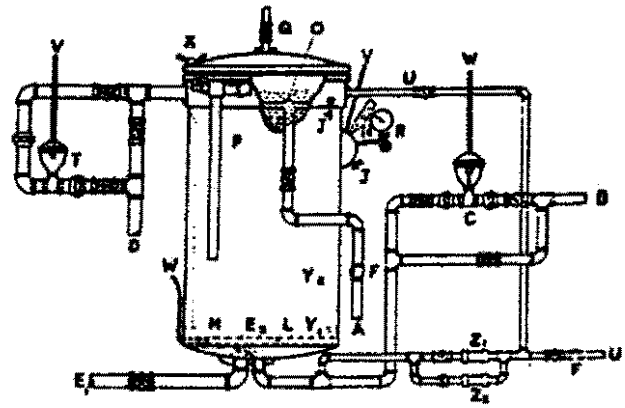
(ii) Each retort should have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

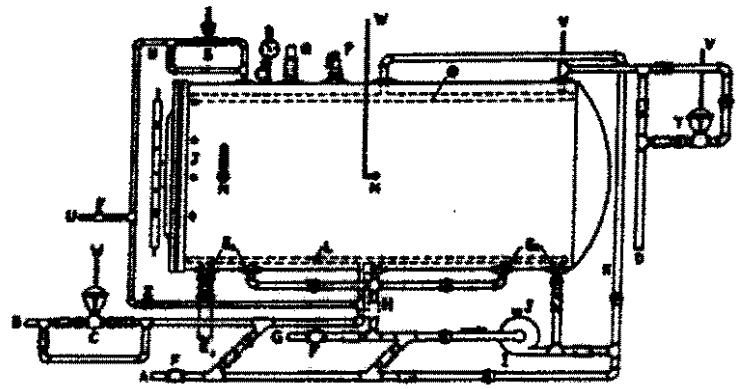
(5) *Steam introduction.* Steam shall be distributed in the bottom of the retort

Other installation and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data or other suitable information, which shall be kept on file, that demonstrates that the heat distribution is adequate.

Vertical Retorts



Horizontal Retorts



LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
E_1—Drain line.
E_2—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.
K—Recirculating line.
L—Steam distributor.
M—Temperature-controller bulb.
N—Thermometer.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.

should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eight inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged so that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate or shall be equipped with an automatic alarm system(s) that would serve as a continuous monitor of condensate-bleeder functioning. Visual checks should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that the bleeder is functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall be operated in such a way that ensures that the product is commercially sterile, or the retort is to be cooled promptly and all containers either reprocessed, repacked and reprocessed, or discarded. When operated as a still retort, all containers shall be given a full still retort process before the retort is cooled. If, in such an emergency, a scheduled still process or another process established to ensure commercial sterility is to be used, it shall be made readily available to the retort operator.

(i) Any containers in the retort intake valve or in transfer valves between cooker shells of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops

18

the retort. External wells or pipes shall be connected to the retort through at least a ¼-inch-diameter opening, and equipped with a ⅛-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2 °F within a range of 10 °F of the processing temperature. Each chart shall have a working scale of not more than 55 °F per inch within a range of 20 °F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a ⅛-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers, at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of heat within the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in a way that enables the operator to observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for containing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the schedules process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed-adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means of preventing unauthorized changes.

(6) *Air supply and controls.* Means shall be provided for introducing compressed air at the proper pressure and rate, which shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vaccum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1 °F and whose temperature range does not exceed 17 °F per inch of graduated scale. Thermometer shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. The thermometer shall be located in the steam dome near the steam-water interface. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording device shall not exceed 2 °F within a range of 10 °F of the processing temperature. Each chart shall have a working scale of not more than 55 °F per inch within a range of 20 °F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized

exceed 17 °F per inch of graduated scale. Thermometers and temperature-indicating devices shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer and temperature-indicating device should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to essential agreement with the standard shall be repaired or replaced. Thermometers and temperature-indicating devices shall be installed where they can be accurately and easily read. The temperature-indicating device shall be the reference instrument for indicating the processing temperature.

(*b*) *Temperature-recording device.* There shall be an accurate temperature recording device on each product sterilizer. The device shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. Temperature-recording devices shall have graduations that do not exceed 2 °F within a range of 10 °F of the processing temperature. Each chart shall have a working scale of not more than 55 °F per inch within a range of 20 °F of the desired product-sterilization temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, a known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. A lock; or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

(*c*) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of ensuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2 °F within a range of 10 °F of the desired product sterilization temperature. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(*d*) *Product-to-product regenerators.* When a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator is from the sterilized product into the unsterilized product.

(*e*) *Differential pressure recorder-controller.* When a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on the working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(*f*) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(*g*) *Product holding tube.* The product-sterilizing holding tube shall be designed to give continous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube

means; and proper performance of seam seals or other similar devices. The measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment*—(a) *Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Automatic recording devices shall be used to record, when applicable, the sterilization media flow rates, temperature, concentration, or other factors. When a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(*b*) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes must be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(ii) *Operation*—(*a*) *Startup.* Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(*b*) *Loss of sterility.* A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler, by preventing containers from entering the filler, or by other suitable means. In the event product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated and handled in accordance with §113.89. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(*c*) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product from each code; records of the test results should be maintained.

(4) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(*h*) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure

Required	Optional
Cover hook Body hook Width (length, height) Tightness (observation for wrinkle) Thickness	Overlap (by calculation). Countersink.

(*b*) Seam scope or projector:

Required	Optional
Body hook Overlap Tightness (observation for wrinkle) Thickness by micrometer	Width (length, height). Cover hook. Countersink.

(*c*) Can double seam terminology:

(3) "Deadhead": A seam which is incomplete due to chuck spinning in the countersink.

(4) "Droop": Smooth projection of double seam below bottom of normal seam.

(5) "False seam": A small seam breakdown where the cover hook and the body hook are not overlapped.

(6) "Lap": Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length=
CH+BH+T−W, where
CH=cover hook
BH=body hook
T=cover thickness, and
W=seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling water.* Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* When cans are handled on belt conveyors, the conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated as to preserve the can seam or other container closure integrity.

Subpart E—Production and Process Controls

§ 113.81 Product preparation.

(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling

made readily available to the supervisor and any duly authorized employee of the Food and Drug Administration.

(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A written record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time and venting time specified in the scheduled process are achieved. Pocket or wrist watches are not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process.

(e) Clock times on recording-temperature charts should reasonably correspond to the time of day on the written processing records to provide correlation of these records.

(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence such as a letter from the manufacturer, the designer, or a competent processing authority.

§ 113.89 Deviations in processing, venting, or control of critical factors.

Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commerical processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commerical sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the

product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed.

(d) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(e) Copies of all records provided for in this part, except those required under §113.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

PART 114—ACIDIFIED FOODS

Subpart A—General Provisions

Subparts B–D [Reserved]

Subpart E—Production and Process Controls

Subpart F—Records and Reports

AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

SOURCE: 44 FR 16235, Mar. 16, 1979, unless otherwise noted.

Subpart A—General Provisions

§114.3 Definitions.

For the purposes of this part, the following definitions apply.

(a) *Acid foods* means foods that have a natural pH of 4.6 or below.

(b) *Acidified foods* means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled ." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and recalled under refrigeration are excluded from the coverage of this part.

(c) *Lot* means the product produced during a period indicated by a specific code.

(d) *Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(e) *Scheduled process* means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

(f) *Shall* is used to state mandatory requirements.

(g) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

16

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TEL 011-340-528
FAX 011-340-531

Mr. Waddah Abdel-Hai
Harvest Foods
Zone 3, Lot 65
6th of October City

Dear Waddah:

On behalf of the Agriculture Led Export Businesses (ALEB) project, we would like to thank you and your colleagues for the hospitality extended to Mr. Tom Ragusa during his April 1 visit. As you can see from his attached report, he was quite impressed with your operation. You are one of the few processors here in Egypt who actually keep retort records. He suggests that you;

1. Conduct Temperature Distribution Tests on the Retorts – This is a necessity to assure that processes are based on how containers heat in your systems.
2. Develop Processes Based on Scientific Heat Penetration Studies – All processes should be based on heat penetration studies on your products. These processes must include critical factors such as fill weight, initial temperature or headspace.
3. Backup Generator – We strongly support Mr. Ragusa's recommendation that you invest in a generator. This is the type of investment that will help assure smooth operations and the production of high quality, safe foods. Having a generator would have eliminated the buckling problem that you discussed.

Mr. Ragusa also observed one point that needs to be addressed.

Birds in the Plant – The birds must be removed from the plant and a concerted effort made to keep them out. The use of strips is one option, but a rapid roll-up door might be more effective. There are only a few processors who have such units in Egypt, but if you would like to see one in operation, please let us know. We believe that we could arrange a visit for you.

Thank you again. Please feel free to contact Eng. Morad Ahmed or myself should you have any questions or require any additional information.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: Files, M. Ahmed

April 3, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On Sunday April 1, 2001, we visited **Harvest Foods** in 6th October City. We met with Mr. Waddah Abdel-Hai the general manager, Mr. Mokhtar Barakat, the production manger, Mr. Ossama Abdel-Maksoud, the quality control engineer and Mr. Helmy Zeidy.

The plant was not running during this visit. This plant is only about a year old. The plant has all new product handling and processing lines and equipment. The outside of the buildings was very well kept. The inside of the plant was well kept. The plant did have a bird problem inside the food processing area. They were addressing the problem during my visit. They are planning on installing plastic curtain doors to prevent birds from entering the plant. Apparently the doors do not have to be open for a long period of time for birds to enter. A pellet gun is probably the answer to the birds already in the plant. The insect electrocution devices were placed over the food processing area. I suggested the placement to a nearby wall to help prevent an electrocuted insect from landing in the food. The plant was very orderly. There was no visible trash lying around the plant.

This plant location has not filed for a FCE number.

The plant processes a variety of food products. There include fava beans in brine, green peas in brine, baked beans, and okra. The majority of production is packed in 401x204 2-piece draw-redraw cans that are made on the premises with a German-made Karges-Hammer press with tinplate sheets from France. These cans are doubleseamed with full panel easy opening end unit.

All the equipment in the processing area is made of stainless steel. The dry beans are transported through a blower, grader, size sorter, and then to the soak tanks. The beans are typically soaked for about 17 hours in cool water. After soaking the beans are blanched, cooled, inspected, filled with a pocket filler, then to an oil filler if required then to the brine or sauce filler. After doubleseaming the cans are washed and filled in Busse type stainless steel crates with plastic

divider sheets. The crates are filled into 5-crate Italian Panini Steam/Air stainless steel retorts.

These retorts are computer controlled. The retorts are equipped with both mercury-in-glass and a recording chart and working pressure gauge. The chart did not, however, printout temperature directly, but a function of temperature. The chart also provided a tracing of pressure. The retort records include the process log, and chart. Double seam measurements are taken and recorded.

The most glaring shortcoming in the plant is the lack of documentation proving adequate temperature distribution and heat penetration testing proving a safe thermally processed canned food. We spent the majority of our time discussing the nuts and bolts of collecting both types of data. I showed examples of both types of data. I showed them different ports in the retort where the thermocouple wires could be introduced into the retort.

I emphasized the importance of establishing thermal processes scientifically. Currently the thermal processes are based upon experience and incubation. They spend considerable amount of time and money conducting processing experiments evaluating the effects of different processing time/temperature combinations. I suggested to them that once they collect heat penetration data for their products they would be able to mathematically convert it to different initial temperature and retort temperatures.

Process deviations were also discussed. Currently, when a failure occurs during a retort process, for example the fan stops turning, the retort operator is instructed to very quickly open the retort and place these partially processed crates into another retort, and complete the process. For example if the scheduled process calls for 60 minutes and the first retort failed at the 40 minute mark, the final 20 minutes are given in the second retort. I explained that the processes were designed to be a continuous thermal process.

We also reviewed some basic thermal bacteriology concepts such as D-value, z-value and F-value. We reviewed how D, z, and F values were all inter-related.

We reviewed a problem that occurred with 603x700 cans of green peas in brine. Apparently, during the cool, the pressure was lost in the retort and the end units buckled. A back-up generator that will provide an immediate source of power in the case of a power outage may help.

We also reviewed a product-related problem with cans of green peas in brine. When the 603x700 cans are opened there was white foam of bubbles on the surface of the brine. This is objectionable to their client. I suggested that the foam was due to proteins released by the peas during processing. Keeping the cans still prior to opening should solve this problem.

Finally, both Waddah and Mokhtar asked for information about the necessary hardware and software necessary to conduct their own thermal processing studies. I told them that I would send them information about dataloggers, thermocouples, and software.

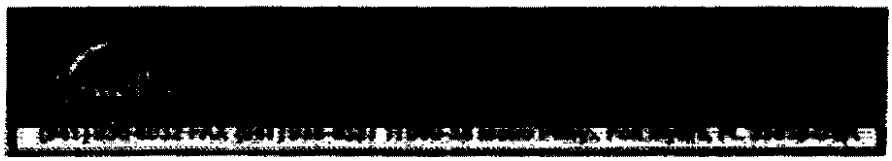
Recommendations:

Temperature distribution tests are required for these retorts. These tests must be conducted with the smallest can size that will be processed in the retort.

The processes need to be based upon scientific heat penetration tests. All the low-acid food products and can sizes should have scientifically based processes.

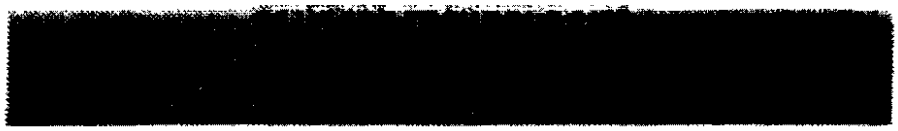
A back-up generator that will provide an immediate source of power in the case of a power outage may help prevent process deviations due to loss of power in the plant.

Here is a source of thermocouples and wires:



Here is a source for dataloggers:

Kaye Instruments of Bedford MA. 617-275-0300.



TechniCAL 250 Plauche St. New Orleans, LA 70123 www.tcal.com

For wireless systems try:

DataTrace http://www.mesalabs.com/

Respectfully submitted,

Thomas J Ragusa
Thermal Process Technology, Inc.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

SECTION I - SCOPE

This code of hygienic practice applies to fruit and vegetable products which are packed in hermetically sealed containers and which are processed by heat either before or after being filled into the containers.

SECTION II - DEFINITIONS

A. *Hermetically sealed* means air-tight.

B. *Container* means any hermetic enclosure for food including, but not limited to, metal, glass or laminated plastics.

C. *Heat processed* means processed by heat to an extent which results in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation.

SECTION III - RAW MATERIAL REQUIREMENTS

A. **Environmental Sanitation in Growing and Food Production Areas**

(1) **Sanitary disposal of human and animal wastes.** Adequate precautions should be taken to insure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygienic hazard, and extreme care should be taken to protect all food products from contamination with these wastes.

(2) **Sanitary quality of irrigation water.** Water used for irrigation should not constitute a public health hazard to the consumer through the product.

(3) **Animal, plant pest and disease control.** Where control measures are undertaken, treatment with chemical, biological or physical agents should be done only in accordance with the recommendations of the appropriate official agency, by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of toxic residues being retained by the crop.

B. **Sanitary Harvesting and Production of Raw Food Materials**

(1) **Equipment and product containers.** Equipment and product containers should not constitute a hazard to health. Containers which are re-used should be of such material and construction as will facilitate thorough cleaning, and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Sanitary techniques.** Harvesting and production operations, methods and procedures should be clean and sanitary.

(3) **Removal of obviously unfit materials**. Unfit products should be segregated during harvesting and production to the fullest extent practicable and should be disposed of in such a place and in such a manner that they cannot result in contamination of the food and water supplies or other crops.

(4) **Protection of product from contamination**. Suitable precautions should be taken to protect the raw product from being contaminated by animals, insects, vermin, birds, chemical or microbiological contaminants or other objectionable substances during handling and storage. The nature of the product and the methods of harvesting will indicate the type and degree of protection required.

C. **Transportation**

(1) **Facilities**. Conveyance for transporting the harvested crop or raw product from the production area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Handling procedures**. All handling procedures should be such as will prevent the product from being contaminated. Extreme care should be taken in transporting perishable products to prevent spoilage or deterioration. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product, it should be of sanitary quality as required in Section IV - A - 2(c).

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. **Plant Construction and Layout**

(1) **Location, size and sanitary design**. The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; should be of sufficient size for the purpose intended without crowding of equipment or personnel; should be of sound construction and kept in good repair; should be of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and should be so designed as to permit easy and adequate cleaning.

(2) **Sanitary facilities and controls**

(a) ***Separation of processes***. Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) ***Water supply***. An ample supply of hot and cold water should be available. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the "International Standards for Drinking Water" World Heath Organization, 1971.

(c) ***Ice***. Ice should be made from water of potable quality and should be manufactured, handled, stored and used, so as to protect it from contamination.

(d) ***Auxiliary water supply***. Where non-potable water is used - for such purposes as fire control -

it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) ***Plumbing and waste disposal*** All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies. The plumbing and the manner of waste disposal should be approved by the official agency having jurisdiction.

(f) ***Removal of solid or semi-solid wastes*** from the product preparation and canning areas should be on a continuous or near continuous basis using water and/or appropriate equipment so that these areas are kept clean and there is no danger of contaminating the product. Also they should be disposed of in a way that they cannot be used for human food. Waste materials should be disposed of in a place and in such a manner that they cannot contaminate food and water supplies and cannot offer harbourages or breeding places for rodents, insects or other vermin.

(g) ***Lighting and ventilation.*** Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, obnoxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fill into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage.

(h) ***Toilet-rooms and facilities.*** Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet-rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(i) ***Hand-washing facilities.*** Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be approved by the official agency having jurisdiction. The facilities should be kept in a sanitary condition at all times.

B. **Equipment and Utensils**

(1) **Materials.** All food contact surfaces should be smooth; free from pits, crevices and loose scale; non toxic; unaffected by food products; and capable of withstanding repeated exposure to normal cleaning; and non-absorbent unless the nature of a particular and otherwise acceptable process renders the use of a surface, such as wood, necessary.

(2) **Sanitary Design, construction and installation.** Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils.** Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products.

C. Hygienic Operating Requirements

While additional and more specific requirements may be established for certain products, the following should apply as minimal in all food production, handling, storage and distribution.

(1) **Sanitary maintenance of plant, facilities and premises**. The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(2) **Vermin control**. Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals**. Dogs, cats and other domestic animals, should be excluded from areas where food is processed or stored.

(4) **Personnel health**. Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms.

(5) **Toxic substances**. All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing including suitable headdress should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) *Acceptance criteria*. The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) *Storage*. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) *Water*. Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting**. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation**. Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing**. Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

(5) **Packaging of finished product**

(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

(b) ***Techniques***. Packaging should be done under conditions that preclude the introduction of contamination into the product.

(6) **Preservation of the finished product**

(a) ***Heat processing***. Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

(b) ***Cooling of processed containers***. Where processed containers are cooled in water, the water should be of potable quality or suitably treated so as not to constitute a public health hazard. If cooling water is recirculated it should be effectively disinfected by chlorine or otherwise before use or each re-use.

(c) ***Decrating and handling of processed containers***. After processing and cooling, containers should be handled n such a manner as to avoid contamination of the product. Rough handling of processed cans, especially while they are still wet, should be avoided. Belts, runways and other processed can-conveying equipment should be maintained in good hygienic condition.

(d) ***Inspection of processing containers***. Containers should be inspected before labelling and casing and defective containers withdrawn.

(7) **Storage and transport of finished product**. The finished product should be stored and transported under such conditions as will preclude the contamination with, or development of pathogenic or toxigenic microorganisms or infestation and protect against deterioration of the product or of the container.

E. Sanitation Control Programme

It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

F. Laboratory Control Procedures

In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of products processed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all foods that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. For certain products it may also be desirable to check the process by incubation of samples.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and analysis or determination to meet the following specifications.

A. To the extent possible in good manufacturing practice the products should be free from objectionable matter.

B. The products should not contain any pathogenic microorganisms or any toxic substance originating from microorganisms.

C. The products should comply with the requirements set forth by the Codex Committees on Pesticide Residues and Food Additives as contained in permitted lists or Codex Commodity Standards.

D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

April 13, 2001

Mr. Ibrahim Ali Ibrahim
Dr. Olivee
Manshiet El-Sadat
Zadazig

Dear Mr. Ibrahim:

On behalf of the ALEB project, we would like to thank you for taking the time to work with Mr. Tom Ragusa when he visited your facility on April 2. His report is attached. As you can see from the report, he is quite concerned that your staff does not appear to understand the basics of thermal processing. In fact, based on what he observed, he would advise against your processing low-acid canned foods. Dr. Olivee staff need to make a commitment to understanding why following a scientific approach to process development and implementation is so vital to assuring public health. By doing so, you are protecting both your business and your reputation. Canning of low-acid foods is much more than putting food in the can, sealing and retorting it. His recommendations include;

1. Improving Plant Sanitation – This has been addressed in past reports, the most recent of which was prepared by Dr. Lopez-Garcia. For example, it is unacceptable to have any animals, including birds in your plant. If you hope to build your export business, sanitation as described in the Codex Guidelines and as we, at ALEB, have talked about in our workshops, will be an important part of that process.

2. Temperature Distribution Studies – These will be required with the new retort system. We would hope that Levati would assist you with this as part of the installation process.

3. Science-Based Thermal Processes – Thermal processes need to be established by a recognized process authority. As part of developing processes, the process authority will set several "critical factors". These will need to be followed to assure safety. Documentation that the processes are being followed will also be required.

We are fully aware that some of your staff feel that meeting "*Egyptian Standards*," will be adequate. We also suspect that they may wonder why we continue to base audits and workshops on American standards and regulations. As you know, our mission is to help you and others increase exports. To do that, processors looking to export need to make an effort to comply with international, not Egyptian standards. We feel that if we can get processors to follow US guidelines, they will be able to meet both the Egyptian and international guidelines. You will find a copy of the "*Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Product*" attached to the report. Section IV, D, 6, entitled Heat Processing, may be seen below;.

Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

This will be the basis for evaluation of Egyptian processors of canned foods involved in international trade in the near future. You need to train your staff and develop the appropriate record-keeping programs to assure compliance with this guideline.

Thank you again for your hospitality. Should you have any questions or require any additional information, please do hesitate to contact us.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: M. Ahmed, Files

April 4, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On Monday April 2, 2001, we visited Dr. Olivee Co. in Zagazig, Manshiet Alsadat. We met with Mr. Ibrahim Ali Ibrahim, general manager, Dr. Attia El. Makhzangy, technical consultant to Dr. Olivee Co., and Assistant Professor of Food Technology, at Zagazig University, in the Institute of Efficient Productivity, and Mr. Essam Abdallah, the quality manager.

You should refer to plant visit reports by other ALEB consultants for a description of this olive processing plant. The plant is situated on a dirt road in a residential area. No GMP's or sanitation guidelines are followed in the plant. Employees are barefoot, there are birds flying in the olive processing area. Women were sitting on the floor in the plant cutting vegetables using a piece of wood as a cutting board. The plant was in need of a thorough cleaning.

I did not spend any significant time talking about their green olive processing since Dr. Olivee has just received a brand new Levati stainless steel 6-crate steam/air retort. They plan on processing California style black olives, which are a low-acid canned food, and fall under 21 CFR part 113. The retort was not yet unpacked during this visit. The new Turkish boiler was in place but none of the burners or any of the controls were installed. The water treatment apparatus for the boiler had not been installed. I did not see a can handling line, filler, or double-seamer but they may have been on the premises. The new air compressor to supply air to the retort was installed.

We discussed the importance of setting up the retort correctly. We discussed the need for temperature distribution studies and for heat penetration studies for each product and can size. I believe that Levati is scheduled to conduct these studies for Dr. Olivee once the retort is up and running. I emphasized the importance of record keeping and gave them a copy of a retort operator's log for their review.

Dr. Olivee is planning on producing black olives in two can sizes. One can size looked like a 603x812 can the other can was not available but was smaller. I was asked for a process time for the large can size. I asked for the fill-in weight,

style, pitted or not, etc. I explained that there was much work involved in determining the process schedule.

I was asked if the retort could be used for processing glass containers. I said that it should handle glass containers well. I reminded them that the closures had to be designed to withstand a pressure process and the need for temperature distribution studies and heat penetration studies. They asked if flexible containers could be processed in the retort. I said they could. However, I told them of the need to have custom-made divider sheets to handle the flexible material. I also told them of the need to conduct temperature distribution and heat penetration studies. I do not know how they plan on filling and sealing flexible or semi-ridge containers in this plant.

It is my opinion that this plant should not processing acidified olives let alone low-acid black olives. I have very serious concerns about this plant producing low-acid canned foods. I do not believe the plant management understands what is involved in canning low-acid foods, and I do not believe the plant personnel have a level of training or education to safely can food.

Recommendations:

Temperature distribution tests are required for this new Levati Steam/Air retort. These tests must be conducted with the smallest can size that will be processed in the retort.

The processes need to be based upon scientific heat penetration tests. All the low-acid food products and can sizes should have scientifically based processes. A system of records and records keeping must be established at this plant.

A good sanitation program needs to be established in the plant along with following good manufacturing practices. The whole plant is in need of a good thorough cleaning and sanitation program.

Respectfully submitted,

Thomas J Ragusa
Thermal Process Technology, Inc.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

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(3) **Removal of obviously unfit materials**. Unfit products should be segregated during harvesting and production to the fullest extent practicable and should be disposed of in such a place and in such a manner that they cannot result in contamination of the food and water supplies or other crops.

(4) **Protection of product from contamination**. Suitable precautions should be taken to protect the raw product from being contaminated by animals, insects, vermin, birds, chemical or microbiological contaminants or other objectionable substances during handling and storage. The nature of the product and the methods of harvesting will indicate the type and degree of protection required.

C. **Transportation**

(1) **Facilities**. Conveyance for transporting the harvested crop or raw product from the production area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Handling procedures**. All handling procedures should be such as will prevent the product from being contaminated. Extreme care should be taken in transporting perishable products to prevent spoilage or deterioration. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product, it should be of sanitary quality as required in Section IV - A - 2(c).

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. **Plant Construction and Layout**

(1) **Location, size and sanitary design**. The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; should be of sufficient size for the purpose intended without crowding of equipment or personnel; should be of sound construction and kept in good repair; should be of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and should be so designed as to permit easy and adequate cleaning.

(2) **Sanitary facilities and controls**

(a) ***Separation of processes***. Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) ***Water supply***. An ample supply of hot and cold water should be available. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the "International Standards for Drinking Water" World Heath Organization, 1971.

(c) ***Ice***. Ice should be made from water of potable quality and should be manufactured, handled, stored and used, so as to protect it from contamination.

(d) ***Auxiliary water supply***. Where non-potable water is used - for such purposes as fire control -

it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) ***Plumbing and waste disposal.*** All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies. The plumbing and the manner of waste disposal should be approved by the official agency having jurisdiction.

(f) ***Removal of solid or semi-solid wastes*** from the product preparation and canning areas should be on a continuous or near continuous basis using water and/or appropriate equipment so that these areas are kept clean and there is no danger of contaminating the product. Also they should be disposed of in a way that they cannot be used for human food. Waste materials should be disposed of in a place and in such a manner that they cannot contaminate food and water supplies and cannot offer harbourages or breeding places for rodents, insects or other vermin.

(g) ***Lighting and ventilation.*** Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, obnoxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fall into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage.

(h) ***Toilet-rooms and facilities.*** Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet-rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(i) ***Hand-washing facilities.*** Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be approved by the official agency having jurisdiction. The facilities should be kept in a sanitary condition at all times.

B. **Equipment and Utensils**

(1) **Materials.** All food contact surfaces should be smooth; free from pits, crevices and loose scale; non toxic; unaffected by food products; and capable of withstanding repeated exposure to normal cleaning; and non-absorbent unless the nature of a particular and otherwise acceptable process renders the use of a surface, such as wood, necessary.

(2) **Sanitary Design, construction and installation.** Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils.** Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products.

95

C. Hygienic Operating Requirements

While additional and more specific requirements may be established for certain products, the following should apply as minimal in all food production, handling, storage and distribution.

(1) **Sanitary maintenance of plant, facilities and premises**. The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(2) **Vermin control**. Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals**. Dogs, cats and other domestic animals, should be excluded from areas where food is processed or stored.

(4) **Personnel health**. Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms.

(5) **Toxic substances**. All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing including suitable headdress should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) ***Acceptance criteria.*** The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) ***Storage.*** Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) ***Water.*** Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting.** Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation.** Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing.** Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

(5) **Packaging of finished product**

(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

(b) ***Techniques***. Packaging should be done under conditions that preclude the introduction of contamination into the product.

(6) **Preservation of the finished product**

(a) ***Heat processing***. Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

(b) ***Cooling of processed containers***. Where processed containers are cooled in water, the water should be of potable quality or suitably treated so as not to constitute a public health hazard. If cooling water is recirculated it should be effectively disinfected by chlorine or otherwise before use or each re-use.

(c) ***Decrating and handling of processed containers***. After processing and cooling, containers should be handled n such a manner as to avoid contamination of the product. Rough handling of processed cans, especially while they are still wet, should be avoided. Belts, runways and other processed can-conveying equipment should be maintained in good hygienic condition.

(d) ***Inspection of processing containers***. Containers should be inspected before labelling and casing and defective containers withdrawn.

(7) **Storage and transport of finished product**. The finished product should be stored and transported under such conditions as will preclude the contamination with, or development of pathogenic or toxigenic microorganisms or infestation and protect against deterioration of the product or of the container.

E. **Sanitation Control Programme**

It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

F. **Laboratory Control Procedures**

In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of products processed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all foods that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. For certain products it may also be desirable to check the process by incubation of samples.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and analysis or determination to meet the following specifications.

A. To the extent possible in good manufacturing practice the products should be free from objectionable matter.

B. The products should not contain any pathogenic microorganisms or any toxic substance originating from microorganisms.

C. The products should comply with the requirements set forth by the Codex Committees on Pesticide Residues and Food Additives as contained in permitted lists or Codex Commodity Standards.

D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

April 13, 2001

TEL 02-570-1615
FAX 02-570-2187 .

Mr. Said Hegazy
Vitrac
Tersa, Toukh
Kalioubia

Dear Mr. Said:

On behalf of the Agriculture Led Export Businesses project (ALEB), we would like to thank you and you colleague, Dr. Abd El-Rahman M. Khalaf Allah for taking the time to visit with Mr. Tom Ragusa during his visit to the plant on April 3. As you will see when you read the enclosed report, Mr. Ragusa was very impressed with your operation. He does have a few recommendations as to how you might improve operations and improve efficiencies, however. He also offers several ideas as to why your strawberry jam may be darkening during storage.

1. Use of Ultraviolet Light on Caps – I concur with Mr. Ragusa's assessment on the value, or lack thereof, of ultraviolet light (UV) as a tool for sanitizing closures. Hot filling, inversion and hot water pasteurization are the usual mode for assuring that lids are sanitized. Since this unit is only on one line, it may be useful to "tag" containers from this and other lines, and to conduct a study to see if there is any difference in the rate of spoilage.

2. Pest Control – While Mr. Ragusa was at the plant, your staff or the agent that you have hired for pest management was spraying for insects. Mr. Ragusa observed a "*blue haze*" of pesticide floating into the plant as a result of this operation. This is an unacceptable practice. Your equipment and all the products being manufactured at that time could have been contaminated. Most spraying is done at night or on "*off-days*" to minimize the potential for contamination, and to allow the operator to wash down his equipment prior to startup in the event that there is any residual pesticide. We strongly suggest that you adopt this practice.

3. Strawberry Jam Color – As noted above, Mr. Ragusa offers several suggestions for controlling color degradation over time in your strawberry jam. We also posed the question to Mr. Rod Frost, who has visited your factory. He sent us an email with his thoughts, which are incorporated into Mr. Ragusa's report. You may want to consider reducing the length of the process for the product as excess temperature is one of the factors that will compromise color. We would suggest doing test batches where you vary factors such as the length of the time in the pasteurizer and initial vacuum. In fact, one of Mr. Ragusa's recommendations is that you reduce the processes on your jams. Controlling pH and solids, and assuring that you

are getting good vacuums should be adequate to assure a stable finished product. It may also reduce energy consumption, which would result in a cost savings.

We are also very pleased to learn that our workshops on HACCP and sanitation have been of help to you in upgrading your sanitation programs and developing HACCP. If you would like, we are willing to visit to review your HACCP plans upon their completion to assure that you have addressed all significant hazards.

Thank you again for your time. Should you have any questions, or require any additional information, please do not hesitate to contact Eng. Morad Ahmed or myself.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: M. Ahmed, Files

April 6, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On April 3, 2001, we visited Vitrac, a Jam and Juice processor located in Tersa, Toukh, Qalyobia. We met with Dr. Abd El-Rahman M. Khalaf Allah professor in Food Science at Cairo University and Mr. Said Hegazy the research and lab manger.

The plant was running normal production during this visit. The outside of the plant is very well maintained. The inside of the plant was also in very good condition. We had a quite tour of the plant. Vitrac makes about 12 types of jams and 11 types of juices. They pack product glass, plastic, small portion pack, and foil pouches.

Vitrac personnel have taken both a HACCP and sanitation course through ALEB. They are 95% completed on their HACCP document.

We briefly reviewed their juice and jam processing. On one glass line, an ultraviolet light is used on the closures prior to the capping operation. I do not believe the UV light is useful in this application to kill microorganisms present on the closure. Sterilization of the closure occurs after hot filling and subsequent bottle tilt/inversion or hot water pasteurization. After hot filling (85-90°C) all lines have a continuous live steam pasteurization step and cooling step. The pasteurization time is about 15-20 minutes. The product pH ranges from 3.5 to 4.0 for juices lower for jams. Hot filling and a 3-minute hold should be more than adequate to safely pasteurize these products

Strawberry Jam

The plant had a question about the color of their strawberry jam that tends to darken on storage. I suggested that vacuum was critical and suggested that they conduct an analysis of the head space gas. Traces of oxygen in the headspace will react with the product on storage. I also suggested they have the product analyzed for iron.

After hot-filling the product is pasteurized for about 15-20 minutes in flowing steam. If the temperature of the finished product in the jar immediately after filling is 190°F or higher, the soluble solids of the strawberry jam is 65% or higher, and the pH value of the jam is 3.4 or lower, a sterile package is normally obtained without further processing. The additional heating in the pasteurizer is not helping the color of the jam.

Here are some thoughts by Mr. Rod Frost;

"Strawberries picked for jam are usually picked without stems, thus allowing oxidation and mold to start immediately. The temperature of the fruit in the fields is critical, it should be cooled and out of the sun ASAP. Sorting, washing and freezing are done at night. Quick freezing at minus 40°F is good. We used a cap of sugar-ascorbic acid and corn syrup to help retard oxidation in storage. Thawing at cool temperatures is helpful. I believe Vitrac has vacuum pans, which help if they are used properly. Final cook to high temperature should be as brief as possible with spray cooling immediate. "

We have discussed the importance of 100 percent coverage in cooling tunnels - water must be at least 30 degrees cooler than product for good heat transfer. Egypt temperature of 100°F will cause color change. Warehouse stacking in un-insulated rooms can result in temperatures of 130°F or higher on top layers. Vacuum readings of 21 inches or lower will result in darkening due to oxidation. You will remember my hounding everyone on the importance of headspace control and dry steam at the capper. Strawberry color and flavor are very fragile and require very careful processing to maintain their light color and distinctive flavor.

They might also examine the color of the sugars used, make up syrups and compare with water. They could be adding color without knowing it. If they are using a puree for their products, and not whole fruit, they could be too dark to begin with due to browning reactions."

Orange Marmalade

Another question from the plant was with regards to syneresis of Orange Marmalade. Where there is the proper amount of acid, pectin, sugar and water (fruit) present and gelation occurs, precipitates in the form of a fine network of interlacing fibers occur. The more pectin that is present, the more dense are the interlacing pectin fibers giving greater firmness rigidity, and elasticity to the marmalade. Within the structures of these interlacing fibers, the syrup is held and circulates freely somewhat like the water in the tubes of an automobile radiator. The marmalade will manifest syneresis when cut or otherwise disturbed, for the fiber structure has then been partially or almost completely destroyed, permitting some of the syrup held to run out. When there is an insufficient amount of any one of the four ingredients entering into a pectin gel

system, the pectin gel does not form perfectly or fails to jellify completely. It is important not to disturb marmalade while the setting process is taking place, otherwise the continuous network of fibers will be destroyed and the jelly strength and texture maybe impaired.

Recommendations:

One item that needs improvement is the area of pest control. During our visit, fumigation for insects was underway. This work was being conducted on the outside of the plant, however, a blue haze was observed moving inside the plant. This is not good for the health of the workers or the quality of the food being processed.

The plant, I believe is over-processing their products. As long as the product pH and solids are under control they can reduce or eliminate the pasteurizer after hot filling.

In conclusion, I appreciate the warm hospitality that was shown to me and I believe that the visit was worthwhile for both Vitrac and for me. I look forward to working with the plant in the future.

Best regards,

Thomas J Ragusa
Thermal Process Technology, Inc.

April 13, 2001

Eng. Zeinab Ebada El Kashef
Edfina
El Ras El Souda
Alexandria

Dear Eng. Zeinab:

On behalf of the Agriculture Led Export Businesses project (ALEB), we would like to thank you and Eng. Ibrahim Moustafa for taking the time to work with Mr. Tom Ragusa and Eng. Morad Ahmed during their April 5 visit. From the discussions that we had and his report (copy attached), he had mixed feelings about the operation. He was quite impressed with your openness and willingness to talk about problems and learn, but expressed concerns about the lack of sanitation throughout the factory. Mr. Ragusa's recommendations are summarized in his report.

Since Edfina has an FCE number from FDA, and you have already imported product to the United States, you are ahead of most operations here in Egypt. As a licensed processor, however, the United States Food and Drug Administration may decide to conduct an inspection at some time. To do so, they would need to coordinate with the government of Egypt. To assure that you are compliant with FDA regulations and the Codex Alimentarius guidelines, an effort should be made to;

- Improve sanitation
- Install proper mercury-in-glass thermometers
- Obtain ink for the controllers and be sure that they are working, and used properly.
- Install bleeders on the retorts
- Begin monitoring and recording initial temperatures on cans
- Establish a time for venting
- Conduct temperature distribution studies on the retorts.
- Upgrade recordkeeping procedures

If I am not mistaken, Edfina has had several persons attend the Better Process Control Schools that at ALEB offered in 2000 and 2001. Perhaps they can apply what was taught at these schools to upgrading your systems. We encourage you to make these changes in the spirit of protecting the public health, building your business and assuring compliance with international regulations governing the production of low-acid foods. Also, if the Food & Drug Administration made an inspection with the operation in its present state, product from the facility would be embargoed due to the deficiencies noted above.

We are fully aware that your people are doing a good job in that the product being manufactured at Edfina is meeting "*Egyptian Standards*," and also understand that you and others may wonder why we continue to base audits and workshops on American standards and regulations. As you know, our mission is to help you and others increase exports. To do that, processors need to make an effort to comply

with international, not Egyptian standards. We feel that if we can get processors to follow US guidelines, they will be able to meet both the Egyptian and international guidelines. You will find a copy of the "*Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Products*" attached to the report. Please note Section IV, D, 6, entitled Heat Processing. This will be the basis for evaluation of Egyptian processors involved in international trade in the near future.

Finally, we were pleased that Mr. Ragusa was able to help you with your process filing forms, and even more pleased that the documents were accessible. Access to records is something that our FDA and potential buyers believe is important. Please keep us posted on progress in this area.

Thank you again for your time. Should you have any questions or require any additional information, please feel free to contact Eng. Morad Ahmed or myself.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: M. Ahmed, Files

April 12, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On Thursday April 5, 2001, we visited the Edfina Company for Preserved Foods in El Ras Elsoda Alexandria. We met with Eng. Zinab Ebada El Kashef; she is the Head of Research Development and Quality Control Sector and Eng. Ibrahim Moustafa the R & D Quality Control Manager. Mr. Mourad Ahmed from ALEB was also present at this meeting. I thought the meeting was well worthwhile. I enjoyed the folks in the plant. They were very cordial and answered my questions.

This is a huge food manufacturing plant. This plant employs numerous types of food processing equipment and technologies from juice processing to tomato processing to low-acid canned foods. It was interesting to see all these technologies under one roof.

The plant uses an array of different packaging. These include foil pouches, metal cans, (self-manufacturer), glass jars, glass bottles, and portion pack plastic.

The outside of the buildings had all kinds of vegetation growing next to the plant buildings. Doors were wide open and no screens were seen. The plant was dirty. There was rubbish scattered throughout the plant. In short, the plant was in need of a good cleaning. No sanitation or GMP's are followed in this plant. Employees were smoking in the food handling/processing area. They were drinking water from factory finished cans. Birds were flying all over the food product lines.

Apparently, the Edfina plant has exported products to the US. It was my understanding that the Fava Beans in Brine was detained at customs because they had failed to register their plant and had no process filing. The plant subsequently filed both FDA form 2541 (plant registration) and FDA form 2541a (process filing). The plant could not find their FCE number during this visit.

I reviewed their process filings. There were numerous problems with them and I am surprised that the FDA did not return the filings for corrections. The NFPA

bulletin 26-L was listed as the source of the process. However, 26-L does not list processes for can sizes or products listed on the process filing. The products with process filings include Eggplant with Tahina, Fava Beans in Tomato Sauce, Chickpeas with Tahina, Fava and ChickPeas in brine, Fava beans in chili in brine. The can size listed on the process filing forms was 203x410.

The process times listed were extremely long. The filing form listed process times of 180 minutes at 240°F with an initial temperature of 170°F. For comparison purposes, I converted our pet food data (conduction heating product) that we have in our database (over 150 tests) to the 203x410 can size and the longest calculated process time was 65 minutes at a temperature of 240°F and I.T. of 170°F.

We took a tour of the plant. They were processing beans in brine during this visit. The beans were processed in one of 6 three-crate horizontal retorts. The retorts had Taylor controllers. The recording thermometers were not working. The plant needs a source of ink for the recorders. The charts that I saw had multiple curves on them representing different days. I suggested that after they obtain ink, the charts should be changed every day. No fill-in weights were being measured.

The retorts were equipped with mercury-in-glass thermometers, however, some of these were quite small and I do not know how the retort operator was able to observe the temperature. The retorts are vented to a temperature of 232°F, with no time requirement. No bleeders were found on these retorts.

We also visited a glass filling juice line. This was a relatively new line; however, the capper was not working so the 38-mm closures were being applied by hand. I mentioned that the closures were designed to be applied by a capper that has a steam device to warm the Plastisol prior to application. I warned of the possibility of low-vacuum bottles when the closures are applied by hand. I suggested that the closures should be held in hot water to help soften the Plastisol prior to hand application.

When we returned to the office we filled out a new process filing form and we discussed what data is required in the different parts of the form. We discussed the need for scientifically designed thermal processes and vent schedules.

Recommendations:

The retort temperature recorders need ink and should be calibrated. The thermometers should be replaced with calibrated ones that meet the FDA regulations for length (17°F/inch) and readability (1°F).

Temperature distribution tests are required for these retorts. These tests must be conducted with the smallest can size that will be processed in the retort.

Bleeders must be installed in these steam retorts. Bleeders are used to help circulate the steam in the retort. Without circulation, cold spots may occur in the retort, which may result in underprocessing.

The processes need to be based upon scientific heat penetration tests. All the low-acid food products and can sizes should have scientifically based processes. Fill-in weights must be measured with an accurate scale. A system of records and records keeping must be established at this plant. By having scientifically based thermal processes, the plant will save money by having shorter process times, which will allow for increased production and increase product quality.

The vegetation around the plant should be removed. Screens must be installed. The birds must be eliminated. Employee training must be implemented.

A good sanitation program needs to be established in the plant along with following good manufacturing practices. The whole plant is in need of a good thorough cleaning and sanitation program.

Respectfully submitted,

Thomas J Ragusa
Thermal Process Technology, Inc.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR CANNED FRUIT AND VEGETABLE PRODUCTS (CAC/RCP 2-1969)

SECTION I - SCOPE

This code of hygienic practice applies to fruit and vegetable products which are packed in hermetically sealed containers and which are processed by heat either before or after being filled into the containers.

SECTION II - DEFINITIONS

A. ***Hermetically sealed*** means air-tight.

B. ***Container*** means any hermetic enclosure for food including, but not limited to, metal, glass or laminated plastics.

C. ***Heat processed*** means processed by heat to an extent which results in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation.

SECTION III - RAW MATERIAL REQUIREMENTS

A. **Environmental Sanitation in Growing and Food Production Areas**

(1) **Sanitary disposal of human and animal wastes.** Adequate precautions should be taken to insure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygienic hazard, and extreme care should be taken to protect all food products from contamination with these wastes.

(2) **Sanitary quality of irrigation water.** Water used for irrigation should not constitute a public health hazard to the consumer through the product.

(3) **Animal, plant pest and disease control.** Where control measures are undertaken, treatment with chemical, biological or physical agents should be done only in accordance with the recommendations of the appropriate official agency, by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of toxic residues being retained by the crop.

B. **Sanitary Harvesting and Production of Raw Food Materials**

(1) **Equipment and product containers.** Equipment and product containers should not constitute a hazard to health. Containers which are re-used should be of such material and construction as will facilitate thorough cleaning, and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Sanitary techniques.** Harvesting and production operations, methods and procedures should be clean and sanitary.

(3) **Removal of obviously unfit materials.** Unfit products should be segregated during harvesting and production to the fullest extent practicable and should be disposed of in such a place and in such a manner that they cannot result in contamination of the food and water supplies or other crops.

(4) **Protection of product from contamination.** Suitable precautions should be taken to protect the raw product from being contaminated by animals, insects, vermin, birds, chemical or microbiological contaminants or other objectionable substances during handling and storage. The nature of the product and the methods of harvesting will indicate the type and degree of protection required.

C. **Transportation**

(1) **Facilities.** Conveyance for transporting the harvested crop or raw product from the production area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(2) **Handling procedures.** All handling procedures should be such as will prevent the product from being contaminated. Extreme care should be taken in transporting perishable products to prevent spoilage or deterioration. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product, it should be of sanitary quality as required in Section IV - A - 2(c).

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. **Plant Construction and Layout**

(1) **Location, size and sanitary design.** The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; should be of sufficient size for the purpose intended without crowding of equipment or personnel; should be of sound construction and kept in good repair; should be of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and should be so designed as to permit easy and adequate cleaning.

(2) **Sanitary facilities and controls**

(a) ***Separation of processes.*** Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) ***Water supply.*** An ample supply of hot and cold water should be available. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the "International Standards for Drinking Water" World Heath Organization, 1971.

(c) ***Ice.*** Ice should be made from water of potable quality and should be manufactured, handled, stored and used, so as to protect it from contamination.

(d) ***Auxiliary water supply.*** Where non-potable water is used - for such purposes as fire control -

it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) ***Plumbing and waste disposal.*** All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies. The plumbing and the manner of waste disposal should be approved by the official agency having jurisdiction.

(f) ***Removal of solid or semi-solid wastes*** from the product preparation and canning areas should be on a continuous or near continuous basis using water and/or appropriate equipment so that these areas are kept clean and there is no danger of contaminating the product. Also they should be disposed of in a way that they cannot be used for human food. Waste materials should be disposed of in a place and in such a manner that they cannot contaminate food and water supplies and cannot offer harbourages or breeding places for rodents, insects or other vermin.

(g) ***Lighting and ventilation.*** Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, obnoxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fill into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage.

(h) ***Toilet-rooms and facilities.*** Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet-rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(i) ***Hand-washing facilities.*** Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be approved by the official agency having jurisdiction. The facilities should be kept in a sanitary condition at all times.

B. **Equipment and Utensils**

(1) **Materials.** All food contact surfaces should be smooth; free from pits, crevices and loose scale; non toxic; unaffected by food products; and capable of withstanding repeated exposure to normal cleaning; and non-absorbent unless the nature of a particular and otherwise acceptable process renders the use of a surface, such as wood, necessary.

(2) **Sanitary Design, construction and installation.** Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils.** Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products.

C. Hygienic Operating Requirements

While additional and more specific requirements may be established for certain products, the following should apply as minimal in all food production, handling, storage and distribution.

(1) **Sanitary maintenance of plant, facilities and premises.** The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(2) **Vermin control.** Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals.** Dogs, cats and other domestic animals, should be excluded from areas where food is processed or stored.

(4) **Personnel health.** Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms.

(5) **Toxic substances.** All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing including suitable headdress should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating and the use of tobacco or chewing gum should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food.

(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. **Operating Practices and Production Requirements**

(1) **Raw material handling**

(a) ***Acceptance criteria***. The raw material should not be accepted by the plant if known to contain decomposed, toxic or extraneous substances which will not be removed to acceptable levels by normal plant procedures of sorting or preparation.

(b) ***Storage***. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration.

(c) ***Water***. Water used for conveying raw material into the plant should be from a source or suitably treated as not to constitute a public health hazard and should be used only by permission of the official agency having jurisdiction.

(2) **Inspection and sorting**. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials should be used in further processing.

(3) **Washing or other preparation**. Raw materials should be washed as needed to remove soil or other contamination. Water used for such purposes should not be recirculated unless suitably treated to maintain it in a condition as will not constitute a public health hazard. Water used for washing, rinsing, or conveying final food products should be of potable quality.

(4) **Preparation and processing**. Preparatory operations leading to the finished product and the packaging operations should be so timed as to permit expeditious handling of consecutive units in production under conditions which would prevent contamination, deterioration, spoilage, or the

development of infectious or toxigenic microorganisms.

(5) **Packaging of finished product**

(a) ***Materials***. Packaging materials should be stored in a clean and sanitary manner and should not transmit to the product objectionable substances beyond limits acceptable to the official agency having jurisdiction and should provide appropriate protection from contamination.

(b) ***Techniques***. Packaging should be done under conditions that preclude the introduction of contamination into the product.

(6) **Preservation of the finished product**

(a) ***Heat processing***. Products packaged in hermetically sealed containers should be so processed by heat as to result in a product that is safe and will not spoil under normally expected temperatures of non-refrigerated storage and transportation. Processing conditions for specific formulations of canned foods should be based on the recommendation of technical specialists competent in canning technology. Such processing should be supervised in the cannery by technically competent personnel and be subject to check by the official agency having jurisdiction. Processing records adequate to identify the processing history should be kept and made available for inspection.

(b) ***Cooling of processed containers***. Where processed containers are cooled in water, the water should be of potable quality or suitably treated so as not to constitute a public health hazard. If cooling water is recirculated it should be effectively disinfected by chlorine or otherwise before use or each re-use.

(c) ***Decrating and handling of processed containers***. After processing and cooling, containers should be handled n such a manner as to avoid contamination of the product. Rough handling of processed cans, especially while they are still wet, should be avoided. Belts, runways and other processed can-conveying equipment should be maintained in good hygienic condition.

(d) ***Inspection of processing containers***. Containers should be inspected before labelling and casing and defective containers withdrawn.

(7) **Storage and transport of finished product**. The finished product should be stored and transported under such conditions as will preclude the contamination with, or development of pathogenic or toxigenic microorganisms or infestation and protect against deterioration of the product or of the container.

E. **Sanitation Control Programme**

It is desirable that each plant in its own interest designates a single individual, whose duties are preferably divorced from production, to be held responsible for the cleanliness of the plant. His staff should be a permanent part of the organization and should be well trained in the use of special cleaning tools, methods of disassembling equipment for cleaning, and in the significance of contamination and the hazards involved. Critical areas, equipment and materials should be designated for specific attention as part of a permanent sanitation schedule.

F. **Laboratory Control Procedures**

In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of products processed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all foods that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. For certain products it may also be desirable to check the process by incubation of samples.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and analysis or determination to meet the following specifications.

A. To the extent possible in good manufacturing practice the products should be free from objectionable matter.

B. The products should not contain any pathogenic microorganisms or any toxic substance originating from microorganisms.

C. The products should comply with the requirements set forth by the Codex Committees on Pesticide Residues and Food Additives as contained in permitted lists or Codex Commodity Standards.

D. Products with an equilibrium pH above 4.5 should have received a processing treatment sufficient to destroy all spores of *Clostridium botulinum*, unless growth of surviving spores would be permanently prevented by product characteristics other than pH.

April 15, 2001

Eng. Nabeel M. Ibrahim
Egyptian Dairy & Foodstuff Company (Viva)
3rd Industrial Zone
10th of Ramadan City

Dear Eng. Nabeel:

We would like to thank you and your colleagues for taking the time to visit with Mr. Tom Ragusa when he visited with on April 4. As you will see when you read through his trip report, he was impressed with your whole operation. In fact, when he got back that day, he said that your plant was one of the nicest facilities that he had *ever* visited. He really had no recommendations to make. In fact, the only recommendation that we have made in two visits our consultants have made is that you formalize a pest management program.

His report does contain several pieces of information that you requested.

- Tables for Batch Pasteurization of Milk Products
- Tables for High Temperature, Short Time Pasteurization of Milk (HTST))Products
- Tables with Calculated Hold Times for Ultra High Temperature (UHT) Pasteurization

Mr. Ragusa will try also and find some information on processing water buffalo milk and on level indicators. One possible source for information on the level indicators would be an organization called the 3-A Symbol Council. They can be reached in the United States by telephone at (319) 286-9221, by fax at (319) 286-9290 or you can look at their website at www.3-a.org/asouncil. Another source would be the European Hygienic Equipment Design Group. Their website is ww.ehedg.org. Log onto the websites of either of the organizations, find the contact icon and ask whether they have a list of equipment suppliers who can provide you with the type of sanitary equipment you want. We would also recommend that someone at Viva join an organization called the International Association for Food protection. The organization prints two journals which we believe that you will find extremely useful.

Thank you again for your hospitality, and should you have any questions, or require any additional information, please do not hesitate to contact us.

Sincerely yours,

Richard F. Stier
Director, Technical Services

cc: Files, M. Ahmed

April 14, 2001

Mr. Rick Stier
Agriculture-Led Export Businesses
12 Dokki Street, 6th Floor
Suites 601 & 602
Dokki, Cairo, Egypt

Plant Visit Report

Dear Rick:

On April 4, 2001, we visited the Egyptian Dairy & Foodstuff Co. that manufactures the Viva! Brand milk and juice products. We visited the company factory in 10th of Ramadan City. We met with Eng. Nabeel M. Ibrahim the production manager, Mr. Sherif A. Mohammed, the quality control manager, Mr. Mohamed Abu Alla, the technical manager, and Mr. Hussein Dawood, the export manager.

The plant was running normal production during this visit. The outside of the plant is very well maintained. In fact, the plant maintains a beautiful garden within the factory property. The inside of the plant was also in very good condition. We had a tour of the plant with Mr. Ibrahim. The report by ALEB consultant Dr. Kathleen Feicht gives a very good description of the plant unit operations and products produced at the plant.

The plant uses two UHT heaters. A direct heater and a double tube heat exchanger. The heat exchanger uses a regenerator. There is a 3 bar differential between the sterile/non-sterile side of the regenerator. The direct heater line uses a vacuum pan cooler to remove the water added in the direct heating. The quality control lab monitors the quality of the boiler water that is used for direct heating. The processing system is all computer controlled.

The sterilization process used for the milks is 137°C for 4 seconds.

There are 5 state of the art TetraPak fillers in a separate filling room. The air in the room is filtered. The operators are required to take notes during the production run and enter their comments in a log. They also take samples of filled packages at least every 7 minutes. The management has added icons to the log that help the operator with identifying what data is required. This is a great idea.

In the quality control lab, I had an opportunity to sample several UHT juices and milk. This lab is a very busy place. This lab conducts all the incoming milk and other raw material tests. It conducts all the finished product tests, boiler water tests, microbiological tests, shelf life determination, and CIP solution tests. The lab calibrates all lab equipment every day.

We were asked about a procedure for calibrating the thermocouples used in the plant. Both Mr. Nabeel Ibrahim and Mr. Mohamed Abu Alla asked this question. I suggested that they use a constant temperature oil bath and a certified mercury-in-glass thermometer.

Mr. Hussein Dawood, the export manager wants to export to the US. He wanted information about FDA nutrition labeling regulations. I told him to go to the FDA website at www.fda.gov for the information.

Mr. Dawood also asked about shelf life of these TetraPak containers. Currently, the shelf life of Viva milks is 6 months, but his distributor in the US says the shelf life is 9 months and wants Viva brand milks to have a 9-month shelf life.

Viva should confirm what materials the US plants are using. As far as I know, Tetra sells both a plastic laminate material and a foil/plastic laminate. The foil material will protect the product better than simply the plastic laminate material. Also the temperature of storage is a factor. The greater the storage temperature, the shorter the shelf life.

This same question about shelf life was mentioned with respect to juices. Again the US distributor wants an 18-month shelf life, but at the current time, juices produced at Viva have a 12-month shelf life. Obviously, some juices have longer shelf lives than others do. For example, apple juice shelf life will have a longer shelf life than orange juice, all things being equal. Again Viva may want to start using foil type laminates. Storage temperatures also play a part in shelf life of juices.

Mr. Dawood also questioned how his competitors could price their mango juice product less than Viva. He wondered if the competitors were diluting the mango juice with other types of juices like apple juice. I suggested that they obtain competitive samples and send them to a laboratory for product analysis. I suggested he contact Silliker Laboratory (www.silliker.com) in the US for that type of work.

Mr. Nabeel asked for the pasteurization temperatures for fresh milk and UHT milk and the types of cream milk (% fat) products that are marketed. Here is a table with that information.

Batch Pasteurization	
Milk	145°F for 30 minutes
Cream	150°F for 30 minutes
Ice cream mix	155°F for 30 minutes

HTST Pasteurization	
Milk	160°F for 15 seconds
Cream	166°F for 15 seconds
Ice cream mix	175°F for 25 seconds

UHT Pasteurization: Calculated, not measured, holding times; applied equally for all fluid products (milk, chocolate or low fat milk, creams, and ice cream mix)

Temperature (F)	Time (second[s])
191	1.00
194	0.50
201	0.10
204	0.05
212	0.01

Cream is the sweet, fatty liquid separated from milk with or without the addition of milk or skim milk and contains not less than 18% milkfat. The common cream products are:

a. Light (coffee or table) cream contains not less than 18% but less than 30% milkfat.
b. Whipping cream contains not less than 30% milkfat.
c. Half-and-Half contains not less than 10.5% milkfat.

Mr. Nabeel also asked about processing buffalo milk. At first, I thought he was talking about American buffalo, and I told him, that in the US we do not used these animals for milk. It wasn't until we were driving back to the ALEB office when I saw an Egyptian water buffalo and I realized that was the animal he was talking about. Apparently, this animal produces milk with about a 6% butterfat content. When this milk is processed, the fat separates and the milk thickens. This phenomenon occurs in about a week. He asked if I could help with information about processing this product. This is really beyond my area of expertise, but I told him I would contact some scientists at Kraft Foods and try to find a solution.

Mr. Nabeel also asked for information about a liquid level indicator that could be used in the milk tanks. I told him I would have to get back to him on that question also.

In conclusion, I appreciate the warm hospitality that was shown to me and I believe that the visit was worthwhile for both Viva and for me. I look forward to working with the plant in the future.

Best regards,

Thomas J Ragusa
Thermal Process Technology, Inc.