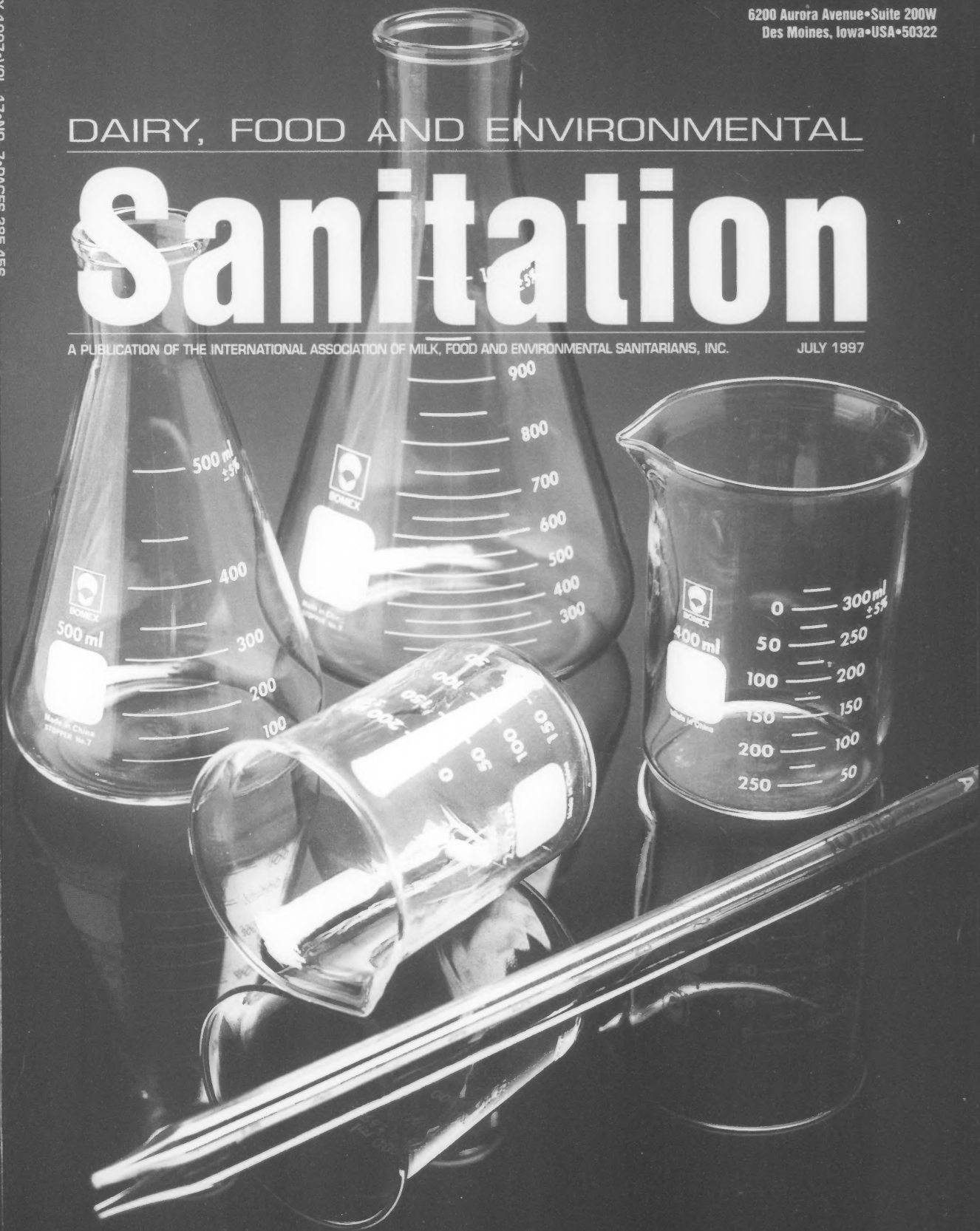


DAIRY, FOOD AND ENVIRONMENTAL

# Sanitation

A PUBLICATION OF THE INTERNATIONAL ASSOCIATION OF MILK, FOOD AND ENVIRONMENTAL SANITARIANS, INC.

JULY 1997



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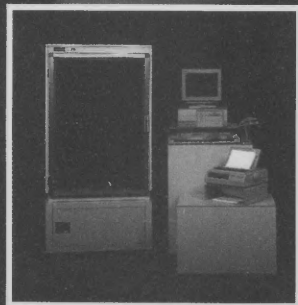
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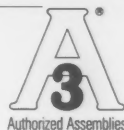
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*Second, Third, fourth, part of a four-part series*

### Editor's Note:

The following is a correction from the article "Salmonella and Cantaloupes," on pages 284 to 286, in the May issue of *Dairy, Food and Environmental Sanitation*. The article was reprinted from *The National Food Safety Database*, on the World Wide Web, and the author was incorrectly identified as Mark Tamplin of the University of Florida. The original author of the article is Tom Schwartz of the United States Food and Drug Administration.

In addition, several of the codes cited in the article have been changed or revised. The latest code citations will appear in the August issue of *Dairy, Food and Environmental Sanitation*.

We apologize for the error.

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**Dairy, Food and Environmental Sanitation** (ISSN-1043-3546) is published monthly beginning with the January number by the International Association of Milk, Food and Environmental Sanitarians, Inc. 6200 Aurora Avenue, Suite 200W, Des Moines, IA 50322-2863, USA. Each volume comprises 12 numbers. Printed by Heuss Printing, Inc., 911 N. Second Street, Ames, IA 50010, USA. Periodical Postage paid at Des Moines, IA 50318 and additional entry offices.

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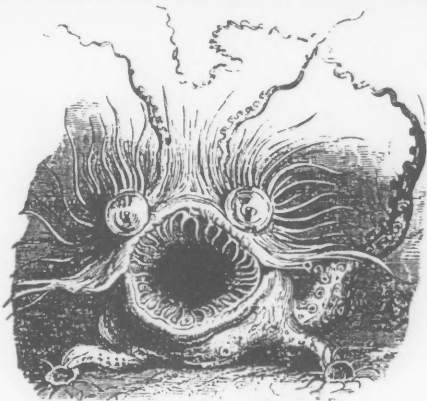
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# COMMENTS

## FROM YOUR PRESIDENT



By GALE PRINCE  
IAMFES President

### “What does the Association mean to you?”

Since this is my first column, let me introduce myself. I started my career in food safety in 1967. I was working for another retail food store chain at the time and received an assignment from the President of the firm to develop a sanitation

program for retail food stores. After surveying the industry to find out what other firms were doing, I found myself a pioneer in the retail food store industry with the responsibility for sanitation. Almost immediately, a member of IAMFES became a mentor and introduced me to the Association. I joined shortly thereafter and attended my first Annual Meeting in 1968 in St. Louis.

I was made to feel very welcome and found the Meeting very educational. One thing that I noted early on about the Association was the willingness of the membership to share knowledge for the benefit of the consumer.

My job, just as yours, has changed in many ways over the years from basic sanitation to more complex food safety challenges of the retail food store operations, distribution, transportation, and food manufacturing. College provides us with a basic education but in a rapidly changing world your professional organization gives a member the opportunity to continue to grow intellectually.

IAMFES has been very helpful to me over the past 29 years by providing me with the latest scientific information on food safety. In addition, it has provided an opportunity to make many new professional friends. The IAMFES publications also provide state-of-the-art scientific information that is beneficial to my job.

The Annual Meetings provide an opportunity to socialize with the leading food safety experts in the world. Many times the information shared in the hallways between sessions may have application in tomorrow's proactive food safety

program or may be the answer to last week's food safety challenge. It is certainly heartwarming to see the contributions from the young developing scientists. Their new perspective makes one look at traditional foods in a different way to ensure product safety.

The changes I have seen in the exhibits over the years have been remarkable. The exhibits provide an opportunity to look at and compare products and services in a way that may not be possible in your laboratory or plant.

You cannot forget the family side of the organization. Each year the Annual Meeting includes activities for families as many attendees plan vacations around the Meeting. They have become a part of the international IAMFES family which is what makes this Association so SPECIAL!

An organization is more than just letters, an acronym, or a name. The heart of an association is members working together for a common cause. I look at IAMFES membership being made up of individuals who are world-renowned professionals in food safety. Each of our members is doing something to contribute to food safety in some way. In the coming year, I would like to investigate how IAMFES can better serve the needs of the membership. What do you expect from your Association? What does the Association mean to you? As your President, I need your help and ideas in leading the organization to fulfill your needs as a member. You can contact me via Phone 513.762.4209; Fax 513.762.4372 or E-mail: gprince@kroger.com.



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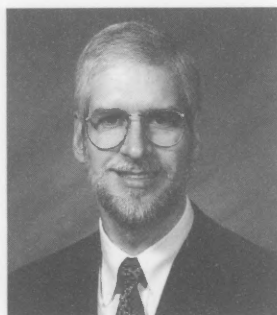
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# COMMENTARY

## FROM THE EXECUTIVE DIRECTOR



By DAVID W. THARP  
IAMFES Executive Director

**“As we progress  
as an association,  
we must make  
changes”**

It is hard to believe that as I write this column, our Annual Meeting is just two weeks away. By the time you read this, the 84th IAMFES Annual Meeting will be history. Incredible is what I'm thinking because time has gone so fast through all of our planning. Incredible, because the Meeting will be completed when you read this. All the many hours and effort by so many people will have come together to benefit our attendees with what we feel is the

best educational conference for people interested in protecting the food supply!

With the completion of the Annual Meeting and accompanying Committee and Board meetings, there will certainly be suggestions and recommendations for changes. At this point in time, I don't know what the changes will be, but as we progress as an association, we must make changes to improve our operations and to adapt to new opportunities.

Change strikes people in many ways. Some people are afraid of change – afraid of how it will affect them. “Will it affect my security?” they may ask. Others embrace change – even if they don't like change, they accept and support change as it occurs. These people may ask, “What part can I play to help with the change?” Where do you fall? Do you like change? Do you adapt to change well? Or, do you fall somewhere in between?

Myself, I like change. Think of how many things may never have occurred if change did not take place. Some easy ones to identify are automobiles, air travel, office technology, computers, television, food safety; the list could be endless. If we continue to do things as we always have, we will be left behind. New technology creates new competition. We must always look ahead, learn from what we have accomplished (and of course learn from our mistakes), build upon this experience, and prepare for the future. The Executive Board and IAMFES staff are working together to assure a strong future for IAMFES. Through this process, you may notice some changes. Bear with us as we institute this change – embrace it! Become involved! Help us to help make the changes that will make IAMFES strong for the future!

Speaking of changes, there were a couple of new items that debuted at this past Annual Meeting. One was a new look to our exhibit booth. We have extensively re-worked the appearance of the display to be “an eye-catcher” and to promote a fresh look for IAMFES. Watch for IAMFES at future food conferences and shows. Stop by our booth and say hello. Let us know if you are a Member (otherwise we'll ask you to join!) and give us your comments on your impression of the IAMFES display. Your comments will help us to improve next time we “change” our display.

The second item is our “Guide to Food Safety in the Home.” This is a pamphlet that was written by the Food Sanitation Professional Development Group and is intended for distribution by county, state and national governmental agencies. The pamphlet describes how to prepare prior to a disaster and gives guidelines on how to determine if food and water is safe for consumption after a disaster has struck. This will be a very beneficial pamphlet for consumers and emergency assistance agencies. Be sure to call our office if you are interested in this new material or see the order form in the back of this issue of *DFES*.

To wrap things up for this month, bear in mind that change must occur to keep up with the times. IAMFES must change to keep up with the times. We have been working hard on your behalf to keep IAMFES and its publications positioned as the leader in providing food protection information to food safety professionals worldwide. I welcome your comments and encourage you to contact me or the Executive Board with your ideas. Thank you for your support!

# We don't care *how* you get it here...



# but we do care *if* we get it!

Affiliates are an important part of IAMFES, and that's why we need you, our Affiliate Associations and Affiliate Members, to let us know what is going on in your organizations. Keep us abreast of meetings, activities, seminars and other events by sending us min-

utes, announcements or just a quick update. In return, we'll publish it in our next issue of *Dairy, Food and Environmental Sanitation*. All we ask is that you please send information regarding upcoming events at least two months in advance.

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## Our Affiliates Count!

# Two-Inch and Four-Inch Food Cooling in a Commercial Walk-In Refrigerator

O. Peter Snyder, Jr.

## SUMMARY

In 1976, the FDA food code (4) called for food to be cooled from hot to 45°F in 4 h. The FDA 1997 food code (5) recommends cooling from 140 to 70°F in 2 h and from 70 to 41°F in 4 h. Actually, if these times are to be achieved, energy-intensive, expensive blast coolers must be used. However, the industry has not been required to purchase them, except under rare circumstances. One reason that blast coolers are not required is that there is no adequate government procedure to measure the cooling of food in containers. Hence, during inspections, regulatory inspectors have been forced to estimate actual cooling rates in refrigerated food containers in retail food operations.

This study shows that food 2 in deep, in a covered pan, in a commercial walk-in refrigerator in a typical restaurant, takes over 10 h to cool from 130 to 45°F. If the food is 4 in deep, the cooling time is over 30 h.

Juneja, *et al.* (6) showed that 15 h cooling from 130 to 45°F is safe. The correct technique is presented for measuring food cooling in a food operation. If 4-h or 6-h cooling is to be enforced, then every inspector must have correct cooling knowledge, have the correct temperature measuring equipment, follow the testing procedure described in this study, and then, enforce the food codes. Otherwise, the ever-present cooling risk will not be controlled.

## INTRODUCTION

In 1976, as a result of the investigative studies of Dr. Frank Bryan (2), the FDA acknowledged that food cooling was the major cause of foodborne illness (4) and recommended that food in retail food operations be cooled from hot to 45°F in 4 h or less. However, no references were given for the 4-h requirement.

In the fall of 1990, at the Food Safety Technical Standards Workshop in Bethesda, Maryland (13), it was learned that this recommendation was based on studies by Lewis, *et al.* (7) and Longrée and White (9). Actually, these two studies and the study by Blankenship, *et al.* (1) are inappropriate to describe the cooling process and the subsequent microbiological safety of food. This problem was corrected by Juneja, *et al.* (6). This study found that continuous cooling of food within 15 h from 130 to 45°F with a 38°F driving force controlled the outgrowth of *Clostridium perfringens*. *Clostridium perfringens* is the organism of concern, because in its spore form, it survives pasteurization in retail food operations.

In 1976, the author began the Minnesota HACCP Program for



Figure 1. Position of test pans in the refrigerator.



Retail Food Safety through Quality Assurance. Studies were conducted at the University of Minnesota, Department of Food Science and Nutrition, to determine how to achieve 4-h cooling. It was immediately evident that food could not be more than 2 in deep, 1 in center to surface. It was also apparent that cooling food 2 in deep in a covered, 2½-in pan from hot (140°F or above) to 45°F in 4 h requires approximately 35°F air at a velocity of >1,000 feet per min (fpm) blowing across the pan of food. For more than 20 years, Victory, a refrigeration company, has had a rapid-chill refrigerator capable of cooling 200 lb of covered, 2-in-deep food to 45°F in 4 h. The air flow in this refrigeration system is >1,000 fpm, and the air temperature is about 28°F at the end of cooling to provide an adequate driving force (8). If air at a lower temperature is used, the cooling rate is not increased to any extent, because ice forms in the outside layer of the food, and the center of the food encounters only a 32°F driving force.

Even though the 4-h cooling recommendation has existed since 1976, there have been no studies to determine adequate testing procedures to accurately perform cooling experiments to determine the actual, safe center-cooling temperature for a food container in a retail food operation. Evidence has shown that even food with a depth of 2 in in a pan takes much longer than 4 h to cool in a typical NSF International-certified foodservice refrigerator. Because of NSF International standards for compressor capability and evaporator fan velocity, most refrigerators and refrigeration systems are adequate only for storing food. If retail food operations had been forced to comply with the 4-h cooling recommendation, most retail food operations would have purchased blast coolers at a minimum cost of \$9,000 each to achieve 4 h cooling.

The dual purpose of this research was to conduct simple cooling experiments to: (1) illustrate how to do a cooling study of food in a foodservice operation and (2) record the actual cooling times

of food at depths of 2 in (in a 2½-in pan) and 4 in (in a 6-in pan) in a typical retail food operation walk-in refrigerator in Minnesota. For many years, Minnesota has required a 40°F cold food temperature, rather than 45°F, as recommended by the 1976 FDA food code (4).

## THE MATHEMATICS OF COOLING

Pflug and Blaisdell (12) and Dickerson and Reader (3) provide thorough descriptions of the mathematics of the cooling process. The mathematics can be reduced to the following equations:

$$k\Delta t = \log(T_{\text{actual}} - T_{\text{cold source}}) \quad (1)$$

$$= \log(T_{\text{start}} - T_{\text{cold source}})$$

where  $k$  is the slope of the cooling line,

or

$$k\Delta t = \log(T_{\text{actual}} - T_{\text{cold source}})$$

$$= \log(T_{\text{start}} - T_{\text{cold source}})$$

To calculate the slope  $k$  of the cooling line, rewrite the equation as:

$$k = \frac{\log(T_{\text{actual}} - T_{\text{cold source}}) - \log(T_{\text{start}} - T_{\text{cold source}})}{\Delta t} \quad (2)$$

To find the actual product temperature after time, use

$$T_{\text{actual}} = T_{\text{cold source}} + (T_{\text{start}} - T_{\text{cold source}}) \times 10^{k\Delta t} \quad (3)$$

To find the actual time to get to a temperature, use

$$\Delta t = \frac{\log(T_{\text{actual}} - T_{\text{cold source}}) - \log(T_{\text{start}} - T_{\text{cold source}})}{k} \quad (4)$$

This means that if the difference in temperature between the center of the hot food and the cold source, such as the air in the refrigerator or water in a cold water bath, is plotted on semilog paper, a straight line is achieved. The bottom point on the  $y$  axis is chosen as 1°F above the cold source temperature, because, in principle, the center of the food can only approach the temperature of the cold source but will never actually reach the temperature of the cold source, as evidenced by the above equations.

Figure 2. 2½-in pan in position.



Figure 3. 6-in pan in position.



## METHODS AND MATERIALS

This experiment was conducted in a commercial full-service restaurant in Minnesota. The kitchen and walk-in refrigerator are 12 years old. This facility and equipment have been inspected regularly by the local sanitarian and have passed inspection. The walk-in refrigerator in which the study was conducted is 7 ft high × 16 ft wide × 6 ft deep. There is a 3-fan blower in the middle of the refrigerator. Figure 1 is a photograph of the inside of the refrigerator showing how the test pans were positioned (center of picture) on a shelf. Figure 2 is the 2½-in pan in position. Figure 3 is the 6-in pan in position.

The air flow was measured with a Sierra Instruments Model 441 meter (Carmel Valley, CA). Air flow was measured with the respective pans in place, in the center, approximately 1 in below and 2 in above each pan. Temperatures were recorded with a Barnant Model 600-1050 dual-channel meter (Barrington, IL) set to provide logging at 10-min intervals. Temperatures were recorded to 0.1°F. Type K 24-gauge thermocouple wire was used to measure the temperature in the middle of the food and the temperature of the air 4 in above the food pan. The thermocouple was held in place by a ¼-in wooden dowel. Figure 4 shows the device used to hold the thermocouple in place. The thermocouple in the food was placed either 1 or 2 in above the end of the dowel, depending on whether the 2-in or 4-in deep food was being measured. The dowel rested on the bottom of the pan, so that the thermocouple junction would be exactly 1 or 2 in, respectively, from the bottom of the pan. Each pan was supported ¼ in off of the solid shelf by ⅛ pan inserts. If the pan had been placed directly on the shelf, there would have been additional thermal resistance from the bottom of the pan, and it would be expected that the cooling time would almost double. The author's

Figure 4. Fixture holding the thermocouple.

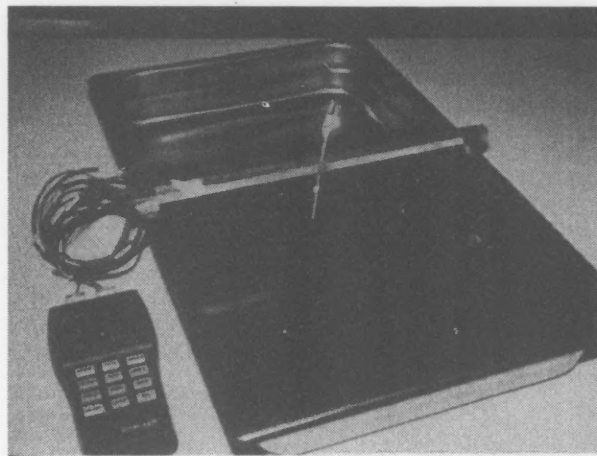
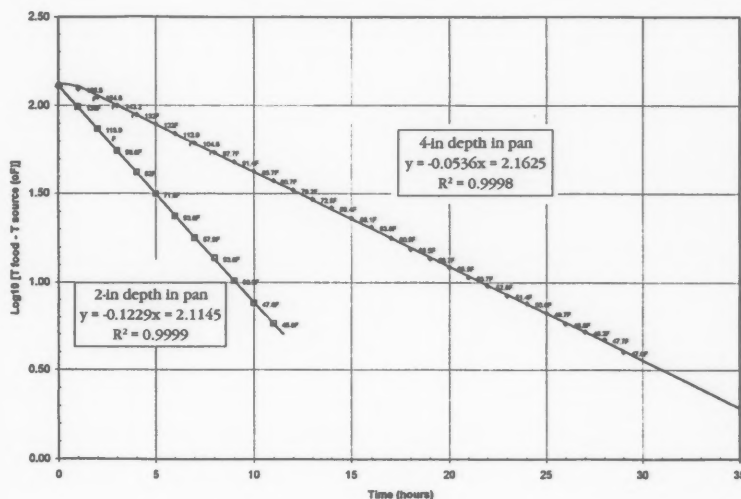


Figure 5. Food cooling (2-in depth in pan compared to 4-in depth in pan).



previous experiments have shown that about 75% of the heat is removed through the bottom of the pan.

The food cooled in this study was a gelatinized starch mixture (water and flour), which is essentially a gravy without flavor. A volume of 7 quarts filled a 2½-in × 12-in × 20-in pan to 2 in; 1¼ quarts filled a 6-in × 12-in × 20-in pan to 4 in. To prepare the gelatinized starch mixture, about 80% of the

water was put on the stove and heated to boiling; the other 20% of the water was cold and was mixed with a flour at a ratio of 7% weight of flour to weight of total water. The cold flour-water mixture was added to the boiling water and stirred for approximately 3 min, at which time it fully thickened to its ultimate viscosity. This gelatinized starch mixture, which has a specific heat of about 1 Btu/lb°F,

was used for a cooling study to eliminate convective heat transfer. If convective heat transfer is not eliminated, the food cools almost twice as fast. The pans containing the gelatinized starch (flour and water) mixture were covered with aluminum foil so that there would be minimal loss of steam and hence, minimal evaporative cooling. (Cooling of surfaces through evaporation accelerates cooling and produces false data.) The pans were placed in the refrigerator, and the logging process began.

## RESULTS

The results of the cooling tests on the covered gelatinized starch (flour and water) mixture at the 2-in and 4-in depth are shown in Figure 5 and Tables 1 and 2. In the case of the 2-in food cooling, the time to reach 45°F was 11 h, 30 min, approximately. The time for the food to cool from 130 to 45°F was about 10¼ h. Because the driving force air temperature averaged about 40°F, the calculated time to reach 41°F would have been 16 h. Cooling time is extremely dependent on the air flow across the pan, which in this case, fluctuated between 30 to 50 fpm underneath the pan and 100 fpm across the top of the pan. At an air flow of approximately 1,000 fpm, food cooling time is cut to ½ the time of food cooled in an air flow of 50 fpm. Hence, this 11-h, 30-min cooling would be approximately 4-h cooling if there had been a fan blowing air directly across the pan.

The graph and tables (Figure 5, Tables 1 and 2) for the covered, 4-in food cooling show that at 29 h, when the cooling was stopped, the center temperature of the food was 47°F. Had the study continued until the center temperature reached 45°F, the time would have been close to 35 h. Figure 5 shows that the time to cool food from 130 to 45°F is about 30¾ h. Because the effective average air temperature of the refrigerator was about 43°F, this food would never have reached 41°F.

TABLE 1.

Time Hours	2-in food cooling		
	Temp. °F	Temp. -40°F	Log Temp. -40°F
0	171.3	131.3	2.12
1	138.3	98.3	1.99
2	113.9	73.9	1.87
3	95.6	55.6	1.75
4	82.0	42	1.62
5	71.6	31.6	1.50
6	63.6	23.6	1.37
7	57.9	17.9	1.25
8	53.8	13.8	1.14
9	50.2	10.2	1.01
10	47.6	7.6	0.88
11	45.8	5.8	0.76

The apparent effective driving force (air temperature) is developed from the experimental data, because the walk-in refrigerator compressor is cycling, and the air temperature is not stable. The on-off period for the compressor on the refrigeration system used in this study was approximately 40 min (data not shown). The compressor turned on when the air temperature inside the unit reached approximately 45°F and turned off when it reached 38°F. The food in the refrigerator acts as a "fly wheel" to stabilize the refrigerator temperature. When the compressor is on, the food loses heat and gets colder; when the compressor is off, the food helps to keep the refrigerator cold.

## DISCUSSION

The author has been conducting similar experiments since 1976 and teaching operators throughout the U.S. how to cool food. The results of all of these studies have been typical of this test. In Minne-

sota today, there is a requirement for 4-h cooling to 40°F because of a decision made 40 years ago to set Minnesota cold food holding at 40°F (10). Actually, many sanitarians in Minnesota know the results of the author's studies over the past 20 years.

The results show that no commercial NSF International refrigerator will cool food 2 in deep in 4 h, according to the FDA 1976 code (4), or from 140 to 70°F in 2 h and 70 to 41°F in 4 h, according to the 1997 food code (5). If the FDA code or cooling recommendations were strictly enforced, every operator in Minnesota would be required to purchase a blast cooler at a cost of at least \$9,000. No epidemiological evidence has shown that anyone becomes ill from food cooled 2 in deep in a covered pan in a normal NSF International foodservice (storage) refrigerator.

Some sanitarians say that food should remain uncovered during cooling. It is true that if food is left uncovered, it cools more rapidly. However, it will also become

contaminated with mold from the fan blades and the refrigerator coil. Although NSF International listed, the fans and coils are basically uncleanable in walk-in or reach-in refrigerators. They become extremely contaminated with high levels of bacteria, such as *Listeria monocytogenes*, and with mold.

Food can also be cooled in pots and buckets in an ice bath. When food is cooled in this manner, it must be stirred almost constantly. In addition, the ice water must also be agitated to assure that 32°F water is next to the container, because heat transfers from the outside of the container. The safe, simple answer for cooling food without large labor costs is to cool food 2 in deep in a covered container in a refrigerator.

The author has found that it is not necessary to spend a lot of money on a blast cooler to achieve a 4-h cooling rate if the code were to be enforced. A simple, \$12.00 box fan (which can be purchased at a discount store) blowing air directly across the food, is adequate, if the food is on a rack so that the bottoms of the pans are exposed to the blowing air. However, the research of Juneja, *et al.* (6) has shown that 4- or 6-h cooling is unnecessary. If a fan is combined with the 15-h safety limit, a major advantage is that food 4 in deep, and 5-gallon buckets of sauce, for example, can be cooled safely. The fan increases the cooling rate by a factor of three. Therefore, if food with a depth of 4 in in a pan takes about 30 h to cool in a standard refrigerator, it will cool safely in 10 h. The 5-gallon bucket of food will cool in about 15 h (unpublished data).

The gelatinized starch (flour and water) mixture used in this study is the correct food simulator to use for this kind of study, because it is very inexpensive and is a very difficult food product to cool. It is so viscous that the only type of heat transfer during cooling is conduction. Water has the highest specific heat of any food

TABLE 2.

Time Hours	4-in food cooling		
	Temp. °F	Temp. -43°F	Log Temp. -43°F
0	173.9	130.9	2.12
1	166.5	123.5	2.09
2	154.8	111.8	2.05
3	143.2	100.2	2.00
4	132.0	89.0	1.95
5	122.0	79.0	1.90
6	112.9	69.9	1.84
7	104.8	61.8	1.79
8	97.7	54.7	1.74
9	91.4	48.4	1.68
10	85.7	42.7	1.63
11	80.7	37.7	1.58
12	76.2	33.2	1.52
13	72.5	29.5	1.47
14	69.4	26.4	1.42
15	66.1	23.1	1.36
16	63.6	20.6	1.31
17	60.9	17.9	1.25
18	58.5	15.5	1.19
19	56.7	13.7	1.14
20	55.2	12.2	1.09
21	53.7	10.7	1.03
22	52.6	9.6	0.98
23	51.4	8.4	0.92
24	50.6	7.6	0.88
25	49.7	6.7	0.83
26	48.8	5.8	0.76
27	48.2	5.2	0.72
28	47.7	4.7	0.67
29	47.0	4.0	0.60

item. Hence, the gelatinized starch (flour and water) mixture thickened with a 7% flour-water mixture at about 190°F makes this test the correct one for a HACCP test of refrigeration in actual restaurant operations.

The chemical properties of the food also affect the outgrowth of *C. perfringens* and hence, the necessary cooling rate to keep the food safe. The cooling study by Juneja, *et al.* (6) was done on hamburger media, which is optimum for the growth of *C. perfringens*. If this study were done on tomato-based products or sauces with wine and fruit, which have much lower pHs in the range of 4.3 to 5.2, the outgrowth of *C. perfringens* would be significantly limited, if not prevented, and safe cooling times would be much longer than the 15 h for hamburger.

## CONCLUSIONS

This study summarizes two simple experiments to show the correct way to perform a cooling study and to evaluate the effectiveness of cooling in retail food operations. It is also appropriate for home refrigerators. It presents the materials and methods that provide a consistent cooling test result each time. The cooling experiment is very easy to do. NSF International Standards 4 and 7 (11) still do not deal correctly with cooling in retail food operations. In addition, these NSF standards can be reproduced only in a laboratory and do not predict performance in actual operations. The procedure described in this study can be used to provide full validation of HACCP cooling in a retail operation.

It is time now, in 1997, after almost 20 years, to begin accurately measuring the temperature of food cooling and to determine accurately what is necessary for safe cooling and what rate is actually needed for each food item, based on its ingredients and

microbiological growth hurdles. Depending on the ingredients, the outgrowth of *C. perfringens* will vary, and safe cooling times can be much longer.

*Clostridium perfringens* is a very common food contaminant. It survives normal pasteurization; its spores outgrow to high levels in food (14). Before the FDA publishes cooling recommendations, it should be able to accurately show the relationship between spore outgrowth, pH, and other parameters. In this way, the retail food industry can avoid spending money on blast coolers when these devices may not be necessary to improve the safety of food products.

Much research remains to be done. The retail food industry, as it institutes HACCP self-control, must solve the problem of correct cooling and provide correct data tables for cooling throughout the U.S. This will allow operators maximum, yet safe, food cooling times.

There have been many cooling rules and regulations written by sanitarians throughout the U.S. since 1976, and much imprecise information based on these rules

and regulations has been given to the retail food industry. Each government food inspector must learn how to measure food cooling correctly in food operations and be provided with the necessary, accurate instruments to perform cooling evaluations if food inspections are to effectively monitor cooling risk.

#### ABOUT THE AUTHOR

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# A Literature Review Linking Microbial Risk Assessment, Predictive Microbiology, and Dose-Response Modeling

W. Bruce McNab

## SUMMARY

Foodborne diseases are responsible for significant losses each year. As a result, food safety is increasingly important to trade. There is movement toward equivalent inspection systems among trading partners, including the use of Hazard Analysis and Critical Control Point (HACCP) methods and risk assessment. This literature review illustrates that HACCP and quantitative risk-assessment techniques are evolving in microbial food safety, and that there is still some disagreement concerning terminology. Risk is a function of the probability of something undesirable happening and the impact of the consequences. Risk assessments should include analyses of uncertainty. The probability of exposure to pathogens is influenced by a number of factors along the food chain. Predictive microbiology attempts to model microbial growth, survival, and death. It has considerable potential, but also many limitations and needs much data. Dose-response modeling is also evolving. It links exposure to pathogens to the biological-impact component of risk. More data are needed. The impact component of risk should be measured in terms of the biologic and economic impacts on society. Some studies have been published that attempt to link these analytical techniques.

## INTRODUCTION

The negative biological impacts of foodborne pathogens range from mild to severe illness or death, involving many people, with large direct and indirect economic impacts on society. The true incidence of food poisoning is difficult to estimate because the vast majority of cases are not captured in health statistics (7, 22). It has been estimated that the ratio of the number of illnesses not reported for each one that is reported lies between 4:1 to > 7,000:1 (7). The Council for Agricultural Science and Technology (CAST) estimated that the incidence of foodborne disease may range from 6.5 to 33 million cases with as many as 9,000 deaths per year in the USA (7). It has been estimated that 2.2 million cases occur annually in Canada (77). Furthermore, between one and five percent of acute episodes lead to serious, often chronic sequelae, such as rheumatoid conditions, nutritional and malabsorption problems, haemolytic-uraemic syndrome, or atherosclerosis (16). Also, there are differences in exposure experience, immunity, and susceptibility among people,

such as the young, the elderly, and immunocompromised individuals (16, 39).

Some recent apparent increases in incidence may be artificial, because of increased awareness of the number of organisms that cause foodborne disease, increased surveillance, and improved test methodologies. But other changes may be responsible for a true increase in incidence, such as increased use of intensive farming, recycling of waste products, larger feed and animal production units, changes in methods and scale of food processing, storage, distribution and preparation, and changes in consumption practices (7, 16, 22).

Direct economic impacts include costs of treatment and lost production. There are also very significant indirect economic impacts that may include costs of lost trade and lost consumer confidence, legal costs, and costs of perception-driven, but ineffective and inefficient control programs (42, 78). The annual cost of foodborne disease has been estimated at \$5-6 billion in the USA and \$1-2 billion in Canada (77).

Historically, many aspects of food inspection have been based on qualitative assessments, but systematic quantitative methods are now required to facilitate more objective assessment and monitoring (22, 42). Hazard Analysis Critical Control Point (HACCP) principles and risk assessment methods provide such systematic and quantitative tools. The further development and application of these tools requires input and cooperation from several disciplines (7, 16, 22, 25).

This literature review summarizes and compares recent publications concerning quantitative approaches to microbial food-safety including HACCP, risk analysis, risk assessment, predictive microbiology and dose-response mathematical modeling; quantification of

uncertainty; and recent examples of attempts to link all the components. This review illustrates that readers should be aware of differences in terminology and methods reported in the literature. This paper is deliberately presented as almost a written debate. Some suggestions for middle ground and next steps are presented. Readers may wish to review the organization of information in this report by considering its headings and sub-headings before proceeding to read the detailed text.

## HACCP

### What is a hazard?

Two terms that serve as cornerstones for Hazard Analysis Critical Control Point (HACCP) and risk-assessment systems are the words hazard and risk. Unfortunately, even these two key words are not used with consistent meaning in the literature (2, 3, 7, 9, 14, 43, 58, 63). Sometimes hazard is defined or used to imply the cause of the negative outcome (3, 9, 63). For example, *Salmonella enteritidis* may be thought of as a foodborne hazard because it causes disease. Sometimes hazard is defined or used to imply the negative outcome of concern, such as illness or the seriousness of the illness (3, 14, 58). In some papers, the nuances of hazard are mixed within the same document (9, 43). It has been suggested that the term hazard be consistently used to mean an agent or action that can cause adverse effects (e.g., a foodborne pathogen, toxin, or chemical) (10) and that terms, such as impact or consequences be used when referring to the negative impact caused by the hazard (54).

### What is HACCP and why use it?

Hazard Analysis Critical Control Points (HACCP) is a system used to identify and prevent food-safety

problems in the production, processing, and distribution of foods. Briefly, a HACCP program includes seven steps: (1) hazard identification, (2) identification of critical control points (CCPs) where a hazard can be eliminated or reduced to acceptable levels, (3) setting of standards for CCPs, (4) monitoring, (5) taking corrective action as needed, (6) documentation, and (7) auditing (4, 17, 57).

It is generally accepted that food quality and safety cannot be "inspected-in," but must be designed into a product through verifiable process control (22, 24). Buchanan and Deroever (22) describe why testing alone cannot be depended upon to provide microbiologically safe foods. HACCP or similar systems have been made mandatory or strongly encouraged (23) by agencies around the world including the Codex Alimentarius Commission (4), Agriculture and Agri-Food Canada (6), the U.S. Department of Agriculture (USDA) (11), and the European Union (17). This international recognition and implementation has made HACCP extremely important for companies to maintain and expand markets.

### HACCP's potential use of risk assessment

Buchanan stressed the importance of understanding the relationship between HACCP and risk assessment (23). Several authors have noted that quantitative risk assessment and predictive microbial modeling contribute to the design of HACCP programs (17, 23, 25, 34, 42, 43, 52, 57, 63, 79). These tools are especially relevant to the first three steps of HACCP (23). Notermans, *et al.* (57) noted the appropriateness of quantitative risk assessment to help specify relevant criteria in developing a HACCP program. Quantitative risk assessment has not yet been used to



its full potential, and data required to produce such assessments and models are scarce (57).

## **RISK ANALYSIS AND RISK ASSESSMENT**

### **What is risk?**

Sometimes "risk" is defined to mean the probability or likelihood of something undesirable happening (7, 43, 58, 63). More frequently, risk is defined to include elements of both probability and impact, i.e., the likelihood of the occurrence and the magnitude of the consequences of an undesirable outcome (3, 9, 14, 63). Frequently the term risk is defined to include elements of both probability and impact but is subsequently used to imply only probability (14). In many environmental risk assessments, the impact component of risk is treated as fixed (e.g., death from cancer). Such assessments default to an investigation of the probability of experiencing that impact.

The impact of concern within a risk may depend on one's point of view. A food company may be worried about the short- and long-term consequences to the company (34). Conflicting definitions can lead to miscommunication and loss of trust. For example, an official may use the word risk to mean that the probability of a child dying is extremely low. However, a mother may use the word risk to mean that the impact of such a death is unacceptable. She might be very insulted when the official says that the risk is negligible. If the official empathized with the mother's concern about the impact component of the risk and explained why the probability of that outcome actually occurring was negligible, then communication may be improved.

### **What is risk analysis?**

Risk analysis and risk assessment are becoming increasingly important to trade. In 1992 Agri-

culture and Agri-Food Canada and the USDA initiated the development of a comprehensive risk-assessment and risk-analysis programs within their respective organizations (43, 53). Unfortunately, the terms risk analysis and risk assessment are sometimes interchanged and sometimes used to mean different things. This has led to some confusion and miscommunication. Most workers in food safety, animal health, plant health, and environmental risk fields, use the term risk analysis as a larger concept, consisting of elements of risk assessment, risk management and often risk communication (5, 9, 10, 12, 14, 43, 58, 59, 62, 63). However, exceptions occur in the literature that include a transposition of these terms, where risk assessment is used as the larger concept which includes risk analysis and risk control (2, 3, 79).

The following is a summary of the concepts as they are used in this review. Risk analysis is a process that includes (1) risk assessment, (2) risk management, and (3) risk communication. (1) Risk assessment is a process within risk analysis that involves identifying a hazard that can cause a negative impact and characterizing the risk presented by that hazard. The risk is characterized in qualitative or quantitative terms. This includes assessing (a) the probability that the negative event occurs because of the identified hazard, (b) the magnitude of the impact of the negative event, and (c) consideration of the uncertainty of the data used to assess the probability and the impact components of the risk. (2) Risk management is a process within risk analysis that includes identifying, evaluating, selecting, and implementing alternatives for mitigating risk. (3) Risk communication is a process within risk analysis that includes an open exchange of information and opinion leading to a better understanding of risks and risk-related decisions. Clearly, risk management and risk communication are

important components of risk analysis (18). However, the emphasis of this review is on the application of quantitative risk assessment within food-safety risk analysis.

### **What is risk assessment and why use it?**

Risk assessment may be viewed as a method of organizing information systematically. This systematic documentation of the sequential components of risk allows decision makers to better understand the factors that contribute to the probability and impact components of risk and the uncertainty of the data. The classical model of risk assessment consists of four steps: (1) hazard identification, (2) hazard characterization (also called response characterization or dose-response or exposure-response assessment), (3) exposure characterization, and (4) risk characterization. Step 4 is defined as an integration of steps 1 through 3 with consideration of the uncertainty of the data (1, 5, 9, 42, 49, 60, 62, 63, 80). This model has evolved primarily in assessing health risks from chemicals, with cancer often identified as the impact of concern (5, 80). The practice of this type of health risk assessment has been reviewed by Paustenbach (60). However, the principles of health risk assessment may also be applied to nonhuman species (including animals and plants) for hazards other than chemicals (e.g., bacterial, viral or physical hazards) and for outcomes other than cancer (including other negative health and nonhealth impacts).

As a general rule, chemical hazards remain at the same concentration, breakdown over time, or are reduced in concentration through dilution. In contrast, depending on environmental conditions, microbial agents may rapidly increase or decrease in prevalence and concentration or change in their ability to cause negative health impacts through changes in virulence. Application of quantitative risk assessment to

**TABLE 1. Transition from classical risk assessment to proposed general model**

Classical risk assessment	Modified classical	Proposed general
(1) Hazard identification	(1) Hazard identification	(1) Hazard identification
(2) Response characterization	(2) Risk characterization	(2) Risk characterization
(3) Exposure characterization	(2a) exposure characterization	(2a) probability
(4) Risk characterization (i.e., roll-up of 1 through 3, plus uncertainty)	(2b) response characterization (2c) uncertainty	(2b) impact (2c) uncertainty

microbial food safety is just beginning and needs further refinement (25). However, progress is being made (86). It is recognized that microbial hazards are important, but the quantitative assessment of their risk is complex.

In most trade issues concerning food safety and animal or plant health, it has already been proven that the hazards of concern cause disease (e.g., VTEC O157:H7, foot and mouth disease virus or blueberry maggot in food safety, animal or plant health issues, respectively). As a result, hazard identification does not require experimental trials to prove a causal association between the suspected hazard and disease. Hazard identification consists of creating a microbiological profile, listing known pathogens that may be associated with the source of the food, animals, or plants, or the method of production, processing, or preparation (22).

One can appreciate the logic of the classical system, which characterizes the response to exposure to a new chemical before characterizing the likelihood of exposure. However, it may be more logical and risk communication may be clearer, if one reports the probability and impact components of risk in the same order that they occur biologically (i.e., exposure, then impact), which is

the same order they must follow in a sequential mathematical model of risk. The four traditional steps of classical risk assessment have been presented in a slightly different format (53, 54), to facilitate broader application of risk assessment across the disciplines of food safety, animal health, and plant health and to more clearly depict the concept of risk including elements of probability and impact. Table 1 summarizes the transition from classical human health toxicological risk assessment to the broader model of risk assessment suggested by McNab, *et al.* (54).

Buchanan (23) stressed the importance of understanding the relationship among HACCP, microbiological criteria, and risk assessment. Hathaway noted that quantitative risk assessment can provide the systematic methodology for scientifically evaluating different food inspection and regulatory programs, such as postmortem inspection of meat (41). The benefits of such an assessment include: (1) information on estimates of risk including probability and impact, (2) information on the relative importance of different conditions within the system, which may facilitate better assignment of priorities and application of risk reduction resources, and (3) identification of key areas where information is missing and where research may be needed to acquire more information (25, 79).

#### **Quantitative risk assessment's use of mathematical modeling**

Mathematical models can be used to predict microbial growth, survival, and death. Predictive models can help estimate the probability component of risk by estimating human exposure to pathogens from food that has experienced specific environmental conditions (52). Factors entering the predictive models can include initial pathogen concentration, temperature, pH, water activity, and time. Similarly, models that describe the response to exposure to pathogens (dose-response models) can be used in risk assessments to help model the biological-impact component of risk. The variability and uncertainty of the data can be incorporated through MonteCarlo simulation.

#### **PREDICTIVE MODELING IN MICROBIAL FOOD SAFETY**

##### **What is predictive modeling and why use it?**

Ross and McMeekin noted that predictive modeling in microbiology is based on the premise that "...the responses of populations of microorganisms to environmental factors are reproducible, and that by considering environments in terms of identifiable dominating constraints it is possible, from past

observations, to predict the responses of those microorganisms" (71). There is growing interest in quantitative predictive food microbiology because it has many potential applications, such as predicting the effect of changes or errors in product processing or storage conditions, estimating shelf life, designing, validating, optimizing, and controlling production, processing, storage and distribution systems, and HACCP programs and government regulations, all to ensure effective and efficient delivery of safe foods (17, 34, 38, 48, 51, 52, 71, 72, 73, 75). At the first international conference on predictive microbiology in 1992, Adair and Briggs noted the potential utility of mathematical models in the development of user-friendly computerized expert systems in the field of microbial food safety. In opening comments at the second international conference in 1996 in Tasmania, Roberts commented that "...the future could provide user-friendly software that will couple modeling of microbial responses with risk assessment and HACCP, taking into account the formulation and properties of the food and the intended process and play an important role in maintaining a safe and wholesome food supply" (70). Nevertheless others have warned that, although predictive models are useful, they are not appropriate as the only criterion for evaluating food safety (75). The successful application of such modeling depends on developing and validating models in real world conditions (52).

### Summary of model types

Authors of recent review papers have reminded readers that the calculation of thermal destruction (*D*-values), botulinum cook studies, and shelf-life challenge testing are forms of predictive modeling that began in the 1920s (69, 71, 85). These tools have served the food industry well. For example, *D*-values (i.e., decimal

reduction time, the time required for a 90% reduction in concentration at a given temperature) (15) allow microbiologists to design cooking treatments that reduce the probability that an initial single organism or spore survives (25). Once the *D*-value for a pathogen has been established, the number of organisms present after the cook step can be estimated by equation (1),

$$\log_{10}(N) = \log_{10}(N_0) - (t/D) \quad (1)$$

where *N* is the number of organisms after the cook step (CFU/g), *N*<sub>0</sub> is the initial number (CFU/g), *D* is the *D*-value (min/log[CFU/g]), and *t* is the duration of the cook step (min) at the temperature of the *D*-value.

Although thermal death calculations have been used for some time, the application of mathematical modeling of growth and survival of microorganisms in foods is relatively new (19, 48, 71, 75, 84, 85, 87). Ross and McMeekin (71) noted that models can be divided into two broad groups including: (1) kinetic models in which the response variable is expressed in time-based units (i.e., either growth rate or time to a particular response), and (2) probability models in which the outcome is expressed in terms of the probability that a single cell initiates growth as a result of the conditions (71). However, they concluded that the two types of models may be considered as "...extremes of a spectrum of modeling needs, and research from both ends is now converging" (71). They noted that "...the two approaches converge in situations where growth up to some threshold is acceptable, but for which the environmental conditions are such that the responses are highly variable" (71). Ratkowsky and Ross (68) suggested that modeling the bacterial-growth vs. no-growth interface might be easier and provide more practical information for the food industry than attempting to model kinetic growth in such a dynamic and complex environment.

Through a series of papers, the "square root" or Belehradek-type temperature models were developed to a four parameter model (13, 50, 51, 65, 66, 67, 88). The resultant model relates the square root of growth rate *k* to the difference between conditions experienced and minimal values supporting growth, for temperature *T*, water activity (*a*<sub>w</sub>) and pH:

$$k^5 = b * (T - T_{min}) * (a_w - a_{wmin})^5 * (pH - pH_{min})^5 \quad (2)$$

where *b* is a fitted parameter of the model.

A series of Arrhenius-type models (as reviewed by Ross and McMeekin (71) and Skinner, *et al.* (75), were developed from the classical Arrhenius equation as follows in equation (3):

$$\ln k = \ln A - (E_a/RT) \quad (3)$$

relating ln of growth rate *k* to a fitted model parameter *A*, temperature *T*, a universal gas constant *R*, and a growth-rate limiting characteristic of activation energy *E*<sub>a</sub>. Davey (29, 30) proposed a modified Arrhenius-type model relating ln growth rate to temperature and water activity.

The Gompertz function describing an asymmetrical sigmoidal curve has become the most widely used model to describe microbial growth (25, 37, 48, 85). It has four parameters as follows in equation (4):

$$\log_{10}(N_t) = A + C e^{-e^{-B(t-M)}} \quad (4)$$

where *N*<sub>*t*</sub> is population density (CFU/mL) at new time *t*, *A* is the initial population density ([log<sub>10</sub> (CFU/mL)]), *C* is the difference between the initial and maximum possible log population densities (log<sub>10</sub> [CFU/ml]), *B* is a transformed slope term representing the relative rate of growth at the point of inflection of the sigmoid curve, *M* is the time of the inflection point and *t* is time.

Several sigmoidal functions (logistic, Gompertz, Richards, Schunte and Stannard) were compared, with the conclusion that the modified Gompertz equation was

easy to use, more parsimonious, and statistically sufficient to describe the growth data of *Lactobacillus plantarum* (87). Other authors warned of the limitations of extrapolating of Gompertz-based models, because at least some of the parameters (e.g., *B* and *C*) are not intrinsic. They are purely controlling parameters because they are influenced by the initial inoculum (19).

#### **Information required, limitations, and software for modeling**

The general equations above represent the basic relationship between environmental factors and growth. But to obtain specific models for specific microorganisms, a two-step approach is used where: (1) data are derived experimentally by monitoring growth under different conditions, such as pH,  $a_w$ , and temperature, then (2) model parameters of one of the above general models are fit to the data, often using the maximum likelihood method (see dose-response section below) (48). Unfortunately, a very large amount of data are required to develop models for different microorganisms and strains, under a wide variety of environmental conditions (28). Growth can be monitored without sampling by tracking turbidity (47) or conductance measurements (20). Experiments require an integrated and efficient design with automated, electronic data capture and handling (55). When setting up an experiment, researchers must consider the sources of variability, the potential use of screening experiments, and the optimum spacing between data points along a continuous scale to develop the most appropriate experimental design (31).

The need for large data sets has led to the development of cooperative studies involving several laboratories and organizations. For example, the Ministry of Agriculture Fisheries and Food in the UK initiated a nationally coordinated

five-year program of research into the growth and survival of microorganisms in foods to develop a computerized predictive microbiological database (48, 83). The resultant computer models are marketed as a software package called Food MicroModel™, through Food MicroModel Ltd. of Leatherhead, Surrey, UK. This is a user-friendly program that allows entry of environmental conditions such as temperature,  $a_w$  or pH, to predict death, growth, or survival over time for selected microorganisms (8). In Europe, about 30 laboratories have cooperated similarly to examine growth responses of spoilage and pathogenic organisms in a wide range of products through the Food Linked Agriculture and Industrial Research program (FLAIR) (48, 71). In the USA similar work has been conducted by Buchanan *et al.* (21) through the Microbial Food Safety Research Unit of the USDA. Their models are available free of charge in the "Pathogen Modeling Program" from the USDA Agriculture Research Services, Eastern Regional Research Centre, Philadelphia, PA. Buchanan has stressed the importance of developing applications and making them readily available (21).

Delignette-Muller *et al.* (33) reviewed the growth predictions using square-root and polynomial models published in 14 papers, concentrating on errors in quantities of practical interest such as lag time, generation time, or time to reach a given increase in number of cells. The distributions of these errors were studied and found alarmingly high, leading to significant average errors and unsafe predictions in some cases (33). They noted that good knowledge of the accuracy and precision of predictive models is required. Unfortunately they found that original authors rarely provided pragmatic information on average relative error or range of errors in predictions. They stressed the need for systematic validation of models with independent data from foods

and that the relative errors of predicted values should be presented (33). A key stage in model development is validation for use in foods (48). This is not always done and/or not always reported in sufficient detail (48). Modeling of microbial growth and death under combined stress conditions is evolving (64). However, interactions and competitive inhibitions of mixtures of organisms in food matrices under conditions that vary over time present a complex biological system that researchers are not yet able to model.

In conclusion, quantitative predictive modeling has considerable potential for food microbiologists, providing a cost-effective means of predicting the microbiological safety of foods, in conducting risk assessments, and developing HACCP programs. Although great strides have been made, the limitations of predictive microbiology have been noted by Cerf (28). Much work is needed. Care must be taken to validate models under various conditions. Users must appreciate the complexity of the biological systems being modeled and the dangers of extrapolation beyond the limits of the data used to generate the model (45, 82).

## **DOSE-RESPONSE MATHEMATICAL MODELING**

### **What is, and why use dose-response modeling?**

Subsequent to exposure to pathogens, there is variability among people in their biological response. Dose-response modeling attempts to mathematically model the variability in impact (response), following exposure to different doses (27, 35, 39, 86). Dose-response modeling can serve as an integral part of quantitative risk assessment that links the exposure component of risk with the biological-impact component of risk. This is done by including dose-response as a component of a sequence of quantitative analyses,

in which the output from exposure estimates is used as input in dose-response modeling. Subsequent output from the dose-response modeling can be used in further analysis of biologic and economic impacts (27, 35, 86).

### Examples of dose-response model types

Currently there are two basic theories concerning the initiation of infection by microorganisms. One is a deterministic process or a hypothesis of complete cooperation, in which organisms are required to be present at a minimal threshold dose. If a person is exposed to a level in excess of this, the organisms cooperate and infection is a deterministic process (35, 39). The second theory suggests that infection is a random process involving independent action of microorganisms where one cell of a pathogen may cause infection. It assumes that even though the probability of infection from a single organism may be exceedingly small, it is not zero (25, 27, 35, 39). The Log-Probit model describes the first hypothesis of complete cooperation (minimal ineffective dose). The Exponential and Beta-Poisson models model the hypothesis of independent action (35, 39).

Equation (5) is the Log-Probit model, giving the fraction  $P$  of the population for which a response is predicted (i.e., infection or disease, whichever is the outcome of concern being modeled):

$$P = I [\log N - u] / s \quad (5)$$

where  $I$  is the normal distribution integral,  $N$  is the dose,  $u$  is the mean log, and  $s$  the log standard deviation of the normal distribution characterizing a minimal ineffective dose (35, 39).

The exponential model of the hypothesis of independent action is presented in equation (6),

$$P = 1 - e^{-rN} \quad (6)$$

where  $P$  is the probability of infection at a dose of  $N$ ,  $e$  is the root of the natural log (i.e.,

2.71828), and  $r$  is the fraction of independent ingested organisms that survive to cause infection. This is a specific constant for the pathogen but may be influenced by the host and the food matrix (35, 39, 86). For example, investigation of outbreak data has suggested that the infective dose for VTEC O157:H7 in terms of CFU/g of food, may be lower when consumed in dry cured salami, than in ground beef (23). Factors that might affect human susceptibility to pathogens have been published (57).

The Beta-Poisson model of the hypothesis of independent action is presented in equation (7):

$$P = 1 - (1 + N/B)^{-a} \quad (7)$$

where,  $P$  is the probability of infection at dose  $N$ , and  $a$  and  $B$  are parameters specific to the pathogen (25, 27, 35, 39, 86). Equation (7) can be rewritten substituting "B" with equation (8),

$$B = N_{50} / (2^{1/a} - 1) \quad (8)$$

where  $N_{50}$  represents the average number of organisms in a dose that is required to infect half of the exposed population (35). It should be noted that as the slope parameter  $a$  becomes very large, the Beta-Poisson model approaches the Exponential model (35), because of the mathematical relationships among Poisson, Exponential and Gamma distributions.

An advantage of the Beta-Poisson model is that it recognizes variability in the response not just between doses, but also between hosts at a given dose. This is analogous to recognizing between host variability in the  $r$  coefficient of the Exponential model, at each dose of  $N$ . This variability in response has been recognized previously (22, 57). In the Beta-Poisson model, the variability between hosts at a fixed dose is assumed to follow a Beta distribution. When parameterized with  $a$  and  $B$ , the Beta distribution yields the probability of infection from exposure to a single organism. But the dose of exposure also varies. In the Beta-Poisson model, the dose

is assumed to vary in a manner following a Poisson distribution with a mean  $N$ . Historically, the Poisson distribution is appropriate when describing the variability of rare events, such as exposure to pathogens in foods (i.e., the situation being modeled). It is this combined use of Beta and Poisson distributions that gives the Beta-Poisson model its name. The Beta-Poisson model described above yields the expected value  $P$  of the percentage of the population that would respond to the mean concentration of  $N$ . Cassin noted that a more valuable output would be a distribution of the variability of  $P$ , not just the expected value of  $P$  (27). He proposed a modified Beta-Poisson model, equation (9):

$$P = 1 - e^{-rN} \quad (9)$$

where  $R$  is a beta distribution of Beta ( $a, B$ ) and  $N$  is the dose, which is the output from a Poisson distribution of exposure. This Modified Beta-Poisson model more closely resembles the structure of the Exponential model of equation (6), but the  $r$  term of equation (6) is now a random variable  $R$  [Beta ( $a, B$ )], describing the variability in response among individuals at a given dose, and the dose  $N$  is allowed to vary as a Poisson distribution (27). These characteristics can be incorporated in MonteCarlo simulation in quantitative risk assessments (see below) (27). Cassin also went on to incorporate variability in the severity of the biological impact in his quantitative risk assessment of *E. coli* O157:H7 in hamburgers. He did this by including distributions describing the conditional probabilities of an infection advancing to haemolytic uraemic syndrome and death (27).

In all of the models above, the method of maximum likelihood is used to obtain estimates of the parameters in the respective models. This method finds the parameters with the maximum likelihood of describing the data (35, 40). Haas described an example of this method, fitting a dose-response model using a spreadsheet

program with a built-in optimization macro to describe the dose-response of chloroform as a carcinogen in male rats (40).

Haas compared the performance of the three model forms (Log-Probit, Exponential, and Beta-Poisson) in their ability to fit actual dose-response data for exposure to *Salmonella* spp., *Entamoeba coli*, Echovirus and Poliovirus (39). He concluded that, in general, the Beta-Poisson model performed the best in describing observed dose-response data.

### Limitations of and information required for dose-response models

Users should avoid a false sense of security from the application of sophisticated mathematics and computer modeling. Known and unknown variability in the number and range of variables involved in microbial food safety and their interactions with one another result in potential biological permutations and combinations that number beyond systematic analyses and scientific experimental confirmation. In the absence of data from large experimental trials and in the absence of solid quantitative knowledge of the biological mechanisms, we are left with theory and extrapolation from current data. Any mathematical model of such a complex biological system is a vast oversimplification of reality. Haas cautioned that the models were developed to extrapolate below the range of doses, for which data were available, to make predictions about dose-responses at low doses (39). From a mathematical point of view, this is generally not advised. Others have cautioned that unless one is careful, it is dangerously easy to generate models that violate core mathematical assumptions of the distributions used (81). One needs to be careful that a given model is biologically and mathematically valid.

The biggest problem in modeling dose-response is the lack of

solid scientific data. Data from controlled trials of feeding variable doses of pathogens to humans are limited. Also, the data that do exist tend to involve healthy adult volunteers who were exposed to relatively large doses. These data may not be very representative of subpopulations at greater risk, such as infants or immunocompromised individuals. Nor do they tend to include large numbers of subjects exposed to very low doses that might be more representative of the real situations occurring in food-safety issues. Consequently, the data currently available are limited to outbreak investigations and small trials.

Martin *et al.* designed a "judgment-encoding method" of interviewing "experts" for acquiring information and "uncertainty" about dose-response in the absence of solid experimental data. The authors did not suggest that their method could serve as a substitute for solid scientific data, but given difficulty in getting such data, they suggested that it might be a reasonable approach (46).

## UNCERTAINTY

### Why worry about uncertainty?

Within the context of this review, the overall objective is to reduce the incidence and impact of food poisoning by presenting microbiologically safer foods for consumption. If we are uncertain of the factors that influence the probability and impact of food poisoning, then we are less certain of achieving our objective. Therefore, understanding uncertainty is important in quantitative risk and policy analysis (56). Two broad classifications of uncertainty are (1) the uncertainty due to inherent variability and measurement error in the system, such as variability in the prevalence of VTEC in cattle, and (2) the uncertainty due to lack of information or understanding, such as the lack of data and our lack of understanding of dose-

response systems. This second type of uncertainty can be further subdivided into (2a) uncertainty that could be improved upon if we had more data representative of the system of concern. We may know how to get such data, but perhaps because of ethical or resource constraints we are unable to obtain it; (2b) uncertainty due to a lack of understanding of the underlying mechanisms. Said differently, we don't know what we don't know.

### Some methods of dealing with uncertainty

The best way to reduce uncertainty is to obtain more, high quality, scientific data. Unfortunately this is often not possible. Frequently decisions must be made in the face of uncertainty, before such data can be obtained. Attendant uncertainty should be discussed and preferably assessed quantitatively in characterizing risk (5, 24, 56). This allows better interpretation of risk assessments by all stakeholders.

Examples of quantitative methods for incorporating uncertainty in risk assessments, include the application of MonteCarlo simulations (24, 25, 26, 27, 56, 86), and the relatively new field of fuzzy mathematics (44). Software programs are available for personal computers that allow users to easily define distributions describing the variability of factors entering models and then run MonteCarlo simulations (25). One example is a program called "@Risk" (Palisade Corporation, Newfield, New York). It works as an add-on to standard spreadsheet software programs. For example, a user may have information on the appropriate parameters of a Beta distribution describing the variability in the response of hosts to exposure to a dose of a pathogen. The distribution can be easily inserted at the appropriate position in the spreadsheet model. Then, a simulation can be run, in which the spreadsheet program is run many many times (e.g., 5000 iterations).

During each run through the model, the program randomly selects a value from within the bounds of each distribution programmed into the model. The result is a series of 5000 individual predictions that can themselves be summarized in the form of a distribution. The output distribution of the simulation thus incorporates the uncertainty of input variables, as described by their respective distributions. Thompson, *et al.* (76) and Finley, *et al.* (36) noted the utility of using distributions for exposure factors and MonteCarlo techniques for quantitative uncertainty analysis in public health risk assessments. More recently, Seiler and Alvarez (74) describe the importance of care in selecting distributions for variables.

Developments in theory and applications of fuzzy sets, fuzzy mathematics, and fuzzy logic are relatively new (44). Their application to uncertainty in food safety is even more recent (32, 34). Fuzzy-set theory differs from traditional crisp-set theory, in that fuzzy sets may overlap in their membership, whereas traditional sets are defined with crisp cutoffs. Elliott (34) gave an example in food safety where a crisp cutoff of 100 CFU/g would mean that a lot with 99 CFU/g would be acceptable, but one with 101 CFU/g would not. Fuzzy-set theory does not use a crisp line to artificially force elements into "black and white" sets. It allows overlap of sets, weighted by degree of membership that is analogous to a fuzzy "grey" zone. Fuzzy mathematics provides tools for working with fuzzy sets and for designing decision and control systems. This may be useful in developing HACCP plans (34).

## EXAMPLES OF LINKING COMPONENTS

Buchanan and Whiting (25) present hypothetical examples showing how predictive microbiol-

ogy and dose-response modeling could be linked in MonteCarlo simulations to conduct quantitative risk assessments, that could contribute to the first three steps of HACCP plan development. Considerable progress has been made in developing components for this approach (e.g., predictive modeling, dose-response modeling) (25). However, relatively few specific studies have been published for microbial food safety issues that have attempted to pull all the components together into an integrated quantitative assessment. The following examples are presented in order of increasing sophistication.

One assessment attempted to quantify factors that influence the probability and impact of human infection by pathogens from cracked eggs (79). The study also presented six risk management options in a qualitative and semiquantitative manner. The study did not really link the sequential factors in a continuous quantitative model, and it did not attempt to quantify or discuss uncertainty in any detail. Nevertheless, it was one of the first examples of a systematic risk assessment for a foodborne pathogen from "gate to plate" (79).

Peeler and Bunning (61) systematically quantified the sequential factors leading to the exposure of humans to *Listeria monocytogenes* in pasteurized milk from infected cows. They included factors quantifying the increase from growth and decrease from pasteurization. Furthermore, they linked the sequential factors into one continuous quantitative model with an output estimating the probability of exposure to a concentration of organisms per mL of milk. The authors used point estimates for each contributing factor at their respective 50th and 95th percentiles of probability. Cassin, *et al.* (26), noted that this otherwise well-organized study could have been significantly improved if the authors had used MonteCarlo modeling in their

estimates of probability of exposure.

Whiting and Buchanan published a quantitative risk assessment model for *Salmonella enteritidis* in pasteurized liquid eggs (86). They identified and linked four sequential sections of a quantitative microbial risk assessment model including (1) quantitative information on the prevalence of pathogens in raw ingredients, (2) changes in CFU/g during defined processing operations, including thermal destruction at pasteurization and potential growth during storage, (3) quantification of food consumption, and (4) modeling of the dose-response relationship. They used MonteCarlo simulations to incorporate uncertainty in their assessment and demonstrated how the model could be used to help develop a HACCP program (86).

Cassin developed a quantitative model of the production and consumption of ground beef hamburger patties to estimate the human health risk presented by *E. coli* O157:H7 in a specific scenario (27). This model was the most mathematically sophisticated quantitative risk assessment published to date for a foodborne microbial pathogen. It linked O157:H7 prevalence in cattle, concentration in faeces, contamination of beef at slaughter, growth and inactivation in retail display and cooking, consumption, dose-response and different biological outcomes including infection, haemolytic uraemic syndrome, and death. It used MonteCarlo simulation to incorporate variability and uncertainty (27). Cassin did not attempt to model the direct and indirect economic impacts resulting from infection. The greatest contribution of this work was the demonstration of the value of modeling the process. Cassin called this a Process Risk Model (PRM) and noted the ability of the PRM to demonstrate the relative importance of factors contributing to the overall risk (27).

## FUTURE NEEDS

Notermans, *et al.* (57) noted that more data are needed. They provided schematic flow charts and decisions trees to help in obtaining and using data required for setting criteria for CCPs and the development of a full HACCP program (57). Buchanan and Whiting (25) recognized the importance of obtaining improved dose-response data. Nevertheless, they believed that improved predictive modeling will be more important in identifying options for managing risks associated with foodborne pathogens (25). Ratkowsky and Ross (68) suggested that modeling the bacterial-growth vs. no-growth interface might be easier and provide more practical information for the food industry than attempting to model kinetic growth in such a dynamic and complex environment. Todd and Harwig (79), and McNab *et al.* (53, 54) noted that direct and indirect economic impacts should be included in risk assessments. To date, this has not been attempted in a fully integrated assessment. Historically, cross-contamination, inappropriate storage, errors in food preparation and recontamination after cooking have been blamed for the majority of outbreaks of foodborne infections (16). Yet, these control errors have not been included in quantitative risk assessments published to date. There is a need to include these factors in future assessments. The relatively new tool of fuzzy mathematics has not yet been applied to any extent in microbial food safety (32, 34), but there may be opportunities for its application in this field. Whiting and Buchanan (86), Cassin (27), and McNab *et al.* (53, 54) noted the necessity of identifying the specific situation being assessed so that quantitative estimates generated by the risk assessment would be relevant. Nevertheless, there may also be a need to develop flexible templates

for generic quantitative models for pathogen X, product Y, and consumer population Z, that could be used as teaching tools to illustrate the principles of quantitative modeling as applied to microbial food safety.

## ACKNOWLEDGMENTS

I thank Mike Cassin, Anna Lammerding, Robin McKellar, and Olivier Cerf for their editorial suggestions and for reviewing the review. I thank the Ontario Ministry of Agriculture, Food and Rural Affairs for funding this project.

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## Correction/Clarification

In the article the "Disinfection of Kitchen Sponges and Dishcloths by Microwave Oven," which appeared on pages 146 to 149 in the March issue of *Dairy, Food and Environmental Sanitation*, the symbols in the figure legends were transposed. They should have appeared with the □ indicating dry conditions, and the • indicating wet conditions.

*The authors regret any confusion this may have caused.*

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This is the second part of a four-part series

# Beef Franks

## EDITOR'S NOTE:

The following are the final three sample HACCP plans first outlined in the June issue. The Overview that ran in the June issue provides background information about the HACCP plans that would not normally be found in the HACCP plan text and should be referred to when reviewing the following plans. These plans were developed by a team of HACCP trainers and persons experienced in the application of HACCP to be used as examples during training of the detail needed to develop an operational HACCP plan.

Those involved include: Dane T. Bernard, National Food Processors Association; William R. Cole, TechniCal Inc.; David E. Gombas, Integrity Food and Drug Consulting, Inc.; Merle Pierson, Virginia Tech.; Robert Savage, HACCP Consulting Group LLC; R. Bruce Tompkin, Armour Swift-Eckrich; and Robert P. Wooden, The Pillsbury Company.

## PREREQUISITE PROGRAMS

Prior to implementation of the attached HACCP plan, the following plantwide programs were reviewed by the HACCP team and found to be adequate, functioning, and maintained. The plant conducts quarterly audits of the prerequisite programs.

- separation of raw material and cooked product;
- plant construction and maintenance (materials, waste disposal, toilet and handwashing facilities);
- potable water supply;
- pest control program;
- SOPs for cleaning and sanitizing;
- equipment maintenance and calibration program;
- temperature control program for the refrigerated rooms used from receiving through shipping;
- training programs for all personnel regarding job requirements, employee hygiene procedures, and

responsibilities pertaining to this HACCP plan.

- purchasing specifications and letters of guarantee that ingredients comply with regulatory requirements and meet plant needs for quality;
- SOPs for receiving and storing ingredients;
- nitrite control program;
- SOPs for shipping/distribution, including temperature specifications for trucks;
- recall procedure including traceability of raw materials to suppliers, coding of finished product, and traceability through distribution.

These programs are the foundation for the total process control system within the establishment. The procedures for these programs are not in the HACCP plans for the products produced in Establishment No. 44-Y, unless they are associated with a specific CCP.

Note: This plan was developed for training purposes only; this is not an actual HACCP plan.

Midwest Meat Processing, Inc. HACCP	Estab. No. 44-Y	Page 1 of 9
Product: Beef Franks, Retail	Effective Date: October 30, 1996	

## HACCP TEAM

E. C. Taylor, Plant Manager;  
F. J. Taylor, Operations Manager;  
A. E. Taylor, Quality Assurance  
Manager; S. R. Kolwin, Plant  
Engineer; and A. M. Callen, Process  
Control.

## PRODUCT DESCRIPTION AND DISTRIBUTION

Beef franks are made with beef, water, flavorings, corn syrup, salt, dextrose, ascorbic acid, and sodium nitrite. The expected shelf life at 40°F is at least 60 days from the date of packaging. During the course of the refrigerated shelf life, a spoilage flora of lactic acid producing bacteria develops and causes a decline in pH to 5.0 or below. The free fluid in the package becomes milky in appearance and the packages may begin to swell as gas is produced. If the franks are placed at ambient temperature, the same spoilage pattern occurs but in a shorter time. Product is shipped in refrigerated trucks.

## INTENDED USE AND CONSUMERS

The product is intended for the general public. The franks are intended to be reheated before use. Recommended procedures are on the package. Although most consumers thoroughly reheat the franks, a few eat the franks without reheating. Some do not follow the instructions.

## FLOW DIAGRAM

The flow diagram from receiving raw materials to shipping the palletized product is attached.

## PLANT LAYOUT

A copy of the plant layout is included.

## PROCESS DESCRIPTION

Fresh beef is received in combos of about 2,000 pounds/ combo from six major suppliers, all under USDA inspection. Upon receipt, the combos of beef are sampled for fat content and placed into a holding cooler. The spice blend, ascorbic acid, and nitrite/salt blend are received from one supplier. This supplier has been the major source of these ingredients for the past 10 years. The corn syrup and dextrose have been purchased from several suppliers over the past 10 years. Rework beef franks are used as an ingredient. The plant's water is from the city of Columbus.

A production schedule is prepared to satisfy the orders for new product. The ingredients are assembled in the staging cooler in the amounts needed for the day. The amount and type of beef is determined using a least cost formula. This enables the plant to minimize raw material cost, meet the fat target in the finished product, and satisfy product quality requirements.

The beef is ground and transferred to a blender. The other ingredients are added, the "blend" is mixed, and then pumped to a chopper for vacuum chopping. The chopped material is pumped through an emulsifier and into the stuffing hopper. Then it is stuffed into shirred casings, automatically linked, looped, and hung on smoke sticks. The sticks are placed on an oven rack and pushed into an oven.

The franks are cooked to an internal temperature exceeding the USDA requirement of 148°F for a cooked sausage. The higher temperature is used to develop the desired product characteristics and inactivate thermotolerant spoilage bacteria.

The franks are showered, blast chilled, and transferred into a cooked product holding cooler for chilling.

The chilled franks are peeled, collated, packaged, placed into boxes, palletized, and transferred to the shipping cooler. From the time the franks are cooked and moved to the cooler they are chilled, stored, peeled, and packaged in refrigerated rooms. The plant frequently loads the palletized product directly into refrigerated trucks and ships to an outside warehouse for subsequent distribution. Very little inventory is maintained at the plant. The only time the franks are exposed to higher temperatures is the short distance between the ovens and the blast chill units.

Approved by Plant Manager

*E. Christopher Taylor*

Date: 10/31/96

Midwest Meat Processing, Inc. HACCP	Estab. No. 44-Y	Page 2 of 9
Product: Beef Franks, Retail	Effective Date: October 30, 1996	

## HAZARD ANALYSIS

The hazard analysis was conducted by considering the likelihood of occurrence and severity of each potential hazard to determine which hazards are "significant" and must be addressed in the HACCP plan. When conducting the analysis, the team determined that beef franks have only rarely been reported to be a source of foodborne illness. The epidemiological data and circumstances leading to illness in those few instances were lacking, but it is likely that the sites where the food-handling error(s) occurred were in food service or in the home.

### Ingredients

Raw beef contains enteric and sporeforming pathogens. It is neither possible, nor necessary, to purchase pathogen-free meat. Certain other ingredients, (i.e., spices) may contain sporeforming pathogens. Even though the spices are "treated," spores may be present. Nothing would be gained by testing the meat or the other ingredients for the possible pathogens. It is better to assume that pathogens are present.

One possible chemical hazard involved in producing beef franks is sodium nitrite. We started our hazard analysis with the thought that, if too much is added, there may be a risk of illness, even death, to the consumer. Young children are more susceptible to the effects of consuming high levels of sodium nitrite. The USDA recognized this concern when it approved the direct addition of sodium nitrite in the mid-1920s and established strict procedures for handling and documenting the use of sodium nitrite.

It is also known that sodium nitrite is an effective antimicrobial

agent for certain pathogens, particularly *Clostridium botulinum*. Thus, in the event cured meats are temperature abused, sodium nitrite can provide some degree of protection by delaying the outgrowth of these pathogens. Our approach to controlling the level of sodium nitrite has been to purchase a preblend of sodium nitrite and sodium chloride. The preblend is produced by a supplier with a HACCP plan in place for this ingredient. The supplier's processing procedures and performance are reviewed annually when the purchasing agreement is renewed.

After considerable discussion, the HACCP team concluded that using a commercial preblend of salt and nitrite to control the sodium nitrite content of our franks offers important safeguards. The preblend provides the USDA permitted level of 156 ppm sodium nitrite based on the meat content. Considering that the formulation includes water and other nonmeat ingredients, the actual amount of sodium nitrite added to the product is only 110 ppm. Even if an error occurred and twice the amount of preblend were added, this would result in a product with only about 220 ppm of added sodium nitrite. Furthermore, the additional amount of salt would be objectionable. The human oral lethal dose for sodium nitrite has been reported to be 22-33 mg/kg of body weight. Thus, at the 22-mg/kg level, a 50-lb child would have to consume about 5 lbs of franks containing twice the permitted level of sodium nitrite (i.e., 220 ppm). Another report indicates the oral lethal dose for sodium nitrite is 1g. This would be equivalent to a 2-oz frank being formulated with more than 18,000 ppm. This would be impossible when using the salt-nitrite blend.

The risk to consumers of an excessive level of nitrite is further

reduced by the fact that the nitrite ion is not stable and decreases significantly during processing and storage. Thus, the residual level of sodium nitrite is normally 30-90 ppm after packaging and 10-30 ppm when purchased. All of this information led us to conclude that illness from too much nitrite is unrealistic, that sodium nitrite is not a significant hazard in this product, and its control does not require a CCP. The existing prerequisite program that ensures compliance with the USDA regulation for control of nitrite is adequate to address this issue.

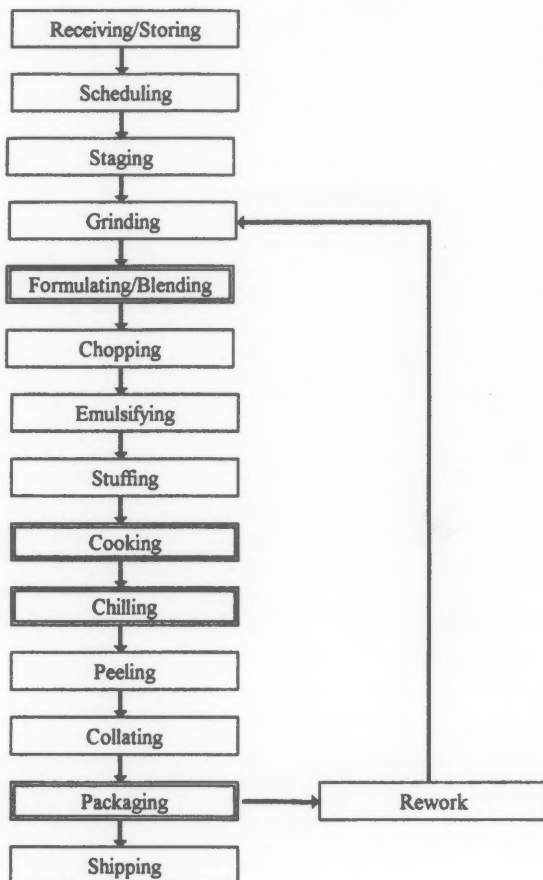
Consideration was also given to the potential for contamination with antibiotics and hormones, both of which are used in live animal production. The conclusion was that these potential hazards are appropriately controlled via prerequisite programs, such as purchasing specifications and letters of guarantee, as well as the USDA tissue-residue monitoring program.

Other chemical hazards include lubricating greases, oils, cleaning compounds, and sanitizers. These hazards, however, are of low risk and severity because the potential for contamination is also controlled through GMPs and SOPs. These chemicals have been approved by the USDA-FSIS for use on processing equipment, such as we use for making franks. Copies of the approval letters and material safety data sheets are on file and available for review. Employees are trained to assure correct use of the materials.

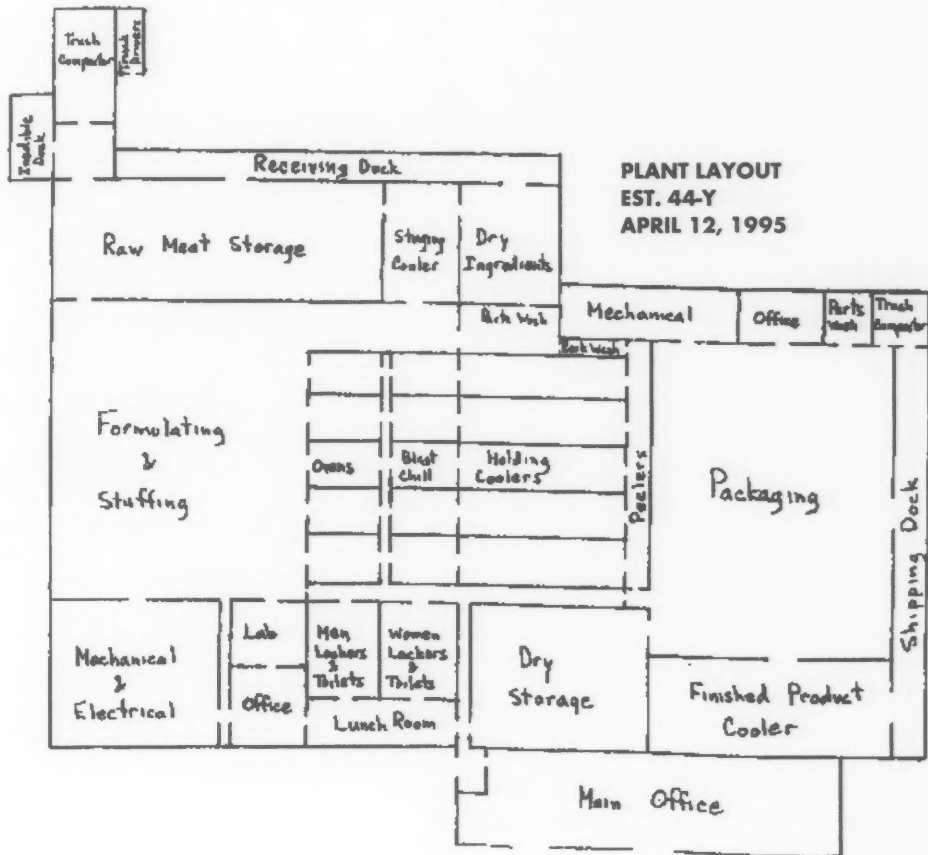
Meat species is important. Some consumers may be sensitive to meat from certain species of animals. The percent of the population with this sensitivity is unknown. This concern, however, has been raised by the USDA in the past 10 years. The agency has classified

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FLOW DIAGRAM



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recalls for "species contamination" as class II, suggesting a low risk to health. The agency has established a guideline to control this potential hazard and has developed a testing procedure to verify compliance. This plant produces different franks which may contain various combinations of pork, beef, chicken, and turkey. Thus, the plant has an SOP to control the risk of adding meat from a species which does not appear in the ingredient phrase of the product label. Even though the risk of this hazard may be low, the severity could be high for those consumers who are sensitive to a meat other than beef. On the other hand, some believe that species contamination is an issue of economic adulteration and not pertinent to food safety. It is hopeful that future research clarifies the food safety significance of species contamination. Until this is clarified, the HACCP team decided to include it in the HACCP plan and establish CCPs for its control. The team also agreed to conduct further investigation into the actual risk involved.

Potential physical hazards include bone chips, plastic, wood, metal and similar hard or sharp materials. An ongoing program of ingredient inspection and working with suppliers has been the most effective means to minimize the risk of these hazards. The grinder is equipped with a bone collector which diverts bone from behind the grinder plate to a discharge tub. The tub is checked every batch to see that the bone collector is working. Meat with a higher than normal amount of bone is noted. This information is passed back to the supplier and used when rating suppliers. Other in-process checks are used to monitor for foreign material. Ingredients are visually inspected when they are received and as they are being added to the grinder and blender. The grinder is

disassembled after every four batches of meat and checked for foreign material accumulated behind the grinder plate.

After blending the ingredients, the blend is emulsified by chopping and passing through plates with openings of 2.5 and then 1.4 mm. If present, any foreign material would be reduced to a size that is close to harmless. A metal detector is in line between the blender and the chopper primarily to protect the chopper and emulsifier from damage. The detector has been difficult to maintain and occasionally breaks down. The plant continues to operate without the detector. This detector may provide some food safety benefit, when it is working, but this is a secondary benefit.

Metal and other physical hazards of significant size can get into our product by entering the process between emulsifying and stuffing. Our history indicates that this occasionally occurs. Future modifications in our equipment may correct this, but for the present, metal is a significant hazard that we must address in our HACCP plan and not just through an SOP as done by some plants in our company. A second metal detector is located after packaging. To ensure the safety of our franks and prevent harm to our consumers, all packages must be metal detected before the product is released for shipment. This combination of control measures has proven effective for minimizing the risk of physical hazards in the finished product.

#### **Processing, packaging, and distribution**

The USDA requirement for cooking ( $\geq 148^{\circ}\text{F}$  internal temperature) destroys the vegetative pathogens of concern. Bacterial spores survive at very low levels

(normally  $<10/\text{g}$ ). Chilling the product after cooking controls their outgrowth. Cooking is the step in the process that separates the raw material environment from the ready-to-eat environment. Fortunately, this plant is of relatively recent design (built in 1984) and has a layout favorable for clearly separating these two environments. The ovens have doors on each end, so freshly stuffed franks are loaded from the raw processing side and, after cooking, moved into the cooked product side. The ovens are properly maintained and checked bimonthly for temperature uniformity. A product target temperature of  $160^{\circ}\text{F}$  for reasons of product quality and shelf life provides a substantial margin over the minimum USDA requirement of  $148^{\circ}\text{F}$ .

The rate of chilling is important. Although the franks have been cooked sufficiently to destroy vegetative pathogens (e.g., salmonellae, *E. coli* O157:H7), a low level of spores (e.g., clostridia, *Bacillus* spp.) survive. The product also acquires surface contaminants from showering, air currents, and from moving the franks into the blast chill and holding coolers. Franks, being of small diameter, are quick to chill. After cooking, the franks are initially blast chilled and then moved into the holding coolers. Our holding coolers were designed with sufficient capacity to hold the volume of product produced each day. The temperature of the franks is reduced at a rate well within the USDA cooling guideline for cured products. If an unexpected event occurs (e.g., power failure) and the product does not chill at the required rate, microbial growth can occur. The extent and type of growth depends on time and temperature. Due to the many possibilities, it is not possible to identify the specific microbiological hazards that might result. There are, however, several different control



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measures available for such circumstances. The HACCP team has not experienced such a problem but concluded that the chilling rate is a food safety concern that should be addressed in the plan.

Once chilled, the likelihood that the franks are exposed to temperatures supporting rapid pathogen growth is extremely remote. The process of peeling, collating, packaging, boxing and moving the palletized product into distribution for shipping normally takes much less than an hour. Our plant's target is to have the packaged product into the boxes at 35°F or below to enhance shelf life. The lower limit for the growth of sporeformers of significance is about 50°F. The franks have been formulated for a brine level of 4.0% [% brine = (% salt/% salt + % water) × 100] and sodium nitrite. This combination retards the outgrowth of surviving sporeformers. Holding times are necessarily kept short. Franks cooked one day normally must be packaged and shipped the next day to make room for new production except for weekends and holidays. Another reason to avoid long holding times is excessive weight loss and unacceptably low net weight packages. Underweight franks must be reworked or packed off as a bulk item and downgraded. Furthermore, the longer they are held, the more difficult they are to peel. These factors plus the existence of an effective temperature control program for the rooms led the HACCP team to conclude that the likelihood of temperature abuse between chilling and shipping is too low for a significant microbiological hazard to develop.

Epidemiological data indicate that the risk of foodborne illness from sporeforming pathogens is very low. There have been no reported outbreaks of botulism in North America from commercially

produced franks. There also is no evidence which implicates franks as a source of foodborne illness from *B. cereus* or *C. perfringens*. This may be attributed to the combined effect of the "Keep Refrigerated" statement, general knowledge of the perishability of vacuum-packaged franks, product formulations which retard growth of sporeformers, presence of a readily fermentable carbohydrate, growth of lactic acid bacteria which cause the product pH to decline to inhibitory levels, and a very low number and prevalence of spore-forming pathogens in cooked franks. It was concluded that these sporeformers are not a significant hazard in vacuum-packaged beef franks during distribution, storage, and retail display.

One case of listeriosis has been reported which implicated frankfurters. Although an initial case control study by the Centers for Disease Control reported that franks may be a source of human listeriosis, a follow-up study did not corroborate this finding. It is recognized that postprocess contamination with *L. monocytogenes* is a possibility, and the prerequisite GMPs and SOPs must address this concern. The sanitation procedures used in the areas where cooked franks are chilled, stored, and packaged have been designed to minimize the risk of contamination with *L. monocytogenes*.

Existing published data and experience indicate that the risk of postprocess contamination with salmonellae is negligible in plants which meet current GMPs.

There is no evidence to implicate franks with illness from *Yersinia enterocolitica* or *Aeromonas hydrophila*. Since these pathogens multiply at refrigeration temperatures, there has been speculation that they may occur in the cooked product environment. The HACCP team decided that these pathogens do not fit the definition of a "significant hazard."

The risk of *Staphylococcus aureus* also is very low due to the personal hygiene requirements adopted by the plant. Our sanitation SOP requires that employees wash their hands with a bactericidal hand soap and, when handling cooked product, wear disposable gloves. The gloves are replaced if they become soiled and each time employees return to their jobs from a break. Employees also wear disposable paper wrist guards over long-sleeved disposable frocks to further reduce the risk of contamination. In the event contamination with *S. aureus* occurs, the organism cannot multiply below 45°F. Furthermore, it must multiply to high levels (e.g., about 10<sup>6</sup>/g) to produce sufficient enterotoxin to cause illness. The risk of this occurring is minimal because *S. aureus* competes poorly with the lactic acid bacteria which predominate in vacuum-packaged franks. Thus, *S. aureus* has not been a significant hazard in commercially produced, vacuum-packaged franks.

The information provided on chemical and physical hazards in the ingredients section also applies during processing. Species contamination is prevented during packaging by having the packaging supervisor visually check that the franks being packaged are beef franks and the film is correct. This is checked off on the packaging department production record. In addition, the tags from the racks are saved as the franks are removed for peeling. The packaging supervisor checks the tags before they are discarded. All packaged product must pass through an operable metal detector before it can be shipped. If the detector is inoperable or not performing with the required sensitivity, the packaged franks are put on hold by Q.A. until the detector is working and they can be checked.

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**TABLE 1. Steps in the process where significant hazards can occur**

(Summary of hazard analysis)

Step	Identified hazard	Control measure
Farmulating/ Blending	Species contamination	Visual check for type of meat, order of grinding meat
Cooking	Vegetative pathogens (e.g., salmonellae, <i>E. coli</i> O157:H7)	Cooking
Chilling	Sporeforming pathogens (e.g., <i>B. cereus</i> , <i>C. botulinum</i> )	Rate of chilling
Packaging	Metal	On-line metal detector
Packaging	Species contamination	Visual check for type of franks and correct packaging film

**TABLE 3. Verification schedule**

Verification activity	Frequency	Person(s) responsible for verification	Person(s) having overview and authority to change the activity
Individual CCPs	As per HACCP Plan	As per HACCP Plan	HACCP team
CCP revalidation	When a significant factor (e.g., equip- ment) associated with the CCP has been changed.	Quality assurance or independent expert	HACCP team
Review of manitaring, corrective action, and CCP verification	Monthly	Quality assurance	HACCP team
HACCP system verification/audit	Annually, upon system failure or significant change, whichever comes first.	Outside HACCP expert	Plant manager

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**TABLE 2. HACCP plan summary**

CCP	Hazard	Critical limit	Monitoring	Corrective action	Record keeping	Verification
Formulating/Blending	Species contamination	Blend "all beef" formulations first	Formulating operator looks at each comba of meat and tub of rework as they are being emptied into the blender. Operator makes the "all beef" blends first in the day to avoid contamination from product containing other species.	If meat other than beef is suspected, the operator stops and notifies the formulating supervisor.	Operator checks off the formulating/blending record indicating only beef has been added. Tags are attached to racks of links to properly identify product.	Supervisor periodically checks operator for ability to differentiate beef from other meats. Supervisor reviews, dates, and initials blending record.
Cooking	Vegetative pathogens	Minimum internal temperature of 148°F	Oven operator follows cooking chart and oven temperature. Internal temperature of product is checked with a thermometer.	Operator continues cooking until 148°F internal is reached. If cook cycle is interrupted by power failure or other reason, the operator notifies both the supervisor and QA. Hold and evaluate any product which did not reach 148°F.	Oven operator initials and dates the cook charts for each oven load. The cook charts are retained for 2 years. Mechanics maintain records of oven checks and repairs. QA maintains log of operator's thermometer accuracy.	Supervisor over the oven operation reviews, dates, and initials cook charts each day or before the product is packaged. Mechanics check heat distribution and oven performance at least once every 2 months or when a problem is suspected. QA verifies accuracy of oven operator's thermometer each day.
Chilling	Spare-farming pathogens	Chill to ≤50°F within 4 h.	Cooler operator checks internal temperature of product periodically during chilling. Mechanic checks operating temperature of blast chill units once per day.	If product is not chilling within the USDA guideline, several options are available (e.g., increase air circulation, reduce temperature of room, spread out product more). If the cooling units fail, move product to another cooked meat cooler, packaging room, or shipping cooler.	Cooling operator records time, temperature, and date in cooling log book. Record is retained 2 years. QA maintains log of checks of cooling operator's thermometer.	Packaging supervisor periodically checks cooler to see that it is operating normally. The log book is reviewed, dated, and initialed weekly. QA verifies accuracy of cooling operator's thermometer weekly.

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**TABLE 2. (Continued) HACCP plan summary**

CCP	Hazard	Critical limit	Monitoring	Corrective action	Record keeping	Verification
Packaging	Species contamination	Beef only	Packaging supervisor looks at the franks being packaged to be sure they are beef. He/she also checks each roll of printed film to be sure it is for beef franks. Rack tags are checked to assure proper species control.	Supervisor places questionable product on hold and notifies QA. Together they collect and assess the information and product to arrive at a decision.	Supervisor records results of tag check on packaging report.	QA verifies the franks being packaged are beef and that they match the packaging material (i.e., label, ingredient statement).
Packaging	Metal	No metal of $\geq 2.0$ mm	Metal detector checks all packages before they are placed into boxes.	Rejected packages are discarded. If large numbers occur, QA may examine for information as to cause and how to prevent. If detector is not operating within specification, product must be placed on hold until the detector is repaired or replaced. All product must pass through a detector that is functioning correctly before it can be shipped.	QA check is noted in the QA log book for the packaging room.	QA verifies twice per shift that the detector is working and is sensitive at 2.0 mm ferrous and nonferrous.

**Note:** If a deviation occurs, the deviation is recorded in the appropriate record for that department. QA maintains a chronology of all deviations including the type of deviation, pertinent information, and final disposition of the product.

This is the third part of a four-part series

# Frozen, Raw Beef Patties for Food Service

FBP Products, 1000 FBP Place, New York, NW 60036; 212.555.1000\*

## BACKGROUND INFORMATION

### Prerequisite programs and activities

Before implementing this HACCP plan, the following plant-wide programs and activities were evaluated by the HACCP team and shown to be adequate, functioning, and maintained. The plant conducts routine audits of the prerequisite programs.

- current diagram of the plant layout indicating product flow;
- plant construction and maintenance (materials, waste disposal, toilet, and handwashing facilities);
- potable water supply;
- pest control program;
- cleaning and sanitizing procedures, including SSOPs;
- preventive maintenance program for equipment, including calibration;
- temperature control programs for all refrigerated rooms;

- training programs;
- procedures for receiving and storing ingredients;
- shipping/distribution procedures, including temperature specifications for trucks;
- recall procedure including, traceability of raw materials to suppliers, coding of finished product, traceability through distribution, and periodic mock recalls to verify that it works in the event of an actual recall;
- supplier audit program (e.g., review of supplier HACCP plans, purchase specifications, and letters of guarantee).

These programs are the foundation on which the HACCP plan was developed and are important to the reliable functioning of the HACCP plan. The procedures for these programs are outside the scope of the HACCP plan.

## HACCP PLAN FOR FROZEN, RAW BEEF PATTIES

### HACCP team

R. B. Lewis, Plant Manager; R. L. Jones, Operations Manager; V. L. Johnson, QA Manager; L. M. Smith, Plant Engineer; C. D. McIntyre, R&D.

### Product description, distribution, and intended use

"100% Pure Beef Hamburgers" are raw beef patties manufactured from only domestic beef. The product is coded for a shelf life of 90 days when stored at <0°F (-17.7°C). All product is packaged in corrugated boxes. Product is kept frozen until use. It is intended to be fully cooked in a food service establishment and served to the general public in a hot sandwich.

### Ingredients

USDA approved boneless beef (primal cuts and trimmings) is purchased from numerous suppliers nationwide. Product is received in refrigerated 2000 pound combo bins. Beef is the only ingredient used.

\*This is a fictional HACCP plan, the company referenced here is not real.

## Process flow diagram

See to right.

## Process description

Fresh beef is received in 2000 pound combos. Each combo is inspected on receipt for condition, temperature, and date of pack. Combos are color coded for rotation and moved into a holding cooler maintained at 30-35°F.

The meat is coarse ground through an initial grinding plate, emptied into a blender, mixed, and analyzed for fat content. Normally, within an hour, different batches of meat are blended to meet customer specifications for fat content, mixed, and then chilled with carbon dioxide to about 30°F. The purpose of chilling is to control the quality of the ground product by enhancing particle definition and preventing smearing of the fat over the lean meat. Then the chilled meat passes through a final grinding plate which includes a bone collection system. The final grind size is specified by our customers.

Beef patties are formed by a forming machine, quick frozen, passed through a metal detector, packaged into corrugated boxes with a polyethylene film liner, code dated, taped, and stored in a freezer maintained at 0 to -10°F.

Rework generated through the process is reused within a two-hour period. Rework product is re-introduced at the blender before final grinding.

## HAZARD ANALYSIS

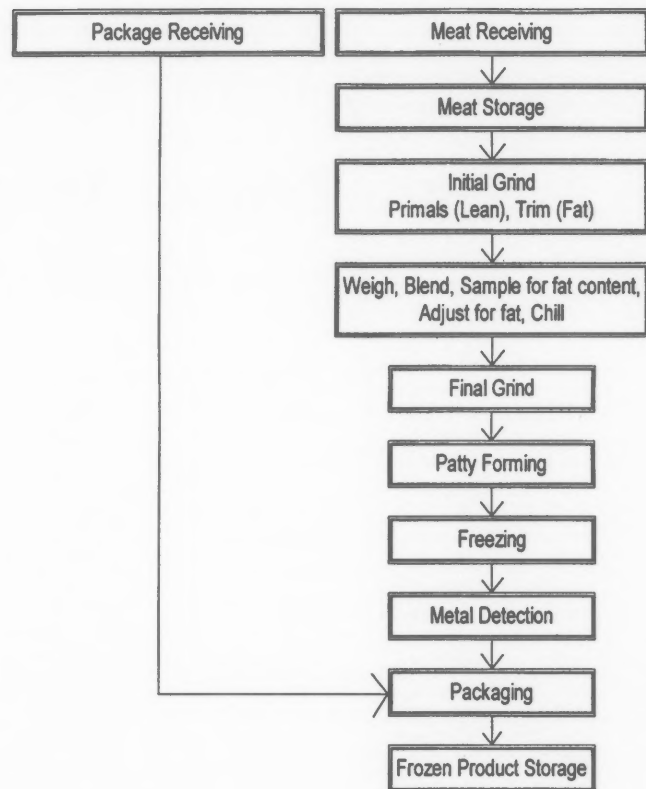
### Biological Hazards

Fresh beef contains enteric pathogens, particularly salmonellae and possibly *Escherichia coli* O157:H7. The extent to which these pathogens are present is influenced by a number of factors. The source of these pathogens is the intestinal tract of cattle. Research is being conducted to determine if it is possible to reduce the presence of these pathogens

during live animal production and to minimize shedding during live animal hauling. Slaughtering facilities can minimize contamination and apply certain interventions (e.g., antimicrobial sprays) to reduce their presence.

We have continued using our microbiological testing program, which includes testing for total plate count and generic *E. coli* in incoming meat and finished patties. This program generates data that have helped us to identify and eliminate problem suppliers. Data are shared with our suppliers and used for our continuous improvement program. We place greatest emphasis on the *E. coli* data to indicate the level of control being practiced by our suppliers. We

Flow Diagram  
Frozen Beef Patties



have set a goal of 20% reduction in the level of *E. coli* in our frozen beef patties over the next year through improvements at the supplier level. This goal is not a CCP nor a critical limit and is not considered a part of our HACCP plan. The data on finished patties are used to assess the effectiveness of our total process control system. In addition, this may help us comply with the salmonellae performance standard and that has been established by USDA-FSIS.

At our suppliers, carcasses are chilled and cut into parts for packaging and shipping. Certain portions of the carcass, including trimmings, are collected into combos for shipment to our facility for further processing into ground

beef. In addition, some slaughtering facilities ship chilled carcasses to other plants where the carcasses are cut into portions. These plants specialize in deboning meat and generate meat that is then shipped to us for making ground beef. Our supplier specifications require that suppliers have documented prerequisite programs and verified HACCP systems.

All of the meat received in our plant is fresh, refrigerated, hand-deboned beef. There are no steps in our process that can reduce the presence or number of microbial pathogens that may be present in the raw meat we purchase. The meat is received refrigerated and quickly passes through our process. All storage and processing occurs at refrigeration temperatures until the product is frozen and packaged. The process is relatively simple as is obvious from the flow diagram. Through temperature control, timely processing of incoming meat, and then freezing the product, we control the risk of multiplication of pathogens of concern. We have an effective sanitation program to assure the cleanliness of our processing equipment and the environment in which the meat is received, stored, and processed. This basic sanitation program, however, does not reduce or eliminate pathogens in the meat. The low temperatures of our process preclude the growth of salmonellae and *E. coli* O157:H7 in the equipment during production. This statement is based on information on the growth rates of these pathogens that will be discussed later.

The microbial content of our finished product reflects the microbial composition of the incoming raw meat. As we blend from various sources to achieve our fat targets and other customer specifications, we also blend the microbial populations in the various meats. This has the effect of diluting higher populations with lower populations. It is also true, however, that when meat from one

source contains a pathogen, such as *E. coli* O157:H7, then this meat serves as an inoculum for all the blends of meat in which it is used. All of these factors have been considered as we have worked to enhance the microbial safety of our frozen beef patties. This information is also important to our hazard analysis.

There is a theoretical risk that psychrotrophic pathogens grow throughout the fresh meat processing and shipping chain. There are no data linking ground beef products to foodborne illness associated with psychrotrophic pathogens (*Yersinia enterocolitica*, *Aeromonas hydrophila*, *Listeria monocytogenes*). Pathogenic strains of *Yersinia enterocolitica* have been associated with pork, but not beef. A debate continues over the significance of *A. hydrophila* as a foodborne pathogen. The data available for *L. monocytogenes* have not linked fresh meats, including ground beef, with foodborne listeriosis. The HACCP team concluded, therefore, that the psychrotrophic pathogens are not significant hazards and they were excluded from further consideration.

The significant microbial hazards consist of salmonellae and *E. coli* O157:H7. Because the potentially high rate of illness and mortality among young children, in particular, *E. coli* O157:H7 is of great concern. There are no control points in our process at which salmonellae and *E. coli* O157:H7 hazards are prevented, eliminated, or reduced to acceptable levels, and the HACCP team could not conceive of a change in the process that would provide such control. Therefore, the presence of these pathogens cannot be controlled by this HACCP plan. Control has to occur at the customer level, and efforts to minimize the potential presence will be focused on our suppliers.

To enhance the safety of our product, we have decided to work closely with our suppliers to

facilitate their implementation of HACCP and adoption of new control measures as they become available to reduce possible contamination by these pathogens. In addition, we purchase shipping cartons with the USDA safe food handling instructions preprinted on the side and maintain a customer assistance/education program for those food service operators who need this service. This includes instructions on how to cook our products to assure safety and still obtain optimum quality. Our cooking instructions are based on the 1995 *Food Code* which specifies cooking beef patties to an internal temperature of 155°F with a holding time of 15 seconds.

We have determined that dehydration (i.e., freezer burn) of the frozen beef patties during storage in the freezer slows the rate of heating in areas of freezer burn. This leads to undercooking and to the survival of pathogens. Because the current recommendations in the *Food Code* are based upon killing a large population of salmonellae in the center of the patties, there should be a margin of safety even if freezer burn occurs. Because research data are not available to assess the impact of freezer burn on pathogen survival, the true impact on food safety is uncertain. Our experience indicates that freezer burn does not develop if the patties are stored at less than 10°F. Although the time of storage at 10°F and above is also a factor, we do not have data to define the time-temperature relationship involved in the development of freezer burn. To address this concern, we recommend to our customers that the patties be stored at 0°F or below and not to use patties with freezer burn. This information is included with our storage and cooking instructions and in our customer assistance/education program.

The time-temperature during chilling, deboning, shipping, storage, grinding, patty forming, and freezing influences whether

the growth of these pathogens occurs prior to cooking. Based on the time and temperatures that are encountered in commercial practice, the risk that salmonellae and *E. coli* O157:H7 multiply is minimal. The lower limit for their multiplication is 5.2°C (41°F) for salmonellae (most strains cannot multiply below 45°F) and about 7° to 8°C (about 45°F) for *E. coli* O157:H7. At 50°F, the time for a one log (i.e., ten fold) increase in population is greater than 24 hours when determined in the favorable conditions of a broth medium. The USDA Pathogen Modeling Program indicates that the lag time for salmonellae and *E. coli* O157:H7 at 50°F is 50 hours or greater.

An Australian study found that 15 hours was required for salmonellae to double in number on beef at 12°C (53.6°F). At 15°C (59°F) and 20°C (68°F), doubling would occur in 8.45 and 4.18 hours, respectively. A study from the UK reported that the mean doubling times on beef were 8.1 hours at 10°C (50°F), 5.2 hours at 12.5°C (55°F), and 2.9 hours at 15°C (59°F). Based on this information, the HACCP team concluded that the meat temperature would have to exceed 10°C (50°F) before the risk of these pathogens is increased. At temperatures greater than 10°C (50°F), spoilage of the meat is an important factor. Routine handling practices in our establishment make storage temperatures above 50°F for any appreciable time highly unlikely.

The HACCP team considered sampling and testing the incoming raw material and frozen patties for *E. coli* O157:H7. We concluded that because the prevalence of this pathogen is so low, this approach would not assure the safety of our product. Statistics do not support this approach to assuring food safety. Furthermore, we would not learn much from the expected large number of negative values. The data, based on discussions with other producers, customers and the USDA, indicate that prevalence may

be about 0.07% in ground beef. To place the value of sampling and testing in perspective, we learned that, if the contamination level in a production lot was 0.5%, then 600 samples would be required for a 95% probability of detecting a positive sample. If the contamination level was 0.1%, then with 600 samples the probability of detecting a positive sample would decrease to 45%. This assumes that the methodology is sufficiently sensitive to detect *E. coli* O157:H7 every time it is present in a sample. Since the USDA survey data for ground beef has shown that the level of contamination is about 0.07% (7 positives out of 9773 samples to date), we concluded that a sampling program based upon one, or even one hundred samples across each lot would not be of value for enhancing public health. Thus, our microbiological testing program focuses on total plate count and generic *E. coli*. We have instituted a program to follow reports in the literature from public health agencies and the USDA-FSIS. Our HACCP plan will be modified, if necessary, based on this information.

A few of our customers have a microbiological specification that requires us to test our frozen patties for *E. coli* O157:H7. Product for those customers is placed on QA hold until the product is tested and we have received a written report from the lab. Since the test for *E. coli* O157:H7 requires the use of a positive control, all our analyses for this pathogen are done by an outside laboratory rather than maintaining a live culture of this pathogen in our facility. Our laboratory is quite capable of conducting routine analysis for nonpathogens (i.e., total count, generic *E. coli*).

#### Physical hazards

Physical hazards associated with frozen beef patties consist of bone and metal in the raw material. Metal detectors and bone collection

systems have been installed to reduce the risk of these hazards in the product.

Metal also occurs from the normal wear and tear on our equipment. Even though we have a preventive maintenance program for equipment, we do check the final product for metal to reduce the risk of this hazard. In addition, we work closely with our suppliers to facilitate their adoption of new control measures as they become available.

Our purchase specifications require that the primals and trimmings be free of detectable bone. In addition, our bone collection system includes a 3/32 inch grinder plate with a spiral 1/8 inch groove. This groove provides a travel path of least resistance for the bone to exit the grinding process. The bone collection system prevents bone in excess of 3/32 inch from entering the ground beef. The equipment design makes it impossible to grind product without the bone collection system in place. Should this groove become plugged, bone may collect behind the plate, thereby interfering with product manufacture. Another possibility is that entrapped bone continues to be ground until it is reduced to 3/32 inch and passes through the holes in the plates. The grind size specified by our customers may allow small pieces of bone or gristle in the ground product. The grinder plate is checked on an hourly basis to determine if foreign material has accumulated and whether the bone collector is operating correctly. These precautions reduce the risk of bone, gristle, and foreign materials (e.g., plastic, wood) in the ground product. Thus, it is possible to reduce but not eliminate all bone from the product.

The grind size (i.e., 3/32 inch) establishes the size of bone in the product. A special USDA panel has concluded that there is no health concern if bone particles are less than 0.4 inches in size. They also concluded that bones in the range



of 0.4 to 0.8 inches are of low risk to consumers. This information led our HACCP team to conclude that bone particles are not a significant hazard and grinding is not a CCP in our facility. The frequency of bone particles is determined by our ability to visually detect bone in incoming meat, our suppliers providing meat with low bone content, and by confirming that the bone collector is functioning

properly. So, although bone is not addressed in our HACCP plan, it is being addressed by our prerequisite programs.

#### Chemical hazards

The HACCP team considered the potential for contamination of the incoming combos with antibiotics and hormones, both of which are approved for controlled

use in live animal production. The conclusion was that these potential hazards are appropriately controlled via the supplier audit prerequisite program and the USDA tissue-residue monitoring program at the slaughter facilities. Additional potential chemical hazards, such as lubricants, oils, cleaning agents, and sanitizers present a low risk to consumers and are adequately controlled via the prerequisite programs.

### FROZEN, RAW BEEF PATTIES FOR FOODSERVICE

Operational Steps	Hazard	Critical Limit	Monitoring	Frequency	Corrective Action	Records	Verification
Metal Detection	Metal	Patties do not contain metal >1.2 mm ferrous or >1.5 mm stainless.	Line Operator observes that patties are conveyed through the metal detector.	Each shift	Adjust, repair or replace metal detector to obtain required sensitivity. If detector is not operating correctly, then patties produced since last acceptable QA check must be held until they can be passed through a detector that is functioning correctly. Rejected patties are discarded. If the quantity is excessive or indicates a continuing problem, QA will examine patties and investigate source.	Production form for packaging line, indicating metal detector was on, patties were scanned, results of sensitivity check, and any corrective actions needed.  Metal detector's monthly calibration records.	Line supervisor reviews production forms before lot is shipped.  Maintenance calibrates metal detector monthly.
		Patties pass through functioning detector.	QA checks operation and sensitivity of metal detector.	Each shift			

Date plan approved: OCTOBER 1, 1996 by Robert Lewis  
Plant Manager

This is the fourth part of a four-part series

# Frozen Dough Products for Food Service

Baking Foods Inc.  
HACCP Plan  
Sometown, NY

PLAN #: 900

Date: 12/15/96

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### CRITICAL CONTROL POINT LOG SHEETS

\*Authors' note: for simplicity, only two-unit operations are shown in this plan.

**Note:** This plan was developed for training purposes only; this is not an actual HACCP plan.

## HACCP Plan Approval

Plant No.: 900  
Business: Baking Foods Inc.  
Facility Location: Sometown, NY  
Date: 12/15/96

This is to certify that the HACCP Plan has been examined for food safety hazards and that the HACCP plan is complete and effective for controlling the identified hazards, provided that the CCP's outlined are implemented and maintained in full. Furthermore, this HACCP Plan is approved on the condition of compliance with the other programs of the Quality Management System (QMS).

***Additional Requirements:***

Approved: Bill Westerman

Title: Director, Food Safety & Regulatory Compliance

Date: 12/15/96

**HACCP Team**

**Business Name:** Baking Foods Inc.    **Facility Location:** Sometown, NY    **Date:** 12/15/96

**Product/Process:** Frozen Dough Products

**Team Members:**

Dale Guarino                      QA Manager                      (HACCP Team Leader)

Dennis Beckett                      Plant Engineer

Brian Thomas                      Manufacturing Manager

Marilyn Peters                      Supervisor Line 2

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**Consultants:**

Roberta Strong                      HACCP Consultants Inc.

Bob Collins                      Food Safety Ltd.

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### HACCP Plan History

Business Name: Baking Foods Inc.

Plant Number: 900

Facility Location: Sometown, NY

Date	Activity	Action	Approved
6/30/93	Annual Verification	Completed, no changes	Dale Guarino
6/30/94	Annual Verification	Completed, no changes	Dale Guarino
12/4/94	HACCP Plan Review by Food Safety Ltd.	Updated & Simplified Plan, Removed 40 Control Points	Dale Guarino
11/30/95	Refurbished Packing Line 2	New metal detector with new standard	Dale Guarino
12/5/95	Annual Verification	Completed, no changes	Dale Guarino
12/15/96	Annual Verification	Completed, no changes	Dale Guarino

Baking Foods Inc.  
HACCP Plan  
Sometown, NY

**PRODUCT DESCRIPTION  
AND HAZARD ANALYSIS  
SUMMARY**

The food products manufactured in this plant are all frozen doughs. The products are baked by the customer directly from the frozen state. No products for direct retail sale are produced at the plant in Sometown, NY. Because these products are sold to food service customers, the consumers are of all age groups. This HACCP plan represents over 20 individual Universal Product Codes (UPCs). The processes to produce these products are outlined in the flow diagram summarizing all the unit operations (Reference number 901).

All products use similar ingredients, as listed below:

**Ingredient**

Enriched flour  
Water  
Hydrogenated vegetable shortening  
Dried milk  
Sugar  
Baking powder  
Salt  
Sodium caseinate  
Mono- and diglycerides  
Dried egg albumen  
Enzyme-modified butter

All products are packed in bulk quantities in polyethylene-lined corrugated boxes.

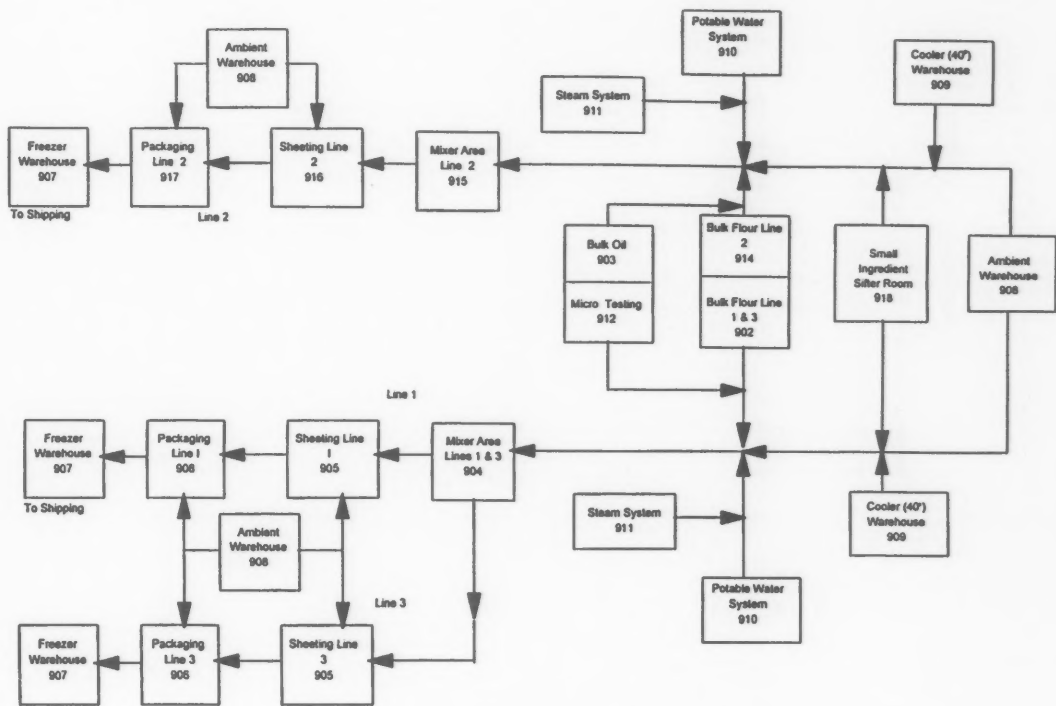
Hazards inherent in the ingredients and products as formulated have been analyzed, and the results considered in writing the raw material and finished product specifications. During the hazard analysis, the HACCP team considered the following facts. Raw material specifications require that milk- and egg-derived ingredients are purchased from suppliers with HACCP plans. These ingredients have been pasteurized. The purchasing agreements include microbiological specifications appropriate to each ingredient. The ingredients are checked randomly to assess compliance by the various suppliers. Our supplier base has been fairly stable, and there has not been a problem with compliance. Experience with these ingredients and suppliers has demonstrated no significant chemical or physical hazards. When baked according to instructions, these products reach an internal temperature lethal to enteric pathogens. Underbaked products are unacceptable to consumers and are typically rejected.

The company has considered the possibility of temperature abuse

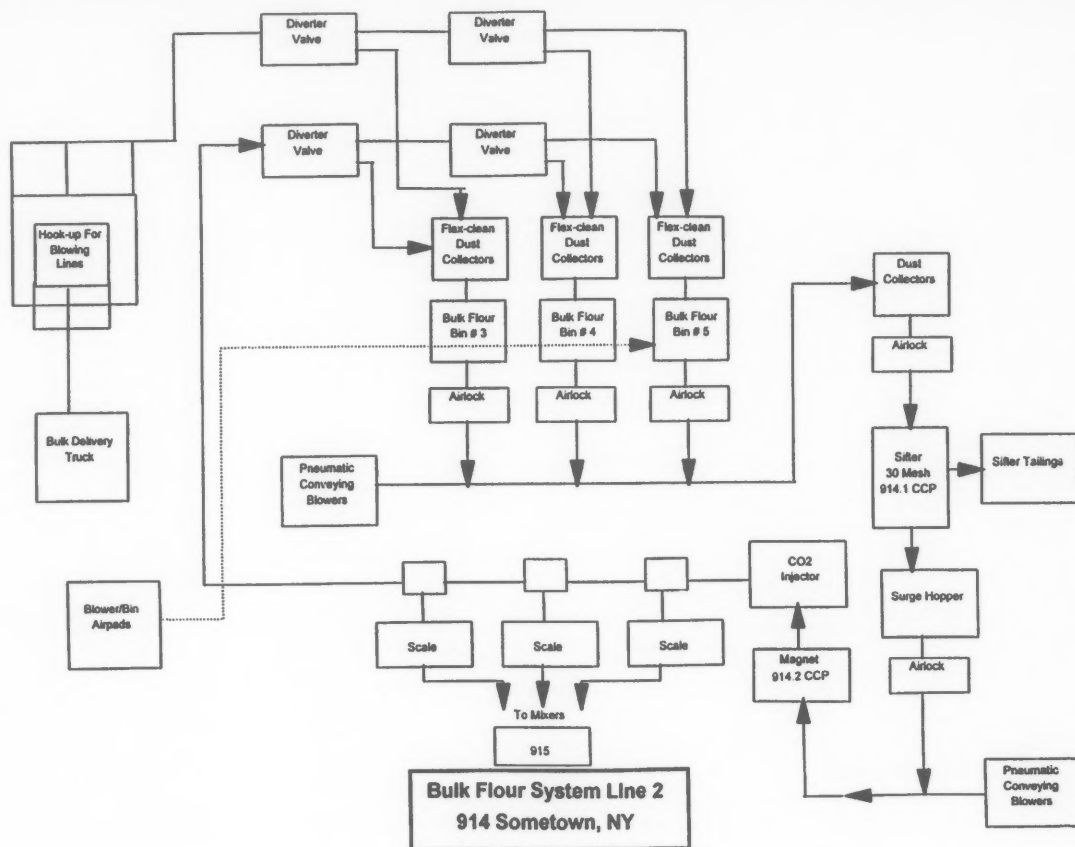
by the customer. When thawed, the  $a_w$  of the various doughs ranges from 0.93 to 0.94. Challenge studies have demonstrated no pathogen growth at 70°F except for *Staphylococcus aureus*. Results of these studies show that, after seven days at 70°-75°F, growth of *S. aureus* is still so limited that no toxin formation occurs.

The physical manufacturing systems in the plant have been assessed and the possibility of foreign objects, mainly metal, have been noted in various unit operations. For line 2, the risk of metal contamination hazard is controlled at the bulk flour system (#914) and the packaging line (#917). The three CCPs in this process line are all intended to control metal contamination. Although the three CCPs appear redundant, the HACCP team decided that they are useful in making a decision on product disposition when there is a deviation at any one of the CCPs. All product must pass through a metal detector that meets critical limits prior to shipment.

When formulated and manufactured as specified, these products pose no other significant hazards of a chemical, physical, or biological nature.



**Process Flow Diagram**  
901 Sometown, NY



### HACCP Plan Summary

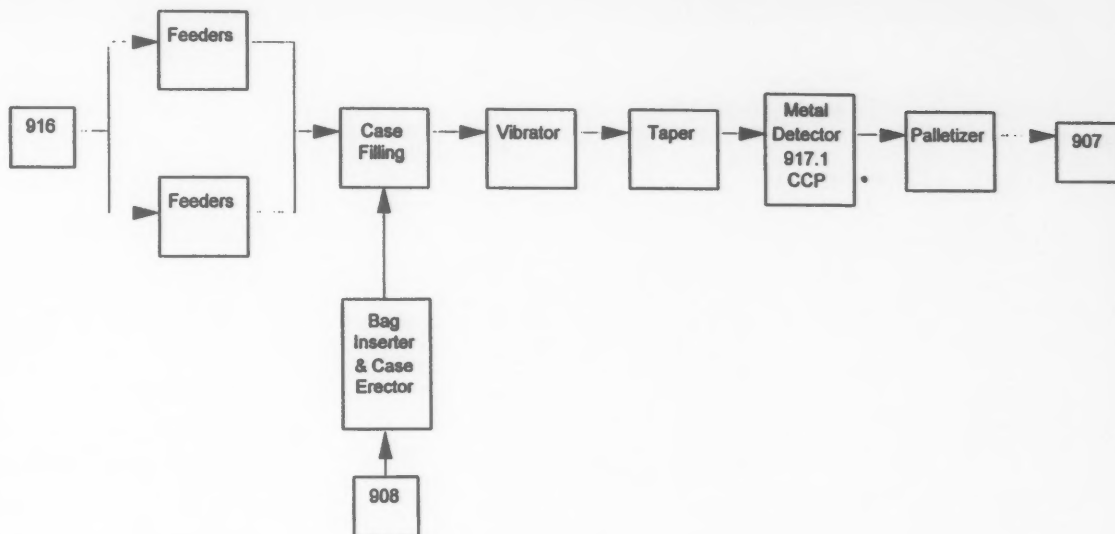
Business Name: Baking Foods Inc.

Facility Location: Sometown, NY

Bulk Flour Line 2: Reference Number 914	Date: <u>12/4/94</u>	Approved by: <u>Dale Sciarino</u>
---	----------------------	-----------------------------------

Process Step	CCP No.	Hazard(s)	Control Measures	Critical Limits	Monitoring	Actions to be Taken if Deviation Occurs	Records	Verification
SIFTER FOR BULK FLOUR TO SURGE HOPPER	.1	METAL	INTACT SIFTER WITH 30 MESH SCREEN (NYTEX)	SCREEN IN PLACE AND NOT DAMAGED	LINE SUPERVISOR INSPECTS WEEKLY AND LOGS RESULTS	NOTIFY Q.A. MANAGER AND REPLACE SCREEN.  VERIFY CONTROL AT DOWNSTREAM CCPs #914.2 AND #917.1	CCP #914.1 LOG SHEET	QA INSPECTOR REVIEWS CCP LOG MONTHLY
MAGNET FOR BULK FLOUR TO SURGE HOPPER	.2	METAL	RARE EARTH QUICK CLEANING BULLET MAGNET	IN PLACE AND OPERATING	LINE SUPERVISOR INSPECTS DAILY AND LOGS RESULTS	NOTIFY Q.A. MANAGER AND REPLACE MAGNET.  VERIFY CONTROL AT DOWNSTREAM CCP #917.1	CCP #914.2 LOG SHEET	QA INSPECTOR REVIEWS CCP LOG WEEKLY





**Packaging Line 2**  
 917 Sometown, NY

**HACCP Plan Summary**

Business Name: Baking Foods Inc.

Facility Location: Sometown, NY

Packaging Line 2: Reference Number 917	Date: <u>11/30/95</u>	Approved by: <u><i>Dele Aquino</i></u>
--	-----------------------	--

Process Step	CCP No.	Hazard(s)	Control Measures	Critical Limits	Monitoring	Actions to be Taken if Deviation Occurs	Records	Verification
METAL DETECTOR	.1	METAL	100% OF PRODUCT IS SCANNED BY GORING KERR TEK 21 METAL DETECTOR	DETECTOR ON, REJECTOR WORKING, 2 mm FERROUS	LINE OPERATOR CHECKS AND LOGS HOURLY THAT DETECTOR IS WORKING WITHIN CRITICAL LIMITS	NOTIFY QA MANAGER; SEGREGATE AND RETEST PRODUCT SINCE LAST GOOD CHECK	CCP #917.1 LOG SHEET	QA INSPECTOR REVIEWS CCP LOG SHEET AND VERIFIES DETECTOR SENSITIVITY DAILY

# NewMembers

## AUSTRALIA

**Stefan Fabiansson**  
Meat Research Corporation  
Sydney South, NSW

**M. Mackenzie**  
Inghams Ent. Pty. Ltd.  
Browns Plains, Queensland

**Keabbe Orvac**  
Monash University  
Clayton, Victoria

**Leanne Prucic**  
Monash University, Clayton, Victoria

## CANADA

**Jill Bollman**  
University of Manitoba  
Winnipeg, Manitoba

**Vivien Carson**  
Health Community Service  
Saint John, New Brunswick

**Don J. Coady**  
Marine Institute  
St. John's, New Foundland

**Shirley Dzogan**  
Enviro-Test Laboratories  
Winnipeg, Manitoba

**Shelagh McDonagh**  
Canadian Food Inspection Agency  
Calgary, Alberta

**David McLennon**  
Canadian Food Inspection Agency  
St. John's, Newfoundland

**Frances Nattress**  
Agriculture & AgriFood Canada  
Lacombe, Alberta

**James Reffle**  
London Health Unit  
London, Ontario

**Eva Sanz-Solé**  
Guelph Food Technology Centre  
Guelph, Ontario

**Connie Zagrosh**  
Alberta Agriculture  
Edmonton, Alberta

## GREECE

**Chris V. Papadopoulou**  
University of Ioannina, Ioannina

## INDIA

**R. B. Jain**  
Jain Plastics & Chemicals Ltd.  
Jalgaon, Maharashtra

## PORTUGAL

**Madalena Vilela Pimentel**  
Faculdade De Farmacia  
Forgas, Lisboa

## SOUTH AFRICA

**Ifigenia Geornaras**  
Johannesburg

**John Hastings**  
University of Natal  
Pietermaritzburg

## UNITED STATES

### CALIFORNIA

**Bill Huntley**  
DASI LINDA LLC  
West Covina

**Stan Wallen**  
Zacky Farms, Fresno

**Lisa Yagi**  
PE Applied Biosystems  
Foster City

## COLORADO

**Henry Zerby**  
Colorado State University  
Fort Collins

## CONNECTICUT

**Roger Mshar**  
State of CT, Dept. of Public Health,  
Hartford

## FLORIDA

**Hines Boyd**  
Florida Dept. of Agriculture  
Tallahassee

**Gregory Muszynski**  
Universal Studios Pl., Orlando

## GEORGIA

**Chrysté Best**  
Food and Drug Administration  
Atlanta

**Janice G. Chisholm**  
Puritan Food Service, Marietta

**Ron Crawford**  
Food and Drug Administration  
Atlanta

**Carl E. Davis**  
USDA-ARS-RRC, Athens

**Mary F. Elmore**  
Puritan Food Service, Marietta

**Robert W. McMahon**  
Bio-Tek Industries, Inc., Atlanta

## KENTUCKY

**Karen Sloat**  
Flav-o-Rich, London

**Richard Westerdale**  
Winchester Farms Dairy  
Winchester

**Gord Whitney**  
Brown Forman, Louisville

## **LOUISIANA**

**Jackie A. Souther**  
Dutch Quality House II  
Bossier City

## **MASSACHUSETTS**

**Shri Thakker**  
Garelick Farms, Inc., Franklin

**Marie T. Walsh**  
Arlington Board of Health  
Arlington

## **MICHIGAN**

**Susan Alles**  
DiverseyLever, Plymouth

**Jim Bail**  
Domino's Pizza, Inc., Ann Arbor

**Ronald Holben**  
Michigan Dept. of Environmental  
Quality, Lansing

**Kausar Malik**  
Amway Corp., Ada

**Carla Mitchell**  
Sanilac County Health Dept.  
Sandusky

**Jon Wannlund**  
Analytical Luminescence Lab  
Saline

## **MINNESOTA**

**Chris Binsfeld**  
3M, St. Paul

**Kirsten Buck**  
Ecolab, Inc., St. Paul

## **MISSOURI**

**Deborah M. Dugo**  
bioMérieux Vitek, Hazelwood

## **NEW JERSEY**

**Steve McKee**  
Middletown Township Health  
Dept., Middletown

**James Trevor**  
Rhône-Poulenc Inc., Cranbury

## **OREGON**

**Philippe R. Neuville**  
Chz M Hill F.G., Portland

## **PENNSYLVANIA**

**Joel Simpson**  
Food Safety Solutions  
Holidaysburg

**Craig Weaver**  
Milk Marketing Inc., Windber

## **RHODE ISLAND**

**Jianning Ye**  
University of Rhode Island  
West Kingston

## **SOUTH CAROLINA**

**Rachel S. Montgomery**  
Ferm Pro, Kingstree

## **TENNESSEE**

**Diane Butler**  
U.S. Army, Clarksville

**Janay Griffin**  
Melaleuca, Knoxville

## **TEXAS**

**Steve L. Berry**  
City of Plano, Plano

**Scott Brooks**  
USAF School of Aerospace  
Medicine, San Antonio

**Patrick Jones**  
City of Plano, Plano

**David Paulk**  
City of Lubbock, Lubbock

**Tim Stevenson**  
U.S. Army, College Station

## **VIRGINIA**

**Peter F. Eberle**  
Foodservice & Packaging Institute  
Arlington

## **WASHINGTON**

**Carol Larson**  
WSDA, Olympia

**Sally L. Pytel**  
WSDA, Olympia

## **WISCONSIN**

**Karen Etter**  
The Masterson Co., Milwaukee

**Gerrit Keizer**  
Gist-brocades, Menomonee Falls

**Becky Peterson**  
Food Research Institute, Madison

## **New IAMFES Sustaining Member**

**James R. LeRoy**  
Cogent Technologies Ltd.  
Cincinnati, OH

# UpDates

## Sam Raimond Promoted at Fristam Pumps

Fristam Pumps is pleased to announce the promotion of Sam Raimond to the position of Applications Engineer. In his new assignment, Sam will be providing technical support and customer service. Sam has been employed at Fristam since July of 1987. During these 10 years, Sam has held positions in Fristam's assembly, quality assurance, and sales departments.

Fristam Pumps, Inc., Middleton, WI, is a manufacturer of sanitary centrifugal and positive displacement pumps sold to the food, dairy, beverage, and pharmaceutical/biotech industries.

## Sales Manager, Automation Engineers Join A & B

Regional Sales Manager and two Automation Engineers have joined A & B Process Systems Corp.

Jim Banks returns as Regional Sales Manager to A & B, where he began his career in 1979 as a Mechanical Designer. He has held sales positions with various service and O.E.M. companies and most recently was Regional Sales Manager for the Damrow Company, where he promoted systems, equipment and automation services. At A & B, his primary focus will be sales and service of existing clients and the development of new clients.

The two new Automation Engineers further strengthening A & B's capabilities in that area are Chunsheng (Charlie) Fu, who has a university research background,

and Christopher D. Otto, who has a strong background in designing and programming electrical controls for a control manufacturer and a stainless steel fabricator.

Fu comes to A & B from the University of Cincinnati, where he was a Research Associate in control system modeling and simulation software development. Among his duties there was to develop control system models and simulation software. Prior to that he was with a university in Barcelona, Spain, where he designed a supervisory control system for an industrial bioreaction process. He has also served as a Process Control Engineer for a pharmaceutical company in China, where among other things he designed and installed a computer optimization and advanced control system for an industrial batch pharmaceutical fermentation process.

Fu holds a bachelor's degree in industrial automation from the East China University of Chemical Technology in Shanghai, China, and master's and Ph.D. degrees in industrial automation from Zhejiang University, Hangzhou, China.

Otto has designed and developed custom man-machine interface applications; written, modified and documented PLC programs; managed projects from design through startup; provided project documentation including operator manuals, assembly drawings and spare parts lists; and has done on-site installation, startup, field service and retrofitting. After serving with a control manufacturer for six years, he most recently was an Electrical/Mechanical Design Engineer for a stainless steel fabricator in Wisconsin.

Otto holds a bachelor's degree in materials science from the University of Wisconsin-Milwaukee.

## Pro-Tek Packaging Group Adds a National Distributor Sales Manager and Western Regional Sales Representative

Pro-Tek Packaging Group, Inc., expands their sales force with the addition of Tom Gallo, National Distributor Sales Manager, and Al Amato, Western Regional Sales Representative.

Pro-Tek offers a full range of stock and custom, plain and printed, tamper-evident PVC shrink bands, product labels, multi product banding, and pre-formed container seals.

## Corriveau Named Director of Human Resources for Prism and PCO Services, Inc.

PRISM™ Integrated Sanitation Management has named Roger A. Corriveau Director of Human Resources for all North American Service Businesses. Paulo S. Bello, company President, says Corriveau will be based in the Miami headquarters facility. He will head human resources and customer services for Prism Pest Elimination, Prism Professional Kitchen Services, and PCO Services, Inc., the firm's Toronto-based Canadian operation.

Since 1995, Corriveau served as Director of Human Resources for PCO Services, the largest pest control firm in Canada. His previous experience includes more than

20 years in the service industry, with increasing responsibilities in all areas of human resources. A graduate of the University of Ottawa, he holds degrees in management, labor relations and public administration.

## OSMONICS Appoints New Vice President of Operations

**D**ean Spatz, Chairman and CEO of OSMONICS, Inc. announced the appointment of Kenton C. Toomey to the position of Vice President of Operations.

Toomey comes to OSMONICS with years of experience in process and component manufacturing and most recently total operations responsibility in the water-handling industry. Kent received his bachelor of science degree in industrial engineering from the University of Iowa. After studying at Keller Graduate School of Management in Chicago, he worked for 26 years at the 3M Company. Most recently, Toomey served as Vice President of Operations for DeZurik, a \$150

million division of General Signal Company.

OSMONICS is a manufacturer of high technology water purification and fluid filtration, fluid separation, and fluid transfer equipment, as well as the replaceable components used in purification, filtration, and separation equipment.

## Kilbryde Appointed World Dryer Vice President

**W**orld Dryer Corporation announces the promotion of Linda M. Kilbryde to Vice President of Marketing and Business Development. Linda joined World Dryer in 1982 and has held various positions, including Director of Marketing, Canadian Operations Manager, New Product Development Manager, Human Resources Manager, and Staff Accountant. She was instrumental in the development of the company's hand sanitation line, World washstations, and the newest product, the baby changing station for public restrooms.

In her new position, Linda will be responsible for the development

of programs for key national accounts and all marketing functions. She will also continue to work with new product introductions and international joint venture opportunities. A native of Chicago, Linda resides in the western suburbs and is currently attending Elmhurst College. World Dryer is a division of Specialty Equipment Companies, Inc.

## Dan Osiedacz Joins Fristam Pumps

**F**ristam Pumps, Inc. is pleased to announce Dan Osiedacz has joined the company as an Applications Engineer. Dan will be providing in-house and in-field technical support and customer service. Dan has a bachelor of science degree from the University of Wisconsin in agricultural engineering/power & machinery.

Fristam Pumps, Inc., Middleton, WI, is a manufacturer of sanitary centrifugal and positive displacement pumps sold to the food, dairy, beverage, and pharmaceutical/biotech industries.



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## Vice President Releases Plan to Strengthen, Improve Food Safety

*Calls For Stricter Precautions for Fruit & Vegetable Juices, Improved Inspections*

**V**ice President Gore announced a five-point plan to significantly increase the safety of the nation's food supply. The plan sets forth steps the Administration will take this year to strengthen food safety and details how we will use \$43.2 million in new funds the President has requested in his fiscal year 1998 budget.

The plan, *Food Safety from Farm to Table* is outlined in a report presented to the Vice President by Health and Human Services Secretary Donna E. Shalala, Department of Agriculture Secretary Dan Glickman, and Environmental Protection Agency Administrator Carol M. Browner. The President requested the report in January. It calls for improved inspections, public education and greater use of the latest science to dramatically reduce foodborne illness. It calls for stricter safety precautions for fruit and vegetable juices, improved seafood inspections, and increased investment in research, risk assessment and surveillance.

In his January 25 radio address, the President announced he was requesting \$43.2 million for food safety in his FY 1998 budget and requested a report detailing recommendations on ways to further improve food safety. The Departments of Agriculture and Health and Human Services, and the Environmental Protection Agency, working with state and local officials, the food industry, scientists, consumer and producer groups, developed the report.

These actions build on previous Administration steps to modernize the nation's food safety programs first proposed by the Vice President's National Performance



# NEWS

Review. Specifically, the National Performance Review encouraged widespread adoption of preventive controls to food safety, and the implementation of the Hazard Analysis and Critical Control Point (HACCP) systems.

A key element of the Administration's food safety efforts has been the Hazard Analysis and Critical Control Point (HACCP) approach that requires the food industry to use the most modern science to identify sources of potential contamination in food production and transportation and then put in place preventive measures. Already required by the Food and Drug Administration for seafood and by USDA for meat and poultry, FDA will propose preventive measures, including HACCP, for the manufacturer of fruit and vegetable juice products, and USDA will propose HACCP and other appropriate regulatory and nonregulatory options for egg products.

In addition to moving toward a science-based, preventive approach to food safety, the Administration continues to improve the effectiveness of food safety inspections. Specifically, the additional funds requested for FY 1998 will allow the FDA to add inspectors to implement seafood HACCP and to

expand its program to develop additional mutual recognition agreements (MRAs) with United States trading partners ensuring that imported foods are produced and manufactured under systems that offer comparable safety measures to those used in the United States. With the new funds, FDA will also be able to provide technical assistance to foreign countries on safe growing and handling practices.

The Administration is already taking steps to put in place the new National Early Warning System, President Clinton announced in January, to track and combat outbreaks of foodborne illness. This fiscal year, two new FoodNet sentinel sites were added in New York and Maryland. With funds requested for the upcoming fiscal year, an eighth site will open. This surveillance system is supported by the CDC, FDA, and USDA, working with state authorities. New funds included in the FY 1998 budget will also allow these sites to update technology and build a "fingerprinting" database of bacterial DNA. This will enable food safety experts to clear any geographic hurdle to their work by having a national resource that can help them quickly identify contaminated foods that are the sources of foodborne illness.

Under the Administration's plan, work will start immediately on a national public education campaign on safe food handling. An unprecedented public-private partnership was established among government agencies and industry and consumer groups to develop a food safety education campaign aimed at consumers.

Research to develop quick, reliable scientific methods for detecting contamination such as the Hepatitis A virus and *Cyclospora* will ensure that public health agencies have the necessary tools to prevent and control outbreaks of foodborne illnesses. The latest research will also explore how pathogens become resistant to traditional food preservation tech-

niques such as heat and refrigeration and will support new pathogen control methods.

Also under the new initiative, EPA, FDA and the CDC will collaborate with state and local health departments on research to help health officials better predict and control outbreaks of waterborne microbial contaminants, such as *Cryptosporidium*.

### **Patrick O'Quinn Receives Salt Institute's 1997 Tony J. Cunha Award**

**P**atrick R. O'Quinn, a graduate student at Kansas State University in Manhattan, Kansas has received the Salt Institute's 1997 Tony Cunha Award.

Nine years ago, the Salt Institute initiated this \$1,500 research support award to commemorate Dr. Tony Cunha's contribution in promoting the understanding of the role of salt in animal nutrition and to recognize the need for research in this important area. Mr. O'Quinn hypothesized that chloride from salt can effectively replace the chloride from L-lysine HCl in swine diets, thus reducing the need for supplemental synthetic lysine.

The 1998 Tony J. Cunha Award deadline is April 15, 1998, and will be announced in June. Graduate students interested in being considered for this prestigious recognition should contact the Salt Institute at 700 N. Fairfax, #600, Alexandria, VA 22314, or Phone 703.549.46.48, or E-mail: bert@saltinstitute.org.

### **Walker Stainless Opens New Sales Office in Hong Kong, China**

**W**alker Stainless, a subsidiary of Carlisle Companies Incorporated announces the opening of its Asia Pacific sales office to be located in Hong Kong.

Mr. Lau Leuk To (Jonathan Lau) was named Director of Sales. Mr. Lau will be responsible for sales and marketing in the Asia Pacific region, and with particular focus on China and Japan. He will also handle project management.

Mr. Lau joins Walker from Holvricka where he was the Director of Sales.

Walker Stainless provides transportation, process and storage products for the food, dairy, beverage, pharmaceutical, chemical and cosmetic industries.

### **Millipore Corporation and Celsis International to Form an Alliance in Microbiological Testing Services**

**M**illipore Corporation announced that it has begun discussions with Celsis International (Cambridge, UK) to market that company's microbiological testing services to the pharmaceutical and beverage industries in the U.S. and Canada. The two companies intend to sign a formal agreement by the end of this year.

Under the proposed arrangement, Millipore will sell a select number of testing services through its North American salesforce under the company's Access trade name. The services will include GMP sterility and bioburden testing, feasibility and validation studies, and unique rapid microbiology services.

The services will be performed by the Celsis Laboratory Group-Leberco Division (Roselle Park, NJ). The Celsis Laboratory Group provides expert microbiology, analytical chemistry, and toxicology analyses, as well as methods development and validation studies for a variety of industries. The Leberco Division was founded in 1939 and acquired by Celsis in 1996.

### **New Online Source of Food Industry Suppliers Launched**

**T**he Int'l. Association of Food Industry Suppliers (DFISA), has expanded its services to include an online database of their supplier members accessible to food, dairy, beverage, pharmaceutical and related sanitary processors 24-hours a day. DFISA has more than 700 companies offering processing, packaging and distribution equipment, ingredients, services and supplies to the worldwide food industry.

The DFISA Worldwide Connection is a free service to the entire food industry, and is available now, worldwide, 7 days a week, 24 hours a day, at <http://www.dfisa.org>. In addition to the searchable database and Worldwide Food Expo '97 information, the DFISA Worldwide Connection offers invaluable tools to the industry, such as a job bank, sanitary standards, data and industry capital equipment statistics; and specific to members are global trade leads and association updates.

### **Busta Gives Frazier Memorial Lecture**

**D**r. Francis (Frank) F. Busta gave the sixth annual Frazier Memorial Lecture at the University of Wisconsin-Madison on May 14, 1997. The lecture was given in conjunction with the annual meeting of the Food Research Institute. Busta, a Professor of food microbiology, is Head of the Department of Food Science and Nutrition at the University of Minnesota; and a Member of IAMFES.

In his lecture, "Food Safety in the 21st Century: To Test or Not to Test, That is the Question," Busta pointed out that in 1997 there will be  $2 \times 10^8$  to  $10^9$  microbiological tests done on food worldwide. Such testing is prompted by establishment of microbiological criteria and specifications for foods, international trade, the work of Codex Alimentarius, and efforts to

validate Hazard Analysis and Critical Control Points (HACCP).

The Frazier Memorial Lectureship was established to annually bring an outstanding food microbiologist to the University campus and also to honor the late Dr. William C. Frazier, pioneering Food/Dairy Microbiologist who excelled in research, teaching, and administration. Earlier Frazier Memorial lecturers include Drs. Douglas Archer, Richard Gilbert, Mitchell Cohen, Robert Buchanan, and Mr. Peter Barton Hutt.

### FDA Announces a Pilot Project for NCIE Submission

**T**he Food and Drug Administration (FDA) is announcing the Notice of Claimed Investigational Exemption (NCIE) Electronic Submissions Pilot Project developed by the Center for Veterinary Medicine (CVM). This project is intended to increase the efficiency of the review process of the investigational new animal drug file (INAD), the new animal drug application (NADA), the investigational food additive petition (IFAP), and the food additive petition (FAP) by providing for the electronic submission of NCIEs, commonly known as drug shipment notices.

The purpose of the pilot project is to determine the practicality and feasibility of electronic submission and review as an alternative to the current paper-based processes. The pilot, anticipated to begin September 8, 1997, and run for six months (March 9, 1998), is limited in scope in order to apply metrics to a defined set of variables to be evaluated at the conclusion of the project. The sponsors who participate in the pilot must anticipate at least one drug shipment within the six-month pilot and must also agree to submit all NCIEs in an electronic format for the duration of the pilot. Submissions may be to any of the

CVM Divisions – HFV-110, HFV-120, HFV-130, and/or HFV-220.

CVM is requesting that interested sponsors submit, on a voluntary basis, electronic copies of NCIE, via E-mail, for review in a portable document format (PDF), in lieu of the paper submission. A copy of the draft guidance document for this pilot project may be obtained from the CVM Home Page on the Internet (<http://www.cvm.fda.gov>) or by calling CVM's Communications Staff at 301.594.1755. Prospective participants must notify CVM by June 16, 1997.

For further information about participation in the pilot project, please contact Charles J. Andres, Ph.D., Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855 by telephone 301.594.2604 or E-mail ([candres@bangate.fda.gov](mailto:candres@bangate.fda.gov)).

### Trade Dispute Over SCC and Bacteria Levels Resolved

**A**n arrangement between the U.S. and the European Commission (EC) will allow U.S. dairy exports to the European Union (EU) to resume. Dairy product trade with Europe was halted April 1, 1997 after the U.S. and the EC failed to reach an agreement on compliance requirements for dairy products.

EC compliance requirements for dairy products are outlined in Council Directive 92/46. This directive addresses, among other things, issues related to milk production and processing. Countries outside the EU that wish to provide dairy products to that market are required to provide certificates indicating compliance with the requirements contained in the directive.

During negotiations over the last two years, the U.S. and EC agreed on all compliance issues

relating to dairy products except for somatic cell count (SCC) and bacteria count levels. The maximum allowable SCC and bacteria count levels in the U.S. are higher than the levels allowed in the EU. In the U.S., limits for SCC and bacteria counts are 750,000 and 100,000 respectively, for Grade "A" milk; and 750,000 and 500,000 respectively, for manufacturing grade milk. The EU limits for manufacturing grade products are 500,000 somatic cell count and 400,000 bacteria plate count. For the EU equivalent of U.S. Grade "A" products, the SCC limit is 400,000 and plate count limit is 100,000. (The EU manufacturing grade requirements will change on January 1, 1998 to match those required for the EU Grade "A" equivalent products.) Due to these differences, the U.S. could not issue the required export certificate that must accompany all dairy products imported into the EU.

A program has now been established which will allow the U.S. Government to issue certificates for dairy product export. Under the program, dairy product manufacturers must provide assurance that bacteria and somatic cell counts in the raw milk used to manufacture dairy products do not exceed those contained in the EC directive. Although several different systems may be used to show compliance with the EU requirements, the USDA AMS Dairy Grading Branch considers the following as minimal requirements:

- The dairy plant shall have SCC and bacterial standard plate count records available.
- The dairy plant shall randomly sample 10% of the tankers providing milk to the plant on one randomly selected day per month for SCC, and on two randomly selected days per month for bacterial standard plate count. Sample results from the same day are averaged.
- A rolling three-month geometric mean for SCC and two-month geometric mean for plate



count will be determined. These means must meet the EU requirements.

Upon establishing proper documentation of SCC and bacteria records, export certificates will be issued by the USDA AMS Dairy Grading Branch. The effective date for this program was April 21, 1997.

Source: U.S. Dept. of Agriculture, AMS, Dairy Division, "Instructions for Certification of Dairy Products Exported to the European Union" (No. 929-6) April 27, 1997.

## Avian Influenza, Pennsylvania, USA

**T**he initial virus was found through normal USDA-APHIS AI surveillance program in the Northeast and they have been monitoring the area very closely. Below is a USDA summary of the situation as of May 20, 1997. There doesn't appear to be very much concern at present. Non-pathogenic Type A H7N2 Avian Influenza Virus in Pennsylvania A nonpathogenic Type A H7N2 Avian Influenza (AI) virus has been isolated in three commercial poultry flocks in Pennsylvania during 1997, one flock in February and two in May. All of the poultry farms are located in or near Lancaster County, PA. Under the state's authority, all affected premises have been quarantined by the Pennsylvania Department of Agriculture and the flocks voluntarily destroyed as a safeguard measure. To date, all of the AI H7N2 virus isolates tested at the USDA, National Veterinary Services Laboratories (NVSL) in Ames, Iowa were found to be nonpathogenic to chickens. These AI H7N2 virus isolates were also tested at the USDA, Southeast Poultry Research Laboratory in Athens, GA, and again the virus isolates were found to be nonpathogenic to chickens. The gene sequence for the viruses have been

found to be identical to earlier AI H7N2 viruses isolated from birds at live poultry markets.

By the standards set up by the Office of International Epizootics (OIE) and the United States Animal Health Association (USAHA), this AI H7N2 virus does not meet the guidelines for being a reportable disease. However, the State of Pennsylvania has issued a General Quarantine Order to restrict the movement of all live poultry and poultry products in four Lancaster county townships until all poultry in those areas are tested for AI. The USDA, Animal and Plant Health Inspection Service (APHIS) and the Pennsylvania Department of Agriculture are continuing to conduct an intense AI surveillance program in the state and surrounding northeast region. The Pennsylvania Poultry Federation has requested the APHIS to authorize the production and storage of a killed H7N2 AI vaccine for possible emergency use in Pennsylvania. The current APHIS policy for use of the vaccine is that it is to be used only in the face of a potential HPAI outbreak. The current virus in Pennsylvania does not meet this description.

## Health Officials Warn of Beef Superbug — Caution Urged in Food Preparation After 207 Cases of Poisoning Reported

**A** recent story in the *Vancouver Sun* by Scott Simpson cited Dr. John Spika of the Laboratory Centre for Disease Control, Canada, as saying that federal officials have linked an antibiotic-resistant strain of the *Salmonella typhimurium* phage type 104 to 207 cases of food poisoning in Canada. The story states that *Salmonella typhimurium* is the single most common type of *Salmonella* in food poisoning cases in British Columbia, but

type 104 is a new arrival believed to have evolved as a response to use of antibiotics to treat livestock.

Type 104 was first noted 13 years ago in Great Britain. There, the number of reported cases of food poisoning connected to it has risen rapidly, says the story — reaching 3,500 in 1995 compared to about 150 when it was first identified in 1984.

The story also cites British Columbia Health Officer Dr. John Miller, who attended a Montreal conference, as saying there are "hundreds" of *Salmonella* variants that can cause disease and that he had no idea that the Federal Researchers would reveal that they had discovered type 104 in Canada. Miller added that the risk of death from such an infection is relatively low compared to many other risks in life — such as driving an automobile.

Dr. Jean Kamanzi, Acting Chief of the Canadian Food Inspection Agency's foodborne pathology laboratory, was quoted as saying that, "With the current technology we have for processing meat, we cannot assume it is free of contamination."

The story goes on to state that the only known outbreak of type 104 in North America occurred in 1996 in Nebraska among a group of school children. But health officials were unable to determine if the source was contaminated milk consumed by several children, or a kitten or a turtle passed around during show and tell. Ben Thorlakson, Vice President of the Canadian Cattlemen's Association, was cited as saying that he was outraged by a comment from Spika at the Montreal conference that type 104 poses a greater health risk than mad cow disease, adding that "If you want to spread fear and alarm, I guess this is a pretty good way of doing it. We have the highest health standards of any major beef producing nation in the world. It almost seems as if the government is working against us."

# IndustryProducts



Sensitech Inc.

## Quickcheck Revolutionizes Food Processing Production

QuickCheck is revolutionizing the way Food Processors are assessing their food quality assurance programs. Whether it be the temperatures of storage areas or the cooking temperatures of processed foods, Inspectors are now able to collect vital temperature information throughout the plant in the palm of their hand. The results prove that this easy-to-use, portable data logger not only assists processors with their temperature monitoring needs, it also saves them time and money.

In addition to automating HACCP recordkeeping, QuickCheck data attests to the quality and safety of temperature monitoring procedures. Temperature readings are automatically stored and protected in the unit until they are downloaded into QuickCheck Manager software for quick analysis. QuickCheck gives instant knowledge of product safety and provides Managers with a user-

friendly tool to pinpoint critical control points in their food preparation processes. Preprogrammed safe temperature ranges insure consistent procedures, allowing any employee to take on temperature monitoring responsibilities, and assuring Managers that their employees are adhering to standard operating procedures.

Sensitech Inc., Beverly, MA

Reader Service No. 388

## Rapid and Clean Blending

Tekmar provides rapid, clean and safe blending of samples in the Stomacher® Lab Blender. With this unique blender, the sample never directly contacts the machine. Mixing is done in a sturdy, disposable plastic bag. With preset speeds, time settings and a three-year warranty, the Stomacher is perfect for blending of food microbiology, biomedical research, and clinical applications.

Tekmar-Dohrmann, Cincinnati, OH

Reader Service No. 389

## Ecobal Introduces Matrixx™ Next Generation Dairy Sanitizer

Ecobal's new Matrixx™ peracid-based dairy sanitizer is significantly more effective in killing spoilage microorganisms than conventional sanitizers, and is especially effective in controlling yeast, mold, and sporicidal activity.

In addition to affecting a higher log reduction on microorganisms, Matrixx functions at a lower pH, so it removes more mineral film. Its fast-breaking foam serves as a visible indicator that a sanitizer is present in manual or central sanitize applications.

Matrixx works more effectively at low temperatures than other conventional sanitizers. And since it essentially breaks down to water and acetic acid (vinegar) in the waste stream, Matrixx is an environmentally responsible alternative.

Ecobal, St. Paul, MN

Reader Service No. 390

## New Potassium Chloride Deactivated Alumina GC PLOT Column

J&W Scientific announces the availability of a new potassium chloride deactivated alumina GC PLOT column for the analysis of light hydrocarbons.

Hydrocarbons such as ethylene and propylene are used in many manufacturing processes, and the presence of certain impurities, even in trace amounts, can be detrimental to the processes in which they are used. Due to the volatile nature of these impurities, the GC columns required for effective chromatography must be extremely retentive to qualitatively separate the solutes at normal temperatures (>35°C).

*The publishers do not warrant, either expressly or by implication, the factual accuracy of the products or descriptions herein, nor do they so warrant any views or opinions offered by the manufacturer of said articles and products.*

Several surface deactivations are used for alumina columns within the industry, and each manufacturer has their own "secret" recipes. J&W's new GS-Alumina/KCL is, as the name implies, a potassium chloride deactivated alumina column. J&W's standard GS-Alumina column uses a proprietary deactivation that is slightly more polar than the KCl deactivated column. Depending on the needs of the chromatographer, these alumina PLOT columns can successfully isolate the impurities of such compound pairs like cyclopropane from propylene. Both J&W's GS-Alumina and GS-Alumina/KCL GC PLOT columns are available in 0.53 mm I.D., in 30 and 50 meter lengths.

J&W Scientific, Folsom, CA

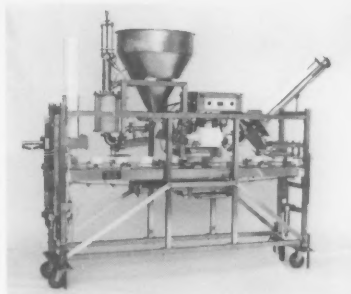
Reader Service No. 391

## Mycotoxin Screening for Food and Dairy Industry

ESS Laboratories is pleased to offer Mycotoxin Screening to the Food and Dairy Industry. The rapid method of detection used is AOAC approved and provides quantitative results in a timely manner. Detection includes Aflatoxin M1, B1, B2, G1, and G2; Fumonisin B1 and B2; Ochratoxin A; and Zearalanone. Whether the grain or feed is a beginning ingredient or a finished product, the quality is equally important. Therefore, this service is offered to producers of feeds, grains, milk, nuts, and corn; and any further processing facilities purchasing these raw ingredients for their products.

ESS Laboratories, Culpeper, VA

Reader Service No. 392



Amalga Composites, Inc.

## Tindall Packaging Using New Food Grade Amalgon Tubing in Filling Machines

Tindall Packaging, Inc. of Vicksburg, MI, is now using Food Grade Amalgon (FGA) tubing from Amalga Composites in all of their food-industry filling machines. The new tubing is made of filament-wound fiberglass and is designed to be a lightweight, high-strength, cost-effective alternative to stainless steel.

Before the introduction of Amalga's FGA tubing, Tindall Packaging was utilizing specially honed and polished stainless steel for its machine pumps. Owner Frank Tindall switched to FGA tubing for many reasons: smoother finish for an easier fit with his machines; improved I.D. consistency for more efficient pumping; high dent-resistance for easier cleaning; and cost-effectiveness.

Amalga's FGA tubing also offers high corrosion resistance; self-lubrication; dent-resistance; operating temperatures ranging from -200°F to +200°F; specific strength which is nine times that of stainless steel; and availability from stock with precision tolerances. The precision I.D.'s surface is finer than honed stainless steel, providing quicker product flow and less bacteria build-up. Product costs are reduced because the manufacturing process does not require honing to

achieve the desired I.D. finish. Standard bore sizes range for 1" to 20".

Amalga Composites, Inc., Milwaukee, WI

Reader Service No. 393

## Toxicity, Biokinetic and Bioremediation Testing With One Respirometer

The Bioscience, Inc. BI-1000 Electrolytic Respirometer is capable of performing all of your toxicity, biokinetic and bioremediation oxygen uptake experiments. Special instrumentation is not needed for your variety of applications. The BI-1000 has flexibility, compatibility and expandability built into its design. The BI-1000 supplants the multiple capital expenditures for specific instrumentation needed for your various projects. This greatly reduces your costs and improves the "bottom line" on your projects.

The BI-1000 Electrolytic Respirometer is a highly automated and accurate system for performing oxygen uptake measurements on wastewater, sludge and soil samples. An expanded line of reactors makes the BI-1000 uniquely suited to applications including biochemical oxygen demand (BOD), toxicity, biodegradation and biotreatability testing.

The BI-1000 monitors the oxygen-uptake rate, manages the experimental process, allows for review of acquired data in graphical and/or tabular form, and saves the information to a hard drive or disk for additional data processing. A multitude of configurations are available for your specific application now and expansion is available for your applications in the future.

Bioscience, Inc., Bethlehem, PA

Reader Service No. 394



Zeltex, Inc.

## Benchtop KJT-200 Moisture Meter Provides Lab Accuracy in Seconds

Zeltex, Inc., has announced availability of their improved benchtop KJT-200 Moisture Meter for analyzing chemicals, pharmaceuticals, and foods, including grains.

Twelve inches high and less than 20 lbs., the KJT-200 uses near-infrared reflectance principles of spectrum analysis to measure moisture in diverse materials including ceramics, cement, adhesives, cellulose, plastics, alumina, wood, liquids, grains, etc., from 0.05% to 45%.

A typical lab accurate analysis can be performed in seconds using the KJT-200's internal microprocessor without contacting or destroy-

ing the product. The KJT-200's fast sampling speed provides for the measurement of moisture absorption rate in extremely hygroscopic materials. Data can be transmitted via RS-232C port to a printer or computer for statistical analysis. Automatic measurement starts when a sample is placed on the turntable and an automatic zero adjustment and rotating turntable assure accuracy over the entire sample.

Zeltex, Inc., Hagerstown, MD

Reader Service No. 395

## New LSM 510 Confocal Laser Scanning Microscope

The LSM 510 Laser Scanning Microscope from Carl Zeiss offers the field of biomedical research a unique combination of confocal microscopy and high-performance, highly automated research microscopy. This new concept combines the compact LSM 510 scanning module with the proven performance of the upright Axioplan 2 and inverted Axiovert microscopes. The scanning module can easily be attached to either type of microscope.

With the Axioplan 2 and Axiovert microscopes, the user achieves a high level of system integration and the shortest possible light paths. This ensures not only high optical precision and stability, but also uncompromising flexibility. The modular design of the system allows upgrading and retrofitting as the demands of research change.

In the LSM 510 module, six detectors are integrated in an extremely small space. Each of their four confocal channels has its own computer-controlled optical spatial filter, a vital requirement for multifluorescence applications.

The maximum resolution of 2048 x 2048 pixels with simultaneous 12 bit AD conversion for up to 4096 brightness levels provides brilliant images for even the most difficult preparations. Large scanning fields display the tiniest details without any loss of information.

Carl Zeiss, Inc., Thornwood, NY

Reader Service No. 396

## Bacteria Counter

The new IDEXX Quanti-Tray® Sealer Model 2X helps automate the sample handling of bacterial enumeration, while offering reliability, ease-of-use, and speed. In just one minute, it can process four Quanti-Trays® (counts to 200 per 100 ml) or Quanti-Tray®/2000s (counts to 2,419 per 100 ml) with IDEXX Colilert® reagent (24 hour total coliform/*E. coli* counts), Colilert®-18 (18-hour total coliform/*E. coli* counts), and Enterolert™ (24-hour enterococci counts). Quanti-Tray, Quanti-Tray/2000, Colilert, and Colilert-18 are all U.S.-EPA approved.

IDEXX Laboratories, Inc., Westbrook, ME

Reader Service No. 397

# BusinessExchange

## Services/Products

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Reader Service No. 153



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## DEADLINE EXTENDED!

### CALL FOR PAPERS PANAMERICAN CONGRESS ON MASTITIS CONTROL AND MILK QUALITY

Deadline November 30, 1997

Merida, Yucatan, Mexico

March 23-27, 1998

Co-Sponsored by IAMFES

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# Coming Events

## AUGUST

• **11-15, Intro. to Food Science: Principles and Recent Advances**, Brunswick, NJ. The best food technologists need a broad understanding of food science that includes food microbiology, color and flavor chemistry, protein biochemistry, sensory evaluation and nutrition. This five-day program will give you a solid background in the science and applications of emerging technologies in the food industry. For additional information, contact Keith Wilson at (908) 932-9271 ext. 617 or Fax: (908) 932-1187.

• **24-29, 1997 World Congress on Food Hygiene**, at the Congress Centre, The Hague in The Netherlands. For further information, contact Royal Netherlands Veterinary Association, P.O. Box 14031, NL-3508 SB UTRECHT, The Netherlands or Fax +31-30-251 1787, E-mail: KNMVD@PO BOX.RUU.NL.

## SEPTEMBER

• **3-5, Producing Safe Dairy Foods Workshop**, held in Madison, WI. The information presented will deal with foodborne illnesses associated with dairy foods and the means to control the problems. For more information, contact Mary Thompson, Outreach Specialist, Wisconsin Center for Dairy Research, University of Wisconsin, Madison, WI; Phone (608) 262-2217 or E-mail: thompson@cdr.wisc.edu.

• **7-9, Quality Through Diversity Conference**, Renaissance Airport Hotel in Orlando, FL. The American Hotel and Motel Association and Conrad N. Hilton College at the University of Houston are joining together in announcing the 1997 Hospitality Industry Quality Through Diversity

Conference. For more information, contact Laura Sutherland at (713) 743-2446.

• **8-10, Artisan Bread Decorating Techniques**, Manhattan, KS. This course will teach bread decorating techniques to create display loaves for use in bread displays. For additional information, or to enroll, contact American Institute of Baking, 1213 Bakers Way, Manhattan, KS 66502 or Phone: (913) 537-4750; Fax: (913) 537-1493.

• **8-10, Cell Culture and Hybridomas: Quality Control and Cytopreservation Techniques Workshop**, sponsored by the American Type Culture Collection (ATCC). For more information, contact ATCC, Workshop Coordinator, 12301 Parklawn Dr., Rockville, MD 20852; Phone: (800) 359-7370; Fax: (301) 816-4364; E-mail: workshops@atcc.org.

• **10-11, The Wisconsin Laboratory Association's 21st Annual Education Conference**, Holiday Inn, Fond du Lac, WI. For more information, please contact Wisconsin Laboratory Association, P.O. Box 28045, Green Bay, WI 54304.

• **11-12, HACCP Workshop**, in Chicago, IL. This workshop provides for an intensive day and a half evaluation of HACCP principles and elements for developing a successful program for your facility. Participants evaluate their HACCP plan against those designed by the experts. For additional information or to enroll, contact: AIB, 1213 Bakers Way, Manhattan, KS 66502; or Phone: (913) 537-4750; Fax (913) 537-1493.

• **17-18, Washington Milk and Food Sanitarians Association's 1997 Annual Meeting**, in Wenatchee, WA at the Wenatchee Red Lion Inn. Inquiries can be sent to Dr. Lloyd Lueddecke, Dept. of Food Science &

Tech., Washington State University, Pullman, WA 99164-6376.

• **23-25, New York State Association of Milk and Food Sanitarians Annual Conference**, Sheraton Saratoga, Saratoga Springs, NY. For more information, contact Janene S. Lucia, 172 Stocking Hall, Ithaca, NY 14853; Phone (607) 255-2892; Fax (607) 255-7619; E-mail: jgg3@cornell.edu.

• **27-30, ACIL 60th Annual Meeting**, The Ritz-Carlton, Kapalua, Maui, Hawaii. The meeting is designed for scientific and engineering laboratory, testing and R & D businesses. Sessions will focus on changes in the laboratory marketplace and workforce, facilities management and risk management. For further information, contact Sheila Way, Operations Director, ACIL, 1629 K Street, N.W., Washington, D.C. 20006 at (202) 887-5872; Fax (202) 887-0021.

## OCTOBER

• **5-9, Saudi Agriculture 97, 16th Agriculture, Water and Agri-Industry Show**, at the Riyadh Exhibition Centre. Further information can be obtained from Virginia Jensen, Kallman Associates, 20 Harrison Ave., Waldwick, NJ 07463.

• **8-10, Quality Management in the Food Industry**, Statler Hotel, Cornell University, Ithaca, NY. This 3-day introductory course is co-sponsored by the IFT Continuing Education Committee, IFT Food Quality Assurance Division, and Cornell University. For further information, contact Institute of Food Technologist's Professional Development Department at (312) 782-8424.

• **12-16, American Association of Cereal Chemists 82nd Annual Meeting**, at the San Diego Convention Center, San Diego, CA. The An-

nual Meeting includes a technical program, technical and poster sessions, table-top exhibits, new product/services sessions, educational short courses and social events. For additional information, contact AACC Headquarters, 3340 Pilot Knob Road, St. Paul, MN 55121-2097, or Phone: (612) 454-7250; Fax: (612) 454-0766.

• **13-16, ASI Fall Workshop, HACCP Workshop for Food Processors**, in Atlanta, GA. For information, contact Vicki Bodrow, ASI Food Safety Consultants, Inc. 7625 Page Blvd., St. Louis, MO 63133; Phone (800) 477-0778.

• **13-16, Environmental Seminar Series for Asian Processors**, in Las Vegas, NV. For more information, contact Sacha Helfand at (703) 684-1080; E-mail: fpmsa@clark.net.

• **20-23, Packaging Basics for the Food Industry, School of Packaging**, Michigan State University, E. Lansing, MI. This 3-day introductory course is co-sponsored by the IFT Continuing Education Committee, IFT Food Quality Assurance Division, and Cornell University. For further information, contact Institute of Food Technologists Professional Development Department at (312) 782-8424.

• **21-22, Food Safety Conference**, in Saratoga, NY. Co-Sponsored by IAMFES. The two-day conference will feature nationally-recognized food science experts and will provide quality assurance, plant, and line managers, regulators, and others involved in food processing with invaluable information on food safety. For further information, contact Carol Miklos at (802) 656-5808.

• **22-24, Food Microbiology Symposium and Workshop**, The University of Wisconsin - River Falls, River Falls, WI. The symposium title is "Current Concepts in Foodborne Pathogens and Rapid and Automated Methods in Food Microbiology." A Rapids Methods in Food Microbiology workshop designed to provide

practical demonstrations and discussion of various tests and instruments available for rapid detection, isolation and characterization of foodborne pathogens and toxins as well as prediction of shelf life and checking hygiene and sanitation in food processing facilities is also scheduled. For additional information, contact Dr. Purnendu C. Vasavada, Animal and Food Science Dept., University of Wisconsin - River Falls, River Falls, WI 54022 or Phone: (715) 425-3150; Fax: (715) 425-3785; E-mail: purnenduc.vasavada@uwrf.edu.

• **27-29, International Whey Conference**, sponsored jointly by the American Dairy Products Institute (ADPI), the U.S. National Committee of IDF (USNAC), and the International Dairy Federation (IDF), at the Westin Hotel O'Hare, Rosemont, IL. For additional information, contact American Dairy Products Institute, 130 N. Franklin St., Chicago, IL 60606; Phone (312) 782-4888/5455; Fax (312) 782-5299.

• **27-30, Freezing and Freeze-Drying of Microorganisms Workshop**, sponsored by the American Type Culture Collection (ATCC). For more information, contact ATCC, Workshop Coordinator, 12301 Parklawn Dr., Rockville, MD 20852; Phone: (800) 359-7370; Fax: (301) 816-4364; E-mail: workshops@atcc.org.

• **29-2, Nov., Worldwide Food Expo 97**, Chicago, IL. The Dairy and Food Industries Supply Association (DFISA), the International Dairy Foods Association (IDFA), and the National Food Processors Association (NFPA) will cosponsor Worldwide Food Expo 97 in Chicago's McCormick Place. To have Worldwide Food Expo 97 information faxed to you, call (503) 402-1352.

• **30-2 Nov., American Meat Institute's (AMI) 1997 International Meat Industry Convention and Exposition**, held in Chicago, IL at McCormick Place. For more information, contact AMI's Convention

Management Group at (703) 876-0900.

## NOVEMBER

• **3-4, International Dairy Federation Holds Symposium on Standards and Trade**, at the Palmer House Hilton Hotel in Chicago, IL. The symposium will examine the role of Codex Alimentarius, its relationship with the World Trade Organization (WTO) and its impact on dairy product standards - both national and international. For further information, contact Anne Divjak at the International Dairy Foods Association, 1250 H Street N.W., Suite 900, Washington, D.C. 20005; Phone (202) 737-4332; Fax: (202) 331-7820; E-mail: adivjak@idfa.org.

• **12-13, Food and Drug Administration's Veterinary Medicine Advisory Committee Meeting**. The topic will be veterinary medical issues related to the quality standards for the manufacture of animal drugs, such as current good manufacturing practices (CGMPs). For further information, contact Ms. Jacquelyn Pace, FDA/Center for Veterinary Medicine (HFV-200), 7500 Standish Place, Rockville, MD 20855; Phone (301) 594-5920; Fax (301) 594-4512.

• **17-20, ASI Fall Workshop, Food Safety and Sanitation**, in Chicago, IL. For information, contact Vicki Bodrow, ASI Food Safety Consultants, 7625 Page Blvd., St. Louis, MO 63133; Phone (800) 477-0778.

## DECEMBER

• **3-5, 3rd Annual SERDP Symposium**, at the Washington Hilton Hotel, Washington, D.C. For the first time, it will be sponsored in cooperation with the Environmental Security Technology Certification Program (ESTCP). For further information, contact SERDP Program Office, 901 N. Stuart St., Suite 303, Arlington, VA 22203; Phone (703) 696-2117; fax (703) 696-2114.











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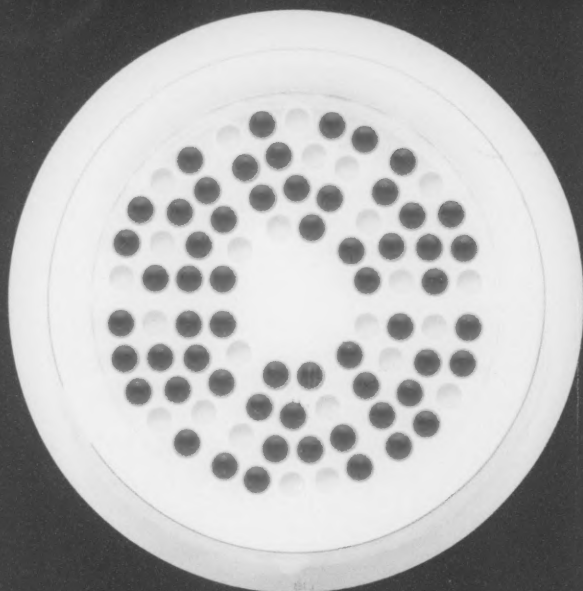
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