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BEFORE FEDERAL COURTS AND AGENCIES

February 23, 2006

BY FEDERAL EXPRESS

REC'D FEB 28 2006

Dr. Robert L. Martin
Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Room 2045
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notification for Use of Carbon Monoxide in Brine and Modified Atmosphere Packaging for Red Meats

Dear Dr. Martin:

As we discussed, we are hereby submitting four copies of a new GRAS Notification (GRASN) for the use of carbon monoxide in brine and modified atmosphere packaging for red meat products on behalf of our client, Freezing Machines, Inc. (FMI). This Notification includes the re-submittal of information previously submitted by FMI in GRASN 166.

In addition to the information previously submitted, we are herewith submitting one additional report, "Retail Display Life of Case-Ready Beefsteaks Enhanced by FMI Technology" attached as Appendix III, details a study performed by South Dakota State University evaluating the effect of the modified atmosphere packaging on the appearance and shelf life of case-ready meat products.¹ In this study, 50 steaks were treated using the modified atmosphere packaging and then placed in storage conditions intended to simulate retail practices. The appearance of the steaks was

¹ In GRASN 166, FMI also submitted a report entitled "Retail Display Life of Case-Ready Beefsteaks Enhanced by FMI Technology." That report, dated November 9, 2004 is also attached to the Notification as Appendix II.

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Letter to Dr. Robert L. Martin, Office of Food Additive Safety
February 23, 2006
Page 2

evaluated on a daily basis to determine if the steak would be "acceptable" to an average consumer. Once the evaluating panel determined that the steaks were "unacceptable," the steaks were evaluated to determine the concentration of spoilage bacteria present. In all cases, the steaks were found to be too discolored to be acceptable before the meat was spoiled by bacteria.

In addition, this Notice has been the subject of extensive discussion between FMI and USDA's Food Safety Inspection Service. These discussions culminated in the February 7, 2006 letter from Dr. Shaukat H. Syed of FSIS to Mr. Dennis Johnson of our firm. In this letter, FSIS reviewed the use of the FMI process and determined that the process is acceptable to FSIS provided that the meats are labeled with a "use or freeze by" date or "in some other way that discloses the material fact that the shelf life of the product has been affected and thus to assure that the consumer is not misled." A copy of this letter is included in Appendix III. Also included in Appendix III is additional information submitted to FSIS during its review of the FMI process. While this information does not directly relate to carbon monoxide, it is included herewith so that both FDA and FSIS have a complete record of all materials submitted on behalf of FMI.

Should you have any questions regarding the enclosed Notice, please do not hesitate to contact me.

Regards,

Mark L. Itzkoff

MLI:jdm
Enclosures

000003

**GRAS Claim for the Use of Carbon Monoxide
In Brine and Modified Atmosphere Packaging
For Red Meat Products**

Submitted by Freezing Machines, Inc.
February 23, 2006

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Section I

GRAS Claim

Freezing Machines, Inc. hereby submits this GRAS claim for the use of carbon monoxide (CO) in brine and modified atmosphere packaging (MAP) for red meat products.

A. Name and Address of Notifier:

Freezing Machines, Inc.
891 Two Rivers Drive
Dakota Dunes, SD 57049

B. Common or Usual Name of Substance:

The common or usual name of the substance is carbon monoxide. The Chemical Abstract Services Registration Number (CASRN) for this substance is 630-08-0.

C. Conditions of Use:

In this Notification, CO will be used in water-based brine or marinade for MAP packaging for red meat products. This application is the same end use and technical purpose, for MAP packaged red meat products, described in GRAS Notices GRASN 83, 143 and 167. This Notice differs only in the method used to introduce CO to the food.

In the previous notices, CO was added to the gas mixture used to package the brined meat. In this application, CO will be introduced via the brine or marinade solution that is injected into the red meat products. The quantity of brine or marinade is limited to 27.8 percent by weight of the processed red meat ("28 percent pump"). At this level, the concentration of CO in the processed red meat will be equal to or less than the concentration that may be present from the applications described in GRASN's 83, 143 and 167, *i.e.*, 1.88 mg/250 grams of red meat in the pre-cooked product.

D. Basis for GRAS Determination:

FDA has previously reviewed the safety of the use of CO in modified atmosphere packaging in three GRAS Notifications, GRASN 83, 143 and 167. The data submitted to FDA in those Notices is hereby included by reference in this Notice.

The use of CO proposed herein will not result in any increased dietary exposure to CO. The dietary exposure will not increase because the potential concentration of CO in red meat processed using the method described in this Notice will be less than or equal to the levels that are expected to result from the applications detailed in the previous Notices. Since the final product of this instant application is the same product currently packaged using the process detailed in the previous Notices, the exposure to CO from this proposed use is already included in the exposure estimates for the previous Notices, *i.e.*, there will be no increase in CO consumption. Since neither the concentration of CO in the processed food

Freezing Machines, Inc.
GRAS Notification for Carbon Monoxide
February 23, 2006

nor new applications for CO will result from the use described herein, there will be no increase in total dietary exposure. Therefore, the data used to support the three effective GRAS Notices also demonstrate the safety of CO in this application.

In addition to the question of CO consumption, a secondary safety question has been raised regarding the possibility that the use of CO in this application will "mask" normal spoilage of the processed red meat during storage prior to use by consumers. Freezing Machines, Inc has sponsored two studies conducted by South Dakota State University, both are titled "Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology." The first one is dated November 9, 2004 and the second November 2, 2005. These studies demonstrate that the effect of the CO on retail cuts of red meat will dissipate before the end of the product's retail shelf life, and that the retail cuts will, therefore, be discolored to the point of rejection by a consumer panel before spoilage will occur. However, as an added measure of safety, FMI has decided to label meat products produced with this system with a validated "use-or-freeze-by" date.

E. Data Availability Statement:

The data and information that are the basis for the Notifier's GRAS determination will be sent to FDA upon request.

Respectfully Submitted,

Mark L. Itzkoff
Counsel for Freezing Machines, Inc.

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Section II

Identity of the Notified Substance

The substance that is the subject of this Notice is Carbon Monoxide (CO), a colorless, odorless gas, with the CASRN 630-08-0. A Material Safety Data Sheet for this material is attached in Appendix I.

The specific CO used in this process will be commercial, "food grade" CO. The purity specifications will be the same as those set forth for CO in GRASN 143, *i.e.*, the minimum purity will be 98 percent carbon monoxide while the other 2 percent will be residual atmospheric gases (nitrogen, oxygen, carbon dioxide, argon, water, hydrogen and/or methane). Thus, the use of carbon monoxide set forth herein will not result in the introduction into processed red meat of any materials not previously considered under either GRASN's 83, 143 or 167.

Section III

Information on Self-Limiting Levels of Use

As noted in Section I, this Notification is limited to the use of CO in brines and marinades that are injected into the red meat products. Notifier is proposing to limit the concentration of the brines and marinades to 27.8 percent by weight of red meat. As shown in the following calculation, even assuming that all of the CO in the brine is absorbed by the meat, the proposed limit on brine/marinade concentration will also limit the concentration of CO in the processed red meat to 0.136 mg per ounce of red meat, and will limit the quantity of CO to 1.3 mg per serving 250 g serving.

The following data is used to calculate the quantity of CO per serving:

- The solubility of carbon monoxide in water at room temperature (RT) is 21.4 ml/liter.
- The density of CO at RT is 1.145 g/liter.

Then the quantity of CO in 1 l (1000 ml) of water at RT is:

$$(21.4 \text{ ml})(1.145 \text{ g}/1000 \text{ ml}) = 24.5 \text{ mg}$$

$$24.5 \text{ mg}/\text{liter} = 2.45 \text{ mg}/100 \text{ ml}.$$

At the Notification limit for the pump (27.8% per 1 kg of red meat), 278 grams of brine/marinade will be added to each kilogram of red meat. Thus the total weight of each kilogram of injected red meat will be 1278 g.

Assuming that the density of the brine is 1.0 g/ml, 278 g of brine = 278 ml. The quantity of CO in the marinade used in 1 kg of red meat, assuming saturation of CO in the brine, will be:

$$(278 \text{ ml})(2.45 \text{ mg}/100 \text{ ml}) = 6.8 \text{ mg}.$$

The concentration of CO in the red meat will be:

$$(6.8 \text{ mg})/[(1000 \text{ g red meat}) + (278 \text{ g brine})] = 5.3 \times 10^{-3} \text{ mg/g red meat}.$$

For a 250 g portion of uncooked red meat, the quantity of CO that would be present in the product before cooking would be:

$$(250 \text{ g})(5.3 \times 10^{-3} \text{ mg/g}) = 1.3 \text{ mg.}^1$$

¹ Similarly, for a typical 20% pump, the quantity of CO that would be present in 250 g of uncooked red meat would be 1.0 mg.

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This quantity is equivalent to the amount estimated by Precept in GRASN 143 (1.2 mg CO/ 8.8 ounce serving) and is small when compared to the level of CO exposure deemed to be safe by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).²

In the previous GRASN's, Precept Foods, Pactiv Corporation and Tyson Food estimated that 85% of the CO present in the uncooked red meat would volatilize out of the meat during cooking. Using the same estimate, the quantity of CO present in 250 grams (8.8 ounces) of red meat at the 27.8% pump level after cooking would be:

$$(1.3 \text{ mg})(0.15) = 0.195 \text{ mg}$$

At the 20% pump level, the quantity of CO present in the same amount of meat after cooking would be 0.15 mg. Thus, the quantities of CO that would be consumed per serving from the FMI application are comparable to the quantities that are estimated to be consumed under GRASN's 83, 143 and 167. Since GRASN's 143 and 167 are applicable to all red meat products, the FMI process would not result in the use of CO in new meat products. Thus, there would be no increase in the total dietary exposure to CO.

² "EPA's National Ambient Air Quality Standards is 9 ppm CO in air, resulting in the inhalation of 52 mg CO in 8 hours. The OSHA Permissible Exposure Limit is 50 ppm in air, resulting in the inhalation of 290 mg CO in 8 hours." FDA, Agency Response Letter GRAS Notice No. GRN 000143, July 29, 2004 (footnote 1).

Section IV

Basis for Notifier's Claim

The proposed use of carbon monoxide raises two safety issues: (1) an assessment of the safety of the consumption of CO from the application; and (2) whether the use of CO will "mask" the effect of spoilage organisms on the processed red meat.

The use of CO in the same food products (red meat) is the subject of GRAS Notifications 143 and 167. The use of CO in this application for beef products was also the subject of GRASN 83. The information referenced in those Notices is hereby included in this Notice by reference. Further, as discussed in Section III, we have demonstrated that the method of application proposed by Freezing Machines, Inc will not result in any increase in the dietary consumption of carbon monoxide. Since neither the food products nor the potential concentration of CO in those food products will change, the data cited in support of the previous Notifications also demonstrates the safety of carbon monoxide when applied using the Freezing Machines process.

To answer the second issue, Freezing Machines has sponsored two studies to review the impact of the new process on the appearance of the processed beef.³ The studies exposed steaks that had been prepared using the FMI process to typical retail display case conditions. The steaks were evaluated daily to determine if they had become discolored. When the steaks were considered to be too discolored to be sold, they were removed from the test chamber and tested to determine the level of microbial contamination.

In the first study, only some of the steaks were tested following the "retail case" exposure, so the second study was conducted. The second study in this series determined that all the steaks reached a point of unacceptable color before the meat was spoiled by bacteria. "In other words, steaks enhanced by FMI technology were not spoiled at any time in the retail case while the color was still acceptable."⁴ Based on this study, Freezing Machines has determined that the proposed use of carbon monoxide will not affect the consumer's ability to discern the suitability of the processed beef. However, as an added measure of safety, FMI has decided to label all meat products produced with this process with a validated "use-or-freeze-by" date.

³ Wulf et al, Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology, November 9, 2004 (Study 1). Attached as Appendix II, and Wulf et al, Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology, November 2, 2005 (Study 2). Attached as Appendix III.

⁴ Id. (Study 2) at 3.

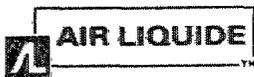
Freezing Machines, Inc.
GRAS Notification for Carbon Monoxide
February 23, 2006

Based on the information previously cited to FDA and the case-life study discussed above, Freezing Machines, Inc. has determined that carbon monoxide is generally recognized as safe when used in brine for pumping followed by modified atmosphere packaging. The CO saturated brine or solution is pumped into the red meat prior to MAP packaging, and will not exceed 27.8 percent by weight of the pre-brined meat.

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APPENDIX I

000012



Gases

[SITE MAP](#) [CONTACT](#)



Gas Data

This application enables data on many gas molecules to be accessed rapidly. You can search on a raw chemical formula, chemical name or UN transportation code. The values displayed on this page are extracted from the literature and the proprietary current AIR LIQUIDE Group data.

[User guide](#)
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Gases

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[Publications](#)
[SDS \(MSDS\)](#)

Gas selection	Chemical Formula	Name	UN Transportation Code
<input type="button" value="Go"/>	Carbon monoxide		

[Main applications](#) |
[Gas Properties](#) | [Vapor Pressure Graph](#) | [Liquid Gas Conversion](#) |
[Material Safety Data Sheets](#) | [Major Hazards](#) | [Material compatibility](#) |
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CO ; Carbon monoxide
CAS Number : 630-08-0
UN1016

C=O

Carbon oxide; Carbonic oxide

GENERALITIES:

Carbon monoxide (CO) gas is formed from the combination of a carbon atom with an oxygen atom. Not only flammable, it is also very hazardous since it is very toxic and odorless. It cannot sustain life and is produced, among other things, from incomplete combustion due to lack of oxygen. It can therefore cause domestic accidents if heating systems are poorly maintained. It is produced on a large scale in industry, in combination with hydrogen, by reforming hydrocarbons, generally natural gas. It is used in large quantities to produce various intermediary organic chemicals, such as acetic acids, isocyanates, formic acid, and also certain polymers such as polycarbonates and polyketones.

SUPPLY MODE:

Carbon monoxide can be supplied in cylinders, or pipeline.

Main applications

[TOP](#)
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Industries Applications

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Chemicals	Carbon monoxide and synthesis gas are the raw materials in the polycarbonate, polyurethane and oxy-alcohol manufacture based on SMR and ATR processes or on partial oxidation. Carbon monoxide is also used in the manufacturing of metal carbonyls.
Laboratories & analysis	Carbon monoxide is used in calibration gas mixtures for petrochemical industry; environmental emission monitoring, industrial hygiene monitors and trace impurity analyzers.

[TOP](#)

Gas Properties

[Go back to choosing the units](#)

Molecular Weight

- Molecular weight : 28.01 g/mol

Solid phase

- Latent heat of fusion (1,013 bar, at triple point) : 27.873 kJ/kg

Liquid phase

- Liquid density (1.013 bar at boiling point) : 788.6 kg/m³
- Liquid/gas equivalent (1.013 bar and 15 °C (59 °F)) : 674 vol/vol
- Boiling point (1.013 bar) : -191.6 °C
- Latent heat of vaporization (1.013 bar at boiling point) : 214.85 kJ/kg

Critical point

- Critical temperature : -140.3 °C
- Critical pressure : 34.987 bar
- Critical density : 301 kg/m³

Triple point

- Triple point temperature : -205.1 °C
- Triple point pressure : 0.1535 bar

Gaseous phase

- Gas density (1.013 bar at boiling point) : 4.355 kg/m³
- Gas density (1.013 bar and 15 °C (59 °F)) : 1.184 kg/m³
- Compressibility Factor (Z) (1.013 bar and 15 °C (59 °F)) : 0.9996
- Specific gravity (air = 1) (1.013 bar and 21 °C (70 °F)) : 0.968
- Specific volume (1.013 bar and 21 °C (70 °F)) : 0.862 m³/kg
- Heat capacity at constant pressure (Cp) (1.013 bar and 15.6 °C (60 °F)) : 0.029 kJ/(mol.K)
- Heat capacity at constant volume (Cv) (1.013 bar and 15.6 °C (60 °F)) : 0.02 kJ/(mol.K)
- Ratio of specific heats (Gamma:Cp/Cv) (1.013 bar and 15.6 °C (60 °F)) : 1.402488
- Viscosity (1.013 bar and 0 °C (32 °F)) : 0.0001662 Poise
- Thermal conductivity (1.013 bar and 0 °C (32 °F)) : 23.027 mW/(m.K)

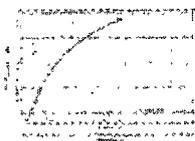
Miscellaneous

- Solubility in water (1.013 bar and 20 °C (68 °F)) : 0.0227 vol/vol
- Solubility in water (1.013 bar and 0 °C (32 °F)) : 0.0352 vol/vol
- Autoignition temperature : 630 °C

[Go back to choosing the units](#)

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Vapor Pressure Graph



The vapor pressure curve may be obtained by clicking on the image. On the graph, pressure is in bar or 0.1 MPa, temperature in K or °C. The critical point is indicated by a black spot on the liquid-vapor equilibrium curve.

[TOP](#)

Liquid Gas Conversion

Liquid to gas conversion

This module enables a volume (measured at 1 atmosphere and boiling point) or a mass of liquid gas to be converted into a volume or a mass of gas measured at 1 atmosphere and 15 °C.

Data : liquid Phase

Input the volume : (m³) or mass : (kg)

000014

[Calculate](#)

Gas to liquid conversion

This module enables a volume (measured at 1 atmosphere and 15 °C) or a mass of gas in gaseous phase to be converted into a mass or a volume of liquid (measured at 1 atmosphere and boiling point).

Data : Gas Phase

Input the volume (m³) or mass (kg)

[Calculate](#)[Go back to choosing the units](#)[TOP](#)

Material Safety Data Sheets

The European Material Safety Data Sheets (MSDS) are made available for information only. Visitors to this site may only use them at their own risk. The MSDSs were prepared by EIGA (the European Industrial Gas Association) according to European Union standards. Although Air Liquide believes the information in the MSDSs to be correct, Air Liquide cannot be held responsible in any event if the contents do not meet the regulatory requirements of countries outside the European Union. Material Safety Data Sheets are subject to revision. Refer to this web site to ensure that you have the latest version.

MSDS Language  Carbon monoxide[TOP](#)

Major Hazards

- Major hazard : Fire and Inhalation
- Toxicity (Am. Conf. Of Gov. Ind. Hygienists ACGIH 2000 Edition) : 25 ppm
- Flammability limits in air (STP conditions) : 12.5-74 vol%
- Odour : None
- UN Number : UN1016
- EINECS Number : 211-128-3
- DOT Label (USA) : FG
- DOT Hazard class (USA) : Flammable Gas

[TOP](#)

Material compatibility

Air Liquide has assembled data on the compatibility of gases with materials to assist you in evaluating which products to use for a gas system. Although the information has been compiled from what Air Liquide believes are reliable sources (International Standards: Compatibility of cylinder and valve materials with gas content; Part 1: ISO 11114-1 (Jul 1998), Part 2: ISO 11114-2 (Mar 2001)), it must be used with extreme caution. No raw data such as this can cover all conditions of concentration, temperature, humidity, impurities and aeration. It is therefore recommended that this table is used to choose possible materials and then more extensive investigation and testing is carried out under the specific conditions of use. The collected data mainly concern high pressure applications at ambient temperature and the safety aspect of material compatibility rather than the quality aspect.

Material

Compatibility

Metals**000015**

General Behavior : Risk of formation of toxic carbonyl metals.

Aluminium	Satisfactory
Brass	Satisfactory
Copper	Satisfactory
Ferritic Steels (e.g. Carbon steels)	Satisfactory but risk of corrosion in presence of CO ₂ and moisture.
Stainless Steel	Satisfactory

Plastics

Polytetrafluoroethylene (PTFE)	Satisfactory
Polychlorotrifluoroethylene (PCTFE)	Satisfactory
Vinylidene polyfluoride (PVDF) (KYNAR™)	Satisfactory
Polyamide (PA) (NYLON™)	Satisfactory
Polypropylène (PP)	Satisfactory

Elastomers

Buthyl (isobutene - isoprene) rubber (IIR)	Acceptable but notable acceleration of the process of ageing.
Nitrile rubber (NBR)	Satisfactory
Chloroprene (CR)	Satisfactory
Chlorofluorocarbons (FKM) (VITON™)	Non recommended, significant swelling.
Silicon (Q)	Satisfactory
Ethylene - Propylene (EPDM)	Satisfactory

Lubricants

Hydrocarbon based lubricant	Satisfactory
Fluorocarbon based lubricant	Satisfactory

[TOP](#)

Selection of the units

You can choose the units in which the values are displayed. By default, SI units are selected.

Quantity	Units
Mass	<input checked="" type="radio"/> kg <input type="radio"/> lb <input type="radio"/> g
Volume	<input checked="" type="radio"/> m ³ <input type="radio"/> ft ³ <input type="radio"/> l
Pressure	<input checked="" type="radio"/> bar <input type="radio"/> psi <input type="radio"/> kPa
Temperature	<input checked="" type="radio"/> °C <input type="radio"/> °F <input type="radio"/> K <input type="radio"/> °R
Density	<input checked="" type="radio"/> kg/m ³ <input type="radio"/> lb/ft ³ <input type="radio"/> mol/l <input type="radio"/> (lb-mol)/ft ³
Enthalpy	<input checked="" type="radio"/> kJ/kg <input type="radio"/> Btu/lb <input type="radio"/> kJ/mol <input type="radio"/> kcal/kg <input type="radio"/> kcal/mol <input type="radio"/> Btu/lb-mol
Heat Capacity	<input checked="" type="radio"/> kJ/(mol.K) <input type="radio"/> Btu/(lb.°F) <input type="radio"/> kJ/(kg.K) <input type="radio"/> Btu/(lb-mol.°F) <input type="radio"/> kcal/(kg.K) <input type="radio"/> cal/(mol.K) <input type="radio"/> J/(mol.K)
Viscosity	<input checked="" type="radio"/> Poise <input type="radio"/> lb/(ft.s) <input type="radio"/> µPa.s <input type="radio"/> Pa.s
Thermal Conductivity	<input checked="" type="radio"/> mW/(m.K) <input type="radio"/> Btu.ft/(h.ft ² .°F) <input type="radio"/> cal.cm/(h.cm ² .°C) <input type="radio"/> W/(m.K) <input type="radio"/> (cal.cm)/(s.cm ² .°C)
Concentration	<input checked="" type="radio"/> vol % <input type="radio"/> vol ppm <input type="radio"/> vol/vol
Solubility	<input checked="" type="radio"/> vol/vol <input type="radio"/> lb/ft ³ <input type="radio"/> (lb-mol)/ft ³ <input type="radio"/> mol/l <input type="radio"/> g/l
Specific volume	<input checked="" type="radio"/> m ³ /kg <input type="radio"/> ft ³ /lb <input type="radio"/> l/mol <input type="radio"/> ft ³ /lb-mol

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[Click to change the values](#)

[TOP](#)

Main applications |
Gas Properties | Vapor Pressure Graph | Liquid Gas Conversion |
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APPENDIX II

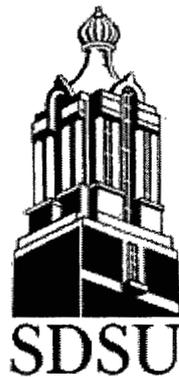
000018

Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology

A Report to Freezing Machines Inc.
891 Two Rivers Drive
Dakota Dunes, SD

Duane Wulf, Tanya Koger, and Robert Maddock
South Dakota State University

November 9, 2004



000019

Materials and Methods

Retail Display. Upon arrival to the SDSU Meat Lab, all steaks were held in dark storage in boxes at 39°F. Steaks were removed from dark storage on d 7 after FMI enhancement, and assigned a random number within each subprimal (4 subprimals). Three of the subprimals had 12 steaks and one of the subprimals had 11 steaks. The steaks were randomly placed on tables in a cooler at 39°F under cool fluorescent lighting. The lighting was 1000 to 1800 lux at the steak surface level. Steaks were evaluated subjectively for color at approximately the same time each day for eleven days of retail display. Subjective evaluation was performed by a four-member trained panel. Panelists were trained using the process of open discussion. Evaluators assigned scores to the steaks for lean muscle color and percent surface discoloration. Lean muscle color (oxygenated pigment) was characterized on an 8-point scale (8 = bright cherry-red, 7 = moderately bright cherry-red, 6 = cherry-red, 5 = slightly dark-red, 4 = moderately dark-red or brown, 3 = dark-red or brown, 2 = very dark-brown, 1 = extremely dark-brown or green). Percent surface discoloration was characterized on an 8-point scale (8 = none, 7 = 1-5%, 6 = 6-10%, 5 = 11-25%, 4 = 26-50%, 3 = 51-75%, 2 = 76-99%, 1 = complete). At each evaluation time, the evaluators also answered yes or no to the question "Do you think that the average consumer would purchase this steak today?" Once three out of the four panelists indicated that the average consumer would not purchase that steak, it was considered "too discolored to sell" and removed from the retail display and frozen. The 5th, 6th, and 7th steaks to be considered "too discolored to sell" from each subprimal were used for microbial analysis, meaning that 12 steaks were used for microbial analysis (4 subprimals × 3 steaks per subprimal = 12 steaks).

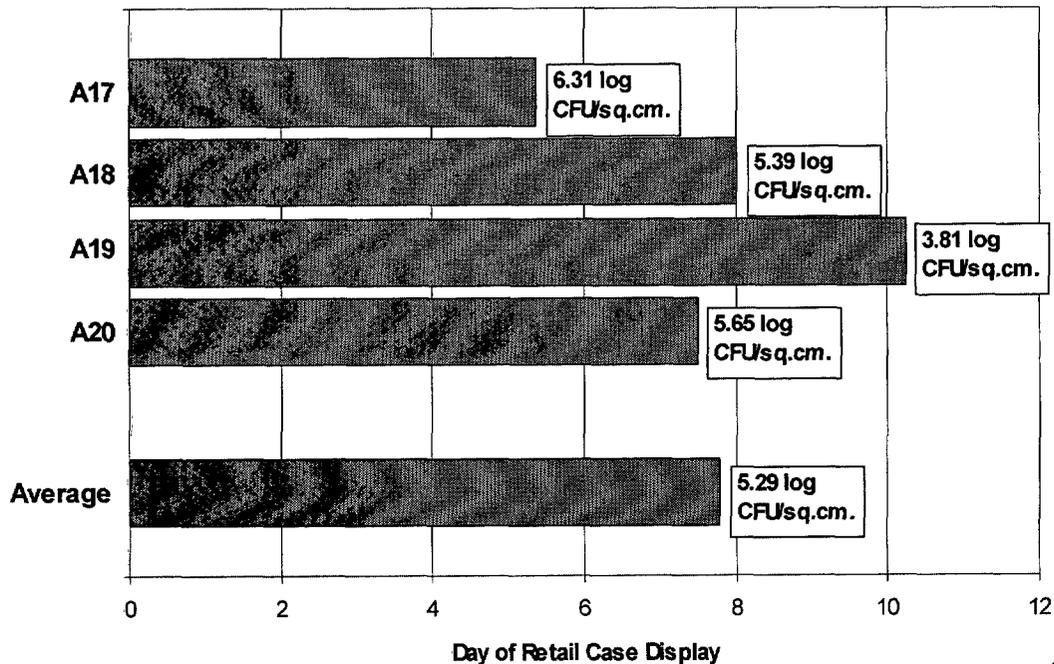
Microbiological Analyses. Frozen steaks were kept in the original modified-atmosphere case-ready package and defrosted in a 113°F water bath for approximately 7 minutes. The package was opened with a sterile scalpel blade to expose the steak surface. A sterile scalpel blade and sterile template was used to cut around the edge of a 10-cm² (approximately 2-mm-thick) area. This area was then removed from the center of each steak using flame-sterilized forceps to hold the steak and a sterile scalpel to cut under the 10-cm² area. The 10-cm² sample was placed in a stomacher bag along with 100 mL of Butterfield's Buffer (Weber Scientific, Hamilton, NJ) and macerated in a stomacher for 2 min. Several 100-fold serial dilutions with 99 mL of Butterfield's Buffer were obtained for each sample. Plating was performed in duplicate with Standard Methods Agar (Becton, Dickinson, and Company, Sparks, MD). The plates were incubated at 95°F for 48 h. The plates were counted and the duplicate plates averaged. The number of CFU/mL in the stomacher bag were calculated, and then multiplied by 100 since there were 100 mL in the bag. We then divided that number by 10 to get CFU/cm². The counts were then converted to logarithms and then the three replications from each subprimal were averaged and reported as log CFU/cm². We analyzed for CFU per cm² versus CFU per gram because we were testing an intact muscle cut versus a ground meat product. Most of the data in the scientific literature for intact steaks are expressed on a per-cm² basis, whereas most of the data in the scientific literature for ground meat are expressed on a per-gram basis. Microbial data for intact steaks is typically presented on a per-cm² basis because we assume that the interior of whole muscle cuts is virtually sterile and bacteria are only present on the surface of the cut. Therefore, the bacteria counts presented in this report are probably slightly higher (expressed on a per-cm² basis) than they would be if they were expressed on a per-gram basis.

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Results

Based on visual appraisal, the Freezing Machines Inc. (FMI) steaks had an average retail caselife of 7.8 days, beyond the 7 days of dark storage, until the panelists determined the steaks were "too discolored to sell" (Figure 1). The length of retail caselife varied between subprimals; the steaks from subprimal A19 averaged 10.3 days of retail caselife, whereas the steaks from subprimal A17 averaged only 5.4 days of retail display. The average aerobic plate count at the end of visual caselife was 5.29 log CFU/cm² (Figure 1). Longer display times did not necessarily lead to greater bacterial counts; in fact, the steaks that had the longest caselife (A19) had the lowest bacterial counts. These plate counts were assessed when each individual steak was determined to be "too discolored to sell", because the objective was to determine if the visual caselife ended before or after the meat was spoiled by bacteria. Based on a review of scientific literature, aerobic plate counts of greater than 8 log CFU/g of meat would produce off-flavors (Walker, 1980), and aerobic plate counts of greater than 7 log CFU/g of meat are considered indicative of spoilage (Ayres, 1960; Branen, 1978). The microbial counts in this study were all less than 7 log CFU/cm², and because bacteria counts expressed on a per-cm² basis would be less if they were expressed on a per-gram basis (as described on page 2), we can conclude that these steaks had not reached the point of spoilage. Therefore, the steaks in this study discolored to the point of unacceptability before the meat was spoiled by bacteria. In other words, steaks enhanced by FMI technology were not spoiled at any time in the retail case while the color was still acceptable. Therefore, the enhanced caselife created from the application of FMI technology did not mask bacterial spoilage.

Figure 1. Retail caselife of steaks enhanced by FMI technology. Each bar represents the number of display days until the panel determined that the steaks were "too discolored to sell", averaged for each subprimal (A17 to A20) and overall. The bacteria counts represent the aerobic plate count on the day the steaks were determined "too discolored to sell".

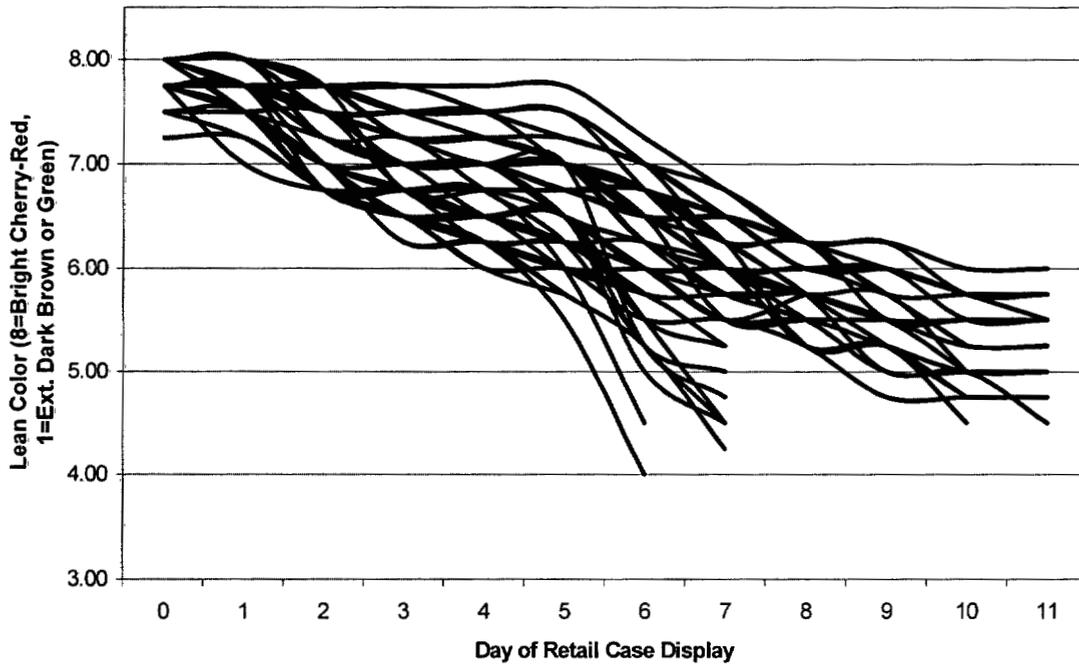


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A report to Freezing Machines Inc.

Lean color for each of the individual 47 steaks is shown in Figure 2. The color started to darken slightly on day 2 of retail display and continued to darken at a slow, but steady, rate through day 11 of retail display. These results indicate that case-ready steaks enhanced with FMI technology will gradually darken in color during retail display.

Figure 2. Lean color scores for 47 individual steaks enhanced by FMI Technology evaluated for 11 days of retail display. Each line terminates at the end of retail caselife for that particular steak, when the panel determined that the steak was "too discolored to sell".

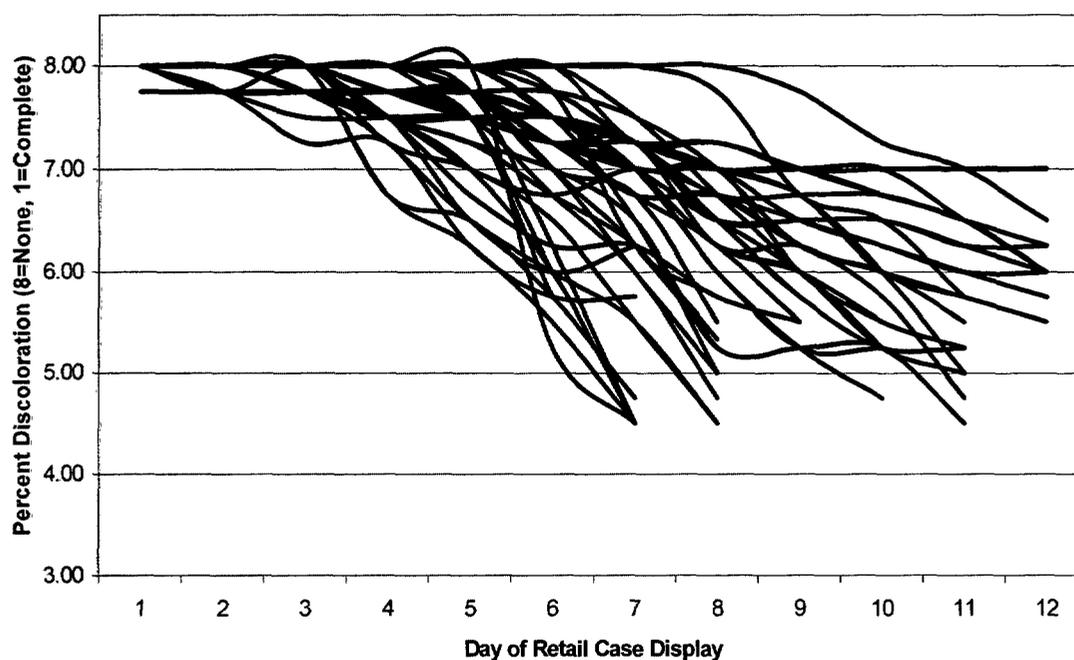


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A report to Freezing Machines Inc.

Percent surface discoloration for each of the individual 47 steaks is shown in Figure 2. There was little to no surface discoloration on any of the steaks until day 4 of retail display. Most of the steaks showed their first surface discoloration on days 5 to 7 of retail display. One steak lasted 8 days and one steak lasted 9 days before any surface discoloration; however, all steaks eventually discolored. These results indicate that case-ready steaks enhanced with FMI technology will discolor during retail display.

Figure 3. Percent surface discoloration scores for 47 individual steaks enhanced by FMI Technology evaluated for 11 days of retail display. Each line terminates at the end of retail caselife for that particular steak, when the panel determined that the steak was "too discolored to sell".



Literature Cited

- Ayres, J.C. 1960. Temperature relationships and some other characteristics of the microbial flora developing on refrigerated beef. *Food Res.* 25:1.
- Branen, A.L. 1978. Interaction of fat oxidation and microbial spoilage in muscle foods. *Proc. Reciprocal Meat Conf.* 31:156.
- Walker, H.W. 1980. Effects of microflora on fresh meat color. *Recip. Meat Conf. Proc., Am. Meat Sci. Assoc.* 33:33.

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APPENDIX III

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Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology

A Report to Freezing Machines Inc.
891 Two Rivers Drive
Dakota Dunes, SD

Duane Wulf and Louis Muench
South Dakota State University

November 2, 2005



000025

A report to Freezing Machines Inc.

Materials and Methods

Retail Display. Fifty beef boneless strip steaks representing five different subprimals (10 steaks per subprimal) were treated using FMI technology and transported in coolers with ice packs to South Dakota State University. Upon arrival at the SDSU Meat Lab, all 50 steaks were randomly placed on tables in a cooler at 35°F under cool fluorescent lighting. The lighting was 1000 to 1800 lux at the steak surface level. Steaks were evaluated subjectively for color at approximately the same time each day until all steaks had been determined visually unacceptable. Subjective evaluation was performed by a three-member panel of experts. Panelists were trained using the process of open discussion. At each evaluation time, the evaluators also answered yes or no to the question "Do you think that the average consumer would purchase this steak today?" Once two out of the three panelists indicated that the average consumer would not purchase that steak, it was considered "too discolored to sell" and removed from the retail display and frozen.

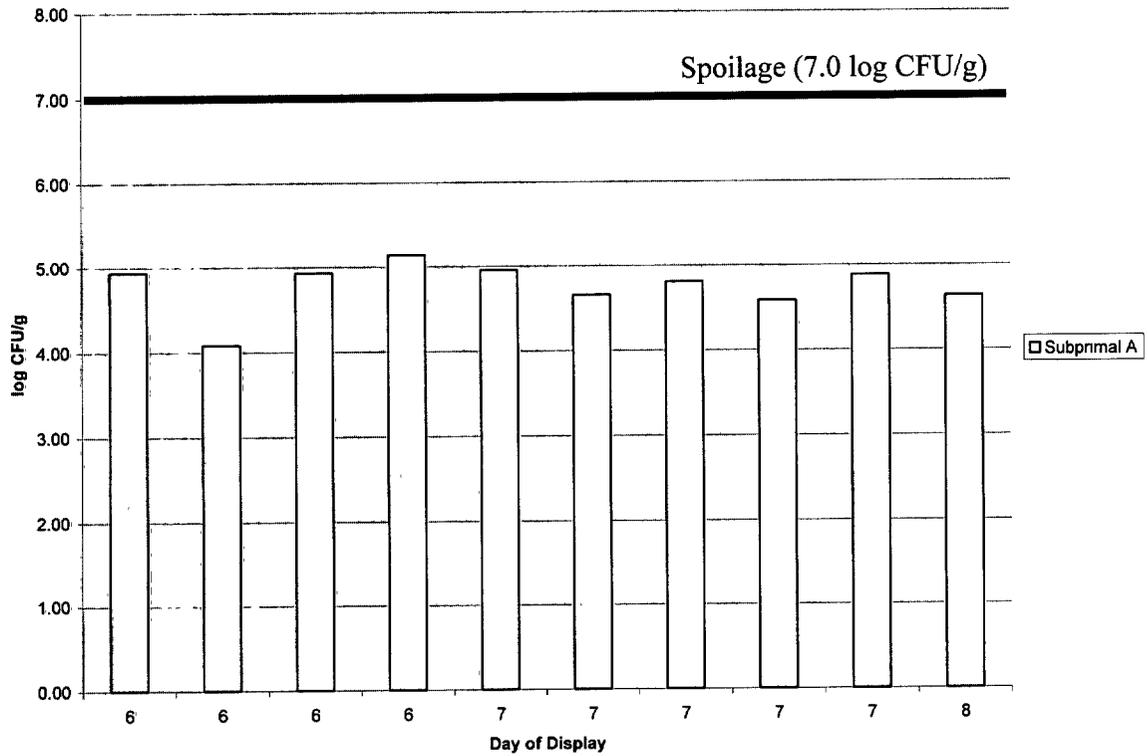
Microbiological Analyses. Frozen steaks were kept in the original retail package and defrosted at 70°F. Each package was opened with using aseptic techniques and the entire steak was placed in a stomacher bag along with 198 mL of Butterfield's Buffer (Weber Scientific, Hamilton, NJ) and stomached for 2 min. Several 100-fold serial dilutions with 99 mL of Butterfield's Buffer were obtained for each sample. Plating was performed in duplicate with Standard Methods Agar (Becton, Dickinson, and Company, Sparks, MD). The plates were incubated at 95°F for 48 h. The plates were counted and the number of CFU/g of sample was calculated. The counts were then converted to logarithms and reported as log CFU/g.

Results

Based on visual appraisal, the Freezing Machines Inc. (FMI) steaks had an average retail caselife of 7.1 days (5 to 8 days), until the panelists determined the steaks were "too discolored to sell" (Figures 1 to 5). Some subprimals had longer caselife than others; steaks from subprimal E lasted an average of 8.0 days (Figure 5), whereas steaks from subprimal D lasted an average of 5.9 days (Figure 4). The average aerobic plate count at the end of visual caselife for all 50 steaks was 4.43 log CFU/g (Figures 1 to 5). There was little difference among subprimals for aerobic plate count; steaks from subprimal A had the highest average aerobic plate counts with 4.76 log CFU/g (Figure 1), and subprimal B had the lowest average aerobic plate counts with 4.23 log CFU/g (Figure 2). Longer display times did not necessarily lead to greater bacterial counts. These plate counts were assessed when each individual steak was determined to be "too discolored to sell", because the objective was to determine if the visual caselife ended before or after the meat was spoiled by bacteria. Based on a review of scientific literature, aerobic plate counts of greater than 8 log CFU/g of meat would produce off-flavors (Walker, 1980), and aerobic plate counts of greater than 7 log CFU/g of meat are considered indicative of spoilage (Ayres, 1960; Branen, 1978). The microbial counts in this study were all less than 7 log CFU/g. Therefore, the steaks in this study discolored to the point of unacceptability before the meat was spoiled by bacteria. In other words, steaks enhanced by FMI technology were not spoiled at any time in the retail case while the color was still acceptable. Therefore, the enhanced caselife created from the application of FMI technology did not mask bacterial spoilage.

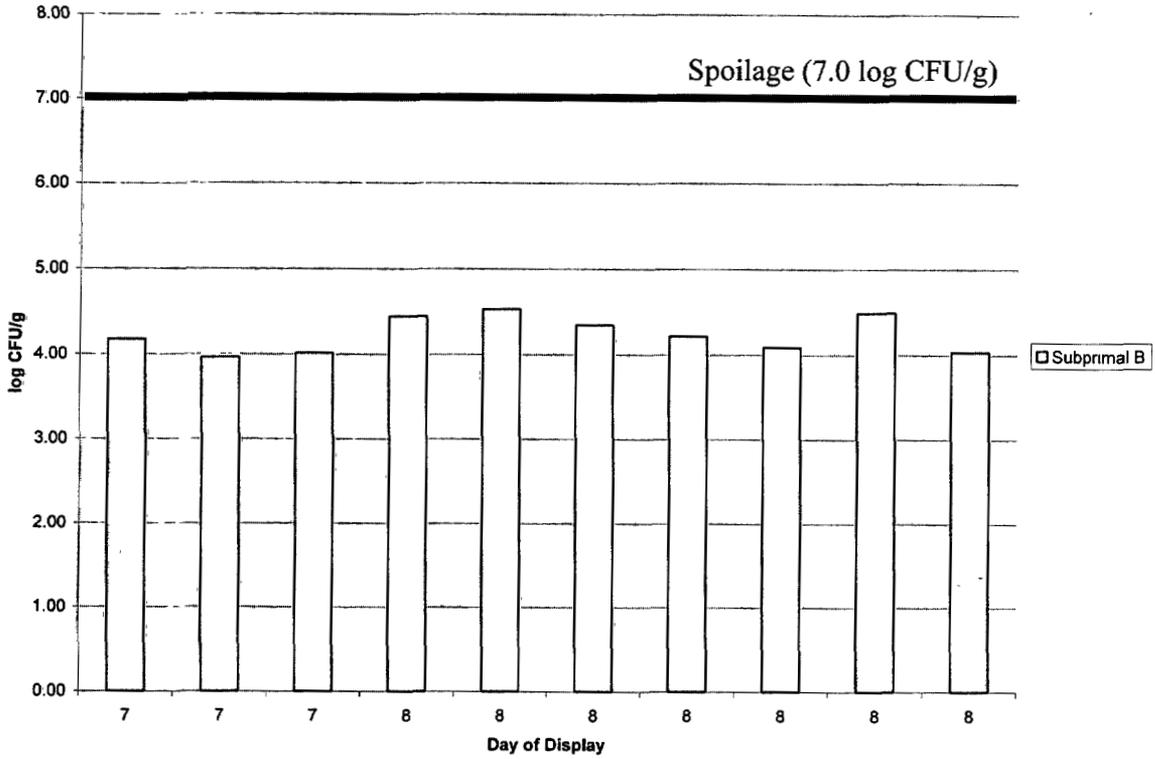
A report to Freezing Machines Inc.

Figure 1. Total aerobic plate counts (APC) for 10 individual steaks from subprimal A. Each bar represents the APC for an individual steak at the time when the panelists determined that the steak was "too discolored to sell". The bacteria counts represent the aerobic plate count on the day the steak was determined "too discolored to sell".



A report to Freezing Machines Inc.

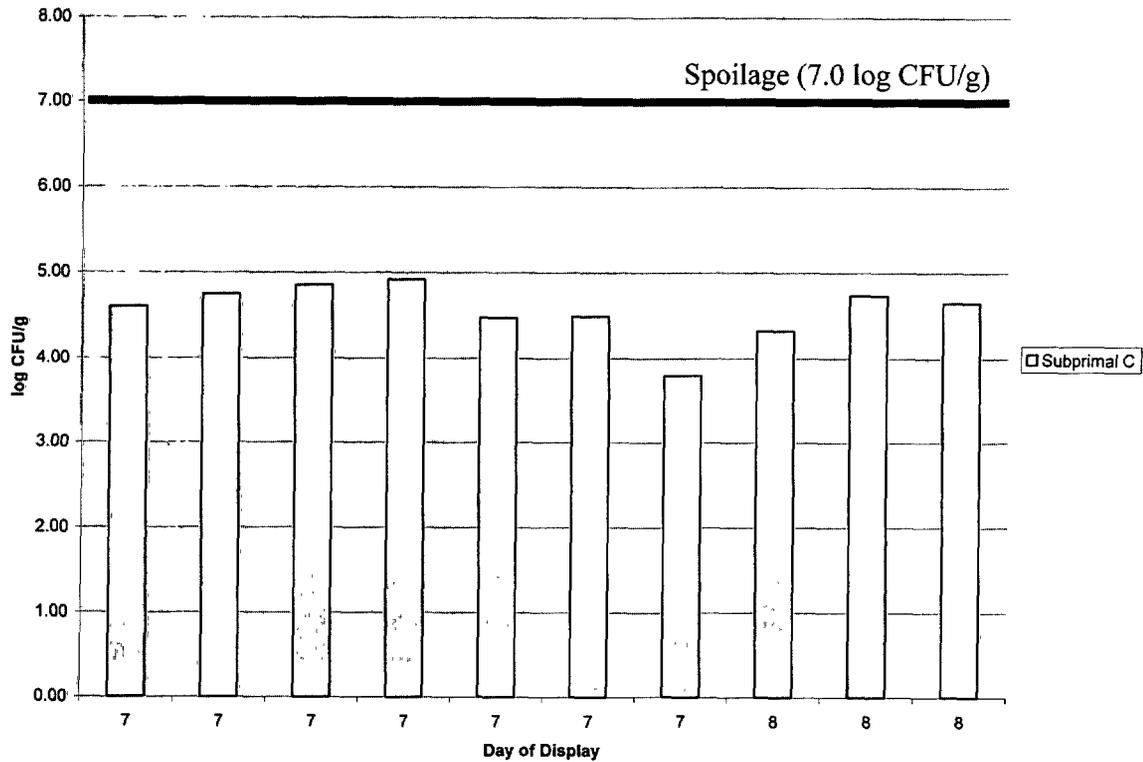
Figure 2. Total aerobic plate counts (APC) for 10 individual steaks from subprimal B. Each bar represents the APC for an individual steak at the time when the panelists determined that the steak was "too discolored to sell". The bacteria counts represent the aerobic plate count on the day the steak was determined "too discolored to sell".



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A report to Freezing Machines Inc.

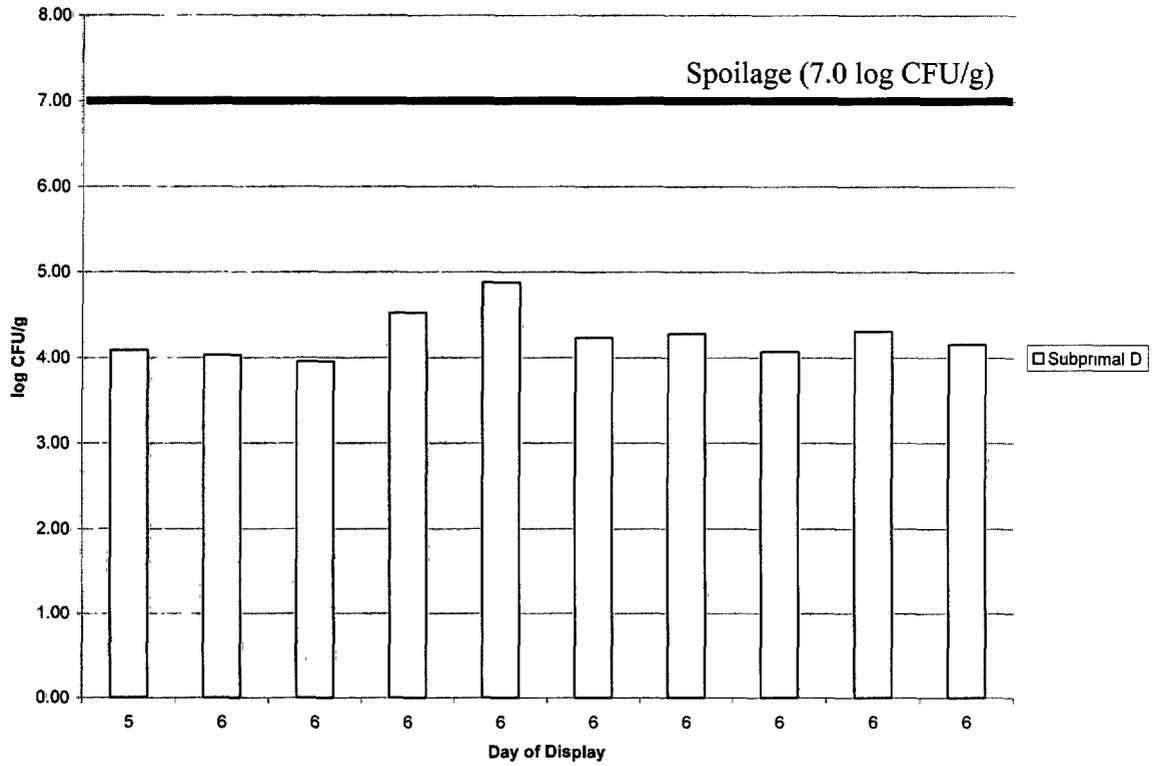
Figure 3. Total aerobic plate counts (APC) for 10 individual steaks from subprimal C. Each bar represents the APC for an individual steak at the time when the panelists determined that the steak was "too discolored to sell". The bacteria counts represent the aerobic plate count on the day the steak was determined "too discolored to sell".



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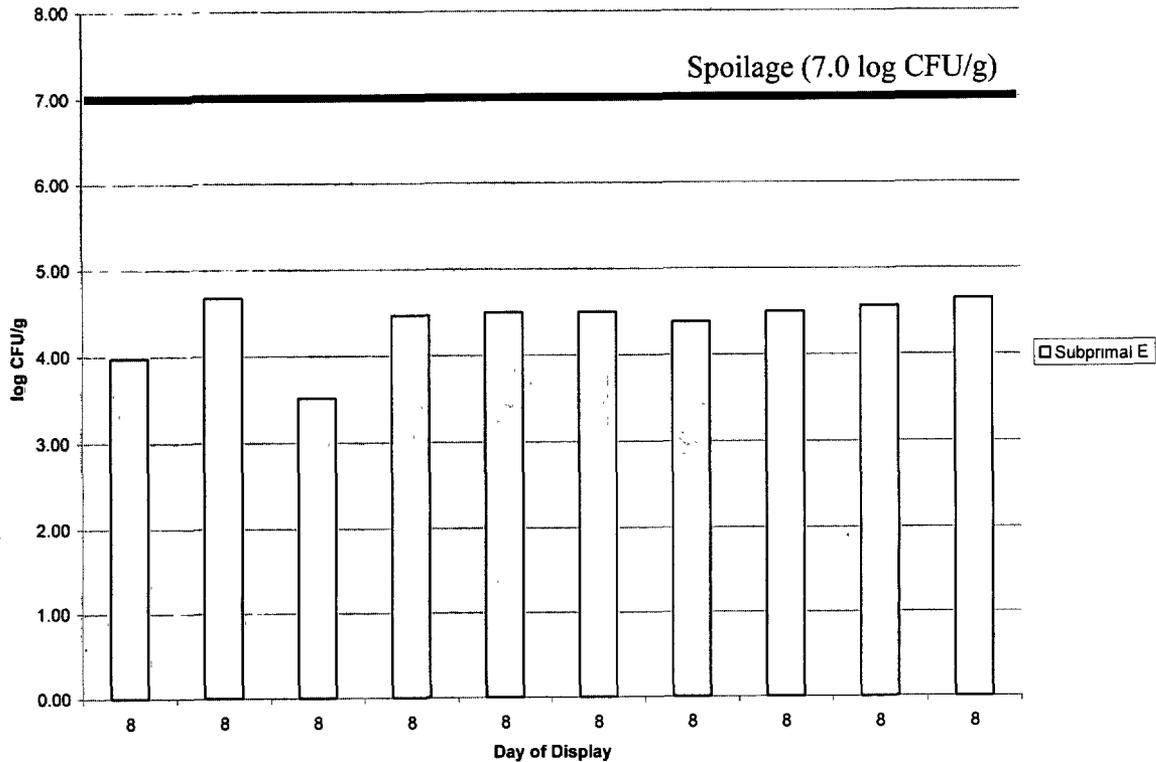
A report to Freezing Machines Inc.

Figure 4. Total aerobic plate counts (APC) for 10 individual steaks from subprimal D. Each bar represents the APC for an individual steak at the time when the panelists determined that the steak was "too discolored to sell". The bacteria counts represent the aerobic plate count on the day the steak was determined "too discolored to sell".



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Figure 5. Total aerobic plate counts (APC) for 10 individual steaks from subprimal E. Each bar represents the APC for an individual steak at the time when the panelists determined that the steak was "too discolored to sell". The bacteria counts represent the aerobic plate count on the day the steak was determined "too discolored to sell".



Literature Cited

- Ayres, J.C. 1960. Temperature relationships and some other characteristics of the microbial flora developing on refrigerated beef. *Food Res.* 25:1.
- Branen, A.L. 1978. Interaction of fat oxidation and microbial spoilage in muscle foods. *Proc. Reciprocal Meat Conf.* 31:156.
- Walker, H.W. 1980. Effects of microflora on fresh meat color. *Recip. Meat Conf. Proc., Am. Meat Sci. Assoc.* 33:33.

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Microbial Analysis of Individual Samples

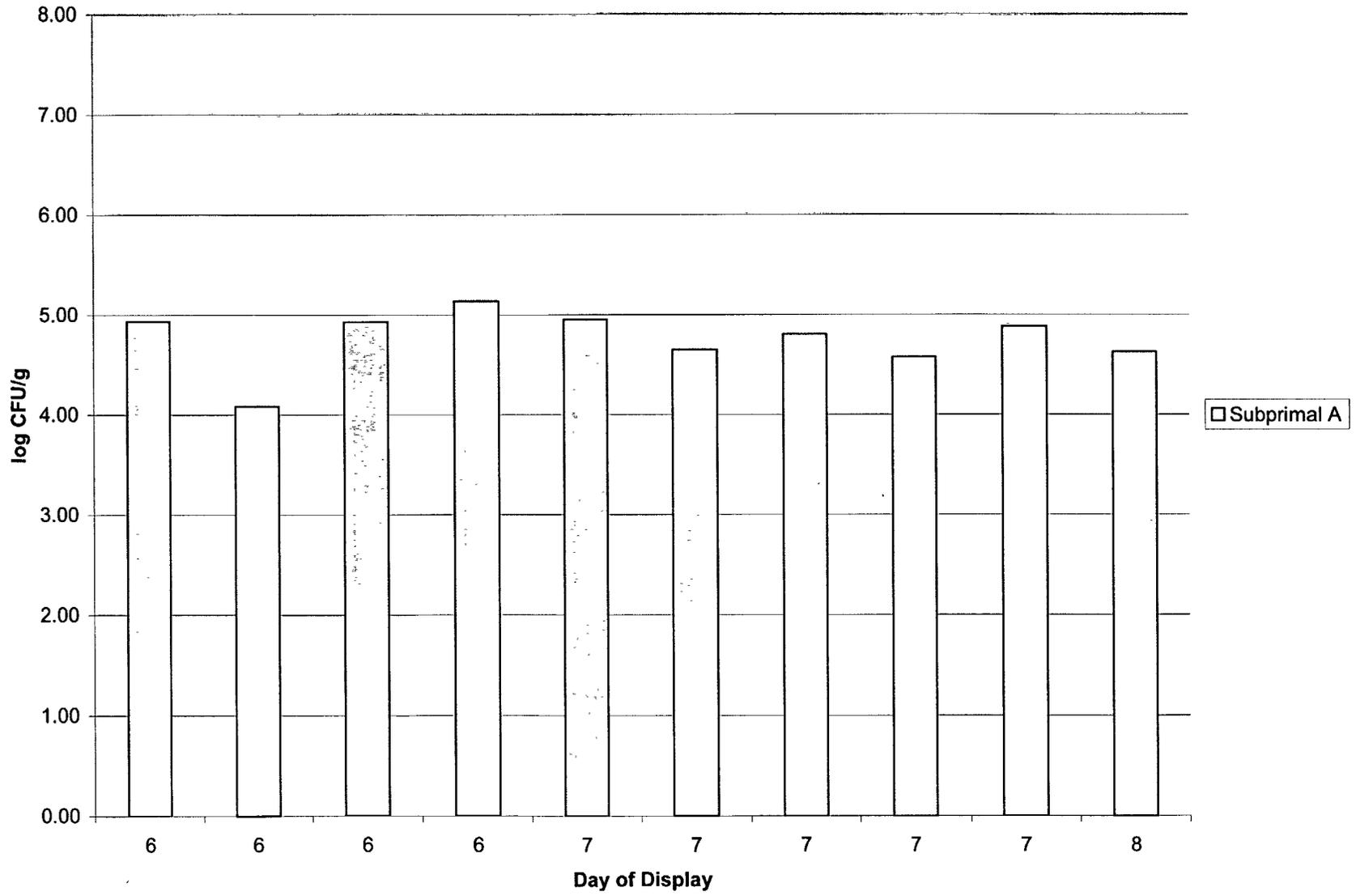
<u>Sample</u>	<u>Subprimal</u>	<u>Days stored</u>	<u>Weight (g)</u>	<u># Colonies Counted</u>	<u>Dilution Factor</u>	<u>CFU/g</u>	<u>Log CFU/g</u>
103	A	6	384.5	57	6.601E-04	8.635E+04	4.936
104	A	6	383.8	8	6.597E-04	1.213E+04	4.084
105	A	6	380.7	56	6.579E-04	8.513E+04	4.930
106	A	6	831.6	111	8.077E-04	1.374E+05	5.138
101	A	7	381.4	59	6.583E-04	8.963E+04	4.952
102	A	7	364.7	29	6.481E-04	4.474E+04	4.651
107	A	7	380.2	42	6.576E-04	6.387E+04	4.805
108	A	7	385.7	25	6.608E-04	3.783E+04	4.578
109	A	7	403.5	51	6.708E-04	7.603E+04	4.881
110	A	8	341.5	27	6.330E-04	4.265E+04	4.630
201	B	7	401.7	10	6.698E-04	1.493E+04	4.174
202	B	7	369	6	6.508E-04	9.220E+03	3.965
203	B	7	414.9	7	6.769E-04	1.034E+04	4.015
204	B	8	376.1	18	6.551E-04	2.748E+04	4.439
205	B	8	379	22	6.568E-04	3.349E+04	4.525
206	B	8	417.8	15	6.785E-04	2.211E+04	4.345
207	B	8	402.4	11	6.702E-04	1.641E+04	4.215
208	B	8	377.2	8	6.558E-04	1.220E+04	4.086
209	B	8	423.1	21	6.812E-04	3.083E+04	4.489
210	B	8	358	7	6.439E-04	1.087E+04	4.036
301	C	7	336.7	25	6.297E-04	3.970E+04	4.599
302	C	7	356.4	36	6.429E-04	5.600E+04	4.748
303	C	7	315.7	44	6.146E-04	7.160E+04	4.855
304	C	7	356.7	53	6.431E-04	8.242E+04	4.916
305	C	7	306.4	18	6.075E-04	2.963E+04	4.472
306	C	7	322.7	19	6.197E-04	3.066E+04	4.487
307	C	7	346.1	4	6.361E-04	6.288E+03	3.799
308	C	8	331.4	13	6.260E-04	2.077E+04	4.317
309	C	8	359.5	35	6.448E-04	5.428E+04	4.735
310	C	8	337.8	28	6.305E-04	4.441E+04	4.648

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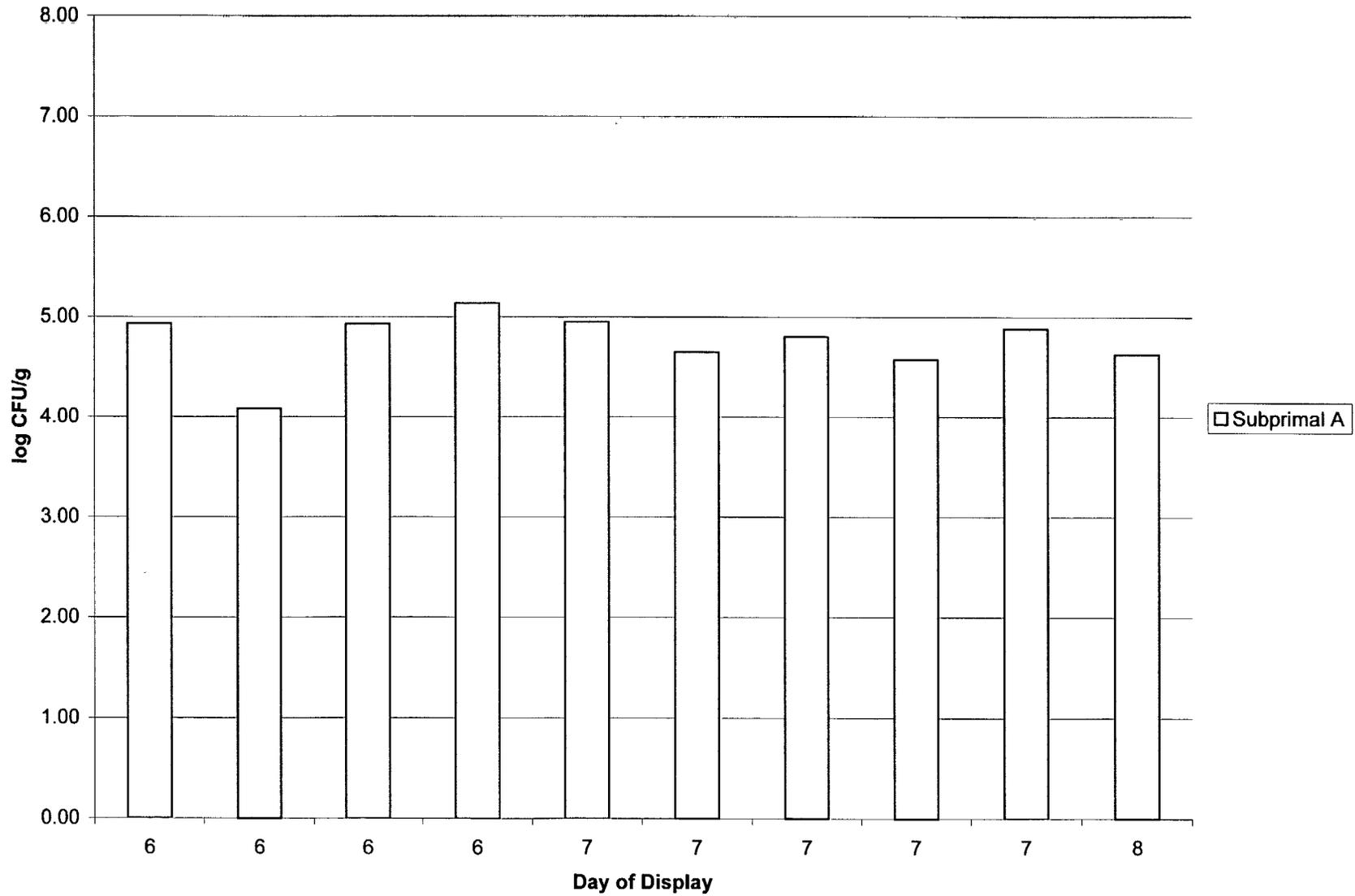
410	D	5	381.8	8	6.585E-04	1.215E+04	4.085
401	D	6	377.2	7	6.558E-04	1.067E+04	4.028
402	D	6	391.3	6	6.640E-04	9.036E+03	3.956
403	D	6	387.7	22	6.619E-04	3.324E+04	4.522
404	D	6	363.7	49	6.475E-04	7.568E+04	4.879
405	D	6	362.7	11	6.469E-04	1.700E+04	4.231
406	D	6	350.6	12	6.391E-04	1.878E+04	4.274
407	D	6	419.5	8	6.794E-04	1.178E+04	4.071
408	D	6	361.1	13	6.459E-04	2.013E+04	4.304
409	D	6	342	9	6.333E-04	1.421E+04	4.153
501	E	8	346.1	6	6.361E-04	9.433E+03	3.975
502	E	8	413.7	32	6.763E-04	4.732E+04	4.675
503	E	8	296.5	2	5.996E-04	3.336E+03	3.523
504	E	8	309.6	18	6.099E-04	2.951E+04	4.470
505	E	8	392.1	21	6.645E-04	3.160E+04	4.500
506	E	8	382.5	21	6.589E-04	3.187E+04	4.503
507	E	8	327.8	15	6.234E-04	2.406E+04	4.381
508	E	8	340.6	20	6.324E-04	3.163E+04	4.500
509	E	8	340.6	23	6.324E-04	3.637E+04	4.561
510	E	8	413.7	30	6.763E-04	4.436E+04	4.647

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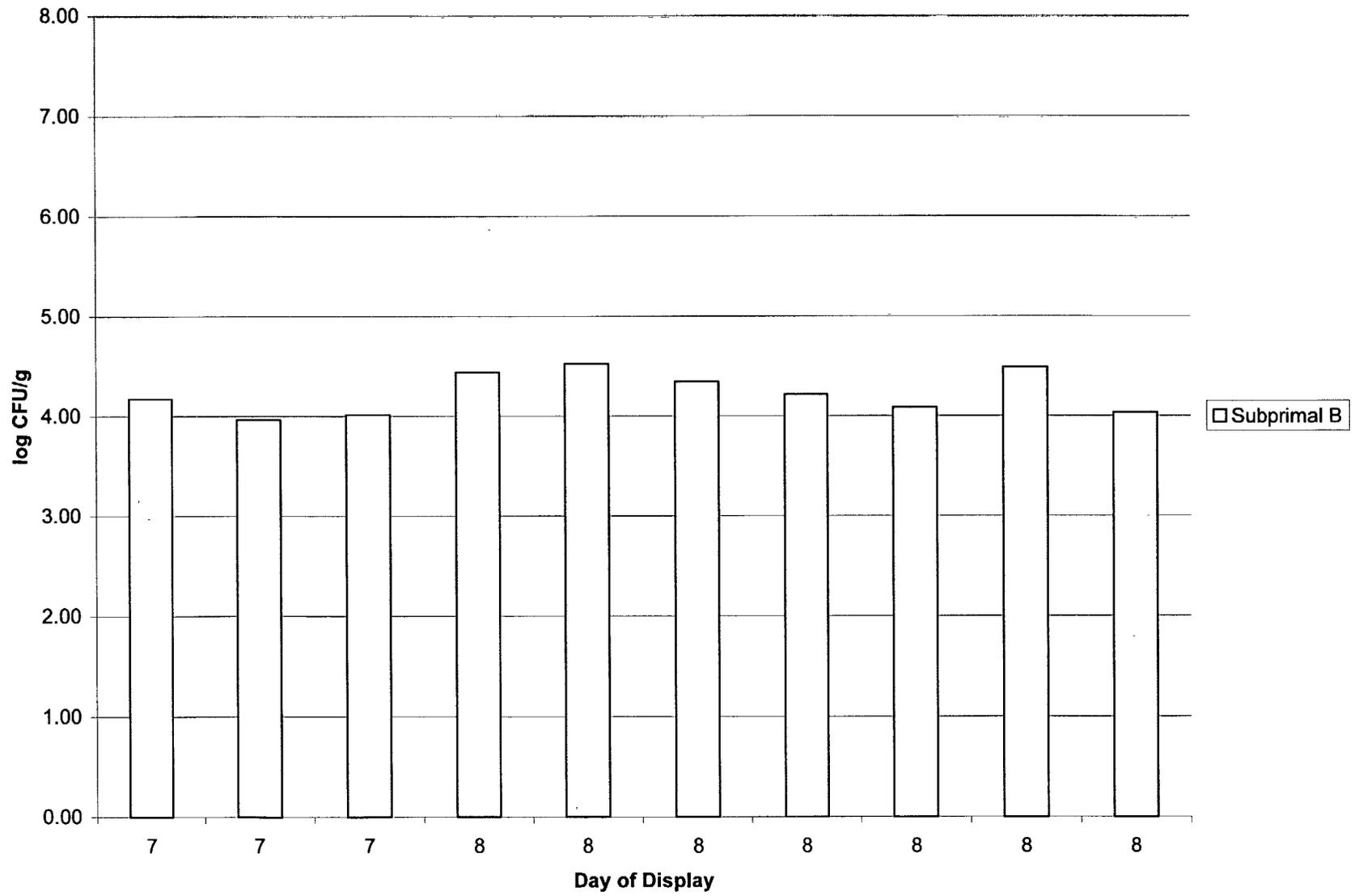
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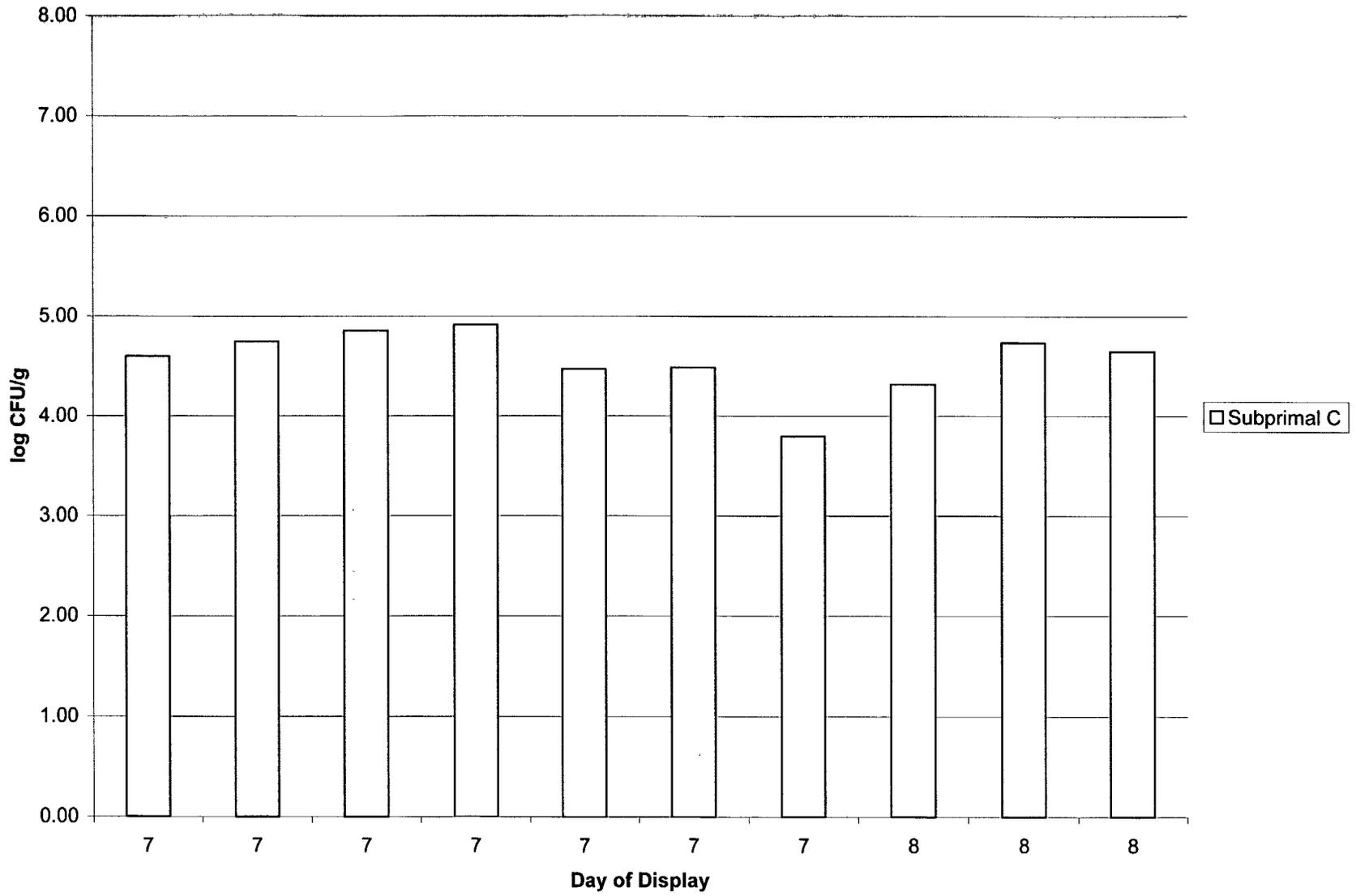
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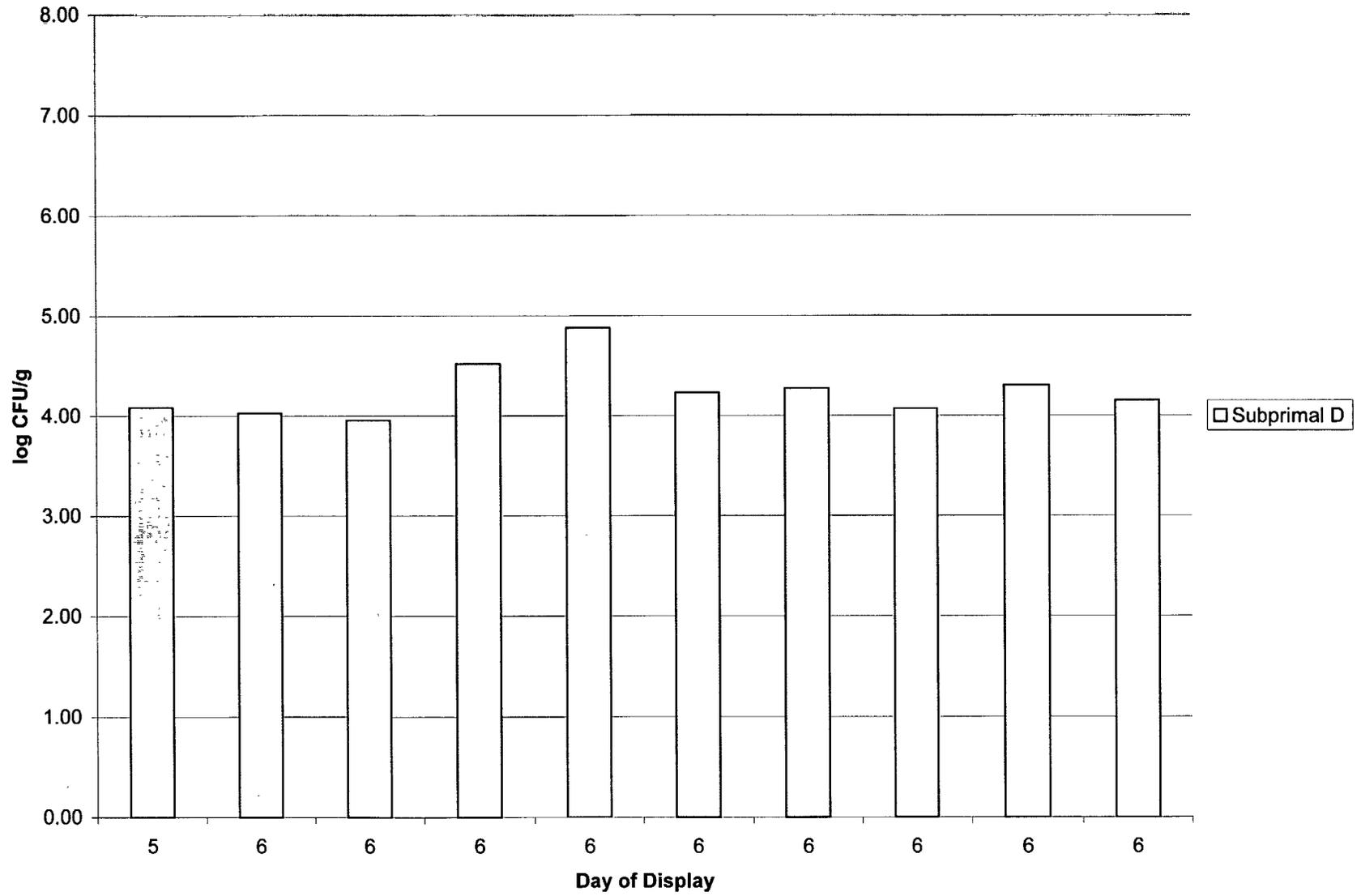
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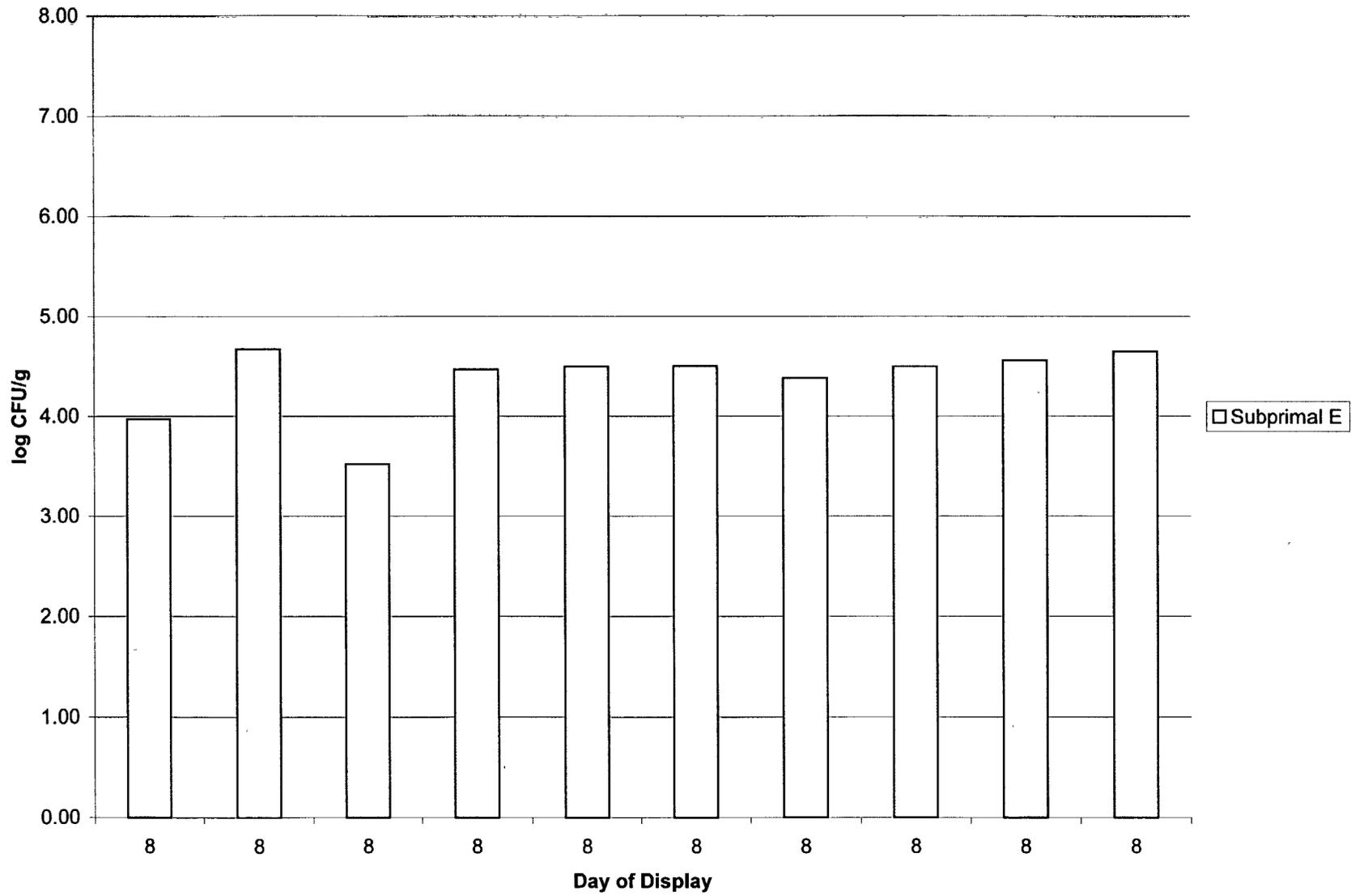


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APPENDIX IV

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

February 7, 2006

Mr. Dennis Johnson, Esq.
Olsson, Frank and Weeda, P.C.
Attorneys At Law
Suite 400
1400 Sixteenth Street, NW
Washington, D.C. 20036-2220

Dear Mr. Johnson:

This letter is in response to the additional information submitted February 2, 2006 on the notification and submission "Freezing Machines – Use of CO solution in MAP Products" (05-NT0176-NA). This technology is described as a Modified Atmosphere Packaging (MAP) system that inserts carbon monoxide (CO) and ammonium hydroxide, as part of a brine solution, into meat immediately followed with insertion of a gas flush into the meat that includes oxygen, nitrogen, carbon dioxide, or other inert gases to flush out the carbon monoxide.

As detailed in the Food Safety and Inspection Service (FSIS) letter, dated January 13, 2006, The Federal Meat Inspection Act, Title I, Section 1 (m)(8), states that product is adulterated if any substance has been added or mixed or packed so as to make it appear better or of greater value than it is. In addition, FSIS regulations (9 CFR 424.23(a)) prohibits the use of any substance in or on meat if it makes the product appear to be better or of greater value than it is. FSIS and FDA have concerns that the use of CO in direct contact with fresh meat may cause the meat to retain its fresh color longer than untreated meat, creating the possibility that the consumer will be misled about how long the product has been on display. This is because CO causes a chemical reaction to form a red pigment. The red pigmentation is not seen with other gases used in MAP systems (e.g., CO₂ and N₂). As a result, FSIS has required that all MAP systems that use CO to enhance the appearance of meat during retail display be labeled with a "use by or freeze by" date to ensure consumers will not be misled. The "use by or freeze by" date is applied by the Federal establishment under in-plant controls and is based on shelf life data that each company develops.

In regard to the two studies described above titled, *Retail Display Life of Case Ready Beef Steaks Enhanced by FMI Technology*, FSIS finds that they are insufficient to conclusively show that consumers will not be misled. To show that the use of a mechanism such as a validated "use by or freeze by date" or a product name qualifier such as "color enhanced to maintain quality" is not needed to ensure that consumers are not misled, data would need to show that FMI treated steaks discolor at a rate similar to

Mr. Johnson

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untreated steaks (i.e., show that the product does not appear to the consumer as fresher when compared to untreated product).

These two studies show that the MAP system has an effect on retail case life. For example, as stated above, in the study conducted in 2004 some steaks treated with FMI's MAP system were held in dark storage for 7 days and then still showed no discoloration until the eighth or ninth day of retail display. The study concluded that steaks subjected to FMI's MAP system had an average retail caselife of 7.8 days after removal from storage based on visual assessment and microbial analysis. These findings show that retail case life is enhanced because of residual CO binding with the muscle tissue to form a red pigment. Consequently, FSIS will require that meat subjected to FMI's MAP system be labeled with a "use by or freeze by" date or labeled in some other way that discloses the material fact that the shelf life of the product has been affected and thus to ensure that the consumer is not misled. If a validated "use by or freeze by" date is used, the suitability data that the Agency received supports a case life of up to 15 days. FSIS will consider any request for a longer "use by or freeze by" date if FMI has any additional suitability data to submit to the Agency in support of a longer retail caselife.

In regard to the use of ammonium hydroxide in the MAP system, on February 2, 2006, FMI has submitted additional supplemental information to show that the proposed use of ammonium hydroxide meets FDA's definition of a processing aid. Specifically, a report dated February 1, 2006, from South Dakota State University detailed the results from a 2004 research study conducted for FMI by the university. The study evaluated the pH values of a control sample of untreated beef eye of rounds as compared to beef eye of rounds that were subjected to FMI's MAP system. The results showed no significant difference in the pH of treated and untreated product. Because there is no significant difference in the pH, the use of ammonium hydroxide in the brine that is injected into beef as part of the MAP system should not provide a lasting technical effect.

In addition, on February 2, 2006, FMI submitted a study titled, *Effects of FMI treatment of beef steaks on subsequent growth of E. coli O157:H7*, dated November 17, 2005. The study evaluated ten ½ inch thick steaks inoculated with a non-pathogenic strain of *E. coli* O157:H7. Half of the steaks were then used as an untreated control sample while the other half were subjected to FMI's MAP system. The results show that the MAP system did cause some initial kill of *E. coli* O157:H7. However, the results also show that FMI's MAP system does not inhibit the growth of *E. coli* O157:H7 in treated beef (i.e., the use of ammonium hydroxide only provided a momentary antimicrobial effect in beef subjected to FMI's MAP system).

Based on the new data submitted on February 2, 2006 to the Agency, FSIS has determined that FMI's use of ammonium hydroxide meets FDA's definition of a processing aid. The data show that the use of ammonium hydroxide only provides a momentary technical effect in beef when used as part of FMI's MAP system. Therefore, FSIS does not object to use of FMI's MAP system which includes CO provided that CO-

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Mr. Johnson

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treated meat is labeled with a mechanism to ensure that consumers will not be misled (e.g., a product name qualifier or a validated "use by or freeze by date" of up to 15 days) as described above and in the Agency's letter of January 13, 2006. FSIS will notify FDA of its new determination that the use of ammonium hydroxide will not require ingredient labeling. If you have any questions, please contact Dr. David Zeitz at (202) 205-0675.

Sincerely,

Shaukat H. Syed, DVM
Director
New Technology Staff
Office of Policy, Program, and Employee Development

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January 27, 2006

HAND DELIVERED

Dr. Barbara J. Masters, DVM
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington, DC 20250-3700

Re: Supplement to Freezing Machines Appeal on the Suitability of its CO Process

Dear Dr. Masters:

On behalf of Freezing Machines, Inc. (FMI), we respectfully supplement our appeal on the suitability of FMI's carbon monoxide (CO) process and on the process' use of ammonium hydroxide as a processing aid for anti-microbial control.

On January 13, 2006, we submitted our appeal on the delay in providing an "Agency Response Letter to the Freezing Machines, Inc. GRAS Notification" that concludes the FMI process is suitable for use with fresh red meats without condition. Following our meeting with you on our appeal, we received a letter from the New Technology Division. Attachment 1. According to conclusion on page 4 of the letter, "FSIS does not object to FMI's MAP system for meat provided: 1) treated meat is labeled with a mechanism to ensure consumers will not be misled (e.g. a product name qualifier or a validated 'use by or freeze by date;' and 2) ammonium hydroxide is labeled as an ingredient."

As regards the CO process, the New Technology letter indicates that data previously provided by FMI "supports a case life of up to 15 days." Attachment 1 at page 3. FMI has never opposed the condition of a "use by" date label statement if the statement reasonably represented the product's shelf life. Accordingly, we respectfully withdraw that part of our appeal dealing with the CO process and accept the agency's condition that the product label bear a statement "use by or freeze by" 15 days from the date the product is placed in the MAP package. We do reserve the right to justify a longer period with validation data generated under the same protocol as used with the November 17, 2005 GRAS Notification to the Food and Drug Administration.

This once again leaves what we have always seen as the crux of the matter – the use of ammonium hydroxide as an anti-microbial in the process.

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As indicated above, the January 13 letter from New Technology would require the labeling of ammonium hydroxide as an ingredient in the treated product. As we read the letter, three justifications are advanced:

- The ammonium hydroxide "significantly change[s] the pH of the brine solution."
- The FMI studies refer to the treated product as "pH enhanced."
- "Under FDA's regulations, 21 CFR 170.3(o)(23), pH control is a technical functional effect for which ingredients are added to food."

For the reasons discussed below, we respectfully submit that none of the proffered justifications support declaration of the ammonium hydroxide as an ingredient on the label of the treated meat product.

"Significant change" to the pH of the Brine Solution

Admittedly, the ammonium hydroxide does adjust the pH of the brine solution. However, this change is solely for the purpose of achieving the anti-microbial result. It is basic microbiology that bacteria are killed physically (cooking), biologically (antibiotics) or chemically.

The most common chemical treatment involves pH adjustment which damages the cell membrane of the bacteria. In the case of gram-negative organisms, such as *E. coli* O157:H7, the pH change which is generally most effective is an alkaline. Some substances with a high pH are listed in Amendment 6 to FSIS Directive 7,120.1:

- Ammonium hydroxide (BPI process) (alkaline)
- Trisodium phosphate (alkaline)
- Sodium metasilicate (alkaline)

There are also low pH substances which have been recognized as anti-microbials, including organic acids and acidified sodium chlorite.

However, no pH adjusting substance is applied as such, rather the treatments are applied as part of a solution. The use of the anti-microbial dramatically modifies the pH of the solution. For example, the following are the pH levels of an antimicrobial solution made according to the specifications in Directive 7,120.1, Amendment 6:

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- Trisodium phosphate (alkaline) – Solution pH of 12.33-12.35
- Organic acids (acidic) – Solution pH of 2.10-2.39 (lactic); 2.11 -2.36 (citric)
- Sodium metasilicate (alkaline) – Solution pH of 12.85-12.99

Food Safety Net Laboratory Report on pH of certain anti-microbial solutions.¹ Attachment 2

If all the above pH anti-microbial treatments significantly change the pH of the application solution, the mere fact that the use of ammonium hydroxide changes the pH of the solution should not be a reason to require labeling here.² This is especially true given that the pH change caused by the ammonium hydroxide is not nearly as significant as that caused by any other recognized anti-microbials.

The Studies Refer to the Treated Product as “pH enhanced.”

The company has always used this terminology (“pH enhanced”) to refer to the treatment, rather than the undesirable (but technically correct) phrase “ammonium hydroxidetreated.” This term has been repeatedly used by the company in correspondence with FSIS when identifying the process currently recognized for treating boneless lean beef trimmings (finely textured), without any questions being raised as to whether the ammonium hydroxide would now need to be labeled. See, e.g., Letter from Brett T. Schwemer to Philip Derfler, December 16, 2003 at pages 4, 5 & 8 (previously supplied).

Regardless of the company’s use of a more “socially acceptable” name, the fact remains the treatment is designed to destroy pathogens, primarily *E. coli* O157:H7, not to change the pH of the finished product. Indeed, the ammonium hydroxide in the solution is very effective at destroying pathogens, but is not effective in significantly changing the meat’s pH. Given this, we fail to understand how the company’s coined term would require labeling if we are otherwise eligible as a processing aid.

Ammonia Hydroxide is a pH Control Agent Under FDA’s GRAS Regulation

In the final justification, the New Technology Division simply asserts that pH control is a functional effect under 21 CFR 170.3(o)(23) and since ammonium hydroxide adjusts pH, it is a functional ingredient, not a processing aid. Admitting the accuracy of the regulatory citation, we

¹ See also anti-microbials listed in Amendment 6 which specify particular pH levels, e.g., Acidified Sodium Chlorite (acidic): Solution pH of 2.3-2.9; solution of octanoic acid, et al: Solution pH of 1.5 to 4.0.

² We have previously submitted the study conducted by Dr. James Dickson of Iowa State University which demonstrates FMI’s use of ammonium hydroxide is at the lowest level necessary to achieve the requisite pathogen lethality

Letter to Dr. Barbara J. Master, DVM
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respectfully submit that pH control has never been determinative on the issue of whether the substance is a processing aid and must be labeled.

In pages 5-8 of our initial appeal we addressed the issue of our eligibility as a processing aid under both FDA definitions and under the Codex definition. We respectfully reiterate those arguments here. The remainder of this section will provide additional support for our position that labeling is not required.

First, as demonstrated above, all chemical anti-microbials have an effect on the pH of the solution used to convey the substance to the product. Indeed, the magnitude of the change for the other pH treatments is far greater than the change for ammonium hydroxide. There seems to be no articulated reason as to why the pH change would mandate labeling here and not for all other pH enhancing anti-microbials.

Second, FSIS precedents imply that changing the pH of the solution is not determinative; only if there is a significant change in the pH of the meat would labeling be required. Compare the entries in FSIS Directive 7,120.1, Amendment 6 for "Solution of water, acidic calcium sulfate and 85-95,000 ppm lactic acid (solution with a pH range of 0.35 to 0.55)." When used as a pH control agent in water used in meat and poultry processing, no labeling of the solution is required, whereas when the same solution used to adjust the pH of the meat in grinding operations, labeling is required.

Here, the effect of the ammonium hydroxide on the pH of meat is not significant. The pH of meat generally runs between 5.3 and 5.7; the pH of the treated product is between 5.6 and 5.9. Additionally, in the case of the initial FSIS No Objection letter on the use of ammonium hydroxide as an anti-microbial treatment of meat, there was recognition that the treatment did have some effect on the pH of the meat, but this was not determinative and did not result in labeling of the substance since there was no function or effect in the finished product. Letter from Philip S. Derfler to Dennis R. Johnson, May 11, 2001. Attachment 3.

Third, we respectfully submit that the use of an injection process is not determinative. Here, the simple fact is that the treatment must be injected to address the risks posed by the injection itself. Other anti-microbial substances (applied in a significant pH solution) are also incorporated in the finished product and although the solution is labeled, the anti-microbial is not. For example, TSP is used on poultry carcasses. During the processing of the poultry, there is moisture pick-up with the result that TSP residues could be as high as 0.11% in the finished product. 59 Fed Reg 553 (January 5, 1994). Although the poultry label must declare the "added water," there is no mention of the TSP residue. Likewise, sodium metasilicate (SMS) is "approved" as an anti-microbial in marinades without labeling of the SMS. The effect of the SMS is to significantly increase the pH of the marinade (attachment 1) and though the marinade

Letter to Dr. Barbara J. Master, DVM
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solution must be labeled on the finished product, there is no declaration of SMS. It is important to note that in the above two examples, neither TSP and SMS is a natural component in meat and would not be expected by a consumer. Conversely, ammonia is a natural constituent of meat.

Fourth, even assuming that the ammonium hydroxide's effect on the solution's pH is somehow different than all the other pH anti-microbial treatments, labeling of the ammonium hydroxide would *not* be required here. FSIS follows the FDA regulations exempting processing aids from label disclosure. 21 CFR § 101.100(a)(3)(ii). However, processing aids are only one class of incidental additives exempt from ingredient disclosure. 21 CFR § 101.100(a)(3). The FDA incidental additive regulation also exempts:

- (i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated as an ingredient in another food, in which the substance did have a functional or technical effect.

Hence, even assuming for the sake of argument that the ammonium hydroxide must be declared on a label of the solution because it adjusts the solution's pH, it need not be declared on the finished meat product since it serves no function or effect (other than the one-time anti-microbial treatment) in the meat.³ Given the public health imperative of valid interventions to address possible *E. coli* O157:H7 contamination of non-intact meat by an injection process, we respectfully submit sound policy would support use of the alternative incidental additive subsection here.

Conclusion

For the foregoing reasons, we respectfully request you affirm that no labeling of the ammonium hydroxide would be required on the label of meat processed with the FMI technology. Based on this, we also respectfully request that an "Agency Response Letter to the Freezing Machines, Inc. GRAS Notification" be forwarded to FDA that concludes the FMI process is suitable for use with fresh red meats, provided the finished product label bear a statement "use by or freeze by" 15 days from the date the product is placed in the MAP package or such other time period as is supported by validation data.

³ As noted above, in connection with the first use of ammonium hydroxide, the increase of the pH of the meat was insignificant with a residue of 800 ppm compared to 150 ppm for untreated beef. Attachment 3. Here, the maximum amount of ammonium added by a 28% solution is approximately 200 ppm. If the higher residue was not found to have a functional effect, it follows the lower level cannot have an effect.

Letter to Dr. Barbara J. Master, DVM
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We appreciate the prompt resolution of this matter. If you have any questions, please do not hesitate to contact me.

Respectfully submitted,

Dennis R. Johnson
Counsel to Freezing Machines, Inc.

Attachments
DRJ:mhh



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

ATTACHMENT 1

January 13, 2006

Mr. Brett T. Schwemer, Esq.
Olsson, Frank and Weeda, P.C.
Attorneys At Law
Suite 400
1400 Sixteenth Street, NW
Washington, D.C. 20036-2220

Dear Mr. Schwemer:

This letter is in response to your notification and submission "Freezing Machines – Use of CO solution in MAP Products" (05-NT0176-NA) dated and received December 5, 2005. This technology is described as a Modified Atmosphere Packaging (MAP) system that inserts carbon monoxide (CO) and ammonium hydroxide, as part of a brine solution, into meat immediately followed with insertion of a gas flush into the meat that includes oxygen, nitrogen, carbon dioxide, or other inert gases to flush out the carbon monoxide.

Your notification included three reports to Freezing Machines Incorporated (FMI) from studies conducted by South Dakota State University. One study titled, *Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology*, dated November 9, 2004, evaluated 47 steaks (12 steaks from three subprimals and 11 steaks from one subprimal) that were treated with FMI's MAP system. Steaks were treated with FMI's MAP system and then held in dark storage for 7 days. After removing the steaks from storage, the steaks were evaluated subjectively for color at approximately the same time every day for eleven days of retail display. Subjective evaluation was performed by a four member trained panel. Evaluators assigned scores to the steaks for lean muscle color and percent surface discoloration. At each evaluation time the evaluators also answered yes or no to the question "Do you think that the average consumer would purchase this steak today?" Once three out of four panelists indicated that the average consumer would not purchase that steak, it was considered "too discolored to sell" and removed from the retail display and frozen. The 5th, 6th, and 7th steaks to be considered "too discolored to sell" from each subprimal were used for microbial analysis, meaning that 12 steaks were used for microbial analysis.

A second study titled, *Retail Display Life of Case-Ready Beef Steaks Enhanced by FMI Technology*, dated November 2, 2005, evaluated 50 boneless strip steaks representing five different subprimals treated with FMI's technology. Subjective evaluation was performed by a three member panel of experts. At each evaluation time evaluators were asked to answer yes or no to the question "Do you think that the average consumer would purchase this steak today?"

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Once two out of three panelists indicated that the average consumer would not purchase that steak, it was considered "too discolored to sell" and removed from the retail display and frozen.

In the first study (based on visual appearance), treated steaks had an average retail case life of 7.8 days until the panelists determined the steaks were visually "too discolored to sell." The average aerobic plate count when the steaks were determined to be visually unacceptable was 5.29 logs CFU/cm². Because the average aerobic plate count was below 7 logs CFU/cm² (an amount that was suggested via scientific literature to indicate spoilage) when the steaks were determined to be visually unacceptable, the study concluded that FMI's MAP system does not mask spoilage. Similarly, treated steaks in the second study (also based on visual appearance) had an average case life of 5 to 8 days. The average aerobic plate count at the end of visual caselife for all 50 steaks was 4.43 log CFU/g. Therefore, FMI believes that a "use by or freeze by" date is not needed in this particular system because the studies show that all steaks tested at the point of being visually unacceptable were not microbiologically spoiled.

The Federal Meat Inspection Act, Title I, Section 1 (m)(8), states that product is adulterated if any substance has been added or mixed or packed so as to make it appear better or of greater value than it is. In addition, FSIS regulations (9 CFR 424.23(a)) prohibits the use of any substance in or on meat if it makes the product appear to be better or of greater value than it is. FSIS and FDA have concerns that the use of CO in direct contact with fresh meat may cause the meat to retain its fresh color longer than untreated meat, creating the possibility that the consumer will be misled about how long the product has been on display. This is because CO causes a chemical reaction to form a red pigment. The red pigmentation is not seen with other gases used in MAP systems (e.g., CO₂ and N₂). As a result, FSIS has required that all MAP systems that use CO to enhance the appearance of meat during retail display be labeled with a "use by or freeze by" date to ensure consumers will not be misled. The "use by or freeze by" date is applied by the Federal establishment under in-plant controls and is based on shelf life data that each company develops.

In regard to the two studies described above titled, *Retail Display Life of Case Ready Beef Steaks Enhanced by FMI Technology*, FSIS finds that they are insufficient to conclusively show that consumers will not be misled. To show that the use of a mechanism such as a validated "use by or freeze by date" or a product name qualifier such as "color enhanced to maintain quality" is not needed to ensure that consumers are not misled, data would need to show that FMI treated steaks discolor at a rate similar to untreated steaks (i.e., show that the product does not appear to the consumer as fresher when compared to untreated product).

These two studies show that the MAP system has an effect on retail case life. For example, as stated above, in the study conducted in 2004 some steaks treated with FMI's MAP system were held in dark storage for 7 days and then still showed no discoloration until the eighth or ninth day of retail display. The study concluded that steaks subjected to FMI's MAP system had an average retail caselife of 7.8 days after removal from storage based on visual assessment and microbial analysis. These findings show that retail case life is enhanced because of residual CO binding with the muscle tissue to form a red pigment. Consequently, FSIS will require that meat subjected to FMI's MAP system be labeled with a "use by or freeze by" date or labeled in some other way that discloses the material fact that the shelf life of the product has been affected and thus to ensure that the consumer is not misled. If a validated "use by or freeze by" date is used, the suitability data that the Agency received supports a caselife of up to 15 days. FSIS will consider any request for a longer "use by or freeze by" date if FMI has any additional suitability data to submit to the Agency in support of a longer retail caselife.

In regard to the proposed use of ammonium hydroxide as part of FMI's MAP system, you believe the residual levels of ammonium hydroxide are similar to the residual levels of other antimicrobial agents (e.g., trisodium phosphate (TSP) and sodium metasilicate (SMS)) that do not require labeling when used to treat meat. FMI included a study titled, *The Effects of Pre-pump Aging, Post-pump Aging, and Freeze/Thaw on the Palatability of pH-enhanced Beef Strip Steaks*, dated July 15, 2005, to support your claim that the use of ammonium hydroxide qualifies as a processing aid. The study consisted of two treatments (non-injected control and pH enhanced beef), five pre-pump aging times, six post-pump aging times, and two storage types (fresh vs. frozen) for a total of 120 treatment combinations. The experiment was replicated three times, and separate steaks were used. The pH enhancement used FMI's patent pending technology (ammonium hydroxide based). Trained taste panels (consisting of nine panelists) were conducted according to standards set by the American Meat Science Association. In addition shear force was determined according to standards set by the American Meat Science Association. The results indicated that pH enhancement of the steaks did not result in any statistically significant difference in the flavor intensity of the products compared to the non-injected controls. Differences noted in tenderness, texture, and juiciness were determined most likely a result of added water (i.e., control samples were not injected with any solution).

In addition, FSIS was provided a letter dated August 2, 2005, from Iowa State University that included microbiological data from inoculation studies conducted with FMI's MAP system. The letter concluded that the data shows that the use of ammonium hydroxide in the brine solution of the MAP system adjusted the pH to a point where it was effective in reducing microorganisms in the meat upon injection as well as in the brine solution.

Mr. Schwemer

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In regard to processing aids, FSIS does not have a regulatory definition for this term. On a case-by-case basis, FSIS will apply FDA's definition of a processing aid described in Title 21 of the Code of Federal Regulations (CFR), Section 101.100 (a)(3)(ii). To show that the use of a substance meets FDA's definition of a processing aid, FSIS requires data to be submitted to the Agency to show that there is no lasting functional effect, and that there is an insignificant amount of the substance in the finished product under the proposed conditions of use.

Based on the data that FMI has provided, the use of ammonium hydroxide has been shown to significantly change the pH of the brine solution. Both the July 15, 2005 study and the Iowa State University study refer to the product as being pH enhanced. Under FDA's regulations, 21 CFR 170.3(o)(23), pH control is a technical functional effect for which ingredients are added to food. Ammonium hydroxide is thus an ingredient of this food, and ingredient labeling is required.

In summary, FSIS does not object to FMI's MAP system for meat provided: 1) treated meat is labeled with a mechanism to ensure that consumers will not be misled (e.g., a product name qualifier or a validated "use by or freeze by date," and 2) ammonium hydroxide is labeled as an ingredient. FSIS will notify FDA of FSIS' determination. If you have any questions, please contact Dr. David Zeitz at (202) 205-0675.

Sincerely,

Shaukat H. Syed, DVM
Director
New Technology Staff
Office of Policy, Program, and Employee Development

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Food Safety Net Services, Ltd.

Analytical Results

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Contact: Rich Jochum - Amanda Dean
Customer: BEEF PRODUCTS INC.
 891 Two Rivers Dr.

Dakota Dunes, SD 57049

Phone: 605-217-8000
Fax: 605-217-8007

Report Number: 06-04569

Report Date: 1/26/2006

Samples Received: 01/25/2006

Start of Testing: 01/25/2006

Check Number:

PO Number:

Billing Code	Sample Date	Sample Number	Sample Description	Analyses - FBNS Method Number	Result	Units
PH02	1/25/2006	1	Trisodium Phosphate TSP Na3PO4 5% Composite Type: None	pH #C07.1 (AOAC)	12.33	
PH02	1/25/2006	2	Trisodium Phosphate TSP Na3PO4 10% Composite Type: None	pH #C07.1 (AOAC)	12.35	
PH02	1/25/2006	3	Trisodium Phosphate TSP Na3PO4 12% Composite Type: None	pH #C07.1 (AOAC)	12.35	
PH02	1/25/2006	4	Sodium metasilicate SMS Na2SiO3 1% Composite Type: None	pH #C07.1 (AOAC)	12.85	
PH02	1/25/2006	5	Sodium metasilicate SMS Na2SiO3 2% Composite Type: None	pH #C07.1 (AOAC)	12.99	
PH02	1/25/2006	6	Lactic Acid C3H6O3 1% Composite Type: None	pH #C07.1 (AOAC)	2.39	
PH02	1/25/2006	7	Lactic Acid C3H6O3 2% Composite Type: None	pH #C07.1 (AOAC)	2.18	
PH02	1/25/2006	8	Lactic Acid C3H6O3 2.5% Composite Type: None	pH #C07.1 (AOAC)	2.10	
PH02	1/25/2006	9	Citric Acid C6H8O7-H2O 1% Composite Type: None	pH #C07.1 (AOAC)	2.36	
PH02	1/25/2006	10	Citric Acid C6H8O7-H2O 2% Composite Type: None	pH #C07.1 (AOAC)	2.18	
PH02	1/25/2006	11	Citric Acid C6H8O7-H2O 2.5% Composite Type: None	pH #C07.1 (AOAC)	2.11	

BEST ORIGINAL COPY

BEEF PRODUCTS INC. **Report Number: 06-04569** **Report Date: 01/26/2006**

Sample Temperature Upon Receipt:	N/A
Remarks:	Printed on: 01/26/2006

Supervisor Approval By: raymond collins

Signature:

BEST ORIGINAL COPY



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of Policy, Program
Development and
Evaluation

Washington, D.C.
20250

MAY 11 2001

Mr. Dennis R. Johnson
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, N.W.
Suite 400
Washington, DC 20036-2220

Dear Mr. Johnson:

I am responding to BPI Incorporated's, March 16, 2001, submission and to your letter of May 2, 2001, providing supplemental information regarding BPI' use of anhydrous ammonia to treat beef.

On March 16, 2001, BPI submitted a letter to the Food Safety and Inspection Service (FSIS) requesting a "no objection" letter for the use of a new food safety technology, for reducing pathogenic bacteria in lean finely textured beef. The process developed by BPI involves rapidly increasing the pH of the meat via treatment with anhydrous ammonia, quickly chilling to 28°F, and then mechanically stressing the product. The rapid pH adjustment causes cell injury, especially to gram negative organisms. Ice crystals formed during freezing punctures the weakened cell walls, and the organisms are destroyed when the meat product is subjected to mechanical stress. BPI provided data that show that this process, when applied to lean finely textured beef, reduced *E. coli* O157:H7 by greater than 8.5 logs, *Salmonella* by greater than 5.95 logs, and *Listeria monocytogenes* by about 1.55 logs.

Attached to the BPI letter was a legal opinion that you prepared asserting that anhydrous ammonia should be considered a processing aid because it is converted into constituents normally present in the food, and because it does not significantly increase the amount of the constituents normally found in the food. You also asserted that the insignificant levels in the finished food do not have any technical or functional effect in that food.

Although we are satisfied with the data provided to prove suitability, we have expressed some concerns about the levels of ammonia found in the treated product. You submitted data, compiled by BPI, that show that the treated beef had ammonia levels of 800 ppm versus 150 ppm found in the untreated beef product. The Agency requested that you provide data on whether the residual ammonia has any functional effect in the finished product. Finally, we requested clarification concerning the characteristics of production and composition of the "lean finely textured beef."

You have confirmed that the "lean finely textured beef" is produced using the basic technology that was reviewed and approved by FSIS in 1990. Boneless beef trimmings are tempered to a level below post-mortem slaughter carcass temperature (approximately 107°F to 109°F) to facilitate the production of lean beef by removing fat with centrifugal force. The lean meat is

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Mr. Dennis R. Johnson

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then transferred to a Roller Press Freezer, where it is frozen to 15°F in approximately 90 seconds and packaged. The product is treated with the BPI food safety technology immediately after it leaves the centrifuge and before the roller freezer. BPI is also adhering to the compositional profile established by FSIS: fat (11 percent and 10 percent maximums, respectively); protein (13 percent and 14 percent minimums, respectively); and a process average of 2.5 PER or 33 percent essential amino acids.

You provided data that show there is no significant difference in appearance, texture, flavor, or overall acceptability between the treated product and untreated product. Also, data in your submission show that, while initially reducing total plate count, this treatment did not have any long-term effect on the growth of spoilage organisms. Eleven days after treatment, the levels of spoilage organisms on both the treated and untreated products were essentially the same. Based on that data, the residual ammonia appears to have no functional effect in the finished product.

Therefore, we would not have any objection to the use of the food safety technology described above on lean finely textured beef produced using the basic technology that was reviewed and approved by FSIS in 1990. We are satisfied that you have demonstrated that anhydrous ammonia can be considered a processing aid when used in this process. Anhydrous ammonia does not have to be listed in the ingredients statement on the label for the treated product.

If you have any questions or we can be of further assistance, please contact Dr. Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, at Area Code (202) 205-0279.

Sincerely,

Philip S. Dersler
Deputy Administrator
Office of Policy, Program Development
and Evaluation

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OLSSON, FRANK AND WEEDA, P. C.

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RICHARD L. FRANK
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BRENT W. GATTIS

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEEDINGS
BEFORE FEDERAL COURTS AND AGENCIES.

January 13, 2006

BY HAND DELIVERY

Dr. Barbara J. Masters, DVM
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington, DC 20250-3700

Re: Freezing Machines, Inc., Appeal on the Suitability of its CO Process

Dear Dr. Masters:

On behalf of Freezing Machines, Inc. (FMI), we respectfully appeal the actions and inactions of the Food Safety and Inspection Service's (FSIS) New Technology Division with regard to the suitability of FMI's carbon monoxide process for use on raw beef. As discussed in greater detail below, FMI has been attempting to obtain a determination from FSIS since July 2004 but has been unsuccessful. We submit that all necessary information has been provided and we are entitled to a favorable suitability determination on this process with no special conditions imposed.

Regulatory Framework

The Memorandum of Understanding (MOU) between the FSIS and the Food and Drug Administration (FDA) "Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products" (May 23, 2000), establishes "fast track" procedures for agency reviews of ingredients, including processing aids, to be used in meat and poultry products.

Under these procedures, whenever FDA receives a GRAS (generally recognized as safe) notification for a substance to be used in meat or poultry, FDA will review the safety of the substance. Concurrently, FDA will forward the notification to FSIS for FSIS' review of the

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Letter to Dr. Barbara J. Masters, DVM
January 12, 2006
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“suitability” of the substance for use in meat or poultry. According to the MOU, “suitability relates to the effectiveness of the additive in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers.” FSIS will forward its suitability determination in an “Agency Response Letter” to FDA, generally within sixty days. FDA then will notify the submitter by letter. This letter could convey any FSIS concerns about the suitability of the substance and any special conditions upon its use as recommended by FSIS.

As regards the safety of FMI’s CO process, we have been informed, both directly and indirectly, that FDA has no safety concern regarding the process or any substances used. The delay that has occurred has been solely due to FSIS.

FMI’s CO Process

In the past two years, there has been a movement away from retail trimming and packaging of fresh beef cuts, relying instead on case ready packages from federally inspected establishments. This movement has been possible through changes in packaging – changes to combat the problem that case ready product will lose its red color during distribution so that the inspected product will be unsalable at retail.

Two companies, Pactiv Corporation and Precept Foods, LLC, developed a technique that enables product packaged at the inspected establishment to retain the desirable red color during distribution and retail display. This technique involved the low level use of carbon monoxide (CO) as part of the gas flush in modified atmosphere packages (MAP). This technique works because the CO reacts to the myoglobin in meat to produce carboxymyoglobin that has a red color. In the absence of the CO, the myoglobin oxidizes to form metmyoglobin, which has a brownish color. We are aware of eight specific acceptability determinations for this use of CO. In every case, the CO maintains the color even after the product has spoiled from a microbial perspective. To address this, FSIS has required a 35 day “use by” statement appear on any products packaged with the CO method.

At the same time, there have been heightened concerns with mechanically tenderized raw beef. In June 2003, there was an *E. coli* O157:H7 food borne outbreak involving mechanically tenderized steaks. According to FSIS, this outbreak was caused by contamination of the injection solution at the producing establishment. 70 Fed. Reg. 30331 (May 26, 2005). Although the contamination rate of subprimals is exceptionally low, the potential exists for the solution itself to become contaminated and this “single acorn can grow into a forest.” Hence, companies began to consider methods to eliminate such cross contamination attributable to the injection process. Indeed, FSIS expects processors of such steaks to have an intervention to address the presence of this pathogen.

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FMI developed a process that combines the desirability of CO with an anti-microbial treatment designed to destroy pathogens that may be on the surface of beef being mechanically tenderized and injected.

Under this process, CO is applied to the meat as part of a brine solution as opposed to a gas flush. This method of application does not increase the amount of CO used over the amount used in the Pactiv or Precept methods. However, the method of application does not result in as strong a bond of the CO to the myoglobin as exists with the gas flush method. This means the red color is not maintained indefinitely. Based on studies discussed below and previously provided to New Technology, the products manufactured with the FMI process discolor after 5-8 days of retail display (as opposed to approximately 2 days for untreated and virtually unlimited for the gas flush method).

In addition, the brine contains ammonium hydroxide. FMI's sister company, BPI, has previously obtained a favorable suitability determination for the use of ammonium hydroxide as an anti-microbial in raw beef. In the FMI process, the ammonium hydroxide works by increasing the pH level of the brine to approximately 11.0. Should there be any *E. coli* O157:H7 on the beef, the moment the injection needle touches the surface, the high pH caused by the ammonium hydroxide destroys the pathogen by damaging the pathogen's cell membrane resulting in lethality by the stress of the injection. Once again, based on studies discussed below and previously provided, the anti-microbial effect on the meat is limited to the time of application – there is no continuing function or effect, anti-microbial or otherwise, in the finished product.

Procedural History

When FMI developed the injection process, it initially contacted the FDA to determine whether the agency would consider the FMI use covered by the Pactiv and Precept GRAS Notifications. FDA apprised FMI that, given the method of application was different, FMI should submit its own GRAS Notification simply as a matter of form; FDA did not see any issues being raised by the manner of application. In addition, FMI contacted FSIS New Technology to apprise them of the method and to seek guidance on the information that should be provided. For your convenience, we are attaching a timeline of the various correspondence and meetings between FSIS and FMI. Attachment 1. During this process, there have been various times when the issues have been narrowed to a single issue, but when FMI addressed that issue, new issues magically appeared.

Appeal

Based on the evidence previously supplied, we respectfully submit that there are no true or valid issues remaining and we are entitled to a favorable suitability determination for the FMI CO process.

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We have provided the requested data to demonstrate suitability. More importantly, a denial of a favorable determination here would be inconsistent with determinations given other companies. There is no factual, policy, or legal basis to treat the FMI process in a disparate manner.

As discussed above, the issue for resolution in connection with FMI's GRAS Notification is whether the process is "suitable." Such a suitability determination focuses on two factors:

- Whether the substance achieves the intended technical purpose of use, at the lowest level necessary, and
- Whether the conditions of use will result in a non-adulterated and non-misleading product.

For the reasons discussed below, we unquestionably comply with both factors.

As regards achieving the intended technical purpose, we note that FSIS has focused on both "active" substances in the brine: CO and ammonium hydroxide. Accordingly, we will address both in turn.

On the CO, we have provided data that demonstrate the brine increases the shelf life of the packaged product to 5-8 days of retail display. Attachment 2.¹ There have been no questions raised as to whether the CO treatment is effective. Moreover, since the effect is transitory, we submit there can be no issue as to whether the substance is being used at the lowest level necessary.²

On the ammonium hydroxide, we have provided data demonstrating that the brine acts as an anti-microbial. During the July 13, 2005 meeting, FSIS officials had requested FMI to provide data that the ammonium hydroxide was being used at levels not in excess of that reasonably required to produce the intended effect. A draft protocol was submitted and the study conducted. The results were provided on August 5, 2005 showing the effectiveness and the appropriate level of ammonium hydroxide. Attachment 3. Since the submission, FSIS has not raised any questions as to whether the ammonium hydroxide achieves the intended technical purpose of use, at the lowest level necessary.

The controversy surrounding this process involves the second prong of suitability; more specifically, whether the conditions of use could render the product misleading. There have been

¹ Attachment 2 is the FMI GRAS Notification filed with FDA on November 17, 2005. The study concerning the effect of the CO on appearance was included therein as Appendix II. The study was also provided to New Technology on November 10, 2005.

² We do note that the amount of carbon monoxide being used is consistent with the safe levels recognized by FDA in response to the previous companies GRAS Notifications. Moreover, FDA officials have conveyed their agency's position that there is no safety issues with the FMI use to FMI and, we believe to FSIS officials as well.

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three possible assertions, none of which have merit: (1) the use of CO requires a 35 day use by label; (2) the use of CO requires CO to be declared on the label of products in which it is used; and (3) the use of ammonium hydroxide requires the substance to be declared on the label of products in which it is used.

We respectfully submit that any requirement that the product which uses the FMI bear a 35 day use by label is not only illogical, it is itself misleading.³ The 35 day requirement has been applied to other CO uses. However, in each and every one of those uses, the product still looked fresh when indeed it was spoiled from a microbial perspective. In the case of product manufactured with the FMI process, the products will look spoiled before they are spoiled microbially. Indeed, based on the data previously provided as to shelf life (Attachment 2 at Appendix II), the product will look spoiled within 5-8 days of retail display. Although the product was not microbially spoiled at that point, we can only envision the micro-level of the product 27-30 days later.

On the issue of whether CO should be declared on the label, we can find no basis in existing precedent. FSIS has provided favorable suitability determinations for eight uses of CO to maintain color during distribution.⁴ Interestingly, when the Precept GRAS Notification was first reviewed by FSIS, the Director of the Labeling and Consumer Protection Staff indicated to FDA that the use of CO "to stabilize the color of the meat" would render its use misleading. Here, the FMI process does not go so far as to stabilize the color; rather it merely delays the oxidation of the myoglobin. If a process that stabilizes the fresh meat color does not have to be declared on a label, it follows that a process that only delays the change in color need not be declared either.⁵

The Crux of the Dispute – Ammonium Hydroxide

This brings us to the true controversy surrounding this process -- the labeling of ammonium hydroxide. We would like to begin with a few points that are incontrovertible:

- Ammonium hydroxide has been recognized by FSIS as an anti-microbial processing aid in the past for a different application without declaration. See FSIS Directive 7,120.1, Amendment 6.

³ The issue of requiring a use by date was raised by FSIS in its June 28, 2005 letter to FMI. It is being addressed in this appeal since it potentially is still an open issue, though we believe the data provided (and attached hereto as Appendix II to Attachment 2) conclusively resolves the use by date issue.

⁴ We note that it may be possible to argue that the manner of application, injection versus flush, calls for a different result here, but such an argument is one of form over substance. As discussed below with regard to the injection of ammonium hydroxide, the manner of application would make no difference as to whether the substance is a processing aid. Moreover, the CO process has been acceptable for non-intact meats, specifically ground beef, and FDA has raised no concerns as to the manner of application.

⁵ The record is silent on why the initial determination of the Director was subsequently changed three months later. However, we cannot envision any basis for change that would not grant equal treatment to the FMI process.

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- The level of ammonia remaining after the application here is similar to the ammonia level in fresh meat (360 ppm total versus 50-150 ppm in untreated meat).
- The level of ammonia is significantly less than the residues of other undeclared anti-microbials (e.g., tri-sodium phosphate leaves a residue of approximately 1,200 ppm).
- Virtually all anti-microbials (TSP, acidified sodium chlorite, organic acids) work by dramatically changing the pH level on the product. Regardless of the method of application, the pH level of the treated product, both on the surface and internally (through absorption), will be different than the untreated product.
- Ammonium hydroxide and other ammonia compounds are among the most widely used processing aids. Though it is difficult to demonstrate this since, as a processing aid, it does not appear on product labels, it is used as a pH adjuster for caramel, cola beverages, cheeses, freeze dried tofu, and a variety of other products.⁶

Beyond the above, we have provided data to demonstrate that the ammonium hydroxide serves no function nor has an effect in the finished product following the initial anti-microbial effect: it does not increase shelf life (Attachment 2 at Appendix II), nor does it affect the organoleptic properties on the product (attachment 4, provided FSIS on August 5, 2005). Finally, we can demonstrate that the treatment has no effect on growth should the product be subsequently re-contaminated with a pathogen.

Under FSIS policy, if the use of a substance comports with FDA regulations governing processing aids, the substance need not be declared on the product label. The subsection of the regulations normally used by FSIS defines processing aids as:

Substances that have no technical or functional effect but are present by reason of incorporation as an ingredient in another food where the substance did have a functional or technical effect. 21 CFR 101.100(a)(3)(i)

⁶ "FDA states that the levels of ammonia and ammonium compounds normally found in food do not pose a health risk. Maximum allowable levels in processed foods are as follows: 0.04-3.2% ammonium bicarbonate in baked goods, grain, snack foods, and reconstituted vegetables; 2.0% ammonium carbonate in baked goods, gelatins, and puddings; 0.001% ammonium chloride in baked goods and 0.8% in condiments and relishes; 0.6-0.8% ammonium hydroxide in baked goods, cheeses, gelatins, and puddings; 0.01% monobasic ammonium phosphate in baked goods; and 1.1% dibasic ammonium phosphate in baked goods, 0.003% in nonalcoholic beverages, and 0.012% in condiments and relishes." Public Health Service, "Draft Toxicological Profile for Ammonia," 2002.

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Based on the data discussed above, we submit that the use of ammonium hydroxide here comports with the definition since it has no functional or technical effect in the meat.⁷

However, the above regulation is not the only definition of processing aid in the FDA regulations. Another sub-section provides:

Substances added for the functional effect during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of such constituents. *Id.* at (3)(ii)(b).

Here, the ammonium hydroxide is added to act as an anti-microbial during processing. However, the substance is also a constituent normally found in meat (as ammonia) and we respectfully submit the increase of ammonia by approximately 200 ppm does not constitute a significant increase (especially when compared to other anti-microbials not being declared).

Finally, there is a definition of processing aid developed by Codex that seems to be the clearest and most logical definition and one which could be adopted by FSIS:

Processing aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods, or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

In the case of FMI's use of ammonium hydroxide, it is clear ammonium hydroxide is not consumed as a food ingredient by itself, it is being used solely for its anti-microbial effect. Moreover, if there was some way FMI could remove the substance after treatment, it would, but the amount remaining is simply unavoidable.

Notwithstanding the above, FSIS has raised concerns in conversations that the FMI process is different in that all other anti-microbial processing aids are applied to the surface of the product whereas the FMI process involves injection; the thought being that the difference in application could justify disparate treatment. We respectfully and vehemently disagree – such a justification is not based on existing precedent, regulation, nor on sound public policy.

First, we know that for at least one substance, FSIS recently issued two favorable suitability determinations where the substance is used as an anti-microbial in a marination injection (sodium metasilicate). There is no valid basis to treat

⁷ To facilitate the use of anti-microbials, FSIS has excluded one-time anti-microbial effects from consideration as to whether a substance is a processing aid.

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ammonium hydroxide differently than that substance. We further note that these two determinations were rendered at the same time we have been attempting to obtain a favorable suitability determination for the same method of application.

Second, the use of ammonium hydroxide here qualifies under two FDA processing definitions and the Codex definition – none of which depend on the method of applying the processing aid. There is no valid basis to suddenly include a new condition not referenced in the definitions

Third, from a public health perspective, it is illogical to limit the manner of applying an effective anti-microbial, especially when the manner of application is intended to address the public health risk (it is the act of injection which results in the potentially contaminated surface being moved to the interior of the product which poses the health risk and results in the presence of *E. coli* O157:H7 being deemed an adulterant).

Fourth, it can be argued that this use is really a surface treatment in that it is being applied to the surface of the product before the surface is forced internally by the injection process.

Fifth, as noted above, any surface treatment does permeate, to some extent, to the interior of the product.

Most importantly, we understand and submit that ammonium hydroxide would not be required to be labeled on the injection solution under FDA rules since the substance is used as a processing aid to adjust pH. If ammonium hydroxide would not be required on the label of the solution, there is no possible justification to require its declaration on the fresh beef bearing such solution.

Conclusion

For the foregoing reasons, we respectfully request FSIS forward an "Agency Response Letter to the Freezing Machines, Inc. GRAS Notification" that concludes the FMI process is suitable for use with fresh red meats without condition.

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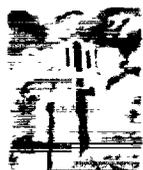
We appreciate the prompt resolution of this matter. If you have any questions, please do not hesitate to contact me.

Respectfully submitted,

Dennis R. Johnson
Counsel to Freezing Machines, Inc.

Attachments
DRJ:mhh

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South Dakota State University

Muscle color, pH, and shear force relationships among eight beef muscles.



SDSU Meat Science

T. J. Koger and D. M. Wulf

Abstract

One hundred beef carcasses were selected at three packing plants and used to determine muscle color, pH and shear force relationships among eight muscles. Individual muscles were excised from one hindquarter of each carcass at d-7 postmortem: longissimus lumborum (LL), psoas major (PM), gluteus medius (GM), tensor fasciae latae (TF), rectus femoris (RF), semimembranosus (SM), biceps femoris (BF), and semitendinosus (ST). Ultimate pH and colorimeter readings were measured on freshly-cut surfaces following a 90-min bloom time for all eight muscles at d-7 postmortem. Samples were frozen at d-7 postmortem and later thawed and cooked to 70°C for Warner-Bratzler shear force determination. Coefficients of determination (r^2) were calculated using linear regression for inter-muscle relationships and quadratic regression for intra-muscle relationships. Coefficients of determination (r^2) for using LL L* to predict L* readings of other muscles were significant ($P < 0.05$) for GM (0.71), ST (0.70), SM (0.65), TF (0.41), RF (0.34), PM (0.30), and BF (0.24). Coefficients of determination (r^2) for using LL pH to predict pH readings of other muscles were significant ($P < 0.05$) for GM (0.58), ST (0.49), SM (0.42), BF (0.13), PM (0.09), RF (0.05), and TF (0.04). Coefficients of determination (r^2) for individual muscles for using LL shear force to predict shear force values of other muscles were significant ($P < 0.05$) for RF (0.27), GM (0.22), SM (0.19), ST (0.15), BF (0.13), and TF (0.09). Coefficients of determination (R^2), calculated separately for each muscle, for using pH and pH² to predict shear force were significant ($P < 0.05$) for SM (0.26), GM (0.25), LL (0.11), and ST (0.08). When dark cutters (n=11) were excluded from analysis, the relationship between pH and shear force was generally weaker ($R^2 = 0.11$ for SM, 0.10 for GM, 0.04 for LL, 0.07 for ST). Coefficients of determination (R^2), calculated separately for each muscle, for using L* and L² to predict shear force were significant ($P < 0.05$) for LL (0.20), SM (0.14), GM (0.12), TF (0.09), and RF (0.08). When dark cutters (n=11) were excluded from the analysis the relationship between L* and shear force changed only slightly ($R^2 = 0.17$ for LL, 0.10 for TF and RF, and 0.09 for SM). For BF and PM, the relationships of shear force with pH and shear force with L* were not significant ($P < 0.05$). In general, color, pH, and shear force of LL exhibited weak to moderate relationships to color, pH, and shear force of the other muscles. Within muscles, shear force was related to color and pH of SM, GM, and LL.

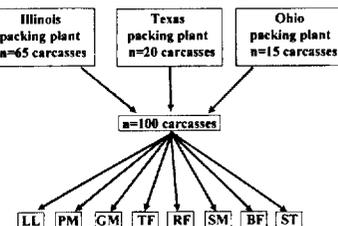
Introduction

Kropf (1980) suggested that muscle color is probably the single greatest factor determining the purchase of meat at retail. Moreover, muscle color, as related to carcass maturity and muscle pH, is evaluated to determine quality grades by USDA graders (USDA, 1997). Muscle color and ultimate pH are also important because several researchers have shown that tenderness is correlated with muscle color (Jeremiah et al., 1991; Wulf et al., 1997) and ultimate pH (Purchas, 1990; Watanabe et al., 1996). Most research examining the relationships among muscle color, ultimate muscle pH, and tenderness has focused on the longissimus muscle. Furthermore, the longissimus muscle is the only muscle used for USDA quality grading. However, the longissimus constitutes only 8.0% of the total muscle mass of the beef carcass. Shackelford et al. (1995) and Wheeler et al. (2000) found that the tenderness of the longissimus muscle was correlated to the tenderness of some, but not all, other muscles. Correlations of longissimus color and ultimate pH with the color and ultimate pH of other muscles have not been established. Furthermore, minimal research has been conducted on the relationships among muscle color, ultimate pH, and tenderness within muscles other than the longissimus.

Objectives

- 1) Determine if muscle color, ultimate pH, and shear force of the beef longissimus muscle is related to color, ultimate pH, and shear force of other beef muscles.
- 2) Determine if shear force is related to muscle color and ultimate pH within eight beef muscles.

Materials & Methods



- Eight individual muscles were excised from one hindquarter of each carcass at d-7 postmortem
- Colorimeter readings, ultimate pH, and Warner-Bratzler shear force was determined for all eight muscles at d-7 postmortem.
- Coefficients of determination (r^2) were calculated using linear regression for inter-muscle relationships and quadratic regression for intra-muscle relationships.

Results and Discussion

Table 1. Relationship (r^2) of various muscle L* readings to longissimus L* readings

Muscles	Mean (SD)	All carcasses (n=100)	Excluding dark cutters (n=89)
Longissimus	39.0 (3.9)		
Psoas major	41.4 (2.8)	0.30*	0.37*
Gluteus medius	43.4 (4.3)	0.71*	0.70*
Tensor fasciae latae	44.9 (3.7)	0.41*	0.49*
Rectus femoris	45.1 (4.4)	0.34*	0.47*
Semimembranosus	40.3 (3.9)	0.65*	0.62*
Biceps femoris	42.0 (3.6)	0.24*	0.33*
Semitendinosus	44.7 (4.3)	0.70*	0.68*

* ($P < 0.05$)

• Longissimus L* readings were useful predictors of L* readings of other muscles, especially for the gluteus medius, semitendinosus, and semimembranosus.

• Coefficients of determination changed only slightly when dark cutters were excluded.

Table 2. Relationship (r^2) of various muscle pH readings to longissimus pH readings

Muscles	Mean (SD)	All carcasses (n=100)	Excluding dark cutters (n=89)
Longissimus	5.57 (0.19)		
Psoas major	5.73 (0.15)	0.09*	0.23*
Gluteus medius	5.56 (0.10)	0.58*	0.34*
Tensor fasciae latae	5.62 (0.15)	0.04*	0.20*
Rectus femoris	5.64 (0.04)	0.05*	0.23*
Semimembranosus	5.55 (0.19)	0.42*	0.23*
Biceps femoris	5.53 (0.06)	0.13*	0.27*
Semitendinosus	5.58 (0.15)	0.49*	0.12*

* ($P < 0.05$)

• Longissimus pH readings were useful predictors of pH readings of other muscles, especially for the gluteus medius, semitendinosus, and semimembranosus.

• Among "normal" carcasses only, longissimus pH was moderately correlated with the pH of all other muscles.

Table 3. Relationship (r^2) of various muscle shear force values to longissimus shear force values

Muscles	Mean (SD)	All Carcasses (n=100)	Excluding dark cutters (n=89)
Longissimus	4.15 (1.39)		
Psoas major	3.27 (0.40)	0.02	0.07*
Gluteus medius	4.48 (1.11)	0.22*	0.25*
Tensor fasciae latae	3.78 (0.66)	0.09*	0.16*
Rectus femoris	3.72 (1.14)	0.27*	0.31*
Semimembranosus	4.54 (1.06)	0.19*	0.11*
Biceps femoris	5.16 (1.01)	0.13*	0.10*
Semitendinosus	4.21 (0.66)	0.15*	0.21*

* ($P < 0.05$)

• In general, the relationship of longissimus shear force to the shear force of other muscles was weaker than the relationship of longissimus color and pH to the color and pH of other muscles.

• Shear force of the psoas major had little to no relationship to the shear force of the longissimus, probably because there was very little variation in psoas major shear force (i.e., all psoas major steaks were tender).

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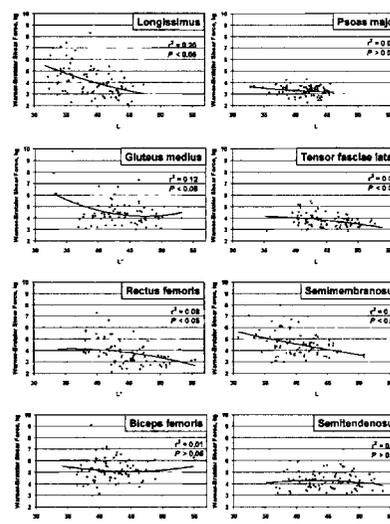
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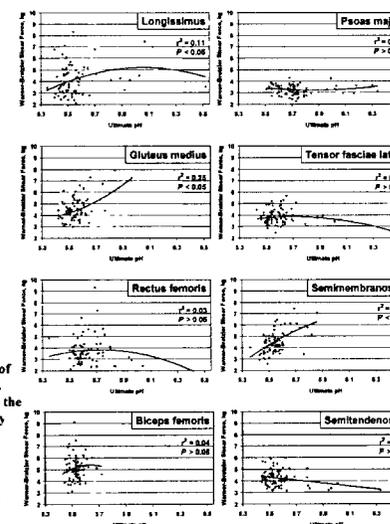
Figure 1. Relationship between L* and shear force



• Within muscles, the relationships between muscle color and shear force was moderate for the longissimus, weak for the semimembranosus, gluteus medius, tensor fasciae latae, rectus femoris, and non-existent for the psoas major, semitendinosus, and biceps femoris.

• For those muscles exhibiting a significant relationship between L* and shear force, lower L* ratings were associated with higher shear force values.

Figure 2. Relationship between pH and shear force



• Within muscles, the relationships between ultimate pH and shear force were moderate for the semimembranosus, and gluteus medius, weak for the longissimus and semitendinosus, and non-existent for the semitendinosus, tensor fasciae latae, biceps femoris, rectus femoris, and psoas major.

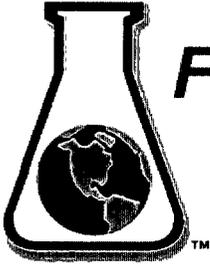
• For those muscles exhibiting a significant relationship between ultimate pH and shear force, higher ultimate pH values were associated with higher shear force values of the gluteus medius, semimembranosus, and longissimus, whereas in the semitendinosus, higher ultimate pH values were associated with lower shear force values.

Conclusions

- Longissimus muscle color and ultimate pH were useful indicators of color and ultimate pH of other muscles.
- As reported previously by Shackelford et al. (1995) and Wheeler et al. (2000), we confirmed that tenderness of the longissimus muscle is correlated to the tenderness of some, but not all, other muscles.
- Higher ultimate pH was associated with less tender cooked beef of the longissimus, gluteus medius, and semimembranosus.

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Contact: Rich Jochum - Amanda Dean
Customer: BEEF PRODUCTS INC.
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Phone: 605-217-8000

Fax: 605-217-8007

Report Number: 06-04569

Report Date: 1/26/2006

Samples Received: 01/25/2006

Start of Testing: 01/25/2006

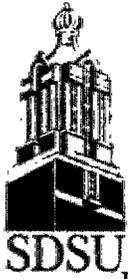
Check Number:

PO Number:

Billing Code	Sample Date	Sample Number	Sample Description	Analyses - FSNS Method Number	Result	Units
PH02	1/25/2006	1	Trisodium Phosphate TSP Na ₃ PO ₄ 5% Composite Type: None	pH #C07.1 (AOAC)	12.33	
PH02	1/25/2006	2	Trisodium Phosphate TSP Na ₃ PO ₄ 10% Composite Type: None	pH #C07.1 (AOAC)	12.35	
PH02	1/25/2006	3	Trisodium Phosphate TSP Na ₃ PO ₄ 12% Composite Type: None	pH #C07.1 (AOAC)	12.35	
PH02	1/25/2006	4	Sodium metasilicate SMS Na ₂ SiO ₃ 1% Composite Type: None	pH #C07.1 (AOAC)	12.85	
PH02	1/25/2006	5	Sodium metasilicate SMS Na ₂ SiO ₃ 2% Composite Type: None	pH #C07.1 (AOAC)	12.99	
PH02	1/25/2006	6	Lactic Acid C ₃ H ₆ O ₃ 1% Composite Type: None	pH #C07.1 (AOAC)	2.39	
PH02	1/25/2006	7	Lactic Acid C ₃ H ₆ O ₃ 2% Composite Type: None	pH #C07.1 (AOAC)	2.18	
PH02	1/25/2006	8	Lactic Acid C ₃ H ₆ O ₃ 2.5% Composite Type: None	pH #C07.1 (AOAC)	2.10	
PH02	1/25/2006	9	Citric Acid C ₆ H ₈ O ₇ -H ₂ O 1% Composite Type: None	pH #C07.1 (AOAC)	2.36	
PH02	1/25/2006	10	Citric Acid C ₆ H ₈ O ₇ -H ₂ O 2% Composite Type: None	pH #C07.1 (AOAC)	2.18	
PH02	1/25/2006	11	Citric Acid C ₆ H ₈ O ₇ -H ₂ O 2.5% Composite Type: None	pH #C07.1 (AOAC)	2.11	

Sample Temperature Upon Receipt:	N/A
Remarks:	Printed on: 01/26/2006

Signature:



South Dakota
State University

College of Agriculture and
Biological Sciences

Department of Animal and
Range Sciences

Box 2170, SDSU
Brookings, SD 57007-0392
Phone 605-688-5165
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February 1, 2006

Dear Dennis Johnson,

As per our conversation, here is the data of pH values from control and treated beef eye of rounds from our 2004 research trial for Freezing Machines, Inc. The data presented represents the pH of samples at various pumped percentages. The pH data from the control samples ranged from 5.20 to 5.71.

% pump	Control	Treated
15.00	5.24	5.5
16.00	5.2	5.89
16.80	5.49	6.08
18.60	5.28	6.13
20.00	5.29	5.93
20.40	5.31	5.95
21.30	5.43	5.78
21.70	5.45	6.24
22.10	5.39	6.02
22.20	5.45	6.1
22.80	5.39	6.3
24.30	5.71	6.52
24.30	5.33	5.94
28.60	5.43	6.21

Also attached is paper published at the 2003 Reciprocal Meat Conference that shows the typical pH range of beef eye of round (semitendinosus muscle). According to the attached paper (Koger and Wulf, 2003), the typical pH range reported for eye of round was 5.45 to 6.35 (see lower right graph on Figure 2).

I hope that this answers your questions.

Sincerely,

Duane Wulf
Associate Professor

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SUBMISSION END

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