Fig

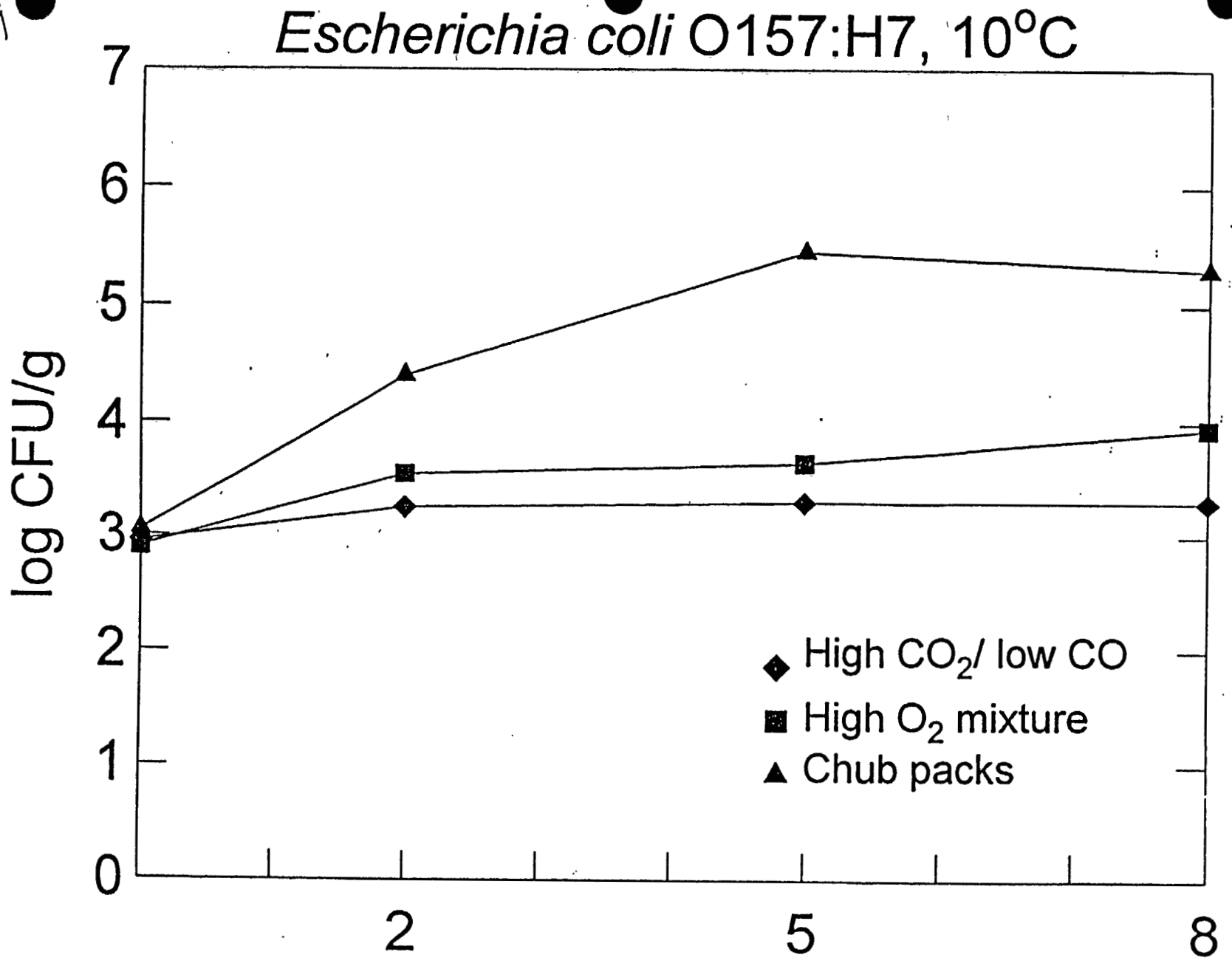

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Fig

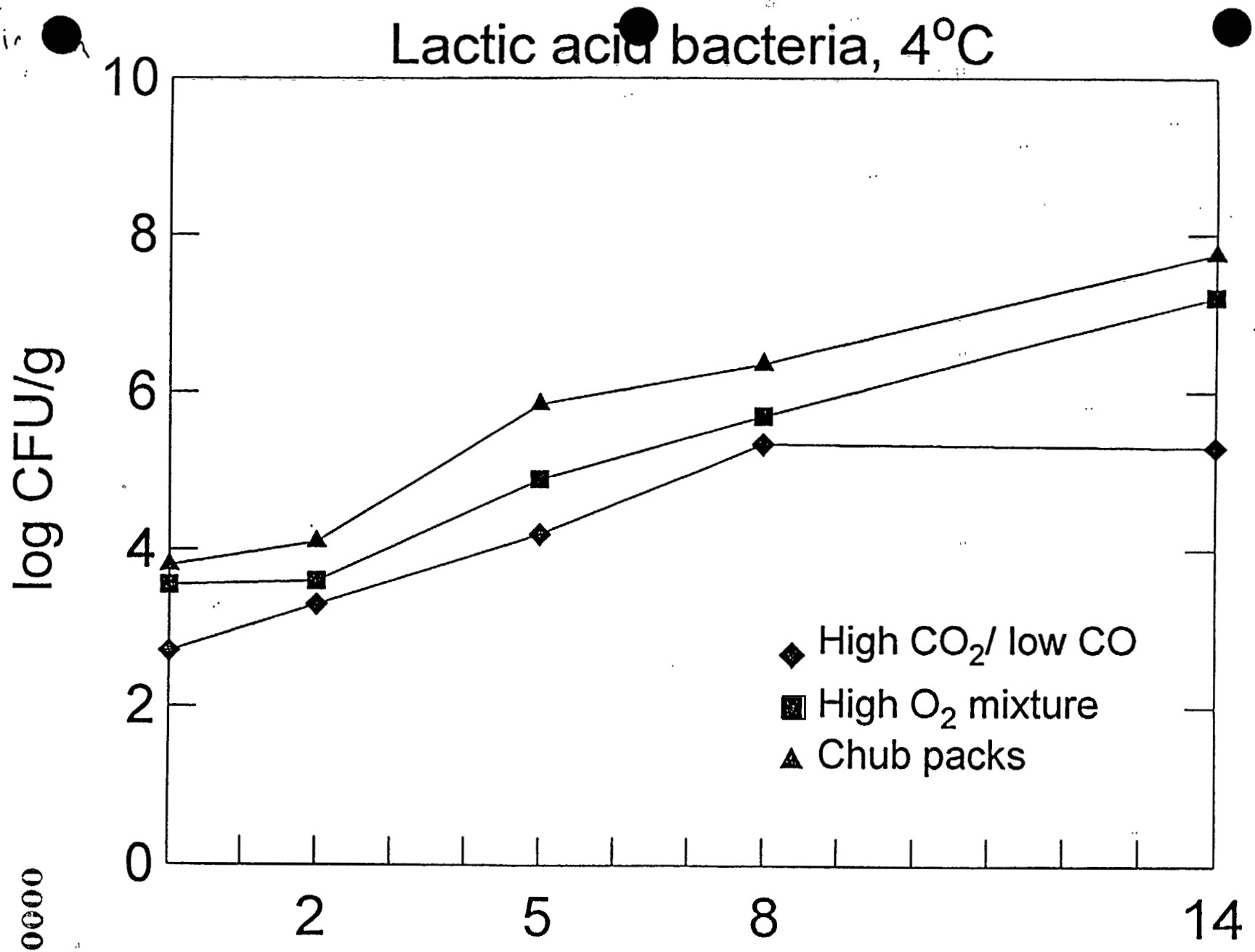

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Fig. 16

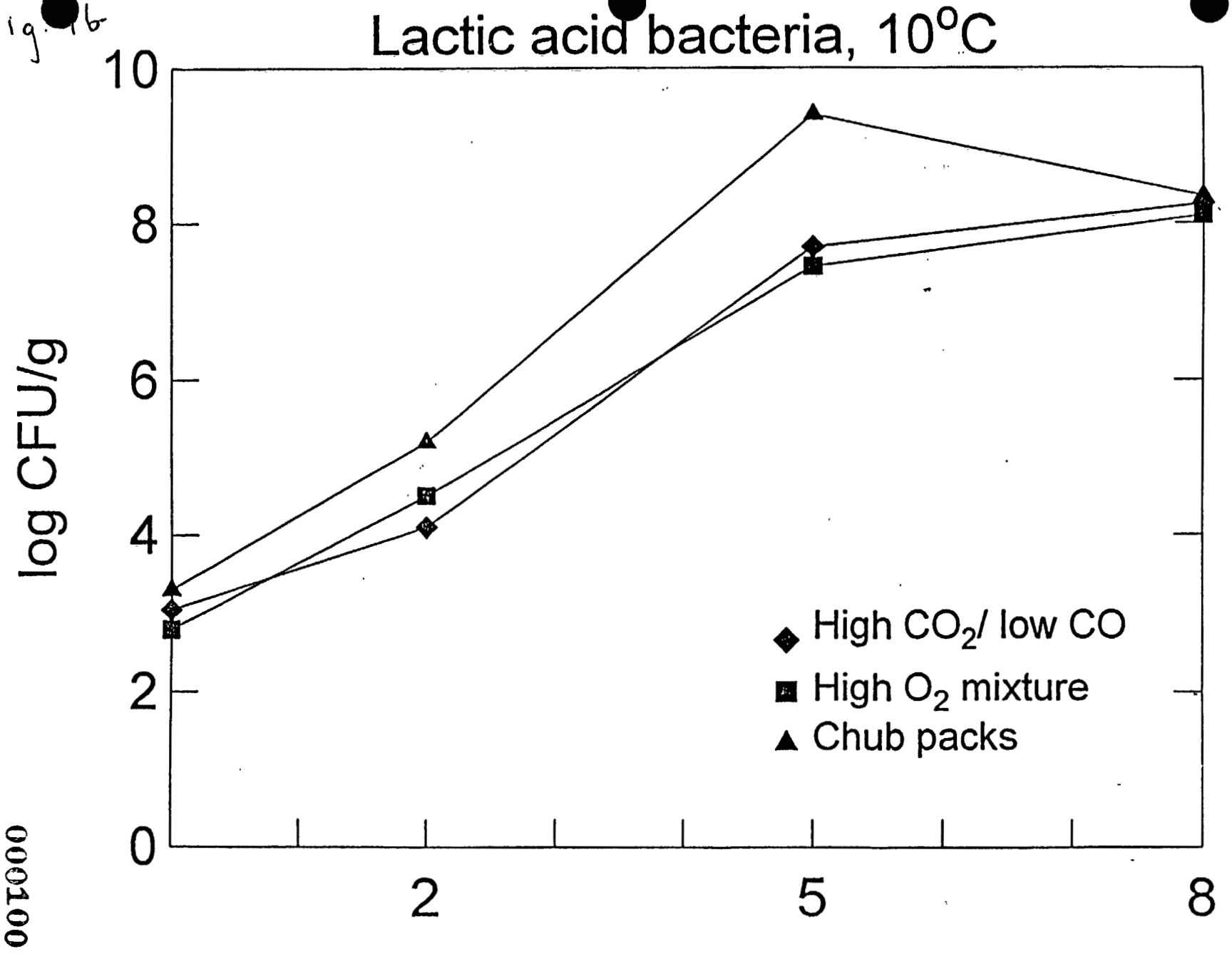

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Fig 6a

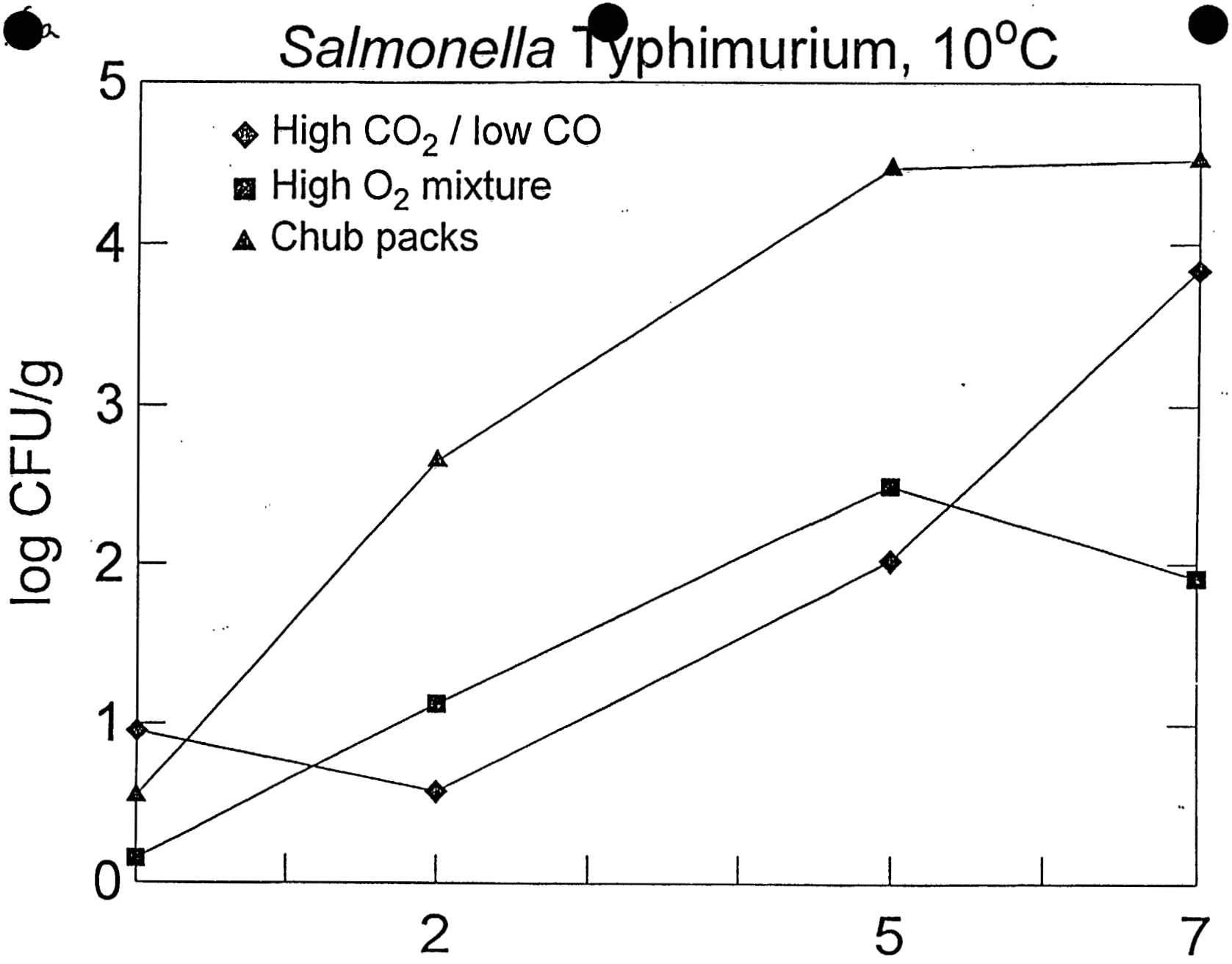

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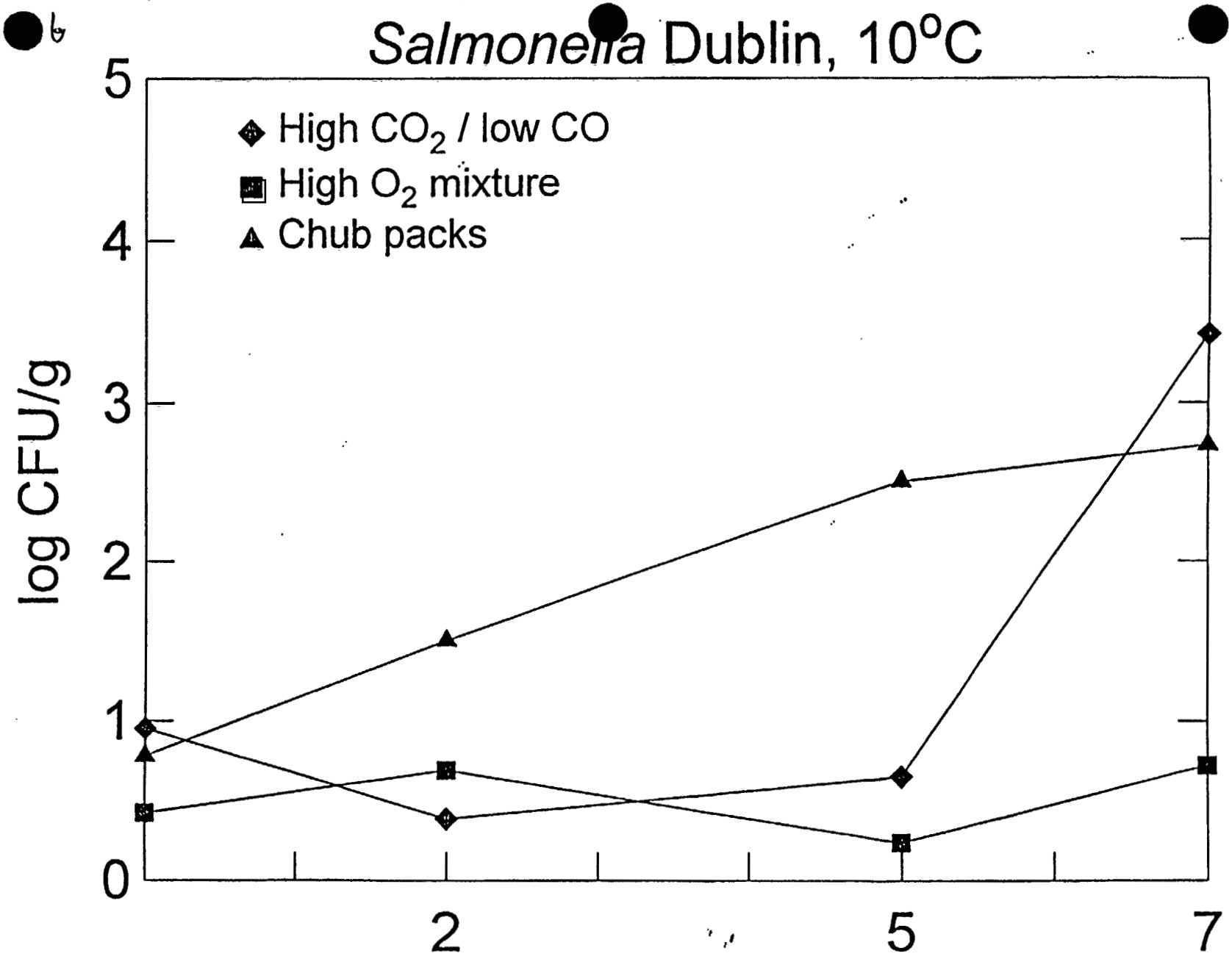
Fig 6



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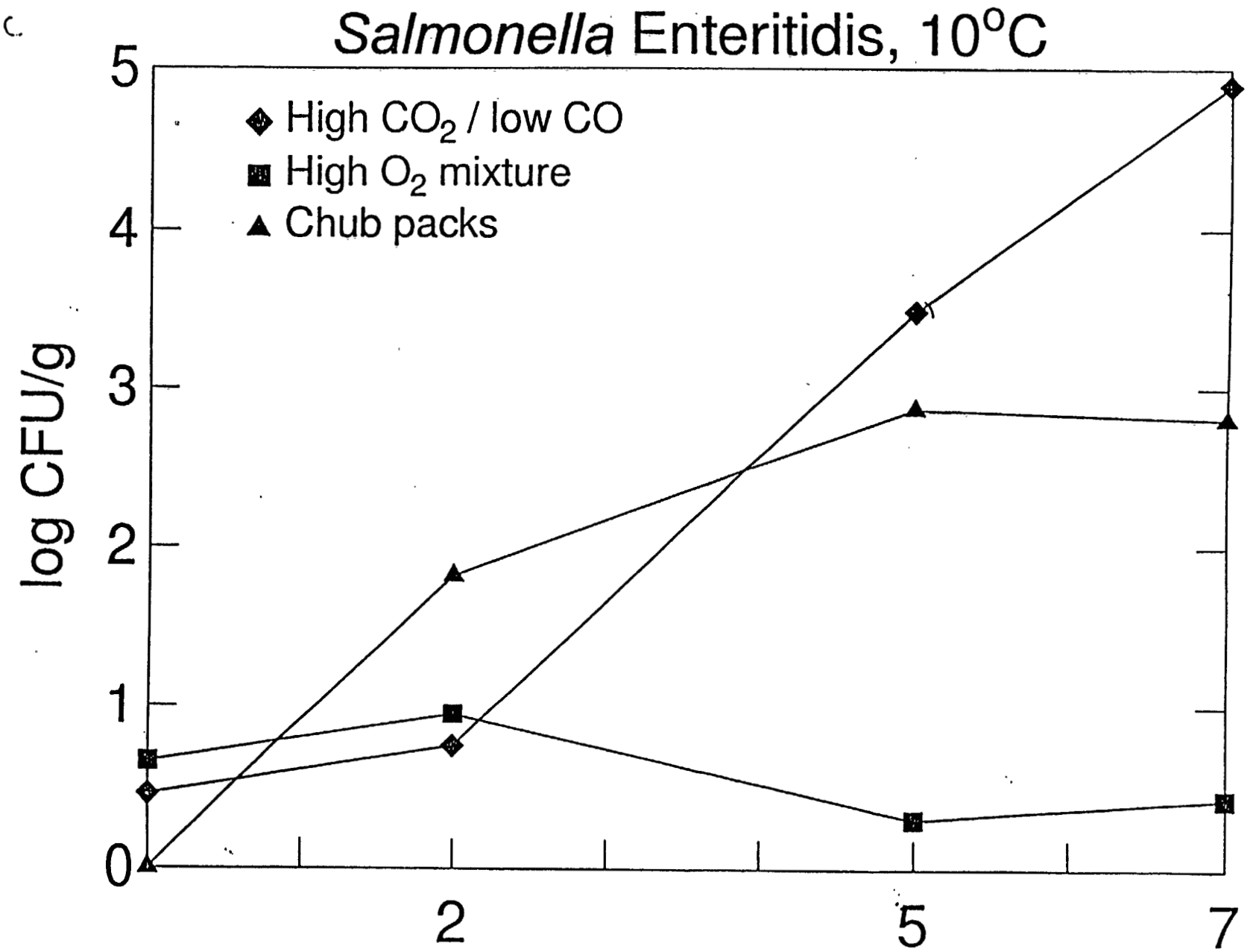
Salmonella Enteritidis, 10°C
High CO_2 / low CO
High O_2 mixture
Chub packs
log CFU/g
0
1
2
3
4
5
2
5
7

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Fig. 5d

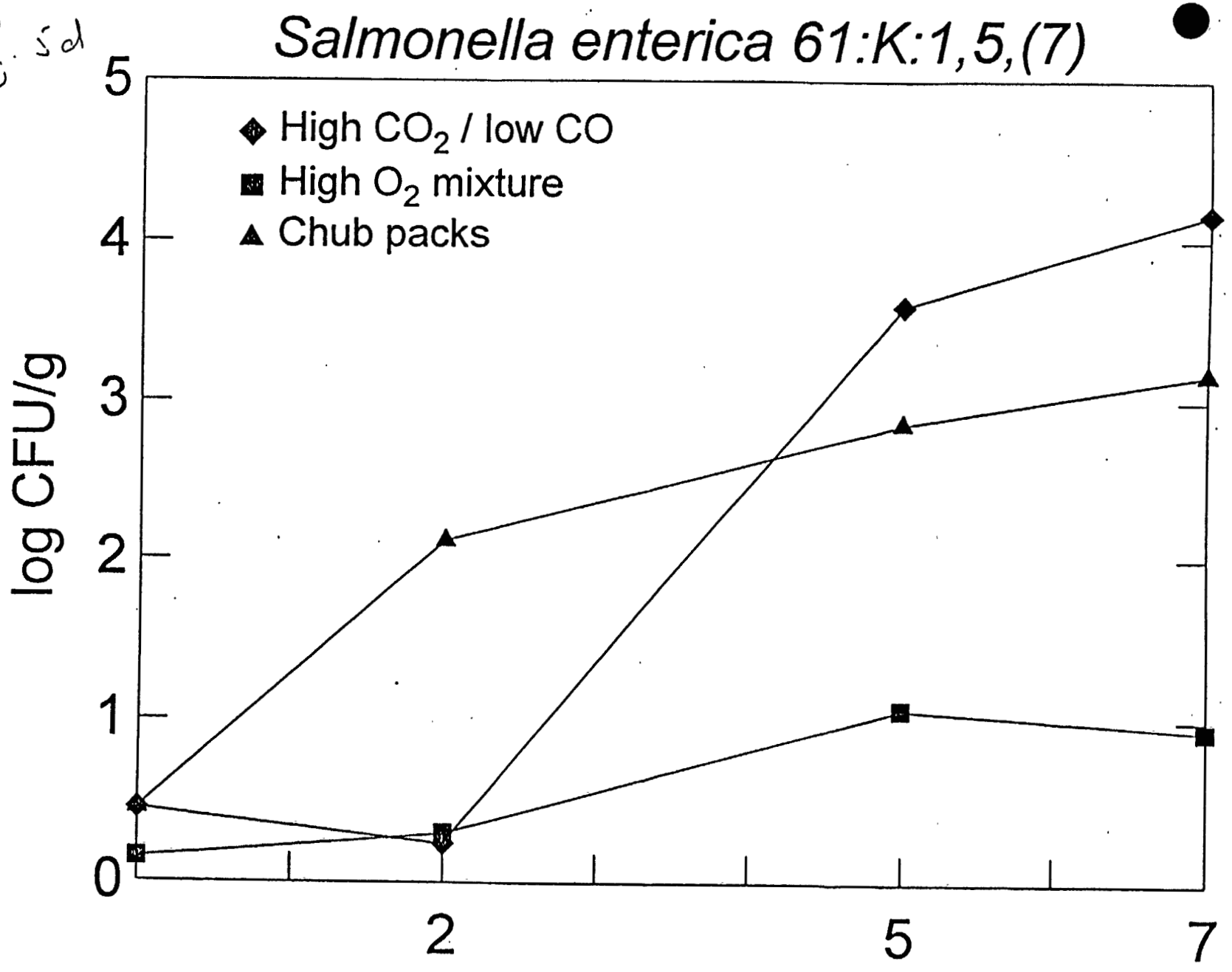

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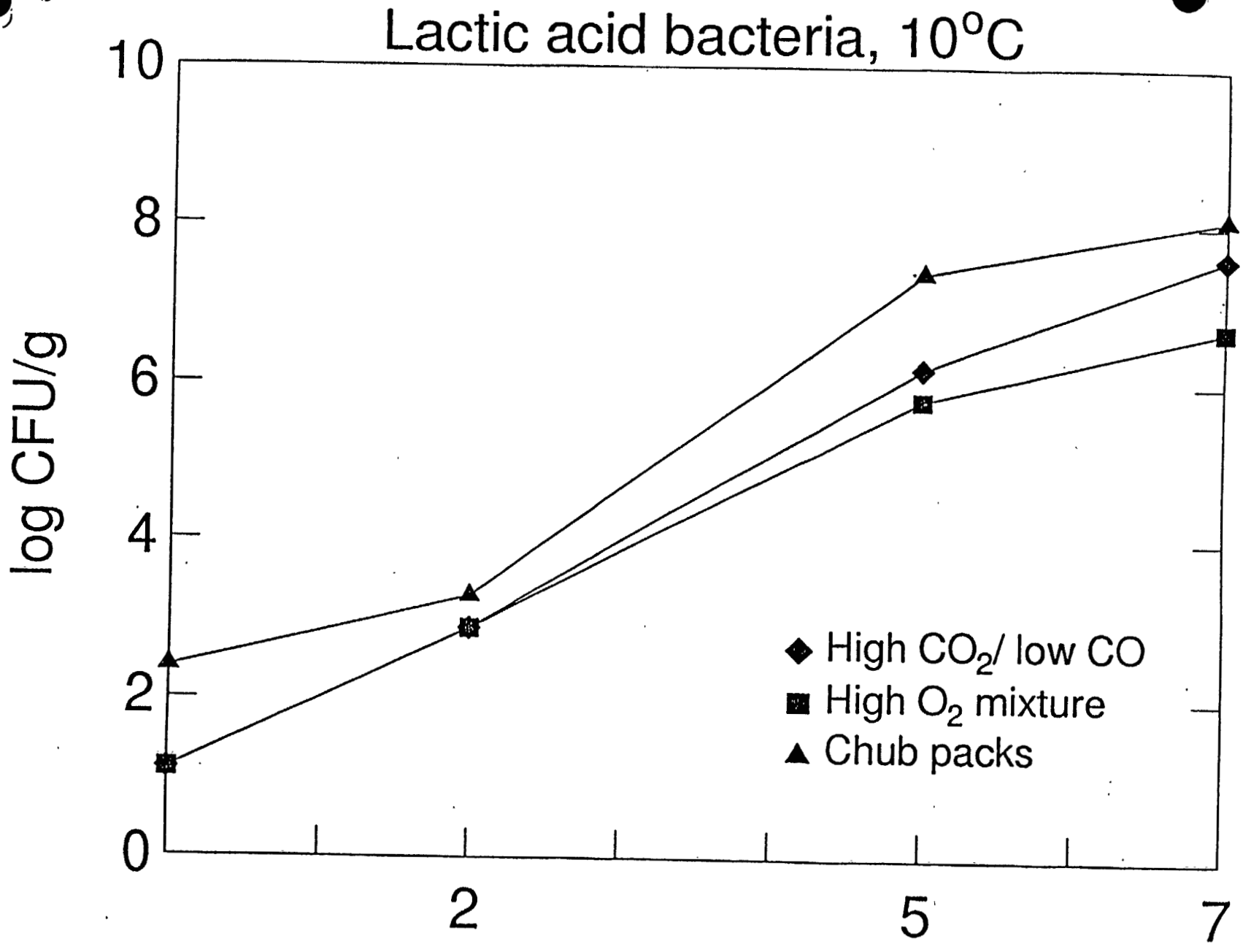
Fig 6



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English summary

3

CONSUMER PURCHASE PROBABILITY OF BEEF AND PORK PACKAGED IN DIFFERENT ATMOSPHERES

Ragnhild Solheim, MATFORSK, Norwegian Food Research Institute, Oslovn. 1, 1430 Ås, Norway

Ground beef, beef loin steaks and pork chops were packaged in modified atmospheres of 0.4% CO/ 60% CO_2/ 40% N_2 (high CO_2/low CO mixture) and 70% O_2/ 30% CO_2 (high O_2 mixture). In addition ground beef was packaged in clipped chub packs, beef loin steaks were vacuum packaged, and pork chops were packaged in an atmosphere of 60% CO_2/ 40% N_2 with each pack containing an O_2 absorber. The purchase probability data were collected by interviewing 126 consumers usually purchasing meat and meat products. The consumers visually compared the samples within each type of meat. The consumers preferred ground beef packaged in the high CO_2/low CO mixture or the high O_2 mixture compared to ground beef packaged in clipped chub packs. Purchase probability increased when pork chops were packaged in the high CO_2/low CO mixture. Pork chops in packs containing an O_2 absorber, were rated lowest in purchase probabilities. The purchase probability for beef loin steaks was similar when packaged in the high CO2/low CO mixture or the high O2 mixture, and these products were preferred compared to beef loin steaks packaged in vacuum.

COMMISSIONED REPORT

MATFORSK – Norwegian Food Research Institute

Osloveien 1, N-1430 Ås
Tel: (+47) 64 97 01 00

Report No.:
O-7224
Availability: Confidential

Report Title: Consumer Survey of Meat Products	**Date:** July 11, 1996
Project Manager/Author: Ragnhild Solheim	**Signature of Project Manager:** [Signature]
Head of Department: Bjørg Egelandsdal	**Signature of Head of Department:** [Signature]
Department: Analysis Methodology	**Project No:** O-7224 FBT
Commissioned by: Norsk Kjøtt [Norwegian Meat]	**Commissioner's contact:** Truls Nesbakken

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Pages 000111-000120 removed under the Privacy Act of 1974.

Prosjektmedarbeidere:

Ansvarlig for *opplegg og rapport*:	Ragnhild Solheim
Ansvarlig for *prøvemottak og lyssetting*:	Oddvin Sørheim
Ansvarlig for *praktisk gjennomføring*:	Inger Johanne Fjøsne
Øvrige deltakere i gjennomføring:	Asgeir Nilsen Janne Haugdahl Vibeke Høst Oddvin Sørheim
Ansvarlig for *statistisk bearbeiding*:	Per Lea

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(4)

English summary

DISCOLORATION OF MEAT AS AN INDICATOR OF LEAKAGES IN PACKAGES CONTAINING A CO GAS MIXTURE

Oddvin Sørheim, MATFORSK, Norwegian Food Research Institute, Oslovn. 1, 1430 Ås, Norway

The aim of the experiment was to study discoloration of meat packaged in a gas mixture of 60 % CO_2/40 % N_2/ 0.4 % CO with different concentrations of residual O_2 added. Tests were performed on ground beef with 1 % NaCl, aged beef loin steaks and pork chops. Leakages were simulated by injecting different amounts of air with a syringe into the packages after two days storage. Discoloration of the meat was measured as reduction in a* (redness) values and evaluated visually. Ground beef had a low tolerance level of residual O_2 because it was discoloured in atmospheres containing more than 1 % O_2. Beef loin steaks and pork chops were slightly discoloured in more than 2 and 5 % O_2, respectively. The results suggest that discoloration can be an indicator of leakages for ground beef, but not for beef loin steaks and pork chops.

COMMISSIONED REPORT

MATFORSK – Norwegian Food Research Institute

Osloveien 1, N-1430 Ås
Tel: (+47) 64 97 01 00

Report No.: O-7224.col	
Availability: Confidential	

Report Title: Meat Discoloration as an Indicator of Leaks in Packaging with CO Gas Mixtures	**Date:** November 28, 1996
Project Manager/Author: Oddvin Sørheim	**Signature of Project Manager:** [Signature]
Head of Department: Astrid Nilsson	**Signature of Head of Department:** [Signature]
Department: Product and Raw Material Science	**Project No:** O-7224.col
Commissioned by: Norsk Kjøtt [Norwegian Meat]	**Commissioner's contact:** Truls Nesbakken

Summary/Abstract:

Tests were carried out to find the tolerance limits for residual O_2 for discoloration of meat packaged in CO gas mixture with simulated leak. Various concentrations of air were added to the packages of ground meat, top loin and pork chops with a mixture of 60% CO_2 / 40% N_2 / 0.4% CO two days after packaging. Ground meat packaged in gas containing more than 1% O_2 was clearly discolored, while top loin and pork chops, respectively packaged in gas containing more than 2 and 5% O_2 showed only minor discoloration. The results indicate that discoloration can serve as an indicator of leakage for ground meat, but not for top loin and pork chops.

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SWEDISH MEATS

Date	Ref. No.
April 9, 1999	33

Reference:
Lars Wedén, (+46) 8-725 81 03

Date	Ref. No.

Svein E. Skorstad
Norsk Kjott [Norwegian Meat]
P. O. Box 60 Refstad
N-0513 Oslo 5 NORWAY

RECEIVED:	*April 14, 1999*
CASE WORKER:	*K. Framstad*
FILE NO.:	*561*
J. NO./DOC. NO.:	*99/00721*

Brother:

Please refer to our conversation at the Scandinavian Butchers' Association meeting on March 19 regarding CO as a packaging gas. Here at Swedish Meats we are committed to creating opportunities to increase the meat packaging done by the manufacturer in Sweden. An approval of CO as a gas for use in foods would entail significantly greater possibilities of brand profiling of meat products in the future, which could help improve our service to the retailers. Moreover, efficient factory packaging could even reduce costs across the entire distribution chain ending with the consumer.

We therefore support Norsk Kjott's proposal to submit a joint application to the EU Commission for the addition of CO to EU's list of additives. The plan is to submit a joint application in June 1999.

Sincerely,

Swedish Meats

[signature]
Lars Wedén

[letterhead information]

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DANSKE SLAGTERIER [Danish Bacon and Meat Council]	Axelborg, Axeltorv 3 1609 Copenhagen V Denmark Tel. (+45) 33 11 60 50	Fax (+45) 33 11 68 14 Telex 22 975 ds dk Telegram "danslagt"	[Logo]

February 11, 2000
Tel. (+45) 33 73 25 68

Norsk Kjøtt [Norwegian Meat]
att: Jorunn Vormeland
PB 360 Økern
N-0513 Oslo
Norway

[Stamp:]Received: *February 14, 2000*
Case Worker: *JVO*
File No.: *562*
J. No./Doc. No. *00/00204*

Use of CO as Packaging Gas

In Norway, CO has so far been used in very minute quantities together with other packaging gases for gas packaged cuts of meat and ground meat. This packaging gas has not been approved in the EU yet, and has not been used in Denmark this far.

CO and the other packaging gases help ensure the storage life and color stability of fresh meat, which are important for central packaging and distribution of meat. The trend in Denmark is toward increased central packaging of fresh meat, since this is both efficient and ensures high microbiological quality. It would therefore be interesting to take advantage of the positive Norwegian experiences with the use of CO in this country, as well.

Published research shows that the risk of growth of a range of pathogenic bacteria is the same or reduced when using CO in combination with the traditional packaging gases. The use of this gas can thus help improve food safety (Food Microbiology and Food Safety into the Next Millennium, Proceedings of the Seventeenth International Conference of International Committee on Food Microbiology and Hygiene, Netherlands, 1999).

The use of CO in the given concentration of 0.3–0.5% should not represent any toxicological risk to consumers. CO is generally supplied in a concentration of 1% in a mixture with either N_2 or CO_2 and does therefore not represent any workplace hazard to operators during the packaging process.

We are not aware that the use of CO was discussed in the process of drafting Directive 95/2/EU of February 20, 1995 concerning additives other than colorings and sweeteners. This may be due to the fact that no country had expressed any interest in using this kind of gas at the time.

Since there are advantages to the use of CO as a packaging gas, as mentioned, and since there are no negative effects to either consumers or packaging operators, DANSKE SLAGTERIER can support an

application to the EU Commission to include CO on the list of approved additives, possibly limiting the amount.

Sincerely,

DANSKE SLAGTERIER
[Signature]
Anne Birgitte Lundholt
(Managing Director)

(10)

Asociación de Industrias de la Carne de España

TELEFAX

To: Dirk Dobbelaere
Secretary (CLITRAVI)

Subject: CO gas at meat packaging gas

Date: 14 of February 2000

N° of pages: 1

Dear Dirk:

After reading the scientific documents that Mr. Truls Nesbakken handed out in the last T&L working group meeting. We will support the Norwegian proposal for authorization CO gas as a packaging gas within the UE.

We look forward to hearing from you soon.

Yours sincerely,

Miryam de Miguel
Dpto. Calidad-AICE

For info
To Norwegian CLITRAVI member
From CLITRAVI

General Rodrigo, 6 • 28003 MADRID
Teléfono: 91 554.70.45 - Fax: 91 554.78.49 - E-mail: aice@aice.es

14/02 '00 14:09 FAX 32 2 2032244 → FRAMSTAD VORMELA 001/001

Finnish Meat
Research Institute

(11)

21.2.2000

Truls Nesbakken
Fagsentret för kjøtt
PB 396 Økem
0513 Oslo
Norge

Use of CO as packaging gas for meat and meat products

After going through the scientific documents sent to us and having own projects supporting the results, our institute is ready to support the Norwegian proposal to allow CO gas as a packaging gas in EU.

Finnish Meat Research Institute

Markku Raevuori
Managing Director

Raymond Tuominen
Laboratory Director

Finnish Meat Research Institute
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The Use of CO as a Packaging Gas for Fresh Meat.

By Magne Yndestad

A previous report on the use of CO as a packaging gas concluded that there is unsatisfactory documentation on factors such as the development of pathogenic bacteria in the gas mixture in question (0.4% CO/60% CO_2/40% N_2). The Norwegian Research Center for Meat forwarded recent and complementary documentation on September 13, 1999.

Following scientific review, the content of this documentation can be summed up as follows:

Bacteriological Conditions

Numerous studies have been undertaken regarding trial storage involving concentrations of CO_2 in a range consistent with the "Norwegian" mixture (60-75% CO_2). Moreover, there are articles documenting the bactericidal effect of various other concentrations of gas mixtures containing CO_2. The conclusion to these trials is the following:

The low CO concentration (<0.5 CO) has no apparent effect on bacterial flora in products packaged with gas. This also holds true for N_2 (filler gas).

Concentrations of CO_2 below 5% may stimulate the growth of certain types of bacteria. Between 5 and 50%, we see an approximately linear inhibiting effect. This effect is somewhat significant, since the inhibition of growth of the sensitive flora is as much as 50% at 10% CO_2. The documented effect of CO_2 in high concentrations primarily applies to the psychrotrophic flora, including the most important spoilage bacteria.
As for the pathogenic bacteria, scientific literature in general points to the same tendency, i.e. inhibition of growth at both 4°C and higher temperatures (e.g. 10° C).
In comparison to other packaging methods or gas mixtures used, the mixture in question seems favorable both in terms of storage life and in terms of the relevant pathogens.

Following the last round of applications, The Norwegian Research Center for Meat has performed a relatively extensive study on freshly ground meat packaged in 0.3-0.5% CO/60-70% CO_2 and 30-40% N_2. Various pathogens, such as *E.coli* O157:H7, *Listeria monocytogenes*, and *Yersinia enterocolitica* were tested in this trial. The Research Center has evaluated factors such as the important possibility that the strong suppression of the general psychotrophic flora may favor certain pathogens, which will not be inhibited to the same degree. The main conclusion, however, is that the aforementioned pathogens are inhibited both at 4°C and 10°C. Comparing the CO packaging method to packaging employing a high concentration of O_2 or vacuum, shows that the risk for growth of the applied pathogens is identical or lower when packaging with CO.

The Research Center has studied the circumstances concerning salmonella bacteria and the gas mixture in question in the same products. Since none of the cultures grew at +4°C, studies were only undertaken at 10°C.
In this case, storage with packaging gas containing CO performed worst with regard to *S. dublin, S. enteritidis* and *S.diarizonae*, as a relatively strong growth occurred following Day 2. *S. typhimurium* too had considerable growth, although "sausage" packaging scored lower.

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This is completely in line with what is known about a whole range of salmonella bacteria in foods, i.e. that they hold up very well when competing with other bacteria, and also grow very well at temperatures around 8-10°C.
These facts emphasize the importance of cooling regardless of what packaging method is chosen.

Sensorial Circumstances

The last report pointed to the particular fact that the CO packaged meat could retain a fresh red color for days after spoilage set in. Hence, the consumer cannot *see* whether the meat he or she buys is spoiled, as opposed to fresh meat packaged in other types of gas packaging.
The Research Center notes that when opening a package, the consumer will detect any spoilage odor, and hence not eat the product. This may be true, but it is a fact that many people won't react to any incipient decay when the products looks completely "fresh." However, the packaging method for which approval is sought is meant for fresh meat that will be treated with heat prior to use. This is an additional safety factor that is important in a comprehensive evaluation.

Conclusion

The first bacteriological/sanitary statement made was based on the documentation available at the time. The new data and other relevant information from scientific literature indicate that there is sufficient evidence that the use of CO as a packaging gas as described in the application won't result in any increased risk of transmittal of food-borne diseases among consumers.

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[Handwritten:]
From the report "Fresh Meat in Consumer Packaging" with modified gas containing CO_2 [illegible]

IV. Report by Tore Aune: "Fresh Meat in Consumer Packaging – A Toxicological Evaluation of the Use of up to 0.5% CO in a Gas Mixture."

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FRESH MEAT IN CONSUMER PACKAGING – A TOXICOLOGICAL EVALUATION OF THE USE OF UP TO 0.5% CO IN A GAS MIXTURE

By Tore Aune

Carbon monoxide (CO) is a colorless gas that is primarily generated by incomplete combustion of organic material. The background concentration of CO in the atmosphere is approximately 0.01-0.09mg/m^3 (0.009-0.08 ppm), while the concentration in larger cities may excede 50mg/m^3 as an 8 hour mean, depending on traffic.

General Health Effects

CO attaches to the iron of the hemoglobin in the red blood cells during generation of carboxyhemoglobin (COHb), and can thus affect the transport of oxygen in the blood and the supply of oxygen to the tissues. Compared to its affinity to oxygen, hemoglobin has approximately 240 times greater affinity to CO. CO also attaches to myoglobin, cytochromes, and some other enzymes, but these reactions are considered less important than the formation of carboxyhemoglobin (WHO 1979). The health impact on humans is mainly restricted to effects on the cardiovascular system, the nervous system, and certain types of proteins and cells in the bloodstream, as well as effects on embryos (SFT 1992).

The carboxyhemoglobin percentage (COHb %) is a function of the CO concentration in the inhaled air, the exposure time and the level of physical activity (Coburn et al., 1965) (see Table 1). A CO exposure resulting in a COHb concentration above 2% in the bloodstream of the most sensitive individuals (cardiovascular patients) has been shown to give symptoms of localized oxygen deficit and chest pains. Reduced work capacity occurs at a somewhat higher COHb%, and persons suffering from angina can tolerate less strain before an attack occurs. No health effects have been detected in healthy adults at COHb concentrations below 5%.

Table 1: Blood carboxyhemoglobin percentage as a function of CO concentration in air, exposure time and different degrees of physical activity (Coburn et al., 1965):

Exposure		COHb%		
CO Conc.	Time in Hours:	At rest	Moderate Activity	Strenuous Activity
10 mg/m^3	8	1.3	1.4	1.4
25 mg/m^3	1	1.0	1.5	2.0
40 mg/m^3	1	1.3	2.2	2.9

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CO attachment to the hemoglobin is reversible. The half-life at ventilation at rest is approximately 4.5 hours.

A small amount of CO is continually formed in the body as a result of the decomposition of substances such as hemoproteins. This results in a COHb% of approximately 0.5. The uptake of CO through inhalation comes in addition to that. The average COHb level in non-smokers is estimated at 1.2-1.5%, while the level is 3-4% in smokers.

Survey of Health Effects Associated with CO Exposure

The negative health effects of CO are due to the fact that CO competes with oxygen for points of attachments on the hemoglobin molecule. Moreover, the release of oxygen in the tissues is reduced (WGHO 1987). Myoglobin is closely related to hemoglobin. It stores oxygen and promotes the diffusion of oxygen to muscle cells. In cardiac and skeletal muscles, myoglobin binds CO with an affinity that is 30-50 times higher than the corresponding affinity for oxygen. No reported studies have shown that the binding of CO to myoglobin can cause any health effect at a COHb level of 4-5%.

Uptake and liberation of CO occur at a relatively slow pace (hours), which means that short-time exposure to elevated CO levels will not result in any noticeable increase in the COHb level. SFT report No. 92/16 (1992) includes an overview of the correlation between blood COHb levels and health effects (Table 2).

Table 2: Correlation between blood carboxyhemoglobin levels and health effects (SFT 1992):

COHb%	Observed Effects in Humans:
50 and above	Unconsciousness, lethal when untreated.
30 and above	Headache, dizziness, nausea, and vomiting.
10 and above	May be lethal to cardiovascular patients. Headache in healthy individuals.
5 and above	Reduction of peak oxygen consumption under strenuous activity in healthy individuals.
5 and above	Impaired vision, learning ability and fine motor response.
5 and above	Exposure during pregnancy may affect the embryo.
2.9 and above	Individuals suffering from angina can tolerate less strain before an attack occurs.
2.3 and above	Reduced capacity for physical work, especially stamina.
2 and above	Possible reduced ability to concentrate and pay attention.
2 and above	Symptoms of localized oxygen deficit and incipient chest pains in cardiac patients.

The literature in the field does not seem to indicate that health effects have been proven in healthy adults exposed to CO resulting in a blood COHb concentration of less than 5%.

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However, the data indicate that a COHb level of 2-3% may have negative effects on sick and sensitive individuals, such as people suffering from cardiovascular diseases.

Exposure to CO through the Air

With regard to CO as an air pollution factor, a team of Norwegian experts (SFT 1992) suggested air quality criteria at CO concentrations resulting in a maximum of 1.5% COHb during light physical activity (including the CO produced endogenically). The correlation between CO concentration, activity level, and exposure time in order not to exceed 1.5% blood COHb is shown in Table 3.

Table 3: Calculation of CO concentrations in the air resulting in a COHb level of 1.5%, including endogenic CO production (SFT 1992):

	CO Concentration, mg/m^3		
Exposure Time:	At Rest:	Moderate Physical Activity:	Strenuous Physical Activity:
15 min	170	80	52
30 min	86	42	29
1 hour	48	24	18
8 hours	11.5	9.2	9.2

Exposure to CO through Consumption of Fresh Meat Treated with a Gas Mixture

There is a paucity of information in scientific literature concerning exposure to CO through the consumption of fresh meat treated with a gas mixture containing CO. One of the most interesting references in this regard is a 1954 publication by A. L. Tappel et al., which is unfortunately not easily accessible. However, their work has been cited in other publications, e.g. in the study by Clark et al. (1976): Tappel et al. considered a US industrial sanitary norm for CO of 50 ppm (8 hours/day), and found that such exposure would result in a blood COHb level over a longer period of time that is approximately 14 times higher than the temporary increase caused by consumption of approximately 225 g meat, provided that the myoglobin and hemoglobin in the meat are saturated with CO, and that 100% of CO from this source is transferred to the blood of the consumer (an estimate representing a hypothetical worst-case scenario). According to the authors, such treatment of meat will thus cause only a very minor effect in comparison to what is considered the safety limit, even when assuming maximum uptake of CO. Watts et al. (1978) exposed beef to a gas containing 1% CO for 3 days, and found that this resulted in a CO saturation of approximately 30% of the myoglobin. CO was lost under such storage conditions, with a half-life of approximately 3 days. After cooking, the CO concentration in the meat decreased to

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below 0.09 ppm (equivalent to approximately 0.1 mg/kg). Maximum loss after cooking (on burner at 195°C) amounted to approximately 85%.

Comparison of CO Exposure through Air and Meat (CO Treated)

There is little data available for such a comparison, but a rough overview nevertheless provides some points of reference. An adult inhales 10-20m^3 air per 24 hours (depending on the activity level). This is the equivalent of 0.42-0.84m^3 per hour (or 3.36-6.72 m^3 per 8 hours).

To stay within a maximum blood COHb level of 1.5%, the CO concentration in the air must be 24 mg/m^3 for 1 hour at moderate physical activity, at 9.2 mg/m^3 for 8 hours (according to Table 3). In comparison, the CO exposure is 0.1 mg/kg after consumption of 250 g of heated CO-treated meat that has been treated for 72 hours in a gas containing 1% CO (Watts et al., 1978). Table 4 shows a calculation of CO intake from the air and a meal of CO-treated meat.

Table 4: Comparison of CO intake from air within a range without any health impact and theoretical intake of CO through consumption of a meal of CO-treated meat:

Path of Exposure:	CO Intake, 1 hour:	CO Intake, 8 hours
Lungs (15 m^3/24 hours)	24mg x 0.625 = 15.1mg	9.2mg x 5 = 46.0mg
Meat	0.025mg	0.025 mg

For CO balance between air and blood is only achieved after a considerable period of time (hours). The absorption of gases from the intestinal canal to the blood is probably considerably less efficient than from the lungs, where the tissue allows for maximum gas exchange between the alveoli and the bloodstream. This implies that intake of CO through meat probably won't cause any demonstrable increase in the blood CO level (in the form of COHb). And at any rate, the exposure from meat is much lower (approximately one thousand times lower) than through the airways, as shown in the calculations above.

According to the Norwegian Institute of Air Research (SFT 1992), the CO concentration in larger Norwegian cities is on average between 1 and 2 mg/m^3 during the winter. Maximum hourly values have been measured to approximately 60 mg/m^3, and maximum values for 8 hours to about 40 mg/m^3.

Evaluation of Other Gases Used in Foods in the EU

EU's Research Committee on Foods (SCF) has not considered CO. However, the expert team has considered other gases (EUR 1981), such as carbon dioxide (CO_2) and nitrogen oxide (NO). In this connection, the committee employed the following evaluation method, which should be applicable for CO, as well:

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CO_2: This compound is a natural product of metabolism, and people are constantly exposed to carbon dioxide from the atmosphere, food and drink. Compared to this exposure, the residual content from its use as an extraction agent is insignificant. Establishing an ADI for this compound is unnecessary. The committee considers this compound acceptable as an extraction agent. It is unnecessary to determine concentration values for the residue.

N_2O: The pharmacological and pharmacokinetic properties of this gas are well known from the extensive use of N_2O as an anaesthetic. Even though no data on residual content are available, such amounts are probably so minor that they are not hazardous to the consumer. The committee finds that it is unnecessary to establish an ADI, and considers the use of N_2O as an extraction agent acceptable.

Toxicological Evaluation of the Use of CO as a Packaging Gas for Meat

People are continually exposed to carbon monoxide, both by means of endogenic production and by inhaled air. Toxicologically, it is the amount of CO bound to the blood hemoglobin (the carboxyhemoglobin percentage) that determines any health effects. The very first effects in sensitive individuals occur at COHb concentrations from approximately 2-3%. To prevent possible health effects even in the most sensitive individuals, a team of Norwegian experts has suggested limits for CO in the air that do not result in COHb concentrations above 1.5%, including the endogenic production at 0.5%. The above-mentioned estimates indicate that even if all CO in the prepared meat is transferred to the consumer's blood, the CO concentration – even a temporary concentration – will remain well below accepted limits in air. From a health perspective, the use of CO in concentrations below 0.5-1 % for fresh meat thus represents no toxicological risk.

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ATTACHMENT 4

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Final Report

EVALUATION OF BEEF STEAKS AND GROUND BEEF IN THE PACTIV ACTIVE TECH PACKAGING SYSTEM: EFFECTS OF CARBON MONOXIDE IN THE PACKAGE ATMOSPHERE

for

Pactiv Corporation
Canandaigua, NY
May 2001

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PROJECT SUMMARY

The effects of carbon monoxide (CO) in Active Tech modified atmosphere packages (MAP) were determined for:

A. Initial product color,
B. Stability of color during display, and
C. Relationships of color deterioration and microbial populations.

Steaks from three beef cuts (strip loin, tenderloin, and inside round steaks) and ground beef were packaged in a MAP certified gas blend (0.4% CO, 30% carbon dioxide and 69.6% nitrogen) and stored at 35°or 43°F for up to 35 days. Cuts then were removed from MAP and displayed at 34°F until their color was approaching consumer unacceptability. Color and microbial parameters were measured and compared to baseline data of comparable product exposed to oxygen but not CO.

A fundamental goal of this research was to determine if CO extended the color life of beef cuts and ground beef beyond their microbial soundness, i.e., did color mask spoilage.

CONCLUSIONS

- The Active Tech MAP system containing CO in the gas blend produced products that were equally as red as products packaged with traditional oxygen permeable overwrap.
- Improvement in visual appearance especially in the tenderloin and inner portion of the inside round steaks were observed on day zero of display and throughout display.
- Color of products exposed to CO was a typical, bright red when the outer MAP bag was removed and products were allowed to bloom for 60 to 90 minutes.
- Color declines for products stored in MAP with CO compared well to baseline products exposed to oxygen. Hence, a typical discoloration pattern was seen in both baseline and MAP studies.
- Color life for tenderloin and inside round steaks (and to a lesser extent ground beef) was slightly longer than their baseline counter parts, especially when stored 35°F vs. 43°F.
- Although microbial growth curves changed in slope and exponential growth based on the environment in the packages, bacterial growth was neither encouraged nor suppressed by the addition of CO to the MAP gas blend.
- Aerobic bacteria and facultative anaerobes followed typical patterns of growth contingent upon the environmental conditions.
- Effects of storage temperature (35° vs. 43°F) and increased storage time (21 or 35 days) resulted in typical redness decline, increase in off-odors and microbiological changes.
- CO neither masked spoilage nor resulted in color life extension beyond the point of microbial soundness.

INTRODUCTION

Marketing of case-ready meats has moved beyond the concept stage to reality. This method of delivering meat to retailers is expected to be the predominate system within five years. Some of the largest retailers are already paving the way for this makes-sense marketing system.

Modified atmosphere packaging (MAP) systems are a necessity for case-ready meats because current retail meat over wrapping does not fulfill requirements for shelf life and other needs. Processors can choose either high-oxygen or low-oxygen MAP for retail-ready meats. Both systems rely upon the meat having certain functional properties needed to optimize delivery of cuts with excellent display color life and sound microbial quality.

In low-oxygen MAP, such as the Active Tech System of Pactiv Corporation, it is essential that the meat achieve a stable red color that extends throughout storage and display. This usually is accomplished by modifying the package atmosphere so that the meat pigment returns to its purple-red state (deoxymyoglobin). Then, at display, packaged cuts are re-exposed to oxygen (air) to re-form a bright-red color (oxymyoglobin). Some muscles can easily accomplish this function whereas other muscles have a difficult time – due principally to short comings of their inherent muscle chemistry. Thus, novel ways to aid in obtaining desirable color during storage and display would be beneficial.

Gas atmosphere composition plays a critical role in the functionality and efficacy of MAP systems for meat. The atmosphere affects one or more of the following: product appearance, shelf life, microbial and palatability issues, gas dynamics, purge, and myoglobin functionality. Typical atmospheres for low-oxygen MAP utilize carbon dioxide (CO_2) and/or nitrogen (N_2) prior to the meat being re-exposed to oxygen. Addition of small amounts of carbon monoxide (CO) to a CO_2 and/or N_2 atmosphere could aid in producing a more functional pigment color in MAP, especially in meat cuts known to have lower color stability. CO is well known for its ability to bind to myoglobin and form a bright, crimson-red colored pigment known as carboxymyoglobin. However, carboxymyoglobin is believed to stabilize meat color beyond its microbial shelf life. Consequently, consumers may not be able to rely on color as an indicator of quality at time of purchase. Research is needed to address the use of low levels of CO in a MAP system.

HYPOTHESIS AND OBJECTIVES

This research was based on the hypothesis that a small quantity (<0.5%) of CO combined with the typical gases of MAP (CO_2 and N_2) would produce meat color complimentary to the quality needs of a case-ready meat delivery system without compromising consumer quality issues. More specific objectives evaluated the effects of CO in the Active Tech System for:

- **The initial color of intact muscles and ground beef** – this objective addressed color differences between meat in MAP containing CO vs. packaging in O_2.
- **The color deterioration of these products during display** – these data defined the color display stability of meat in MAP containing CO vs. packaging in O_2.
- **The microbial profile of the meat stored with or without mild temperature abuse** – this portion provided information about microbial growth with CO in MAP relative to the time-honored relationship between color deterioration and spoilage.

EXPERIMENTAL PROCEDURES

This project involved two phases. The **Baseline Display Study** characterized the color and microbial traits of selected cuts and ground beef using typical oxygen-permeable packaging under typical retail display conditions. The **MAP Display Study** utilized the Pactiv Active Tech Packaging System in combination with a unique, certified gas blend (0.4% CO, 30% CO_2 and 69.6% N_2) in the package atmosphere during storage conditions (pre-display). The outer MAP bag was removed and the products were displayed in the same manner as the baseline samples. All data from the MAP Portion were compared to the Baseline product.

RAW MATERIALS:

Twelve beef strip loins (NAMP #180 containing the *Longissimus* muscle), 18 tenderloins (NAMP #189A containing the *Psoas major* muscle), 12 inside rounds (NAMP #169A containing the *Semimembranosus* muscle), and 6 batches of ground chuck (80% lean) were obtained from a commercial source (Prairieland Processors, Inc., Kansas City, KS) at four to six days postmortem. Vacuum packaged subprimals and trim that were received at the KSU Meats Laboratory had an internal temperature of 34°F and had never been frozen. Prior to product preparation, subprimals were stored at 34°F. This product was allocated to 6 replications (2 each of the strip loins and inside rounds and 3 tenderloins constituted a replication).

PRODUCT PREPARATION AND PACKAGING:

One inch thick steaks cut from each subprimal and ground beef formed into about one-pound blocks (Beef Steaker, Model 600, Hobart Corp., Troy, OH) were placed on Styrofoam trays (17S for strip loins, 4P for inside rounds, 1 for tenderloins, and 2P for ground beef) containing an absorbent pad (Ultra Zap Soakers, Paper Pak Products, La Verne, CA). Product was overwrapped with polyvinyl chloride (PVC) film (23,000ccO_2/m^2/24hrs; Filmco MW4, LinPac, UK or Omnifilm 4P, Huntsman, Salt Lake City, UT) using a mechanical wrapper (Filmizer Model CSW-3, Hobart Corporation, Troy OH) and was assigned randomly to either a **Baseline Display Study** using only PVC-wrapped packages or a **MAP Display Study** using the Active Tech System of Pactiv Corporation. Trays for MAP were placed individually in barrier bags (4.5ccO_2/m^2/24hrs: NXE 1-300, Alec Enterprises, Burnsville, MN) along with an oxygen absorber (MRM-200, Multisorb Technologies, Buffalo, NY) activated using Pactiv Active Tech Activator No.1. Barrier bags were evacuated, flushed with a certified gas blend containing 0.4% CO, 30% CO_2, and 69.6% N_2, and sealed (Freshvac Model A300, CVP Systems, Inc., Downers Grove, IL).

TREATMENTS:

Baseline Display Study: Twelve packages of ground beef and one steak (≤1/8" fat trim) from each subprimal (12 strip loins, 12 inside rounds, 18 tenderloins, and the 6 batches of ground beef), were evaluated in a baseline study to establish the color and microbial parameters for meat never in MAP and exposed only to atmospheric oxygen. These packages were placed in display about 4 hours post-packaging (see display and measurement details below).

MAP Display Study: To test the effects of CO in MAP, one package of each product from each of 6 replications was selected at random for assignment to all possible combinations of two storage temperatures (35 and 43°F) and three storage times (7,14, and 21 days for ground beef and 7, 21, and 35 days for steaks). The lower temperature represented reasonably good industry practice, and the higher temperature represented a mildly abusive storage conditions. The storage times represented current industry practice.

Prior to display (post-MAP), the O_2 and CO_2 levels in the outer barrier bags were measured using a MOCON head space analyzer (Pac Check™ Model 650, MOCON/Modern Controls, Inc., Minneapolis, MN).

DISPLAY CONDITIONS:

Meat samples were placed in simulated retail display at 34 ± 3°F under 1614 lux (150 ± 5 foot candles; Model 201, General Electric, Cleveland, OH) light intensity (Philips, 34 Watt, Ultralume 30) in open-top display cases (Unit Model DMF8, Tyler Refrigeration Corporation, Niles, MI). Cases were programed to defrost two-times per day at 12 hour intervals. Display case temperatures were monitored during display using temperature loggers (Omega Engineering, Inc., Stamford, CT). Display times varied based on product type, initial microbial loads, and storage conditions. Product was removed from display when the color score was deemed unacceptable by a visual panel (a color score of 3.5). Baseline products were displayed 7, 5, 4, and 3 days for strip steaks, inside rounds, ground beef, and tenderloins, respectively.

VISUAL COLOR EVALUATION:

Ten trained visual panelists evaluated color using a five-point scale where 1 = very bright red, 2 = Bright red, 3 = Slightly dark red or tan, 4 = Moderately dark red or tan, and 5 = Extremely dark red or brown. The cut-off score for consumer acceptable color was ≥3.5. Two portions of the inside round muscle were scored separately. The outer 1/3 portion (OSM) and the deep, inner 1/3 portion (ISM). The middle 1/3 area was not scored. The 10 panel scores were averaged for statistical analysis.

INSTRUMENTAL COLOR AND SPECTRAL DATA:

Samples were instrumentally analyzed for lightness (L*), redness (a*), and yellowness (b*) for Illuminant D-65 (daylight) using a HunterLab MiniScan Spectrophotometer (1.25 inch diameter aperture, Hunter Associates Laboratory, Inc., Reston, VA). Multiple readings (2 to 4 depending on cut size) were taken and averaged for statistical analysis on each cut at each testing period.

ODORS:

At the end of display, each package from the MAP Display Study was evaluated for off odors by two experienced panelists using a 5-point scale were 1 = no, 2 = slight, 3 = small, 4 = moderate, and 5 = extreme off odor. A score of 3.5 was assumed to be unacceptable to consumers.

MICROBIOLOGICAL PROCEDURES:

Microbial populations were estimated at the end of MAP storage (day 0 of display) and at the end of display (day of unacceptable color). For each post-display sample, a portion of the surface area (top surface) that had been exposed to light was excised. After each package was opened aseptically, two cores (ca 2 in^2) were removed (approximately 1/8 inch depth), placed in a sterile stomacher bag, and blended two minutes with 0.1% peptone diluent. Serial dilutions of the homogenate were prepared in 0.1% peptone and appropriate dilutions were plated in duplicate on Aerobic Plate Count Petrifilm™ to determine total aerobic bacterial populations and on E. coli Count Petrifilm™ to estimate generic *E. coli* and total coliform bacterial counts. In addition, appropriate dilutions also were plated in duplicate on MRS agar to determine lactic acid bacterial populations. Aerobic Plate Count Petrifilm™ and E. coli Count Petrifilm™ (3M Microbiology Products, St. Paul, MN) were incubated at 90°F for 48 hours prior to enumeration. LAB populations were counted after 48 hours of 92°F incubation in a CO_2 chamber. Microbial detection limits for intact muscle and ground beef were 1.76 count/cm^2 and 5.0 count/gram, respectively.

pH:

pH was determined on intact muscle and ground beef samples collected on the day of production. Ten grams of sample were added to 100 mL of distilled water and blended for two minutes. A standardized pH meter with an electrode was used to measure pH according to the procedure outlined in the Handbook for Meat Chemists.

FAT AND MOISTURE:

Ground beef samples collected on the day of production were analyzed in duplicate for moisture and fat using AOAC procedures 985.14 and 985.15, respectively.

EXPERIMENTAL DESIGN AND STATISTICS:

The design was a randomized complete block with six replications. A replication consisted of 1 to 3 subprimals (number depended on the size of each cut). Steaks cut from the subprimals and separate batches of ground beef trim were randomly assigned to replication and the treatment combinations. Data were analyzed using analysis of variance and significant differences determined using least significant difference tests at $P<0.05$.

SAMPLING TIMES/PARAMETERS MEASURED:

1. **MAP Gas Composition for oxygen and carbon dioxide levels**
   - Subsample of several ActiveTech packages on production day (2-3 hours post-packaging) to verify gas composition being obtained
   - End of MAP storage at two temperatures
2. **Microbiology:**
   - Initial counts for subprimals and ground beef on the day of production
   - End of MAP storage at two temperatures
   - End of display

3. **Visual Color:**
   - Initial color prior to display lighting
   - End of MAP storage at each of two temperatures and after 60 to 90 min bloom at 34°F (equal to 0 time of display)
   - Daily during display
4. **Instrumental Color:**
   - Initial color = After packaging in PVC on production day for baseline data, minimal exposure to light
   - End of MAP storage at each of two temperatures and after 60 to 90 min bloom at 34°F (equal to 0 time of display)
   - Daily during display
5. **Odor:**
   - At end of display (prior to microbial testing)

RESULTS AND DISCUSSION

The Baseline Study: A random selection of all steaks and ground beef packaged in PVC film were placed in display to serve as a baseline for color and microbiological comparisons. Products were expected to have the lowest microbiological load and ideal color stability using traditional packaging and display conditions for products exposed only to atmospheric oxygen. The inherent muscle chemistry responsible for good color life also was optimal. If the product exposed to CO were to have extended meat color life, then it will be compared to the baseline "control" with the "best" possible color.

Color Reference Points: The discussion below involves both visual and instrumental measures of color. Visual scores were considered the "standard" with instrumental color being discussed relative to its agreement or disagreement with the visual panel, ie, did the objective measurements confirm what the color panel saw. Visual scores of ≥3.5 were considered borderline acceptable. When samples reached this discoloration, they were removed from display. Normally, a* values (higher values indicate more redness) are highly correlated to visual appraisal.

Inside round steaks typically are two-toned in color. The inner portion (ISM) is much less color stable compared to the outer portion (OSM). These portions were scored separately since one portion may have acceptable color while the other has unacceptable color that would be discriminated against by consumers resulting in the whole cut being judged

unacceptable in color. The effects of CO on this bi-colored muscle were needed to confirm that color was not excessively extended in either portion.

FAT AND MOISTURE, pH, AND INITIAL MICROBIAL LOAD:

Average fat and moisture contents of the ground beef were 19.5 and 61.6%, respectively. pH of both intact muscles and the ground beef ranged from 5.3 to 5.7. The initial aerobic plate counts and lactic bacteria counts for all products were relatively low and indicative of microbial quality of the raw materials and good sanitation. Furthermore, coliforms and *E. coli* were below the detection limit throughout the study.

GAS COMPOSITION AT END OF MAP:

At the end of MAP storage, each package atmosphere was analyzed for O_2 and CO_2 (Table 1). Only 6 (each from a different treatment combination) of 288 packages were removed from the experiment due to leakage.

INITIAL PRODUCT COLOR AND APPEARANCE:

The color of ground beef and steaks entering display (after MAP storage at 2 temperatures) was an attractive, typical red color. Although there were several significant differences in visual scores and a* values (Table 2 and Figures 1-10 at day 0) for product in CO vs. baseline cuts, the variation in color was usually within ± 0.5 of a color score. In general, the initial color of product exposed to CO was very similar to the color of steaks from the baseline display (never exposed to CO). When differences occurred, they were more related to either storage temperature or postmortem age of the product.

Panelists did not consider the color of product exposed to CO atypical. Cuts exposed to CO generally appeared more uniformly bright-red and would be expected to have high consumer appeal. These results were expected, as CO is known to preferentially form a ligand with the colored pigment (myoglobin) in meat resulting in an intensely red pigment known as carboxymyoglobin. At higher levels of CO (0.4% vs. 0.6 to 1%) than used in this experiment, meat color has been described as being an unusual crimson, bright-red color compared to the normal red of oxymyoglobin.

A critical next question was whether the carboxymyoglobin formed on the surface was more stable than the oxymyoglobin formed in baseline product. Further, did the carboxy

pigment deteriorate in a predictable way that consumers could continue to use visual color to judge freshness or potential spoilage.

COLOR DETERIORATION PROFILE:

Visual panel scores (Figures 1-5) and instrumental color (a* values, Figures 6-10) clearly showed that product exposed to CO during MAP storage had color deterioration during display. As expected, visual scores increased (color deteriorated) and a* values decreased (loss of redness) as days in display increased.

In several instances, color appeared to improve late in display – as indicated by a decrease in visual scores (see ground beef, strips loins and tenderloins at 43°F). These decreases were not a return of redness. Rather the apparent decrease resulted from removal of discolored packages the preceding period, leaving product with less overall discoloration remaining in the case.

In general, the color deterioration profiles followed an expected pattern. Namely, the freshest product (baseline packages) had the most stable, red color and the most days in display needed to reach borderline discoloration (Table 3 scores to 3.5) of all treatments. Exceptions occurred for the inside portion of the inside round and tenderloin products, where the product exposed to CO had slightly more stable color than the baseline product (Table 3). These two muscle areas are well known by retailers as having short color life. Thus, CO appeared to improve color life when the inherent muscle chemistry desired for color was limited.

For product from MAP, the longer the storage time, the faster the deterioration, especially at the higher storage temperature (Tables 2 and 3). For packages stored at 43°F, which was a mildly abusive temperature, color deterioration would be expected to accelerate. This phenomenon also is illustrated in Figures 1-10.

Changes in a* values (and other instrumental measures of color not shown) followed the same pattern of color deterioration observed by the visual panelists. There was no evidence that color shelf life was unexpectedly lengthened by exposure of meat to CO in MAP. The question remaining is whether the color life of product in CO masked spoilage, ie, were microbial counts higher than expected based on the degree of discoloration?

COLOR DETERIORATION AND MICROBIAL GROWTH:

Baseline Display Study: Initial, pre-display microbiological data suggested that the raw materials were fresh and processed using good hygienic practices. For intact cuts, lactic acid bacteria, generic *E. coli*, and total coliform counts were below the detection limit of 1.76 CFU/in^2. Initial, pre-display APC for intact muscles ranged from 1 to 1.63 $\log_{10}$ CFU/in^2. Post-display counts were higher ($P<0.05$) than pre-display APC which was an increase in bacterial proliferation and typical deterioration. However, all product had sufficient microbes to be susceptible to spoilage.

Baseline products were pulled from display when the visual panel scores reached ≥3.5. However, the APC did not exceed 5 $\log_{10}$ CFU/unit as shown in Figures 11-14 and lactic bacterial did not exceed 6 $\log_{10}$ CFU/unit as shown in Figures 15-18. Furthermore, off-odor scores for product at end of display (Table 3) ranged from no to slight off odor. Thus, color life in this base population did not exceed microbial soundness.

MAP Display Study: Similar trends in microbial growth occurred in post-displayed samples stored in MAP compared to baseline products. Microbial patterns for product deterioration are shown in Table 4 and Figures 11-18. Products stored under MAP at a slightly abusive temperature showed, as expected, a more rapid increase ($P<0.05$) in microbial counts compared to samples stored at 35°F. For post-MAP (pre-display) and post-display samples, APC were higher at 43°F than 35°F (Table 4), and during the later days of storage at the higher temperature, differences were more obvious. Significant changes ($P<0.05$) occurred in all cuts and ground beef with the exception of SM. Counts for the SM muscle were lower than expected and no significant changes occurring until day 35 of MAP storage. This suggests that quality products that have been handled in a sanitary fashion can be stored in the MAP system up to 35 days without comprising microbial quality. The APCs for intact strip loin and tenderloin steaks stored at 35°F were lower ($P<0.05$) on all days of display on days 21 and 35 post-MAP than steaks stored at 43°F (Figures 12 and 14). Although products did not show a difference in APCs 7 days post-MAP, those products stored at the higher temperature (43°F) were more inferior 21 and 35 days post-MAP.

Did Color Mask Spoilage? Central to this research was to evaluate the idea that the color of CO treated meat might mask spoilage. Food scientists generally agree that meat

color is seriously discolored when microbial counts approach log 10^6, and that off odors frequently appear at counts of 10^7 to 10^8. Numerous studies of ground beef, frequently the product with the highest counts, show that consumer-purchased retail product often has counts of 10^5 to 10^8.

Visual color scoring was considered as the "standard" for determining the time to remove products from display. Because the visual panel scores were the deciding factor for length of shelf life, the interdependence between visual color and APC, LAB, and odor were considered quite important.

Figures 19-21 show aerobic and lactic bacterial growth and odor scores at the end of display plotted against their corresponding visual color scores. All data observations were summed over storage temperature, storage time, and product type and plotted in one graph. If color masked spoilage, then there should be multiple points in the upper left quadrant of the plot, the area represented by unacceptable microbial counts and off odors but with acceptable color (i.e., scores <3.5). This did not occur with any frequency in any of the three plots. Thus, it does not appear that exposure of meat to CO during extended (up to 35 days at either 35° or 43°F) caused meat color to hide spoilage.

Table 1 - Carbon Dioxide (CO_2) and Oxygen (O_2) Levels in MAP Packages of ground beef (GB) and steaks from strip loins (LD), inside round (SM), and tenderloin (TL).

Meat Cut	Storage Temperature, °F	Storage Time, days	CO_2, %	O_2, %
GB	35	7	28.4	0
GB	43	7	28.7	0
GB	35	14	27.7	0
GB	43	14	28.3	0
GB	35	21	27.4	0
GB	43	21	28.0	0
LD	35	7	33.3	0
LD	43	7	34.2	0
LD	35	21	32.4	0
LD	43	21	31.8	0
LD	35	35	31.1	0
LD	43	35	28.5	0
SM	35	7	28.9	0
SM	43	7	29.7	0
SM	35	21	27.9	0
SM	43	21	27.3	0
SM	35	35	26.8	0
SM	43	35	24.6	0
TL	35	7	34.3	0
TL	43	7	34.8	0
TL	35	21	33.6	0
TL	43	21	32.3	0
TL	35	35	32.5	0
TL	43	35	29.2	0

Table 2 - Means for initial visual color and a* values for beef cuts exposed to carbon monoxide during storage at 35°and 43°F in Active Tech MAP vs. baseline cuts exposed only to oxygen.

Trait	Product	Baseline cuts	Time[d] in Active Tech MAP, days at 35° F		
			7	14 / 21	21 / 35
Initial Visual Color	GB	1.3a	1.6b	1.7b	1.8b
	LD	2.2b	2.5b	1.8a	2.2b
	ISM	1.8ab	2.0b	1.7a	2.0b
	OSM	2.6b	2.6b	1.9a	2.5b
	TL	1.9a	2.0a	1.9a	2.1a
Initial a* Values (redness)	GB	23.4a	25.6b	25.9b	25.6b
	LD	25.8a	25.7a	27.1ab	28.1b
	ISM	28.5a	26.9a	30.0a	29.4a
	OSM	27.4a	27.7a	29.8a	29.5a
	TL	23.6a	27.5b	30.0c	29.3c
			Time[d] in Active Tech MAP, days at 43° F		
Initial Visual Color	GB	1.3a	1.7b	1.8b	2.5c
	LD	2.2a	2.3a	2.1a	2.0a
	ISM	1.8a	1.8a	1.7a	2.4b
	OSM	2.6b	2.2a	2.2a	2.0a
	TL	1.9a	2.0ab	1.8a	2.2b
Initial a* Values (redness)	GB	23.4a	25.7b	25.1b	25.5b
	LD	25.8a	25.5a	28.7b	27.5b
	ISM	28.5a	28.7a	28.6a	27.5a
	OSM	27.4a	27.7a	30.2b	29.4ab
	TL	23.6a	27.8b	28.7b	26.4b

[a-c] Means in the same row with a different letter differ ($P<0.05$).

[d] Ground beef stored 7, 14, and 21 days, other muscles 7, 21, and 35 days.

Table 3 - Means for days to visual unacceptable visual color (score of 3.5) and odor at end of display for beef cuts exposed to carbon monoxide during storage at 35° and 43°F in Active Tech MAP vs. baseline cuts exposed only to oxygen.

Trait	Product	Baseline cuts	Time[e] in Active Tech MAP, days at 35° F		
			7	14 / 21	21 / 35
Days in display to unacceptable color	GB	3.6c	3.0b	3.0b	2.3a
	LD	6.2c	5.0b	5.2b	3.8a
	ISM	3.2a	4.8c	4.0bc	3.5ab
	OSM	4.8c	3.5b	3.4b	2.6a
	TL	2.6a	3.0b	3.2b	2.8ab
			Time[e] in Active Tech MAP, days at 43° F		
Days in display to unacceptable color	GB	3.6d	3.0cd	2.3b	1.5a
	LD	6.2d	5.0c	3.3b	2.3a
	ISM	3.2b	4.0bc	3.1b	2.0a
	OSM	4.5d	3.0c	2.4b	1.6a
	TL	2.6ab	3.0b	2.3ab	1.7a
			Time[e] in Active Tech MAP, days at 35° F		
Off-odor score[f] at end of display	GB	1.5a	1.9a	2.8b	2.4ab
	LD	1.3a	1.3a	2.3b	2.3b
	SM	1.5a	2.2a	3.0b	3.0b
	TL	1.6a	1.2a	3.1b	3.3b
			Time[e] in Active Tech MAP, days at 43° F		
Off-odor score[f] at end of display	GB	1.5a	3.3a	3.6a	3.9a
	LD	1.3a	2.9a	3.3ab	3.6b
	SM	1.5a	2.2a	3.4b	4.0b
	TL	1.6a	2.7a	3.3b	3.8c

[a-d] Means in the same row with a different letter differ ($P<0.05$).

[e] Ground beef stored 7, 14, and 21 days, other muscles 7, 21, and 35 days.

[f] Off-odor scale: 1 = none, 2 = slight, 3 = Small, 4 = Moderate, 5 = Extreme.

Table 4 - Means for aerobic plate counts (APC) on beef cuts exposed to carbon monoxide during storage at 35°and 43°F in Active Tech MAP vs. baseline cuts exposed only to oxygen.

Trait	Product	Baseline cuts	Time[e] in Active Tech MAP, days at 35° F		
			7	14 / 21	21 / 35
End of MAP storage APCs, log 10 cfu	GB	2.7a	2.6a	4.7b	5.5b
	LD	.7ab	0.2a	1.4bc	1.7c
	SM	1.0b	0.3a	0.3a	0.3a
	TL	1.3b	0.2a	2.6bc	3.1c
End of display APCs, log 10 cfu	GB	4.3a	4.4ab	5.6b	5.5b
	LD	1.4ab	0.4a	2.9bc	3.4c
	SM	0.6a	0.1a	0.6a	2.0b
	TL	0.3a	1.3b	3.5c	3.4c
			Time[e] in Active Tech MAP, days at 43° F		
End of MAP storage APCs, log 10 cfu	GB	2.7a	4.6b	5.8c	6.0c
	LD	0.7a	1.3ab	3.2c	5.1d
	SM	1.0b	0.1a	0.1a	2.8c
	TL	1.3a	1.6a	3.7b	4.0b
End of display APCs, log 10 cfu	GB	4.3a	5.8b	5.9b	6.1b
	LD	1.4a	1.3a	2.8b	5.3c
	SM	0.6a	0.3a	0.7a	2.5b
	TL	0.3a	3.3b	4.2b	4.6b

[a-d] Means in the same row with a different letter differ ($P<0.05$).

[e] Ground beef stored 7, 14, and 21 days, other muscles 7, 21, and 35 days.

Figure 6
Ground Beef a* Values (Redness) Deterioration During Display Following Storage

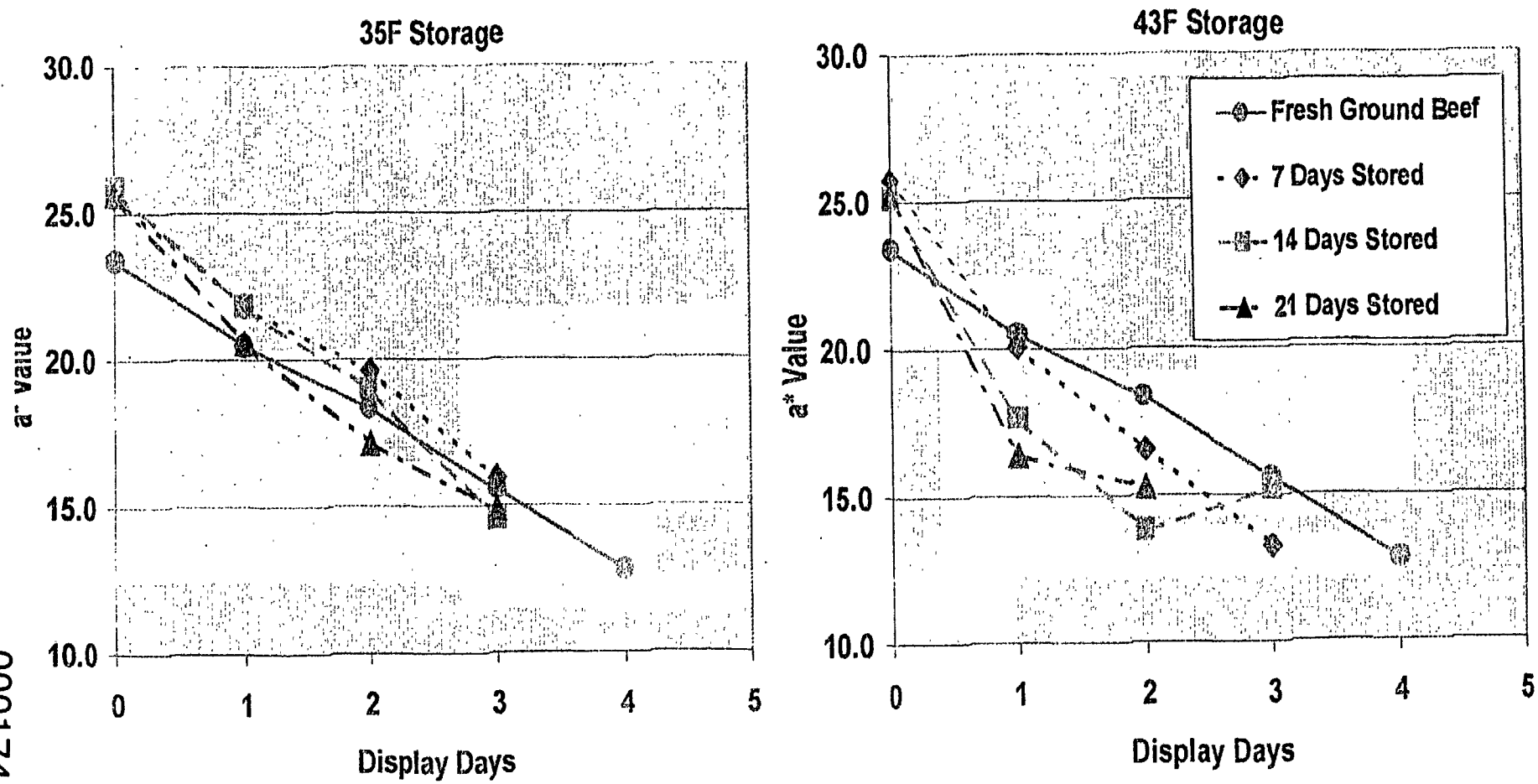


Figure 7
Strip Loin a* Values (Redness) Deterioration During Display Following Storage

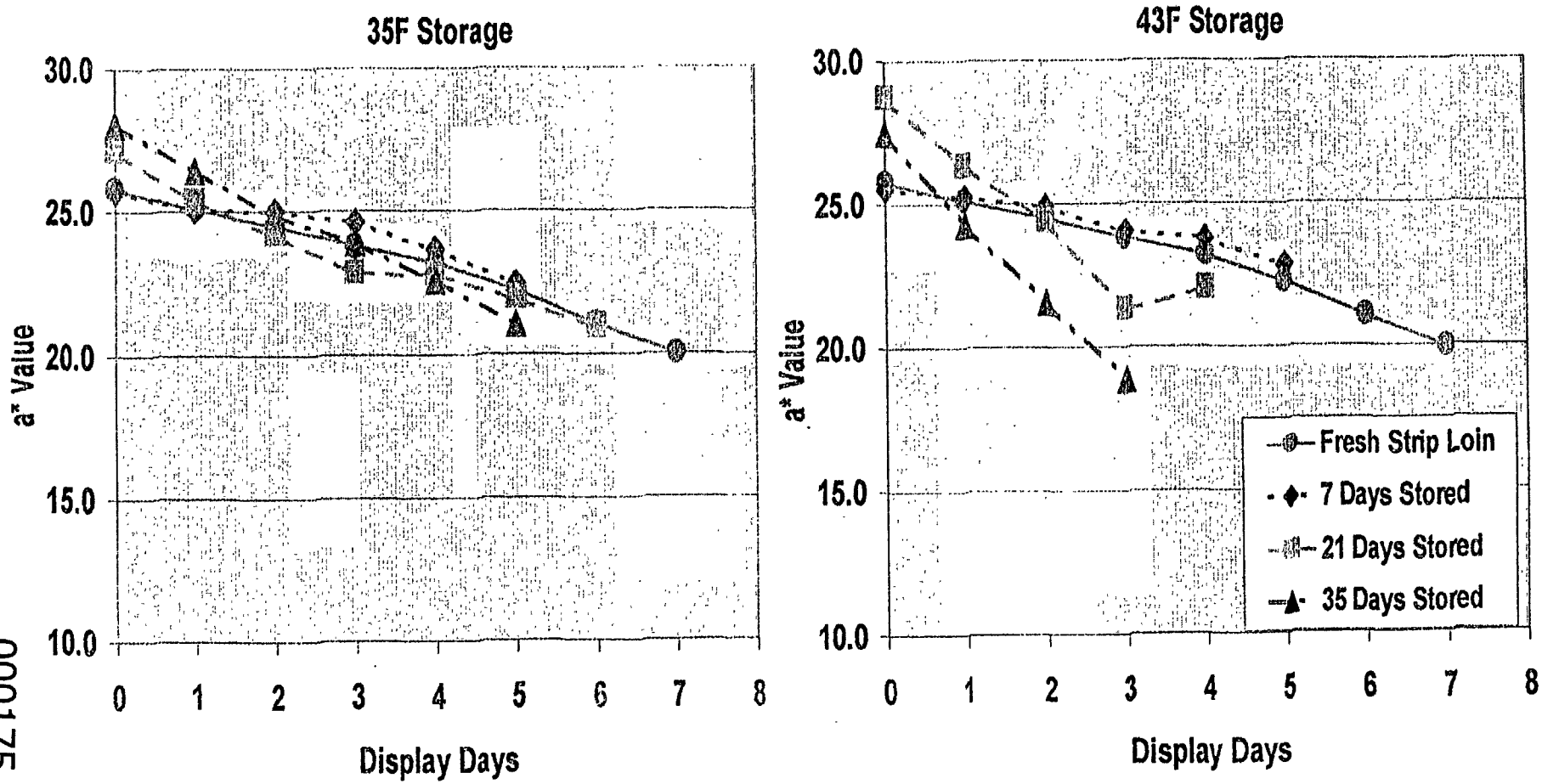


Figure 8
Inside Round (inside portion) a* Values (Redness) Deterioration During Display Following Storage

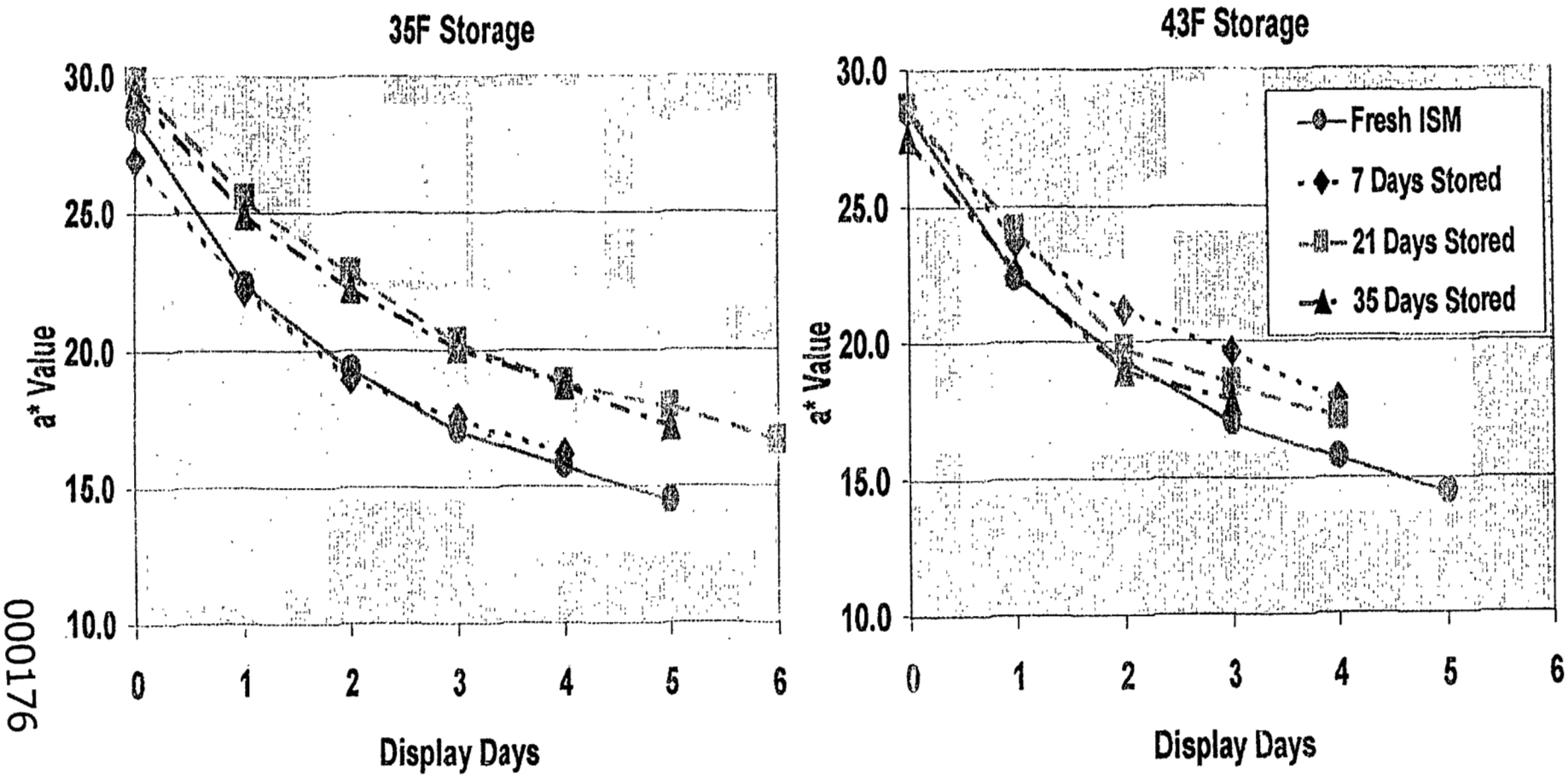


Figure 9
Inside Round (outside portion) a* Values (Redness) Deterioration During Display Following Storage

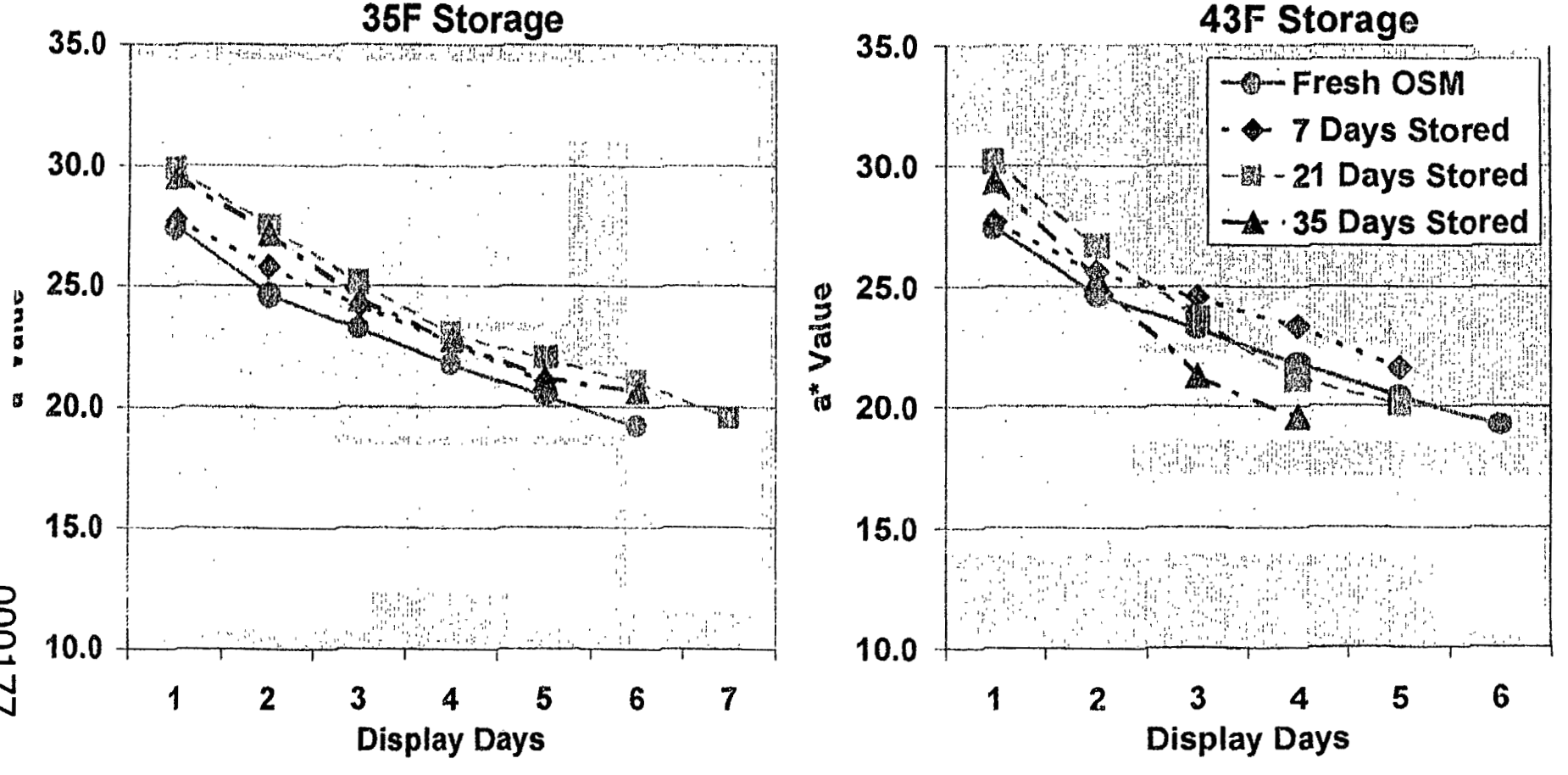


Figure 10
Tenderloin a* Values (Redness) Deterioration During Display Following Storage

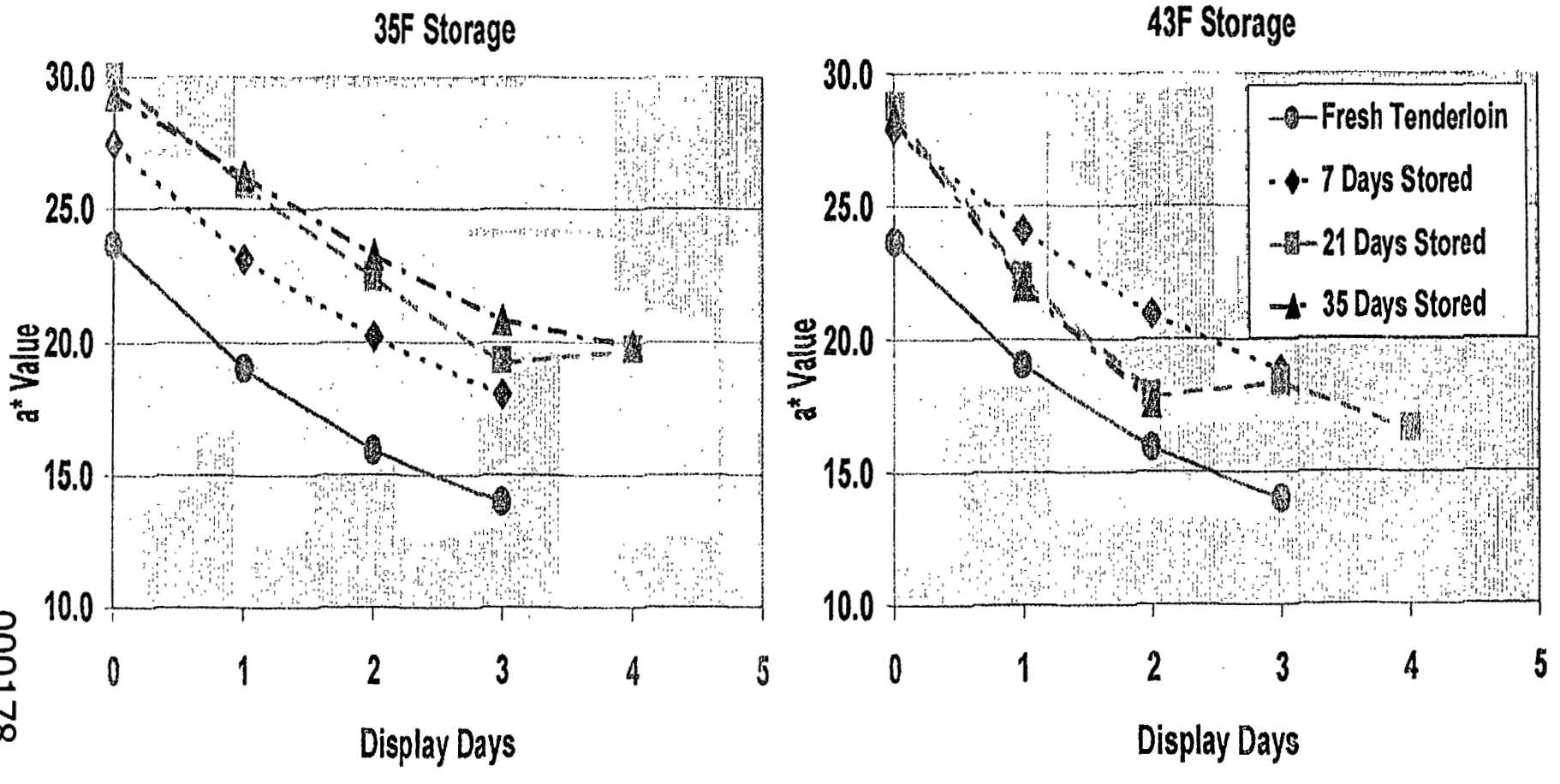


Figure 11
Ground Beef Total Aerobic Plate Counts During Display Following Storage

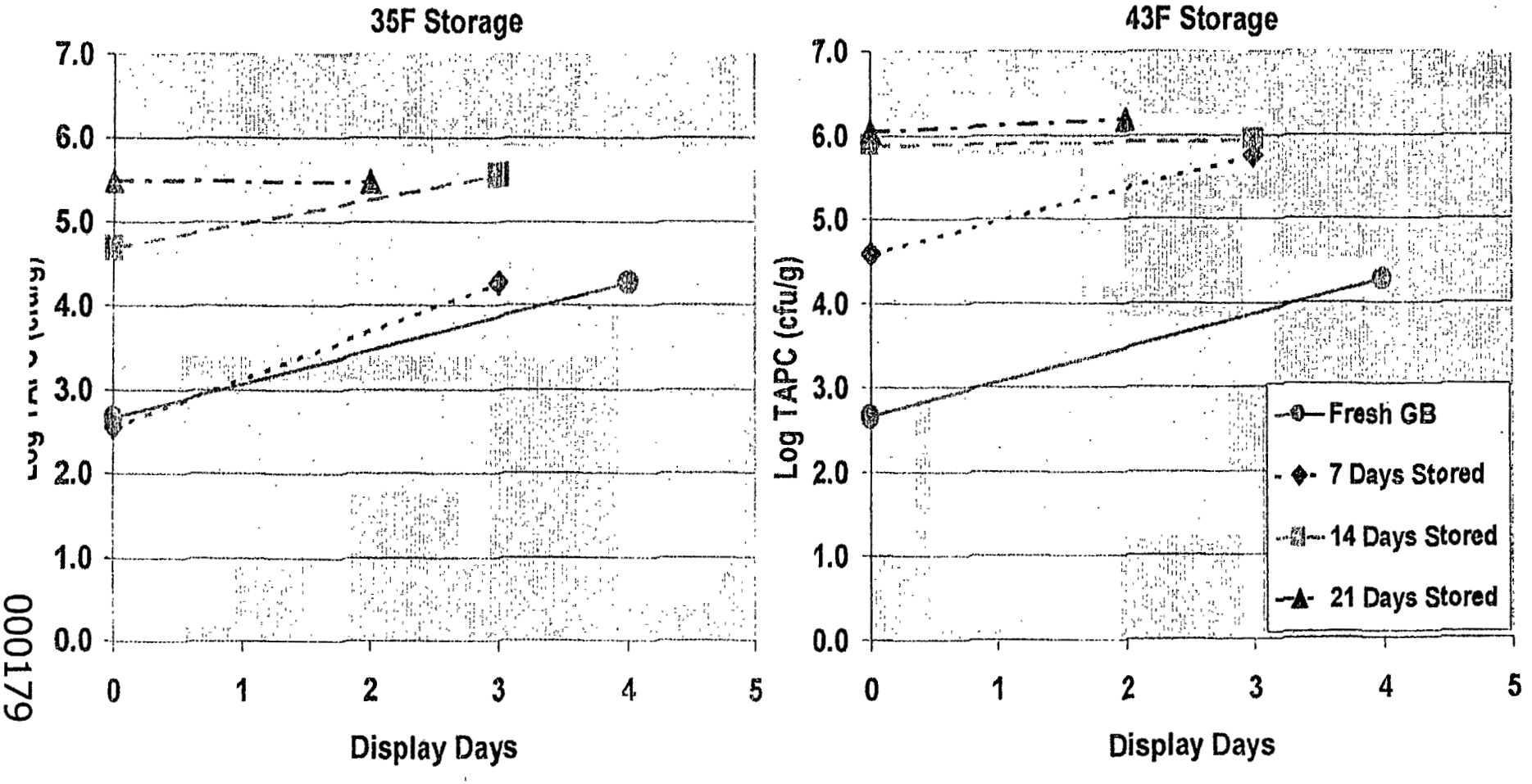


Figure 12
Strip Loin Total Aerobic Plate Counts During Display Following Storage

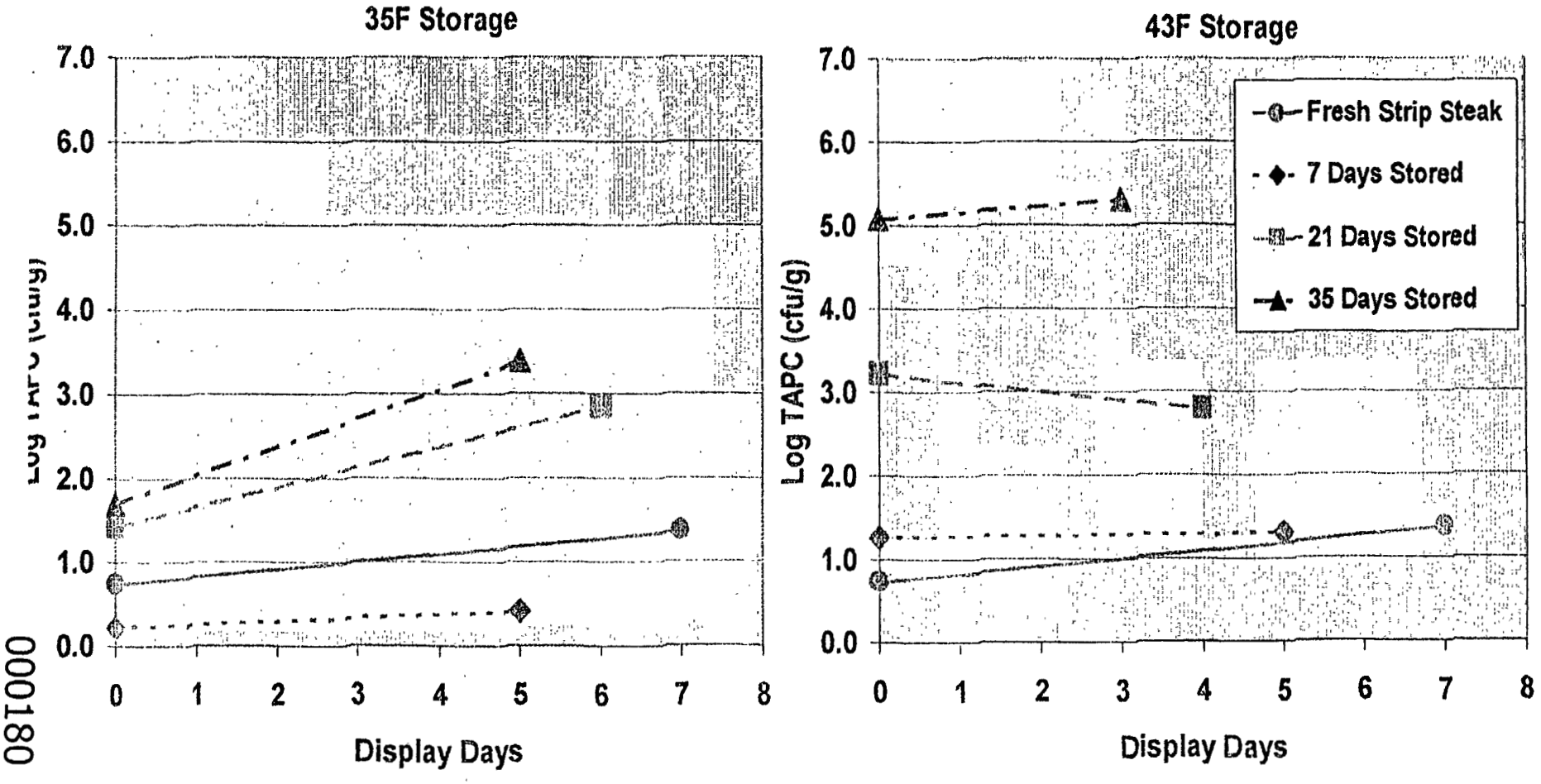


Figure 13
Inside Round Total Aerobic Plate Counts During Display Following Storage

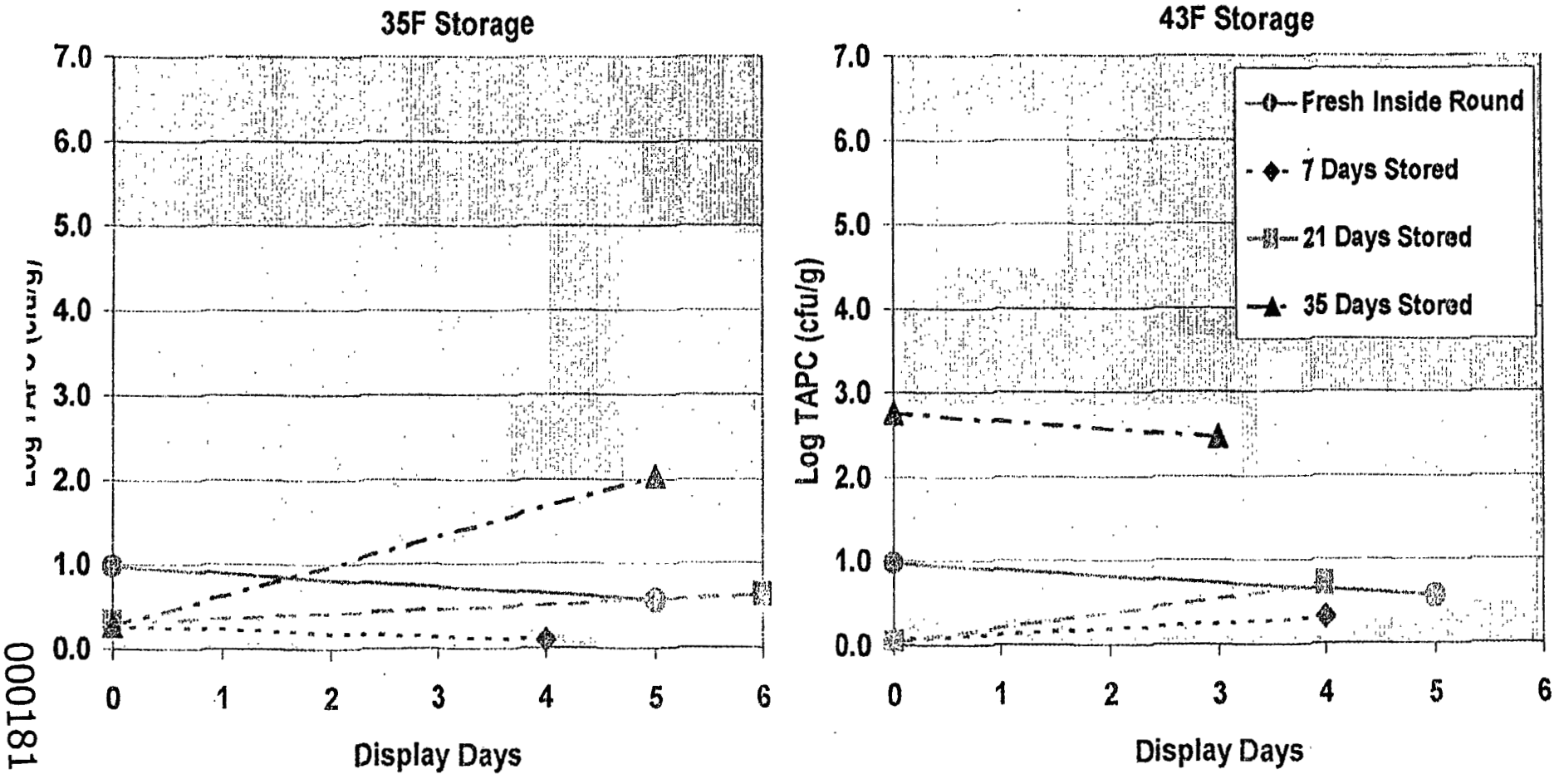


Figure 14
Tenderloin Total Aerobic Plate Counts During Display Following Storage

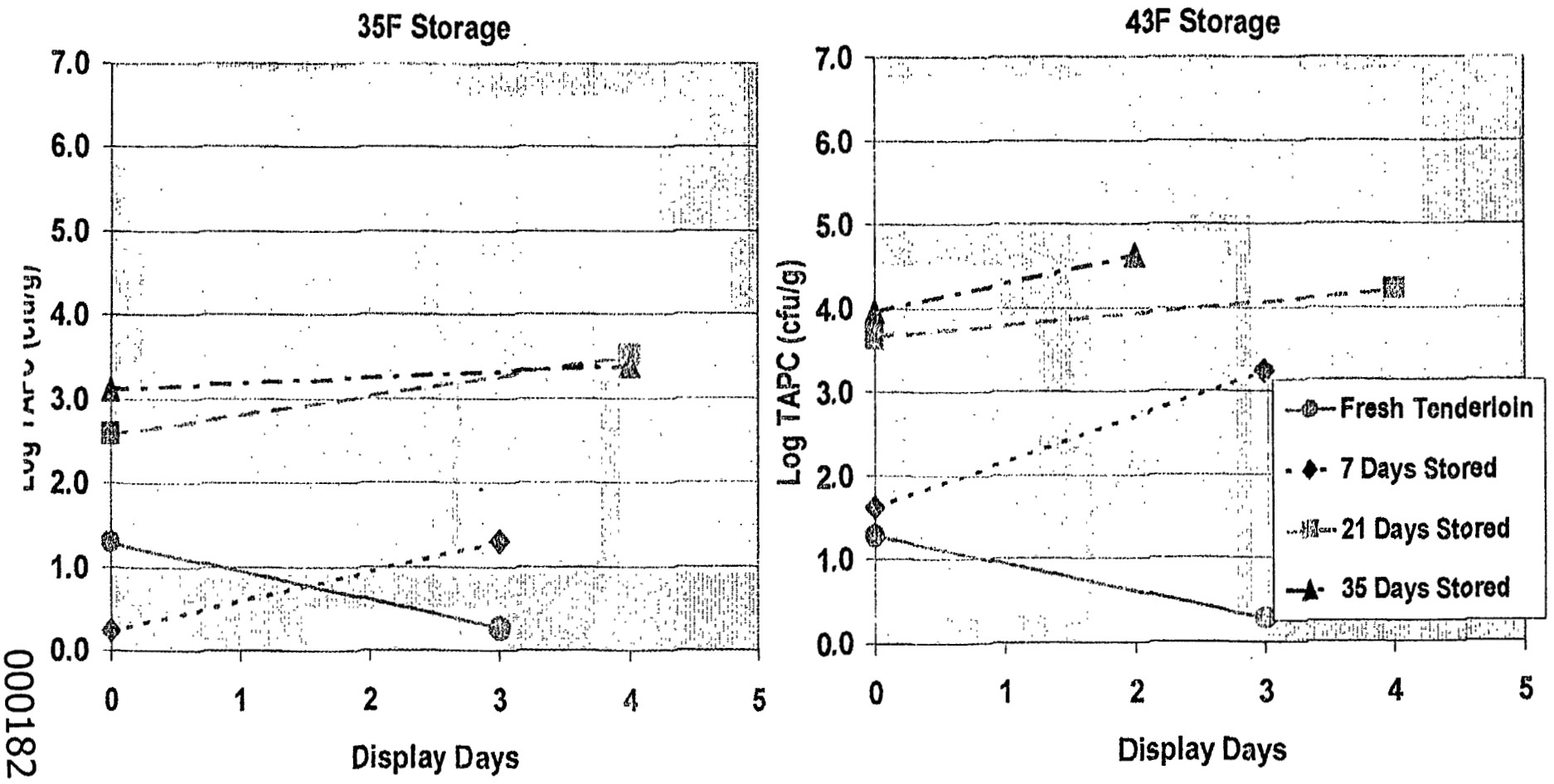


Figure 15
Ground Beef Lactic Acid Bacteria During Display Following Storage

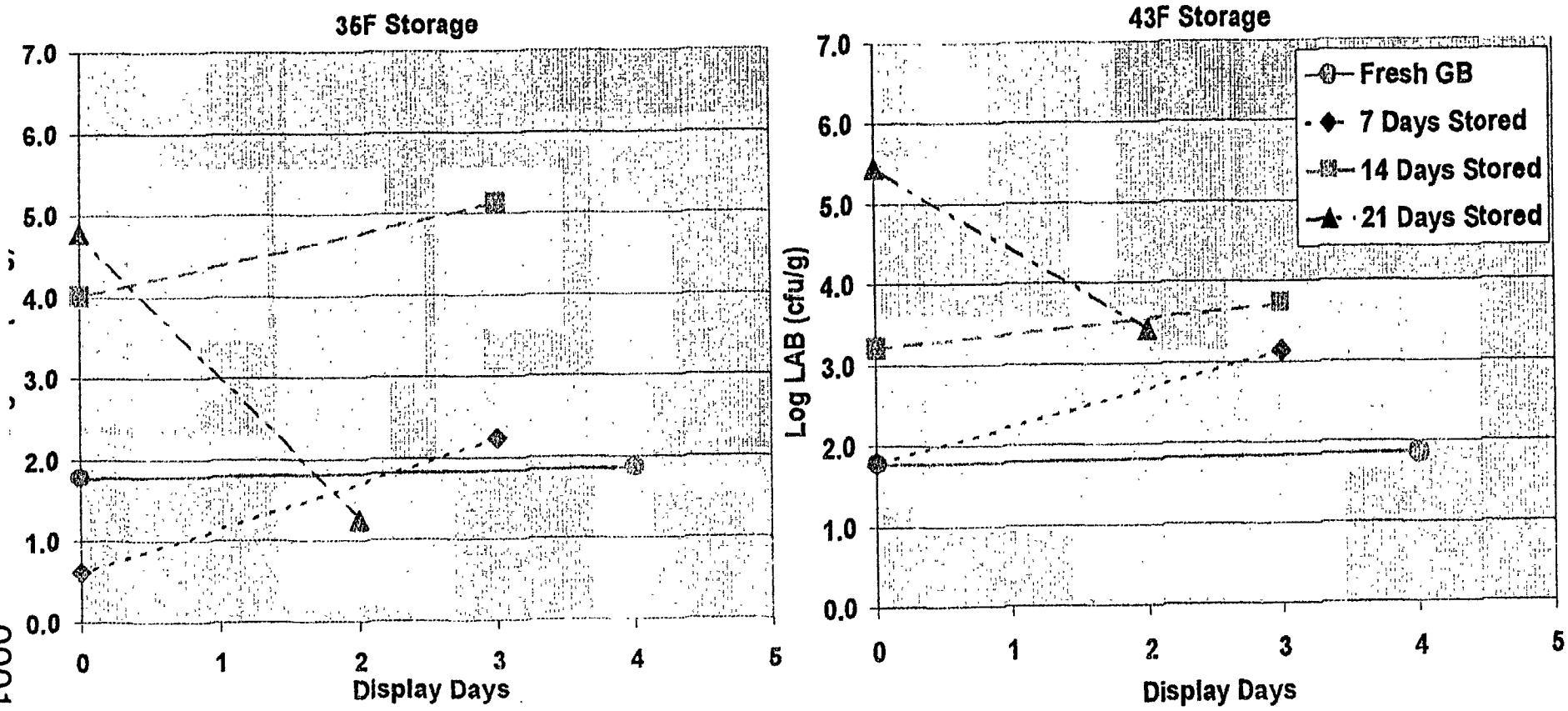


Figure 16
Strip Loin Lactic Acid Bacteria During Display Following Storage

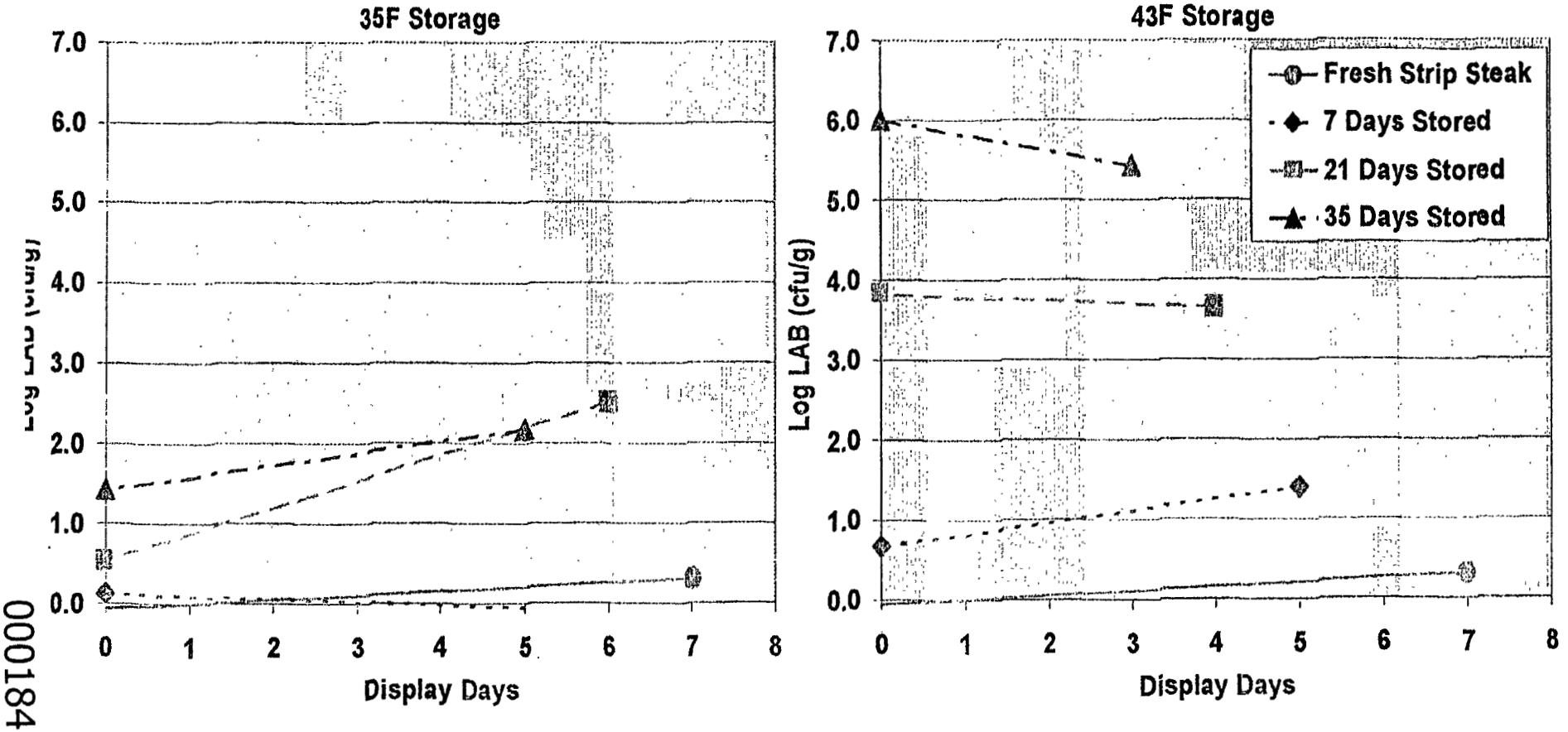


Figure 17
Inside Round Lactic Acid Bacteria During Display Following Storage

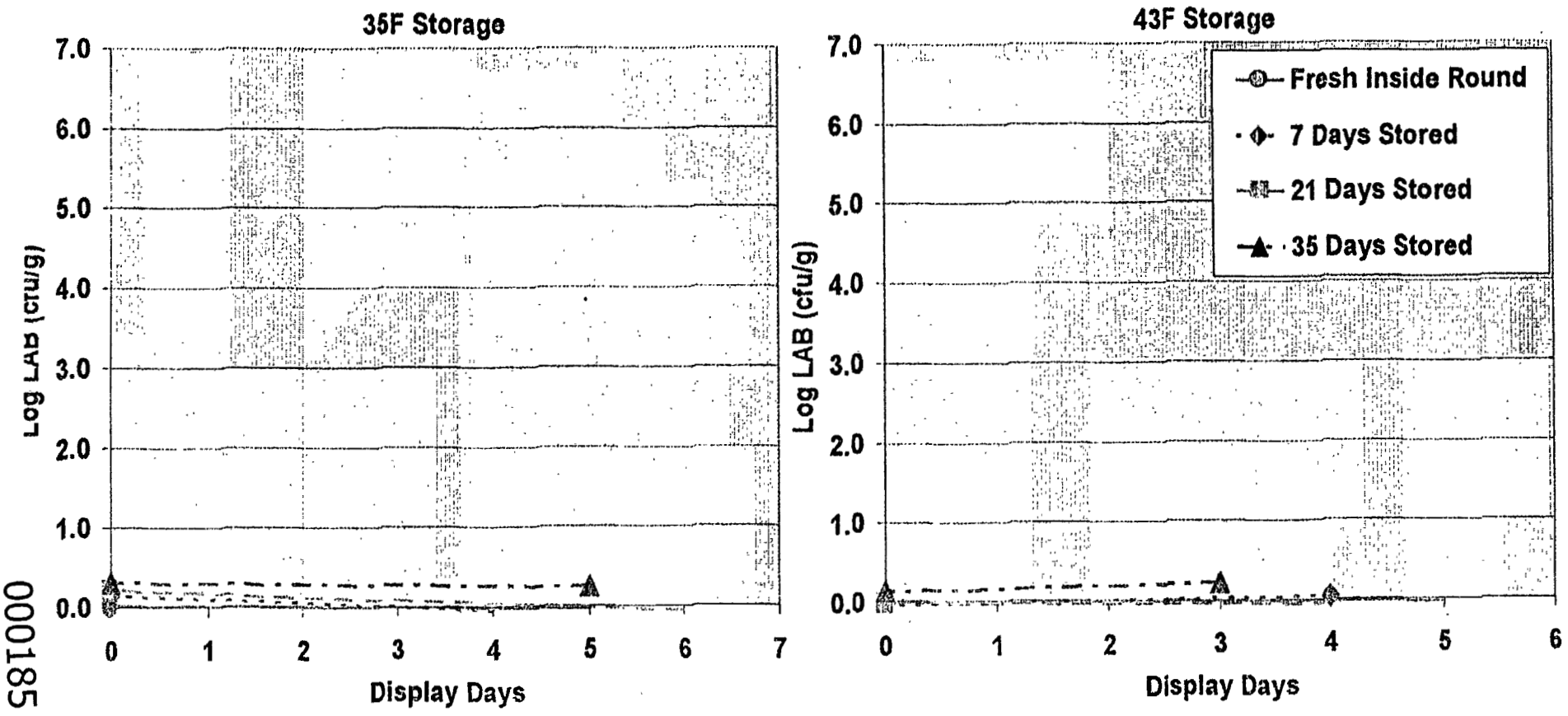


Figure 18
Tenderloin Lactic Acid Bacteria During Display Following Storage

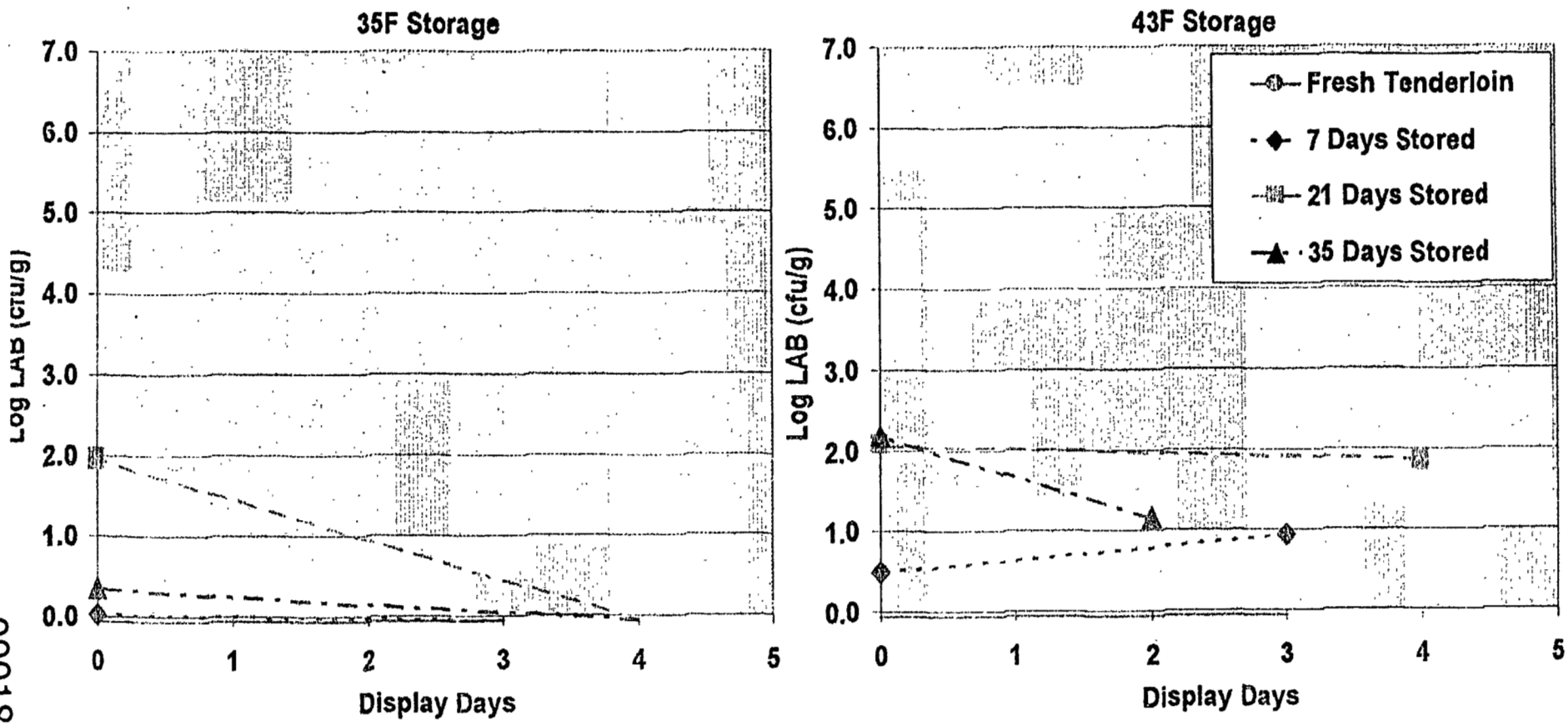


Figure 19
Aerobic Plate Count Log_{10} CFU vs Visual Color

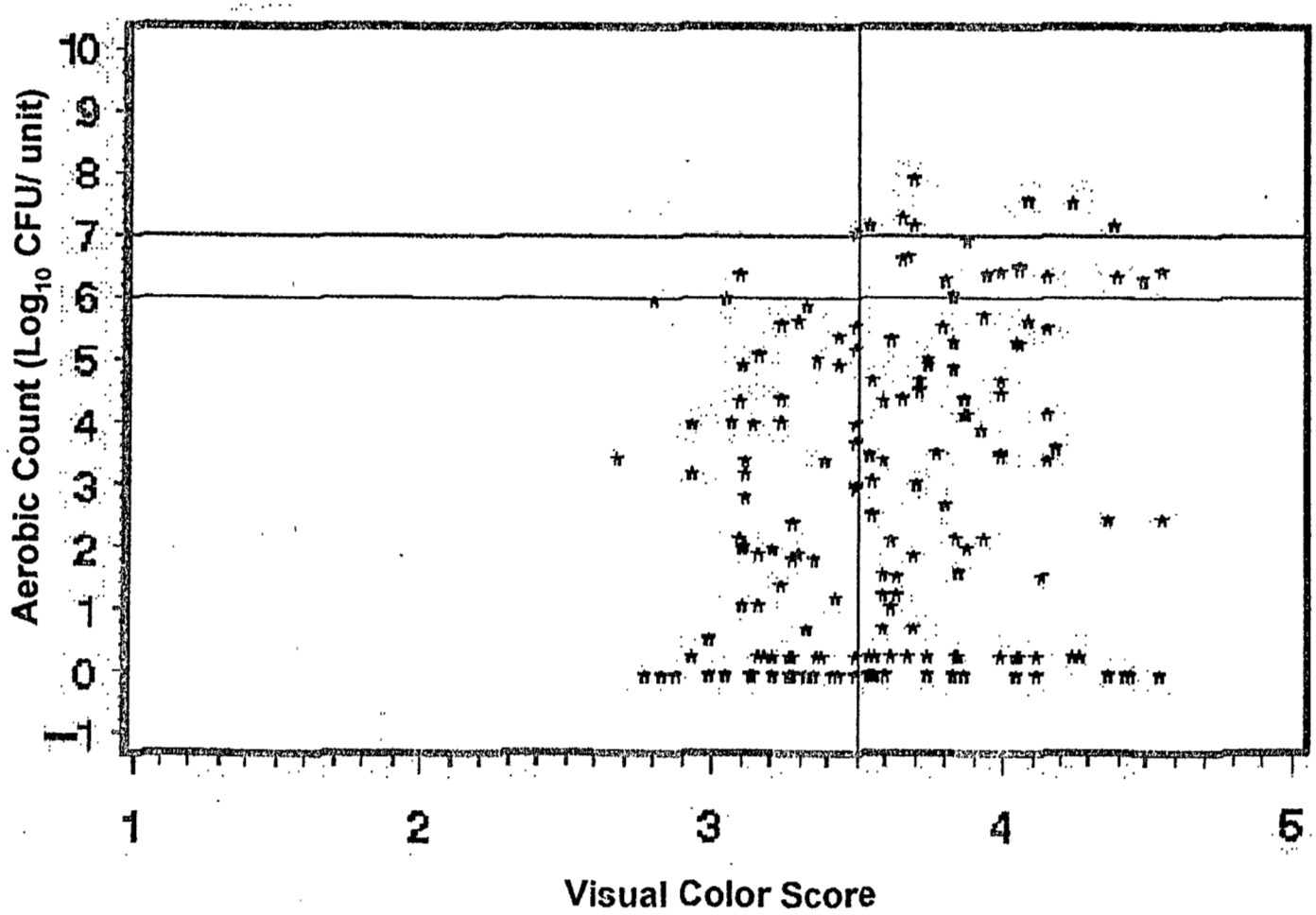


Figure 20
Lactic Acid Bacteria Count Log_{10} CFU vs Visual Color

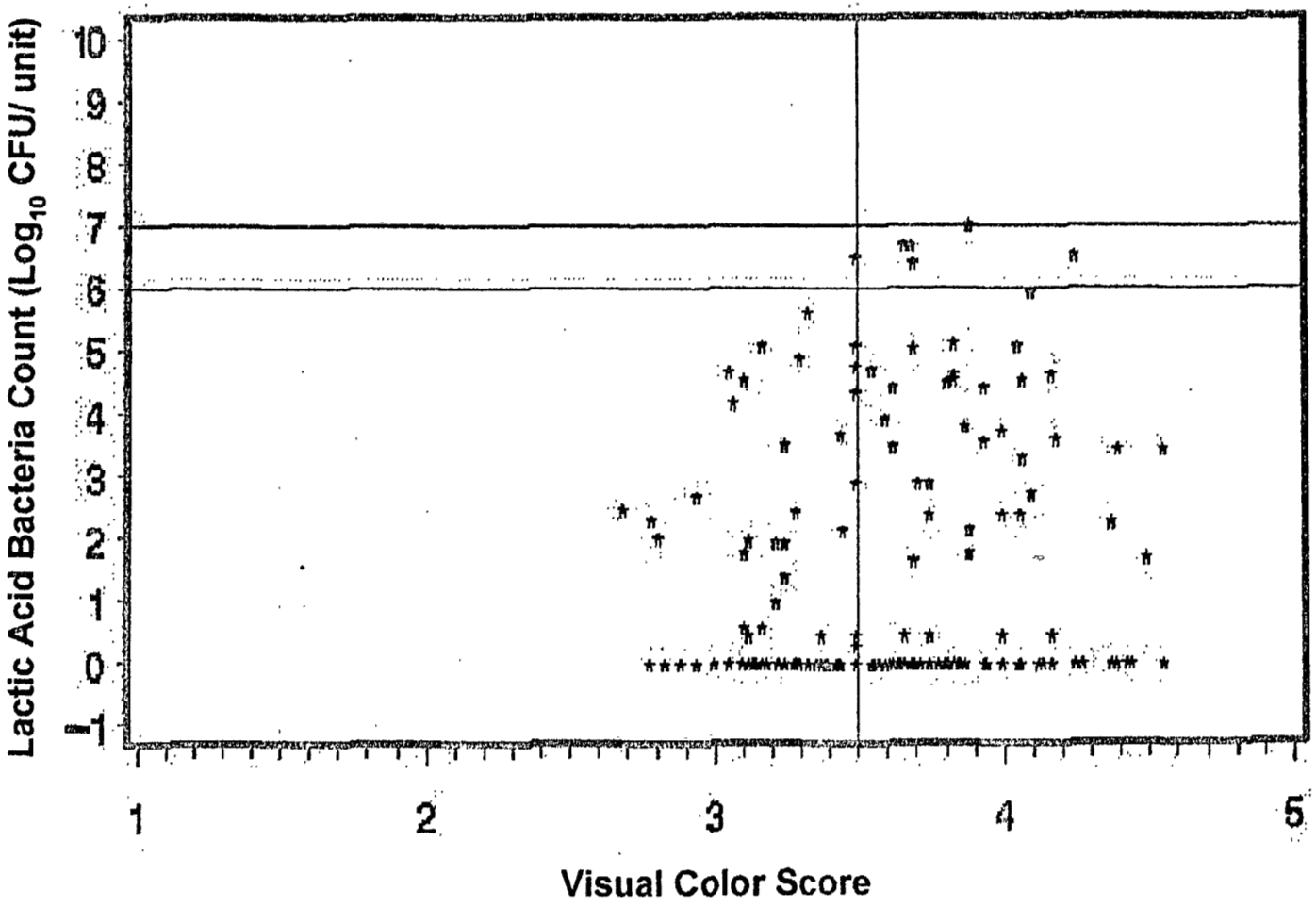
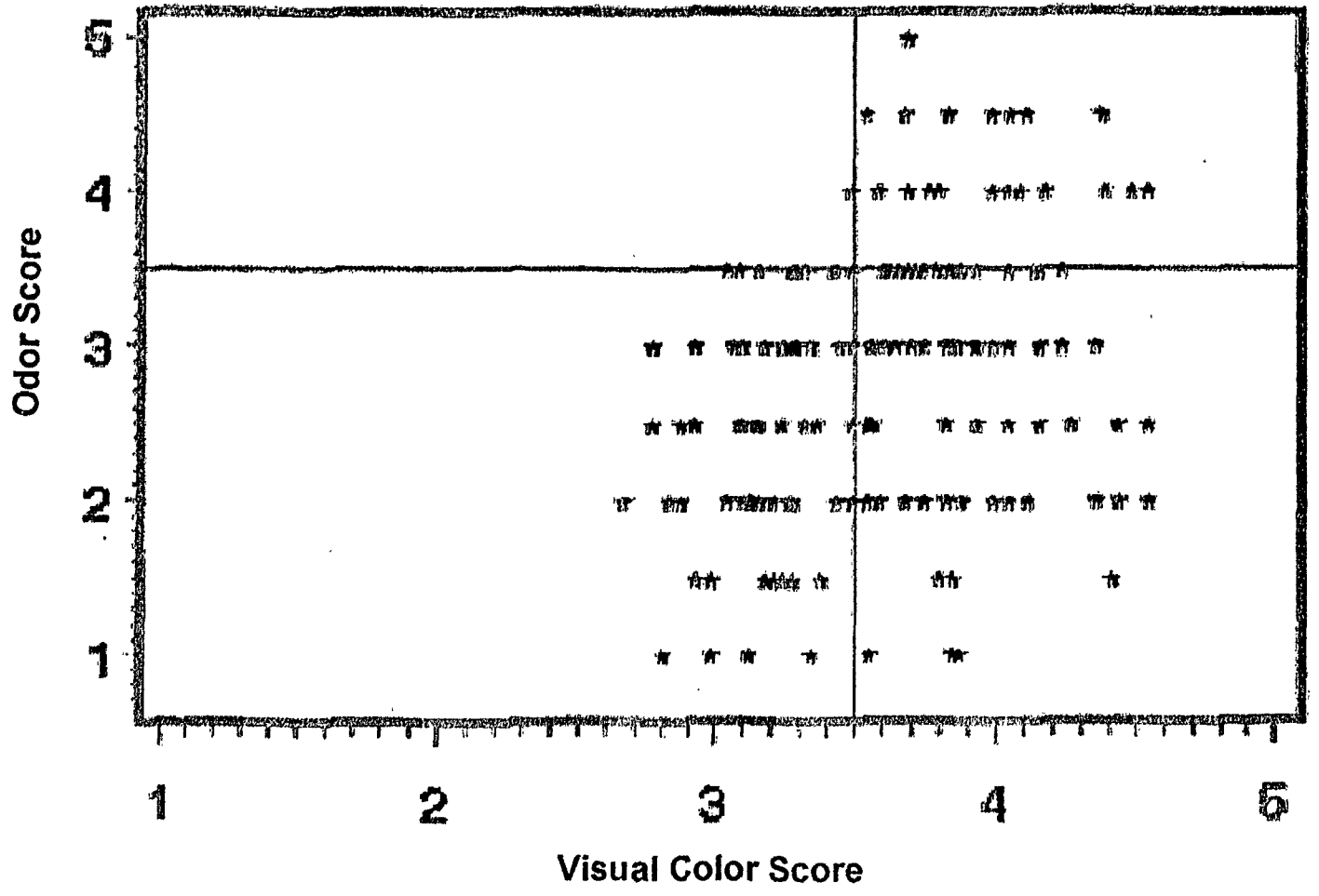


Figure 21
Odor vs. Visual Color



ATTACHMENT 5

HAUN
WELDING SUPPLY, INC.
SPECIALTY GASES DIVISION

Certificate of Conformance

6000 COURT STREET ROAD
SYRACUSE, NEW YORK 13206
(315) 463-5241

6670 MARTIN STREET
ROME, NEW YORK 13440
(315) 339-3378

214 NORTH FOURTH STREET
FULTON, NEW YORK 13069
(315) 592-6012

23791 STATE ROUTE 12
WATERTOWN, NEW YORK 13601
(315) 785-5438

10149 STATE HIGHWAY 56
MASSENA, NEW YORK 13662
(315) 764-8728

311 CLARK STREET
AUBURN, NEW YORK 13021
(315) 252-5338

1 LEE STREET
UTICA, NEW YORK 13502
(315) 724-3382

417 COMMERCE ROAD
VESTAL, NEW YORK 13850
(607) 797-6348

1446 MILITARY TURNPIKE
PLATTSBURGH, NEW YORK 12901
(518) 563-1240

5 GREGORY DRIVE
SOUTH BURLINGTON, VT 05403
(802) 862-4572

48 DORAN AVENUE
GENEVA, NEW YORK 14456
(315) 781-6880

Customer: Pactiv Packaging

Material Submitted: Carbon Monoxide, Research Purity 99.99% min.

Date Reported: 05/08/01

Component	Specification
Carbon Monoxide	99.99% min.
Oxygen	≤ 0.5 PPM
Nitrogen	≤ 10 PPM
Carbon Dioxide	≤ 20 PPM
Methane	≤ 5 PPM
Ethane	≤ 1 PPM
Propane	≤ 1 PPM
Dimethyl Ether	≤ 1 PPM
Hydrogen	≤ 1 PPM
Moisture	≤ 1 PPM

Note: Analysis are conducted utilizing approved analytical method (s) and are correct to within the analytical accuracies of this (these) method (s).

Quality Control Approved _____ 05-08-01

CONSISTENLY FULFILLING CUSTOMER'S EXPECTATIONS THROUGH INNOVATIVE SOLUTIONS AND TEAMWORK

ATTACHMENT 6

Pages 000194 - 000197 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

ATTACHMENT 7

Utah State
UNIVERSITY

DEPARTMENT OF NUTRITION AND FOOD SCIENCES
College of Agriculture
College of Family Life
Logan, UT 84322-8700
Telephone: (435) 797-2126
FAX: (435) 797-2379

Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St, SW
Washington, DC 20204

August 17, 2001

Dear FDA Personnel,

I am a meat scientist with experience in studying the effects on fresh meats of various modified atmospheres. Based on my review of the details of the ActiveTech 2001 modified atmosphere system employing 0.4% carbon monoxide gas in a mixture with 60 percent carbon dioxide and the remainder nitrogen, as well as the published literature and common knowledge in the field, I confirm that the use of modified atmospheres including 0.4% CO to package fresh meats as used in the ActiveTech 2001 system is both safe and generally recognized as safe. If I can provide any further information or clarification, please contact me.

Sincerely yours,

Daren Cornforth, Ph.D.
Professor, Nutrition & Food Sciences
Utah State University
435-797-2114
darenc@cc.usu.edu

000200

[redacted]

Daren Cornforth, Ph.D.

Birthdate: May 23, 1949 Birthplace: Fort Collins, Colorado

Current Address: Department of Nutrition and Food Sciences
Utah State University
Logan, Utah 84322-8700
(435) 797-2114 fax (435) 797-2379
e-mail darenc@cc.usu.edu

Education

Institution	Degree	Year Conferred	Scientific Field
Colorado State University	B.S.	1971	Animal Science
Colorado State University	M.S.	1973	Animal Science
Michigan State University	Ph.D.	1978	Food Science & Human Nutrition

Research and Professional Experience

Dates	Position	Duties
1978 to present	Asst., Assoc., Full Prof., NFS	Teaching/Research, Meat Processing
1974 to 1978	Graduate Research Assistant at Michigan State University East Lansing, Michigan	Dissertation on cold- induced shortening and toughening of beef muscle.
1971 to 1973	Graduate Research Assistant at Colorado State University Fort Collins, Colorado	Thesis on the effects of breed, sex, and diet on muscle fiber type and fat cell development in growing calves.

Memberships

Institute of Food Technologists, Amer. Assoc. for the Advancement of Science, Sigma Xi (Past President, USU Chapter), American Meat Science Association, Farm House Fraternity, Rocky Mountain Elk Foundation (Life Member), Pheasants Forever, Nature Conservancy, Cache Valley Wildlife Federation (and on Executive Board).

Current Teaching Assignment

NFS 5560	Chemistry of Food Systems
NFS 6450	Meat Science
NFS 1000	World of Food and Nutrition

I also assist with the NFS Food Science Club College Bowl team, and coordinate (with Dr. Carpenter) the Utah Future Farmers of America (FFA) state contest in Food Science and Technology.

Invited Speaker (1997-2001)

Cornforth, D. P. 1997. *Pigment concentration and pH effects on degree of doneness of beef patties.* FMC Corporation. Atlanta, Ga, January, 1997.

Cornforth, D. P. 1997. *Nitrogen dioxide causes surface pinking on meats cooked in gas ovens.* Meat Industry Meat Conf. Chicago, IL, Oct 28-29.

Cornforth, D. P., Jiang, C. and Mumford, B. 1998. *Effect of storage time, storage and cooking temperature, and holding time after cooking on pigment levels in beef patties.* Symposium, New Developments in Meat Processing, Amer. Meat Sci. Assn. National Meeting, Storrs, CT., June 28-July 2.

Cornforth, D. P. 2000. Keynote speaker. *Pinking in Cooked Poultry. Current situation and general theories.* Given at the Symposium on Pinking in Cooked Poulty, Center for Excellence in Poultry Science, University of Arkansas, Fayetteville, Oct 12-13, 1999. Co-sponsored by Tyson Foods, NewlyWed Foods, and KFC, Inc.

Cornforth, D. P. 2000. *Pinking in Cooked Poultry.* Michigan State University, E. Lansing, MI, Nov. 7.

Cornforth, D. P. 2000. *Pinking in Cooked Poultry.* Michigan Turkey Processors, Zeeland, MI, Nov. 8.

Cornforth, D. P. 2001. *Meat Color.* Dinner speaker for the joint meeting of the Southern Minnesota section of IFT and the Meat Processing Short Course sponsored by the Agricultural Utilization Research Institute, Southwest State University, Marshall, MN, April 25.

National Offices and Committees (1997-2001)

USDA Advisory Committee for the Safe Preparation of Ground Beef - 1997-8.

AMSA (American Meat Science Association)
Graduate Student Poster Competition committee, Reciprocal Meat Conference, 1998-2002.

Executive Board 2000-2002.

IFT Executive Committee, Muscle Foods Division, Institute of Food Technologists, 1998-99.

Chair-Elect, Muscle Foods Division, 2000-2001.

Chair, Muscle Foods Division, 2001-2002.

Executive Council, Bonneville Section, IFT (Councilor representing Bonneville Section at National Meetings), 1998-99.

Journal of Muscle Foods – Editorial Board, 1998-2002

University Committee Assignments

Committee for Laboratory Safety. 1997-2001.
Faculty Senate, 2000 – 2003.
Faculty Senate Executive Committee 2000 – 2001.

Grants (1997-2001)

Cornforth, D. P. 1997-98. Factors affecting hamburger degree of doneness. McDonald's Corp. Oak Brook, IL. $8,480.

Cornforth, D. P. 1998. Evaluation of various dairy fractions as inhibitors of lipid oxidation in precooked meats. Western Dairy Foods Center, Logan, UT, $9,560.

Cornforth, D. P. 1999. Verification of nutritent label claims on lowfat milk, lean hamburger, and breakfast cereals. Dr. Alan Luke (Alumni Donor), $1,500.

Cornforth, D. P. and Carpenter, C. E. 1999-2000. Evaluation of carbon monoxide treatment in modified atmosphere or vacuum packaging to increase color stability of fresh beef. National Cattlemen's Beef Association, $14,500.

Carpenter, C.E. and Cornforth, D. P. 1999-2000. Effect of consumer bias for beef color and packaging on eating satisfaction. National Cattlemen's Beef Association, $15,000.

Cornforth, D. P. 1999-2002. Evaluation of antioxidant properties of milk powders in cooked meats. Glanbia Foods, Twin Falls, ID. $30,000.

Cornforth, D. P. 2000-2002. New antioxidants in cooked meats. Utah Agric. Exp. Stat. $15,000.

Bailey, D. and Dickinson, D. (Cornforth, D.P., co-investigator). 2001-2003. Traceability: A market opportunity or threat to the US meat industry. USDA-CREES. $160,000.

Cornforth, D. P. 2001-2002. Dried whey minerals as an antioxidant in processed meats. Dairy Management Institute (DMI). $97,500.

Graduate Committees Chaired (1997-2001)

Heaton, K. M. 1998. Minimum levels of nitrite, nitric oxide, and carbon monoxide causing pinking in cooked beef and turkey rolls. M. S. thesis, Utah State University, Logan, Utah. (Now Extension Agent, Garfield & Kane Counties, Utah).

Moiseev, I. V. 1998. Prevention of pink discoloration and microbial safety of rolls and patties made from dark-cutting beef, PhD dissertation, Utah State University, Logan, Utah. (Now lab chemist, Borden Foods, Columbus, OH).

Racz, J. M. 1998. An inoculated pack study using *Clostridium sporogenes* PA 3679 to determine the shelf stability of a vacuum packaged meat/vegetable stick. M. S. thesis, Utah State University, Logan, Utah. (Now lab chemist, Fresenius Medical, Ogden, UT).

Jayasingh, P. 2001. Dried milk minerals as an antioxidant in processed meats. Ph.D. dissertation, Utah State University, Logan, Utah (work in progress).

Product Development and Extension

Stew Sticks are currently in retail production by Utah Jerky, Inc., Ogden, UT.

Cornforth, D. P., Bailey, D., and McEvoy, R. 1997. Developed a video of ostrich slaughter and processing, used by the new plant in Filmore, UT for employee training, and also used by USU extension agents.

Refereed Publications (1997-2001)

Moiseev, I. V. and Cornforth, D. P. 1997. Sodium hydroxide and sodium tripolyphosphate effects on bind strength and sensory characteristics of restructured beef rolls. Meat Sci. 45:53-60.

Quinton, R. D., Cornforth, D. P., Hendricks, D. G., Brennand, C. P. and Su, Y. K. 1997. Acceptability and composition of some acidified meat and vegetable stick products. J. Food Sci. 62:1250-1254.

Cornforth, D. P., Rabovitser, J. K., Ahuja, S., Wagner, J. C., Hanson, R., Cummings, B. and Chudnovsky, Y. 1998. Carbon monoxide, nitric oxide, and nitrogen dioxide levels in gas ovens related to surface pinking of cooked beef and turkey. J. Agric. Food Chem. 46:255-61.

Lee, B., Hendricks, D. G. and Cornforth, D. P. 1998. Antioxidant effects of carnosine and phytic acid in a model beef system. J. Food Sci. 63:394-398.

Lee, B., Hendricks, D. G. and Cornforth, D. P. 1998. Effect of sodium phytate, sodium pyrophosphate, and sodium tripolyphosphate on physicochemical characteristics of restructured beef. Meat Sci. 50:273-283.

Moiseev, I. V. and Cornforth, D. P. 1999. Treatments for prevention of persistent pinking in dark-cutting beef patties. J. Food Sci. 64:738-43.

Lee, B., Hendricks, D. G. and Cornforth, D. P. 1999. A comparison of carnosine and ascorbic acid on color and lipid stability in a ground beef pattie model system. Meat Sci. 51:245-253.

Heaton, K. M., Cornforth, D. P., Moiseev, I. V., Egbert, W. R. and Carpenter, C. E. 2000. Minimum sodium nitrite levels for pinking of various cooked meats as related to use of direct or indirect-dried soy isolates in poultry rolls. Meat Sci. 55:321-329.

Carpenter, C. E., Cornforth, D. P., Whittier, D. 2001. Consumer preferences for beef color and packaging did not affect eating satisfaction. Meat Science 57:359-363.

Jayasingh, P. Cornforth, D. P., Carpenter, C. E., and Whittier, D. 2001. Evaluation of carbon monoxide treatment in modified atmosphere packaging or vacuum packaging to increase color stability of fresh beef. Meat Science, In press.

Book Chapters

Cornforth, D. P. 2000. **Miscellaneous Colorants - Cured Meat.** Unit F6.2 in *Current Protocols in Food Analytical Chemistry*. S. J. Schwartz, Ed. John Wiley & Sons, Inc. New York, NY.

Cornforth, D. P. 2001. **Potential use of phytate as an antioxidant in cooked meats**. Ch. 11 in *Food Phytates*. R. Reddy and S. K. Sathe, Eds. Technomic Publ., Inc., Rowayton, CT.

ATTACHMENT 8

000206

[redacted]

ENVIRON

August 27, 2001

Eric Greenberg
Ungaretti & Harris
3500 Three First National Plaza
Chicago, IL 60602-4283

Re: Generally recognized as safe ("GRAS") determination for carbon monoxide from Pactiv ActiveTech food-contact packaging.

Dear Eric:

This letter reports my assessment, based on my review of the available information, that the potential consumer exposure to carbon monoxide from the Pactiv ActiveTech food-contact packaging is safe, and is also generally recognized as safe ("GRAS"), under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") when used under conditions defined in the attached GRAS determination document. First, the safety of carbon monoxide in this use is demonstrated by comparison of the U.S. Environmental Protection Agency ("USEPA") national ambient air quality standard ("NAAQS") for carbon monoxide with the estimated daily intake ("EDI") of carbon monoxide under the intended conditions of use of the product. Exposure to a substance generally is considered safe for its intended use if the EDI is a fraction of the allowable daily intake ("ADI"). Second, the GRAS status of carbon monoxide in this use is affirmed by demonstrating that the safety of carbon monoxide from Pactiv ActiveTech food-contact packaging material in its intended use is generally recognized.

My GRAS determination was based on scientific procedures as outlined in the U.S. Food and Drug Administration ("FDA") regulations (at §170.30(b)). This section requires that the same quantity and quality of scientific evidence is available and is reviewed as is required to obtain approval of the substance as a food additive. Moreover, in addition to requiring scientific evidence of safety (as with a food additive), a GRAS determination also requires that this scientific evidence of safety be generally known and accepted by experts qualified in the appropriate scientific and technical fields. This common knowledge requirement of a GRAS determination includes two elements: (1) the data and information relied upon to establish the scientific basis for safety must be generally available; and (2) there must be a basis to conclude that there is a consensus among qualified experts about the safety of the substance for its intended use.

Based on the scientific literature, studies, conclusions, and restrictions presented in the GRAS determination document, I regard the proposed uses of carbon monoxide from Pactiv ActiveTech packaging material as generally recognized as safe because the use will result in an exposure that is well below an acceptable exposure level for carbon monoxide.

000207

ENVIRON International Corporation
4350 North Fairfax Drive, Suite 300 • Arlington, VA 22203 USA
Tel: (+1) (703) 516 2300 • Fax: (+1) (703) 516 2393 • www.environcorp.com

[redacted]

No evidence exists in the available information on carbon monoxide that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public health when carbon monoxide is used at levels that might reasonably be expected from its proposed use as an additive in the Pactiv ActiveTech food-contact packaging material as defined in the GRAS determination document.

It is my opinion that other qualified and competent scientists reviewing the same publicly available data would reach the same scientific conclusion. Therefore, carbon monoxide, as an additive in the Pactiv ActiveTech food-contact packaging material, is generally recognized as safe.

Vasilios H. Frankos, Ph.D.
Principal, Health Sciences
ENVIRON International Corporation
Arlington, Virginia

VASILIOS H. FRANKOS, Ph.D.

EDUCATION

1977 Ph.D., Pharmacology and Toxicology, University of Maryland Pharmacy School

1973 M.S., Biology, University of Maryland

1970 B.A., Biology, University of Maryland

EXPERIENCE

Dr. Frankos is a Principal at ENVIRON Corporation and has over 20 years of experience in the toxicological and pharmacological evaluation of data used to assess the risks posed by foods and food additives, drugs, medical devices, cosmetics, pesticides, and environmental and occupational exposures. He has also been involved in the development of exposure and risk assessment methodology. Since joining ENVIRON, Dr. Frankos has led, contributed to, or managed hundreds of projects in these areas.

Foods and Food Additives:

Dr. Frankos has worked on a wide variety of projects evaluating the safety of foods, direct and indirect food additives, and food contaminants. As part of these food-related safety evaluations, he has developed strategies for testing new direct and indirect additives, evaluated toxicity test data to support safety determinations, prepared Generally Recognized as Safe (GRAS) reviews, performed exposure and risk assessments, and developed regulatory strategies. Dr. Frankos has also presented safety evaluations to the FDA on behalf of clients. Some of his major projects in the area of foods and food additives include:

- Provided ongoing FDA-related scientific and technical support to the Coalition for Safe Ceramicware (CSC). Performed a safety assessment of ceramic pitchers with glazes containing lead using data collected on migration of lead into a food simulant and into real foods. This assessment was submitted to the FDA as part of the CSC's comments on the FDA's proposed rule changing the action level for lead from ceramic pitchers.
- Developed direct food additive petitions and GRAS self-affirmation documents for numerous food additives including, novel fibers sources, an anti-caking agent, enzymes, sugars, and a major new class of food additives.
- Conducted a GRAS self-affirmation review, including an evaluation of safety data, of the first bioengineered food approved by the FDA. Presented this GRAS review to the FDA on behalf of the client, a major biotechnology company.
- Developed a GRAS affirmation document for a cellulose product, manufactured by a novel bacterial fermentation process, with proposed food use as a suspending/thickening agent. Designed, placed, and monitored preclinical toxicity studies required for FDA approval.
- Estimated doses posing no significant risk for chemicals that could potentially leach from packaging into food. Assessed the potential human exposure to these chemicals from migration from packaging into food. Compared the potential ingested dose to the no significant risk dose.

- Petitioned the FDA to sanction expanded use in foods of an approved food additive. Prepared a review and update of existing toxicological literature on the material and estimated the increase in exposure likely to result from proposed new uses.
- Evaluated the carcinogenic risk associated with exposure to acrylamide residues in food and methylene chloride in decaffeinated tea.
- Addressed issues relating to FDA's regulation of polychlorinated biphenyl (PCB) residues. Examined whether tolerances for PCBs in fish could be reinterpreted for less chlorinated PCBs that have lower or no carcinogenic potency. Determined necessary research to establish differences in potency between PCBs.
- Developed an innovative exposure and safety assessment for a novel single cell protein (mycoprotein) meat substitute that has been submitted to the FDA for approval.
- Conducted a simulated FDA review of a food additive petition on a new artificial sweetener submitted to the FDA by the client's competitor. Review included critical evaluation of product chemistry, efficacy, estimates of human exposure, animal and human toxicology data, pharmacokinetics and metabolism information, and the basis for determining the acceptable daily intake of the sweetener.
- Performed a detailed evaluation of toxicity and carcinogenicity studies sponsored by a major drug company and studies from the published literature for the company's non-nutritive sweetener and assessed the toxicological significance to humans. Assisted in submission of a food additive petition. Provided continued regulatory support during the FDA review process.

Human and Veterinary Drugs, Medical Devices, and Cosmetics:

Dr. Frankos has provided scientific and regulatory guidance to clients in the human and veterinary drug, medical device, and cosmetic industries. He has been involved in identifying and assessing the risks to humans associated with exposure to constituents of these products. He has assisted clients in these industries in interacting with the FDA and has assisted them in complying with all aspects of FDA regulations. Some of his major projects in the areas of drugs, medical devices, and cosmetics include:

- Reviewed two large epidemiological studies on the differences in adverse drug reaction rates between two types of radiographic contrast media. Prepared a safety review document on animal and human literature on contrast media.
- Performed an independent evaluation of a New Drug Application (NDA) submission to the FDA, with emphasis on review of efficacy studies.
- Assisted the medical device manufacturer in complying with FDA's post-approval requirements for its device including compliance with the Medical Device Reporting (MDR) rule, submission of updates to the PMA application, and ensuring that all labeling and marketing materials are in compliance with FDA regulations. Designed a post-marketing clinical trial for the device to comply with FDA recommendations.
- Evaluated the potential carcinogenic risks to humans of an over-the-counter (OTC) medication that is applied to the skin. Prepared a report on these findings that was submitted to the FDA.

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- Prepared and submitted to the FDA a New Drug Application (NDA) for a drug that holds promise for dramatically decreasing the high percentage of reocclusion that occurs in angioplasty patients.
- Assisted a major pharmaceutical manufacturer in assessing potential health risks associated with a specific ingredient of various over-the-counter (OTC) drugs.
- Critically evaluated both published and unpublished studies on a psychoactive drug and rendered an opinion to the client on potential health effects of the drug and whether a no-observed-effect level (NOEL) had been established.
- Provided guidelines for subchronic testing to evaluate the safety for human use of an allergen desensitizer that was produced by polymerizing the allergen through a glutaraldehyde treatment.
- Analyzed the potential risk to humans resulting from the use of Furazolidone as an animal drug. Determined an estimate of this risk and presented the estimate to the FDA at a public hearing.
- Assisted a major manufacturer of veterinary drug products in developing an approach to dealing with mouse liver tumors and their usefulness as evidence of carcinogenicity.
- Reviewed and evaluated a New Animal Drug Application for FDA submission. Advised on the necessity of future studies.
- Assembled an expert panel to address the safety of an antimicrobial agent, extracted from a plant source, for use in oral hygiene products (e.g. toothpaste and oral rinse). The evaluation included a review of the preclinical and clinical toxicologic database, analysis of exposure, and determination of margin of safety associated with the proposed oral uses.
- Critically evaluated the evidence cited by FDA as the basis for considering nitrofuran animal drugs to be carcinogenic under the meaning of the Delaney Clause of the Federal Food, Drug, and Cosmetic Act.
- Reviewed toxicity data to be submitted in support of an Investigational Device Exemption (IDE) for an implantable medical device. Recommended and monitored the performance of supplemental tests, performed an exposure assessment of substances leaching from the device into the systemic circulation, characterized the risk to health from such exposures, and assisted in the presentation of these findings to the FDA.
- Evaluated toxicity data on the materials used in a device intended to be implanted in the abdominal cavity. Examined the adequacy of the existing data on the device material, the safety of the material used, and the safety of the proposed replacement material. Recommended studies to improve the data for submission to the FDA.
- Conducted a quantitative risk assessment on numerous color additives used in dermally applied cosmetics including an evaluation of toxicity, an analysis of exposure, and a determination of quantitative risks.
- Performed a hypothetical risk assessment for two colors used in cosmetics, based on the assumption that, if tested, they would produce tumors in rats. Demonstrated that such an outcome would still allow continued safe use of these colors in cosmetics.

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Pesticides:

Dr. Frankos has assisted U.S. and foreign manufacturers in obtaining EPA and California registration of agricultural, forestry, and homeowner use pesticide products. Some of his major projects in the area of pesticides include:

Reviewed EPA's assessment of dietary oncogenic risk of two fungicides and advised the manufacturers of additional data needed to perform a quantitative risk assessment.

- Designed and supervised a field study to estimate exposure to a pesticide during "worst case" application. The study monitored the application of the chemical, measured exposure of the user during various phases of application and determined the effect of protective clothing on exposure.
- Reviewed the results of an aquatic organism field monitoring study and its supporting laboratory data for a major manufacturer of agricultural chemicals.
- Evaluated toxicity and prepared a risk assessment for residues of a fungicide in imported wines. Counseled client on process necessary to receive an EPA import tolerance for the fungicide. Advised client on additional data needed to support a tolerance.
- Designed and monitored toxicology studies for a German firm required for registration of a plant growth promotor and assisted in submitting data to the EPA.
- For a West German pesticide manufacturing company wishing to purchase the patent rights to a new pesticide developed in the U.S., provided counsel on the acceptability of the available data to EPA and OECD and the further data needed to obtain a registration in the U.S.

Environmental and Occupational Exposures:

Dr. Frankos has directed numerous exposure and risk assessments involving hundreds of chemicals that have been associated with industrial processes, toxic waste or municipal incinerators, and hazardous waste sites. These assessments have used computerized models and include all routes of exposure. Some of his major projects in the areas of environmental and occupational exposures include:

- Performed a safety assessment for the consumption of drinking water in contact with a piece of equipment that could potentially release lead, including an estimation of 1990 baseline blood lead levels for four subpopulations using the Integrated Uptake/Biokinetic Model and a determination of the maximum acceptable concentration of lead in drinking water that was potentially in contact with the equipment. Collected and reviewed information on factors that affect the leachability of lead into drinking water.
- Assisted manufacturers of the plasticizer di-(2-ethylhexyl) phthalate (DEHP) in developing a method for estimating exposure resulting from the chemical's presence in polyvinyl chloride (PVC) consumer products such as vinyl-covered furniture, vinyl wallpaper, flooring, and shower curtains.
- Critically reviewed acrylamide's carcinogenic activity in Fischer 344 rats and designed a new cancer bioassay in rats that will improve risk assessments for acrylamide.

- Reviewed the scientific basis for establishing safety factors needed to protect workers from reproductive toxicity associated with glycol ether exposure.
- Reevaluated the data from a National Cancer Institute (NCI) bioassay on dibutyltin diacetate to resolve discrepant interpretations by NCI and FDA.
- Reviewed FDA and National Toxicology Program (NTP) evaluations of the bioassay on dimethylterephthalate and rendered an opinion on the adequacy of the NTP and FDA decisions.
- Supported the EPA Office of Solid Waste in developing measures of inherent toxicity which can be combined with exposure estimates to provide a relative ranking for scheduling hazardous solid waste.
- Provided scientific litigation support for a municipality in which its waste treatment plant and landfill were contaminated with PCBs.
- Participated in a number of projects examining the developmental, embryotoxic, and teratogenic effects of lead observed in animals, including the effects of lead on the reproductive systems of male and female rats. Recommended a no-observed-adverse-effect level (NOAEL) for lead.

Exposure and Risk Assessment Methodology Development:

Dr. Frankos has participated in the development of new exposure and risk assessment methodologies for federal and state regulatory agencies. He has also been integral in the development of exposure and risk modeling software. Some of his major projects in these areas include:

- Developed a background document for the EPA on reproductive toxicity risk assessment for use in drafting interagency risk assessment guidelines.
- Directed development of a scheme for the EPA that allows severity of toxic effects to be incorporated into safety evaluations of EPA regulated products.
- Summarized and compiled comments received by EPA on their proposed guidelines (1985) for developmental toxicity assessment.
- Assisted in evaluating EPA's procedures for estimating safe short-term exposure limits and in developing an alternative method that could be uniformly used by the entire agency.
- Assisted in the development of criteria for listing chemicals as developmental toxicants under California's Proposition 65.
- Directed the development of a computer software system, ERMA (Exposure and Risk Modeling Assistant) that enables ENVIRON to provide high quality, scientifically defensible evaluations of potential exposures and resultant risk.

Before joining ENVIRON Corporation, Dr. Frankos held the following positions:

- Associate Director, Life Sciences Division, Clement Associates. In that position he had the following experience:
  - Supervised a staff of eight scientists who assessed the risk posed by environmental contaminants, occupational carcinogens, pesticides, drugs, commercial product

constituents, and food additives. Many of these projects involved evaluating human and animal toxicology data for use in conducting human risk assessments. This position required management of time constraints, budgetary limitations, and personnel allocations in a manner that provided the client with a scientifically defensible document.

- Directed preparation of reports for industry clients that included "Safety Assessment Strategies for Feminine Hygiene Products"; "The Impact of a Proposed Salicylate Warning on the Risk Associated with Diseases and Conditions in Children"; and "A Proposed Mechanism of Action for a Carcinogenic Hair Dye Ingredient."
- Directed and prepared a report to OSHA entitled "Formaldehyde Risk Assessment for Occupationally Exposed Workers" and assisted in developing guidelines for interspecies data extrapolation for use by OSHA in its revised cancer policy.
- Provided litigation toxicity support to private and industry clients and assisted private concerns in the development of testing protocols for the purposes of fulfilling regulatory requirements.
- Served as expert reproductive toxicity witness in the House of Representative's hearing on the "Relationships of Exposure to Toxic Chemicals and Reproductive Impairment."

• Staff Science Advisor, Office of Health Affairs, Commissioners Office, Food and Drug Administration.

- Provided professional scientific expertise in pharmacology, toxicology, biochemistry, and biology requisite to the effective accomplishment of the Agency's scientific overview and leadership function. Served as technical expert, scientific advisor, and liaison of the Commissioner at the Bureau level on matters relevant to toxicologic and pharmacologic safety assessment of toxic substances to which humans and animals are exposed.
- Responsibilities included performing risk assessments on compounds (such as PCB's, methapyraline, caffeine, etc.) that could be utilized by the Commissioner's office in choosing between various regulatory options. Routinely reviewed toxicity data on compounds as diverse as caffeine, methylsalicylate, xylitol, and sodium nitrite. Provided litigation support and testified as expert toxicology witness at the Administrative Law Judge hearing on the safety of cyclamate.
- Participated in the National Toxicology Program (NTP). Duties included review of agency nominations for toxicity testing by NTP, research planning for the regulatory needs of FDA, preparation of the Annual Carcinogen Report, and participation in numerous NTP workgroups.
- Interagency and international initiatives included chairing the Interagency Regulatory Liaison Group (IRLG) Workgroup on Reproductive Toxicity Risk Assessment. Planned, coordinated, and published a three-day symposium entitled, "The Effects of Foods and Drugs on the Development and Function of the Nervous System." Chaired and organized a national workshop on Reproductive Toxicity Risk Assessment.
- Served as Project Director of a contract with the Environment Teratology Information Computer Division, Oak Ridge National Research Laboratory to develop computerized teratology literature data extraction, indexing, and collation. This data base system is being

integrated into the ETIC master computer file and will be manipulated through the INQUIRE data base management system.

- Senior Toxicologist, Division of Toxicology, Center for Food Safety and Applied Nutrition, Food and Drug Administration.
  - Responsible for the toxicologic evaluation of compounds of special interest to the agency. Required expert review of data on carcinogenicity, promotion, reproduction, teratology, and pharmacokinetics. Presented scientific evaluations to congressional, departmental, and agency directors. Represented the agency on sensitive scientific issues. Areas of emphasis included evaluation of toxicity data on artificial sweeteners (saccharin, cyclamate, xylitol, etc.), development of reproductive toxicity risk assessment criteria, pharmacokinetics evaluation of compounds (methylene chloride, sodium nitrite, saccharin, etc.), and risk assessment.
  - Directed the development of a PC computer network to be used by the Review Toxicologist of the FDA Bureau of Foods. This system allows direct access to toxicology data bases at NLM, Oak Ridge, Dialog, and extensive FDA internal data bases and full manipulation, storage, and collation of personalized literature data bases.
- Toxicologist, Division of Toxicology, Bureau of Foods, Food and Drug Administration.
  - Responsible for toxicologic review of substances used as direct and indirect food additives. Duties required discussions with manufacturers, formulators, toxicologists, universities, and other agencies on experimental procedures for showing safety and estimating risk.
  - Additional duties and accomplishments included primary involvement in planning, testing, and implementing new proposed regulations that direct the priority assessment review of all food additives. Duties included designing and implementing modern toxicity testing protocols, protocol quality parameters, criteria for utilizing toxicity data, and computer compatible toxicology test summarization forms. Co-led a 12 person toxicology cyclic review team. This endeavor was awarded a commendable service citation.
  - Served as the toxicology member on the Program Advisory Board for the FDA's effort to modernize the storage and retrieval of safety information in the Bureau of Foods. Over two million dollars was expended for the computerization and microfiching of all Bureau petition files. This system is now fully operational within the FDA and is called SIREN.
- Research Assistant, Department of Pharmacology and Drug Abuse, Maryland Psychiatric Research Center.
  - Laboratory responsibilities included the daily analysis of the catecholamines and their metabolites in the urine of patients under different drug therapies. Used column chromatography to separate the monoamines and their metabolites with subsequent fluorometric determinations of their amounts. Techniques involved using radioisotopic methods to determine monoamine oxidase kinetics, substrate km, and oxygen requirements and preparing mitochondrial isolates to study by oxygraphic assay and radioisotopic methods.
  - Clinical responsibilities included the collection, collation, and statistical analysis of data obtained by researchers in various disciplines, such as clinical and physiological psychology, biochemistry, and pharmacology. Assisted in the design, implementation,

and statistical analysis of a study concerning the use of naloxone and cyclazocine as narcotic antagonists in a population of paroled drug addicts. Implementation of the study involved administering, scoring, and statistically analyzing psychodiagnostic and intelligence tests.

HONORS

1980 FDA Commendable Service Award for Direct Food Additive Cyclic Review

1969-70 Baltimore University Club Scholarship

1966-67 American Hellenic Education Scholarship

PROFESSIONAL ACTIVITIES AND MEMBERSHIPS

Invited presentation entitled "Developmental and Reproductive Toxicity Testing of Implantable Medical Devices." Presentation for: 1996 Summer Short Course Series on Medical Device Biocompatibility: From Material Screening to Final Product Testing. Sponsored by: Case Western Reserve University. July 18-19, 1996, Baltimore, Maryland.

Invited presentation entitled "Risk Assessment: What is it? How can I use it?" Regional Meeting of the Association of Official Analytical Chemists (AOAC), October 27, 1994, College Park, Maryland.

Invited presentation entitled "Testing Requirements for Medical Devices" Annual Genetic Toxicology Workshop, May 3-5, 1993, Rockville, Maryland.

Society of Regulatory Toxicology and Pharmacology 1990 -

Food and Drug Law Institute 1990 -

Guest Lecturer, University of Vermont Law School "Risk Assessment at the Law" June 4-14, 1990, Burlington, Vermont.

Invited presentation entitled "Review of Safety and Toxicity of Sanguinaria and Sanguinarine" Symposium on Sanguinaria, April 25, 1990, Toronto, Ontario, Canada.

Invited presentation entitled "Health Risks and Safety Precautions" PCB Compliance, Cleanup and Disposal, March 27-28, 1990, Toronto, Ontario, Canada.

Environmental Law Institute 1989 -

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Invited panel member "Weight of Evidence Considerations in Identifying Reproductive and Developmental Toxicants" Risk Assessment Issues in Developmental and Reproductive Toxicology, Sept. 18-19, 1989, Berkeley, California.

Invited presentation entitled "Health Risk and Safety Precautions" Current Issues in PCB Compliance, May 24-25, 1989, Toronto, Canada.

Regulatory Affairs Professionals Society 1988 -

Invited presentation entitled "Risk Assessment for Effects Other than Cancer" 1986 Conference for Food Protection, Aug. 17-20, 1986, Ann Arbor, Michigan.

Invited work group member at the EPA sponsored "Consensus Workshop on the Evaluation of Maternal and Developmental Toxicity" May 12-14, 1986, Rockville, Maryland.

Co-author of an invited paper entitled "Acrylonitrile as a Carcinogen: Research Needs for Better Risk Assessment" presented at the International Conference on "Occupational and Environmental Significance of Industrial Carcinogens" October 7-9, 1985, Milan, Italy.

Invited presentation entitled "FDA Perspectives on the use of Teratology Data for Human Risk Assessment" Symposium on "Risk Assessment for Developmental Toxicity" Annual meeting of the Society of Toxicology, March 13, 1984, Atlanta, Georgia.

Guest Lecturer and Expert Consultant to the Environmental Teratology Information Computer Division, Oak Ridge National Research Laboratory. 1982.

Expert Witness before the U.S. House of Representatives Committee on Science and Technology hearing on the "Relationship of Exposure to Toxic Chemicals and Reproductive Impairment," 1982.

Guest speaker, FDA National Scientific Health Professionals Meeting; spoke on the National Toxicology Program. 1981.

Member, National Toxicology Program Chemical Evaluation Committee. 1979-1982.

Member, National Toxicology Program Annual Carcinogen Report Workgroup. 1979-1982.

Invited workshop panel member, Workshop on Biological and Statistical Implications of the ED Study on Related Data Bases, Mt. Sterling, Ohio; sponsored by the Society of Toxicology for the National Center for Toxicological Research. 1981.

Chairman - Interagency Regulatory Liaison Group - Reproductive Toxicity Risk Assessment Group. 1980-1981.

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Chairman and Organizer of the IRLG - Reproductive Toxicity Risk Assessment Workshop held at FDA, Rockville, MD. 1981.

Participated in preparation of the National Science Foundation Third Annual Science and Technology Report. 1980.

Participated in Preparation of the National Science Foundation Five-Year Science Outlook. 1980.

Participated in publication of the First Annual Report on Carcinogens (DHHS/NTP). 1980.

Organizer and lecturer for a State Department and DHHS/FDA sponsored course conducted for the National Organization for Drug Control and Research (Cairo, Egypt), entitled: "A Course in Chronic and Reproductive Toxicity Testing and Risk Assessment." 1980.

Guest lecturer at FDA Consumer Exchange Meeting: Use of Risk Assessment for Decision-Making. 1980.

Co-chairman and organizer of the Fifth FDA Science Symposium on Effects of Foods and Drugs on the Development and Function of the Nervous System: Methods for Predicting Toxicity. Delivered presentation entitled "Symposium Summary and Future Directions for Neurotoxicology Testing." 1979.

Expert witness FDA Administrative Law Judge hearing on the Safety of Cyclamate Used as an Artificial Sweetener. 1979.

PUBLICATIONS

Kruger, C.L., M.H. Whittaker, and V.H. Frankos. 1999. Genotoxicity Tests on D-Tagatose. *Regulatory Toxicology and Pharmacology*. 29(2):S36-S42.

Kruger, C.L., M.H. Whittaker, and V.H.Frankos. 1999.Developmental Toxicity of D-Tagatose. *Regulatory Toxicology and Pharmacology*. 29(2):S29-S35.

Turnbull, D., M.H. Whittaker, V.H. Frankos, and D. Jonker. 1999. 90-Day Oral Toxicity Study of D-Tagatose in Rats. *Regulatory Toxicology and Pharmacology*. 29(2):S1-S10.

Trunbull, D., M.H. Whitaker, V.H. Frankos, and D. Jonker. 1999. 13-Week Oral Toxicity Study with Stanol Esters in Rats. *Regulatory Toxicology and Pharmacology*. 29(1):216-226.

Whittaker, M.H., V.H. Frankos, D.H. Waalkens-Berendsen, A.P.M. Wolterbeek. 1999. 2-Generation Reproductive Toxicity Study of Plant Stanol Esters in Rats. *Regulatory Toxicology and Pharmacology*. 29(1):196-204.

Hester, T.R., N.F. Ford, P.J. Gale, J.L. Hammett, R. Raymond, D. Turnbull, V.H. Frankos, and M.B. Cohen. 1997. Measurement of 2,4-toluenediamine in urine and serum samples from women with même or replicon breast implants. *Plastic and Reconstructive Surgery*. 100(5):1296-1298.

Silverstein, B., K.M. Witkin, V.H. Frankos, and A.I. Terr. 1997. Assessing the Role of the Biomaterial Aquavene in Patient Reactions to Landmark Midline Catheters. *Regulatory Toxicology and Pharmacology.* 25(1).

Rodricks, J.V., V.H. Frankos, and L.M. Plunkett. 1995. Food Additives. In: Regulatory Toxicology. C.P. Chengeliss, J.F. Holson and S.C. Gad (eds.) Raven Press, New York, New York, 51-82.

Spiegel, J.E., R. Rose, P. Karabell, V.H. Frankos, and D.F. Schmitt. 1994. Safety and Benefits of Fructooligosaccharides as Food Ingredients. *Food Technology.* 85-89.

Redenbaugh, K., T. Berner, D. Emlay, V. Frankos, W. Hiatt, C. Houck, M. Kramer, L. Malyj, B. Martineau, N. Rachman, L. Rudenko, R. Sanders, R. Sheehy, and R. Wixtrom. 1993. Regulatory Issues for Commercialization of Tomatoes with an Antisense Polygalacturonase Gene. *In Vitro Cell. Dev. Biol.* 29:17-26.

Frankos, V.H., D.F. Schmitt, L.C. Haws, A.J. McEvily, R. Iyengar, S.A. Miller, I.C. Munro, F.M. Clydesdale, A.L. Forbes, and R.M. Sauer. 1991. Generally Recognized as Safe (GRAS) Evaluation of 4-Hexylresorcinol for Use as a Processing Aid for Prevention of Melanosis in Shrimp. *Regulatory Toxicology and Pharmacology* 14:202-212.

Wilcock, K.E., A.B. Santamaria, V.H. Frankos, H.W. Fischer, F. Laden, E.A. Platz, and B.A. Jackson. 1990. Perspectives on Adverse Reaction Rates Associated with the Use of High Osmolar Ionic and Low Osmolar Nonionic Contrast Media. *Journal of the American College of Toxicology* 9(6):563-607.

Frankos, V.H., D.J. Brusick, E.M. Johnson, H.I. Maibach, I. Munro, R.A. Squire, and C.S. Weil. 1990. Safety of Sanguinaria Extract as Used in Commercial Toothpaste and Oral Rinse Products. *Journal of the Canadian Dental Association* 56(7 Suppl):41-47.

Schmitt, D., V. Frankos, and D. Richardson. 1990. Toxicologic Evaluation of Sanguinaria Extract. Eleventh Annual Meeting of the American College of Toxicology. Program and Abstracts. Abstract.

Schmitt, D., V. Frankos, J. Westland, and T. Zoetis. 1990. Toxicological Evaluation of Cellulon™ Fiber: Genotoxicity, Acute and Subchronic Toxicity. Eleventh Annual Meeting of the American College of Toxicology. Program and Abstracts. Abstract.

Rudenko, L., J. Adgate, M. Aponte-Pons, T. Berner, V. Frankos, R. Gregory, C.K. Lintner, N. Rachman, W. Sherman, T. Winters, and R. Wixtrom. 1990. Application of Risk Assessment Methodology to Genetically Engineered Food Products: A Generic Approach. Society for Risk Assessment. Abstract.

VASILIOS H. FRANKOS, Ph.D.

Frankos, V., M. Stedman, and M.A. Friedman. 1989. A lifetime oncogenicity study of acrylamide administered to F344 rats in the drinking water. Tenth Annual meeting of the American College of Toxicology. Program and Abstracts. p.26. Abstract.

Hanson, C.F., V.H. Frankos, and W.O. Thompson. 1989. Bioavailability of oxalic acid from spinach, sugar beet fibre and a solution of sodium oxalate consumed by female volunteers. Fd. Chem. Toxic. 27,3:181-184.

Frankos, V., L.H. Dulak, M.A. Fiedman. 1989. Use of risk assessment in the statistical design of a carcinogenicity bioassay of acrylamide. The Toxicologist 9:179. Abstract.

Strother, D.E., R.W. Mast, R.C. Kraska, and V. Frankos. 1988. Acrylonitrile as a carcinogen. Research needs for a better risk assessment. Annals of the New York Academy of Sciences 534:169-178.

Hanson, C.F., V.H. Frankos, and W.O. Thompson. 1988. Low dietary availability of oxalic acid present in refined sugar beet pulp compared to spinach and sodium oxalate. The Toxicologist 8:88. Abstract.

Strother, D.E., R.W. Mast, R.C. Krashka, and V. Frankos. 1988. Acrylonitrile as a Carcinogen: Research Needs for Better Risk Assessment, Annals of the New York Academy of Sciences 534:169-178.

Schwetz, A. Bernard, R.W. Tyl et al. 1987. Consensus workshop on the evaluation of maternal and developmental toxicity work group III report: Low dose extrapolation and other considerations for risk assessment - models and applications. Teratogenesis, Carcinogenesis, and Mutagenesis 7:321-327.

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Kimmel, C.A., G.L. Kimmel, and V. Frankos. 1986. Editors IRLG Workshop on Reproductive Toxicity Risk Assessment. *Environmental Health Perspectives,* Vol 66, 193-221.

Rodricks, V. Joseph, V. Frankos, D. Turnbull, R.G. Tardiff. 1986. Risk assessment for effects other than cancer. In Food Protection Technology. Proceedings of the 1986 Conference for Food Protection. Lewis Publishers, Inc.

Frankos, V.H. 1985. FDA perspectives on the use of teratology data for human risk assessment. *Fundamental and Applied Toxicology.* Vol. 5, 615-625.

Flamm, W.G. and V. Frankos. 1985. Formaldehyde: Laboratory Evidence. In "Interpretation of Negative Epidemiological Evidence for Carcinogenicity." IARC Scientific Publication 65.

Siegel, D.M., V.H. Frankos, and M.A. Schneiderman. 1983. Formaldehyde risk assessment for occupationally exposed workers. *Regulatory Tox. and Pharm.* 3, 355-371.

Frankos, V.H. 1982. Relationship of exposure to toxic chemicals and reproductive impairment. Expert testimony for Committee on Science and Technology, U.S. House of Representatives July 27, 1982. United State Government Printing Office.

Frankos, V.H. 1982. Qualitative comparison of chemical teratogenesis in humans and animal species (Abstract). Third Annual Meeting of the American College of Toxicology, Washington, D.C.

Siegel, D.M., V.H. Frankos, and M.A. Schneiderman. 1982. Formaldehyde risk assessment for occupationally exposed workers (Abstract). Third Annual Meeting of the American College of Toxicology, Washington, D.C.

Frankos, V.H. and J. Wassom. 1982. Computerized teratology literature data extraction, indexing, and collation (Abstract). *Teratology.* 25:2 80A.

Frankos, V.H. Symposium Summary and Suggested Future Directions for Detection of Neurotoxicity. 1980. In The Effects of Foods and Drugs on the Development and Function of the Nervous System: Methods for Predicting Toxicity. Edited by Gryder, R.M. and Frankos, V.H. U.S. Department of Health and Human Services, Food and Drug Administration, Publication No. DHHS/FDA 80-1076.

Frankos, V.H. 1980. Reproductive toxicity risk assessment task group: Outline of work plan and request for comments. Federal Register 45:63553-63554.

Gryder, R.M. and V.H. Frankos (eds.). 1980. The Effects of Foods and Drugs on the Development and Function of the Nervous System: Methods for Predicting Toxicity. U.S. Department of Health and Human Services, Food and Drug Administration.

Frankos, V.H. and R. Platt. 1976. Glycerol accumulation and water content in larvae of *Limenitis archippus*: Their importance to winter and survival. *J. Insect Physiol.* 22:623-623.

Frankos, V.H. and G. Butterbaugh. 1976. Characterization of norepinephrine metabolism following simultaneous intraventricular injection of H^3-L-tyrosine and C^{14}-DL-norepinephrine. *Pharmacologist* 18:135.

Messiha, K.F., E. Bakutis, and V.H. Frankos. 1973. Simultaneous separation of acid metabolites of catecholamines: Application to urine and tissue. *Clin. Chim. Acta.* 45:159-164.

ATTACHMENT 9

K·STATE
Kansas State University
Animal Sciences and Industry
K-State Research and Extension
232 Weber Hall
Manhattan, KS 66506-0201
785-532-6533
Fax: 785-532-7059

August 8, 2001

Eric F. Greenberg
Of Counsel
Ungaretti & Harris
3500 Three First National Plaza
Chicago, IL 60602-4283

Dear Mr. Greenberg:

The purpose of this letter is to confirm that I believe the use of a small quantity of carbon monoxide in the modified packaging system know as ActiveTech (by PACTIV) is safe and should qualify as GRAS. I have been a research meat scientist for nearly 30 years and have focused most of that time on factors affecting meat color and shelf life, including packaging systems. Thus, I am familiar with most of the world literature on such systems.

Based on my review of the details of the ActiveTech 2001 modified atmosphere system employing 0.4% carbon monoxide gas in a mixture with 60 percent carbon dioxide and the remainder nitrogen, as well as the published literature and common knowledge in the field, I am confident that the use of modified atmosphere including small quantities of carbon monoxide (0.4%) to package fresh meats as used in ActiveTech 2001 system is both safe and generally recognized as safe.

Sincerely,

Melvin C. Hunt
Professor

000223

Kansas State University
Agricultural Experiment
Station and Cooperative
Extension Service

"Knowledge
ife"

[redacted]

MELVIN C. HUNT

Department of Animal Sciences and Industry

PERSONAL DATA:
Born:
Married

EDUCATION:
B.S. 1965 Animal Husbandry, Kansas State University, Manhattan, KS
M.S. 1970 Animal Science, Kansas State University, Manhattan, KS
Ph.D. 1973 Food Science, University of Missouri, Columbia, MO

PROFESSIONAL EXPERIENCE:
1991- Chair, Undergraduate Food Science Program
1984- Professor, Kansas State University: 50% Teaching - 50% Research
1978-84 Associate Professor, Kansas State University
1975-78 Assistant Professor, Kansas State University
1973-75 Research Chemist, Tennessee Eastman Company
1968-73 Grad Research Assistant, Kansas State and University of Missouri
1966-68 Taught high school chemistry and biology, Kinsley, KS

PROFESSIONAL AFFILIATIONS:

American Meat Science Association:
- President, 1995-96; Past-President, 1996-97
- Director and Executive Board, 1989-91
- Chair 1991 Reciprocal Meat Conference
- Parliamentarian
- Chair or member of numerous committees including:
  Meat Color Guidelines, AMSA Teaching Award, Undergraduate Travel Award, Grad Student Poster Competition, Teaching Display, Resolutions, Meat Tenderness, Biochemistry-Biophysics, Packaging, Meat Color, Growth and Development, Reciprocation, Long Range Planning, Sustaining Membership, Endowment, and Research Priorities.

American Society of Animal Science:
- Chair and Chair-elect, Meat Science-Muscle Biology Section of National ASAS Meeting
- Chair, Midwestern ASAS Meat Science Section
- Editorial Board Journal Animal Science
- Teaching Award Committee, Midwestern ASAS Section

Institute of Food Technologists:
- Chair and Chair-elect of Muscle Foods Division, 1992-94
- Director of Muscle Foods Division
- Chair of Muscle Foods Nominating Committee
- Committee for two National Muscle Foods Symposia
- Journal of Food Science, Manuscript Review

CAST: Contributing member

Journal of Muscle Foods: Editorial Board
Meat Science: Manuscript Review

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HONORARY AFFILIATIONS:

Phi Kappa Phi, Sigma Xi, Phi Tau Sigma, Gamma Sigma Delta, Alpha Zeta

HONORS:

- College of Agriculture Outstanding Faculty Award 1979
- College of Agriculture Outstanding Faculty Award 1982
- College of Agriculture Outstanding Faculty Award 1988
- College of Agriculture Outstanding Faculty Award 1998
- College of Agriculture Outstanding Academic Advisor 1983
- University Selection for Parents' Day Lecture 1979
- Outstanding Lecturer Award, ITAL, Campinas, Brazil 1981
- Honorary State Farmer Degree 1985
- Distinguished Teaching Award, Gamma Sigma Delta 1989
- Selected Instructor, National Food Science Satellite Program 1990
- Certificate of Meritorious Service, Kansas Ag Teachers Association 1992
- CASE Professor of the year, Kansas winner of national competition 1992
- Outstanding Advising Award, Gamma Sigma Delta 1994
- Distinguished Teaching Award, American Meat Science Association 1994
- Outstanding Food Scientist, Phi Tau Sigma 1996
- Outstanding KSU Instructor & Advisor Award, Mortar Board 1997
- Signal Service Award, American Meat Science Association 1997
- USDA Food & Agriculture Science Excellence in Teaching Award, 2000

DEPARTMENT, COLLEGE OF AG, AND UNIVERSITY ACTIVITIES:

- Faculty Advisor: Block and Bridle, 6 years
- Faculty Advisor: Food Science Club, 3 years
- Faculty Advisor: Animal Science Grad Student Association, 16 years
- Faculty Advisor: Ag Student Council, elected for 2 terms (4 years)
- Chair, Weber Hall Building/Renovation Project
- Chair, KSU Meat Science Faculty
- Coordinator of KSU Meat Research Labs
- ASI Graduate Student Selection Committee
- ASI Undergraduate Career Development Committee
- ASI Library Committee
- ASI Scholarship, Loans and Honors Committee
- Department Representative for Gamma Sigma Delta, 10 years
- Student Team Coordinator, ASI Quadrathalon Teams
- Agriculture Student of the Month Selection Committee
- Agriculture Faculty of the Semester Selection Committee
- College of Agriculture Course and Curriculum Committee, chair and member
- College of Agriculture Academic Standards Committee, chair and member
- College of Agriculture Commencement Committee
- University Faculty Senator, College of Agriculture, two terms (6 years)
- University Academic Affairs Committee
- University Coordinating Committee for United Way
- KAES NCR-121 Chair and Secretary: Food & Feed Safety in Animal Production
- Food Science Undergraduate and Graduate Steering Committees
- Chair, Non-Traditional Studies Advisory Committee
- Elected by peers to ASI Teaching Advisory Committee
- Chair, KSU Undergraduate Food Science Program: Coordinate all course & curriculum and policy matters, scholarship, internships, recruitment, and record keeping

INDUSTRY-EXTENSION ACTIVITIES:

- Numerous presentations at: MidWest Meat Processors Seminars, Kansas-Nebraska Curing and Sausage Short Courses, KSU Cattlemen's Day, KSU Swine Day
- Technical Assistance for: Tennessee Eastman Company, Ross Industries, Giant Food

Stores, Excel Corporation, IBP, Doskocil Companies, Tenneco Packaging, Farmland, National Beef, Cryovac, Buckhead Beef, Dupont, Kalsec, Wendy's, Greater Omaha Beef, Hormel
- State FFA Livestock Awards Selection Committee
- State FFA Star Farmer Selection Committee
- State FFA Public Speaking Contest Judge
- Kansas Jr. Livestock Carcass Contest Judge
- Kansas Meat Processor Cured Meat Show Judge
- Missouri Meat Processor Cured Meat Show Judge

TEACHING RESPONSIBILITIES:

Current Courses - KSU Campus:
- ASI 350 Meat Science. 3hr. Lecture-lab introductory meat science
  Enrollment: Since 1979, 2031 students; currently running at maximum seating of 72
- ASI 610 Processed Meat Operations. 2hr. 50% responsibility, value-added processing
  Enrollment: 6 to 12 undergraduate and graduate students; since 1988, 35 students
- ASI 930 Advanced Meat Science. 3hr. Team-taught, highest level meats course
  Enrollment: Varies from 6 to 15 graduate students
- GENAG 500 Food Science Seminar. 1hr. Seminar for graduating seniors
  Enrollment: Varies from 6 to 15 students

Current Courses - KSU Distance Learning Program:
- ASI 340 Principles of Meat Science. 2hr. Web-based course for Continuing Education
  Enrollment: Since 1987, over 680 students
- GENAG 500 Food Science Seminar. 1hr. Seminar series for Distance Learning majors
  Enrollment: 3 to 15 undergraduate students per year, Continuing Education
- GENAG 630 Food Science Problems. 1hr. Detailed written investigation of current topics
  Enrollment: 2 to 8 students per year through Continuing Education

Previously Taught Courses:
- Topics in Meat Science and Muscle Biology
- Meats Judging Team (at University of Missouri)
- Meat Processing
- Livestock and Meat Evaluation
- Animal Agriculture and Consumers

INTERNATIONAL COURSE ACTIVITIES:
- Meat Science and Technology Short Course for Latin America, Institute for Food Technology, Campinas, Brazil, 6 weeks, one of two international lecturers
- Meat Science Facilities, University of Monterrey, Monterrey, Mexico
- Lecturer for five KSU International Meat Science Courses, International Meat and Livestock Program, Kansas State University
- Sabbatical leave, fall 1992, visiting scientist to Norwegian Food Research Institute, As
- Have attended 8 International Congresses of Meat Science and Technology

ADVISING RESPONSIBILITIES:

- Undergraduate Advisees: average of 26 for the last 10 years
- Graduate Students Supervised:
  - 12 Masters Students
  - 6 PhD Students
- Graduate Student Committees:
  - 43 Masters
  - 20 PhD
- Coordinate student-company relations for employment and internships for FSI

RESEARCH INTERESTS:

- Myoglobin chemistry and meat color, Methods of color measurement, Cooked meat color and food safety, Postmortem factors affecting meat quality, Collagen chemistry, Low-fat ground beef and processed meats; Six major company packaging projects funded since 1994 dealing with shelf life, color life, cold chain management, product palatability, and microbiology

PUBLIC AND COMMUNITY ACTIVITIES:

- Manhattan Optimist Club: committees for many youth activities
- Coach, Girls (16-18) ASA fast pitch softball traveling team
- Executive Committee, Riley County Extension Council
- Asst. Superintendent, sheep division, Riley County Fair
- Judge at Manhattan High School oratorical contest
- FarmHouse Fraternity, alumni board and committee work
- Snyder Award for Alumni Service, FarmHouse Fraternity
- Activities of First Presbyterian Church

Melvin C. Hunt
Professor
Department of Animal Sciences and Industry
Kansas State University

Refereed Journal Articles

Hunt, M.C., R.A. Smith, D.H. Kropf and H.J. Tuma. 1975. Factors affecting showcase color stability of frozen lamb in transparent film. J. Food Sci. 40:637.

Hunt, M.C. and H.B. Hedrick. 1977. Profile of fiber types and related properties of five bovine Muscles. J. Food Sci. 42:513.

Hunt, M.C. and H.B. Hedrick. 1977. Histochemical and histological characteristics of bovine muscle from four quality groups. J. Food Sci. 42:578.

Hunt, M.C. and H.B. Hedrick. 1977. Chemical, physical and sensory characteristics of bovine muscle from four quality groups. J. Food Sci. 42:716.

Thomas, J.D., D.M. Allen, M.C. Hunt and C.L. Kastner. 1977. Nutritional regimen, post-slaughter conditioning temperature, and vacuum packaging effects on beef carcass and retail cut bacteriology. J. Food Prot. 40:678.

Harrison, A.R., M.E. Smith, D.M. Allen, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1978. Nutritional regimen effects on quality and yield characteristics of beef. J. Anim. Sci. 47:383.

Loveday, H.D., M.E. Dikeman, M.C. Hunt and A.D. Dayton. 1978. Adipose tissue water related to bovine carcass composition. J. Anim. Sci. 47:606.

Smith, M.E., C.L. Kastner, M.C. Hunt, D.H. Kropf and D.M. Allen. 1979. Elevated conditioning temperature effects on carcasses from four nutritional regimens. J. Food Sci. 44:158.

Gutowski, G.H., M.C. Hunt, C.L. Kastner, D.H. Kropf and D.M. Allen. 1979. Vacuum aging, display, and level of nutrition effects on beef quality. J. Food Sci. 44:140.

Fung, D.Y.C., C.L. Kastner, M.C. Hunt, M.E. Dikeman and D.H. Kropf. 1980. Mesophilic and psychrotrophic populations on hot-boned and conventionally processed beef. J. Food Prot. 43:547.

Hayward, L.H., M.C. Hunt, C.L. Kastner and D.H. Kropf. 1980. Blade tenderization effects on beef longissimus sensory and Instron textural measurements. J. Food Sci. 45:925.

Harrison, A.R., D.H. Kropf, D.M. Allen, M.C. Hunt and C.L. Kastner. 1980. Relationships of spectrophotometric reflectance measurements to beef muscle visual color. J. Food Sci. 45:1052.

Burson, D.E., M.C. Hunt, D.M. Allen, C.L. Kastner and D.H. Kropf. 1980. Ration energy density and time on feed effects on beef longissimus palatability. J. Anim. Sci. 51:875.

Fung, D.Y.C., C.L. Kastner, C-Y. Lee, M.C. Hunt, M.E. Dikeman and D.H. Kropf. 1981. Initial chilling rate effects on bacterial growth of hot-boned beef. J. Food Prot. 44:539.

Wu, J.J., D.M. Allen, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1981. Nutritional effects on beef collagen characteristics and palatability. J. Anim. Sci. 53:1256.

Hall, J.B. and M.C. Hunt. 1982. Collagen solubility of A-maturity bovine longissimus muscle as affected by nutritional regimen. J. Anim. Sci. 55:321.

Sleper, P.S., M.C. Hunt, D.H. Kropf, C.L. Kastner and M.E. Dikeman. 1983. Electrical stimulation effects on myoglobin properties of bovine longissimus muscle. J. Food Sci. 48:479.

Axe, J.E. Bowles, C.L. Kastner, M.E. Dikeman, M.C. Hunt, D.H. Kropf and G.A. Milliken. 1983. Effects of beef carcass electrical stimulation, hot boning, and aging on unfrozen and frozen longissimus dorsi and semimembranosus steaks. J. Food Sci. 48:332.

Lyon, M., C.L. Kastner, M.E. Dikeman, M.C. Hunt, D.H. Kropf and J.R. Schwenke. 1983. Effects of electrical stimulation, aging, and blade tenderization hot-boned beef psoas major and triceps brachii muscles. J. Food Sci. 48:131.

Greathouse, J.R., M.C. Hunt, M.E. Dikeman, L.R. Corah, C.L. Kastner and D.H. Kropf. 1983. Ralgro implanted bulls: performance, carcass characteristics, longissimus palatability and carcass electrical stimulation. J. Anim. Sci. 57:355.

Burson, D.B., M.C. Hunt, D.E. Schafer, D. Beckwith and J.R. Garrison. 1983. Effects of stunning method and time interval from stunning to exsanguination on blood splashing in pork. J. Anim. Sci. 57:918.

Shivas, S.D., D.H. Kropf, M.C. Hunt, C.L. Kastner, J.L.A. Kendall and A.D. Dayton. 1984. Effects of ascorbic acid on the display life of ground beef. J. Food Prot. 47:11.

Choi, Y.I., C.L. Kastner, M.E. Dikeman, M.C. Hunt and D.H. Kropf. 1984. Effects of electrical stimulation and hot boning on functional characteristics of preblended beef muscle in model systems. J. Food Sci. 49:867.

Claus, J.R., D.H. Kropf, M.C. Hunt, C.L. Kastner and M.E. Dikeman. 1984. Effects of beef carcass electrical stimulation and hot boning on muscle display color of polyvinylchloride packaged steaks. J. Food Sci. 49:1021.

Kropf, D.H., M.E. Dikeman, M.C. Hunt and H.R. Cross. 1984. Lighting type and intensity effects on beef carcass grade factors. J. Anim. Sci. 59:105.

Shivas, S.D., C.L. Kastner, M.E. Dikeman, M.C. Hunt and D.H. Kropf. 1985. Effects of electrical stimulation, hot boning, and chilling on bull semimembranosus muscle. J. Food Sci. 50:36.

Claus, J.R., D.H. Kropf, M.C. Hunt, C.L. Kastner and M.E. Dikeman. 1985. Effects of beef carcass electrical stimulation and hot boning on muscle display color of unfrozen vacuum packaged steaks. J. Food Sci. 50:881.

Dikeman, M.E., A.D. Dayton, M.C. Hunt, C.L. Kastner, J.B. Axe and H.J. Ilg. 1985. Conventional versus accelerated beef production with carcass electrical stimulation. J. Anim. Sci. 61:573.

Burson, D.E. and M.C. Hunt. 1986. Proportion of collagen types I and III in four bovine muscles differing in tenderness. J. Food Sci. 51:51.

Burson, D.E. and M.C. Hunt. 1986. Heat-induced changes in the proportion of types I and III collagen in bovine longissimus. Meat Sci. 17:153.

Burson, D.E., M.C. Hunt, J.A. Unruh and M.E. Dikeman. 1986. Proportion of types I and III collagen in longissimus collagen from bulls and steers. J. Anim. Sci. 63:453.

Flores, H.A., C.L. Kastner, D.H. Kropf and M.C. Hunt. 1986. Effects of blade tenderization and trimming of connective tissue on hot-boned, restructured, pre-cooked roast from cows. J. Food Sci. 51:1176.

Unruh, J.A., C.L. Kastner, D.H. Kropf, M.E. Dikeman and M.C. Hunt. 1986. Effects of low-voltage electrical stimulation during exsanguination on meat quality and display colour stability. Meat Sci. 18:281.

Allen, D.M., M.C. Hunt, A. Luchiari Filho, R.J. Danler and S.J. Goll. 1987. Effects of spray-chilling and carcass spacing on beef carcass cooler shrink and grade factors. J. Anim. Sci. 64:165.

McCormick, R.J., D.H. Kropf, G.R. Reeck, M.C. Hunt and C.L. Kastner. 1987. Effect of heating temperature and muscle type on porcine muscle extracts as determined by reverse phase high performance liquid chromatography. J. Food Sci. 52:1481.

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Kluber, E.F. III, J.E. Minton, J.S. Stevenson, M.C. Hunt, D.L. Davis, T.A. Hoagland and J.L. Nelssen. 1988. Growth, carcass traits, boar odor and testicular and endocrine functions of male pigs fed a progesterogen, Altrenogest. J. Anim. Sci. 66:470.

Johnson, R.D., M.C. Hunt, D.M. Allen, C.L. Kastner, R.J. Danler and C.C. Schrock. 1988. Moisture uptake during washing and spray chilling of holstein and beef-type steer carcasses. J. Animal. Sci. 66:2180.

Claus, J.R., M.C. Hunt and C.L. Kastner. 1989. Effects of substituting added water for fat on the textural, sensory, and processing characteristics of bologna. J. Muscle Foods. 1:1.

Claus, J.R., M.C. Hunt, C.L. Kastner and D.H. Kropf. 1990. Low-fat, high-added water bologna: Effects of massaging, preblending, and time of addition of water and fat on the physical and sensory characteristics. J. Food Sci. 55:338.

Kenney, P.B. and M.C. Hunt. 1990. Effect of water and salt content on protein solubility and water retention of meat preblends. Meat Sci. 27:173.

Troyer, D.L., R.O. Oyster and M.C. Hunt. 1991. A combination histochemical stain for equine muscle. Anat. Histol. Embryol. 20:44.

Whipple, G., M. Koohmaraie, M.E. Dikeman, J.D. Crouse, M.C. Hunt and R.D. Klemm. 1990. Evaluation of attributes that affect longissimus muscle tenderness in *Bos Taurus* and *Bos Indicus* cattle. J. Anim. Sci. 68:2716.

Claus, J.R. and M.C. Hunt. 1991. Characteristics of low-fat, high-added water bologna formulated with textural modifying ingredients. J. Food Sci. 56:643.

Whipple, G., M.C. Hunt, R.D. Klemm, D.H. Kropf, R.D. Goodband, J.L. Nelssen, R.H. Hines and B.R. Schricker. 1992. Effects of porcine somatotropin and supplemental lysine on porcine muscle histochemistry. J. Muscle Foods. 3:217.

Troutt, E.S., M.C. Hunt, D.E. Johnson, J.R. Claus, C.L. Kastner, D.H. Kropf and S. Stroda. 1992. Chemical, physical, and sensory characterization of ground beef containing 5 to 30 percent fat. J. Food Sci. 57:25.

Troutt, E.S., M.C. Hunt, D.E. Johnson, C.L. Kastner and D.H.Kropf. 1992. Characteristics of low-fat ground beef containing texture-modifying ingredients. J. Food Sci. 57:19.

Goll, S.J., C.L. Kastner, M.C. Hunt and D.H. Kropf. 1992. Effects of glucose and internal cooking temperature on the characteristics of low fat, pre- and post-rigor restructured beef roasts. J. Food. Sci. 57:834.

Nold, R.A., J.A. Unruh, M.C. Hunt and C.W. Spaeth. 1992. Effects of implanting ram and wether lambs with zeranol at birth and weaning on palatability and muscle collagen characteristics. J. Anim. Sci. 70:2752.

Warren, K.E., M.C. Hunt, C.L. Marksberry, O. Sörheim, D.H. Kropf and M.J. Windisch. 1992. Modified-atmosphere packaging with carbon dioxide for bone-in pork loins. J. Muscle Foods. 3:283.

Nold, R.A., J.A. Unruh, C.W. Spaeth and M.C. Hunt. 1992. Effects of implanting ram and wether lambs with zeranol on pelt characteristics and removal. Sheep Res. J. 8:81.

Brester, G.W., P. Lhermite, B.K. Goodwin and M.C. Hunt. 1993. Quantifying the effects of new product development: The case of low-fat ground beef. J. Agric. & Resource Econ. 18:239.

Garcia Zepeda, C.M., C.L. Kastner, D.H. Kropf, M.C. Hunt, P.B. Kenney, J.R. Schwenke and D.S. Schleusener. 1993. Utilization of surimi-like products from pork with sex-odor in restructured, precooked pork roasts. J. Food Sci. 58:53.

Hague, M.A., K.E. Warren, M.C. Hunt, D.H. Kropf, C.L. Kastner, S.L. Stroda, and D.E. Johnson. 1994. Endpoint temperature, internal cooked color, and expressible juice color relationships in ground beef patties. J. Food Sci. 59:465-470.

Letelier, V., C.L. Kastner, P.B. Kenny, D.H. Kropf, M.C. Hunt, and C.M. Garcia Zepeda. 1995. Flaked sinew addition to low-fat cooked salami. J. Food Sci. 60:245-249.

Lavelle, C., M.C. Hunt, and D.H. Kropf. 1995. Display Life and Internal Cooked Color of Ground Beef from Vitamin E-Supplemented Steers. J. Food Sci. 60:1-4,6.

Sørheim, O., D.H. Kropf, M.C. Hunt, M.T. Karwoski, and K.E. Warren. 1996. Effects of modified gas atmosphere packaging on pork loin colour, display life and drip loss. Meat Sci. 43:203-212.

Campbell, R.E. and M.C. Hunt. 1996. Yields, chemical composition, and value of beef shank tissues obtained using Baader processing. J. Anim. Sci. 74:786-789.

Warren, K.E., M.C. Hunt, D.H. Kropf, M.A. Hague, C.L. Waldner, S.L. Stroda, and C.L. Kastner. 1996. Chemical properties of ground beef patties exhibiting normal and premature brown internal cooked color. J. Muscle Foods. 7:303-314.

Warren, K.E., M.C. Hunt, and D.H. Kropf. 1996. Myoglobin oxidative state affects internal cooked color development of ground beef patties. J. Food Sci. 61:513-515,519.

Luchsinger, S.E., D.H. Kropf, C.M. Garcia Zepeda, M.C. Hunt, J.L. Marsden, E.J. Rubio Canas, C.L. Kastner, W.G. Kuecker, and T. Mata. 1996. Color and oxidative rancidity of gamma and electron beam-irradiated boneless pork chops. J. Food Sci. 61:1000-1005,1093.

Luchsinger, S.E., D.H. Kropf, C.M. Garcia Zepeda, E. Chambers IV, M.E. Hollingsworth, M.C. Hunt, J.L. Marsden, C.L. Kastner, and W.G. Kuecker. 1996. Sensory analysis and consumer acceptance of irradiated boneless pork chops. J. Food Sci. 61:1261-1266.

Campbell, R.E., M.C. Hunt, D.H. Kropf, and C.L. Kastner. 1996. Low-fat ground beef from desinewed shanks with reincorporation of processed sinew. J. Food Sci. 61:1285-1288.

Luchsinger, S.E., D.H. Kropf, E. Chambers IV, C.M. Garcia Zepeda, M.C. Hunt, S.L. Stroda, M.E. Hollingsworth, J.L. Marsden, and C.L. Kastner. 1997. Sensory analysis of irradiated ground beef patties and whole muscle beef. J. Sensory Studies. 12:105-126.

Garcia Zepeda, C.M., C.L. Kastner, J.R. Wolf, J.E. Boyer, D.H. Kropf, M. C. Hunt and C.S. Setser. 1997. Extrusion and low-dose irradiation effects on destruction of *clostridium sporogenes* spores in a beef-based product. J. Food Prot . 60:777-785.

Carmack, C.F, C.L. Kastner, M.C. Hunt, D.H. Kropf, C.M. Garcia Zepeda, and J.R. Schwenke. 1997. Sensory, chemical, and physical evaluation of reduced fat ground beef patties with "natural" flavorings. J. Muscle Foods. 8:199-212.

Luchsinger, S.E., D.H. Kropf, C.M. Garcia Zepeda, M.C. Hunt, S.L. Stroda, J.L. Marsden, and C.L. Kastner. 1997. Color and oxidative properties of irradiated whole muscle beef. J. Muscle Foods. 8:427-443.

Luchsinger, S.E., D.H. Kropf, C.M. Garcia Zepeda, M.C. Hunt, S.L. Stroda, J.L. Marsden, and C.L. Kastner. 1997. Color and oxidative properties of irradiated ground beef patties. J. Muscle Foods. 8:445-464.

Hunt, M.C., O. Sørheim, and E. Slinde. 1999. Color and heat denaturation of myoglobin forms in ground beef. J. Food Sci. 64:847-851.

Powell, T.H., M.C. Hunt, and M.E. Dikeman. 1999. Enzymatic assay to determine collagen thermal denaturation and solubilization. Meat Sci. 54:307-311

Powell, T.H., M.E. Dikeman, and M.C. Hunt. 2000. Tenderness and collagen composition of beef semitendinosus roasts cooked by conventional convective cooking and modeled, multi-stage, convective cooking. Meat Sci. 55:421-425.

Killinger, K.M., M.C. Hunt, and R.E. Campbell. 2000. Factors affecting premature browning during cooking of ground beef purchased at retail. J. Food Sci. 65:585-587.

Campbell, R.G., M.C. Hunt, P. Levis, and E. Chambers IV. 2000. Dry-aging effects on palatability of beef strip loins. J. Food Sci. Accepted.

Campbell, R.G., M.C. Hunt, P. Levis, and E. Chambers IV. 2000. Dry-aging effects on palatability of beef strip loins. J. Food Sci. In Press.

Sammel, L.M., M.C. Hunt, D.H. Kropf, K.A. Hachmeister, C.L. Kastner, and D.E. Johnson. 2001. Influence of chemical characteristics of beef inside and outside semimembranosus on color traits. J. Food Sci. In Press.

Sammel, L.M., M.C. Hunt, D.H. Kropf, K.A. Hachmeister, C.L. Kastner, and D.E. Johnson. 2001. Comparison of assays for metmyoglobin reducing ability in beef inside and outside semimembranosus. J. food Sci. In Review.

Yancey, E.J., M.C. Hunt, M.E. Dikeman, P.B. Addis, and E. Katsanidis. 2001. Effects of postexsanguination vascular infusion of cattle with a solution of saccharides, sodium chloride, phosphates, and vitamins C, E, or C+E on meat display-color stability. J. Anim. Sci. In Press.

Lien, R., M.C. Hunt, S. Anderson, D.H. Kropf, T.M. Loughin, M.E. Dikeman, and J. Velazco. 2001. Effects of endpoint temperature on the internal color of pork patties of different myoglobin form, initial cooking state and quality. J. Food Sci. In Review.

Lien, R., M.C. Hunt, S. Anderson, D.H. Kropf, T.M. Loughin, M.E. Dikeman, and J. Velazco. 2001. Effects of endpoint temperature on the internal color of pork loin chops of different quality. J. Food Sci. In Review.

Lawrence, T. M.C. Hunt, and D.H. Kropf. 2001. Surface roughening of pre-cooked, cured beef round muscles reduces iridescence. J. Muscle Foods. In Review.

Abstracts / Posters

Hunt, M.C., R.A. Smith, D.H. Kropf and H.J. Tuma. 1969. Factors affecting showcase color stability of frozen lamb in transparent film. J. Anim. Sci. 29:123. (Abstr.).

Kropf, D.H., M.C. Hunt and A.D. Dayton. 1970. Reflectance spectrophotometry for following frozen beef and lamb color changes. J. Anim. Sci. 31:185. (Abstr.).

Kropf, D.H., H.J. Tuma, J.A. Santamaria, M.C. Hunt and D.E. Schafer. 1971. Display light intensity effects on frozen beef color stability. J. Anim. Sci. 33:219. (Abstr.).

Hunt, M.C. and H.B. Hedrick. 1973. Properties of bovine longissimus muscle from four quality groups. J. Anim. Sci. 37:263. (Abstr.).

Allen, D.M., M.C. Hunt, C.L. Kastner, D.H. Kropf, V. Chen, A. Harrison and M.E. Smith. 1976. Improving grass-fed beef quality. J. Anim. Sci. 43, 236 (Abstr.).

Kuntapanit, C., B.E. Brent, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1978. Fluorometric TBA analysis for muscle food autoxidation. J. Anim. Sci. Abstr. 13.

Harrison, R.A., M.E. Smith, D.M. Allen, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1978. Nutritional regimen effects on quality and yield characteristics of beef. Ann. Meeting Amer. Soc. Anim. Sci. Abstr. 172.

Harrison, A.R., D.H. Kropf, D.M. Allen, M.C. Hunt and C.L. Kastner. 1978. Nutritional regimen, vacuum packaging and display length effects on color of four beef muscles. Ann. Meeting Amer. Soc. Anim. Sci. Abstr. 173.

Corte, O., D.M. Allen, B.E. Brent, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1978. Longissimus and biceps femoris collagen characteristics of beef finished on four nutritional regimens. Ann. Meeting Amer. Soc. Anim. Sci. Abstr. 163.

Fung, D.Y.C., C.L. Kastner, M.C. Hunt, M.E. Dikeman and D.H. Kropf. 1979. Mesophilic and psychrotrophic populations of hot-boned and conventionally processed beef. 39th Ann. Meeting of IFT, St. Louis, MO. (Abstr.).

Harrison, A.R., D.H. Kropf, D.M. Allen, M.C. Hunt and C.L. Kastner. 1979. Nutritional regimen, vacuum packaging and display length effects on color of four beef muscles. 39th Ann. Meeting of IFT, St. Louis, MO. (Abstr.).

Harrison, A.R., D.H. Kropf, D.M. Allen, M.C. Hunt and C.L. Kastner. 1979. Relationship of various spectrophotometric reflectance measurements to beef muscle visual color. 39th Ann. Meeting of IFT, St. Louis, MO. (Abstr.).

Hayward, L.H., M.C. Hunt, D.M. Allen, C.L. Kastner and D.H. Kropf. 1979. Blade tenderization effects on beef longissimus sensory, and Instron textural measurements. 39th Ann. Meeting of IFT, St. Louis, MO. (Abstr.).

Francis, S., D. Allen and M.C. Hunt. 1980. Animal agriculture and consumers. J. Anim. Sci. Midwest ASAS (Abstr.).

Obanion, D.S., R.R. Schalles and M.C. Hunt. 1980. Relationship among performance of yearling bulls and longissimus amino acids and histochemical characteristics. J. Anim. Sci. Midwest ASAS (Abstr.).

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Educational Materials

Course Syllabi:

Distance Learning - Complete course, *PRINCIPLES OF MEAT SCIENCE* in "any-time or real-time" distance learning format via audiotapes, teleconferencing, on-line discussions involving collaborative learning, problem solving and critical thinking via the Internet.

In-Class - Laboratory Materials for *MEAT SCIENCE*, a series of 14 study guides for lab exercises
- Laboratory Materials for *PROCESSED MEAT OPERATIONS*

Other Materials and Activities:

USDA Grant: - Expanding Undergraduate Education for Food Industry Personnel via Technology. 1994-96 USDA Challenge Grant Program,

Web-based Course - Principles of Meat Science, KSU Division of Continuing Education

Color Guides
- Ground Beef Patty Cooked Color Guide
- Cured Meat Color Guide
- Cooked Pork Chop Color Guide
- Ground Pork Patty Cooked Color Guide

Science Series - Lesson Plans for: Promoting Ag Science for Secondary Schools
Developing New Meat Products
Color Chemistry in Meat Products
Meat Packaging Exercises for High School Students

Slides Series:
- Unraveling the Mystery of Premature Browning in Cooked Ground Beef Patties
- Doneness of Cooked Ground Beef
- Dynamics of Conversion of Myoglobin Forms
- Role of Pigment Layers in Influencing Surface Meat Color
- Spray Chilling of Carcasses
- Don't be Broken-Hearted because of High-fat in Ground Beef
- Commercial Sausage, Ham and Bacon Production
- Food Science at KSU
- ASI Quadrathlon - why I should participate
- Updated: Muscle-Bone Anatomy; Beef-Pork-Lamb Cut Identification

Video Tapes: - Beef Carcass Electrical Stimulation and Hot Boning (Edited with M. E. Dikeman)

Store Survey: - Out-of-class assignment for Analysis of Retail Meat Section of Grocery Stores

Diet Survey: - Out-of-class assignment for computerized class project of Nutritional Value of Muscle Foods in the student's diet

Current topic: Survey - Out-of-class assignment for critically analyzing printed literature on a variety of livestock and meat industry topics

Web Sites: - Out-of-class assignment for evaluation and collection of scientific facts about muscle biology and meat science

Theses and Dissertations

000245

Gutowski, G.H. 1977. Effect of vacuum aging, display and level of nutrition on beef quality. M.S. Thesis, Kansas State University.

Hayward, L.H. 1978. Blade tenderization effects on subjective and instron objective textural measurements of longissimus steaks from cattle fed various nutritional regimes. M.S. Thesis, Kansas State University.

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Burson, D.E. 1979. Ration energy density and time on feed effects on beef longissimus palatability. M.S. Thesis, Kansas State University.

Hall, J.B. 1981. Collagen solubility of A-maturity bovine longissimus muscle as affected by nutritional regimen. M.S. Thesis, Kansas State University.

Greathouse, J.R. 1982. Ralgro implanted bulls: Performance, carcass characteristics, longissimus palatability and carcass electrical stimulation. M.S. Thesis, Kansas State University.

Sleper, P.S. 1982. Myoglobin properties of electrically stimulated bovine longissimus muscle. M.S. Thesis, Kansas State University.

Highfill, G.A. 1984. Effects of sex and compudose implantation on porcine muscle histochemistry. M.S. Thesis, Kansas State University.

Burson, D.E. 1985. Effects of muscle, heat and sex on the proportions of types I and III bovine intramuscular collagen. Ph.D. Dissertation. Kansas State University.

Claus, J.R. 1989. Characterization of low-fat processed meat containing dietary fiber. Ph.D. Dissertation, Kansas State University.

Troutt, S.E. 1990. A chemical, physical and sensory characterization of low-fat ground beef. M.S. Thesis, Kansas State University.

Warren, K.E. 1990. Modified atmosphere packaging with 100% carbon dioxide for bone-in pork loins. M.S. Thesis, Kansas State University.

Hague, M.A. 1992. Internal and expressible juice color of cooked ground beef patties. M.S. Thesis, Kansas State University.

Londono Villegas, J.F. 1993. Effects of realimentation and trenbolone acetate implantation of cull cows on tenderness and cooked color. M.S. Thesis, Kansas State University.

Payne, A.C. 1993. Starch functionality and modification for batter sausages. PhD. Dissertation, Kansas State University.

Warren, K.E. 1994. Factors affecting premature browning of heated myoglobin. PhD. Dissertation, Kansas State University.

Conner, J.G. 1995. Fat trimming and vitamin E effects on subprimal and retail cut yields and shelf life. M.S. Thesis, Kansas State University.

Schoenbeck, J.J. 1997. Effects of carcass infusion on color and display life of several bovine muscles. M.S. Thesis, Kansas State University.

Clark, T.J. 1998. Rebloom and display color stability of beef and pork packaged in an ultra-low oxygen modified atmosphere active packaging system. M.S. Thesis, Kansas State University.

Campbell, R.E. 2000. Effects of internal structure, patty shrinkage, and desinewing on palatability attributes of ground beef. PhD dissertation.

Sammel, L.M. 2000. Chemical characterization, color stability, and comparison of assays for metmyoglobin reducing ability in beef inside and outside semimembranosus. MS thesis.

Lien, R. 2001. Effects of endpoint temperature, pork quality, and cooking factors on internal cooked color of pork chops and patties. MS thesis.

Wendelburg, J. 2001. Physical, chemical and microbial qualities of blade tenderized prime rib. MS Thesis.

Ballard, C. 2002. Carbon monoxide in modified atmosphere packaging. MS Thesis.

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ATTACHMENT 10

MATFORSK
Norwegian Food Research Institute

Mr. Eric F. Greenberg
3500 Three First National Plaza
Chicago, Illinois 60602-4283
USA

29 June 2001
Oso/lsro/O-8652
Direct line +47 64 97 02 39

Dear Mr. Greenberg;

I have evaluated the use of 0.4 % carbon monoxide (CO) in the proposed ActiveTech 2001 packaging system for meat. Based on the information provided, I consider ActiveTech 2001 to be generally recognized as safe (GRAS).

In my position as a meat scientist at MATFORSK - Norwegian Food Research Institute I have studied a gas mixture with 0.4 % CO/ 60 % CO_2/ 40 % N_2 for direct retail meat packaging. Such use of this gas mixture is considered to be safe. Therefore, I also evaluate the CO used in the ActiveTech 2001 system to be safe, as the consumer will be exposed to even lower levels of CO in the meat, due to loss of CO at the retail level, where the meat is packaged in a gas-permeable film.

Yours faithfully

MATFORSK
Norwegian Food
Research Institute

Oddvin Sørheim, Ph.D.
Senior Research Technologist

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[redacted]

CURRICULUM VITAE

Navn/Name:	Sørheim, Oddvin
Privatadresse/Private address:	
E-mail:	
Telefon/Telephone:	
Arbeidssted/Place of employment:	
Stilling/Present position:	Sjefingeniør / Senior Research Technologist Dr.agric. / Ph.D.

Utdanning/Education:

2000, Dr. agric./Ph.D., Norges landbrukshøgskole/Agricultural University of Norway

1982, Cand. agric./M.Sc., Næringsmiddelfag, Norges landbrukshøgskole/Agricultural University of Norway

Erfaring/Experience:

01.05. 1985 til nå ved/ to present at MATFORSK, arbeidet med forskning og industrioppdrag på kjøtt i hovedsak innen gasspakking, farge, mørhet, salting og funksjonelle egenskaper/ mainly working in research and industry consulting on packaging, color, tenderness, salting and functional properties of meat.

01.08. 1989 til 01.06. 1990, forskningsopphold/visiting scientist, Kansas State University, Department of Animal Sciences and Industry, Manhattan, KS, USA

01.06. 1982 til 30.04. 1985, produksjonskonsulent/consultant, Slakterienes Salgssentral/Norwegian Meat Cooperative, Oslo

Vitenskapelige originalarbeider/Scientific publications:

- Sørheim, O., Idland, J., Halvorsen, E.C., Frøystein, T., Lea, P., Hildrum, K.I. 2001. Influence of beef carcass stretching and chilling rate on the tenderness of M. longissimus dorsi. Meat Science, Vol 57, pp 79-85.
- Kjos, N.P., Øverland, M., Bryhni, E.A., Sørheim, O. 2000. Food waste products in diets for growing-finishing pigs: effect on growth performance, carcass characteristics and meat quality. Acta Agric. Scand., Sect. A, Animal Sci., Vol 50, pp 193-204.
- Hunt, M.C., Sørheim, O., Slinde, E. 1999. Color and heat denaturation of myoglobin forms in ground beef. Journal of Food Science, Vol 64, pp 847-851.
- Sørheim, O., Nissen, H., Nesbakken, T. 1999. The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide. Meat Science, Vol 52, pp 157-164.
- Sørheim, O., Aune, T., Nesbakken, T. 1997. Technological, hygienic and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat. Trends in Food Science & Technology, Vol 8, pp 307-312.
- Sørheim, O., Erlandsen, T., Nissen, H., Lea, P., Høyem, T. 1997. Effects of modified atmosphere storage on colour and microbiological shelf life of normal and pale, soft and exudative pork. Meat Science, Vol 47, pp 147-155.
- Sørheim, O., Kropf, D.H., Hunt, M.C., Karwoski, M.T., Warren, K.E. 1996. Effects of modified gas atmosphere packaging on pork loin colour, display life and drip loss. Meat Science, Vol 43, pp 203-212.
- Nissen, H., Sørheim, O., Dainty, R.H. 1996. Effects of vacuum, modified atmospheres and storage temperature on the microbial flora of packaged beef. Food Microbiology, Vol 13, pp 183-191.
- Sørheim, O., Grini, J.Aa., Nissen, H., Andersen, H.J., Lea, P. 1995. Pork loins stored in carbon dioxide - Colour and microbiological shelf life. Fleischwirtschaft , 75, 679-681.

Vitenskapelige publikasjoner og presentasjoner/Other publications and presentations:

- Sørheim, O. 2000. Effects of modified atmosphere packaging on colour and microbiological shelf life of red meats. (Dr.agric./Ph.D.-thesis, Agricultural University of Norway).
- Sørheim, O., Nissen, H. 2000. Current technology for meat MAP. Int. Food Marketing & Technology, Vol 14, No 4, pp 39-42.
- Sørheim, O., Nissen, H. 1996. Modified atmosphere packaging of red meats. The European Food & Drink Review, No 4, pp 77-80.

Bok/book

- Hildrum, K.I., Dainty, R.H., Egelandsdal, B., Larssen, E.G., Mielnik, J., Sørheim, O. 1996. Meat for the Consumer. MATFORSK Ås, 593 pp, ISBN 82-90394-58-6.

Annet/others

- Risvik, E., Hildrum, K.I., Russwurm jr, H., Dainty, R.H., Egelandsdal, B., Green, A., Larssen, E.G., Merok, K.J., Mielnik, J., Norang, R.E., Næs, H., Olsen, M.Ø., Roskifte, P., Slinde, E., Sørheim, O. 1996. The 42nd ICoMST: "Meat for the Consumer", Norway 1-6 September 1996 (organising committee).
- Sørheim, O. 2001 - . Editorial board, Journal of Muscle Foods.

Proceedings:

- Sørheim, O., Nissen, H., Aune, T., Nesbakken, T. 2001. Use of carbon monoxide for retail meat packaging. Proc. International Animal and Agriculture Food Science Conference, Indianapolis, USA, in press.
- Sørheim, O., Lea, P., Nissen, H., Nesbakken, T. 2001. Effects of a high CO_2 /low CO atmosphere on colour and yield of cooked ground beef patties. Proc. 47th ICoMST, Krakow, Poland, 4 p., in press.
- Sørheim, O., Idland, J., Frøystein, T., Lea, P., Hildrum, K.I. 2000. Combined effects of aitch bone suspension and chilling rate on the tenderness of beef muscles. Proc. 46th ICoMST, 27 August - 1 September 2000, Buenos Aires, Argentina, Vol 1, pp 402-403.
- Bryhni, E.A., Kjos, N.P., Øverland, M., Sørheim, O. 1999. Food waste products in diets for growing-finishing pigs. Effect on growth performance, carcass characteristics and meat quality. Proc. 45th ICoMST, 1-6 August 1999, (Eds. Japan Society for Meat Science and Technology) Yokohama, Japan, pp 82-83.
- Sørheim, O., Nissen, H., Nesbakken, T. 1998. Color stabilization of pork chops packaged with a low level of carbon monoxide. Proc. 51st Annual Reciprocal Meat Conference: Current Advances in Meat and Poultry Color, 28 June - 1 July 1998, (American Meat Science Association) Storrs, Connecticut, USA, Vol 51, pp 187-188.
- Sørheim, O., Nissen, H., Nesbakken, T. 1997. Shelf life and colour stability of beef loin steaks packaged in a modified atmosphere with carbon monoxide., Proc. 43rd ICoMST, 27 July - 1 August 1997, (Ed. J. Bass) Auckland, New Zealand, Vol 43, pp 694-695. ISBN 0-473-04549-4.
- Sørheim, O., Lea, P., Gilde, M., Nissen, H. 1996. Effects of packaging gases on the colour of beef . Proc. 42nd ICoMST (Ed. K.I. Hildrum), MATFORSK, Lillehammer, Norway, 1-6 September 1996, pp 110-111, ISBN 82-90394-58-6.
- Hunt, M.C., Sørheim, O., Slinde, E. 1995. Effects of myoglobin form on internal cooked color development in ground beef. Proc. 41st ICoMST, American Meat Science Association, San Antonio, Texas, USA, 20-25 August 1995, Vol II, pp 394-395.

[redacted]

SUBMISSION ENM

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Reference List for Industry Submission, GRN 000083

Pages	*Author*	*Title*	*Publish Date*	*Publisher*	*BIB_Info*
000106 - 000108	Tuijtelaars, A.C.J., Samson, R.A.; Rombouts, F.M.; Notermans, S.	Food Microbiology And Food Safety Into The Next Millennium	September 1999	Proceedings of the Seventeenth International Conference of the International Committee on Food Microbiology and Hygiene (ICFMH)	pgs 285-286
000127 - 000133	Sorheim, Oddvin; Aune, Tore; Nesbakken, Truls	Technological, hygienic and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat	September 1997	Trends in Food Science & Technology	Volume 8, pgs 307 - 312
000134 - 000141	Sorheim, Oddvin; Nissen, Hilde; Nesbakken, Truls	The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide	1999	Meat Science	Volume 52, pgs 157-164
000194 - 000197	American Society for Testing and Materials	Standard Practice for Analysis of Reformed Gas by Gas Chromatography	2000	NA	pgs 1-5

NA- Not applicable

ERIC F. GREENBERG
ATTORNEY AT LAW

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PREMARKET APPROVAL

ERIC F. GREENBERG
Of Counsel
Ungaretti & Harris

VIA FEDERAL EXPRESS

September 5, 2001

Dr. Linda S. Kahl
Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St, SW
Washington, DC 20204

Re: NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT

Dear Dr. Kahl:

This letter is written as a supplement to the Notification Of Claim For General Recognition Of Safety Of Carbon Monoxide In A Modified Atmosphere System For Packaging Fresh Meat (consisting of pages 000001.001-000250), submitted by Pactiv Corporation by letter dated August 29, 2001.

The data and information that are the basis for Pactiv's GRAS determination are available for the Food and Drug Administration's review and copying at reasonable times at the office of Eric F. Greenberg, 3500 Three First National Plaza, Chicago, Illinois 60602, or will be sent to FDA upon request.

Moreover, please note that Pactiv withdraws its claim of protection as Confidential Business Information for each and every portion of the submission that was previously redacted (redactions are listed on page 000001.002), and that the GRAS Notice no longer contains information for which Pactiv is asserting Confidential Business Information protection. We understand that FDA may make an independent determination that portions should be protected from disclosure under the Freedom Of Information Act and implementing regulations.

If you have any questions, please contact me at (312) 977-4647.

Sincerely,

Eric F. Greenberg

000251

efgreenberg@uhlaw.com
3500 THREE FIRST NATIONAL PLAZA, CHICAGO, ILLINOIS 60602-4283
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AM

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Of Counsel
Ungaretti & Harris

FAX COVER SHEET

TO:	Dr. Lane A. Highbarger	FAX NUMBER:	202-418-3131
FIRM NAME	OFFICE OF FOOD ADDITIVE SAFETY – CFSAN, FDA	PHONE NUMBER:	
DATE:	November 30, 2001	TIME:	NUMBER OF PAGES 3 (Including Cover Page)

Dr Highbarger:

The attached 2 letters supplement GRAS Notice 000083. They are also being sent by U.S. Mail.

Sincerely,

Eric F. Greenberg

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If problems occur during transmission, or if all pages are not received, please contact us immediately at 312-977-4647

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November 29, 2001

Mr. Eric F. Greenberg
Of Counsel
Ungaretti & Harris
3500 Three First National Plaza
Chicago, IL 60602-4283

Dear Mr. Greenberg:

This letter is written to supplement and clarify my letter of August 8, 2001 regarding the generally recognized as safe status of the use of carbon monoxide in a modified atmosphere packaging system.

To clarify my opinion as expressed in the second paragraph of my August 8, 2001 letter, based on my review of the details of the Pactiv Corporation Active Tech 2001 modified atmosphere system employing 0.4% carbon monoxide gas in a mixture with carbon dioxide and nitrogen, as well as the published literature and common knowledge in the field, I am confident that the use of a modified atmosphere including small quantities of carbon monoxide (0.4%) to package fresh meats as used in the Active Tech 2001 system is both safe and generally recognized as safe.

If you need additional clarification, please let me know.

Sincerely,

Melvin C. Hunt
Professor and Chair,
Department of Food Science and Industry

Utah State
UNIVERSITY

DEPARTMENT OF NUTRITION AND FOOD SCIENCES
College of Agriculture
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Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St, SW
Washington, DC 20204

November 29, 2001

Dear FDA Personnel,

This letter is written to supplement and clarify my letter of August 17, 2001 regarding the generally recognized as safe status of the use of carbon monoxide in a modified atmosphere packaging system.

To clarify my opinion as expressed in my August 17, 2001 letter, based on my review of the details of the Pactiv Corporation ActiveTech 2001 modified atmosphere system employing 0.4% carbon monoxide gas in a mixture with carbon dioxide and nitrogen, as well as the published literature and common knowledge in the field, I confirm that the use of modified atmospheres including 0.4% carbon monoxide to package fresh meats as used in the ActiveTech 2001 system is both safe and generally recognized as safe.

Sincerely yours,

Daren Cornforth, PhD
Professor, Nutrition & Food Sciences
Utah State University
435-797-2114
darenc@cc.usu.edu