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ORIGINAL SUBMISSION

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April 22, 1999

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Linda S. Kahl, Ph'D
Center for Food Safety and Applied Nutrition
(HFS-206)
Food and Drug Administration
200 C Street SW.
Washington, DC 20204

Dear Linda:

AMPC, Inc. respectfully submits the following GRAS Exemption Claim.

Pork Collagen, used as a binder and purge reducing additive in meat products is exempt from the pre-market approval requirements of the Food, Drug and Cosmetic Act (the ACT) because we (AMPC, Inc.) have determined that its use in such products is GRAS.

Signer
V. P. Quality Assurance

Date 4/22/99

AMPC, Inc.
2325 North Loop Drive
Ames, Iowa 50010

The conditions of use of notifiers substance are:

This binder and purge preventing substance would be used in foods such as; sausage, frankfurters, pizza toppers, luncheon loafs, and foods which will be enhanced by the water and fat absorbing characteristics of this pork collagen.

Levels of use in such foods: 1 – 3.5%

Purpose for which the substance is used:

To be used as a binder and purge reducing additive in meat or meat type products.

Description of population expected to consume the substance:

Individuals who currently consume pork, beef or poultry containing sausages, franks, pizzas, etc., and other processed meats. This would include individuals within a wide age range as well as varied social and economical backgrounds.

The basis for the GRAS determination is: Scientific Procedures

The data and information that are the basis for the notifier's GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at the specific address set out in this notice or will be sent to FDA upon request.

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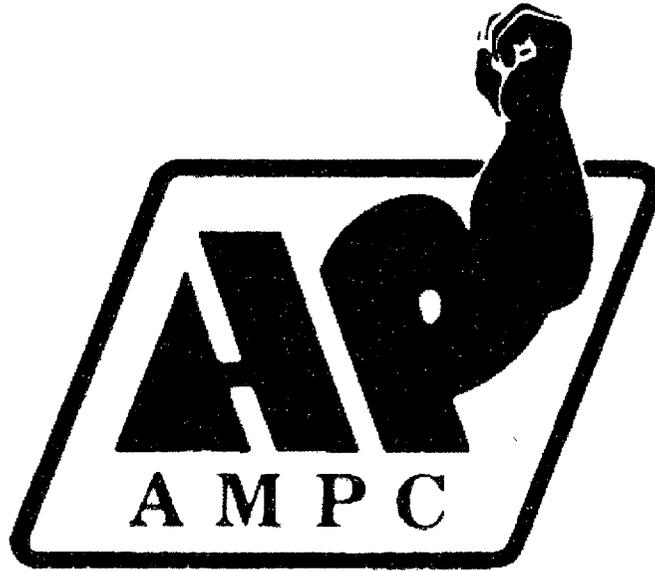
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United States Department of Agriculture: *Standards and Labeling Policy Book*. June 1991 thru July 1993.



GRAS Notification
from AMPC, Inc.
for
Pork Collagen

AMPC, Inc.
2325 North Loop Drive
Ames Iowa 50010

000005

Office of Pre-market Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington, DC 20204

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1.0 Claim

Claim

Pork Collagen, used as a binder and purge reducing additive in meat products is exempt from the pre-market approval requirements of the Food, Drug and Cosmetic Act (the act) because we (AMPC, Inc.) have determined that its use in such products is GRAS.

Signed _____ Date _____

AMPC, Inc.

2325 North Loop Drive

Ames, Iowa 50010

2.0 Food in Which it is to be Used.

Food in which it is to be used

Sausage

Frankfurters

Pizza toppers

Luncheon loafs

Foods which will be enhanced by the water and fat absorbing characteristics of this pork collagen.

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3.0 Level of use in foods

Between 1 to 3.5 %

4.0 Purpose for Which Substance is Used

Purpose for which substance is used

This collagen enriched protein powder, when added in small quantities in meat systems, provides for the absorption and binding of both fat and moisture so that in normal thermal processing moisture and fat purging is reduced or eliminated. AMPC's collagen protein is more compatible in many applications in regards to flavor and functionality than many of the currently approved additives. This additional thermal protection against purge or fat accumulation under the casings of sausages (greasing out) will permit processors to either cook at higher temperatures or longer time, to extend shelf life and possibly improve food safety. This pork collagen can be used in reduced fat sausage products due to its excellent water absorbing characteristics and its flavor compatibility at relative high usage levels thereby replacing fat.

Currently, concentrated milk and vegetable proteins are allowed by the USDA in the products we are proposing this collagen protein be used in. Since this protein will function in many applications superior to those currently proposed, we feel that this collagen material should be allowed in such products. While some of the source material "cooked pork fatty tissue" is used in edible applications, our proprietary method of cooking and further reducing fat produces a product which is more flavor compatible, safe, shelf-stable and since it is easily handled and utilized in the intended products it makes a more nutritional and acceptable ingredient.

Cooked defatted pork tissue is very difficult to handle as it is a very viscous substance which does not lend to rapid cooling after the partial defatting process. To date, only a small portion of this material is presently utilized in food. AMPC has extensively researched a means to effectively process this material into a high value – shelf stable

(over 2 year shelf life), nutritional product which can be utilized both in the United States and internationally. Due to it being a unique functional animal protein powder, to qualify its use, pork collagen must be established as a GRAS substance as are other protein powder concentrates currently being used in the previously mentioned products.

There is a long history of many products which originate from fatty tissue in which this tissue is rendered and the solids remaining are consumed in tact or in other products. I have supplied in the index pages a list of products which contain these materials as defined by USDA in their Standards and Labeling Policy Book (see Appendix A).

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5.0 Population Expected to Consume Product

Population Expected to Consume the Substance

The population expected to consume the substance are those individuals who currently consume pork, beef or poultry containing sausages, franks, pizzas, etc., and other processed meats. This would include individuals within a wide age range as well as varied social and economical backgrounds. According to the Vegetarian Times, 99 percent of all Americans eat meat and 94 percent eat red meat. Of this, the American Meat Institute estimates that 1.5 ounces of processed meat and poultry per individual is consumed daily which would include products in which this substance would be added. There are several religious sectors which would not consume this collagen due to it being derived from pork. Since the product name will be "Pork Collagen", there are no religious issues relating to involuntary consumption of this pork ingredient.

6.0 Basis for GRAS Determination

Basis for GRAS Determination

Historical Perspective of Safety

The basis for GRAS determination could be argued on both a scientific and practical experience basis. It has been used commonly in food for years. Certainly this collagen protein has been consumed in many different forms since before the recording of time. When fat containing meat is cooked, the rendering effects of this cooking allows the fat to escape resulting in the concentration of collagen in the non-liquid portion of tissue. In AMPC's process, the fat is rendered at a relatively low temperature with the assistance of centrifugation, allowing for the tissue to remain functional with minimal denaturation. The subsequent rapid and controlled cooking dehydrates the collagen, again protecting the functionality. In order to further reduce the fat and increase protein in the dehydrated collagen, AMPC mechanically compresses the dried material expelling the fat. This multi-stage collagen enrichment process results in a very high protein powder with excellent functionality when blended into meat systems. Since several of AMPC's processes utilize equipment post dating 1956, we are basing our determination as GRAS on a scientific basis.

The safety of concentrated collagen proteins from fatty tissues has been well proven in common use in foods both as ingredients and as a food itself. Examples are: Fried pork rinds, cracklings, bacon, rendered beef fat tissue solids, pork greaves, and partially defatted pork fatty tissue. Similarly, home preparation of pork meat frequently renders portions of the fatty tissue in items such as a roast to a very dehydrated and collagen enriched material.

Additionally, dried and concentrated pork fatty tissue is included in many animal feed products. This common use is unrestricted in feeds, except for the animal nutritionist's discretion in providing a cost effective healthy diet. Meat by-products in which dehydrated and concentrated collagen proteins (as defined and recognized by AFCO) are as follows:

Dried Meat Solubles

Meat Meal

Meat and Bone Meal

Animal By-Product Meal

Meat Meal Tankage

Meat Protein Isolate

In the case of animal consumption, the exclusive protein source may originate from these sources which could be in a feed formula as high as 80%. These levels would far exceed any of those we are proposing in this GRAS notification and that we have indicated at a maximum of 3.5%. Also, in many applications, animals consume the aforementioned protein daily over extended periods, sometimes lasting the lifetime of the animal such as in pets. If there were any universal adverse effects from this concentrated collagen protein being fed at the levels necessary to provide the dietary proteins for mammalian animals, these effects should have been realized and documented over the hundred years that the rendering industry has existed.

Scientific Perspective for Safety

The raw tissue, pork fat, is a food and is recognized of itself as GRAS through the many years it has been consumed in part or whole. This fat tissue originates in USDA

inspected facilities in which the sanitation and processing is overseen by continuous USDA inspections. At no time is this fatty tissue allowed to deteriorate or become contaminated within the limits of USDA regulations. Manufacturers QA/QC systems maintain the processing facilities in regards to meeting human edible requirements in regards to sanitation and food safety.

The rendering processes used by our suppliers to partially reduce fat are entirely thermal and mechanical with no addition of chemicals. A USDA approved antioxidant mixture is added to the product exiting the fat reduction process to protect the flavor throughout the products expected shelf life. The steam used to heat the tissue for partially defatting occurs in steam jacketed kettles and does not come in contact with tissue. In the unlikely event of mechanical failure in which steam could come in contact with product, the USDA monitors and requires that the steam additives be approved for food use.

Similarly, hydraulic fluids and lubricants must be approved for their respective use in USDA facilities in the unlikely event of mechanical failures where processed food may come in contact with these substances. The refrigerants used for immediate cooling of the partially defatted tissue is propylene glycol and is similarly approved and monitored for its intended use. The tissue is subsequently protected from microbiological deterioration through adherence to CGMPs and continuous storage under refrigerated temperatures until it arrives at AMPC's facilities. Up until this point, the processes described are quite well documented and utilized by the meat industry. The exception may be AMPC's incorporation of a drum freezer/chiller which more rapidly cools the product than the conventional cooling systems.

When AMPC receives this tissue in totes at our facility, it is processed exclusively utilizing thermal and mechanical means with no addition of processing aids, or other ingredients. The drying process utilizes a direct gas fired belt conveyor systems. The subsequent fat extraction utilizes high mechanical pressure, followed by the mechanical milling or grinding of the finished material to the desired mesh screen size.

Potential Hazardous Substances

Safety concerns would involve those resulting from the concentration of potentially hazardous elements or compounds inherent in the fatty tissue, the microbiological quality of the tissue in the form of pathogens or toxins, and any risks associated with the addition of the antioxidant mixture or through the mechanical processes. When considering the ensuing data, it should be recognized that the product in these totes represents tissue from over 100 animals and that both our suppliers and our own processes continuously mixes this product. Therefore our data represents the average data from at least this number of animals.

Heavy Metals

In respect to the concentration of heavy metals, there appears to be no increase in the lead content through our process, as the data shows values remain below 1ppm in the finished product. (Contact AMPC for additional data) This compares favorably to data of dried meat and dried milk and should not pose any additional risk to foods in which this collagen is added. When compared to the CODEX acceptable levels of lead in phosphates which are used for water/fat binding and emulsion stabilization, these phosphates can have lead tolerances 15 times that of which we are finding in our collagen protein (Appendix B).

Pesticides & Antibiotics

Pesticides were tested and were undetected in those samples tested.

The finished collagen protein was tested for the following antibiotics and none were detected except for Chlorotetracycline. (Reference actual Lab Reports in Appendix C)

The reported value is below the tolerance of 2ppm which USDA uses for acceptance in muscle meats. Also as noted later, the collagen protein must be rehydrated before consumption which will reduce this value by at least ¼th. Also, USDA does daily checks at every slaughtering facility for antibiotic residues in animals being slaughtered which assures that safe initial levels will be maintained in the tissue we purchase. The testing for pesticides (see following pages) resulted in “none detected” for the 62 chemicals tested for (Appendix D & E).

Hazardous Substances from Processes

In respect to any hazardous substances resulting from our processing and incorporation of the antioxidant system, we cannot identify any foreseeable or detectable risks. The vegetable oil, mono and diglycerides, lecithin, tocopherol, rosemary extract and citric acid all have been used in similar food systems without any apparent risks. Individually and in combination with foods, these ingredients form no hazardous compounds based on their previously approved GRAS status. Our thermal processes do not elevate the temperature of product to the degree that any excessive oxidation or carbonation occurs. This is verified by the amino acids, free fatty acid profile, the peroxide values, tocopherol levels all showing near identical values to those found previous to drying, considering moisture loss. (Contact AMPC for validating data)

Oxidation

The very low peroxide values and FFA levels as indicated by our standards, coupled with the nitrogen purging of our hermetically sealed bags has provided our current product (Dehydrated Pork Fatty Tissues) with over 2 years shelf life based on chemical and organoleptic testing. This fact assures that the toxic compounds associated with the breakdown of fats and oils do not and will not occur in pork collagen throughout the shelf life of product.

Microbiological Hazards

The hazards associated with the microbiologic toxins or pathogens are controlled by USDA monitored HACCP programs both at our suppliers and our processing facility. Incorporated in these HACCP programs and other processes are the reliance upon rapid heating and cooling of product and maintenance of refrigeration temperature during storage. The scientific verification of these precautions is by the microbiological testing of the material we receive from our suppliers and our finished products (refer to specifications on the following pages). Our microbiological quality levels fall well within those routinely found and specified for dairy products and are equal to or exceed those known to be safe for foods. At no time do the processing conditions or the processing equipment allow for pathogen growth without this being detected by either microbiological testing or Q.C. checks. AMPC's finished products are not released for sale without Quality Assurance confirming compliance to these specifications. Included on page 22 are the microbiological results of 247 lots of AMPC's Dehydrated Pork Fatty Tissue. Since the drying process reduces the water activity to below 0.25, once the pork collagen is dried, and as long as it is protected from re-absorption of moisture, there can

be no additional microbiological growth in product. The thermal drying process is responsible for the thorough destruction of pathogens and the moisture protected packaging assures a safe means to transport and store this concentrated nutritive protein.

Total number of lots analyzed: 247

Dehydrated Pork Fatty Tissue Data

	(cfu/g)	(cfu/g)	(cfu/g)	(cfu/g)	(cfu/g)	
SPC	<u>≤100</u>	<u>101 - 10,000</u>	<u>10,001 - 15,000</u>	<u>15,001 - 50,000</u>	<u>>50,000</u>	
	33	203	3	6	2	
%	13.36	82.18	1.21	2.43	0.81	min = <100 cfu/g max = 115,000 cfu/g

	(mpn/g)	(mpn/g)	(mpn/g)	
Coliforms	<u><3.0</u>	<u>3.0 - 99.0</u>	<u>≥100</u>	
	202	41	2	
%	81.78	16.60	0.81	min = <3.0 mpn/g max = 1,000 mpn/g

	(mpn/g)	(mpn/g)	(mpn/g)	
<i>E.coli</i>	<u><3.0</u>	<u>3.0 - 99.0</u>	<u>≥100</u>	
	231	15	1	
%	93.52	6.07	0.40	min = <3.0 mpn/g max = 460 mpn/g

	(cfu/g)	(cfu/g)	
<i>S.aureus</i>	<u><100</u>	<u>100 - 1,000</u>	
	246	1	
%	99.59	0.40	min = <100 cfu/g max = 200 cfu/g

	(cfu/g)	(cfu/g)	(cfu/g)	
Yeasts	<u><10.0</u>	<u>10 - 100</u>	<u>>100</u>	
	215	31	1	
%	87.04	12.55	0.40	min = <10.0 cfu/g max = 2,500 cfu/g

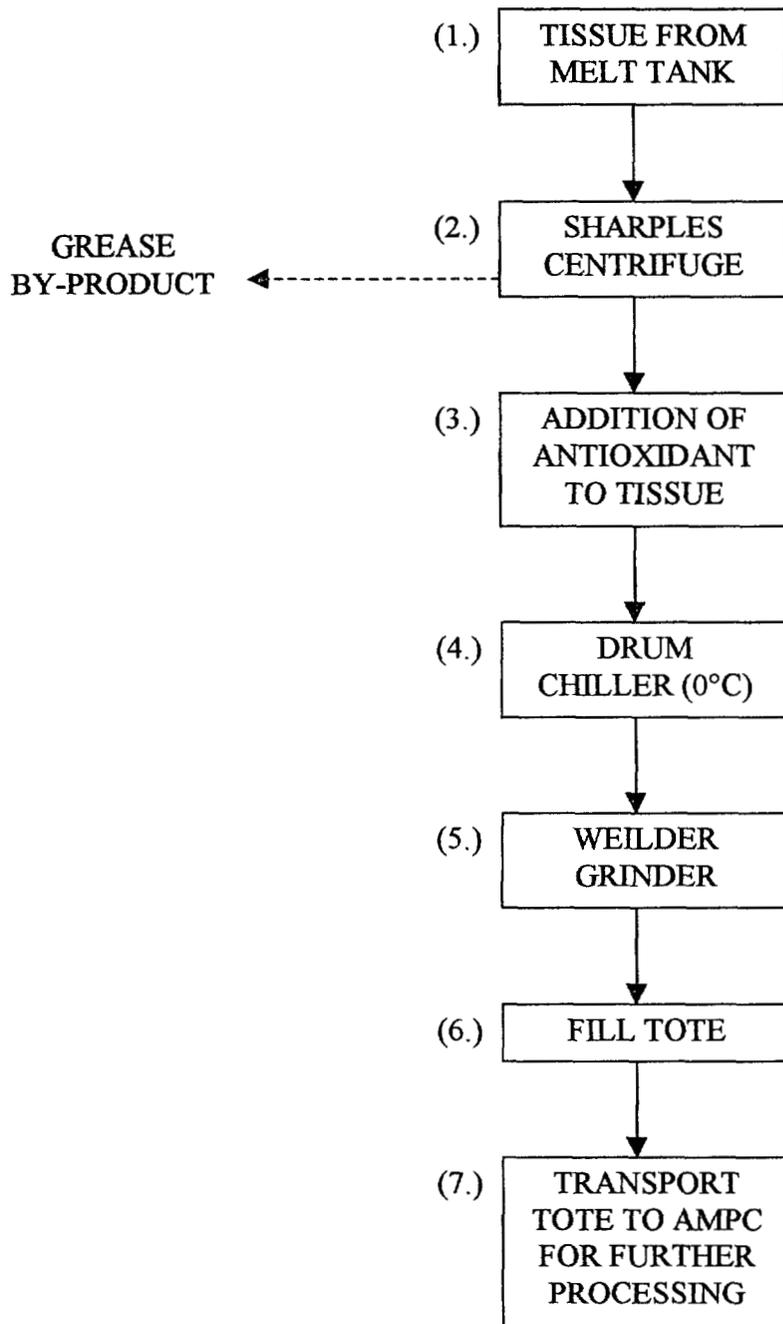
	(cfu/g)	(cfu/g)	(cfu/g)	
Molds	<u><10.0</u>	<u>10 - 100</u>	<u>>100</u>	
	210	36	1	
%	85.0	14.57	0.40	min = <10.0 cfu/g max = 2,500 cfu/g

	Negative in	Positive in
<i>Salmonella</i>	<u>100g</u>	<u>100g</u>
	247	0
%	100.0	0

7.0 Process Flow Charts

7.1 - SUPPLIER'S PROCESS FLOW CHART - SLAUGHTER HOUSE

(Cooked Pork Fatty Tissue)

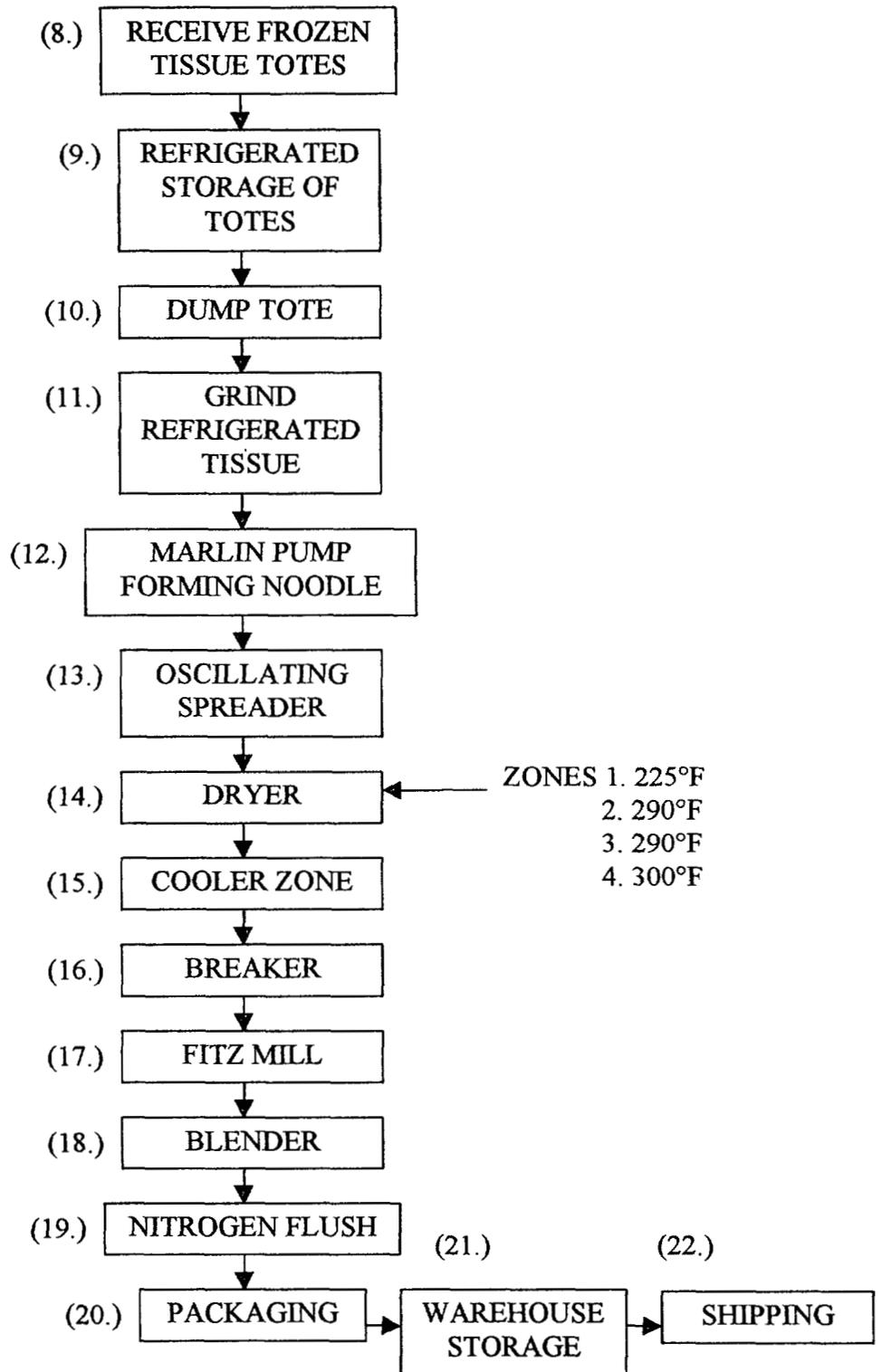


The publications (in Appendix F, G & H) are included to indicate that our suppliers processes are known and well established in the meat industry. Millions of pounds of this cooked pork fatty tissue has been produced and consumed by man and animals, over the past 30 years. If there were any recognizable hazards of such products, surely they would have become apparent by this time.

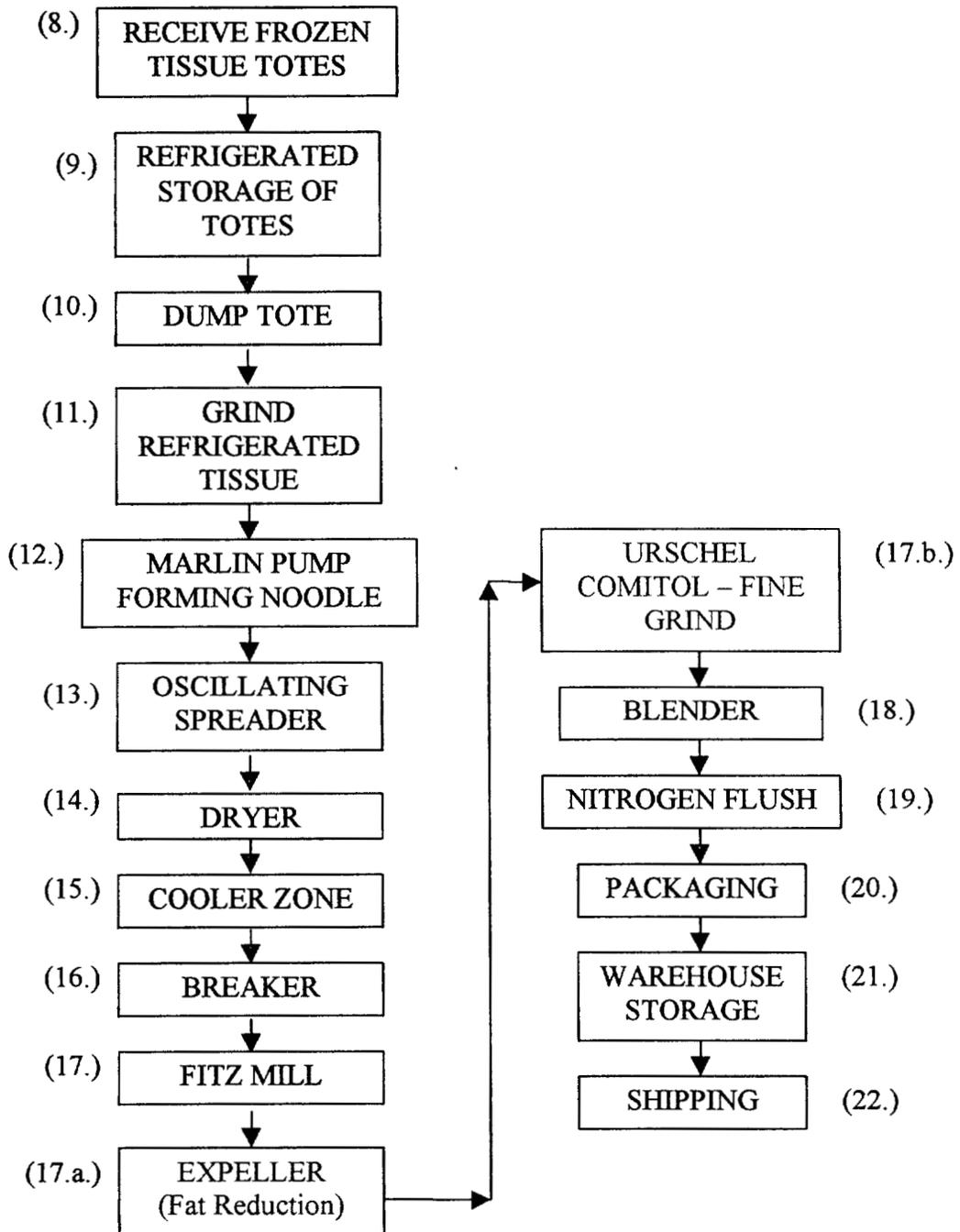
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7.2 - AMPC'S PROCESS FLOW CHART

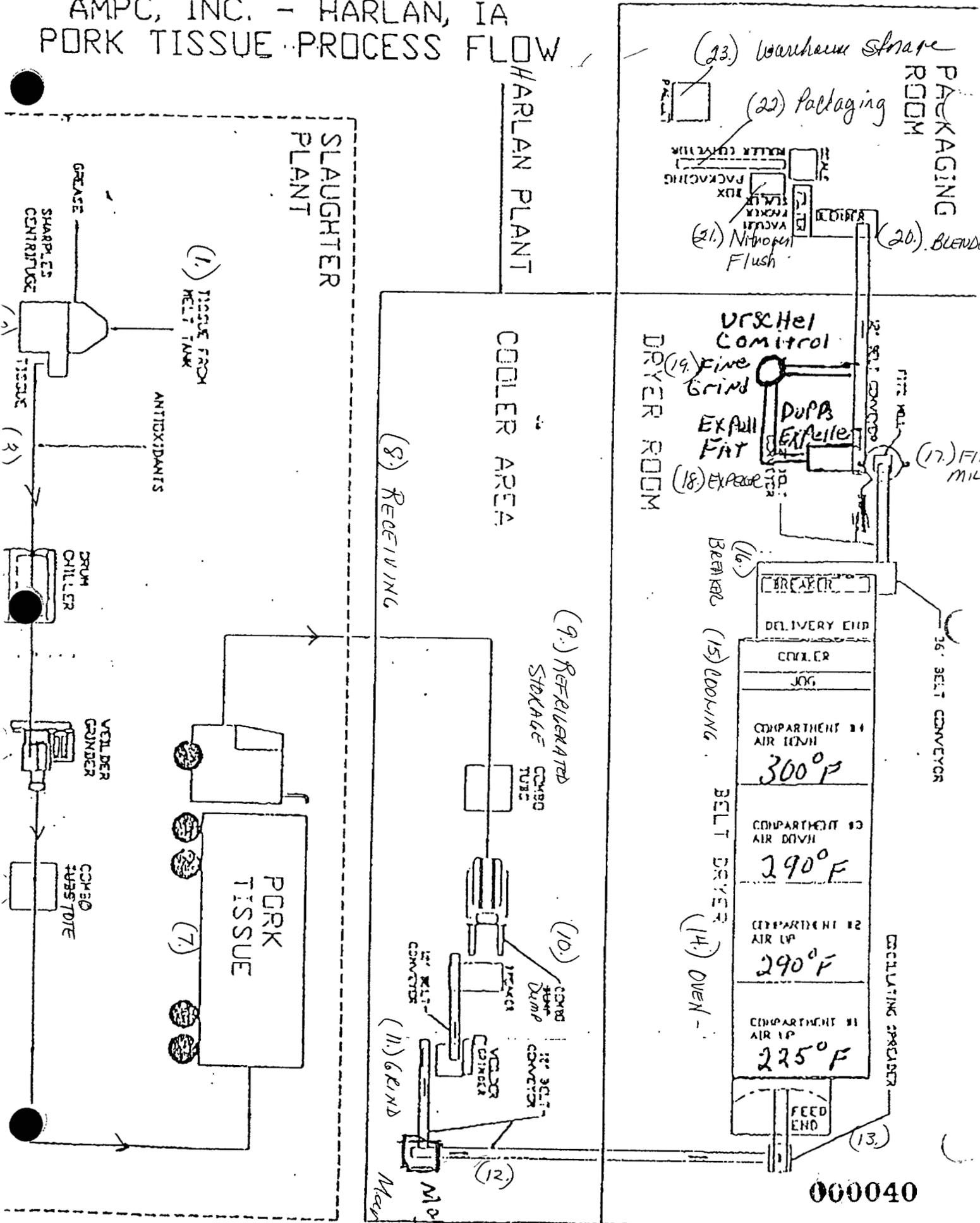
(Dehydrated Pork Fatty Tissue Process)



7.3 - PROPOSED: AMPC'S PROCESS FLOW CHART
(Pork Collagen)



AMPC, INC. - HARLAN, IA PORK TISSUE PROCESS FLOW



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AMPC'S

Summary of Pork Collagen Process

Raw Material

Specie: Porcine

Tissue: Fat trimmings

Type of fat: Belly fat

Fat from loin and hocks

Butt plates and trim

Ham fat

Shoulder fat

Leaf fat

Mesenteric fat

Process

- Fat trimmings are ground to approximately 3/8 inch pieces through a commercial met grinder.
- Ground product is transferred to a stainless steel cook tank heated with indirect steam heat.
- Ground fat is heated to approximately 160°F and pumped from tank to Rietz Disintergrator.
- From Rietz Disintergrator, the ground fat is pumped through a heat exchanger elevating temperature to 195-200°F.

- This collagen material is currently being sold both domestically and internationally to companies that manufacture meat products which permit its use in the standard of identity of such products. The specifications, USDA Label and information regarding this product is found in the next section of this notification.
- The fat of the product at this point in the manufacturing process is a maximum of 40% In order to further reduce the fat, this granular material is then conveyed to a Dupps expeller which compresses material expelling fat and increasing protein to a level of 84 % minimum. This material is heated through the act of compression to approximately 300°F further assuring microbiological safety of this product. This heated material is immediately cooled after expeller.
- The enriched protein material is then conveyed to an Urschel Comitrol which reduces the granulation to a near powder (130 microns)which optimizes its acceptability in the target applications.
- The resulting Collagen protein has the specifications listed on pages 39 & 40, and is microbiologically shelf stable.
- The material is packaged into a nitrogen-flushed polyethylene bag which is heat sealed and then enclosed in a sealed corrugated carton.

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8.0 Product Specifications

8.1 Cooked Pork Fatty Tissue Specifications

(Source material which AMPC purchases as a starting ingredient.)

This material is the same as Partially Defatted Cooked Fatty Tissue (see Appendix I) except it has been heated in excess of 120°F (9CFR 319.29).

See supplier's label approval for Cooked Pork Fatty Tissue (Appendix J).

8.1 – Raw Material Specifications for Cooked Pork Fatty Tissue

(Source material which AMPC purchases as starting ingredient)

Description: Edible Cooked Pork Fatty Tissue containing 0.15% Antioxidant Mixture.

USDA Inspected and Passed

	Specification	Test Method	Reference
<u>Chemical & Physical</u>			
Solids	30% ± 1%	A.O.A.C. 16 th Ed.	934.01
Protein	20% ± 1%	A.O.A.C. 16 th Ed.	992.15
Fat	12% ± 1%	Acid Hydrolysis	
Ash	Less than 1%	A.O.A.C. 16 th Ed.	942.05
Peroxide Value of Fat	3.0 meg/kg max.	A.O.A.C. 16 th Ed.	965.33

No Foreign or Extraneous Material

Microbiological

APC	10,000cfu/gram max.	A.O.A.C. 16 th Ed.	990.12
Coliform	10cfu/gram max.	A.O.A.C. 16 th Ed.	992.30
<i>E. Coli</i>	<3cfu/gram	A.O.A.C. 16 th Ed.	992.30
<i>Salmonella</i>	Negative in 25g	BAM 8 th Ed.	Chap. 10
Yeast & Mold	<10/gm max.	Standard Method 15 th Ed.	Chap. 9
		Compendium of Methods 3 rd Ed.	Chap. 16

8.2 Dehydrated Pork Fatty Tissue Specifications

This current product is presently being produced and sold nationally and internationally by AMPC. The USDA inspects our facility and approves this product for edible consumption as it bears their inspection legend.

8.2 – Dehydrated Pork Fatty Tissue Specification

(This current product is presently being produced and sold nationally and internationally by AMPC. The USDA inspects and our facility and approves this product as it bears their inspection legend.)

Chemical / Physical Characteristics

<u>Test</u>	<u>Specification</u>	<u>AMPC No.</u>	<u>Test Method</u>	<u>Reference</u>
*Protein	60.0% minimum	2800-120-105	A.O.A.C. 16 th Ed.	992.15
*Moisture	5.0% maximum	2800-400-102	A.O.A.C. 16 th Ed.	934.01
Ash	3.0% maximum	2800-400-104	A.O.A.C. 16 th Ed.	942.05
*Fat	40.0% maximum	2800-400-106	Ether Extraction	
Peroxide Value	4.0 meg/kg maximum			
FFA	1.0% maximum (0.2% typical)			
A _w	0.21	2800-120-100	Aqua Lab	
pH	Range: 6.7 ± .3	2800-400-112	10% Soln. @ 20°C	
Gel Strength	N/A	2800-400-100	AMPC Method	
Particle Size	100% thru 3/16" screen		AMPC Method	
Color (Hunter)	L = 55.5 a = 4.4 b = 16.3	2800-120-102	Hunter Miniscan Colorimeter	
Bulk Density	25.3 lbs./cu. Ft.	2800-400-114	AMPC Method	
Flavor / Odor	No off flavors or odors		Organoleptic	
Foreign Material	None detected		Visual	

AMPC, Inc.

2325 North Loop Drive P.O. Box 645 Ames, IA 50010

FAX



Date: 5-6-99

Number of pages including cover sheet: 4

To:

1 JDA'

Phone: 418-3077

Fax phone: 202-418-3181

CC:

From:

Phone:

Fax phone:

REMARKS: Urgent For your review Reply ASAP Please comment

8.2 – Dehydrated Pork Fatty Tissue (cont.)

Microbiological Characteristics

<u>Test</u>	<u>Specification</u>	<u>AMPC No.</u>	<u>Test Method</u>	<u>Reference</u>
Minerals		(Sec Nutritional Data Base)		
*Aerobic Plate Count	50,000 cfu/g max.	2800-400-505	A.O.A.C. 16 th Ed.	990.12
<i>Clostridium perfringens</i>	N/A	2800-400-504	A.O.A.C. 16 th Ed.	976.30
*Coliforms	100 cfu/g maximum	2800-400-501	A.O.A.C. 16 th Ed.	992.30
*E. Coli	10 cfu/g max.	2800-400-501	A.O.A.C. 16 th Ed.	992.30
<i>Enterobacteriaceae</i>	>300 cfu/g	2800-400-507	International Standard ISO 7402	
<i>Listeria monocytogenes</i>	Negative/25g		BAM 8 th Ed.	Chap. 10
* <i>Salmonella</i>	Negative/25g	2800-400-500	BAM 8 th Ed.	Chap. 5
* <i>Staphylococcus aureus</i> 1,000 cfu/g maximum (Coagulase positive)		2800-400-502	A.O.A.C. 16 th Ed.	975.50
*Yeast	100 cfu/g maximum	2800-400-506	Standard Method 15 th Ed.	Chap. 9
*Mold	100 cfu/g maximum	2800-400-506	Compendium of Methods 3 rd Ed. Chap. 16	
Thermophilic Aerobic Spores	300 cfu/g maximum		A.O.A.C. 16 th Ed.	
Thermophilic Anaerobic Spores	300 cfu/g maximum		A.O.A.C. 16 th Ed.	

* Attributes utilized for release of products.

8.3 Pork Collagen Specifications

A low fat, high protein collagen product, our proposed GRAS product for use as an additive in processed meats and other processed foods, as a binder and anti-purge ingredient.

8.3 – Pork Collagen Specification

(A low fat, high protein collagen product, our proposed GRAS product for use as an additive in processed meats, as a binder and anti-purge ingredient.)

Chemical / Physical Characteristics

<u>Test</u>	<u>Specification</u>	<u>AMPC No.</u>	<u>Test Method</u>	<u>Reference</u>
*Protein	84.0% minimum	2800-120-105	A.O.A.C. 16 th Ed.	992.15
*Moisture	5.0% maximum	2800-400-102	A.O.A.C. 16 th Ed.	934.01
Ash	3.0% maximum	2800-400-104	A.O.A.C. 16 th Ed.	942.05
*Fat	8-14% maximum	2800-400-106	Ether Extraction	
Peroxide Value	4.0 meg/kg maximum			
FFA	1.0% maximum (0.2% typical)			
A _w	0.21	2800-120-100	Aqua Lab	
pH	Range: 6.7 ± .3	2800-400-112	10% Soln. @ 20°C	
Gel Strength	300 minimum	2800-400-100	AMPC Method	
Particle Size	30 mesh		AMPC Method	
Color (Hunter)	L = 55.5 a = 4.4 b = 16.3	2800-120-102	Hunter Miniscan Colorimeter	
Bulk Density	28 lbs./cu.ft.	2800-400-114	AMPC Method	
Flavor / Odor	No off flavors or odors		Organoleptic	
Foreign Material	None detected		Visual	
Minerals		(See Nutritional Data Base)		

8.3 – Pork Collagen (cont.)

Microbiological Characteristics

<u>Test</u>	<u>Specification</u>	<u>AMPC No.</u>	<u>Test Method</u>	<u>Reference</u>
*Aerobic Plate Count	50,000 cfu/g max.	2800-400-505	A.O.A.C. 16 th Ed.	990.12
*Coliforms	100 cfu/g maximum	2800-400-501	A.O.A.C. 16 th Ed.	992.30
*E. Coli	10 cfu/g max.	2800-400-501	A.O.A.C. 16 th Ed.	992.30
<i>Enterobacteriaceae</i>	Less than 300 cfu/g	2800-400-507	International Standard ISO 7402	
<i>Listeria monocytogenes</i>	Negative/25g		BAM 8 th Ed.	Chap. 10
* <i>Salmonella</i>	Negative/25g	2800-400-500	BAM 8 th Ed.	Chap. 5
* <i>Staphylococcus aureus</i> (Coagulase positive)	1,000 cfu/g maximum	2800-400-502	A.O.A.C. 16 th Ed.	975.50
*Yeast	100 cfu/g maximum	2800-400-506	Standard Method 15 th Ed.	Chap. 9
*Mold	100 cfu/g maximum	2800-400-506	Compendium of Methods 3 rd Ed.	Chap. 16
Thermophilic Aerobic. Spores	300 cfu/g max.		A.O.A.C. 16 th Ed.	
Thermophilic Anaerobic Spores	300 cfu/g maximum		A.O.A.C. 16 th Ed.	

- Attributes utilized for release of products.

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9.0 Data Availability

The data and information in this report are the basis for the notifier's GRAS determination and are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at the address set out in this notice or will be sent to FDA upon request.

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10.0 Concentration Effect of Solids During Processing

As it may effect the concentration of hazardous substances in tissues or ingredients.

Concentration Calculations of Potential Hazardous Substances in the Fatty Tissue

These concentrations are related to the original substances inherent in the meat itself. The following data summarizes the expected concentration maximums, assuming that whatever substances of concern that were in the fat trimmings at the start remained in total throughout the process, to our finished product. The following step by step concentration will occur:

Estimated Average Composition of the Original Fat Trimmings

70% Fat

6% Protein

24% Moisture

≤1% Ash

Cooked Pork Fatty Tissue We Purchase From Slaughterhouses

12% Fat

20% Protein

68% Moisture

≤1% Ash

Our Current Finished Product "MyoGel" (Dehydrated Pork Fatty Tissue)

31.9% Fat

64.1% Protein

2.1% Moisture

1.9% Ash

Pork Collagen

(The Product we are Requesting Exemption from GRAS Petition)

5 – 14% Fat

85 – 91% Protein

2 – 4% Moisture

2 – 2.5% Ash

The net maximum concentration effect would be 15x of any inherent hazardous substances in the fat trimmings. Since our powdered, dried, collagen protein must be rehydrated to become consumable, the expected water for rehydration will be from 3 to 4 times that of the pork collagen. This will reduce the concentration effect to only 3 to 4 times that of the original tissue at the time of consumption. The lead levels of our pork collagen do not appear to be substantially increased over base levels in the original fat trimmings (less than 1ppm). This would suggest that the concentration of other heavy metals does not occur.

Regarding antibiotics, USDA routinely tests these at slaughtering facilities, and requires that they be below detection levels. Our product will be a composite of an estimated 100 animals and thereby provides a diluting effect of any animals which may contain antibiotic residuals. In order for the concentrating effects of our process to exceed the actual risk associated with a single animal having antibiotics would require a large number of animals being slaughtered at the same time having antibiotic residues. Also, this concentrating effect of potential hazardous substances in meats and fats has been and is presently occurring in a large number of presently manufactured products without any recognized health concerns. The following is a list of food products in which this occurs:

Bacon

Dried beef jerky

Beef greaves

Pork or beef cracklings and products made from them

Partially defatted (beef or pork) fatty tissue

Partially defatted cooked (beef or pork) fatty tissue

Pork skin residue after gelatin extraction

Gelatin

Pork skins, fried

Rendered beef fat tissue solids

Similarly, there are animal feeds which contain many rendered and dried type meat ingredients. These ingredients are being fed to animals at unrestricted levels which would suggest that no adverse levels of concentrated hazardous material in such products have been recognized to date. These ingredients are as follows:

Dried meat solubles

Meat meal

Meat and bone meal

Animal by-product meal

Meat meal tankage

Meat and bone meal tankage

Meat protein isolate

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11.0 Possible Adverse Conditions Associated With The Process or Additives and Safeguards to Control

Microbiological Hazards

Original fat trimmings

- Collected from processing of meat in USDA inspected facilities.
- Held refrigerated throughout time at meat processor.

Pork tissue

- In semi-frozen state within 24 to extreme (over weekend) 72 hours.
- All processing under USDA inspection and in USDA approved equipment.
- Packaged in poly lined virgin totes.
- Transported to AMPC facilities in refrigerated trailers.
- Received material is tested for microbiological quality (see specifications) page 35.
- AMPC Harlan is a USDA/FSIS inspected facility.
- Product is stored at AMPC under continuous refrigerated temperatures.
- Processed under cold conditions until it is extruded on to the dryer belt.
- Dwell time from refrigerated temper until heated to drying temperature is less than 30 minutes.
- Drying temperature is 225-300°F.
- Water activity of finished product is $<0.80 A_w$.

- Product is immediately packaged after processing into nitrogen sparged hermatically sealed polyethylene bags.
- FFAs and P.V.s indicate very low incidence of oxidation.
- Animal drug testing failed to detect any residuals, except for chlorotetracyline at 0.823 MCG/G.

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12.0 Adverse Possibilities Due to Antioxidant

Adverse Possibilities Referencing Antioxidant or Ingredients Included in the Antioxidant Mixture

- The antioxidants and ingredients included in the antioxidant mixture are known to be GRAS as assured and documented by our supplier. (Letter on file)
- All ingredients are currently used with meat products under nearly identical conditions as our present use (9CFR 318.7).
- The antioxidant being used has been approved for our use in the Dehydrated Pork Fatty Tissue we are currently selling which is the raw material for the petitioned product.
- Nothing further is added to the Dehydrated Pork Fatty Tissue, as the further processing only involves mechanical forces.
- The compression and fine grinding elevates the product temperature to 300°F which is below the temperature known to cause breakdown of proteins or ingredients in an antioxidant mixture. This temperature is being realized by many food processing systems without any adverse reactions to such antioxidant systems.

Summary

Does the dehydration and drying process create or concentrate hazardous materials?

- The data in Appendix B indicates lead and other heavy metals are not significantly increased during the process.
- Other rendered type products have not shown any created or concentrated hazardous materials. Millions of pounds of dehydrated rendered materials are either consumed by humans or animals yearly. Bacon, crackling, fried pork rinds, and dehydrated meats have been consumed by man for hundreds of years without any indication of the development or concentration of hazardous substances that occur under normal conditions in meats.
- The enclosed nutritional data (see Appendix J) indicates that the nutritional quality of proteins is preserved throughout our processing.
- The maximum concentrating effect of any naturally occurring substance in the meat is 15 fold in the dehydrated collagen protein. When one factors in the natural ratio of 4:1 water to protein which meat has, this ratio will be generally obtained or targeted in the products in which the product is added. Since this is a powdered product, water will be required for proper rehydration, consumption and digestion. Similar high protein products such as whey and soy protein concentrates and even higher protein items such as isolates require similar rehydration prior to consumption. The net concentration, when rehydrated would only be 3 fold that of the original meat. Since this product is not intended to be consumed except as a

component in other foods, this factor will further reduce the concentration of adverse substances if indeed there are any.

The resulting data of our testing indicates little or no concentration of the following tested items:

Lead

Mercury

Pesticides

Antibiotics

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13.0 Disappearance and Consumption Data

Disappearance Data of Sausage and Hot Dogs

The overall sausage production, as of 1987 reported by the USDA (last numbers reported by the USDA), manufactured under USDA inspection was 448 million pounds.

The overall combined production of meat franks and wieners reported by the USDA in 1987 under USDA inspection was 1.5 billion pounds. 64% of above products contained pork and would be considered candidates for the addition of our product, or approximately 1 billion pounds.

If one assumes that all of the sausage and all the pork containing franks and wieners could use our pork collagen product, then our potential market would be 3.5% of 1.5 billion pounds or 52.5 million pounds as of 1987. The National Hot Dog and Sausage Council (NHD & SC) now estimates that the sales of franks and wieners is at 2 billion pounds. Based on the previous NHD & SC estimates that 64% of this volume contains pork, therefore as of this date there is an estimated 1.3 billion pounds of franks and wieners potentially available for the addition of pork collagen. Assuming a 1/3 corresponding growth rate in the production of sausage, this would result in approximately 600 million pounds of sausage being produced annually as of this date.

The implied greatest consumption of our collagen would therefore be 3.5% of an approximate 2 billion pounds of the sausage and frank market, or 70 million pounds.

At this amount, a per capita consumption would be approximately 1/3 pound annually or 118 grams.

On a daily consumption rate, this would be 0.32 grams. per person per day.

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Appendix A (USDA Labeling Policy Book)



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Regulatory
Programs

Standards and
Labeling Division

June 1991 thru
July 1993

Standards and Labeling Policy Book

Complete Update

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if they appear on labels in relation to meats, they should be shown in conjunction with possessive terms to clearly indicate that it is a labeling declaration about "doneness" that is associated with the producer or distributor. ("Our Rare Beef" or "Jones Packing Company's Medium Cooked Beef.")

See: 318.17

BEEF (Dried or Air Dried):

Product name is "Air Dried Beef" or "Dried Beef." MPR 2.04:1. It is usually cured by rub and/or stitch pump followed by cover pickle for 4 to 8 weeks with several overhauls (turned over for the application of additional cure), then placed in smokehouse or drying chambers for 3 to 10 days.

BEEF AND DUMPLINGS WITH GRAVY:

The product must contain at least 25% meat and not more than 25% water blanched dry dumplings.

BEEF AND GRAVY:

The product contains at least 50% cooked beef.

See: Gravy and Beef

BEEF GRAVY MIX:

The product must contain at least 15% dried beef.

BEEF GREAVES:

This product is usually high temperature rendered beef fat. However, if partially defatted beef fatty tissue is used, the product cannot be rendered above 120° F. The label must have a true product name, e.g., "Cooked Beef Tissue Solids."

BEEF HEART:

The following terms shall be used to identify product from beef hearts:

1. "Beef Hearts" shall refer to untrimmed beef hearts with bone intact.
2. "Beef Hearts - Bone Removed" shall refer to untrimmed beef hearts with bone removed.
3. "Beef Heart Meat" shall refer to beef hearts with auricles (heart cap) and bone removed.

POTATO AND CRACKLING RING:

Product must contain at least 25% pork crackling.

POTATO PUDDING:

A nonspecific product that may be cooked or uncooked with the following requirements:

1. Contains at least 18% potatoes.
2. Product does not meet the other requirements for products identified as "Potato Sausage," "Potato Ring," or "Swedish Style Potato Sausage."

See: Policy Memo 011 dated September 8, 1980

POTATO SAUSAGE, POTATO BRAND SAUSAGE, POTATO RING AND POTATO BRAND RING:

A cooked or uncooked meat food product with the following requirements:

1. At least 45% meat and no byproducts.
2. Water limited to 3% at formulation.
3. Extenders or binders limited to 3.5% of the finished product, except that 2% of isolated soy protein shall be

3. In or on products where they are expected and the product name discloses this fact, or the product name refers to a component expected to contain the ingredients. Examples include: "Beef with Barbecue Sauce," "Beef - Barbecue Flavor," "Chicken Paprikash," "Chicken with Orange Sauce," or similar type products.
4. In fresh whole muscle poultry products, provided their presence is properly described, e.g., "coated with paprika," or "artificially colored," as appropriate.

PARSLEY:

Fresh parsley may be substituted as a seasoning for dehydrated parsley without label change.

PARSLEY, PISTACHIO NUTS, PICKLES:

When added to a product, they may not be listed simply as "Flavoring" but must be specifically named in the ingredients statement.

PARTIALLY DEFATTED (BEEF OR PORK) FATTY TISSUE:

These are byproducts produced from fatty trimmings containing less than 12% lean meat. These ingredients may be used in meat products in which byproducts are acceptable. Products include nonspecific loaves, beef patties, frankfurters with byproducts, bologna with variety meats, imitation sausage, potted meat food product, sauces, or gravies.

See: 319.15(e)
319.29(a)

PARTIALLY DEFATTED CHOPPED (Beef or Pork) (PDCB, PDCP):

Partially Defatted Chopped Beef is not permitted in hamburger, ground or chopped beef. The School Lunch Program requires that when PDCB is used in products like taco mix, which later may be used in preparing other products (e.g., tacos or patties), the PDCB or PDCP must always be declared in the ingredients statement on the labeling of the taco mix.

See: Manual 18.55

PARTIALLY DEFATTED COOKED (Beef or Pork) FATTY TISSUE:

This product may be used as an ingredient in: Beef patties (cooked and uncooked), Potted meat food product, sauces, gravies, imitation sausage, and nonspecific loaves. No limit on quantity is made. It is believed to be self-limiting.

THE AMOUNT AND LABELING OF PDCB AND PDCP IN FOOD PRODUCTS

CLASS	FOOD CATEGORY	AMOUNT	LABELING
			Beef or Pork or both
I	-Beef Patties	No Limit	do
	-Imitation Sausage	Do	do
	-Non Specific Loaf	Do	do
	-Potted Meat Food Product	Do	do
	-Patty Mix	Do	Always must be declared
II	-Chinese Eggroll and other Chinese Specialties	up to 12% of Meat Block	Beef or Pork
	-Chopped Beef Steak	Do	do
	-Corned Beef Hash	Do	do
	-Fabricated Steaks	Do	do
	-Pepper Steak	Do	do
	-Salisbury Steak	Do	do
	-Luncheon Meat (nonspecific)	up to 25% of Meat Block	
	-Pizza Meat Topping	Do	do
	-Pizza With Meat	Do	do
	-Cooked Sausage (319.180(b))	up to 15% of Meat Block	Always must be declared
III	Chili	up to 25% of Meat block or larger	As beef; or pork, if larger must be declared
	-Meat Loaf	Do	do
	-Meat Balls	Do	do
	-Meat Fillings For Tacos, Burritos, Enchiladas, Tamales and other Mexican Foods	Do	do

PORK AND DRESSING:

Product must contain at least 50% cooked pork.

PORK AND DRESSING WITH GRAVY:

Product must contain at least 30% pork.

PORK BURGER:

Product must comply with 319.15(b), substituting pork for beef. Antioxidants are not permitted.

PORK CRACKLINGS:

Product eligible to be labeled as "Pork Cracklings" must be prepared from fatty tissues from which the skin has been detached. If the skin is not removed from the product before rendering, a descriptive name, e.g., "Pork Cracklings, Fried-Out Pork Fat with Attached Skin," must be used.

PORK CUTLETS:

See: Cutlet, Pork

PORKETTE:

A pork product conforming to the standard and labeling of product described in 319.15(d). The term may also be used for products other than fabricated pork steaks if used with a true descriptive name.

PORK FAT:

Pork fat shall be declared as such in the ingredients statement. Clear fatbacks and clear shoulder plates must be declared as "Pork Fat." Pork fat may be declared as pork in the ingredients statement if it contains visible lean and it is used in a standardized product which has a fat limitation.

PORK JOWLS:

Product may be declared as pork if skinned.

PORK LOIN, Short Cut:

This product consists of the loin remaining following the production of "Long Cut" ham. This means the butt portion of the loin remains with the ham product.

PORK PATES:

Pork pate is crown on the top of the head. Tissues from which the skin has been removed that contain approximately 35 to 40% lean tissue should be identified as "pork" in the ingredients statement on the label.

PORK SAUSAGE:

Product identified as pork sausage does not include the use of pork cheeks. When such an item is offered as "Whole Hog," tongues, hearts, and cheeks may be used in the natural proportion as found in the hog carcass. "Fresh" shall be used in the name when the product is not cured, cooked and/or smoked.

PORK SIDE MEAT:

This is an acceptable product name.

PORK SKIN BRACIOLO:

This product is made only with pork skins.

See: Brociola

PORK SKIN RESIDUE AFTER GELATIN EXTRACTION:

This material consists of back fat skins from which the gelatin has been extracted by means of soaking the skin in acid and subsequent low temperature cooking for the extraction of gelatin. It is not permitted in sausage but may be used in imitation sausage, potted meat food product, loaves (other than meat loaves), and other nonspecific products.

PORK SKINS:

Not permitted in salami, bologna, frankfurters, vienna sausage, and braunschweiger. When packed in vinegar pickle, they are not permitted to be artificially colored. When pork skin, either attached to fat and/or muscle tissue or detached from fat and/or muscle tissue, is used to manufacture meat or poultry products, it must be specifically listed in the formulation on the label approval application form and in the ingredients statement on the label, e.g., "Pork Skins," "Unskinned Pork Jowls," "Unskinned Pork Shoulder Trimming," "Unskinned Pork Fat," and "Unskinned Pork Bellies."

"Detached skin" refers to the portion of skin from which most of the underlying fat is removed, e.g., skin from bacon intended for slicing, skin from closely skinned hams, shoulder cuts, fat backs, etc. If removal of skin portions is

incidental to removal of a considerable proportion of underlying fat from ham, shoulder, back, etc., preparatory to rendering such fat, portions of skin so removed should not be regarded as detached skin and may be included with fats and rendered into lard. Ham facings are not regarded as detached skin.

PORK SKINS, FRIED:

When prepared from the skin of smoked pork bellies, it may be labeled as "Fried Bacon Skins," "Fried Bacon Rinds," or "Fried Pork Skins." The kind of skin used must be stated on the transmittal form when submitted for label approvals.

PORK SPARERIBS, ST. LOUIS STYLE:

St. Louis Style Spare Ribs are the same as "Pork Spareribs" except that the sternum and the ventral portion of the costal cartilages are removed with the flank portion. This cut is made at a point in which the sternum and costal cartilages are removed dorsal to the curvature of the costal cartilages. If specified by the purchaser, the diaphragm shall be removed. This anatomical description of the cut must be provided with the information for label approval.

PORK WITH BARBECUE SAUCE:

If unskinned pork or pork skin in natural proportions is used to meet the standard for "Pork with Barbecue Sauce" or "Barbecue Sauce with Pork" products, the term "unskinned" must appear in the product name. If the standard is met using "pork" and any skin is added, then the product name must be qualified with the term "Pork Skin Added."

PORK WITH DRESSING AND GRAVY:

Product must contain at least 30% cooked pork.

"POT STICKER":

This is a fanciful name for a type of dumpling. When this product name appears, a full descriptive name is required, e.g., "Chinese-Style Dumpling with Pork and Cabbage Filling," or, "Pork and Vegetable Dumpling."

POTASSIUM LABELING GUIDELINES:

1. The label of any meat or poultry product may bear quantitative information on the amount of potassium in a serving of the product. When this information is provided, the serving size must appear on the label and must be within the range of serving sizes customarily

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RANCH:

The regulations and policies applicable to "Farm" also apply to ranch.

RECONSTITUTED SKIM MILK:

Water is added to Nonfat Dry Milk at a ratio that cannot exceed 9:1.

RELLENO DE PAPA (PR):

A Puerto Rican product that must show a true product name, e.g., "Potato Balls with Beef," or "Potato Dough with a Beef Filling."

RENDERED BEEF FAT TISSUE SOLIDS:

The solid phase of ground beef fat that has been processed by a high temperature (180 °F) continuous wet rendering system.

RISOTTO (IT):

A rice dish. Must show a true product name, e.g., "Leg of Chicken Stuffed with Italian Rice."

ROASTED:

The term "roasted" may be used to describe products that have been subjected to cooking methods that result in a roasted appearance.

ROLLS:

Six uses exist for the term "Roll" in conjunction with names for meat food products:

1. Items consisting of a solid piece of meat, e.g., "Boned Veal Rib," formed and tied as a roll and usually offered with seasonings.
2. Chopped meat in combination with condiments, also formed and processed. It can be and often is offered in the fresh meat state.

Water is not an ordinary or usual ingredient in these two "Meat Roll" items. If water is an ingredient in these products, then a statement indicating the addition of a solution has taken place must appear contiguous to the product name wherever it appears on the label.

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Appendix B (Heavy Metals Data)

Midwest Laboratories, Inc.

13611 "B" Street • Omaha, Nebraska 68144-3693 • (402) 334-7770 • FAX (402) 334-9121

AMPC Inc.

Attn: Jera
 2325 North Loop Drive
 P.O. Box 645
 Ames, IA 50010

NUT DBASS

ENTERED SEP 0 2 1997

Laboratory Number 345862 (Page 1 of 2)

Report Number 7-205-2074

Sample Identification Myo Gel 1st Quarter T-M 97

Proximates:	Result Found	Amount per 100 g	Detection Limit	Method
Moisture	2.10 %	2.10 g	0.10 %	Vacuum Oven
Protein	64.06 %	64.06 g	0.10 %	Kjeldahl
Fat	31.92 %	31.92 g	0.10 %	Acid Hydrolysis
Ash	1.92 %	1.92 g	0.10 %	Muffle furnace
Carbohydrates	n.d. %	n.d. g	0.10 %	Calculation
Calories	559 Calories	559 Calories	1 Calorie	Calculation
Total Dietary Fiber	n.d. %	n.d. g	1 %	AOAC 991.43
Cholesterol	121 mg/100 g	121 mg	7.5 mg/100 g	US FDA
Fatty Acids:				
Saturated	38.3 % of fat	12.20 g	0.1 % of fat	US FDA
Monounsaturated	48.0 % of fat	15.30 g	0.1 % of fat	US FDA
Polyunsaturated	12.0 % of fat	3.83 g	0.1 % of fat	US FDA
Mineral/Metals:	Result Found	Amount per 100 g	Detection Limit	Method
Lead	n.d. ppm	n.d. mg	1.25 ppm	ICAP
Arsenic	n.d. ppm	n.d. mg	0.5 ppm	Furnace AA
Mercury	n.d. ppm	n.d. mg	0.02 ppm	Cold Vapor

The above analytical results apply only to the sample(s) submitted.

Our reports and letters are for the exclusive and confidential use of our clients and may not be reproduced in whole or in part, nor may any reference be made to the results of the analysis in any advertising, news release, or other public announcements without obtaining our prior written authorization.

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Analytical Laboratories, Inc.

13611 "B" Street • Omaha, Nebraska 68144-3693 • (402) 334-7770 • FAX (402) 334-9121

Laboratory Number 345862 (Page 2 of 2)

Report Number 7-205-2074

Sample Identification Myo Gel 1st Quarter T-M97

Sugar Profile:	Result Found	Amount per 100 g	Detection Limit	Method
Sucrose	n.d. %	n.d. g	0.1 %	HPLC
Glucose	n.d. %	n.d. g	0.1 %	HPLC
Fructose	n.d. %	n.d. g	0.1 %	HPLC
Lactose	n.d. %	n.d. g	0.1 %	HPLC
Maltose	n.d. %	n.d. g	0.1 %	HPLC

Vitamins:	Result Found	Amount per 100 g	Detection Limit	Method
Vitamin B1	n.d. mg/lb	n.d. mg	0.1 mg/lb	AOAC
Vitamin B2	8.0 mg/lb	1.76 mg	1.8 mg/lb	AOAC
Vitamin B12	7.47 mcg/100 g	7.47 mcg	4.87 mcg/100 g	AOAC
Vitamin A	n.d. IU/100 g	n.d. IU	25 IU/100 g	US FDA
Vitamin C	n.d. mg/100 g	n.d. mg	6.5 mg/100 g	AOAC

Amino Acid Profile:

Tryptophan	0.36 %
Aspartic Acid	5.17 %
Threonine	2.06 %
Serine	2.55 %
Glutamic Acid	7.78 %
Proline	6.46 %
Glycine	10.9 %
Alanine	5.04 %
Cystine	0.44 %

Valine	2.51 %
Methionine	0.95 %
Isoleucine	1.71 %
Leucine	3.58 %
Tyrosine	1.33 %
Phenylalanine	2.07 %
Histidine	1.30 %
Lysine, total	3.68 %
Arginine	4.91 %

Respectfully Submitted,

Heather Ramig, Client Services

The above analytical results apply only to the sample(s) submitted.

Our reports and letters are for the exclusive and confidential use of our clients and may not be reproduced in whole or in part, nor may any reference be made to the work, the results, or the company in any advertising, news release, or other public announcements without obtaining our prior written authorization.

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Appendix C (Antibiotics Data)

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**SILLIKER LABORATORIES
OF IOWA**

405 Eighth Avenue SE • Cedar Rapids, IA 52401-2153
(319) 366-3570 • FAX (319) 366-4018

FOOD SAFETY • QUALITY • NUTRITION

LABORATORY REPORT

Report No. 155697 Date 3/29/99 Page 1

155697 3/29/99 1

Purchase Order

CATHERINE SPENCER

MS. CATHERINE SPENCER
QA ADMIN ASSIST
AMPC, INC.
2325 N LOOP DR
AMES IA 50010

SAMPLES RECEIVED: 3/19/99
RECEIVED FROM: AMES, IA

ANALYTICAL RESULTS

SAMPLE
DESCRIPTION

MYOGEL PLUS/T9041

SULFA DRUG SCREEN

ANTIBIOTIC

LEVEL DETECTED

SULFA RESIDUE IN FEED-TLC

< 1 PPM

THIS SCREEN CHECKS FOR ANY SULFA DRUG PRESENT IN THE SAMPLE

RECEIVED APR 05 1999

lj
LYNN JAEGER, PH.D.
LABORATORY DIRECTOR

The results of this report relate only to the samples tested. This report shall not be reproduced unless written approval has been obtained from the laboratory.

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Appendix D (Pesticide Data)

**SILLIKER LABORATORIES
OF IOWA**

405 Eighth Avenue SE • Cedar Rapids, IA 52401-2153
(319) 366-3570 • FAX (319) 366-4018

FOOD SAFETY • QUALITY • NUTRITION

LABORATORY REPORT

Report No. ~~154470~~ Date ~~3/31/99~~ Page ~~1~~

154470 3/31/99 1

Purchase Order ~~154470~~

CATHERINE SPENCER

MS. CATHERINE SPENCER
QA ADMIN ASSIST
AMPC, INC.
2325 N LOOP DR
AMES IA 50010

SAMPLES RECEIVED: 3/04/99
RECEIVED FROM: AMES, IA

ANALYTICAL RESULTS

SAMPLE
DESCRIPTION

MYOGEL PLUS/T9041

ORGANOCHLORINE PESTICIDE SCREEN

PESTICIDE	AMOUNT (PPM)	MRL (PPM)	TOLERANCE (PPM)
A, B, D-BHC	ND	0.05	
ALACHLOR, (LASSO)	ND	0.02	
ALERT, (PIRATE)	ND	0.04	
ALDRIN	ND	0.01	
BENFLURALIN, (BALAN, BENEFIN)	ND	0.03	
BHC, (BENZAHEX)	ND	0.02	
BIFENOX, (MODOWN)	ND	0.05	
BIFENTHRIN	ND	0.04	
BROMACIL	ND	0.1	
CAPTAFOL	ND	0.04	
CAPTAN	ND	0.05	
CHLORDANE	ND	0.25	
CHLOROBENZILATE, (ACARABEN)	ND	0.4	
CHLORTHALONIL, (BRAVO)	ND	0.01	
CYANAZINE	ND	0.1	
CYFLUTHRIN	ND	0.15	
CYPERMETHRIN	ND	0.05	
DACTHAL, (CHLORTHAL)	ND	0.03	
DDD	ND	0.03	
DDE	ND	0.05	
DDT	ND	0.05	
DICHOLOBENIL, (CASORON)	ND	0.03	
DICHLONE	ND	0.05	
DICLORAN, (BOTRAN)	ND	0.02	
DICOFOL, (KELTHANE)	ND	0.05	
DIELDRIN	ND	0.01	
DYRENE, (ANILAZINE)	ND	0.1	
ENDOSULFAN ALPHA	ND	0.01	
ENDOSULFAN BETA	ND	0.01	
ENDOSULFAN SULFATE	ND	0.01	
ENDRIN	ND	0.01	

RECEIVED APR 05 1999

The results of this report relate only to the samples tested. This report shall not be reproduced unless written approval has been obtained from the laboratory.

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* CONTINUED *

SILLIKER LABORATORIES OF IOWA

405 Eighth Avenue SE • Cedar Rapids, IA 52401-2153
(319) 366-3570 • FAX (319) 366-4018

FOOD SAFETY • QUALITY • NUTRITION

LABORATORY REPORT

Report No. 154470 Date 3/31/99 Page 2

154470

3/31/99

2

Purchase Order

CATHERINE SPENCER

CONTINUED:

ANALYTICAL RESULTS

SAMPLE
DESCRIPTION

MYOGEL PLUS/T9041	ESFENVALERATE, (ASANA)	ND	0.02
	ETHALFLURALIN, (SONALAN)	ND	0.03
	FLUVALINATE	ND	0.4
	FOLPET	ND	0.05
	HEPTACHLOR	ND	0.01
	HAPTACHLOR EPOXIDE	ND	0.02
	IPRODIONE, (ROVRAL)	ND	0.05
	LINDANE, (GAMMA-BHC)	ND	0.02
	LINURON	ND	0.05
	METHOXYCHLOR	ND	0.05
	METRIBUZIN	ND	0.02
	MIREX	ND	0.02
	MYCLOBUTANIL, (RALLY)	ND	0.05
	NITROFEN, (TOK)	ND	0.05
	OXADIAZON, (RONSTAR)	ND	0.05
	OXYFLUORFEN, (GOAL)	ND	0.04
	PENDAMETHALIN	ND	0.05
	PENTACHLORONITROBENZENE, (PCNB)	ND	0.02
	PERMETHRIN	ND	0.05
	PERTHANE, (ETHYLAN)	ND	0.05
	POLYCHLORINATED BIPHENYLS	ND	0.25
	PROCYMIDONE	ND	0.05
	PROFLURALIN, (TOLBAN)	ND	0.03
	PRONAMIDE, (KERB, PROPYZAMIDE)	ND	0.2
	PYRETHRINS, (TOTAL)	ND	0.1
	TETRADIFON, (TEDION)	ND	0.05
	TOXAPHENE, (ATTAC), STROBANE	ND	0.25
	TRIDIMEFON, (BAYLETON)	ND	0.05
	TRIFLURALIN, (TREFLAN)	ND	0.02
	VEGADEX, (DIETHYLDITHIOCARB. ACID)	ND	0.05
	VINCLOZOLIN, (RONILAN)	ND	0.02

ND = NONE DETECTED

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Appendix E

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Appendix E (Harmful Residues)

Pages 00095 - 00100 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

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Appendix F (Rendering Article)

000102

Pages 000103 - 000107 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

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Appendix G (History of Process)

Pages 000110 - 000117 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

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Appendix H (Symposium on Rendering Processes)

Page 000120 has been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000121 - 000127 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

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Appendix I (Label Definitions)



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Regulatory
Programs

Standards and
Labeling Division

June 1991 thru
July 1993

Standards and Labeling Policy Book

Complete Update

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3. In or on products where they are expected and the product name discloses this fact, or the product name refers to a component expected to contain the ingredients. Examples include: "Beef with Barbecue Sauce," "Beef - Barbecue Flavor," "Chicken Paprikash," "Chicken with Orange Sauce," or similar type products.
4. In fresh whole muscle poultry products, provided their presence is properly described, e.g., "coated with paprika," or "artificially colored," as appropriate.

PARSLEY:

Fresh parsley may be substituted as a seasoning for dehydrated parsley without label change.

PARSLEY, PISTACHIO NUTS, PICKLES:

When added to a product, they may not be listed simply as "Flavoring" but must be specifically named in the ingredients statement.

PARTIALLY DEFATTED (BEEF OR PORK) FATTY TISSUE:

These are byproducts produced from fatty trimmings containing less than 12% lean meat. These ingredients may be used in meat products in which byproducts are acceptable. Products include nonspecific loaves, beef patties, frankfurters with byproducts, bologna with variety meats, imitation sausage, potted meat food product, sauces, or gravies.

See: 319.15(e)
319.29(a)

PARTIALLY DEFATTED CHOPPED (Beef or Pork) (PDCB, PDCP):

Partially Defatted Chopped Beef is not permitted in hamburger, ground or chopped beef. The School Lunch Program requires that when PDCB is used in products like taco mix, which later may be used in preparing other products (e.g., tacos or patties), the PDCB or PDCP must always be declared in the ingredients statement on the labeling of the taco mix.

See: Manual 18.55

PARTIALLY DEFATTED COOKED (Beef or Pork) FATTY TISSUE:

This product may be used as an ingredient in: Beef patties (cooked and uncooked), Potted meat food product, sauces, gravies, imitation sausage, and nonspecific loaves. No limit on quantity is made. It is believed to be self-limiting.

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Appendix J (Supplier's Label)

FORM (tm) 723 (8822) Ver. 4-83
 U.S. DEPARTMENT OF AGRICULTURE
 Food Safety and Inspection Service
 APPLICATION FOR APPROVAL OF
 LABELS, MARKING OR DEVICE

It has been determined that information provided in items 8, 9, & 10 is exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(4).

ACTION REQUESTED BY USDA FOR APPROVAL

SKETCH
 FINAL

Was label previously approved as sketch? Yes No
 If sketch, date of sketch: / /

8. PRODUCT FORMULA

PORK
 TOCOPHEROL (NATURAL FLAVOR & CITRIC ACID) *PURCHASED

TEMPORARY
 PERMANENT

[] REQUEST FOR EXTENSION
 Prior approval number:
 Number of labels on hand:
 Number of days requested: 0

9. PROCESSING PROCEDURES

PORK TISSUE PRODUCED PER §319.29.
 ANTIOXIDANT ADDED.
 PRODUCT PLACED IN COMBO.
 REFRIGERATE.
 TRANSPORT.

10179

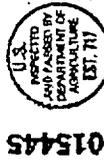
KEEP REFRIGERATED

COOKED PORK FATTY TISSUE

TOCOPHEROL, NATURAL FLAVOR AND CITRIC ACID
 ADDED TO HELP PROTECT FLAVOR.



1 00 70247 10179 9



COMBO

FARMLAND FOODS, INC., KANSAS CITY, MO 64116

TOTAL (pct.): 100.00

11. SIGNATURE OF APPLICANT OR AGENT

10. NAME AND ADDRESS OF FIRM

FARMLAND FOODS INC.
 P.O. BOX 403
 DENISON, IA 51442

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12. SIGNATURE OF INSPECTOR

13. CONDITIONS APPLYING TO USE OF LABELS OR DEVICE
 BAR CODE SHIPPER LABEL APPLIED TO A FULLY APPROVED
 SHIPPING CONTAINER HAVING ALL OTHER REQUIRED LABELING
 FEATURES.

4. ESTABLISHMENT OR PORTS OF ENTRY

717
 Port: 40-0006-15

5. NAME OF PRODUCT
 BAR CODE SHIPPER LABEL #1015445
 COOKED PORK FATTY TISSUE WITH
 TOCOPHEROL, 10179, EST. 717
 CATCH WT.

7. AREA OF PRINCIPAL
 DISPLAY PANEL

n/a

Post-It* Fax Note 7671

To	From	Date	# of pages
Co./Dept.	Co.	10-2	1
Phone #	Phone #		
Fax #	Fax #		

8-12-96
 DATE

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000135

Appendix K (Nutrition Data)

NUTRITIONAL DATA BASE									
PORK TISSUE									
	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #
Protein	214	135695	52595-1	52595-2	7/30/96 A	7/30/96 B	7/30/96 C		
Moisture					70.67	69.59	68.02		
Ash					2.18	2.04	2.19		
Fiber	N/D	N/D	N/D	N/D					
Carbohydrates (Total)	N/D	N/D	N/D	N/D					
Carbohydrates (Complex)	N/D	N/D	N/D	N/D					
Sugars									
Fat (Total)	30.33				30.2	30.6	30.2		
Saturated Fat (Total)									
Cholesterol (mg/100g)									
Calories (calculated)									
Calories (From Total Fat)									
MINERALS (mg/100g)									
Sodium	475	500	510	440	450				
Calcium	109	180	100	84	71				
Iron	6.0	5	6	7	6				
Phosphorus	357.5	380	400	330	320				
Magnesium	31.5	32	34	31	29				
Potassium	245	240	290	280	190				
Zinc (ppm)	3.9	3.3	3.8	4.7	3.8				
Iodine									
Selenium (ppm)									
Copper									
Manganese									
Fluoride									
Chloride									
						0.44	0.43	0.44	
VITAMINS									
Vitamin A (as Retinol) IU/100g									
Vitamin C									
Vitamin B1									
Vitamin B2									

5...df1

PORK TISSUE		Typical	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #
FATTY ACID PROFILE		(Average)	214	135695	52595-1	52595-2	7/30/96 A	7/30/96 B	7/30/96 C						
% Total Fat															
Butyric (C4:0)															
Caproic (C6:0)															
Caprylic (C8:0)		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Capric (C10:0)		0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Lauric (C12:0)		0.02	0.02	0.03	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Myristic (C14:0)		0.39	0.36	0.35	0.40	0.39	0.4	0.41	0.42	0.41	0.41	0.42	0.41	0.42	0.41
Myristoleic (C14:1)		0.01	<0.01	<0.01	0.01	0.01	0.01	<0.01	0.01	<0.01	0.01	0.01	0.01	0.01	0.01
Palmitic (C16:0)		6.817143	6.46	6.17	6.91	6.82	6.91	7.19	7.26	7.19	7.19	7.26	7.19	7.26	7.19
Palmitoleic (C16:1)		0.9	0.83	0.78	0.93	0.94	1.01	0.92	0.89	0.92	0.92	0.89	0.92	0.89	0.92
Stearic (C18:0)		3.77	3.62	3.49	3.54	3.54	3.9	4	4.05	3.9	4	4.05	3.9	4	4.05
Oleic (C18:1)		12.67	11.82	10.89	13.21	15.09	12.11	12.71	12.88	12.11	12.71	12.88	12.11	12.71	12.88
Linoleic (C18:2)		3.45	3.06	2.48	3.96	3.97	3.54	3.44	3.69	3.54	3.44	3.69	3.54	3.44	3.69
Linolenic (C18:3)		0.24	0.2	0.17	0.26	0.26	0.26	0.23	0.28	0.27	0.23	0.28	0.27	0.23	0.28
Arachidic (C20:0)		0.062857	0.06	0.06	0.06	0.06	0.06	0.07	0.07	0.06	0.07	0.07	0.06	0.07	0.07
Gadoleic (C20:1)							0.23	0.24	0.025	0.23	0.24	0.025	0.23	0.24	0.025
Hemogamma Linolenic (C20:3)							0.06	0.05	0.06	0.06	0.05	0.06	0.06	0.05	0.06
Behenic (C22:0)		0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Lignoceric (C24:0)		0.01	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
AMINO ACID PROFILE															
(g/100g Protein)															
Alanine		5.41	5.82	5.21	5.46	5.35	5.22	5.46	5.37	5.22	5.46	5.37	5.22	5.46	5.37
Arginine		4.58	5.13	4.64	4.93	4.8	4.2	4.27	4.08	4.2	4.27	4.08	4.2	4.27	4.08
Aspartic Acid		4.91	5.71	5.44	5.54	5.33	4.05	4.11	4.2	4.05	4.11	4.2	4.05	4.11	4.2
Cystine		0.45	0.52	0.54	0.45	0.44	0.41	0.4	0.4	0.41	0.4	0.4	0.41	0.4	0.4
Glutamic Acid		7.99	8.42	8.07	8.13	8.06	7.54	7.74	7.95	7.54	7.74	7.95	7.54	7.74	7.95
Proline		6.23	6.83	5.65	6.47	6.15	5.95	6.45	6.13	5.95	6.45	6.13	5.95	6.45	6.13
Glycine		11.19	12.75	10.3	11.86	11.43	10.26	11.18	10.53	10.26	11.18	10.53	10.26	11.18	10.53
Histidine		1.62	1.73	1.62	1.71	1.67	1.49	1.58	1.54	1.49	1.58	1.54	1.49	1.58	1.54
Isoleucine		1.73	1.77	1.87	1.82	1.77	1.62	1.6	1.64	1.62	1.6	1.64	1.62	1.6	1.64
Leucine		3.73	3.98	4.1	3.81	3.68	3.49	3.5	3.51	3.49	3.5	3.51	3.49	3.5	3.51
Lysine		3.59	3.8	3.78	3.66	3.68	3.37	3.45	3.4	3.37	3.45	3.4	3.37	3.45	3.4
Methionine		1.03	1.09	1.13	1.11	1.1	0.95	0.98	0.88	0.95	0.98	0.88	0.95	0.98	0.88
Phenylalanine		2.07	2.25	2.25	2.12	2.11	1.93	1.93	1.93	1.93	1.93	1.93	1.93	1.93	1.93
Serine		2.75	2.98	2.81	2.74	2.69	2.66	2.62	2.74	2.66	2.62	2.74	2.66	2.62	2.74
Threonine		2.18	2.33	2.36	2.25	2.19	2.01	2	2.13	2.01	2	2.13	2.01	2	2.13
Tryptophan		0.32	0.34	0.39	0.31	0.31	0.31	0.28	0.29	0.31	0.28	0.29	0.31	0.28	0.29
Tyrosine		1.39	1.42	1.51	1.34	1.33	1.37	1.41	1.33	1.37	1.41	1.33	1.37	1.41	1.33
Valine		2.59	2.72	2.60	2.67	2.58	2.4	2.46	2.49	2.4	2.46	2.49	2.4	2.46	2.49
Hydroxyproline		4.63	4.70	4.20	4.92	4.70									
PORK TISSUE															

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SUBMISSION EEE

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Reference List for Industry Submission, GRN 000021

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Publisher</i>	<i>BIB_Info</i>
000095 - 000100	Moats, William A.	Chemical Residues in Muscle Foods	1994	Muscle Foods: Meat, Poultry, and Seafood Technology	pgs 288-295
000103 - 000107	NA	Increase Profits -- Reduced Pollution: Continuous Edible Rendering At Swift- Marshalltown	May 1974	Meat Processing	NA
000110 - 000117	NA	Preparation of Meat and Meat Food Products	NA	NA	pgs 443 - 450
000120	Maerker, G.	NA	April 1985	JAOCS	Volume 62, Number 4, pg 804
000121 - 000127	Prokop, William H.	Rendering Systems for Processing Animal By- Product Materials	April 1985	JAOCS	Volume 62, Number 4, pgs 805-811

NA- Not applicable