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FSIS Docket Clerk
Food Safety and Inspection Service
US Department of Agriculture
Room 102, Cotton Annex
300 12th Street SW
Washington, D.C. 20250-3700

24 June 2004

03-038IF
03-038IF-29
Stephen H. Cate

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RE: Advanced Meat Recovery; Interim Final Rule, FSIS Docket No. 03-0381, 69 Fed Reg. ppg 1874-1885, Jan 12, 2004

To Whom It May Concern:

Townsend Engineering is a manufacturer of meat processing equipment, based in Des Moines, Iowa. Recently, Townsend Engineering made a donation to the Kansas State University Foundation to support food safety research, specifically addressing the presence of Central Nervous System Tissue (CNS) and Dorsal Root Ganglia (DRG) in meat harvested from beef neck bones. This research was conducted at Kansas State University, Iowa State University, The University of Nebraska and The University of California at Davis. The objectives of this research were to determine whether different methods for removing meat from beef neck bones influence the presence of CNS and DRG, and affect the analytical composition of the harvested meat. The three methods evaluated were:

1. Hand Boning
2. Traditional Advanced Meat Recovery Equipment
3. De-Sinewed Minced Meat (DMM) Technology.

In addition, beef neck bones from two different beef slaughter plants were compared. One of the plants utilized a Jarvis Circular Saw for removal of the spinal cord and spinal cord channel. The second plant utilized a traditional system for removal of the spinal cord.

Townsend Engineering designs and manufactures DMM machines. The technology was developed as a low-pressure de-boning system for removing meat from bones, particularly neck bones and back bones, without incorporating CNS or DRG and minimizing bone constituents in meat. It also meets the original objectives of AMR technology which are the safe and effective removal of meat from bones and the prevention of ergonomic illnesses associated with the hand boning process.

International Headquarters:

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The results of the study were presented by Dr. James Marsden, Regent's Distinguished Professor at Kansas State University at the 2003 meeting of the Food Safety Consortium, and was published in the meeting's proceedings. A copy of the Food Safety Consortium presentation is attached as an appendix to this comment. The main conclusions from the study were:

1. DMM maintains the integrity of meat structure
2. DMM provides meat with levels of bone constituents which are comparable to meat obtained by normal hand boning.
3. DMM in combination with appropriate processes provides meat free from CNS tissue or DRG.

Therefore, the application of DMM technology results in a safe and wholesome product that does not increase the risk of CNS tissue or DRG.

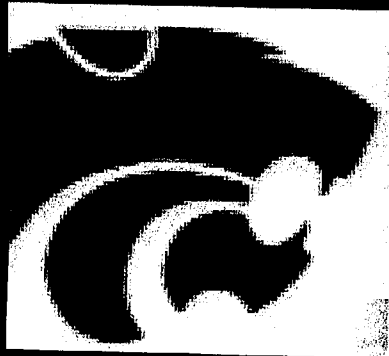
Townsend Engineering appreciates the opportunity to comment in this important food safety issue and will provide the agency additional information if it is required.

Sincerely,

A handwritten signature in black ink that reads "Stephen H. Cate". The signature is written in a cursive, flowing style.

Stephen H. Cate
Vice President Product Development

SHC/j



JAMES L. MARSDEN

Regents' Distinguished Professor

Of Meat Science

Kansas State University



De-sinewed Minced Meat Technology

DMM is a technology being evaluated for mechanically removing meat from bones, particularly from the neck bone and back bone without incorporating nervous tissue and minimizing bone constituents in the meat

WHAT IS AMR?

Mechanical method simplifying the de-boning of meat resulting in meat comparable to manually de-boned

Greatly improves labor conditions compared to manual or semi automated de-boning job with high worker related injuries, both direct as well as cumulative trauma disorders

Reduces general meat cost price by improving carcass meat yield

AMR SYSTEM

Harvests a nutritious meat which has been part of every cuisine all over the world for centuries (bone in meat, soups, bouillon, flavorings, stocks, processed meat ingredients and many others)

Advanced meat recovery “involves applying tremendous pressure to trimmed bones, such as backbones, to extract as much meat as possible”

AMR SYSTEM

Mechanical recovery has helped change meat processor's attitudes in using recovered meat as a food source and not as waste material

It was reported that when visible lean was trimmed off the bones from beef carcasses, this lean could vary from 12.1-27.6% of the beef carcasses weight

Kelly, Fontenot, Graham, Wilkinson, and Kincaid (1968)

AMR SYSTEM

Approx. 10-18% (based on choice grade carcasses) of the carcass weight is discarded when beef, pork, or lamb carcasses are boned

Recovering meat from discarded bones by AMR increases monetary value of the total carcass and supplies additional protein for world needs

Field, Kruggel, and Riley (1976)

AMR SYSTEM

Yields higher percentage of meat than removing lean, fat, and tendon from bones by hand boning

Could add 2.2-2.7 billion kilograms of meat per year to the world's food supply

Field, Kruggel, and Riley (1976)

AMR SYSTEM

In 1989, it was estimate that 1.9 million metric tons of mechanically deboned pork would be potentially produced throughout the world

Newer AMR technology could help processors squeeze 250-300 million pounds of meat off bones each year

Liu and Maga (1994) and Field (1981)

CONCERNS ABOUT THE AMR SYSTEM

Over-adjustment of pressure in the traditional AMR system in an effort to increase yield and reduce time lead to concerns:

- Bone marrow incorporation in the meat
- Structural quality of meat

CONCERNS (contd.)

Infectivity of BSE - found to occur in bovine bone marrow and in the nervous system

Since bone marrow is incorporated in AMR product and nervous system tissue has also been found in AMR product, most food services do not allow AMR meat in their products

CONCERNS (contd.)

The screen sizes used in AMR can cause
disruption of the structure

Further structural disintegration can occur due
to changes in the functional properties of the
recovered meat resulting in softened tissues
and a pasty product

CONCERNS (contd.)

Meat from AMR systems is considered to possess high microbial counts, because of the recovery process

The factors providing opportunities for bacteria to grow in recovered meat include:

- Nutrient composition

- Elevated temperatures throughout the recovery process due to friction

- Tissue disruption creating large surface area

CONCERNS (contd.)

Bacterial contamination, lipid oxidation, haem pigment release and final bone marrow content of the AMR product are four major factors that influence the storage properties of mechanically deboned meat

(Newman, 1981)

What is DMM?

It is an enhanced technology to remove meat from the bones.

The improved filtration system substantially reduces required pressures to harvest residual meat at reduced but still efficient yield levels (pressures < 30%) thus preventing the contamination of resulting meat with unacceptable levels of bone constituents, while maintaining structural quality of the meat

How does DMM work?

Working principle, with emphasis on technical execution prevents excess pressure on bones and thus abuse

Visualization of structural qualities of DMM

Visual proof that bones remain undamaged

SOLUTION

Improvements and adjustments have been made on AMR systems to produce a higher quality product, increase acceptable material that is produced for later human consumption and help in reducing bone particles (≤ 0.5 mm in diameter) to be undetectable by mouth

In addition, most AMR product is chilled quickly immediately after recovery to prevent microbial growth and preserve color.

SOLUTION

DMM maintains the integrity of the meat structure

DMM provides meat with levels of bone constituents in the minced meat which are comparable to minced meat obtained by normal hand boning

DMM in combination with appropriate processes provides meat from CNS tissue

STUDY I: EVALUATION OF DMM FOR CNS TISSUE

This study constituted evaluation of the meat

obtained from the 2 different locations for

presence of CNS tissue

SAMPLE COLLECTION

ESTABLISHMENT 1:

- Neck bones obtained without a JARVIS saw
- AMR product commercially produced with the traditional AMR system

ESTABLISHMENT 2:

- Neck bones obtained by using the JARVIS saw

SAMPLE EVALUATION

Bone samples from the 2 locations were
shipped to Iowa State University Meat Lab.
and deboning was done:

Using the DMM machine

Manually

SAMPLE EVALUATION (contd.)

Deboned samples were collected
randomly and shipped to:

USDA lab. Athens, GA - testing for
CNS tissues in the samples

University of California, Davis -
Immunological [modified Gial

Fibrillary Acidic Protein (GFAP)]
analysis of the samples

University of Nebraska, Lincoln -

histological analysis of the samples

**PROCESSING OF SAMPLES
FOR
HISTOLOGICAL AND GFAP
ANALYSIS**

SAMPLE HANDLING FOR GFAP

Three hundred meat samples, recovered from beef neck and sternum using a traditional AMR system, DMM technology, and hand boning, were collected and transported frozen ($\sim -20^{\circ}\text{C}$) to the Food Safety Laboratory at the University of California, Davis

Sternum meat served as the non-CNST reference (control) as it is distant from the brain and spinal cord locations on a carcass

SAMPLE PROCESSING

Meat samples were thawed prior to analysis

Four random sub samples were obtained from the sample to prepare slides for GFAP and synaptophysin staining

Each slide was independently examined under light microscope to identify nervous tissue

Two replicates were done on each sample

SAMPLE PROCESSING (contd.)

Samples were fixed in 10% neutral buffered formalin (no more than 72 h.)

Processed through a series of alcohols in an automated tissue processor

Processed tissues were embedded in paraffin and sectioned at 4 microns

Sections were placed on charged slides and dried for one to 24 h. at 60 °C

STAINING OF SAMPLES

Performed using Dako automated stainer

Primary antibodies used were:

Monoclonal antibodies Snp88

Synaptophysin (Biogenex AM363-5M)

Glial Fibrillar Acidic Protein (Biogenex
AM020-5M)

STAINING (contd.)

Alkaline phosphate detection (Biogenex QA900-9L) with fast red substrate (Biogenex HK182-5K) was used to detect primary antibody binding

Hematoxylin counterstain (Anatech LTD. #812) used to visualize the tissues

SAMPLE EXAMINATION

BX-40 SWF Olympus scope was used to examine GFAP slides for staining and histologically identifiable nervous tissue at 20X magnification

Synaptophysin slides were examined under 40X after initial screening for nervous tissue by light microscope and GFAP strains

EXAMINATION (contd.)

Suspected tissues were examined under 100X or 400X for identification

Presence of nervous tissue was scored as CNS or ganglia if neurons were seen or if tissues were positive for both GFAP and Synaptophysin

**RESULTS OF
GFAP AND HISTOLOGICAL
ANALYSIS**

RESULTS

Histochemical tests from the USDA Athens lab. showed no evidence of CNS tissue in any of the meat obtained by the DMM

Results for the modified GFAP tests conducted at UC- Davis were negative for CNS tissue in meat obtained from the DMM

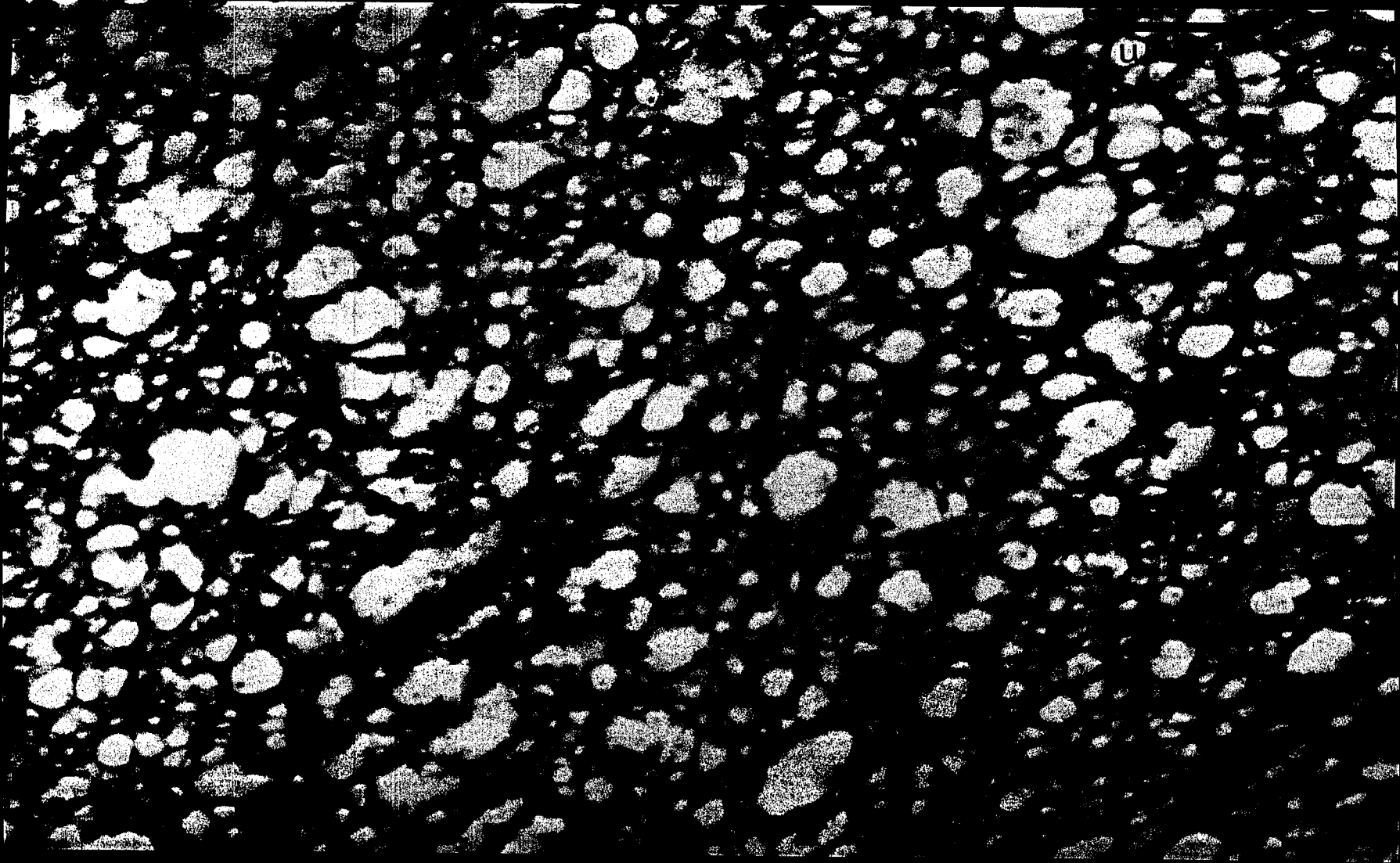
All samples were further analyzed at UNL

RESULTS – GFAP @UNL

All samples from the AMR, DMM, and hand methods showed lower calculated levels of
than the stated limit of
detection (0.1%) of the test kit

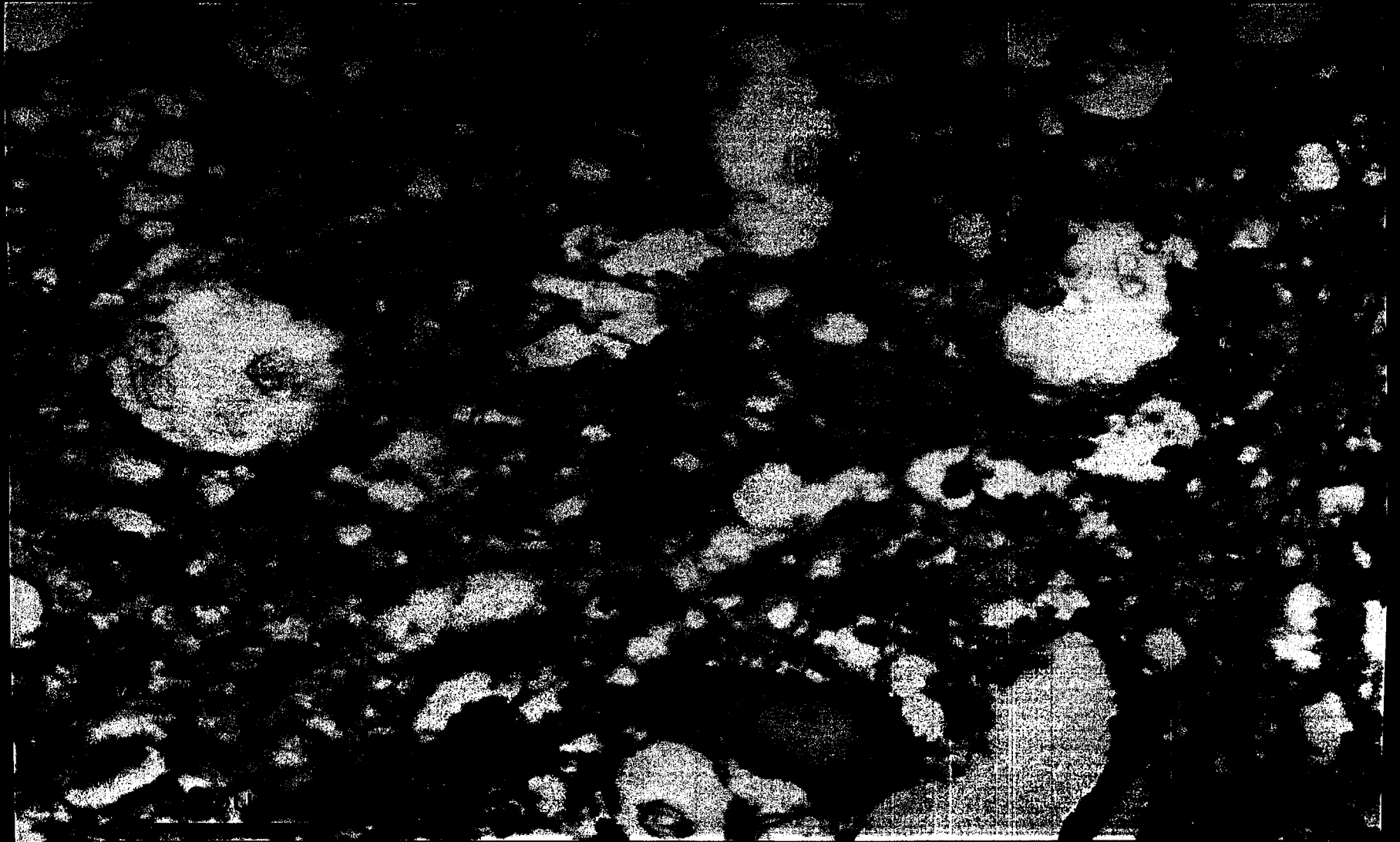
There was no apparent difference among these methods, and use of the Jarvis saw had no apparent advantage

Extensive staining of glial processes in the spinal cord (white matter)



GFAP CONTROL

SYNAPTOPHYSIN CONTROL



Extensive staining around neurons and neuronal processes

RESULTS - GFAP

The averages for estimated risk material in the hand-deboned neckbone products from both establishments were slightly above those of other samples

RESULTS (contd.)

Sternum (DMM) - Negative

Sternum (Hand deboned) - Negative

Neck bone (DMM) samples obtained by using
the Jarvis saw - Negative

Neck bone (Hand deboned) Jarvis -

RESULTS (contd.)

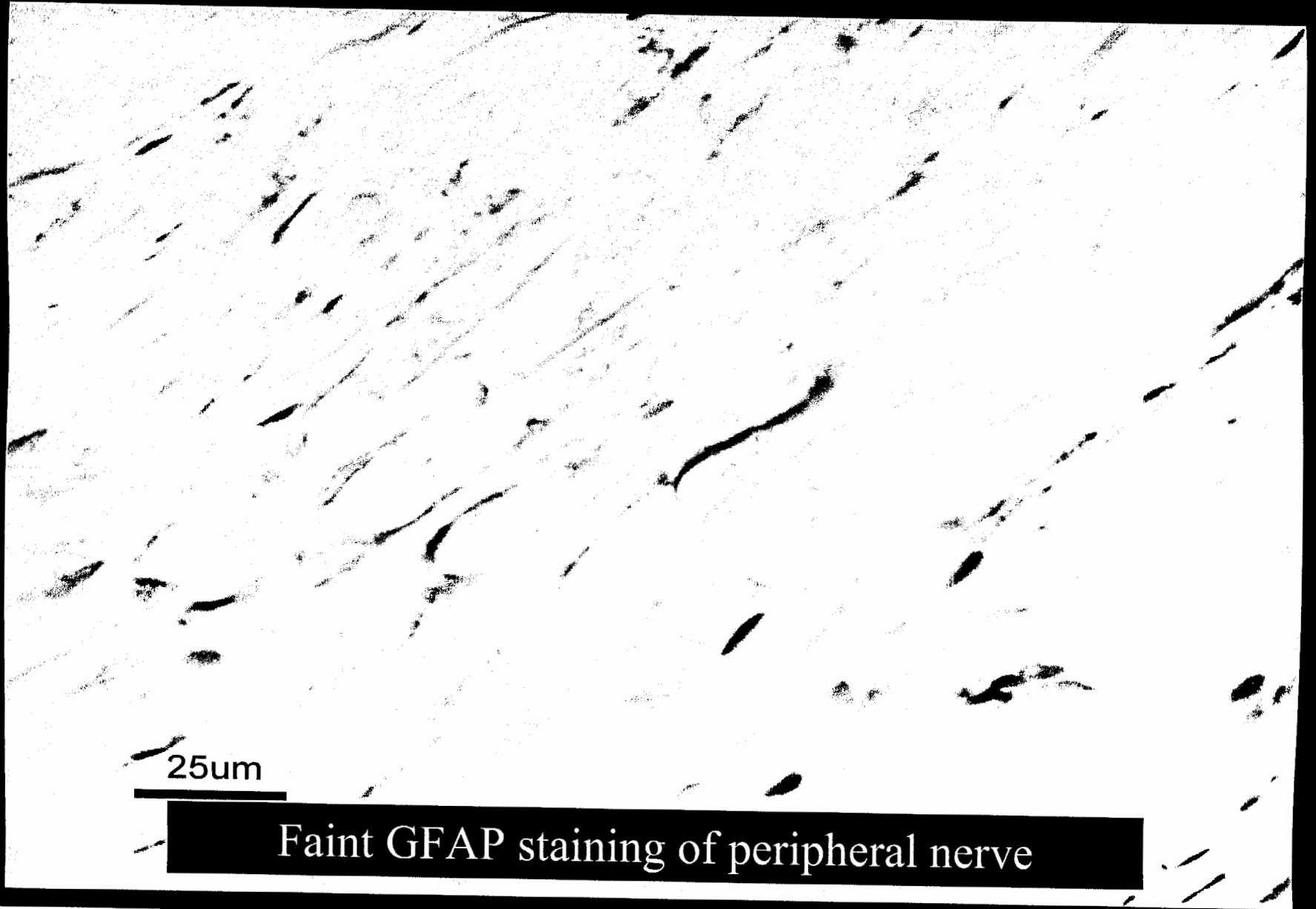
Neck bone (DMM) samples obtained without using Jarvis saw

1 out of 31 samples tested was for ganglion tissue, GFAP staining, synaptophysin, and histologically identifiable ganglion cells

GFAP staining was faint and attributed to peripheral nerve tissue

Synaptophysin staining associated with ganglion structure

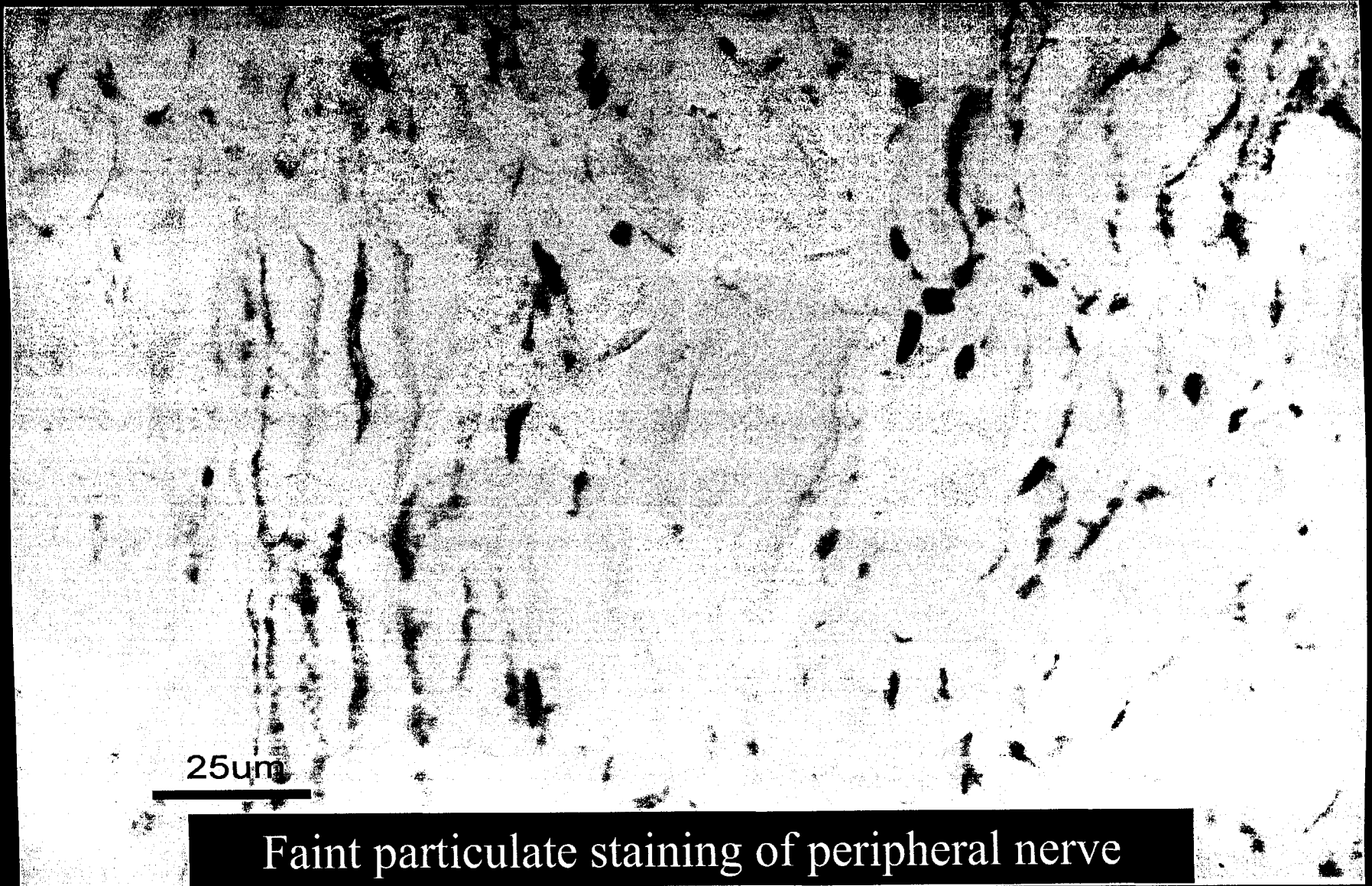
NECKBONE (HAND - NJ)



25um

Faint GFAP staining of peripheral nerve

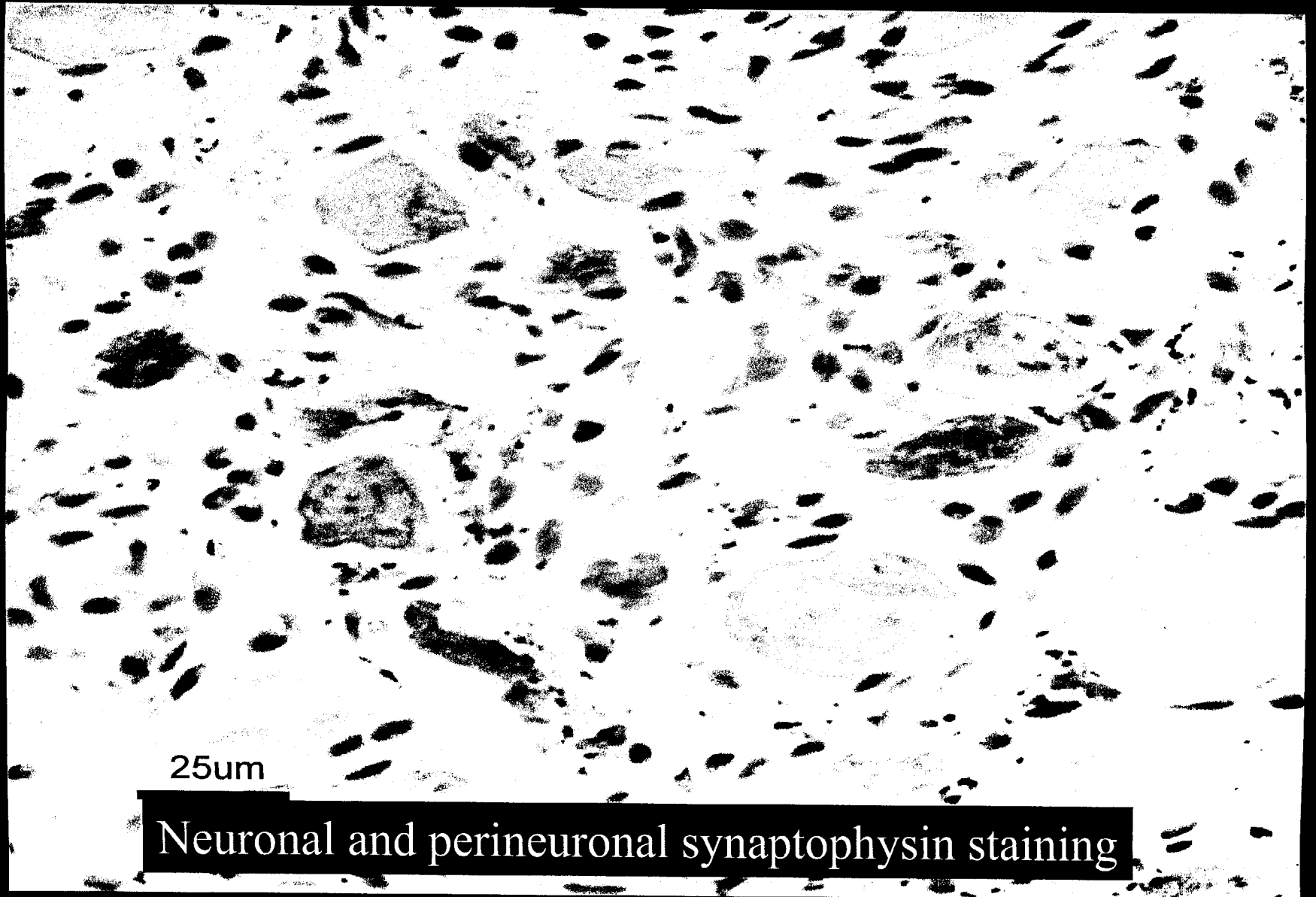
NECKBONE (HAND - JARVIS)



25um

Faint particulate staining of peripheral nerve

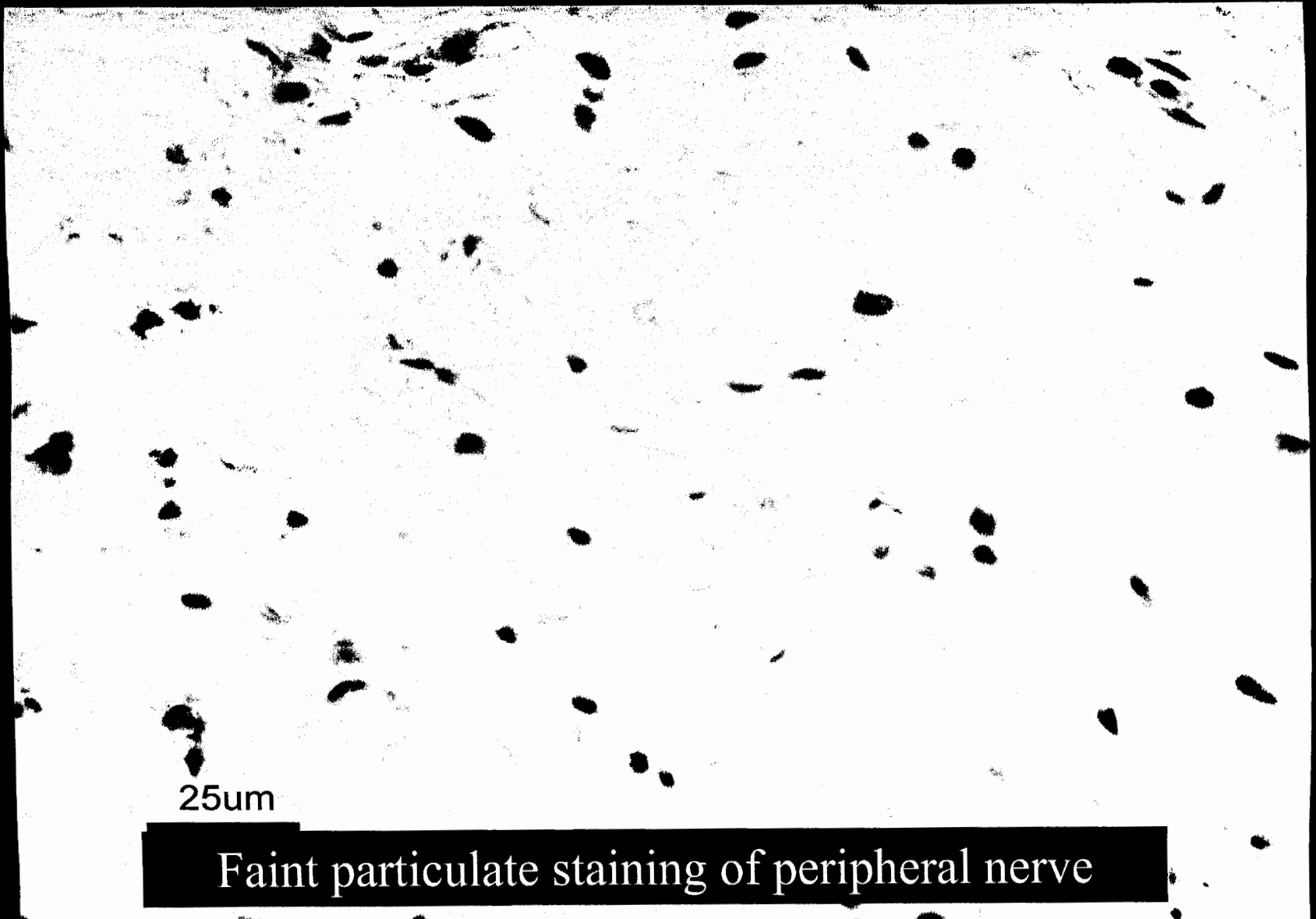
NECKBONE DMM (NON-JARVIS)



25um

Neuronal and perineuronal synaptophysin staining

NECKBONE DMM (JARVIS)



25um

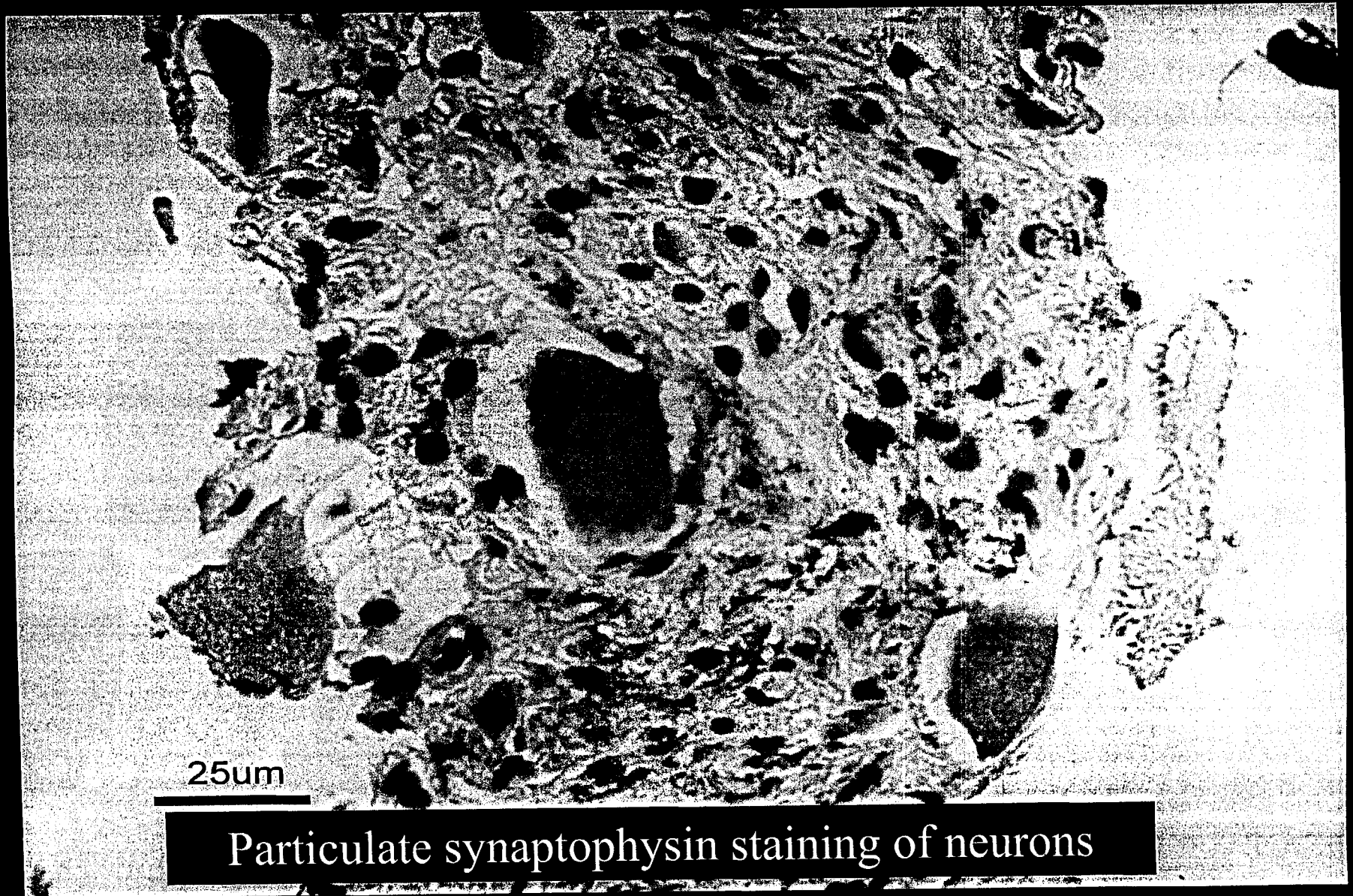
Faint particulate staining of peripheral nerve

RESULTS (contd.)

Meat obtained from the neck bones by the traditional AMR system with or without the Jarvis saw indicated the presence of ganglia which were stained by GFAP as well as Synaptophysin

Beef backbones obtained by using the Jarvis saw and deboned using the DMM system showed staining of Synaptophysin associated with a ganglion identical to that of hand boned samples

NECKBONE (TRAD. AMR)



25um

Particulate synaptophysin staining of neurons

STUDY II: PROXIMATE ANALYSIS

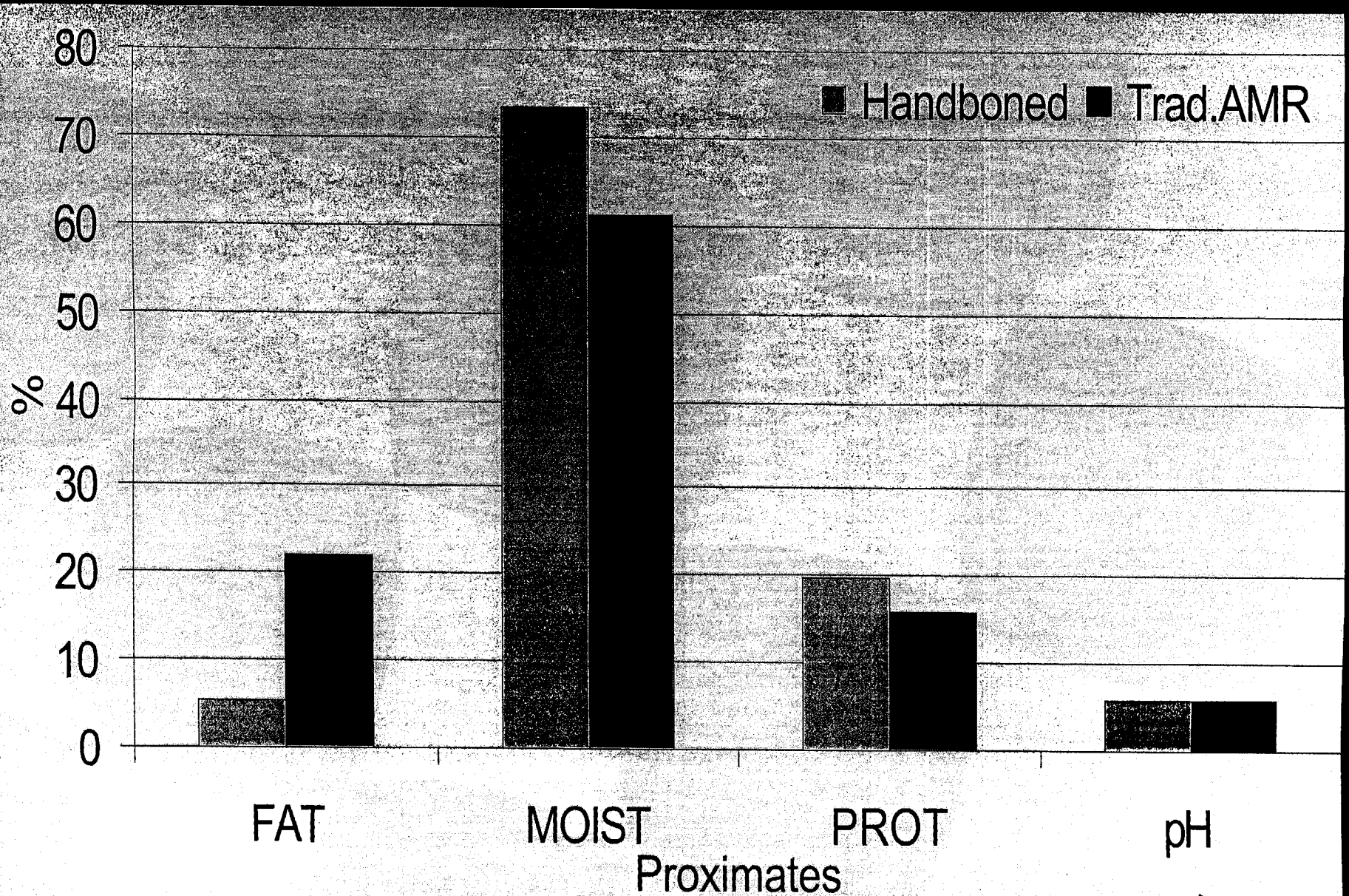
120 samples of DMM neck meat and 40 samples of manually deboned neck meat were analyzed

Samples for proximate analysis were collected from individual locations randomly and shipped (dry ice) to KSU

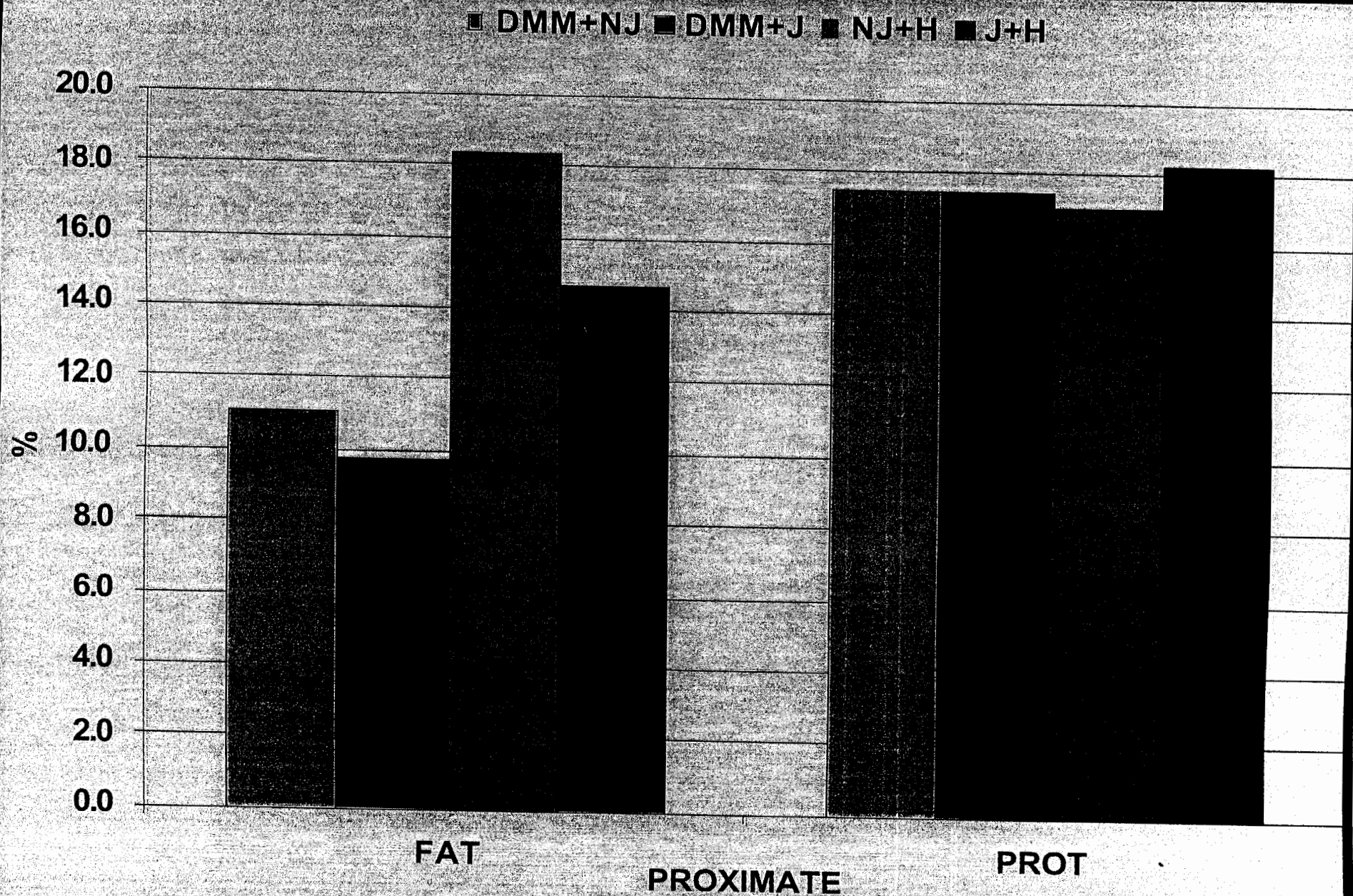
Shipped samples were held at 32 °F overnight

Samples were then fine ground (3/8") and pulverized prior to analysis

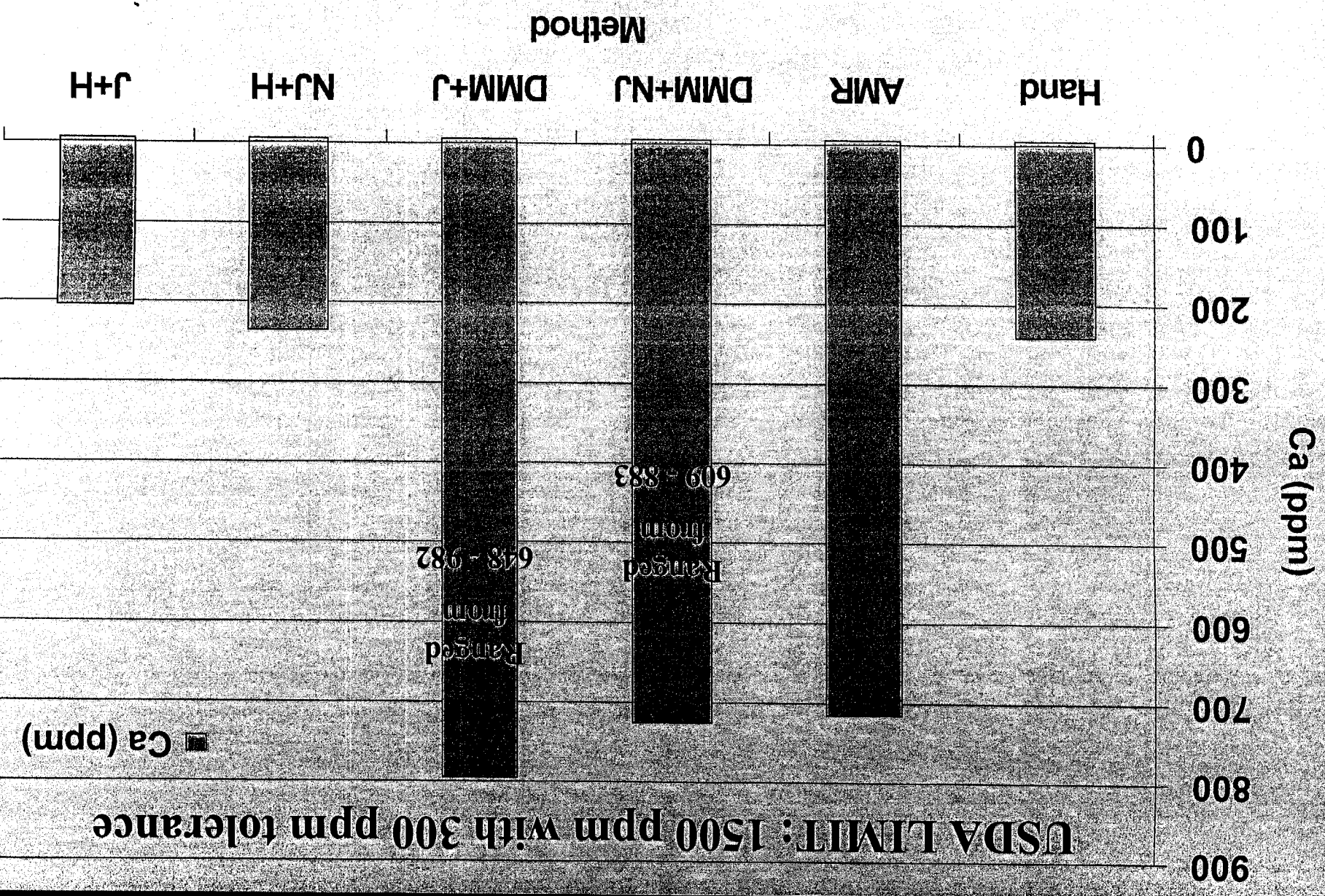
PROXIMATE ANALYSIS



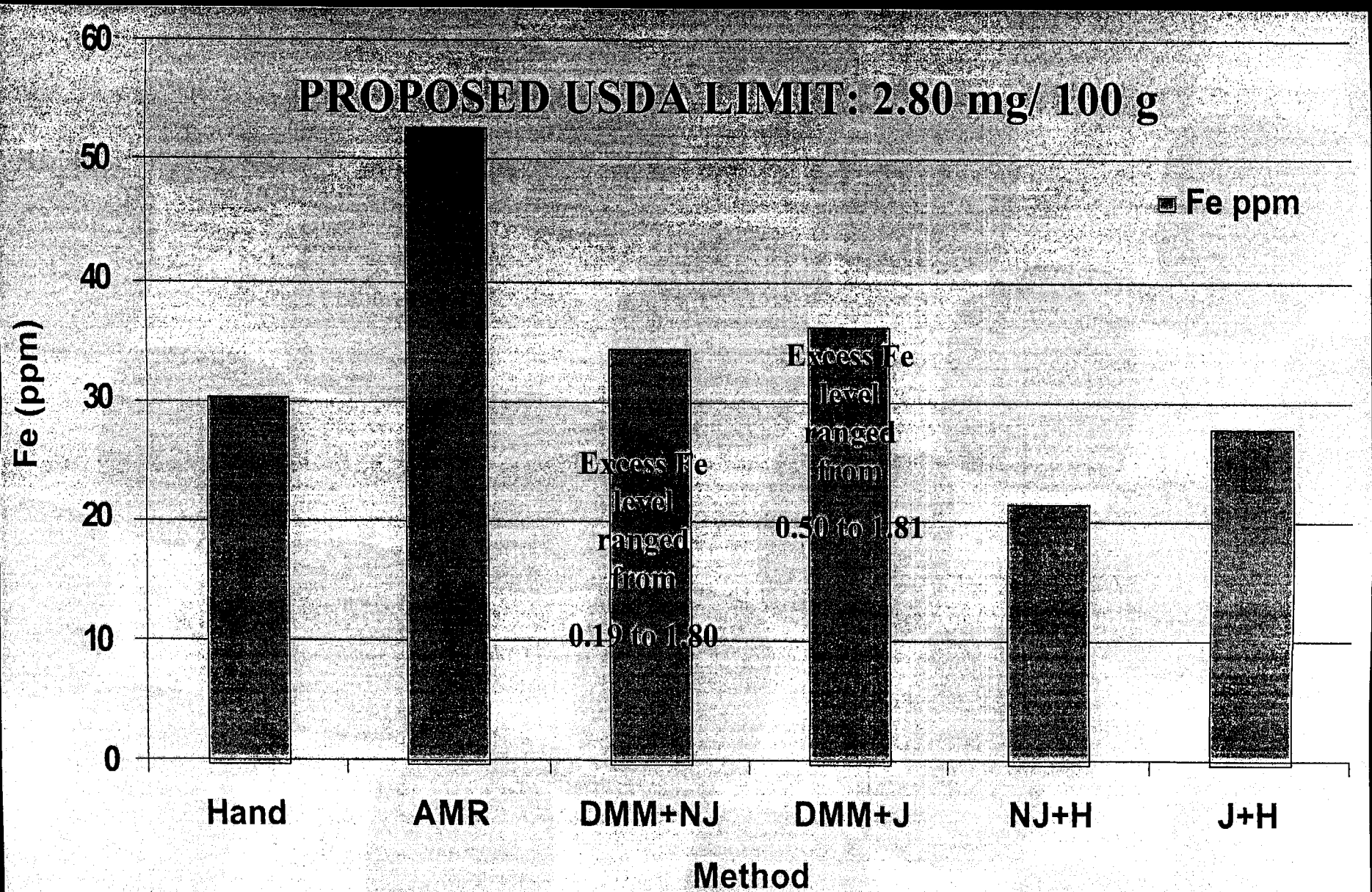
PROXIMATE ANALYSIS



AFFECTS ON Ca



AFFECTS ON Fe



CONCLUSIONS (PROXIMATE)

Ca in DMM not only complies with existing
USDA AMR regulation but also the USDA
proposed stringent regulations

Results from our studies show that 100% of the
DMM (120 samples) is in compliance with the
USDA Fe requirements as opposed to only 38%
of the AMR meat (163 samples) being in
compliance (1996)

CONCLUSIONS

DMM is an acceptable and economical
feasible alternative

It prevents abuse of the AMR legislation

It results in a wholesome high quality meat,

AMR regulation always intended

FUTURE STUDIES

Earlier studies with the test kit had shown that it would detect bovine spinal cord at levels down to at least 0.025%, which is much lower than the manufacturers claim, we have tried to “recalibrate” the semi-quantitative results from the kit (work is in progress)