

SBRUNKHORST INS-0000892056

Inspection Report

Southern Biotechnology Associates Inc

PO Box 26221

Birmingham, AL 35260

Customer ID: 835

Certificate: 64-R-0018

Site: 001

SOUTHERN BIOTECHNOLOGY

ASSOC.

Type: ROUTINE INSPECTION

Date: 25-JUL-2023

2.31(c)(3)

Institutional Animal Care and Use Committee (IACUC).

The reports to the Institutional Official of the semi-annual program of humane care and use of animals review and facility inspection conducted by the IACUC in October 2022 and April 2023 are not complete.

*Both reports are not signed by a majority of the IACUC members. One is signed by the IACUC chair.

*The April 2023 report contains a minor deficiency and a plan for its correction (loose panel on the barn) but does not contain a schedule with dates for correcting the deficiency.

The IACUC's report of the semi-annual evaluations conducted must be complete and contain all the required information in order to allow the research facility, the Institutional Official, and USDA APHIS to be apprised of the nature and extent of the research facility's adherence to the Animal Welfare Act.

The facility shall prepare reports of the semi-annual review of the program of humane care and use of animals and inspection of the facilities. Any departures from the AWA must be described with a reason for the departure, a designation of minor or significant, and a reasonable and specific plan and schedule with dates for correction. The report must also include any minority views and the signatures of a majority of the IACUC members. Correct by 8/1/23 with the next semi-annual evaluations.

2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).

The proposals to conduct activities involving animals for antibody production (Program Goats, Program Rabbits, Program Donkeys) do not include an actual rationale for the appropriateness of the specific species of animals to be used and for the numbers of animals to be used. The rationale for species simply states the need to use species other than mice and rats but not why the specific species requested needs to be used. The proposals request the use of up to 50 animals which is a large group range and give a vague rationale based on demand and the species involved. The justification for the number of animals to be used should be specific to the activities being conducted such as the amount of antibody needed and the amount which can be produced by an animal. The proposals to conduct activities involving animals must include rationales for the appropriateness of the species and numbers of animals to be used in order to give the IACUC the information they need to review the proposals and ensure that they meet the requirements of the Animal Welfare Act. All proposals to conduct an activity involving animals must contain a rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used. Correct by 10/31/23.

Prepared By:SUSANNE BRUNKHORSTDate:USDA, APHIS, Animal Care20-SEP-2023

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Facility Representative Date:

20-SEP-2023



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2.33(b)(2) Critical

Attending veterinarian and adequate veterinary care.

Three animals are currently in need of veterinary care:

*Two goats have developed nodules under the skin secondary to their research related injections. In two of the goats, at least one nodule has become irritated, inflamed and/or infected. A light tan goat with ear tag 531 has an approximately one inch round swelling protruding above the skin over the right side near the shoulder. The swelling has several smaller red irritated areas on it and there is a thick white material oozing from the swelling at the lower edge of the swelling. The male white Savannah goat with ear tag 347 has a half inch darkly pigmented slightly firm swelling protruding above the skin over the right side near the shoulder. There is tan dried material attached to the haircoat around the swelling. The facility representative states that the attending veterinarian has not been notified of these swellings and no treatment is currently being provided. The IACUC approved research protocol states that 'if any animal develops an ulceration and/or infection at the injection site, the vet will be asked to treat the lesion'.

*One New Zealand white rabbit (RBT733) has hairloss in patches across its face encompassing the nose and both sides of the face beside the nose and under the eyes. There are no visible wounds. The facility representative states that the attending veterinarian has not been notified about the hairloss and no treatment is being provided. In addition, five Savannah goats did not receive appropriate veterinary care:

Records reviewed show that one female Savannah goat (ear tag 2338) died on July 11, 2023. The goat arrived at the facility on 6/29/23 and broke one horn near the base of the horn (near head) while she was butting her head when being moved into the chute for her vaccinations. She apparently 'never did well' and died on July 11, 2023. The facility

representative states that the attending veterinarian was not notified of the broken horn or the fact that she was not feeling well. Broken horns are painful and breaks near the base of the horn can be serious.

During the facility inspection on 7/25/23 six Savannah goats were in the quarantine pen in the lower barn. These goats were born on December 1, 2022 and arrived at the facility on 6/29/23. The four seven month old male goats were banded upon their arrival by facility staff. No anesthetics or pain control medication were administered. The program of veterinary care and the goat care SOP do not address castration methods/procedures for the goats. Castration of goats older than a few weeks is considered a painful procedure.

Adequate veterinary care including the use of appropriate methods to diagnose and treat diseases and injuries is necessary to ensure the health and well-being of the animals and to ensure that the animals do not experience unnecessary pain.

The facility shall ensure the availability of adequate veterinary care to include the use of appropriate methods to prevent, control, diagnose and treat diseases and injuries and the availability of emergency care. In addition, correct by having the three animals currently in need of veterinary care (goats 531 and 347 and rabbit RBT733) evaluated by a veterinarian. Correct by 7/29/23.

2.33(b)(3)

Attending veterinarian and adequate veterinary care.

The facility staff is making daily observations of the animals but has not been communicating with the attending veterinarian when they identify problems of animal health, behavior and well-being. During this inspection, two goats (ear tags 531 and 347) were found to have skin nodules protruding above the skin with drainage and one rabbit (RBT733) was found to have facial hairloss. The facility staff was aware of these issues but did not contact the attending veterinarian. In addition, another goat (ear tag 2338) broke her horn near the base of the horn on 6/29/23 and did not feel well for days afterward. The veterinarian was not notified of this emergency and the goat died without treatment. In order for the

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attending veterinarian to provide adequate veterinary care for the animals, the veterinarian needs to be provided with timely and accurate information on problems of animal health, behavior and well-being.

The facility shall ensure daily observation of all animals to assess their health and well-being is conducted and that a mechanism of direct and frequent communication exists so that timely and accurate information on problems of health, behavior and well-being are conveyed to the attending veterinarian. Correct by 7/29/23.

2.35(a)(1)

Recordkeeping requirements.

The meeting minutes for the April 21, 2023 IACUC meeting consist of only a record of attendance and a description of the semi-annual inspection completed. Conversation with the facility representative and review of the research proposals for activities involving animals show that the proposed activities involving animals were reviewed and approved at the meeting. The meeting minutes do not include any notation that this activity was completed, any deliberations about the proposed activities or that a vote was completed and the proposed activities approved. Accurate and complete IACUC meeting minutes are necessary to document the proper functioning of the IACUC.

The research facility shall maintain minutes of IACUC meetings including records of attendance, activities of the Committee, and Committee deliberations. Correct by 8/1/23 starting with the next IACUC meeting.

3.50(a)

Facilities, general.

The lower barn contains several consecutive rooms. The entry hall leads into the airconditioned office and through an open door into the next room that houses the rabbits. Upon arrival at the facility on 7/25/23 the inspector saw a raccoon walking down the center walkway of the elevated rabbit enclosures in the rabbit room heading toward the office. Apparently the raccoon is a wild raccoon that took up residence in the rafters of the barn and has a litter of young hidden somewhere in the barn. The raccoon comes into the office to eat from the cat food bowl. The inspector was told that the construction of the barn does not allow the facility to keep the raccoon out of the rabbit room. Raccoons can carry several diseases that can be spread to other animals and they can cause stress in the rabbits.

The facility shall ensure that housing facilities for rabbits be structurally sound and maintained in good repair in order to restrict the entrance of other animals. Correct by 8/27/23.

3.54(b)

Feeding.

Several rabbit food receptacles used for feeding dry feed are dirty. Dirty feed receptacles can lead to contamination of the feed

Food receptacles shall be kept clean and sanitized at least once every 2 weeks. Correct by 8/9/23.

3.56(b)(1)

Sanitation.

The facility representative stated that the rabbit enclosures are cleaned regularly but that sanitation by flaming is done twice a year in the spring and fall. In addition to regular cleaning to keep the enclosures reasonably free of excreta, hair, cobwebs and other debris, regular sanitization is required to help prevent the spread of disease by removing/destroying to the maximum degree practical the agents (such as microbes) injurious to health.

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Primary enclosures for rabbits shall be sanitized at least once every 30 days by one of the following methods: washing in a mechanical cage wash (with 180 degree water and detergent), washing with a detergent solution followed by a disinfectant or by the use of live steam/flame. Correct by 8/27/23.

3.125(a)

Facilities, general.

Repairs are needed in several pens/enclosures.

*One of the posts of the llama enclosure had been knocked down/loose from the ground. One of the wires was pressed downward and out of its normal position by the weight of the post leaving a double size gap between two of the wires. The llama may injure themselves trying to get through the gap and may possibly be able to escape the enclosure.

*There are insulation boards in the ceiling/top portion of the shelter structures for the goats and sheep in the lower pastures. Several of these boards are loose. If they fall, the animals may be injured or be spooked.

The outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals. Correct the llama enclosure by 7/30/23 and the goat/sheep shelter structures by 8/9/23.

3.130

Watering.

The water receptacles for the breeder goat enclosure and the goat enclosure with the pasture inbetween the two barns need cleaning. The water is dark and murky in color and opaque. The bottom cannot be visualized. There is green material growing in the water and on the sides of the receptacles. Dirty water receptacles can lead to issues with the water becoming contaminated or having a taste that keeps the animals from drinking.

All water receptacles shall be kept clean and sanitary. Correct by 7/27/23.

3.131(a)

Sanitation.

The indoor portions of the goat enclosures in the upper barn have a concrete floor. There is a thick layer of dried fecal material, dirt, debris and shed hair on the floor. This excess accumulation may lead to contamination of the animals, spread of disease, odors and attract pests. Evidence of pests present include many huge cobwebs and rat feces. Excreta must be removed from the enclosures as often as necessary to prevent contamination of the animals contained therein and to minimize disease hazards and to reduce odors. Correct by 8/27/23.

3.131(c)

Sanitation.

*The front part of the upper barn has shelves and storage for tools and chemicals. Immediately adjacent are pallets of unopened feed bags. This area is extremely dirty, dusty and disorganized. Tools and trash are on the ground. Old spilled feed, dust, rodent feces and dirt cover the ground and shelves.

*There is an extreme number of large cobwebs in the upper barn that need to be cleared away. They limit access to certain areas of the barn and cover electrical cords/extension outlets.

Accumulations of dirt, debris, cobwebs and scattered items can attract pests and make routine cleaning difficult.

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Premises must be kept clean to protect the animals and to facilitate prescribed husbandry practices. Accumulations of trash shall be placed in designated areas and cleared as necessary. Correct by 8/9/23.

3.131(d)

Sanitation.

There are an extreme number of large cobwebs in the upper barn in the area housing the goats. Spiders were also noted. The cobwebs made it difficult to access certain areas of the barn and are surrounding electrical wires/extension cord outlet. Cobwebs can be a fire hazard and collect dust that is unhealthy. Spiders themselves may cause irritation to the animals.

A safe and effective program for the control of all pests including insect pests shall be established and maintained. Correct by 8/9/23.

This inspection and exit interview were conducted with facility representatives.

Prepared By: SUSANNE BRUNKHORST Date:

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
835	64-R-0018	001	SOUTHERN BIOTECHNOLOGY ASSOC.	25-JUL-2023

Count 000142 000021 000003 000002 000049	Scientific Name Capra hircus Equus asinus asinus Ovis aries aries Lama glama Oryctolagus cuniculus Sus scrafa domestica	Common Name DOMESTIC GOAT DONKEY / BURRO / ASS SHEEP INCLUDING ALL DOMESTIC BREEDS LLAMA DOMESTIC RABBIT / EUROPEAN RABBIT DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000003	Sus scrofa domestica Total	DOMESTIC PIG / POTBELLY PIG / MICRO PIG