



## ANIMAL WELFARE COMPLAINT

Complaint No.	Date Entered:		Processed By:		
AC18-732	28-Sep-18		GCA		
Referred To:			•	Reply	Due:
Frank/Garland				28-Oc	t-18
	Facility or	Person Compla	aint Filed	Against	
Name:			Custome	er No.:	License No.:
Pro Sci Inc			43309 93-R-0521		93-R-0521
Address:			·	Email Address:	
12170 Flint Place					
City:		State:		Phone No.:	
San Diego		CA	8	58-513-2638	
	C	omplainant Inf	ormation		
Name: (b) (6), (b) (7)(C), (b) (7)(D)			Organiza	ation:	
Address:				Email Add	ress:
				(b) (6), (b) (7)	(C), (b) (7)(D)
City:		State:	Р	hone No.:	
How was the Comp	laint received?	1	I		
Email					
Details of Complain	t:				
SEE ATTACHED					
Results:					
This complaint refer	rs to citations on a p	rior inspection r	eport.		
Animal Care inspect	ors conduct unanno	ounced inspection	ns for all L	JSDA register	red and licensed
facilities. Our autho	rity is to ensure that	t they meet the	standards	required by I	ederal regulations. We
	•				d from the public to
ensure the well-beir	ng of the animals an	d compliance w	ith Federa	l law.	
					inspection report under
	-			•	e noncompliances for
the same issue are only cited when appropriate. With the exception of focused inspections, our					
					Although all regulatory
requirements are assessed, only noncompliant items are listed on the inspection report.					
We will continue to inspect this facility to make sure that past noncompliances are corrected and					
that AWA-regulated animals are protected to the fullest extent of Federal law.					
Application Kit Provided:					
Yes: No:					
Inspector:				Date:	
Program Support					10-Jul-19
Reviewed By:					Date:

From:	Frank, Katharine C - APHIS
To:	Whisenton, Katie M; AC West
Cc:	Garland, Kathleen M - APHIS
Subject:	FW: Official Complaint CLOSE Pro Sci
Date:	Wednesday, October 3, 2018 11:16:02 AM
Attachments:	Pro Sci 6-20-17 Inspection Photos.pdf AC18-732.docm

### Katie,

This complaint appears to be based on my inspection report?

(b) (5)

(b) (5

# Thanks,

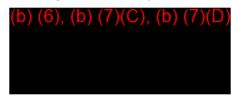
Katie Frank

From: Allums, Gina - APHIS
Sent: Monday, October 1, 2018 1:46 PM
To: Garland, Kathleen M - APHIS <Kathleen.M.Garland@aphis.usda.gov>; Frank, Katharine C - APHIS
Katharine.C.Frank@aphis.usda.gov>
Subject: FW: Official Complaint -- CLOSE Pro Sci

Good evening, attached is a complaint for customer #43309 Pro Sci Inc

### From: (b) (6), (b) (7)(C), (b) (7)(D)

Sent: Tuesday, September 04, 2018 2:36 PM
To: Gibbens, Robert - APHIS <<u>Robert.M.Gibbens@aphis.usda.gov</u>>
Cc: AC West <<u>acwest@aphis.usda.gov</u>>
Subject: Official Complaint -- CLOSE Pro Sci



Dr. Robert Gibbens

9/4/18 Director, Western Region, USDA/APHIS/AC, 2150 Center Ave. Building B, Mailstop 3W11 Fort Collins, CO 80526-8117 Dr. Gibbens.

I am writing to you today regarding the Pro Sci facility (93-R-0521, 93-B-0229), due to the excessive number of violations amassed by this facility since the beginning of 2016, and the seriousness of these violations, especially as they impact the animals held prisoner by this career criminal, I must insist that you take immediate action against this offending institution.

As you know, Pro Sci received an Official Warning for Animal Welfare Act violations in 2015. According to the USDA website, Pro Sci has amassed 38 citations for non-compliances since March of 2016. This shocking number of violations (the most recent citations are listed below) clearly places Pro Sci in very bad company. It has become clear, not only from the number of violations but also from the conditions depicted in the photos from the June 2017 inspection, that this facility has now entered the same arena as Santa Cruz Biotech, the facility against which the USDA levied a \$3.5 million federal fine, as well as requiring the lab to surrender their registration as a research facility and terminating their license as an animal dealer. It is eminently clear that this criminal facility deserves the same fate – CLOSURE.

The USDA MUST CLOSE Pro Sci.

As I stated above, Pro Sci is clearly now in the same arena as Santa Cruz Biotech, another criminal antibody production company. Both labs use rabbits and goats to produce antibodies. Both labs amassed dozens of violations over the

course of several years. Both labs denied the animals in their possession adequate veterinary care, and both labs failed abysmally to maintain anything that even roughly resembled adequate sanitation.

Every day that Pro Sci is allowed to continue to operate endangers the lives of approximately 1000 animals. The lives of rabbits, sheep, and goats are literally in your hands. Do not fail them! CLOSE PRO SCI!

The most recent inspection (2/13/18) discloses four new citations, which quite frankly, are disgusting. One repeat citation under the veterinary care section of the AWA (2.33(b)(2) <u>REPEAT</u> ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE) states:

"The parasite control program of the Program of Vet Care specifies that "fecal material is removed from enclosures a minimum of twice weekly to minimize the attraction of flies." The big llama pen contained an excess accumulation of excreta, and there was no documentation that they had cleaned the pen twice in the last week, in accordance with their PVC."

This citation means that llamas at Pro Sci are likely standing in their own excrement. The next citation, for violating Sec 3.30 Watering is equally disturbing:

# "3.30 WATERING. All three guinea pig enclosures had dirty water bowls at time of inspection. The water in the bowls contained excreta and some shavings. Animals were observed drinking the dirty water during inspection."

So, the animals at Pro Sci are likely not only standing in their own excrement, they are drinking water contaminated with their own excrement.

Yet another citation continues this pattern of disgusting conditions:

### "3.31(a)(1) SANITATION. Cleaning and sanitation of primary enclosures.

Guinea pig enclosures are not being cleaned adequately or often enough to remove accumulations of excreta, soiled bedding, debris and stains. There were accumulations of excreta, soiled bedding, urine stains, and grime on the sides and floors of enclosures. The room log showed that the cage had not been cleaned since February 2nd."

These enclosures had not been cleaned for eleven days.

These issues are not isolated incidents. This facility has been cited for issues of sanitation, watering, facilities, veterinary care, etc. dating back to 3/23/16. Again, in this time period, the research facility registration for Pro Sci has amassed 24 separate AWA citations.

Pro Sci was inspected on 6/20/17 and this single inspection cited Pro Sci for seven Animal Welfare Act noncompliances.

One of these citations was considered critical, while another was a repeat citation.

The first citation under Sec. 2.31 Institutional Animal Care and Use Committee is for failing to weigh rabbits before drawing blood. These weights were to be done to protect the rabbits from losing too much blood.

The second citation under Sec. 2.32 Personnel Qualifications is for use of personnel for whom there was no documentation that the staff was trained.

The third citation, under Sec 2.33 Attending Veterinarian and Adequate Veterinary Care is a repeat citation for inadequate veterinary care because several goats had overgrown hooves.

The fourth citation, one considered critical, is also under Sec 2.33 Attending Veterinarian and Adequate Veterinary Care for failing to provide veterinary care to three rabbits. One of them died, another had a severe malocclusion which can prevent eating, while the third had a severe ear mite infestation.

The fifth citation is also for inadequate veterinary care for multiple rabbits who had dried blood on their ears.

The sixth citation was for improper feeding because feed was contaminated with rodent feces.

The last citation was for improper sanitation because there was a significant fly problem in the sheep and llama enclosure.

This facility is becoming such a repeat criminal that they must be classified in the same arena with Santa Cruz Biotechnology, the laboratory which was the target of the most significant penalty ever issued by the USDA.

In light of the excessive number of citations, the serious and disgusting nature of those citations, and the fact that many animals are suffering and/or dying as a result of Animal Welfare Act violations by Pro Sci, I must insist that your office open a case against Pro Sci, and launch a major investigation of this heinous facility.

Due to the serious nature and numerous quantity of AWA non-compliances by Pro Sci in the last two years (and beyond, see attached Official Warning from 2015 below) I hereby file an Official Complaint against Pro Sci relevant to the clear abuse of many animals.

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations kill, abuse, or seriously injure animals. Since the Pro Sci has compiled the most extensive violations list for any lab in the U.S., I must insist that you take the most severe action allowable under the Animal Welfare Act and immediately begin the process of issuing the maximum fine allowable against Pro Sci at the completion of your investigation – \$10,000 per infraction, per animal.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,





(b) (6), (b) (7)(C), (b) (7)(D)





# ANIMAL WELFARE COMPLAINT

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AC18-732	28-Sep-18		GCA		
Referred To:				Reply	Due:
Frank/Garland				28-Oct	t-18
	Facility or	Person Compla	int Filed	Against	
Name:				Customer No.: License No.:	
Pro Sci Inc			43309 93-R-0521		93-R-0521
Address:				Email Addr	ess:
12170 Flint Place					
City:		State:	Phone No.:		
San Diego		CA	858-513-2638		
	Co	omplainant Info	ormation		
Name:			Organiza	ation:	
(b) (6), (b) (7)(C), (b) (7)(D)			(b) (6), (b) (7 <mark>)</mark> (		
Address:				Email Addr	
				(b) (6), (b) (7)(	C), (b) (7)(D)
City:		State:	Р	hone No.:	
How was the Compla	int received?				
Email					
Details of Complaint	:				
SEE ATTACHED					
Results:					
Application Kit Prov					
Yes:	No:				
Inspector:					Date:
Reviewed By:					Date:
-					



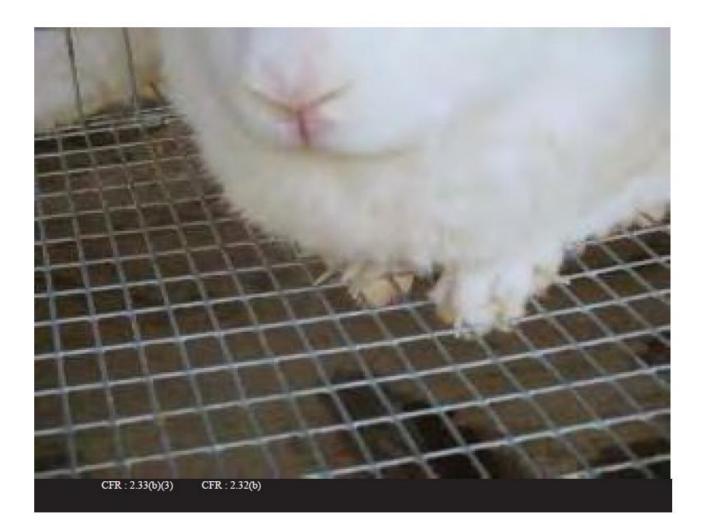
Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with ear mites.



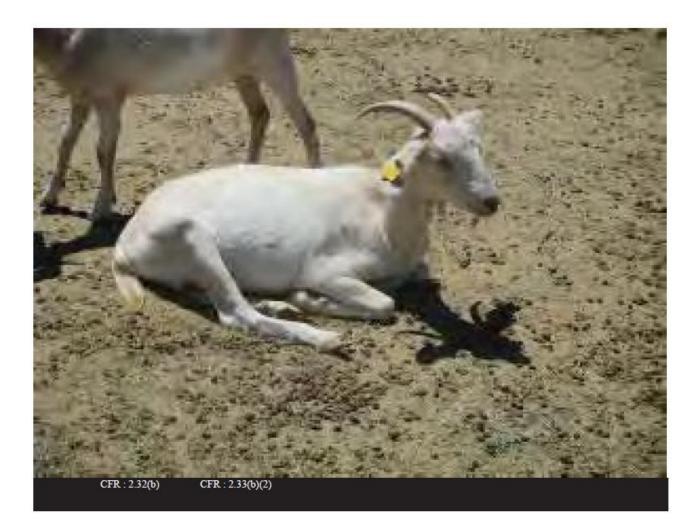
### Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with malocclusion, no record of trimming.

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33(b)(3) CFR : 2.32(b)		

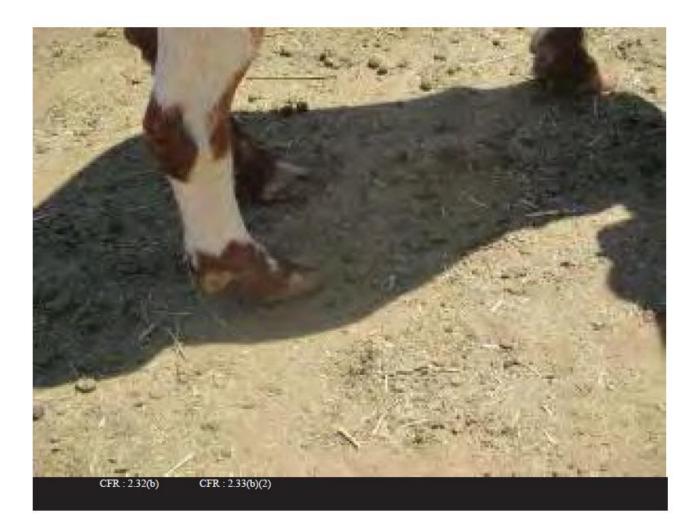
Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with malocclusion, no record of trimming.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with long nails.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Goat with long hooves.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Goat with long hooves, with cracks.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Moldy hay in the feed barn.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rodent feces on the feed bag.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description:

Feed bag chewed open, with rodent feces.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with dried blood on the back of the ear.



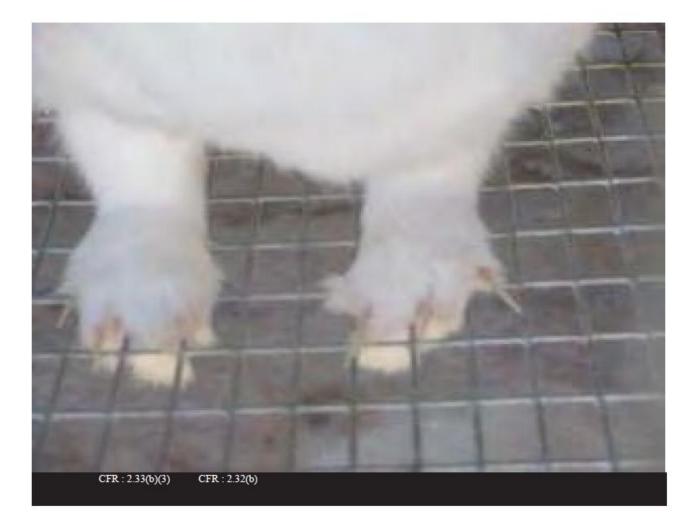
Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with dried blood on the back of the ear.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with dried blood in the fur on the back.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with dried blood on the back of the ear.



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with long toenails (closeup)



Photographer: K. FRANK Date and Time: 20-JUN-17 1100 Inspection No: 2016082568423118 Description: Rabbit with long toenails (wide)

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Inspection Report

Pro Sci Inc.	Customer ID:	43309
12170 Flint Place	Certificate:	93-R-0521
Poway, CA 92064	Site:	002
	PRO SO	CI INC
	Туре:	ROUTINE INSPECTION
	Date:	13-FEB-2018

### 2.33(b)(2) REPEAT

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Several instances were identified in which the facility is not using appropriate methods to prevent, control and treat diseases and injuries.

\*The Baytril 100 multi use bottle had dried medication and debris on the lid, specifically where the needle is inserted to withdraw medication to be injected into the rabbits. The kwikstop/styptic and blue-kote bottles were also sticky with residual medication and are applied to open wounds, and contamination of medication can cause infection.

\*A spray bottle filled with liquid in the supply cabinet was unlabeled. Without a proper label, an employee could injure the animal using a caustic solution directly on the animal.

\*The parasite control program of the Program of Vet Care specifies that "fecal material is removed from enclosures a minimum of twice weekly to minimize the attraction of flies." The big Ilama pen contained an excess accumulation of excreta, and there was no documentation that they had cleaned the pen twice in the last week, in accordance with their PVC.

Failure to provide appropriate methods to prevent, control and treat diseases and injuries could jeopardize the health and well-being of the animals. The facility should ensure that their program of veterinary care appropriately addresses the medical needs of all animals under their care and they are following it.

Correction date: 23 February 2018

### 3.30

### WATERING.

All three guinea pig enclosures had dirty water bowls at time of inspection. The water in the bowls contained excreta and some shavings. Animals were observed drinking the dirty water during inspection. Water for guinea pigs must

Prepared By:	FRANK KATHARINE, D V M	<b>D</b> . (
	FRANK KATHARINE, D V M USDA, APHIS, Animal Care	Date: 27-FEB-2018
Title:	VETERINARY MEDICAL OFFICER 6091	
Received By:		
		Date:
Title:		28-FEB-2018
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### Inspection Report

be clean and potable and provided daily unless food supplements consumed by the animals supplies their normal water requirements. The room log showed that water was checked daily, but fresh water was only provided on February 3rd, 4th, and 11th and that the cage had not been cleaned since February 2nd. The facility SOP AF-211 specifies that "animal cages are cleaned at least once per week" and it has been more than a week since cleaning.

Open containers such as water bowls must be placed in or attached to the primary enclosure as to minimize the contamination from excreta. Water that contains dirty bedding and excreta can expose the guinea pigs to disease hazards or make it unpalatable. Correct by ensuring that potable water is offered as often as necessary to ensure the health of the animals and at least daily. Additionally, ensure that watering receptacles are free from contamination and are properly sanitized when dirty.

Correction date: 23 February 2018

### 3.31(a)(1)

#### SANITATION.

Cleaning and sanitation of primary enclosures. Guinea pig enclosures are not being cleaned adequately or often enough to remove accumulations of excreta, soiled bedding, debris and stains. There were accumulations of excreta, soiled bedding, urine stains, and grime on the sides and floors of enclosures. The room log showed that the cage had not been cleaned since February 2nd. The facility SOP AF-211 specifies that "animal cages are cleaned at least once per week" and it has been more than a week since cleaning. Ineffective cleaning and sanitation exposes the animals to disease hazards such as bacteria, fungal, and parasites. Primary enclosures must be cleaned often enough to prevent accumulations of excreta, soiled bedding, dirt, urine stains and grime. Enclosures must be sanitized at least once every 2 weeks, or in accordance to the facilities SOP. Correct by ensuring that all primary enclosures are kept clean and sanitized often enough to prevent accumulation of excreta and debris.

Correction date: 23 Feb 2018

#### 3.125(a)

#### FACILITIES, GENERAL.

In the large animal pens, there were several pens that were not maintained in good repair and contained elements that were potentially hazardous to the animals:

\*The sheep enclosure had a loose piece of wire with wool caught on it at the height of a sheep head, which could

Prepared By:	FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care	Date: 27-FEB-2018
Title:	VETERINARY MEDICAL OFFICER 6091	211202010
Received By:		
Title:		Date: 28-FEB-2018
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### Inspection Report

cause damage to the face or eyes.

\*Several enclosures had loosely wrapped rusty wire on the pipe corral fence panels, including the previous cow enclosure and the new llama enclosures.

\*The new llama enclosures had areas of rust on the pipe corrals that weakened the structural integrity of the enclosure and created sharp edges that could cause injury to the animals in the enclosure.

\*The first new llama enclosure had a shelter area with a plywood wall that had two holes in it near the ground, creating a potential for a hoof to get caught in one of the holes.

The enclosures must be kept in good repair to protect the animals from injury, and a system of maintenance must be in place to ensure that the enclosures are kept in good repair and are structurally sound.

Correction date: 15 March 2018

Additional Inspectors Schnell Michael, Veterinary Medical Officer



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### Inspection Report

Pro Sci Inc.	Customer ID: 43309
12170 Flint Place	Certificate: 93-R-0521
Poway, CA 92064	Site: 002
	PRO SCI INC
	Type: ROUTINE INSPECTION Date: 20-JUN-2017

### 2.31(c)(7)

### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The Institutional Animal Care and Use Committee (IACUC) approved animal care and use protocols for covered species were changed in late 2016 to require the animals to be weighed prior to bleeding. This change was made in order to ensure that the amount of blood drawn from the animals does not exceed the protocol guidelines, yet the facility only started recording weights in June, 2017 for animals on the rabbit protocol.

Failure to weigh the animals to determine the appropriate maximum blood draw volume constitutes an unapproved significant change to the approved protocol. A system should be in place to ensure that proposed significant changes to activities involving the care and use of animals are reviewed and approved by the IACUC prior to their implementation.

Corrected at the time of inspection.

#### 2.32(b)

#### PERSONNEL QUALIFICATIONS.

There are no training records documenting instruction or capabilities of any of the staff members of the research facility, and in particular for the animal care staff. Facility representatives stated that their staff received training as outlined in the protocols and SOP's, but there is no documentation of the training.

The animal care staff has no documented training regarding identifying conditions that may affect the health of the animals. Examples observed during the inspection included rabbits with long toenails, one rabbit with lesions consistent with an ear mite infection, and overgrown and cracked hooves in goats; all conditions which have the potential to adversely affect the welfare of the animals. There is no documentation of training to recognize when an animal has significant weight loss, such as for animal 8735, which was euthanized at a Body Condition Score of 1 on April 28, 2017. The animal was last handled by staff on April 18, 2017. There is also no documentation of training for animal care staff regarding wound care following routine blood collection to ensure that animals have stopped

Prepared By:	FRANK KATHARINE, D V M	Date:
	FRANK KATHARINE, D V M USDA, APHIS, Animal Care	21-JUN-2017
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Received By:		
Title:		Date: 21-JUN-2017
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### Inspection Report

bleeding. Several rabbits were observed with excessive amounts dried blood on their ears and/or backs.

It is the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. Training and instruction must be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facilities responsibilities.

Correction date: 31 July, 2017

### 2.33(b)(2) REPEAT

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Two goats were observed to have overgrown hooves and three rabbits were observed to have overgrown nails. The goat hooves were misshapen and cracks were observed on the outer wall of one of the goat hooves.

Excessively long and misshapen hooves and nails are susceptible to breaking and cracking and also place abnormal stresses on joints and tendons. Cracks in hoof walls may make animals more susceptible to infections. The facility should ensure that staff members are monitoring the animals so that routine hoof and nail care may be provided when appropriate.

Correction date: 5 July, 2017

### 2.33(b)(3) CRITICAL

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Several rabbits had medical issues that have not been appropriately monitored through daily observation or communicated to the veterinarian for appropriate treatment in a timely manner.

During inspection, a rabbit appeared to have an ear mite infestation that the facility has not identified or treated. Another rabbit has an ongoing malocclusion, and the teeth are overgrown with no records of when the teeth were last trimmed.

Upon review of records, rabbit 8735 was euthanized by the veterinarian on April 28th, 2017. The medical records from April 28th, 2017 documented that rabbit 8735 had hemiparesis of the hindlegs and was "unable to reach food" and "has lost a great deal of weight" with a body condition score of about 1. This animal had undergone a blood collection procedure on 18 April, 2017 and the animal was not weighed and there was no documentation of any

Prepared By:	FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care	Date: 21-JUN-2017
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Received By:		
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The.	Page 2 of 4	



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### Inspection Report

observation of weight loss or communication to the attending veterinarian until April 28th, 2017.

Daily observation of all animals to assess their well-being, appropriate documentation of those observations, and direct and frequent communication with the attending veterinarian regarding health issues are necessary to ensure that the animals at the facility receive timely and adequate veterinary care. A system should be in place to ensure that all animals are observed daily, any health problems are documented, and the attending veterinarian is notified when necessary.

Correct from this date forward.

#### 2.33(b)(5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Adequate post-procedural care was not provided for several rabbits used under the rabbit protocol. During inspection, multiple rabbits had dried blood covering the back of the ears or staining the fur on their backs following blood collection. Dried blood can attract flies and cause skin irritation. Failure to control bleeding may also result in excessive blood loss.

Failure to ensure adequate hemostasis after blood collection and adhere to current established veterinary medical procedures may cause the animals unnecessary discomfort and pain. The facility should ensure that adequate post-procedural care is provided to all animals used in activities regulated by the Animal Welfare Act.

Correct from this day forward

### 3.129(a)

#### FEEDING.

In the hoof stock feed barn, there was contamination of both the hay and the pelleted feed. An area of mold was observed on one bale of straw that was directly adjacent to hay that was meant to be fed to hoof stock. The pelleted feed had evidence of rodent feces on the bag, and one bag of feed was chewed open with rodent feces present in the bag of feed. The rodent feces appeared to be from rats, based on the size.

Contamination of animal feed can result in disease transmission and potentially impact the health of the animals. There should be a system in place to ensure that the food shall be wholesome and free from contamination.

Correction date: 5 July, 2017

Prepared By:	Date:					
	FRANK KATHARINE, D V M USDA, APHIS, Animal Care	21-JUN-2017				
Title:	ETERINARY MEDICAL OFFICER 6091					
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### Inspection Report

### 3.131(d)

### SANITATION.

In the small sheep and the small llama enclosure, the flies were not controlled. Flies were observed on and around several llamas and the animals were observed shaking their heads repeatedly to dislodge the flies. The flies were particularly bad in areas of damp hay on the ground in two hoof stock enclosures where they were observed clustered in and moving on the damp hay. An adhesive fly control string had been placed above one animal enclosure, however the string had not been maintained and was coated with flies and thus was ineffective at the time of the inspection.

Rodent feces (appeared to be from rats) were observed on top of and in the pelleted feed bags in the hoofstock feed barn. There was a bag of pelleted feed that had been chewed open and there were rodent feces contaminating the feed.

Flies and rodents can transmit disease and flies can be irritating to the animals. The facility must establish and maintain an effective method of pest control.

Correction date: 5 July, 2017

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors Rosendale Marcy, Veterinary Medical Officer

Prepared By:	ared By: FRANK KATHARINE, D V M				
	FRANK KATHARINE, D V M USDA, APHIS, Animal Care	Date: 21-JUN-2017			
Title:	VETERINARY MEDICAL OFFICER 6091				
Received By:					
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Title:		Date: 21-JUN-2017			
	Page 4 of 4				



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### Inspection Report

Pro Sci Inc. 12170 Flint Place	Customer ID: Certificate:	
Poway, CA 92064	Site: PRO SC	002 II, INC.
		ROUTINE INSPECTION 22-SEP-2016

### 2.31(e)(1)

### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Several IACUC (Institutional Care and Use Committee) approved animal care and use protocols utilizing a regulated species did not identify the approximate number of animals to be used in the study.

The protocols (1A & 5) states that "number of animals used for a project depends upon the quantity of antiserum needed" for testing or commercial quantities. For testing, two rabbits or guinea pigs will be used per antigen, but the number of antigens tested in a given time period is not identified, while for commercial quantities the number of animals depends on the quantity of antiserum requested by the company (market -driven). The protocols (1C & 8) have similar rationale, starting with 1 sheep or goat for testing, and as many as needed to produce antibodies for commercial projects. The approximate total number of animals is not identified in the protocols.

The IACUC should ensure that a proposal to conduct activities involving animals includes the appropriate information prior to approving the proposal. The approximate number of animals the study proposes to use during a specific time period is important for the IACUC to assess and approve. Additionally, any significant changes (such as the total number of animals used) to activities should have IACUC approval prior to implementation.

IACUC oversight is intended to ensure that the facility is in compliance with the Animal Welfare Act. Inadequate program oversight may be detrimental to the welfare of the animals used in the program.

Correction date 11 November, 2016 for these four protocols and in all protocols by the next routine inspection.

#### 2.31(e)(3) REPEAT

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving covered animals did not provide a complete description of the proposed use of the animals. The protocol specified the minimum size of the animal and the blood collection schedule (volume

Prepared By:	KATHARINE FRANK, D V M	
	KATHARINE FRANK USDA, APHIS, Animal Care	Date: 27-SEP-2016
Title: Received By:		
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Title:	PRODUCT DEVELOPMENT DIRECTOR Page 1 of 5	Date: 27-SEP-2016



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### Inspection Report

every two weeks), but did not ensure that the blood collection protocols do not exceed the industry standard of 7-10% of species specific total blood volume every two weeks.

For example, the IACUC protocol requires rabbits weigh 2.5 Kgs at the initiation of the protocol, and production bleeds are 20 mls and up to two bleeds in two weeks can be performed if the condition and health of the animal allow. Rabbits have a mean blood volume of 62 mls/Kg, so total blood volume for a 2.5 Kg rabbit is 155 mls and 20 mls is 13% of total blood volume.

The IACUC Goat protocol requires goats weigh 35 Kg at the initiation of the study and calls for 500 ml production bleeds typically every two weeks and up to two bleeds in two weeks can be performed if the condition and health of the animal allow. Goats have a mean blood volume of 70 mls/Kg, so a 35 Kg goat would have a total blood volume of 2,450 mls and 500 mls is 20% of total blood volume.

The IACUC protocol does not define what steps are taken to determine that the health and condition of the animal are sufficient for weekly bleeds, such as monitoring packed cell volume or weight. The facility maintains records of animal blood collection, but no record of animal weights, therefore the amount of blood drawn from an individual animals may exceed what is safe and adversely affect their health and well-being.

A complete description of activities using animals must be included in protocols prior to IACUC approval. The facility should ensure that all protocols contain complete descriptions of animal use in order to assess how the procedures will affect the animals health.

### 2.33(b)(2)

### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Several llamas, goats and rabbits were observed to have excessively long hooves or nails. Specifically, approximately twenty rabbits in Barn 1 were observed with long toenails. One goat in the Quarantine pen had front hooves with splits and cracks, while the back hooves were overgrown, and several other goats had overgrown hooves. Several llamas, especially the one adjacent to the cow enclosure had overgrown feet that needed trimming. Overgrown nails and hooves can result in injury, discomfort, and/or lameness.

Appropriate methods and services should be employed in order to provide necessary maintenance of nails and hooves for all the animals.

Correction date 11 October, 2016

Prepared By:	KATHARINE FRANK, D V M	
	KATHARINE FRANK USDA, APHIS, Animal Care	Date: 27-SEP-2016
Title:		
Received By:	(b)(6), (b)(7)(c)	Date:
Title:	PRODUCT DEVELOPMENT DIRECTOR	27-SEP-2016
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### 2.131(b)(1)

### HANDLING OF ANIMALS.

Two llamas were wearing halters with lead ropes attached that dragged on the ground and could wrap around their feet. The llama adjacent to the cow pen and the llama mixed with the large herd of sheep wore long lead lines. The llama in the smaller corral with several goats had a slightly shorter lead line, but there was a lasso underfoot and tangling with the llama's feet.

Long lead lines dragging on the ground while animals are loose in their enclosures has the potential to cause trauma, physical harm or unnecessary discomfort if the lead line is caught underfoot or on something in the enclosure. Animals shall be handled in a careful manner that does not cause trauma or physical harm.

Correction date 11 October, 2016

#### 3.50(d)

#### FACILITIES, GENERAL.

The waste material from the breeding barn of rabbits is flushed out of the barn via a partially open channel, through a large pipe underground and into an uncovered animal waste pile containing manure from farm animal species as well. The channel is not adequately flushed and fecal material is built up in the area where the channel transitions from open channel to underground pipe. The open channel with fecal material built up and sprawling waste pile potentially attract vermin and can result in disease hazards.

Animal waste can contribute to unsanitary conditions, vermin infestation, odors, and disease hazards The facility must ensure that animal waste is removed often enough to minimize any potential contamination, odors or disease hazards.

Correction date 25 October, 2016

### 3.125(d)

### FACILITIES, GENERAL.

The new sheep quarantine/project pen was directly adjacent to the large and uncovered animal waste disposal area. The animal waste disposal area included the runoff from the rabbit breeding barn, as well as the collected waste from the cows, llamas, sheep and goats on the property. This material can attract a variety of pests and could impact the health and well- being of the animals in the enclosure.

	KATHARINE FRANK, D V M	
Prepared By:	KATHARINE FRANK USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFICER 6091	27-SEP-2016
Received By:	(b)(c) (b)(7)(c)	
	(b)(6), (b)(7)(c)	Date:
Title:	PRODUCT DEVELOPMENT DIRECTOR	27-SEP-2016
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A system should be in place to ensure the removal and disposal of animal wastes on a regular schedule so as to minimize vermin infestation, odors, and disease hazards. The disposal facilities shall comply with applicable laws and regulations relating to pollution or the protection of the environment.

Correction date 25 October 2016

### 3.127(b)

#### FACILITIES, OUTDOOR.

In the new quarantine/project pen for ten sheep, the only shelter provided is shade cloth stretched over one side of the enclosure and a small cover directly over the food trough. In the larger sheep pen with approximately forty animals, the shelter covered the food trough, but all the sheep could not all comfortably fit under the shelter, and the bedding under the shelter was damp. In the rainstorm earlier this week, the sheep in the quarantine pen had no shelter provided to afford protection and prevent discomfort, and shelter in the larger pen was not sufficient for all the animals, and the uncovered portion of the ground in the enclosure was muddy.

The inability to shelter from seasonal winter rains could cause discomfort to the animals and adversely impact their health. The facility should ensure that all animals housed at the facility have access to natural or artificial shelter to adequately protect all animals from inclement weather and prevent discomfort.

Correction date 25 October, 2016

#### 3.129(b)

#### FEEDING.

In the llama and goat enclosure, there was a large raised feed bin. The feed bin contained both food and feces and was tall enough that the young goats in the pen would have difficulty accessing the food.

In the cow enclosure, the hay was on the ground and intermingled with fecal matter.

Any food receptacle, hay manger, or platform used is to be sanitizable (the ground is not considered sanitizable). This feeding situation can negatively impact the health and wellbeing of the animals.

Food and food receptacles shall be kept clean and sanitary at all times and shall be placed so as to minimize contamination and accessible to all animals in the enclosure.

Prepared By:	KATHARINE FRANK, D V M	
Fiepared by.	KATHARINE FRANK USDA, APHIS, Animal Care	Date: 27-SEP-2016
Title:	VETERINARY MEDICAL OFFICER 6091	
Received By:	(b)(6), (b)(7)(c)	Date:
Title:	PRODUCT DEVELOPMENT DIRECTOR Page 4 of 5	27-SEP-2016

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### Inspection Report

Correct by 25 October 2016

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors Marcy Rosendale, Veterinary Medical Officer

	KATHARINE FRANK, D V M	
Prepared By:		Date:
к	ATHARINE FRANK USDA, APHIS, Animal Care	27-SEP-2016
Title:	ETERINARY MEDICAL OFFICER 6091	
Received By:		
-	(b)(6), (b)(7)(c)	
	RODUCT DEVELOPMENT DIRECTOR	Date: 27-SEP-2016
Title: P	Page 5 of 5	27-SEP-2016

United States Department of Agriculture Customer: 43309 Animal and Plant Health Inspection Service Inspection Date: 22-SEP-16 Animal Inspected at Last Inspection				
Cust No	Cert No	Site	Site Name	Inspection
13309	93-R-0521	002	Pro Sci Inc.	22-SEP-16
Count 000003 00080 000016 000019 001300 001418	Species Cattle/cow/ox/ Sheep or mou Goat Llama European rabb Total	flon		



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### Inspection Report

Pro Sci Inc. 12170 Flint Place Poway, CA 92064

Customer ID: 43309 Certificate: 93-R-0521

> Site: 002 PRO SCI, INC.

Type: ROUTINE INSPECTION Date: Mar-23-2016

### 2.31 (e) (2)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving cows did not contain an adequate rationale for the numbers of these animals to be used. The protocol stated that for commercial applications, larger numbers of cows may be required for these larger projects. There is no quantity or range provided which corresponds to how many more numbers of the animals this would require.

The rationale approved by the IACUC should provide assurances that the appropriate number of animals is being used to obtain the information the activity is designed to provide. It is the responsibility of the IACUC to ensure that proposals to conduct activities involving animals contain an

It is the responsibility of the IACUC to ensure that proposals to conduct activities involving animals contain an adequate rationale for the number of animals to be used in those activities.

Correct by 05/15/2016.

#### 2.31 (e) (3)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

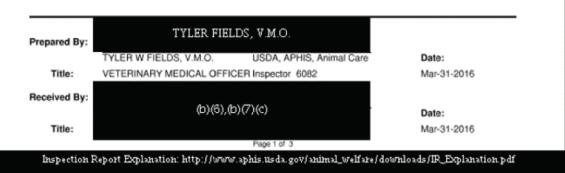
An IACUC approved protocol involving cows did not provide a complete description of the proposed use of the animals.

The protocol does not provide a description of the chemical restraint methods for the cows. According to facility
representatives, chemical restraint may occasionally be administered to the cows.

-The protocol states, up to two bleeds may be taken within a two-week period if the condition and health of the animal allow. There is no information or parameters provided in the protocol which would consider an animal to have an acceptable health status to remain on the study.

A complete description of activities using animals must be included in protocols prior to IACUC approval. The facility should ensure that all protocols contain complete descriptions of animal use.

Correct by 05/15/2016.





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### Inspection Report

### 2.33 (b) (3)

### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The daily treatment records for the rabbits were incomplete. The facility keeps a written, daily observation log including documentation of any medications administered. According to a facility representative, the medication, Oxytetracycline has been given to sick rabbits; however there is no written documentation or instructions for the use of this medication in the records. The lack of complete and accurate documentation of the use of all medications may lead to inappropriate use on the animals. Accurate information and records should also be available in the event of communications with the attending veterinarian. A system of complete, accurate and timely information concerning animal health problems and observations must be in place.

Correct by 04/04/2016.

3.51 (d)

REPEAT

### FACILITIES, INDOOR.

-There were several cracks from 2ft. up to 6 ft. in length in the cement flooring of the rabbit building. Some of the deeper cracks were filled with organic waste/debris which attracted several flies to these areas at time of inspection. Large cracks in the flooring are not impervious to moisture and prevent proper sanitization. Also, these areas may trap debris and bacterial organisms as well as attract flies or pests which all may pose a health risk to the animals.

-Several rabbit cages are moderately covered in rust. The presence of rust may prevent the required cleaning and sanitization of the enclosures, which may adversely affect the health and well-being of the animals. There are improvements being made which include sections of new cages and feeders that have replaced older ones.

The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

Original Correction date of 12/31/2015.



Several, primary enclosures housing adult rabbits did not provide the minimum amount of floor space as required. The rabbit cages were 2 ft. X 1.5 ft. which provides a total of 3 square feet which is the minimum floor space for adult rabbits between 4.4-8.8 lbs. Several rabbits in the facility at time of

Prepared By:	TYLER FIELDS, V.M.O.		
	TYLER W FIELDS, V.M.O. USDA, APHIS, Animal Care	Date:	
Title:	VETERINARY MEDICAL OFFICER Inspector 6082	Mar-31-2016	
Received By:	(b)(6),(b)(7)(c)	Date:	
Title:		Mar-31-2016	
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inspection weighed greater than 8.8lbs, therefore requiring more than the 3 square feet provided by the cages.

Enclosures with insufficient space may have a negative impact on the health and well-being of the animals being maintained within them. A sufficient amount of floor space for rabbits is necessary in order to ensure that they have enough space to make normal postural adjustments and adequate freedom of movement. The facility should ensure that the cages housing their rabbits meet the required minimum floor space set forth in the regulations.

Correct by 09/30/2016.

### 3.127 (a) FACILITIES, OUTDOOR.

In the cow enclosure, there was one shade structure (approximately 3ft X 6ft) provided for the four cows. This is not a sufficiently sized shaded area provided to comfortably protect all animals in this enclosure from the direct rays of the sun.

Failure to provide sufficient shade to allow all the animals kept outdoors to protect themselves from direct sunlight could cause overheating or discomfort to the animals. Additional shade for the animals is required to be in compliance.

Correct by 04/21/2016.

Exit interview was conducted with facility representative, Dr. Alexandra Andricos, VMO and Dr. Tyler Fields, VMO.

Prepared By:	TYLER FIELDS, V.M.O.	
	TYLER W FIELDS, V.M.O. USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFICER Inspector 6082	Mar-31-2016
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Title:		Mar-31-2016
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Inspection F	lep ort Explanation: http://www.aphis.usda.gov/ahimal_welfare/do	wnloads/IR_Explanation.pd

	CASE NUMBER:	
ANIMAL AND PLANT HEALTH INSPECTION SERVICE	CA150159	
100 CON 100	VIOLATOR:	
Statally Con	Pro Sci Inc.	
A THERE AND A THE AND A TH	Registration #	93-R-0521
OFFICIAL WARNING	Customer #	43309
VIOLATION OF FEDERAL REGULATIONS	ADDRESS (Street, City	
	12170 Flint Plac	
A State of the second sec	Poway, CA 920	
a state and the second s	r ondy, or t off	
The U.S. Department of Agriculture has evidence that on or aborganization committed violations of the following sections of t	out <b>July 29, 2015 and Jul</b> the Code of Federal Regul	y 23, 2014, you or your ations, Title 9:
2.33(b)(2) Attending Veterinarian and Adequate Vet Care adequate veterinary care that include the use of appropriate met diseases and injures. (DIRECT on July 29, 2015)	failure to establish and i hods to prevent, control, d	naintain programs of iagnose, and treat
You failed to provide adequate veterinary care to the followi -rabbits numbered 16979, 17313, 17681 and 17329 who h -rabbits numbered 17665 and 17576 who were squinting a -rabbit numbered 16627 who had a thick yellowish eye di -rabbit numbered 1309 was underweight, depressed and so	ad head tilts. and clear discharge from e scharge.	yes.
5.26(b) Facilities, ventilation failure to provide adequate ve	entilation in the guinea pig	and hamster room, the
ambient temperature shall not be allowed to rise above 85°. The	e temperature was 93° F.	(DIRECT on July 29, 2015)
ambient temperature shall not be allowed to rise above 85°. The 5.30 Wateringfailure to maintain open containers used for d o the primary enclosure as to minimize contamination from exc lirty, and sanitized at least once every two weeks. (DIRECT on	e temperature was 93° F. lispensing water to guinea creta. All water receptacle	(DIRECT on July 29, 2015) pigs placed in or attached
ambient temperature shall not be allowed to rise above 85°. Th 3.30 Wateringfailure to maintain open containers used for d o the primary enclosure as to minimize contamination from exe	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015)	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when
ambient temperature shall not be allowed to rise above 85°. The 3.30 Wateringfailure to maintain open containers used for d o the primary enclosure as to minimize contamination from exe lirty, and sanitized at least once every two weeks. (DIRECT on 5.56(c) Sanitationrepeated failure to keep premises clean an	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015)	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when
Analysis in the second	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) id in good repair in order t l regulations to ensure the welfa ns of the regulations can have as fificial Warning for the violation to fa eivil penalty, criminal proc	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help rious and costly impacts that (s) described above. Any secution, or other sanctions.
Analysis and the spread of animal and plant pests and diseases. Since violation of the spread of animal and plant Health Inspection Service (APHIS) created federal prevent the spread of animal and plant pests and diseases. Since violation are detrimental to the public interest, APHIS is providing you with an Of further violation of these federal regulations may result in the assessment If you have any questions concerning this Official Warning or violation (article).	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) id in good repair in order t l regulations to ensure the welfa ns of the regulations can have as fificial Warning for the violation to fa eivil penalty, criminal proc	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help rious and costly impacts that (s) described above. Any secution, or other sanctions.
Institute spread of animal and plant pests and diseases. Since violation of further violation of the spread of animal and plant metal and plant pests and diseases. Since violation are detrimental to the public interest, APHIS is providing you with an Of further violation of these federal regulations may result in the assessment If you have any questions concerning this Official Warning or violation(PHIS OFFICIAL (Name and Title): hester A. Gipson	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) d in good repair in order t l regulations to ensure the welfa ns of the regulations can have so fificial Warning for the violation t of a civil penalty, criminal pro s), please contact the APHIS off	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help rious and costly impacts that (s) described above. Any secution, or other sanctions.
A state in the primary enclosure as to maintain open containers used for do the primary enclosure as to minimize contamination from excellinty, and sanitized at least once every two weeks. (DIRECT on <b>8.56(c) Sanitation</b> repeated failure to keep premises clean an njury and to facilitate proscribed husbandry practices.  The Animal and Plant Health Inspection Service (APHIS) created federal prevent the spread of animal and plant pests and diseases. Since violation are detrimental to the public interest, APHIS is providing you with an Of further violation of these federal regulations may result in the assessment If you have any questions concerning this Official Warning or violation(sector).  PHIS OFFICIAL (Name and Title): Chester A. Gipson Deputy Administrator	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) d in good repair in order t l regulations to ensure the welfa ns of the regulations can have so fficial Warning for the violation t of a civil penalty, criminal pro- s), please contact the APHIS off OFFICE ADDRESS:	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help trious and costly impacts that (s) described above. Any secution, or other sanctions. icial listed in this notice.
A solution of these federal regulations may result in the assessment If you have any questions concerning this Official Warning or violation(speed) when a set the provide the provided for the provided the	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) d in good repair in order t l regulations to ensure the welfa ns of the regulations can have so fficial Warning for the violation t of a civil penalty, criminal pro- s), please contact the APHIS off OFFICE ADDRESS: 4700 River Road Riverdale, MD 30	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help rious and costly impacts that (s) described above. Any secution, or other sanctions. icial listed in this notice.
A state in the primary enclosure as to maintain open containers used for do the primary enclosure as to minimize contamination from excellinty, and sanitized at least once every two weeks. (DIRECT on <b>8.56(c) Sanitation</b> repeated failure to keep premises clean an njury and to facilitate proscribed husbandry practices.  The Animal and Plant Health Inspection Service (APHIS) created federal prevent the spread of animal and plant pests and diseases. Since violation are detrimental to the public interest, APHIS is providing you with an Of further violation of these federal regulations may result in the assessment If you have any questions concerning this Official Warning or violation(sector).  PHIS OFFICIAL (Name and Title): Chester A. Gipson Deputy Administrator	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) d in good repair in order t l regulations to ensure the welfa ns of the regulations can have so ficial Warning for the violation t of a civil penalty, criminal pro- s), please contact the APHIS off OFFICE ADDRESS: 4700 River Road	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help rious and costly impacts that (s) described above. Any secution, or other sanctions. icial listed in this notice.
A solution of these federal regulations may result in the assessment If you have any questions concerning this Official Warning or violation(speed) when a set the provide the provided for the provided the	e temperature was 93° F. lispensing water to guinea creta. All water receptacle July 29, 2015) d in good repair in order t regulations to ensure the welfa ns of the regulations can have so ficial Warning for the violation t of a civil penalty, criminal pro- s), please contact the APHIS off OFFICE ADDRESS: 4700 River Road Riverdale, MD 30 DATE ISSUED:	(DIRECT on July 29, 2015) pigs placed in or attached s shall be sanitized when o protect the animals from re of animals and help trious and costly impacts that (s) described above. Any secution, or other sanctions. icial listed in this notice.

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