



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

April 15, 2019

Re: Animal Welfare Assurance  
A3363-01 [OLAW Case D]

Mr. Thomas L. Spalding  
President  
Pacific BioLabs  
551 Linus Pauling Drive  
Hercules, CA 94547

Dear Mr. Spalding,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 11, 2019 letter reporting an adverse event involving a rabbit at Pacific BioLabs, following up on an initial report on March 21, 2019. According to the information provided, OLAW understands that a rabbit became trapped between the side and bottom panel of its cage. The animal had been struggling and was agonal.

The immediate action taken upon discovery consisted of euthanizing the rabbit and taking the cage out of use. No problems were found with the cage and such an incident has not occurred in 15 years of housing rabbits. The Institutional Animal Care and Use Committee (IACUC) was aware that rabbits from this commercial vendor appear to be more high strung. To reduce the likelihood of a recurrence, the veterinary staff has added soft music in the animal rooms, has asked staff to reduce noise while working in the rooms, and requested more human socialization at the vendor facility.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair

# PBL Pacific BioLabs

*The Service Leader in Bioscience Testing*

April 11, 2019

Alex Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Final Report: Adverse Event

Animal Welfare Assurance number: A3363-01

Dear Dr. Wolff:

Pacific BioLabs, in accordance with Assurance A3363-01 and PHS Policy IV.F.3., provides this final report regarding an adverse event that was reported on March 21, 2019. Specifically, the adverse event concerned a naïve rabbit that had her front limbs entrapped between the side and bottom panel of her cage. She had been struggling and was agonal. The animal was immediately removed from the cage and promptly euthanized. The PBL veterinarians were notified. The cage was inspected and although no signs of damage were found, the cage was taken out of use.

On March 21, a PBL veterinarian also inspected the cage and found no abnormalities. This is a standard stainless steel suspended rabbit cage (6 pack) from Lab Products. We have also looked through previous records and noted this is the first incidence of this occurrence (front limbs stuck under the edge of the cage) at PBL. PBL has housed rabbits at our current facility for more than 15 years.

The animal was a naïve animal that had not yet been assigned to a study therefore, no NIH funds were affected.

The PBL IACUC was informed of the incident. Given this this was an adverse event that does not appear to be related to human error or equipment failure, the IACUC did not have any further recommendations at this time. However, the IACUC is aware that the behavior of these animals (b) (4) has been an on-going problem due to their high strung nature and expects to be continuously updated from the veterinary staff on plans to address the issue. The PBL veterinary staff has been in contact with the vendor and several interventions are currently being implemented, both at PBL and at the (b) (4) breeding facility. These include the introduction of soft background music in the animal rooms at PBL and increased human socialization at (b) (4).

Thank you for your consideration of this matter. Please do not hesitate to contact me further for clarifications or information.

Sincerely,

(b) (6)

Thomas L. Spalding  
President  
Institutional Official  
Pacific BioLabs

(b) (6)

signing on behalf of Tom Spalding

## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, April 15, 2019 7:33 AM  
**To:** Angela@PacificBioLabs.com; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: Adverse Event Final Report # A3363-01

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Angela@PacificBioLabs.com [mailto:Angela@PacificBioLabs.com]  
**Sent:** Friday, April 12, 2019 5:38 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Angela@PacificBioLabs.com  
**Subject:** Adverse Event Final Report # A3363-01

Thank you Dr. Wolff for your response.

Please find attached our final report in regards to an adverse event experience by a naive rabbit at PBL. Thank you in advance for your time and consideration.

Regards,  
Angela

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**From:** OLAW Division of Compliance Oversight (NIH/OD) [olawdco@od.nih.gov]  
**Sent:** Friday, March 29, 2019 4:00 AM  
**To:** Angela Colagross-Schouten  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Prompt Report # A3363-01

Thank you for this preliminary report Dr. Colagross-Schouten. From the description this incident appears to be an adverse event or accident rather than noncompliance. While it is reportable, unless the IACUC finds that someone did something incorrectly you can provide information in the final report on preventive measures but label the incident as an adverse event.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** Angela@PacificBioLabs.com <Angela@PacificBioLabs.com>

**Sent:** Thursday, March 28, 2019 8:11 PM

**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

**Subject:** Prompt Report # A3363-01

Director, Division of Compliance Oversight:

Please find attached a prompt report regarding the death of a rabbit due to accidental entrapment in its home cage. This animal was naive and the incident did not involve any PHS-funded activity. As stated in the attached letter, this is the first incident of such an injury in more that 15 years of housing rabbits at Pacific BioLabs.

Thank you in advance for your review and time.

Angela Colagross-Schouten, DVM, MPVM, DACLAM  
IACUC Chair; Consulting Veterinarian  
Pacific BioLabs  
551 Linus Pauling Drive  
Hercules, CA 94547

March 21, 2019

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Preliminary Report

Animal Welfare Assurance number: A3363-01

Pacific BioLabs, in accordance with Assurance A3363-01 and PHS Policy IV.F.3., provides this preliminary report of noncompliance regarding the death of a rabbit caused by the animal's limb becoming entrapped in her home cage.

On March 18, 2019, Animal Care personnel found a naïve rabbit with her front limbs entrapped between the side and bottom panel of her cage. She had been struggling and was agonal. The animal was immediately removed from the cage and promptly euthanized. The PBL veterinarians were notified. The cage was inspected and although no signs of damage were found, the cage was taken out of use.

On March 21, a PBL veterinarian also inspected the cage and found no abnormalities. This is a standard stainless steel suspended rabbit cage (6 pack) from Lab Products. We have also looked through previous records and noted that this is the first incidence of this occurrence (front limbs stuck under the edge of the cage) at PBL. PBL has housed rabbits at our current facility for more than 15 years.

We have also noted that the rabbits we are currently receiving from (b) (4) are significantly more high strung and active than those from our previous vendor. We are attempting to implement more enrichment, including low levels of noise (e.g. soft music) in the animal rooms, in an attempt to reduce perceived stress. We are also working with employees to reduce noise levels while working in the animal rooms and adjacent hall ways. Finally, we are attempting to work with the vendor to attempt to mitigate the abnormally reactive behavior of these animals.

Thank you for your consideration of this matter.

Sincerely,

Thomas L. Spalding

President  
Institutional Official  
Pacific BioLabs

(b) (6) signing on behalf of Tom Spalding

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 29, 2019 7:01 AM  
**To:** Angela@PacificBioLabs.com  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Prompt Report # A3363-01

Thank you for this preliminary report Dr. Colagross-Schouten. From the description this incident appears to be an adverse event or accident rather than noncompliance. While it is reportable, unless the IACUC finds that someone did something incorrectly you can provide information in the final report on preventive measures but label the incident as an adverse event.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** Angela@PacificBioLabs.com <Angela@PacificBioLabs.com>  
**Sent:** Thursday, March 28, 2019 8:11 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Prompt Report # A3363-01

Director, Division of Compliance Oversight:

Please find attached a prompt report regarding the death of a rabbit due to accidental entrapment in its home cage. This animal was naive and the incident did not involve any PHS-funded activity. As stated in the attached letter, this is the first incident of such an injury in more that 15 years of housing rabbits at Pacific BioLabs.

Thank you in advance for your review and time.

Angela Colagross-Schouten, DVM, MPVM, DACLAM  
IACUC Chair; Consulting Veterinarian  
Pacific BioLabs  
551 Linus Pauling Drive  
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