



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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July 27, 2017

Re: Animal Welfare Assurance
A3236-01 [OLAW Case E]

Dr. Sarah Nusser
Vice President for Research
Iowa State University
2610 Beardshear Hall
Ames, IA 50011

Dear Dr. Nusser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 13, 2017 letter reporting an adverse event involving mice at Iowa State University, following up on an initial email notification on July 5, 2017. According to the information provided, OLAW understands that three mice were found dead and an additional five mice were euthanized on June 6, 2017 following oral administration of glyphosate on May 19, 2017. The cause of the unanticipated observed mortality and morbidity could not be definitively determined as necropsy reports were inconclusive and serology results were negative. The animal activity in question was PHS funded.

The corrective actions included amending the protocol to request additional animals to determine whether pregnancy potentiated glyphosate toxicity and enhanced monitoring of animals during the study to include twice daily observations of treated pregnant animals with prompt euthanasia of glyphosate treated animals, when indicated.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3236-E

IOWA STATE UNIVERSITY

OF SCIENCE AND TECHNOLOGY

Office of the Vice President for Research
2610 Beardshear Hall
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Ames, IA 50011-2036
515-294-6344
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July 13, 2017

Dr. Kristina Borrer
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

Dear Dr. Borrer,

I am writing to share the final report for an incident that occurred at Iowa State University (ISU). Our Animal Welfare Assurance number is: A3236-01.

The grant that supports this work is: 1R21ES026282.

The goal of this study is to better understand if and/or how glyphosate alters ovary function and develop treatments that protect the ovary from environmental chemicals. Per the IACUC-approved protocol, 5-week old mice were orally dosed with 2 mg/kg glyphosate. The last treatment occurred on May 19, 2017. To evaluate the impact of glyphosate on breeding, female mice were then housed with males for a week; male mice were removed from cages. Pregnant female mice were group housed and monitored daily. On June 6, 2017, animal care staff from ISU's Laboratory Animal Resources (LAR) found 3 dead mice in 2 different cages. Both cages housed animals from the glyphosate treatment group. Another five were determined to require euthanasia and were euthanized by a LAR veterinarian. The remaining two were observed closely for any signs of morbidity, and finding none, finished the study and were euthanized per study design.

The LAR veterinarian necropsied the 3 dead and 5 euthanized mice, and samples were sent for serology testing. The PI submitted an unanticipated event form to the IACUC on the day of the incident, outlining the above information.

The IACUC discussed this unanticipated event, necropsy results, and serology results at their meeting on July 5, 2017. The PI attended the meeting and shared the cause of the event remains unknown as necropsy reports were inconclusive and serology tests were negative.

The PI has submitted an IACUC protocol modification to request additional mice to repeat the study to determine if glyphosate, in combination with pregnancy, caused the unexpected deaths. Further, the PI has indicated that frequency of monitoring will increase during the study. The dams will be monitored twice a day during pregnancy, and upon first observance of the need for euthanasia or upon first death, all glyphosate treated animals will be euthanized.

The IACUC determined that the PI handled the unanticipated event appropriately and no further action is required.

Please let me know if you have any questions or concerns.

Thank you,

A handwritten signature in black ink, appearing to read "Sarah Nusser". The signature is fluid and cursive, with the first name "Sarah" and last name "Nusser" clearly distinguishable.

Dr. Sarah Nusser
Institutional Official
Vice President for Research

Ward, Joan (NIH/OD) [E]

From: Secondary Individual @iastate.edu>
Sent: Wednesday, July 05, 2017 5:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC Committee; Secondary Individual; Secondary Individual; Secondary Individual
Subject: Initial report - Iowa State University

Dear Dr. Borrer,

I am writing to make an initial report of an incident that occurred at Iowa State University. Our Animal Welfare Assurance number is: A3236-01. The grant that supports this work is: 1R21ES026282.

Three mice were found dead, unexpectedly, in their cages. We are working with the PI to confirm details and I will submit my formal report soon.

Thank you,

Secondary Individual

Director
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