



United States Department of Agriculture
Office of Inspector General

U.S. Meat Animal Research Center Review



Audit Report 02007-0001-31
September 2016

IMPORTANT NOTICE

This audit report contains sensitive information that has been redacted for public release, due to privacy concerns.



What Were OIG's Objectives

Our objectives were to evaluate the research practices and operations of USMARC and to evaluate the concerns expressed by Congress and reported by the media regarding animal welfare. We also examined ARS' oversight and monitoring of USMARC as it relates to animal welfare.

What OIG Reviewed

We non-statistically selected 33 specific statements to evaluate in an attempt to determine the veracity of the article's expressed concerns. We also examined ARS oversight of USMARC during the time period prior to the publication of this article, primarily between 2012 and 2014.

What OIG Recommends

We recommended that ARS establish adequate policies, procedures, and processes related to oversight of animal welfare at USMARC. We also recommended that ARS consider taking steps to increase the transparency of USMARC's research.

ARS should improve its oversight of USMARC and make its research more transparent to the public.

What OIG Found

The Agricultural Research Service (ARS) is the Department of Agriculture's (USDA) chief scientific in-house research agency. The U.S. Meat Animal Research Center (USMARC), located in Clay Center, Nebraska, is an ARS research facility operated in collaboration with the University of Nebraska-Lincoln. On January 19, 2015, *The New York Times* published an article titled "U.S. Research Lab Lets Livestock Suffer in Quest for Profit." The article contained a number of statements regarding animal care and mortality levels at USMARC.

From *The New York Times* article, we selected 33 specific statements to evaluate in an attempt to determine the accuracy of the statements. Of these 33 statements, we determined that only 7 were materially accurate—26 were inaccurate, lacked sufficient context, or were uncorroborated (see Exhibit A). Overall, we did not note evidence indicating a systemic problem with animal welfare at USMARC.

Although we found the article did not always accurately present animal welfare at USMARC, we did find that ARS could improve its oversight of animal welfare at the facility and take steps to make its research more transparent to the public. In general, the controls for overseeing animal welfare at USMARC lacked specificity, and the steps ARS took to perform inspections or handle complaints were not carefully documented. ARS also did not make it a priority to establish, maintain, and monitor compliance with animal welfare-related policies and procedures. As a result, ARS had reduced assurance that proper safeguards over animal welfare were in place at the facility.

ARS generally agreed with four of the five recommendations. We accepted management decision on four recommendations.



United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250



DATE: September 30, 2016

AUDIT
NUMBER: 02007-0001-31

TO: Chavonda Jacobs-Young
Administrator
Agricultural Research Service

ATTN: Lisa Baldus
Associate Deputy Administrator
Administrative and Financial Management

FROM: Gil H. Harden
Assistant Inspector General for Audit 

SUBJECT: U.S. Meat Animal Research Center Review

This report presents the results of the subject review. Your written response to the official draft is included in its entirety at the end of the report. We have incorporated excerpts from your response and the Office of Inspector General's (OIG) position into the relevant sections of the report. Based on your written response, we have accepted management decision on Recommendations 1 through 4. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

Based on your written response, management decision has not been reached on Recommendation 5. The information needed to reach management decision on this recommendation is set forth in the OIG Position section following each recommendation. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (<http://www.usda.gov/oig>) in the near future.

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Background and Objectives

Background

The Agricultural Research Service (ARS) is the Department of Agriculture's (USDA) chief scientific in-house research agency. The U.S. Meat Animal Research Center (USMARC), located in Clay Center, Nebraska, is an ARS research facility operated in collaboration with the University of Nebraska-Lincoln (UNL). USMARC's mission is to develop scientific information and new technology to solve high priority problems concerning beef, sheep, and swine. USMARC consists of 34,000 acres and has animal livestock populations that can average more than 30,000 in a given year. In 2014, USMARC raised 12,617 cattle, 13,913 swine, and 3,770 sheep.

On January 19, 2015, *The New York Times* published an article titled "U.S. Research Lab Lets Livestock Suffer in Quest for Profit." The article contained a number of statements regarding animal care and mortality levels at USMARC. Following the publication of the article, the USDA Office of Inspector General (OIG) received Congressional requests to examine the specific allegations made in the article and the related conditions and procedures in place at USMARC.

In January 2015, following *The New York Times* article, USDA announced the convening of an independent panel to review USMARC's animal handling protocols, policies, and research practices. The ARS Animal Handling and Welfare Review Panel (ARS-AHWRP) issued its final report regarding its review of USMARC in March 2015. In its report, ARS-AHWRP stated that it observed healthy and well-cared for animals with no visible signs of poor care or neglect. ARS-AHWRP also identified a number of areas in which USMARC's animal care program could be improved. These improvements primarily centered on the processes and documentation associated with the role of the facility's Institutional Animal Care and Use Committee (IACUC), such as the development of a more consistent review process, and the appointment of an individual other than the center's Attending Veterinarian to serve as the IACUC chairperson.

The amended Animal Welfare Act (AWA) regulations require each Federal research facility that uses animals to establish an IACUC.¹ However, AWA legislation² specifically excludes farm animals used or intended for use as food or fiber, or when used or intended for use in agricultural research. Nonetheless, it is ARS policy to use IACUCs to oversee all ARS-owned vertebrate animals at ARS locations or at non-ARS locations. It is also ARS policy to have ARS IACUCs oversee non-ARS animals at ARS locations or non-ARS locations using either ARS funds or personnel.³

¹ 9 Code of Federal Regulations Part 2, Subpart 2C Section 2.37.

² Public Law 89-544, August 24, 1966, as amended by Public Law 91-579 on December 24, 1970, Public Law 94-279 on April 22, 1976, and Public Law 99-198 on December 23, 1985.

³ ARS Directive 130.4, *Animal Care and Use Committee*, August 2002.

An IACUC is a committee that ensures the humane use of animals for research. An IACUC's membership is to be comprised of at least five members, including at least one doctor of veterinary medicine, one experienced scientist currently active in research involving animals, one member whose profession is nonscientific in nature, and one individual who is not affiliated with the institution. An IACUC's responsibilities include reviewing all proposed activities for use of animal subjects, annually reviewing all ongoing activities using animal subjects and approving the activity's continuation or suspending its approval, promptly investigating all complaints concerning abuse of animals, and semiannually inspecting all the location's facilities where animals are held for more than 12 hours.

On September 28, 2015, we issued an interim report providing an update to ARS and Congressional requestors on our progress and initial observations on completed work as of that date.⁴

Objectives

Our objectives were to evaluate the research practices and operations of USMARC and evaluate the concerns expressed by Congress and reported by the media regarding animal welfare. We also examined ARS' oversight and monitoring of USMARC as it relates to animal welfare.

⁴ Audit Report 02007-0001-31(1), *ARS: U.S. Meat Animal Research Center Review—Interim Report*, September 2015.

Finding 1: ARS Needs to Improve its Oversight of the Welfare of Animals Used for Research

Although we did not find evidence indicating a systemic problem with animal treatment and care at USMARC, we did find ARS could improve its oversight of animal welfare at the facility and make its research more transparent to the public. In general, the controls for overseeing animal welfare at USMARC lacked specificity, and the steps ARS took to perform inspections or handle complaints were not carefully documented. This occurred because ARS did not make it a priority to establish, maintain, and monitor compliance with animal welfare-related policies and procedures. As a result, ARS had reduced assurance that proper safeguards over animal welfare were in place at USMARC.

ARS senior level officials are responsible for developing and maintaining effective internal control, as well as evaluating performance and holding individuals accountable for their internal control responsibilities.⁵ Within the scientific research community, the IACUC serves as the primary control for ensuring research is conducted with adequate concern for animal welfare. ARS Directives 130.4 and 635.1 set policies and assign responsibilities related to the IACUC and humane animal care and use.⁶

Improving Establishment, Maintenance, and Monitoring of Policies and Procedures

While ARS directives assigned animal welfare-related internal control responsibilities to the Area Office and research facility level, in many cases the directives referred to out-of-date guidance and were silent regarding the manner in which these responsibilities were to be carried out and documented. Additionally, the ARS National Office did not establish an oversight mechanism to monitor the Area Office's and USMARC's compliance with the directives.

ARS Directives 130.4 and 635.1 contained references to outdated versions of animal research guidance. For example, these directives referred to Chapters 5 through 11 of the first edition of the "Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching," published in 1988. However, the most current version of this document is the third edition, published in 2010. While there are similarities between the two versions, the 2010 version is more comprehensive and contains guidance on topics not discussed in the 1988 version, such as euthanasia. We believe that ARS should implement a process through which its animal welfare-related directives are periodically reviewed and updated to reflect the most current versions of research guidance available.

Furthermore, the ARS National Office did not have any oversight processes. Without proper oversight in place the agency has reduced assurance that Area Offices and research facilities properly implemented and complied with agency policy. We believe

⁵ OMB, *Management's Responsibility for Internal Control*, Circular A-123 (Dec. 21, 2004) and GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Sept 2014).

⁶ ARS Directive 130.4, *Animal Care and Use Committee*, August 2002 and ARS Directive 635.1, *Humane Animal Care and Use*, August 1990. These directives cover all vertebrate animals in all ARS locations, or other locations in which ARS funds or ARS personnel are involved.

ARS should implement a clearly defined process through which a responsible National Office official will oversee the monitoring of compliance with directives and other applicable requirements and hold those responsible for internal control activities accountable.

ARS directives were silent regarding the manner in which these responsibilities were to be carried out. For example, the directives state that Area Directors were responsible for ensuring IACUCs are established where required and maintained, but there is no indication of how an Area Director was expected to carry out this responsibility. Therefore, it was unclear whether an Area Director was expected to perform an in-depth review of the IACUC's activities, periodically attend IACUC meetings to observe the committee's operations, review an IACUC only upon receipt of a complaint, or some combination of these responsibilities.

In the case of USMARC, [REDACTED]
[REDACTED] y. We noted that the information the IACUC was required to submit would not have allowed [REDACTED]
[REDACTED]

C. We believe that ARS should revise its animal welfare-related directives to include explicit instructions on how the responsibilities assigned to various ARS parties are to be carried out.

Also, ARS policy did not adequately describe the manner or the extent to which the completion of various responsibilities was to be documented. For example, ARS Directive 130.4 states that a research facility's IACUC is to conduct an annual review of all activities for use of animal subjects that exceed one year and approve the activity's continuation or suspend its approval, but there was no explicit requirement that this review be documented.

At USMARC, the required annual reviews were reportedly completed by the [REDACTED] [REDACTED] who was also the [REDACTED], and USMARC management, but there was no documentation supporting its completion. Because there was no documentation, we were unable to determine whether this required activity was completed. We also noted that USMARC's approach of including only one IACUC member in the completion of this activity may not comply with agency policy, which assigns the task to the full committee. We believe ARS should revise its animal welfare-related directives to include explicit instructions on how the various ARS parties are to document the completion of their responsibilities.

⁷ This IACUC information was contained in ARS Form 605, which reports all animals owned by ARS and used for agricultural research for food or fiber, and ARS Form 606, which provides the roster of a facility's IACUC.

⁸ The [REDACTED]

Even in some of the cases in which ARS directives were clear, USMARC's IACUC operated outside agency policy. For example, ARS Directive 130.4 states that the IACUC is to review "all proposed research activities for use of animal subjects" and that this review shall conform with 9 Code of Federal Regulations 2C, Section 2.31. This section states, in part, that, prior to the IACUC's review, each member of the committee shall be provided a list of the proposed activities to be reviewed. Written descriptions of proposed activities shall be provided to all IACUC members, and any member may obtain, upon request, a full committee review of the activities.

However, based on discussions with USMARC personnel, proposed research activities underwent two phases of review, one informal and one formal. During the informal phase, the scientist proposing the experiment, the facility's Attending Veterinarian, the center director, the livestock managers, and other research managers would review the proposal. These reviews focused on whether the proposed activity fit within established research objectives, whether the necessary animals would be available for the activity, and whether the scientist was proposing to use appropriate procedures for steps such as euthanasia. If a proposed activity passed this informal review, it was then subjected to the formal review process.

In the formal review process, the IACUC chairperson, who was also the USMARC Attending Veterinarian, would review and sign the proposal on behalf of the IACUC. The proposal was then posted onto the facility's intranet and an email was sent to all staff, including IACUC members, informing them a new proposal had been posted. At this point, IACUC members could raise any questions or concerns regarding the proposal, though there was no requirement for them to certify that they had reviewed the proposal. The applicable livestock managers would then review and sign the proposal after having any concerns or questions addressed. Finally, the center director would review and sign the proposal after all questions and comments had been addressed. Accordingly, USMARC was not complying with ARS policy as proposed activities had already been approved by the IACUC, via the IACUC chairperson's signature, prior to the proposals being made available to the other IACUC members. We believe that a robust oversight role by the ARS National Office would prevent such departures from agency policy in the future.

Handling of Complaints

ARS Directive 130.4 states that the IACUC should promptly investigate all complaints concerning abuse of animals, nonconformance with stipulations of an approved activity, or failure to comply with various requirements concerning care and use of animals. ARS Directive 635.1 states that all allegations of animal abuse must be promptly reported, in writing, to the IACUC, its chairperson, and the Area Director.

However, we found that USMARC reportedly employed an informal, unwritten animal welfare complaint system that utilized the facility's chain of command and produced little documentation of any complaints that may have been voiced or the actions taken to address them. Current USMARC management stated it has never received a formal

complaint about animal welfare at the facility, but since there was no system in place to record such complaints, we found it difficult to evaluate management's claims. In several instances where *The New York Times* reported complaints being made, we could not corroborate the allegations, in part, due to the informality of this system (for example, allegations such as those in Statements 14, 20, 23, and 25 in Exhibit A). We maintain that instituting a formal complaint system, as required by ARS directives, would help to mitigate some of the criticism leveled at USMARC.

Additionally, over the past 30 years, some employees have reportedly been reluctant to report animal welfare complaints for fear of retaliation or indifference by facility management (see Statement 15 in Exhibit A). Accordingly, we assert that ARS should establish a formal, written animal welfare complaint system through which anyone at USMARC, including cooperator employees, can report an animal welfare concern. This reporting system, which could include all ARS research facilities, should be monitored and overseen by an official at the ARS National Office and allow for concerns to be expressed anonymously. Furthermore, this system should thoroughly document the details of any complaint, the manner in which it was investigated, and the final resolution. We believe implementing such a system will enhance ARS' and USMARC's ability to respond to allegations of improprieties.

Improving Transparency of Research on Animals at USMARC

Finally, we believe that ARS can do more to increase the transparency of USMARC's research. Given the level of response to the article in *The New York Times*, the public has shown great concern and desire for information regarding research and the treatment of animals at USMARC. After the publication of *The New York Times* article, Congress directed ARS to engage stakeholders, including producers, industry, and animal welfare experts, regarding the easy care sheep research project⁹ underway at the facility. Ultimately, we believe that Congress' directions to engage stakeholders demonstrates a desire for increased transparency and public awareness of the facility's operations and is an indicator of how ARS should proceed.

In that spirit, ARS should take advantage of any opportunity to increase public awareness regarding the operations and research ongoing at the facility. To that end, we believe ARS could improve its transparency by making USMARC's approved research proposals, IACUC meeting minutes, and other relevant information publicly available on its website.

In conclusion, we believe that ARS can take several important steps to better communicate the nature of its research and its effect on animals to the public. The agency can also improve its oversight over animal welfare concerns. By addressing these recommendations, ARS can mitigate, or prevent, the kind of controversy sparked by *The New York Times'* article.

⁹ USMARC has been researching "low-input, easy care, pasture lambing," which was an attempt to create a subspecies of sheep that could take care of and raise its young with little or no assistance from producers.

Following the release of *The New York Times* article, ARS and USMARC have implemented a number of changes. ARS appointed an Animal Care and Use Officer (ACUO), whose duties include overseeing training requirements and reviewing or coordinating reviews of experimental protocols for animal research at ARS, and an Animal Welfare Ombudsman, who is to provide confidential assistance to individuals with animal welfare concerns at ARS research facilities. The agency has also begun to update its animal welfare-related policies and procedures. Additionally, ARS has entered into a memorandum of understanding (MOU) with the Animal and Plant Health Inspection Service (APHIS), through which APHIS will conduct regular inspections of ARS animal research facilities to assess compliance with the AWA and other regulations.¹⁰ USMARC has revised its IACUC review process for proposed research activities involving animals, which now describes in detail the process through which proposed activities will be reviewed and requires that proposals be provided to all IACUC members prior to approval.

Recommendation 1

Establish an ARS National Office oversight process through which a responsible official oversees the monitoring of Area Offices' and research facilities', including USMARC's, compliance with ARS policies, procedures, and other applicable requirements.

Agency Response

In its September 22, 2016, response, ARS stated that it is committed to animal welfare and the humane treatment of animals employed in research at ARS laboratories. Since January 2015, ARS has taken major actions to strengthen the national animal handling and welfare program that oversees ARS animal research locations.

On June 28, 2015, ARS created a new position and hired a highly qualified individual as the ACUO, who oversees animal health and welfare at all ARS locations, and is a resource for ARS field staff for animal handling and welfare best practices, procedures, and policies. A main responsibility of the ACUO is to coordinate an assessment program to verify the effectiveness of local oversight systems at all ARS locations that conduct research involving animals.

On February 23, 2015, ARS established the Animal Welfare Leadership Committee (AWLC), which is tasked with (1) coordinating, reviewing, and strengthening relevant ARS programs and offices and assisting Agency leadership in ensuring that animal health and welfare responsibility protocols are observed at all times, and (2) providing guidance to line managers in the field. ARS also established the Animal Welfare Task Force, which manages ARS animal welfare and handling program assessment to identify gaps in current ARS animal care and use protocols and procedures, develops implementation plans to address these gaps, and facilitates the sharing of best practices across animal research locations in the agency. The ARS executive chain of command, working through the ACUO and AWLC, oversees and enforces adherence to all animal welfare and handling policies and procedures in ARS.

¹⁰ APHIS' Animal Care program enforces the provisions of the AWA.

In addition, ARS partnered with APHIS and on February 11, 2016, entered into a MOU. The MOU established a process to have ARS' animal research facilities registered, reviewed, and inspected by APHIS to verify full compliance with the AWA and Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide). Inspection reports from unannounced inspections of ARS facilities will be posted online in the Animal Care Information System database, as with all facilities APHIS inspects.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

Revise ARS policies and procedures related to animal welfare to more explicitly state the manner in which Area Offices and research facilities are to carry out their responsibilities, as prescribed within the directives, including the manner in which they are to document the performance of their responsibilities.

Agency Response

In its September 22, 2016, response, ARS stated that it published an updated animal care and use policy and procedure on February 2, 2016. The new policy and procedure ensures that ARS animal care and welfare protocols are consistent, effective, and compliant with the AWA and the Ag Guide. It also describes the responsibilities of the ARS Administrator, Associate Administrators, Deputy Administrator for Animal Production and Protection, National Program Leaders, ACUO, Area Directors, ARS location Senior Management, Institutional Officials (IO), Attending Veterinarians, Research Leaders, Research Scientists and their support staff, and IACUCs.

Area Offices will also be charged to conduct an annual unannounced assessment of: 1) animal welfare, 2) IACUC composition and proceedings, 3) approved protocols, and 4) facility maintenance. This assessment is in addition to IACUC semiannual (2) inspections and routine APHIS annual unannounced inspections. Area Directors, Associate Area Directors, or designee of Area Directors will conduct the assessment. This additional assessment will give each animal research facility four assessments or inspections per year: 1) IACUC semiannual (2) inspections, 2) APHIS unannounced inspections, and 3) Area Office unannounced assessments. The charge will be included in a new version of the USDA-Research, Education and Economics (REE) policy and procedure 130.4.v.2 by December 1, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

Establish a process through which ARS animal welfare-related policies and procedures are periodically reviewed and updated to ensure they reference and reflect the most current versions of applicable research practices and guidance regarding animal research and animal welfare.

Agency Response

In its September 22, 2016, response, ARS stated:

The updated USDA-REE [policy and procedure] 130.4.v.2, Institutional Care and Use Committee describes responsibilities of the ACUO to schedule and coordinate an annual [policy and procedure] review to include advances in best practices, science, and technology. The ACUO coordinates with the AWLC to maintain relevance, ensure animal health and welfare protocols are observed, and receive suggestions from managers in the field. ARS leadership must approve the revised [policy and procedure]. If circumstances arise during the year, ARS will not hesitate to update the [policy and procedure] more frequently.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

Establish a detailed, formal animal welfare complaint process through which any individual at a research facility, including cooperator employees, may report animal welfare issues. This process should include the thorough documentation of the details of the complaint, the steps taken to investigate it, and the ultimate resolution of the issue. This process should provide anonymity to the complainant, if desired, and be monitored by an official at ARS' National Office.

Agency Response

In its September 22, 2016, response, ARS stated that in January 2015, the ARS Administrator appointed an ARS Animal Welfare Ombudsman to provide a confidential, impartial, and independent outlet for individuals and groups who have complaints or concerns related to animal welfare at ARS animal research facilities. The ARS Administrator also established an animal welfare e-mail box for internal and external concerns about ARS animal welfare. The e-mail address is: animalwellbeing@ars.usda.gov.

Anonymous reports can be submitted, and will be investigated fully by the IACUC. USDA-REE policy and procedure 130.4.v.2 also requires each IACUC to develop a local policy that provides

guidance and procedures for identifying, reporting, and investigating concerns related to animal care and use.

The local IACUC receiving complaints will make a determination to review, investigate, and provide any corrective actions needed to resolve the primary issue under investigation as well as to prevent future occurrences. The IACUC's conclusions must be conveyed to the IO and documented as part of the IACUC records within five (5) business days. The IO provides an incident report to that Area Office immediately upon receiving any report from the IACUC of an incident. The Area Offices are responsible for communicating to the Associate Administrator for Research Operations those reports. This process will be spelled out in an updated USDA-REE policy and procedure 130.4.v.2 by December 1, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 5

Increase the transparency of USMARC by making USMARC's approved research proposals, IACUC meeting minutes, and other relevant information publicly available on ARS' website.

Agency Response

In its September 22, 2016, response, ARS stated:

ARS has a number of concerns with implementing OIG's recommendation to increase transparency at USMARC by making USMARC's approved research proposals, IACUC meetings, and other relevant information publicly available on the ARS' Web site.

The safety of ARS personnel at USMARC and other facilities that employ animal research is paramount. Since publication of the *New York Times* article in January 2015, USMARC employees have received multiple threats of physical harm from multiple sources. ARS has decided that the benefits gained from the release of details, other than those already released (discussed in next paragraph), which meet industry standards, do not outweigh the associated risks from domestic terrorism.

Secondly, the objectives and approaches of all approved ARS research projects, both appropriated and cooperatively funded with extramural partners, are readily available on the ARS Web site. Other relevant information is also available for each project through the ARS Web site, including, but not limited to, project objectives and other elements of project design, annual progress reports for the current and previous year's research, and journal publications resulting from the research. This information provides much transparency already. More information on specific experimental design is not included on the ARS Web site for any of our projects because of the competitive nature of agricultural research and the financial implications of premature release of information.

Inadvertent release of research protocols prior to filing a patent at the United States Patent and Trademark Office could jeopardize the ability of ARS and its university cooperators to obtain patent rights, and thus compromise licensing and commercialization of their work. The cost of developing these technologies into products (cost of commercialization) is substantial and protection of intellectual property is key to encouraging industry cooperation in the commercialization process. The Freedom of Information Act (FOIA) process is also available to members of the public.

As for the release of the IACUC reports, ARS intends to follow all relevant guidelines and requirements of the AWA, which does not specifically require public release of the minutes. In not posting the IACUC reports on its Web site, ARS is also following the practices set by other major Federal science agencies including the Department of Defense, the National Institutes of Health, the Veterans Administration, and the Food and Drug Administration, who also do not make their IACUC reports publicly available.

For these three reasons, ARS respectfully declines to accept the recommendation.

OIG Position

We are unable to accept management decision for this recommendation. OIG acknowledges the concerns raised by ARS regarding employee safety as well as the potential financial and competitive risks associated with increased disclosure of information. However, OIG believes that increased transparency of USMARC research can still be accomplished while giving these concerns their due consideration. Information deemed too sensitive could be redacted from the documents that are made readily available to the public, though still potentially accessible through FOIA.

Regarding the release of IACUC reports, OIG agrees that there is no direct requirement that this information be made publicly available. However, in light of ARS's commitment to being a leader on animal welfare within the Federal government, OIG believes that it would be beneficial for the agency to be as transparent as possible regarding the animal welfare-related activities at its facilities. In order to reach management decision for this recommendation, ARS needs to identify and act upon available opportunities to increase the transparency of research activities at USMARC.

Scope and Methodology

We conducted our audit at the ARS National Office in Washington, DC, and Beltsville, Maryland; and the USMARC facility in Clay Center, Nebraska. We performed fieldwork between March 2015 and May 2016.

Our audit covered USMARC activities discussed in *The New York Times* article titled “U.S. Research Lab Lets Livestock Suffer in Quest for Profit,” published January 19, 2015. We examined ARS’ oversight of USMARC during the time period prior to the publication of this article, primarily between 2012 and 2014.

After reviewing *The New York Times* article, we non-statistically selected 33 specific statements from the article to evaluate in an attempt to determine the accuracy of the expressed concerns. These statements were selected based on references to specified dates or timeframes, specific facts or figures (for example, a specific number of animal deaths), and/or sufficient details the audit team could examine. We also included statements identified and clarified by ARS in one of its responses to Congress.

To accomplish our objectives, we performed the following audit procedures:

- reviewed applicable laws, regulations, and agency and USMARC procedures related to animal welfare and ARS oversight of animal welfare;
- interviewed current and former ARS and UNL employees, and other individuals, regarding their knowledge related to statements made in *The New York Times* article and other aspects of USMARC’s operations and practices;
- reviewed ARS and UNL documentation related to statements made in *The New York Times* article and other aspects of USMARC’s operations and practices;
- interviewed ARS National Office, Plains Area Office, and USMARC officials regarding ARS’ oversight of the facility prior to the publication of *The New York Times* article;
- interviewed subject matter experts to obtain opinions regarding USMARC practices and mortality rates;
- investigated and/or referred additional animal welfare concerns expressed by various parties throughout the audit;
- requested to interview the journalist who authored *The New York Times* article and *The New York Times* itself, both of whom declined; and
- researched livestock industry norms and practices through review of industry-related publications and studies.

We assessed the reliability of information systems by comparing specific mortality data within USMARC’s operational database to source mortality documents maintained at the facility. For the purposes of our review, we determined the data to be reliable.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Abbreviations

ACUO	Animal Care and Use Officer
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ARS-AHWRP	Agricultural Research Service Animal Handling and Welfare Review Panel
AWA	Animal Welfare Act
AWLC	Animal Welfare Leadership Committee
FOIA	Freedom of Information Act
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
MOU	Memorandum of Understanding
OIG	Office of Inspector General
OPP	Ovine Progressive Pneumonia
REE	Research, Education and Economics
UNL	University of Nebraska-Lincoln
USDA	Department of Agriculture
USMARC	U.S. Meat Animal Research Center

Exhibit A: OIG Observations

Overall, based on our work, we did not note evidence indicating a systemic problem with animal welfare at USMARC. After reviewing *The New York Times* article titled “U.S. Research Lab Lets Livestock Suffer in Quest for Profit,” published January 19, 2015, we non-statistically selected 33 specific statements to evaluate in an attempt to determine the veracity of the statements. These statements were selected based on references to specified dates or timeframes, specific facts or figures (for example, a specific number of animal deaths), and/or sufficient details to allow us to examine them, as well as statements identified and clarified by ARS in one of its responses to Congress.

Of these 33 statements, we determined only 7 were materially accurate—26 were inaccurate, lacked sufficient context, or were uncorroborated.¹¹ In the pages that follow, we detail our review and conclusions related to each of these statements, providing appropriate context when needed, so a reader can better understand the research performed at USMARC. We contacted *The New York Times* journalist to obtain clarification on numerous items from the article, but he declined to be interviewed. We also contacted *The New York Times* for comment on any statements we identified as inaccurate or uncorroborated, but *The New York Times* officials did not feel the need to discuss the reporting on those items and also declined to be interviewed.

We attempted to verify the accuracy of the selected statements by using information provided to *The New York Times* journalist, data and documentation obtained from ARS and UNL, and interviews of parties with relevant knowledge related to the topics discussed in the article. In our verification of facts and figures in the article and our attempts to provide necessary context, we determined, when possible, whether USMARC departed from industry norms.¹² We used industry norms as the standard against which USMARC should be compared. Since USMARC is a research facility that performs research related to the production of livestock in the meat industry, the welfare of animals (i.e., practices, mortality rates, etc.) at USMARC should be comparable to the meat industry. If USMARC’s conditions are not comparable to the industry, then the applicability of its research could be questioned. Although we recognize that some may regard those norms as insufficiently strict, we believe that industry norms represent the most appropriate standards against which to compare USMARC’s operations.

Accordingly, we believe that significant departure from industry norms could be indicative of systemic animal welfare issues. In many cases, USMARC’s mortality rates associated with the various causes of death discussed within the article are within industry norms, indicating the

¹¹ For the purpose of our audit, we defined the classifications as follows: (1) an item was “accurate” if the audit team was able to verify the sampled verbiage of the statement as materially correct based on its fieldwork/evidence and did not require extensive and/or material additional context to be interpreted; (2) an item was “inaccurate” if the audit team determined the sampled verbiage was materially incorrect based on its fieldwork/evidence; (3) an item was “uncorroborated” if the audit team was unable to definitively determine the correctness of the sampled verbiage; and (4) an item was “lacking context” if the audit team was generally able to determine that the sampled verbiage of the statement is materially accurate but requires extensive and/or material additional context in order to be interpreted in a fair, fully informed, and unbiased manner.

¹² We considered information and statistics from APHIS and industry publications as indicative of industry norms.

conditions at the facility are not systemically deficient compared to industry. For the cases where USMARC’s mortality rates were not within industry norms, or for which we were not able to identify industry norms, we spoke with experts and/or performed additional analysis to see if the mortality rates we calculated were reasonable, given USMARC’s research. For example, when we were not able to identify any published industry norms, we attempted to provide context to the figures by calculating their prevalence within the applicable population of animals.

Statement 1

“At a remote research center on the Nebraska plains, scientists are using surgery and breeding techniques to re-engineer the farm animal to fit the needs of the 21st-century meat industry.”

ACCURATE

Through a review of USMARC documents, we have determined that surgery and breeding have been used as part of the research performed at USMARC. USMARC also performs many experiments on the care of farm animals, including experiments with feed, drugs, and environment.

Statement 2

“Pigs are having many more piglets — up to 14, instead of the usual eight — but hundreds of those newborns, too frail or crowded to move, are being crushed each year when their mothers roll over.”

LACKING CONTEXT

Although *The New York Times*’ wording (i.e., “up to 14” and “usual eight” piglets) is vague, we interpreted it to mean that USMARC averages up to 14 piglets per litter and the industry averages 8. Per the *2014 U.S. Pork Industry Productivity Analysis*, issued by the National Pork Board, the average number of piglets in a litter in the swine industry is around 13. After reviewing USMARC’s data and documents, we determined that the average number of piglets per litter at USMARC since 1985 has been approximately 11. In fact, ARS officials have stated that USMARC has had to take steps to bring their operations more in line with the industry in order to keep their research relevant.

We interpreted *The New York Times*’ use of the term “frail” to mean lightweight. We determined that the prevalence of lightweight piglets at USMARC is in line with industry norms. Per *nationalhogfarmer.com*, pigs born weighing less than 2.2 pounds are considered lightweight. Lightweight births usually account for approximately 15 percent of pig births within the swine industry. From 1985 to 2014, lightweight pigs accounted for approximately 14.8 percent of pig births at USMARC.

Through a review of USMARC data, we determined that hundreds of piglets die each year as a result of being crushed by their mothers. This is one of the most common causes of preweaning piglet mortality in the swine industry. We determined that USMARC’s live birth preweaning

mortality rates were in line with industry norms.¹³ The National Pork Board's *2014 U.S. Pork Industry Productivity Analysis* contains average live birth preweaning mortality rates and associated standard deviations¹⁴ from 2008 through 2013. We considered any rate falling within one standard deviation of the quoted rates to be within industry norms. From 2008 through 2013, all of USMARC's live birth preweaning mortality rates fell within one standard deviation of the rates contained in the National Pork Board's analysis for those years.

In summary, we concluded that the condition of piglets at USMARC is not dissimilar to that of piglets throughout the industry.

Statement 3

“Cows, which normally bear one calf at a time, have been retooled to have twins and triplets, which often emerge weakened or deformed, dying in such numbers that even meat producers have been repulsed.”

LACKING CONTEXT

Cows rarely bear twins—the normal twinning rate in cattle ranges from 1 to 5 percent of births, depending on breed.¹⁵ USMARC initiated a Twinning Project over three decades ago. In this project the average rate of multiple-type births (i.e., twins, triplets, etc.) was much higher, at 46.4 percent between 1985 and 2012.

As *The New York Times* alluded, the mortality rate at birth for the Twinning Project population from 1985 through 2012 was much higher than industry norms. An APHIS study on U.S. beef cow-calf health and management practices in 2007–2008 found that 2.9 percent of all beef calves (i.e., single-type and multiple-type births) were born dead. From 1985 through 2012, approximately 8.4 percent of all calves born into the Twinning Project population were dead at birth.

We also compared the at birth mortality rates of calves within USMARC's Twinning Project population versus that of the rest of USMARC's cattle herd for like-kind births and found similar mortality rates.¹⁶ Accordingly, we concluded the high overall at birth mortality rate of calves within the Twinning Project population appears to be a result of the significantly greater than normal prevalence of multiple-type births and the complications associated with such births, as opposed to a lesser standard of care having been applied to this population.

¹³ Live birth preweaning mortality refers to piglets that were born alive (i.e., not stillborn) and died prior to weaning. To calculate the live birth preweaning mortality rate, the number of live born pigs that died prior to weaning is divided by the total number of live born pigs.

¹⁴ A standard deviation is the positive square root of the variance.

¹⁵ Çobanoğlu, Özden, “Twinning in Cattle: Desirable or Undesirable?”, *Journal of Biological & Environmental Sciences*, 4.10 (2010): 1-8.

¹⁶ The comparison of mortality rates for like-kind births involved the grouping of births within the two populations into subcategories: single-type and multiple-type births (i.e. twins, triplets etc.). The at birth mortality rate for each subcategory was calculated and compared to the rate for the corresponding subcategory in the other population. We did not identify any industry norms for at birth mortality by type of birth.

We discuss the topic of deformity later in Statement 27.

USMARC stopped the Twinning Project in 2013 due to “diminished returns in the contributions to science and to aspects of applied production” from the project.

Statement 4

“Last Mother’s Day, at the height of the birthing season, two veterinarians struggled to sort through the weekend’s toll: 25 rag-doll bodies. Five, abandoned by overtaxed mothers, had empty stomachs. Six had signs of pneumonia. Five had been savaged by coyotes.”

ACCURATE

Through a review of USMARC data, we have determined that a total of 25 sheep died on May 10 and 11, 2014. Of these sheep, five were coded as having died as a result of “starvation-empty stomach” and another five were coded as having died as a result of a “predator strike.” To date, we have not found evidence clearly supporting that six of the sheep had signs of pneumonia.

In summary, we determined this statement to be materially accurate.

Overall starvation mortality at USMARC is discussed in Statement 9.

Overall predation mortality at USMARC is discussed in Statement 12.

Statement 5

“... to be dumped in a vast excavation called the dead pit.”

LACKING CONTEXT

Based on our research into agricultural practices, we determined that the burial of animal remains, particularly sheep remains, is a common and legal practice in agriculture. During our tour of the USMARC facility, we observed the “dead pit.” We estimate the “dead pit” to be a trench measuring approximately 2 feet wide, 10 feet long, and at least 15 feet deep. Animal remains are placed in the trench and immediately covered with dirt.

We believe that describing the dead pit as a “vast excavation” is an overstatement.

Statement 6

“Little known outside the world of big agriculture, the center has one overarching mission: helping producers of beef, pork and lamb turn a higher profit as diets shift toward poultry, fish, and produce.”

INACCURATE

According to USMARC’s webpage, the stated mission of the research center is to “[develop] scientific information and new technology to solve high priority problems for the U.S. beef, sheep, and swine industries.”¹⁷ We noted that solving high-priority problems may result in increased profits for these industries. For example, USMARC is performing research with an objective of developing selection¹⁸ guidelines to reduce the prevalence of ovine progressive pneumonia (OPP) in industry flocks.¹⁹ A study of U.S. sheep has shown that 24 percent of tested animals were positive for OPP.²⁰ The development of selection guidelines to reduce the prevalence of OPP should improve sheep survival, which in turn could increase profits for the industry. However, increasing profits is not USMARC’s stated mission.

Statement 7

“The research to increase pig litters began in 1986;”

ACCURATE

By reviewing USMARC documentation, we determined that research into pig litter size at USMARC began in 1986. We determined that the live birth preweaning mortality rates for the two populations associated with this research were generally in line with industry norms.²¹ From 2008 through 2013, USMARC’s live birth preweaning mortality rates for the two primary populations related to the facility’s pig litter size research fell within one standard deviation of the rates contained in the National Pork Board’s analysis for 4 of those 6 years. For the other 2 years, USMARC’s rate was slightly below industry norms 1 year, and was slightly above in the other year.

Statement 8

“... center scientists have been operating on pigs’ ovaries and brains in an attempt to make the sows more fertile.”

LACKING CONTEXT

Through a review of USMARC documentation and interviews of USMARC officials, we determined that surgeries involving pigs’ ovaries have been a part of USMARC’s research. Our fieldwork found that surgeries performed in connection with research are focused on obtaining

¹⁷ USDA-ARS-Plains Area-USMARC, *About Us* (July 12, 2016),

<http://www.ars.usda.gov/AboutUs/aboutUs.htm?modecode=30-40-05-00>.

¹⁸ Selection refers to the action of a breeder in selecting individual animals from which to breed, in order to obtain some desired quality or characteristic in the descendants.

¹⁹ OPP is a slowly progressive viral disease in adult sheep. The OPP virus can cause disease with symptoms including: severe weight loss, labored breathing, paralysis, swollen joints, and hard, unproductive udders. Once infected with the virus, sheep are carriers for life as there is no effective treatment or vaccine.

²⁰ *Ovine Progressive Pneumonia: Awareness, Management, and Seroprevalence*, APHIS, December 2003.

²¹ For the definition, calculation, and source for industry norms related to live birth preweaning mortality, see Statement 2.

information on how various biological aspects interact and affect pig fertility, which, in turn, could be utilized by the industry in making selection and management decisions.

While surgery on pigs' brains was approved as part of a research plan at USMARC, we did not find any evidence that such surgery was actually performed at the facility. [REDACTED]

Statement 9

“Of the 580,000 animals the center has housed since 1985, when its most ambitious projects got underway, at least 6,500 have starved.”

LACKING CONTEXT

Through a review of USMARC data, we determined that over 6,500 animals have been coded as having died due to starvation since 1985. Based on interviews of current and former USMARC officials, the starvation code within the USMARC data does not indicate that animals were not provided adequate food by USMARC personnel. They explained that this code is used when an animal is found dead with no fat on its body. These deaths generally occur early in life as a result of complications with nursing.

For example, if a newborn lamb failed to nurse from its mother and then died, USMARC employees would code that death as a starvation. It does not mean that USMARC was not feeding animals appropriately.

Statement 10

“A single, treatable malady — mastitis, a painful infection of the udder — has killed more than 625.”

LACKING CONTEXT

Mastitis is an inflammation of the mammary gland, most commonly due to infection or injury.

From 1985 through 2014, 723 USMARC female animals have died from mastitis, including 5 swine, 45 cattle, and 673 sheep. These figures equate to 0.343 percent of female sheep, 0.013 percent of female cattle, and 0.003 percent of female swine that were present at USMARC from 1985 through 2014.²²

²² To calculate the mortality rate, we divided the total number of mastitis deaths in a species since 1985 by the total population of animals in that species that have been housed at USMARC since 1985. If an animal was housed at USMARC multiple years since 1985, it was counted as an individual animal each of those years because the animal had the opportunity to die from mastitis each year (i.e., if an animal was housed at USMARC for 5 years, it would be counted in the total population five times for this calculation).

We were unable to identify sufficient industry norms for cattle, sheep, or swine dying from mastitis.

Statement 11

“The center added a daring twist: pasture lambing, an attempt to take domesticated sheep, which are dependent on human help, and create a breed that can survive on its own.”

LACKING CONTEXT

USMARC has been researching “low-input, easy care, pasture lambing,” which was an attempt to create a subspecies of sheep that could take care of and raise its young with little or no assistance from producers. We do not agree that this is a “daring twist.” Other research of this kind has been conducted at universities well before USMARC began its research.²³ In some areas of the country, producers raise sheep using a similar system; an APHIS study on lambing management practices in 2011 found that 69.4 percent of lambs born in the western United States, 59.4 percent of lambs born in the central United States, and 23.6 percent of lambs born in the eastern United States were born using a pasture lambing management system.²⁴ Additionally, other countries, such as the United Kingdom and New Zealand, routinely raise sheep using this method, though these countries do not experience the predator dangers present in the United States.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²³ For example, “Lambing Ewes Outside as an Integral Part of Low Input Sheep Production in the Mid-Appalachian Region,” *Animal Sciences Research and Reviews*, Special Circular 156. The Ohio State University. Accessed at <http://ohioline.osu.edu/sc156/sc156_44.html> on March 30, 2015.

²⁴ *Lambing Management Practices on U.S. Sheep Operations, 2011*, APHIS, January 2014.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Statement 13

“Out in the fields, the hailstorm sent the next day’s body count soaring to 110. Death rates in the past three years have ranged between about one-quarter and one-third of the lambs, far beyond the 10 percent that many industry experts say is considered acceptable in sheep farming.”

LACKING CONTEXT

We confirmed that 110 sheep died on May 12, 2014. However, we do not agree with the article’s characterization of this storm as a “hailstorm.” This major storm, which produced

10 confirmed tornados in Nebraska, resulted in a Presidential disaster declaration for the county where USMARC is located.

USMARC's preweaning pasture lambing mortality rate was 23.4 percent, 25.3 percent, and 29.0 percent for 2012, 2013, and 2014, respectively. We were unable to identify any industry norms specific to the low-input production system that was being utilized and researched by USMARC. We spoke to multiple sheep experts with knowledge of such systems who stated that they did not believe that USMARC's mortality rates were excessive for the production system being employed and the prolificacy of its sheep.

[REDACTED]

[Redacted] e
[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Statement 17

“The center does not have the veterinarians to be present during experiments, even if it wanted them to. Twenty years ago, it employed six scientists with veterinary degrees...”

LACKING CONTEXT

At present, USMARC employs just one veterinarian, but is assisted by another four veterinarians from UNL.

USMARC previously employed a number of scientists who also possessed veterinary degrees. A scientist’s primary responsibility is to conduct research, and thus scientists would be present at any experiments they conducted, whether they had a veterinary degree or not. All scientists, regardless of whether or not they have a veterinary degree, have the same animal care responsibilities. Per ARS Directive 635.1, all research scientists are to ensure that they personally, as well as their technicians, caretakers, students, and others, follow regulations and standards for humane care of animals used in any manner by them and/or their subordinates. Thus, all scientists have equal responsibility for the humane care of the animals, whether they are veterinarians or not.

The primary responsibility for animal care falls to the [REDACTED], who reportedly attends some surgeries (and has the authority to attend/participate in any and all surgeries or other procedures) and reviews health records to ensure the proper care of animals, including animals on which surgery was performed. The [REDACTED] receives assistance from an experienced veterinary technician, along with faculty and students from UNL’s Great Plains Veterinary Education Center.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]




Statement 21

“...becoming the 245th animal to succumb to an abscess since 1985.”

LACKING CONTEXT

We reviewed USMARC data, and found that more than 245 animals have died at USMARC from abscesses since 1985. The 30-year mortality rate specifically related to abscesses was about 0.006, 0.042, and 0.081 percent in cattle, swine, and sheep, respectively.²⁸ 


Statement 22

“Visiting the center in the late 1980s, the renowned animal welfare expert Temple Grandin approached a herd of cows. They panicked. ‘When cattle run away, that’s indicative of rough handling, screaming and yelling,’ said Ms. Grandin, who gave the center a report suggesting ways to treat cattle more humanely.”

LACKING CONTEXT

After reviewing Ms. Grandin’s report to USMARC, we determined that Ms. Grandin stated that the behavior of some cattle that she observed in one particular building at the facility may indicate rough handling. She also wrote that she had heard of instances of rough handling or yelling by certain employees, though she acknowledged that she could not verify whether those accusations were true. In her report, Ms. Grandin also noted good cattle handling and employee behavior that she observed at numerous buildings.

Furthermore, we spoke to cattle consultants that have visited USMARC in recent years and all of them stated that they had never observed any mistreatment of animals at the facility.

²⁸ To calculate the mortality rate, we divided the total number of abscess-related deaths in a species since 1985 by the total population of animals in that species that have been housed at USMARC since 1985. If an animal was housed at USMARC multiple years since 1985, it was counted as an individual animal each of those years because the animal had the opportunity to die from abscess(es) each year (i.e., if an animal was housed at USMARC for 5 years, it would be counted in the total population five times for this calculation).

[REDACTED]

[REDACTED] e

[REDACTED]

29 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Statement 27

“Yet unsettling side effects surfaced. Some 95 percent of the females born with male siblings had deformed vaginas.”

LACKING CONTEXT

Through interviews of multiple veterinarians, and our own research, we determined that the deformity referenced by the article is called “freemartinism.” Freemartinism is one of the most common forms of intersexuality in cattle. A bovine freemartin is a sterile female calf, born with a male twin, that shows an underdeveloped or mis-developed genital tract due to the in utero passage of male hormones between the twins. The condition is found in over 90 percent of cattle from these types of pregnancies.³¹ We determined that it is a commonly known condition that results from a male/female twin set, rather than a unique side effect that arose as a result of USMARC’s Twinning Project. Furthermore, multiple veterinarians have confirmed that, other than being sterile, animals with this condition suffer no ill effects or pain and can still enter the food supply.

³¹ Alexandra Esteves et al., *Ruminants: Anatomy, Behavior and Diseases*, 99-100 (2012).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Statement 29

“...the Agriculture Department requires that the center do what many universities and companies do: appoint a review committee that holds regular meetings, keeps minutes and approves or rejects each experiment after carefully evaluating animal safety.”

ACCURATE

We reviewed ARS Directives and USMARC documentation and interviewed USMARC officials. We found that USMARC is required to appoint an IACUC that holds meetings, keeps minutes of meetings, and approves or disapproves proposed experiments that involve animal subjects.³²

In February 2015, the Secretary of Agriculture appointed ARS-AHWRP to review animal care and well-being policies, procedures, and standards. On March 30, 2015, ARS-AHWRP reported that it found the IACUC at USMARC was not adequately fulfilling its intended role.

Through our review, we also identified deficiencies in the operation of USMARC’s IACUC. See Finding 1.

[REDACTED]

[REDACTED]

³² ARS Directive 130.4, dated August 1, 2002.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Statement 31

“Last year, the center set out to show that its cows could thrive on a growth stimulant called Zilmax. Months earlier, the drug had been withdrawn by its manufacturer, Merck & Company, amid concern in the meat industry that it caused rare complications, like hooves that slough off, and was associated with higher death rates.”

INACCURATE

Through a review of USMARC documentation and our own research, we found that Zilmax³⁴ was withdrawn from the market in August 2013.³⁵ We determined that, while USMARC has conducted research involving Zilmax since the drug was removed from the market, none of the experiments included an objective to prove that cows could thrive on the stimulant.³⁶

³³ [REDACTED]

³⁴ Zilmax is a beta-agonist, a class of growth promotants.

³⁵ The manufacturer cited the desire to study potential causes of lameness and other mobility issues.

³⁶ Experiment number 5438-31000-092-04, approved January 14, 2014, had an objective to “determine if feeding [Zilmax] decreases or increases the energy requirements of finishing beef steers.” Experiment number 5438-31000-092-07, approved February 26, 2014, had an objective to “estimate the effects of open vs. shaded pens of cattle with and without [Zilmax] on heat stress, animal performance, and carcass characteristics.”

[REDACTED]

37

[REDACTED]

**USDA'S
AGRICULTURAL RESEARCH SERVICE
RESPONSE TO AUDIT REPORT**



September 22, 2016

SUBJECT: United States Meat Animal Research Center Review

TO: Gil H. Harden
Assistant Inspector General for Audit
Office of the Inspector General

THROUGH: Catherine E. Woteki /s/
Under Secretary, REE
Chief Scientist, USDA

FROM: Chavonda Jacobs-Young /s/
Administrator

This memorandum is the Agricultural Research Service's (ARS) response to the five recommendations in the office report for audit number 02007-0001-31 on the United States Meat Animal Research Center (USMARC) Review.

Recommendation 1: Establish an ARS National Office oversight process through which a responsible official oversees the monitoring of Area Offices' and research facilities, including USMARC's, compliance with ARS policies, procedures, and other applicable requirements.

ARS Response:

ARS is committed to animal welfare and the humane treatment of animals employed in research at ARS laboratories. Since January 2015, ARS has taken major actions to strengthen the national animal handling and welfare program that oversees ARS animal research locations.

On June 28, 2015, ARS created a new position and hired a highly qualified individual as the ARS Animal Care and Use Officer (ACUO). The ACUO oversees animal health and welfare at all ARS locations, and is a resource for ARS field staff for animal handling and welfare best practices, procedures, and policies. A main responsibility of the ACUO is to coordinate an assessment program to verify the effectiveness of local oversight systems at all ARS locations that conduct research involving animals. This is executed through announced and unannounced internal audits of ARS animal research locations, Institutional Animal Care and Use Committees (IACUCs), and/or individual research projects to ensure compliance with ARS policy and applicable regulations and guidelines. Through this program, the ACUO is able to incorporate animal care and use best practices into ARS facility operations and research projects.

The ACUO also oversees the training of employees who care for and employ animals in research, and the training of IACUC members. The ACUO coordinates with each location's IACUC to develop site-specific, long-range training programs that will include periodic refresher training and

updates on new regulatory requirements and policies. Furthermore, the ACUO updates and oversees mandatory ARS policies and procedures for handling of all ARS research animals, tracks IACUC meeting minutes from all ARS locations, and reviews annual animal welfare reports from all animal research locations.

On February 23, 2015, ARS established the Animal Welfare Leadership Committee (AWLC), which is tasked with (1) coordinating, reviewing, and strengthening relevant ARS programs and offices and assisting Agency leadership in ensuring that animal health and welfare responsibility protocols are observed at all times, and (2) providing guidance to line managers in the field. This committee is comprised of ARS senior leaders from each ARS geographic area. It is chaired by the ARS Deputy Administrator for Animal Production and Protection and meets every other week.

Furthermore, on February 23, 2015, ARS established the Animal Welfare Task Force to provide leadership in redesigning, implementing, and monitoring ARS animal welfare and handling programs. This group manages ARS animal welfare and handling program assessment to identify gaps in current ARS animal care and use protocols and procedures, develops implementation plans to address these gaps, and facilitates the sharing of best practices across animal research locations in the Agency. This Task Force is composed of senior animal scientists from each ARS area. The ACUO chairs this Task Force.

The ARS executive chain of command, working through the ACUO and AWLC, oversees and enforces adherence to all animal welfare and handling policies and procedures in ARS. The ARS Administrator supervises the Associate Administrator for National Programs, who supervises the Deputy Administrator for Animal Production and Protection (APP), (a senior executive), who supervises the ACUO and chairs the AWLC. The ARS Administrator supervises the Associate Administrator for Research Operations, who supervises all geographic Area Directors with responsibility for implementing the research program at each of ARS' locations.

In addition, ARS partnered with the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). On February 11, 2016, the collaboration was codified in a Memorandum of Understanding (MOU). The MOU established a process to have ARS' animal research facilities registered, reviewed, and inspected by APHIS to verify full compliance with the Animal Welfare Act (AWA) and Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide).

ARS initiated registration of its 36 ARS animal research facilities with APHIS in August 2015 and APHIS began pre-compliance site visits that month. The pre-compliance review provides an opportunity for the agencies to go over the inspection framework with facility staff and helps the facility identify how it can successfully operate under the inspection framework. As of September 21, 2016, all but two animal research facilities have conducted a pre-compliance review. Pre-compliance reviews will be completed by October 21, 2016.

Based on the results of its reviews, APHIS will develop a schedule for carrying out subsequent unannounced inspections of ARS animal research facilities. The facilities will be inspected at least once a year and more often if necessary. APHIS inspectors will review IACUC

membership and training, meeting records from previous years (including the IACUC's review of research protocols and oversight), and other IACUC reports. APHIS inspectors will also inspect animals' health and well-being; animal enclosures and facilities; checklists, standardized forms and templates for consistent animal counts by species; veterinary records; and animal medications. Inspection reports from unannounced inspections of ARS facilities will be posted online in the Animal Care Information System database, as with all facilities APHIS inspects.

Recommendation 2: Revise ARS Policies and Procedures (P&P) related to animal welfare to more explicitly state the manner in which Area Offices and research facilities are to carry out their responsibilities, as prescribed within the directives, including the manner in which they are to document the performance of their responsibilities.

ARS Response:

ARS published an updated animal care and use P&P (USDA-REE P&P 130.4.v.2) on February 2, 2016. The new P&P ensures that ARS animal care and welfare protocols are consistent, effective, and compliant with the AWA and the Ag Guide. It also describes the responsibilities of the ARS Administrator, Associate Administrators, Deputy Administrator for APP, National Program Leaders, ACUO, Area Directors, ARS location Senior Management, Institutional Officials (IO), Attending Veterinarians, Research Leaders, Research Scientists and their support staff, and IACUCs.

Performance standards for Research Scientists and support staff require them to obey applicable animal care and use programs as outlined in USDA-REE P&P 130.4.v.2. This P&P describes the core principles that serve as a foundation for the compassionate care and ethical oversight of all animals that are employed in ARS research activities.

Furthermore, animal welfare is also included in official performance plans for Administrators, Area Directors, the APP Deputy Administrator, and other relevant Senior Executives. All of these ARS senior leaders are responsible for:

“(1) ensuring that the care and treatment of animals used for ARS research activities is consistent with all regulatory and policy requirements; (2) ensuring that all employees involved in animal care and use are properly trained; and (3) collaborating with APHIS to register ARS animal research facilities, and to establish an effective on-site review program to verify compliance with relevant AWA, Ag Guide standards, and ARS policies.”

Area Offices will also be charged to conduct an annual unannounced assessment of: 1) animal welfare, 2) IACUC composition and proceedings, 3) approved protocols, and 4) facility maintenance. This assessment is in addition to IACUC semiannual (2) inspections and routine APHIS annual unannounced inspections. Area Directors, Associate Area Directors, or designee of Area Directors will conduct the assessment. This additional assessment will give each animal research facility four assessments or inspections per year: 1) IACUC semiannual (2) inspections, 2) APHIS unannounced inspections, and 3) Area Office unannounced assessments. The charge will be included in a new version of the USDA-REE P&P 130.4.v.2 by December 1, 2016.

Activities under these responsibilities are to be documented during annual performance appraisals of each individual with responsibilities in animal welfare and handling. Employees

with these responsibilities will be held accountable during annual performance appraisals for failure to meet stated standards.

Recommendation 3: Establish a process through which ARS animal welfare related P&P are periodically reviewed and updated.

ARS Response:

The updated USDA-REE P&P 130.4.v.2, Institutional Care and Use Committee describes responsibilities of the ACUO to schedule and coordinate an **annual P&P review** to include advances in best practices, science, and technology. The ACUO coordinates with the AWLC to maintain relevance, ensure animal health and welfare protocols are observed, and receive suggestions from managers in the field. ARS leadership must approve the revised P&P. If circumstances arise during the year, ARS will not hesitate to update the P&P more frequently.

Recommendation 4: Establish a detailed, formal animal welfare complaint process through which any individual at a research facility, including cooperator employees, may report animal welfare issues. This process should include the thorough documentation of the details of the complaint, the steps taken to investigate it, and the ultimate resolution of the issue. This process should provide anonymity to the complainant, if desired, and be monitored by an official at ARS' National Office.

ARS Response:

In January 2015, the ARS Administrator appointed an ARS Animal Welfare Ombudsman to provide a confidential, impartial, and independent outlet for individuals and groups who have complaints or concerns related to animal welfare at ARS animal research facilities. The ARS Administrator also established an animal welfare e-mail box for internal and external concerns about ARS animal welfare. The e-mail address is: animalwellbeing@ars.usda.gov.

The updated USDA-REE P&P 130.4.v.2, Institutional Care and Use Committee, requires all ARS employees to report animal care incidents and concerns to the appropriate authorities at their location. A variety of options for reporting are available, which include informing a supervisor, an animal facility manager, a veterinarian, any member of the IACUC, and/or facility leadership. Anonymous reports can be submitted, and will be investigated fully by the IACUC. USDA-REE P&P 130.4.v.2 also requires each IACUC to develop a local policy that provides guidance and procedures for identifying, reporting, and investigating concerns related to animal care and use.

The local IACUC receiving complaints will make a determination to review, investigate, and provide any corrective actions needed to resolve the primary issue under investigation as well as to prevent future occurrences. The IACUC's conclusions must be conveyed to the Institutional Official (IO) and documented as part of the IACUC records within five (5) business days. The IO provides an incident report to that Area Office immediately upon receiving any report from the IACUC of an incident. The Area Offices are responsible for communicating to the Associate Administrator for Research Operations those reports. This process will be spelled out in an updated USDA-REE P&P 130.4.v.2 by December 1, 2016.

While individuals should initially communicate concerns directly to their local ARS leadership team as described above, they also have the discretion to report these issues to higher

management, or the ARS Ombudsman. The ARS Ombudsman has the responsibility to investigate and resolve concerns that are received, and works with the facility IACUC to ensure effective corrective actions are implemented to address any deficiencies that are identified in the investigation. The Ombudsman conducts these investigations in consultation with the Animal Welfare Task Force, which is led by the ACUO, as well as the local IO and Area Offices. The Ombudsman is also responsible for ensuring investigations and outcomes are properly documented and subsequently reported to the appropriate IO, Area Office, and the Associate Administrator for Research Operations. The Ombudsman also provides quarterly written reports to the ARS Administrator that summarize any activities.

A poster is prominently displayed at all animal research locations where ARS and/or cooperator employees work with animals. These posters outline the formal complaint process that is codified in the updated USDA-REE P&P 130.4.v.2, Institutional Care and Use Committee, referenced above. The Ombudsman's and alternate Ombudsman's contact information is also displayed on the poster. Furthermore, the Ombudsman's contact information is found on the ARS Web site front page under the "Quick Links," and on the front page of the ARS Web site under the "Resources" tab located here: <http://www.ars.usda.gov/main/main.htm>. Finally, the Ombudsman and alternate Ombudsman have a Web page that is easily searchable on the ARS Web site at: <https://www.ars.usda.gov/Aboutus/docs.htm?docid=25967>.

Recommendation 5: Increase the transparency at USMARC by making USMARC's approved research proposals, IACUC meetings, and other relevant information publicly available on ARS' Web site.

ARS Response:

ARS has a number of concerns with implementing OIG's recommendation to increase transparency at USMARC by making USMARC's approved research proposals, IACUC meetings, and other relevant information publicly available on the ARS' Web site.

The safety of ARS personnel at USMARC and other facilities that employ animal research is paramount. Since publication of the *New York Times* article in January 2015, USMARC employees have received multiple threats of physical harm from multiple sources. ARS has decided that the benefits gained from the release of details, other than those already released (discussed in next paragraph), which meet industry standards, do not outweigh the associated risks from domestic terrorism.

Secondly, the objectives and approaches of all approved ARS research projects, both appropriated and cooperatively funded with extramural partners, are readily available on the ARS Web site. Other relevant information is also available for each project through the ARS Web site, including, but not limited to, project objectives and other elements of project design, annual progress reports for the current and previous year's research, and journal publications resulting from the research. This information provides much transparency already. More information on specific experimental design is not included on the ARS Web site for any of our projects because of the competitive nature of agricultural research and the financial implications of premature release of information. Inadvertent release of research protocols prior to filing a patent at the United States Patent and Trademark Office could jeopardize the ability of ARS and its university cooperators to obtain patent rights, and thus compromise licensing and commercialization of their

work. The cost of developing these technologies into products (cost of commercialization) is substantial and protection of intellectual property is key to encouraging industry cooperation in the commercialization process. The Freedom of Information Act (FOIA) process is also available to members of the public.

As for the release of the IACUC reports, ARS intends to follow all relevant guidelines and requirements of the AWA, which does not specifically require public release of the minutes. In not posting the IACUC reports on its Web site, ARS is also following the practices set by other major Federal science agencies including the Department of Defense, the National Institutes of Health, the Veterans Administration, and the Food and Drug Administration, who also do not make their IACUC reports publicly available.

For these three reasons, ARS respectfully declines to accept the recommendation.

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