

Explanatory Note ASRU 2019-21 Annual Report

April 2024

The Animals in Science Regulation Unit (ASRU) has today issued corrections to data in its Annual Report for the period of 2019 to 2021 and to its non-technical summaries of project licences.

I can confirm that these are corrections to errors in data reporting only and that ASRU has fulfilled its licensing and compliance functions under the Animals (Scientific Procedures) Act 1986 (ASPA) ensuring the protection of animals used in science during this period. The errors relate to processes of data management and assurance that we have now corrected and are improving as part of reforms.

ASRU takes its responsibilities to the public and to the regulated community very seriously, and we understand the trust that is placed in ASRU to ensure the protection of animals in the regulation of animals in science. The actions we have taken, including inviting independent scrutiny and audit of ASRU and the transparent correction and explanation of the errors, demonstrate our determination that ASRU reforms and maintains the confidence of the regulated community, stakeholders and the public, in our vital work to protect animals used in science.

I explain below how the errors came about, what ASRU has done to put them right, and the actions ASRU is taking to ensure this does not happen again. Our annual reports provide transparency and assurance of how ASRU meets its responsibilities to regulate the use of animals in science under ASPA. ASRU published its Annual Report for the period of 2019 to 2021, on 26 October 2022.

In December 2022, ASRU identified discrepancies between the non-compliance cases published in the 2019-2021 Annual Report and the case data held by ASRU. After thorough investigation, ASRU established that there were multiple data errors caused by inadequate information management and quality assurance processes within ASRU. The majority of published errors relate to the numbers of animals involved in each case, details of the breach of law committed and details of the actions taken by ASRU in response. In addition, a small number of non-compliance cases were identified that are in ASRU's records but were not published in the original report. These were data reporting errors only; appropriate compliance action was taken in each case.

ASRU also reviewed non-technical summaries (NTSs) published from 2019 – 2021, which found an error linked to the transition to a new electronic licensing system in August 2019. This resulted in the duplication of 327 NTS in 2019, the omission of 7 NTSs in 2020 and the omission of 4 NTSs in 2021.

ASRU took the following steps in response to the identification of these data errors:

- 1. Conducted an internal investigation and quality assurance (QA) process to assess accuracy of the data published and the extent of errors;
- 2. Commissioned an external review and validation of ASRU's QA by Home Office analysts; and

3. Invited independent audit by the Government Internal Audit Agency (GIAA) to review the adequacy and effectiveness of ASRU's current information management practices, quality assurance controls and governance arrangements.

The external review and independent audit were completed in January 2024.

The correct data has been validated and is published alongside this note. A summary of corrections to the 2019-2021 Annual Report is provided in the re-published document (which can be found here: <u>https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-reports-2019-to-2021</u>)

The independent audit recognised that ASRU has made good progress in its information management since 2019 but that further work is needed to meet the high standard expected of a government department. ASRU has accepted all the GIAA's recommendations and has started work to implement these. ASRU will be held to account through regular reporting to the Home Office Audit and Risk Assurance Committee (details of which can be found here: <u>https://www.gov.uk/government/organisations/home-office/about/our-governance</u>).

In response to the GIAA recommendations ASRU will:

- monitor error rates in non-compliance data to identify underlying causes and ensure published data is correct;
- update standard operating procedures for internal non-compliance processes for managing published data;
- develop further internal guidance to ensure consistency in processes for compiling non-compliance data for annual reports;
- determine the scope and implementation of management information required for monitoring workflows in non-compliance; and
- review how data is controlled to mitigate the risk of errors in stored information.

ASRU has also republished the NTS for every project licence granted from 2019 to 2021 to provide a complete record in an improved and more accessible format. To aid usability and identification of those projects that require a retrospective assessment, NTS are now presented in two documents: one for those that do not require a retrospective assessment and another for those that require a retrospective assessment. ASRU is now publishing NTSs in a routine and predictable manner, every 3 months (which can be found here: https://www.gov.uk/government/collections/animals-in-science-regulation-unit#non-technical-summaries

I trust that the actions taken demonstrate ASRU's commitment to a high standard of delivery, accountability and transparency of its work to protect animals used in science by maintaining compliance with the ASPA.

Kate Chandler, Head of the Animals in Science Regulation Unit, Home Office

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Any enquiries regarding this publication should be sent to us at <u>ASRUOperationalRelationshipManagement@homeoffice.gov.uk</u>.