

Assessment of compliance with the Code of Practice for Official Statistics

Statistics on Scientific Procedures on Living Animals

(produced by the Home Office)

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About the UK Statistics Authority

The UK Statistics Authority is an independent body operating at arm's length from government as a non-ministerial department, directly accountable to Parliament. It was established on 1 April 2008 by the *Statistics and Registration Service Act 2007*.

The Authority's overall objective is to promote and safeguard the production and publication of official statistics that serve the public good. It is also required to promote and safeguard the quality and comprehensiveness of official statistics, and good practice in relation to official statistics.

The Statistics Authority has two main functions:

1. oversight of the Office for National Statistics (ONS) – the executive office of the Authority;
2. independent scrutiny (monitoring and assessment) of all official statistics produced in the UK.

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ASSESSMENT AND DESIGNATION

The *Statistics and Registration Service Act 2007* gives the UK Statistics Authority a statutory power to assess sets of statistics against the *Code of Practice for Official Statistics*.

Assessment will determine whether it is appropriate for the statistics to be designated as National Statistics.

Designation as National Statistics means that the statistics comply with the *Code of Practice*. The *Code* is wide-ranging. Designation can be interpreted to mean that the statistics: meet identified user needs; are produced, managed and disseminated to high standards; and are explained well.

Designation as National Statistics should not be interpreted to mean that the statistics are always correct. For example, whilst the *Code* requires statistics to be produced to a level of accuracy that meets users' needs, it also recognises that errors can occur – in which case it requires them to be corrected and publicised.

Assessment reports will not normally comment further on a set of statistics, for example on their validity as social or economic measures. However, reports may point to such questions if the Authority believes that further research would be desirable.

Assessment reports typically provide an overview of any noteworthy features of the methods used to produce the statistics, and will highlight substantial concerns about quality. Assessment reports also describe aspects of the ways in which the producer addresses the 'sound methods and assured quality' principle of the *Code*, but do not themselves constitute a review of the methods used to produce the statistics. However the *Code* requires producers to "seek to achieve continuous improvement in statistical processes by, for example, undertaking regular reviews".

The Authority may grant designation on condition that the producer body takes steps, within a stated timeframe, to fully meet the *Code's* requirements. This is to avoid public confusion and does not reduce the obligation to comply with the *Code*.

The Authority grants designation on the basis of three main sources of information:

- i. factual evidence and assurances by senior statisticians in the producer body;
- ii. the views of users who we contact, or who contact us, and;
- iii. our own review activity.

Should further information come to light subsequently which changes the Authority's analysis, it may withdraw the Assessment report and revise it as necessary.

It is a statutory requirement on the producer body to ensure that it continues to produce the set of statistics designated as National Statistics in compliance with the *Code of Practice*.

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1 Summary of findings

1.1 Introduction

- 1.1.1 This is one of a series of reports¹ prepared under the provisions of the *Statistics and Registration Service Act 2007*². The Act requires all statistics currently designated as National Statistics to be assessed against the *Code of Practice for Official Statistics*³. The report covers the set of statistics reported in *Statistics of Scientific Procedures on Living Animals, Great Britain 2010*⁴ (SPLA), produced by the Home Office.
- 1.1.2 Section 3 of this report adopts an ‘exception reporting’ approach – it includes text only to support the Requirements made to strengthen compliance with the *Code* and Suggestions made to improve confidence in the production, management and dissemination of these statistics. This abbreviated style of report reflects the Head of Assessment’s consideration of aspects of risk and materiality⁵. The Assessment team nonetheless assessed compliance with all parts of the *Code of Practice* and has commented on all those in respect of which some remedial action is recommended.
- 1.1.3 This report was prepared by the Authority’s Assessment team, and approved by the Board of the Statistics Authority on the advice of the Head of Assessment.

1.2 Decision concerning designation as National Statistics

- 1.2.1 The Statistics Authority judges that the statistics covered by this report are readily accessible, produced according to sound methods and managed impartially and objectively in the public interest, subject to any points for action in this report. The Statistics Authority confirms that the statistics published in SPLA are designated as National Statistics, subject to the Home Office implementing the enhancements listed in section 1.5 and reporting them to the Authority by August 2012.

1.3 Summary of strengths and weaknesses

- 1.3.1 The statistics on scientific procedures on living animals (SPLA statistics) have important legislative uses to meet the requirements set out in the UK’s *Animals (Scientific Procedures) Act 1986*⁶ and European Council Directive *86/609/EEC*⁷ of 24 November 1986. Users told us that the statistics also have an important wider use to provide transparency about the use of animals in research and to inform public debate. The Home Office has taken steps to ensure that it has

¹ <http://www.statisticsauthority.gov.uk/assessment/assessment-reports/index.html>

² http://www.opsi.gov.uk/Acts/acts2007/pdf/ukpga_20070018_en.pdf

³ <http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html>

⁴ <http://www.homeoffice.gov.uk/publications/science-research-statistics/research-statistics/other-science-research/spanimals10/>

⁵ <http://www.statisticsauthority.gov.uk/assessment/assessment/guidance-about-assessment/criteria-for-deciding-upon-the-format-of-an-assessment-report.pdf>

⁶ <http://www.legislation.gov.uk/ukpga/1986/14/contents>

⁷ http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l28104_en.htm

identified a range of classes of user, but is not proactive in its engagement with all of them.

- 1.3.2 The statistics have a long time series which provide a rich source of data demonstrating how trends in the use of animals in research have changed over time. However the commentary presented within the release does not discuss and explain these trends sufficiently. The commentary also does not provide sufficient contextual information to ensure that the statistics are interpreted appropriately.

1.4 Detailed recommendations

- 1.4.1 The Assessment team identified some areas where it felt that the Home Office could strengthen its compliance with the *Code*. Those which the Assessment team considers essential to enable designation as National Statistics are listed in section 1.5. Other suggestions, which would improve the statistics and the service provided to users but which are not formally required for their designation, are listed at annex 1.

1.5 Requirements for designation as National Statistics

| | |
|----------------------|--|
| Requirement 1 | Seek ways to engage users of the statistics, document their needs, and use this information to better support the use of the statistics (para 3.2). |
| Requirement 2 | Publish information about why the UK has adopted a different counting procedure to that used by other countries (para 3.4). |
| Requirement 3 | Improve the information provided about the quality and reliability of the statistics to ensure that users are informed of all main sources of error (para 3.5). |
| Requirement 4 | Improve the commentary and contextual information in the releases so that it aids user interpretation of the statistics (para 3.7). |
| Requirement 5 | Review the choice of email address provided so that users' enquires are directed straight to the statistical team rather than through a generic public enquiries mailbox (para 3.8). |

2 Subject of the assessment

- 2.1 *SPLA* is an annual publication which presents statistics on the numbers of scientific procedures carried out on living animals, by species and type of procedure. The Home Office produces the statistics under the auspices of the *Animals (Scientific Procedures) Act 1986 (ASPA 1986)* and *Article 26 of European Union Directive 86/609/EEC*. A revision to *Directive 86/609/EEC* will be implemented in 2014 which will require the inclusion of a measure of the severity of procedures. The Home Office is currently consulting users about the forthcoming change to the statistics.
- 2.2 The Home Office compiles the statistics from data provided by individuals who hold licenses⁸ for the use of living animals in research. In 2011, the Home Office requested data from roughly 2000 license holders and received responses from 99.5% of them. The Home Office's Animals Scientific Procedures Division and Inspectorate⁹ is responsible for ensuring that all legal requirements are adhered to in relation to the use of animals in scientific procedures. This includes the management of the licensing process and collecting and assuring the quality of the data that are used to produce the statistics. Once quality assured, the data from licensees in Great Britain are passed to the statistical team which produces *SPLA*. The Home Office sends data for licensees who are based in Northern Ireland to the Department of Health, Social Services and Public Safety¹⁰ (DHSSPS). DHSSPS uses the data to produce an annual publication – *Scientific Procedures on Living Animals in Northern Ireland*¹¹. The Home Office is not involved in the production and publication of this release. *Scientific Procedures on Living Animals in Northern Ireland* is not currently designated as a National Statistics publication.
- 2.3 Most data are collected using a paper questionnaire; in 2009 the Home Office piloted a new method of data collection which enabled ten per cent of licensees to return data electronically. The Home Office told us that it plans to offer this method of data collection to all licensees following the implementation of the new European Directive.
- 2.4 Some users of the statistics are invited to sit on the Animal Procedures Committee (APC)¹² which is an advisory non-departmental public body. The APC includes members who have specialist knowledge about scientific procedures that use animals and the Home Office's licensing process, for example medical practitioners and veterinary surgeons. The membership structure is governed by rules set out in the *ASPA 1986* and members are appointed in accordance with guidelines provided by the Office of the Commissioner for Public Appointments. The role of the APC is to advise the

⁸ Individuals must hold both a personal license and a license for the specific programme of work <http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/licences/personal-licences/?view=Standard&pubID=788367> and <http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/licences/project-licences/?view=Standard&pubID=788349>

⁹ <http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/licences/licensing-charter/>

¹⁰ <http://www.dhsspsni.gov.uk>

¹¹ <http://www.dhsspsni.gov.uk/healthprotection-animalscience>

¹² <http://www.homeoffice.gov.uk/agencies-public-bodies/apc/>

Home Secretary on matters concerned with *ASPA 1986*. The APC also contributes to the development of the SPLA statistics by providing the statistical team with specialist information about scientific procedures.

- 2.5 The statistics receive broad media coverage¹³ and are used by some MPs within Parliamentary debate¹⁴. Research organisations use the statistics to monitor changes in the use of animals in research. Academics use the statistics in teaching to present historic trends to students and to prompt discussions within the context of ethical training. An organisation which funds research told us that it uses the statistics in its policy documents, for example when providing responses to government consultations. Several users told us that they think the statistics are important for ensuring that the public is able to access information about the use of animals in research, and hence demonstrate a level of transparency.
- 2.6 The Home Office told us that it costs about £40,000 per annum to produce the statistics. The Home Office also told us that it costs an additional £3,800 every three years to produce the statistics requested under European Directive *86/609/EEC*.

¹³ BBC 4 Today Programme: http://news.bbc.co.uk/today/hi/today/newsid_9537000/9537915.stm
BBC News: <http://www.bbc.co.uk/news/science-environment-14137335>
Daily Express: <http://www.express.co.uk/posts/view/258613/Animal-experimentation-hits-25-year-high-as-3-6-million-animals-are-targeted>
The Times: <http://www.thetimes.co.uk/tto/science/medicine/article3093631.ece>
Financial Times: <http://www.ft.com/cms/s/0/7cebc3bc-ad5f-11e0-bc4f-00144feabdc0.html#axzz1S4BB70J8>
Nature News: http://blogs.nature.com/news/2011/07/upward_trend_continues_for_uk.html
Daily Mirror: <http://www.mirror.co.uk/news/top-stories/2011/07/14/animal-testing-figures-soar-and-leave-campaigners-furious-115875-23269336/>
The Independent: <http://www.independent.co.uk/news/science/experiments-on-animals-rise-again-2313306.html>
The Guardian: <http://www.guardian.co.uk/science/2011/jul/13/animal-experiments-rise>
Daily Mail: <http://www.dailymail.co.uk/sciencetech/article-2014279/Huge-rise-vivisection-3-7m-experiments-animals-carried-year.html>

¹⁴ <http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm090224/halltext/90224h0004.htm>

3 Assessment findings

- 3.1 The Home Office regularly engages with users via a quarterly newsletter¹⁵ which is published on its website. The newsletter includes information about legislation that is relevant to the statistics, and forthcoming consultations and events. The Home Office held a consultation¹⁶ during 2009, and used the feedback to deliver improvements to the statistics, for example the tables are now published in Excel format. However it received only a small number of responses from users.
- 3.2 As well as formal consultations, the statistics team regularly consults the APC about the content of the questionnaire and accompanying guidance that is sent to licensees. However, not all users can become members of the APC because its membership is governed by rules set out in *ASPA 1986*. Several users told us that they had not been contacted by the Home Office in relation to the SPLA statistics but that they would welcome this in future. The Home Office has used the UK Statistics Authority's publication *The Use Made of Official Statistics*¹⁷ to identify several classes of use that are relevant to the statistics, and published this information in a user guide¹⁸. However the Home Office does not proactively engage with all of the types of users that it has identified within the guide. As part of designation as National Statistics, the Home Office should seek ways to engage users of the statistics, document their needs, and use this information to better support the use of the statistics¹⁹ (Requirement 1). In addition, we suggest that the Home Office include a link to the user guide from the main landing page for the SPLA statistics.
- 3.3 *SPLA* and the user guide both contain information about the methods used to compile the statistics. For example, the user guide includes some information about the data collection process and the definitions and classifications that are used. The user guide also includes copies of the questionnaire and guidance notes that are sent to licensees.
- 3.4 *SPLA* explains that the statistics refer to the numbers of procedures that have been carried out, not the numbers of animals that are used²⁰. The Home Office told us that this method of counting is more appropriate for the main uses of the statistics because it enables information to be captured about animals that are used several times within the reference period. However, this approach differs from other European countries whose equivalent statistics refer to numbers of animals rather than numbers of procedures. The Home Office also told us that

¹⁵ <http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/aspa-newsletters/aspa-newsletter-january-2012>

¹⁶ <http://webarchive.nationalarchives.gov.uk/20100418065544/http://www.homeoffice.gov.uk/documents/cons-2009-living-animals-stats/index.html>

¹⁷ <http://www.statisticsauthority.gov.uk/assessment/monitoring/monitoring-briefs/monitoring-brief-6-2010---the-use-made-of-official-statistics.pdf>

¹⁸ <http://www.homeoffice.gov.uk/publications/science-research-statistics/research-statistics/other-science-research/guide-animal-procedures>

¹⁹ In relation to Principle 1, Practice 1 and Protocol 1, Practice 1 of the *Code of Practice*

²⁰ The Home Office also produces some separate statistics on the numbers of animals used in scientific procedures to meet the requirements of Directive 86/609/EEC; these are also included in *SPLA*

it has also adopted a broader definition of 'scientific procedure' than some other countries, to include procedures carried out to maintain breeding colonies. Where comparisons are drawn with statistics from other countries, *SPLA* describes how the UK statistics differ but it does not explain why. As part of the designation as National Statistics, the Home Office should publish information about why the UK has adopted a different counting procedure to that used by other countries²¹ (Requirement 2).

- 3.5 The user guide that is published alongside *SPLA* includes some brief information about the quality of the statistics; for example, it states that the data collection exercise achieved a response rate of 99.5 per cent. However the Home Office has not published information about other aspects of quality, for example the completeness of the returns received from licensees. The user guide includes some information about the quality assurance procedures that the Home Office carries out, for example checking data against previous years, and checking unusual combinations of responses. However, it does not explain potential sources of error that may not be detected by quality assurance processes, for example licensees' misinterpretation of the questionnaire or guidance notes. As part of the designation as National Statistics, the Home Office should improve the information provided about the quality and reliability of the statistics to ensure that users are informed of all main sources of error²² (Requirement 3).
- 3.6 During 2006, the *SPLA* statistics were included within the scope of a review²³ which sought to determine whether or not EU data requirements place an unnecessary burden on data suppliers. In relation to the *SPLA* statistics, the review concluded that licensees find the questionnaire burdensome and complex²⁴ and that simplifying it would be desirable. The Home Office told us that following the outcome of the review, it conducted a survey to assess the level of burden experienced by license holders. However it is not clear how the Home Office has used the results of the survey. We suggest that the Home Office publish the results of the survey and explain how they were used. The Home Office also told us that it is in the process of developing an administrative database to store information from license applications – which could be used in future to produce the *SPLA* statistics. We welcome this and suggest that the Home Office also publish information about its plans to develop such an administrative database.
- 3.7 *SPLA* presents statistics in charts and tables and compares them with previous years. A time series is available from 1945 for some of the statistics; however the commentary presented alongside the data does not sufficiently interpret and explain the trends that are presented. Other parts of the release include helpful commentary, for example by explaining that a large proportion of the increase in the number of procedures is accounted for by breeding procedures. The release does not include any information about the length of time taken to

²¹ In relation to Principle 4, Practice 6 of the *Code of Practice*

²² In relation to Principle 4, Practice 2 of the *Code of Practice*

²³ The review was conducted by Lord Davidson and the outcome is published at <http://webarchive.nationalarchives.gov.uk/+http://www.bis.gov.uk/policies/better-regulation/reviewing-regulation/simplifying-eu-legislation-davidson-review>

²⁴ Paragraphs 2.48 to 2.49 of the review

complete procedures; including this would provide an important context for interpreting the statistics, for example in instances where procedures continue for longer than one year. The release does not sufficiently explain technical terms, such as ‘harmful mutants’ and ‘rodenticide trials’, which makes the release inaccessible to the non-expert user. The release includes some information about the policy context within which the statistics have been collected, for example, Annex A describes *ASPA 1986*. However, as a whole, the release does not include sufficiently accessible information to ensure that the statistics are interpreted appropriately. As part of the designation as National Statistics, the Home Office should improve the commentary and contextual information in the releases so that it aids user interpretation of the statistics²⁵ (Requirement 4). We suggest that in meeting this requirement the Home Office should consider the points detailed in annex 2.

- 3.8 *SPLA* includes the name of the Home Office’s chief statistician and a generic email address. Ordinarily the *Code of Practice* requires that statistical releases include contact details for the responsible statistician. Given the sensitivity and importance of the statistics, we consider that it is appropriate to include the contact details of the Home Office’s senior statistician. However, the email address provided is a general mailbox. As part of the designation as National Statistics, the Home Office should review the choice of email address provided so that users’ enquires are directed straight to the statistical team rather than through a generic public enquiries mailbox²⁶ (Requirement 5).

²⁵ In relation to Principle 8, Practice 2 of the *Code of Practice*

²⁶ In relation to Protocol 2, Practice 6 of the *Code of Practice*

Annex 1: Suggestions for improvement

A1.1 This annex includes some suggestions for improvement to the Home Office's statistics on scientific procedures on living animals, in the interest of the public good. These are not formally required for designation, but the Assessment team considers that their implementation will improve public confidence in the production, management and dissemination of official statistics.

- | | |
|---------------------|---|
| Suggestion 1 | Include a link to the user guide from the main landing page for the SPLA statistics (para 3.2). |
| Suggestion 2 | Publish the results of the survey of licensees and explain how they were used (para 3.6). |
| Suggestion 3 | Publish information about the plans to develop an administrative database which may replace the data collection process in future (para 3.6). |
| Suggestion 4 | Consider the points detailed in annex 2, in seeking to improve the statistical releases (para 3.7). |

Annex 2: Compliance with Standards for Statistical Releases

- A2.1 In October 2010, the Statistics Authority issued a statement on *Standards for Statistical Releases*²⁷. While this is not part of the *Code of Practice for Official Statistics*, the Authority regards it as advice that will promote both understanding and compliance with the *Code*. In relation to the statistical releases associated with SPLI Statistics, this annex comments on compliance with the statement on standards.
- A2.2 In implementing any Requirements of this report (at paragraph 1.5) which relate to the content of statistical releases, we encourage the producer body to apply the standards as fully as possible.

Appropriate identification of the statistics being released

- A2.3 The title of the release describes both the coverage of the statistics (Great Britain) and the period to which the statistics relate. The frequency of the release is not explicitly stated, but it is implied within the text. The release uses standard headings and logos throughout.
- A2.4 The release includes the name of the originating department and the chief statistician. The release includes a contents list at the beginning which indicates what is included in terms of the tables and subjects discussed. The text makes clear which of the statistics presented are new.

Include commentary that is helpful to the non-expert and presents the main messages in plain English

- A2.5 The 'main points' identified in the summary section are difficult to interpret without appropriate explanation of the technical terms that are used, for example 'genetically modified animals' and 'harmful mutants'. It is not clear what is meant by the term 'procedure' and specific procedures that are mentioned, for example, 'non-toxicology procedures' are not explained. The release's use of technical language without sufficient explanation or relevant contextual information prevents the release from being accessible to wider audiences.
- A2.6 Graphs are presented alongside the commentary to illustrate trends and all the statistical tables are presented separately at the end of the release. Pie charts are used to illustrate the proportions of species used in procedures; the pie chart does not specify the base number of procedures, although this information is included within the text. Time trends are presented graphically; however, the commentary does not always explain the trends or provide potential reasons for them. For example, the bar chart in figure 1 (of the 2010 release) shows the number of experiments or procedures that were started in each year going back as far as 1945, but the trend is not described in the text. The release does not include sufficient explanation about the types of scientific

²⁷ <http://www.statisticsauthority.gov.uk/news/standards-for-statistical-releases.html>

activities that count as a 'procedure' or the length of time taken to complete procedures.

- A2.7 The release includes a section on international comparisons which presents a brief summary of the statistics in comparison with equivalent statistics from other EU member states. This section also presents some statistics for the EU as a whole on the total number of animals used in scientific experiments, and links to the European statistics. The release also links to equivalent statistics for Northern Ireland. However, the commentary does not draw comparisons with the equivalent statistics for Northern Ireland.

Use language that is impartial, objective and professionally sound

- A2.8 The language used in the release is impartial and professionally sound. The descriptive statements are demonstrably consistent with the statistics presented.

Include information about the context and likely uses

- A2.9 At the beginning of the release is a brief summary of the policy context within which the statistics have been collected and will be used. There is scope to expand this section so that it also describes the wider uses of the statistics. The release does not include any information about the length of procedures. Given that the statistics show the number of procedures started within the year, it would be helpful to include information about the length of time taken to complete the procedures, as this would provide an important context for interpreting the statistics.
- A2.10 The release does not include sufficient information about the quality and reliability of the statistics in relation to the range of potential uses.

Include, or link to, appropriate metadata

- A2.11 The release includes a brief description of the methods used to compile the statistics, including some information about the definitions and counting procedures that are used. More detailed information is available in a separate 'user guide'; it would be helpful to provide a link to this document. The release does not include or link to sufficient information about the quality and reliability of the statistics.

Annex 3: Summary of assessment process and users' views

A3.1 This assessment was conducted from January to April 2012

A3.2 The Assessment team – Ruth James and Penny Babb – agreed the scope of and timetable for this assessment with representatives of the Home Office in January. The Written Evidence for Assessment was provided on 18 January. The Assessment team subsequently met the Home Office during February to review compliance with the *Code of Practice*, taking account of the written evidence provided and other relevant sources of evidence.

Summary of users contacted, and issues raised

A3.3 Part of the assessment process involves our consideration of the views of users. We approach some known and potential users of the set of statistics, and we invite comments via an open note on the Authority's website. This process is not a statistical survey, but it enables us to gain some insights about the extent to which the statistics meet users' needs and the extent to which users feel that the producers of those statistics engage with them. We are aware that responses from users may not be representative of wider views, and we take account of this in the way that we prepare Assessment reports.

A3.4 The Assessment team received 12 responses from the user consultation. The respondents were grouped as follows:

| | |
|--------------------------------|---|
| Academia | 1 |
| Research organisations/funders | 3 |
| Professional organisation | 1 |
| Voluntary sector | 2 |
| Public body | 1 |
| Data suppliers | 4 |

A3.5 Several users told us that they use the commentary provided by the Home Office and find it helpful. However some also thought that it would be helpful to have more detail, for example by providing some explanation about why the statistics have changed. Users would welcome:

- having the statistics broken down further to show specific types of procedures in different areas of research;
- more detail in certain areas, for example in relation to severity of the procedure;
- a distinction between procedures carried out on animals in academic research and those carried out in industry;
- greater clarity about the distinction between the number of procedures carried out and the number of animals used; and
- a better understanding how the data are processed.

A3.6 Some users told us that they were in regular contact with the Home Office, for example in relation to the implementation of the new European Directive. These users were complementary about the statistical team's engagement. However,

several other users told us that they have not been approached by the Home Office for consultation, but would welcome some form of engagement.

A3.7 Several data suppliers said that they would record some of the information requested anyway, although not necessarily in the same format. Generally, suppliers did not report any problems with returning data, although some said that at first it can be difficult to grasp the concept of what is required.

Key documents/links provided

Written Evidence for Assessment document

