



Home Office

# Updates from the ASRU Team

Will Reynolds, Kate Garrod – 1<sup>st</sup> presentation,  
Kate Chandler, Giles Paiba – 2<sup>nd</sup> presentation  
November 2018

# Topics

## 1st Session

- Fees
- ASPeL replacement
- PPL applications – improving the process
- Current ASPeL
- PPL applications – current situation
- Service licences
- NC3Rs MOU
- Themed inspections

## 2<sup>nd</sup> Session

- Policy Updates
- Brexit
- RoPs and additional data



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# Fees

# Fees – 19/20

- Invoicing...
- To deliver we must be sustainable - fees

Establishment:

Current fee £757

Increase to £826 Increase of £69 (9%)

Personal:

Current fee £257

Increase to £275 Increase of £18 (7%)



# Why the fees uplift?



- To assure continued delivery of the statutory requirements of ASPA – Full Cost Recovery
- Forecast 2019/20 deficit due to:
  - Salary (staff req. and rises)
  - Capital depreciation
  - Risk meetings
- Marginal increases in:
  - Training and conference costs
  - Travel
- Continued investment in IT





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# ASPeL Replacement

# ASPeL – vision (1)



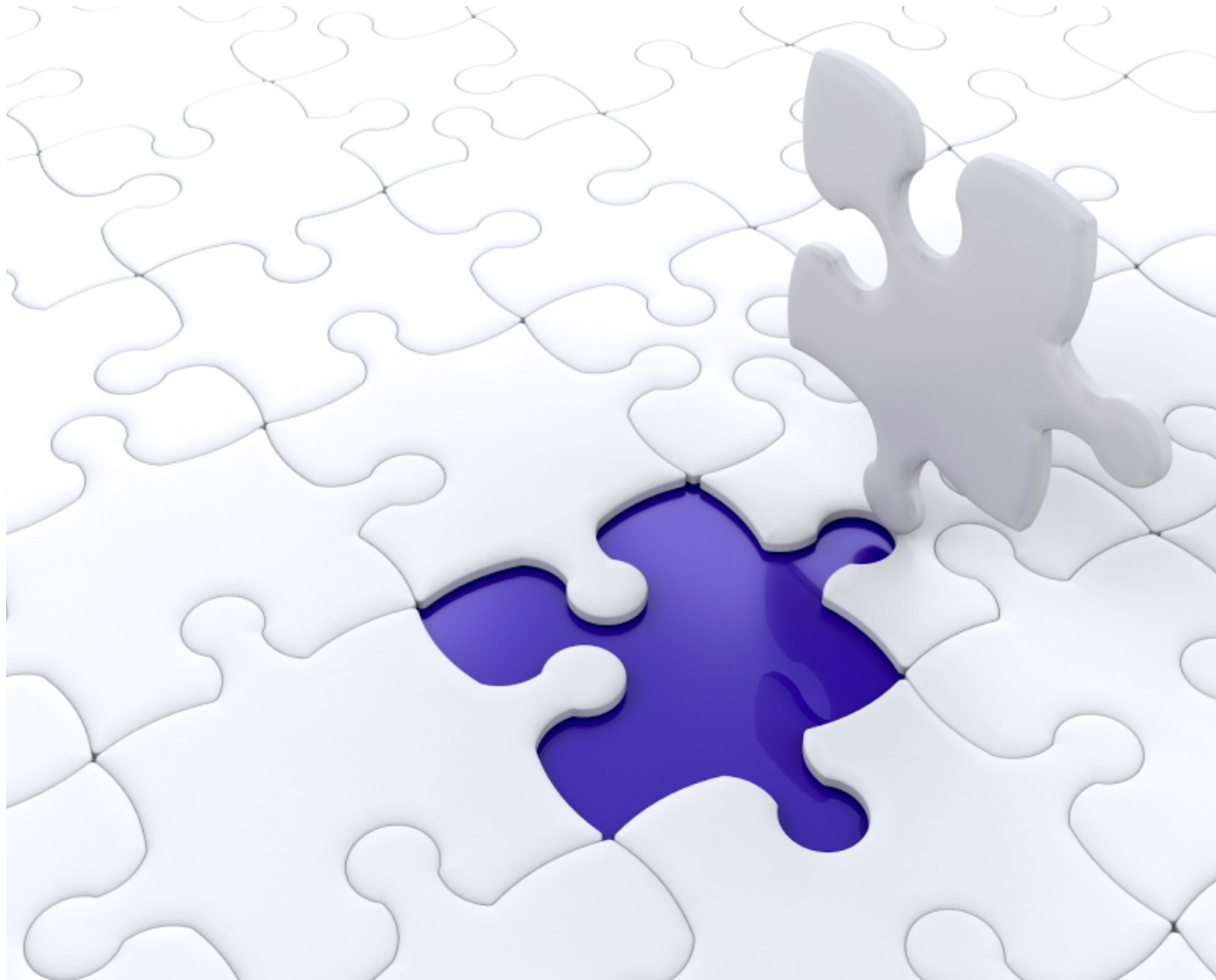
# ASPeL vision (2)



# ASPeL vision (3) (licences)



# ASPeL (vision 4)



# ASPeL replacement: A two task project

- **Replace the current online system**
  - The contract for our existing IT system ends in August 2019
  - Opportunity to rebuild according to Gov.uk standards
- **Redesign the PPL application process**
  - Simultaneously, we will launch a redesigned PPL
  - New application form that is easier to complete
  - New licence that displays authorities more clearly
  - Simplified amendment process

# Design

“It’s instantly familiar to Government websites”

- **Government Digital Standards**
  - Synergy across all Gov.uk systems
  - Produced in agile – future proofing and open for continual development
  - Intuitive and consistent with all Government digital services
  - **“Building so users succeed first time”**

<https://www.gov.uk/service-manual/service-standard>



# Stakeholder engagement

- In developing the backbone to the system the research community has been utilised
- Built based on both user needs and feedback on problem areas of existing ASPeL
- Highly iterative design, refined through extensive user testing and publicly reported each week.

# Weekly reports in public

- [Ukhomeofficegithub.io/asl-reporting](https://ukhomeofficegithub.io/asl-reporting)
- Includes all prototypes and feedback process

## ASL Delivery Reports

### ASL Delivery Reports

[Report 7th November 2018 - Sprint 20 - mid-sprint](#)

[Report 31st October 2018 - Sprint 20](#)

[Report 24th October 2018 - Sprint 19 - mid-sprint](#)

[Report 17th October 2018 - Sprint 19](#)

[Report 10th October 2018 - Sprint 18 - mid-sprint](#)

[Report 3rd October 2018 - Sprint 18](#)

[Report 25th September 2018 - Sprint 17 - mid-sprint](#)



# Designs for PEL

PROTOTYPE This is a new service - your feedback will help us to improve it

Home > Licensed premises

University of Croydon

## Licensed premises

Provides an easily manageable view of the schedule of premises

Filter by:

Site

- All
- Bromley Aviary
- Croydon Farm
- Thornton Heath Fishery

[More...](#)

Suitability

- All
- Small animals (SA)
- Large animals (LA)
- Aquatic species (AQ)
- Birds (AV)

[More...](#)

Holding

- All
- Short term holding (STH)
- Not for overnight holding (NOH)
- Sterile experimental procedures (SEP)
- Non-sterile experimental procedures (NSEP)
- Long term holding (LTH)

Apply filter

[Clear filter](#)

Label

List

Site ▼	Area	Suitability	Holding	NACWO ▼	Restrictions
Bromley Aviary	All cages	AV	LTH	<a href="#">Barry Rogers</a>	-
Bromley Aviary	Recovery Room L2	AV	STH	<a href="#">Edward Lee</a>	<a href="#">Restrictions</a> ▼
Bromley Aviary	Science building Lab 1	AV	NOH, SEP	<a href="#">Edward Lee</a>	<a href="#">Restrictions</a> ▼

# Ability to easily access 'people'

PROTOTYPE This is a new service - your feedback will help us to improve it

Home > Named people and personal licence holders

University of Croydon

## Named individuals and licence holders

[All](#) [A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

All

NACWO

NIO

NVS

NTCO

NPRC

PELH

PIL

HOLC

[Edward Lee](#)  
NACWO



[Natalie Page](#)  
NACWO



[Barry Rogers](#)  
NACWO



### Edward Lee

[Print](#) [Download](#)

Named Animal Care and Welfare Officer  
(NACWO)

[Personal Licence \(ref: xxx licence number\)](#)

**Address**

The Fish facilities lab  
Division of Animal Science  
University of Croydon  
2 Lansdowne Road  
Croydon

**Postcode**  
CR0 1TT



Provides an easily manageable view of people and licence holders



# Web patterns follow gov.uk standards

[◀ Back to Tasks](#)

## Amend approved area

- 1. View proposed amendment
- 2. View inspector recommendation
- 3. Change restrictions
- 4. Make decision

### Step 1: Proposed amendment

Submitted by [Angela Smith](#) on behalf of [William Blanc](#) on 2 June 2018.

	Current	Proposed
<b>Site</b>	Apollo House	Apollo House
<b>Area</b>	1/F	1/F
<b>Name</b>	LG36	LG36
<b>Suitability</b>	SA	SA, <a href="#">AV</a> , <a href="#">DOG</a>
<b>Holding</b>	STH	<a href="#">LTH</a>
<b>NACWO</b>	<a href="#">Gareth Tindall</a>	<a href="#">Gareth Tindall</a>

#### Current restrictions

- Perfusion under general anesthetic & Schedule 1 killing
- Monday to Thursday only

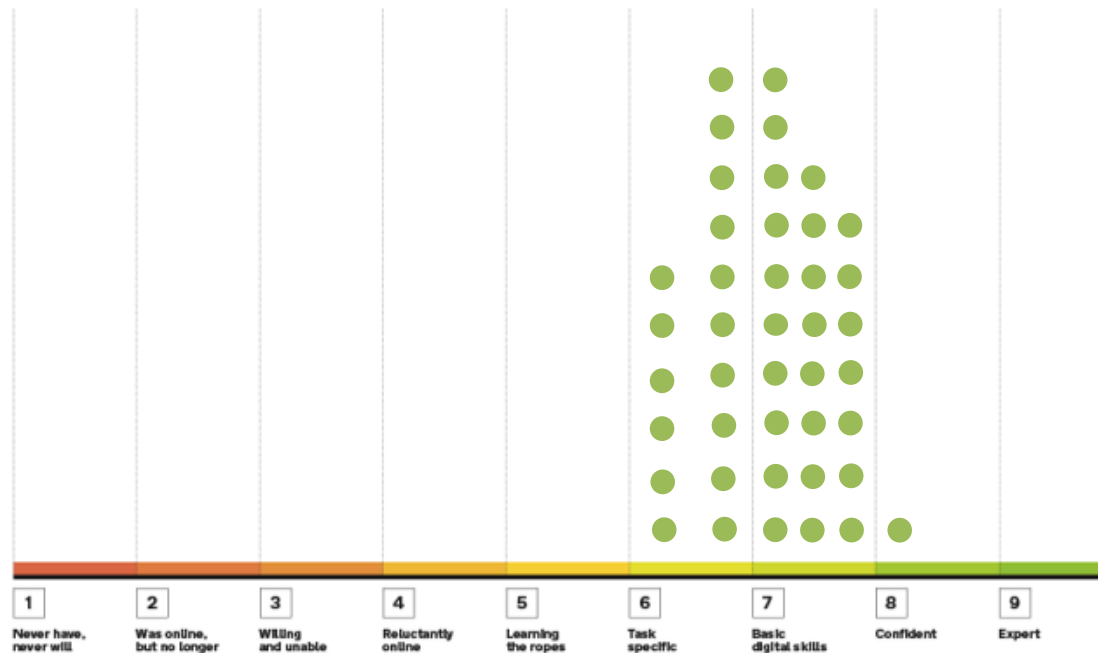
#### What changes are needed to the current restrictions?

[Both restrictions should be removed.](#)

# Engagement so far:

- So far, we engaged individually with:
  - **80+** scientists, named people and HOLCs
  - **21** inspectors (out of 22)
  - **10** licensing / ASRU staff
- Also got feedback from:
  - **70+** HOLCs and named people at two HOLTIF meetings

# Improving accessibility and usability

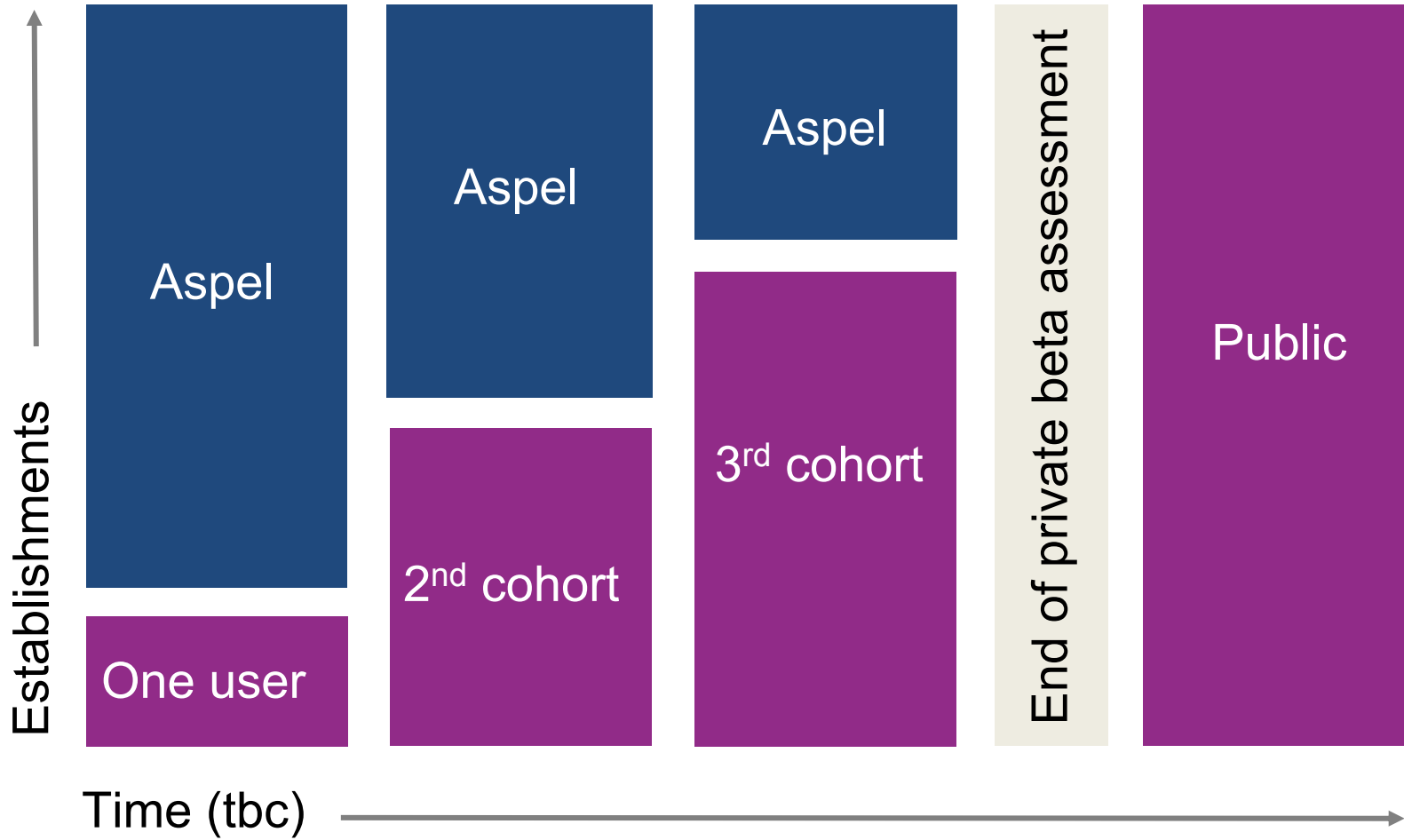


**Digital inclusion scale**



# Roll out plan

- Intense scrutiny and assessments by Cabinet Office to ensure both compliance with gov.uk but also the designs have user testing and acceptance
- First two assessments passed, third due in early Jan.
- Fourth assessment will determine public beta phase – likely to occur in March/April



# Benefits to establishments

- Information more readily available and accessible
- Easier to update schedule of premises
- Easier to manage accounts and named people
- More meaningful notifications
- Simpler application process and better application progress tracking
- Easier movement of PILs between establishments
- **Refined PPL application process**





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# **Applying for a Project Licence: Improving the process**

# This is an opportunity to:

- Re-examine the process
- Take on board feedback gathered over past 2 years on project licences
- Streamline the application while retaining the quality of the information provided
- Address current ASPeL limitations



# What stakeholders told us they wanted

- Speed
- Consistency of assessment and licence authorities
- Clear guidance on what is needed in an application
- Application questions in a logical order
- Clear, unambiguous authorities
- **Ask questions once**

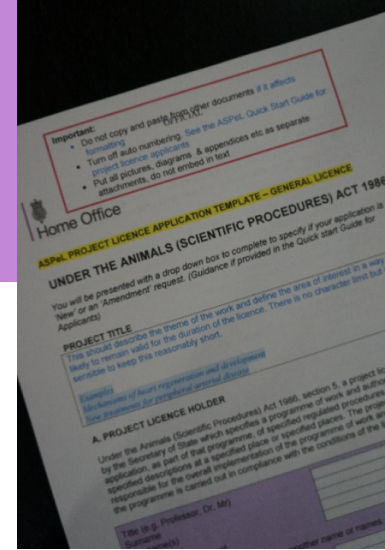


# What ASRU needs

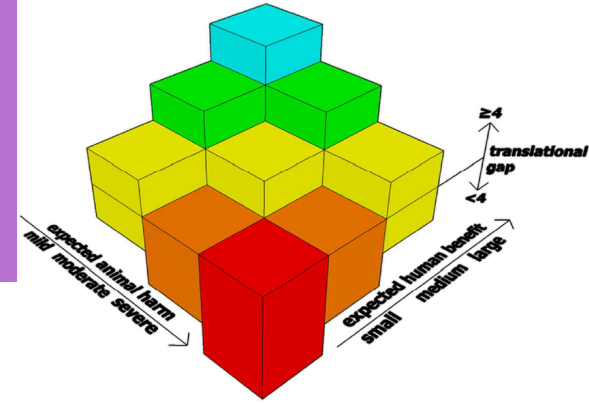
- Good quality applications
  - the right information with the right level of detail
- To maintain the rigour of the harm-benefit analysis
- A user-friendly system
- Consistent, timely and high quality assessment
  - risk (complexity)-based and proportionate
- Clear, concise and unambiguous authorities
- Improved openness and transparency

# How will project licensing be improved?

- At the moment all the information in the application forms the project licence.
- In future the project licence will only contain the necessary legal information
- The application will ask more focused questions relevant to the type of licence being applied for



# What will not change?



- The information required for inspectors to undertake the harm-benefit analysis will be the same
- The licence will be a legal and complete document
- All licences will be fit for purpose:
  - for use by licensees, Named Persons, AWERBs
  - for inspectors to inspect against
- The application, assessment and licensing process will remain robust and proportionate

# What are we planning for the non-technical summary?

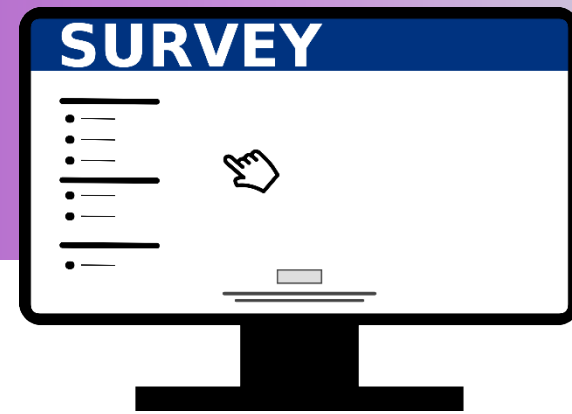
- Will include all mandatory information
- Will include more information on the typical animal experience and on the 3Rs
- Must still not include:
  - confidential information or intellectual property or
  - information that might identify the applicant or others



# What are we planning for applications?

- For clarity and simplicity – you will only see questions appropriate for your application
- We will explore every opportunity to minimise repetition
- We will auto-populate fields wherever technically possible
- Extensive individual user testing is underway to highlight ‘pain points’ to resolve

# Stakeholder engagement



- Individual scientists and named people approached for in-depth consultation
- User research testing – visit Marvell Consulting stand
- **Stakeholder survey live:**

**[surveymonkey.co.uk/r/KFTL9K5](https://surveymonkey.co.uk/r/KFTL9K5)**

Closes 9<sup>th</sup> December



# How will we roll this out?

- We will migrate all project licences currently granted via ASPeL onto the new system
- It will be possible to amend these project licences in the new system
- 5% of licences are on paper, these will remain on paper and will continue to be amended on paper



# New PPL application process

- New PPL applications:
  - We will communicate frequently from now until August 2019 with detailed timings for each Establishment as to their ‘go-live’ date and how to manage their project licence applications
  - Comms via the HOLCs and Operational Newsletter, HOI’s and SPOC’s

**NEW** *application* >

# When should I use the new application process?

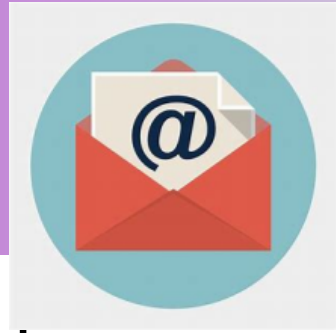
- We will still require a high quality, AWERB reviewed application
- During 2019:
  - Until **March 2019** apply on the current ASPeL system
  - Between **March and July** – it will depend on the complexity of the application, when the project licence needs to be granted by and when the Establishment is scheduled to go live with the new system. Individual plans will be sent out to each Establishment.
  - After **July 2019** apply on the new system

# When can I start drafting my 'new' project licence application

- A PPL drafting tool will be launched in January 2019 to help applicants prepare for and draft using the new form
- This tool will allow application forms to be shared and viewed by others
- The tool will be launched through HOLCs who will be our main liaison



# Communication



- A letter to all PELh is due next week informing them of the process
- We will send out regular Operational Newsletters with increasing detail on timelines
- We will launch the PPL Drafting tool through HOLCS in January 2019
- We will ensure inspectors and SPOCs are fully informed regarding their establishment timelines
- **We will launch a dedicated email help and website in January 2019**



# Beyond August 2019...

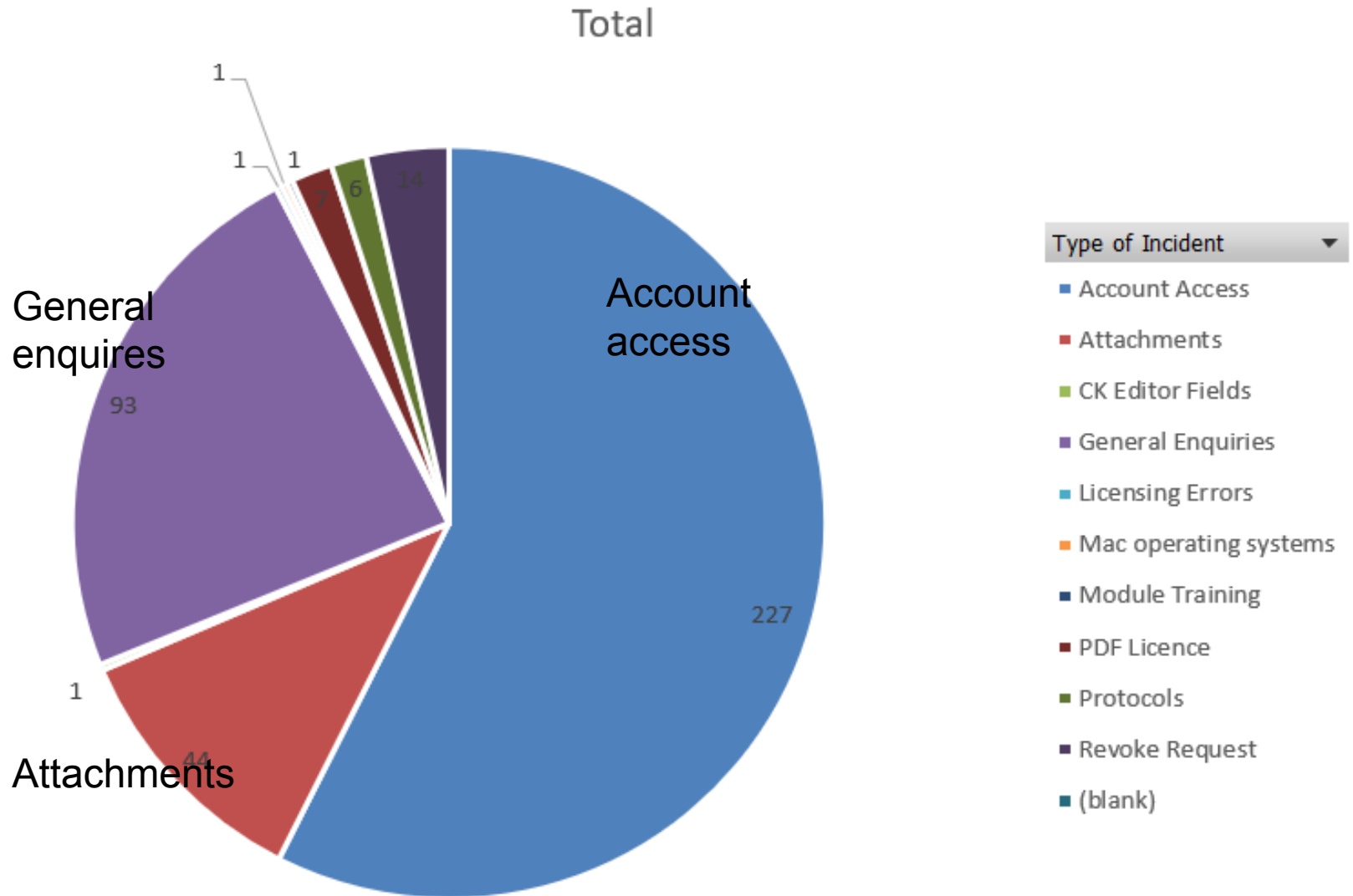
- We will work with Marvell to continue to review, improve and add more functionality to the licensing system
- **We will continue to invest in the system over its life to ensure it remains fit for purpose**



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# Current ASPeL and licensing

# Current ASPeL Queries - 2018



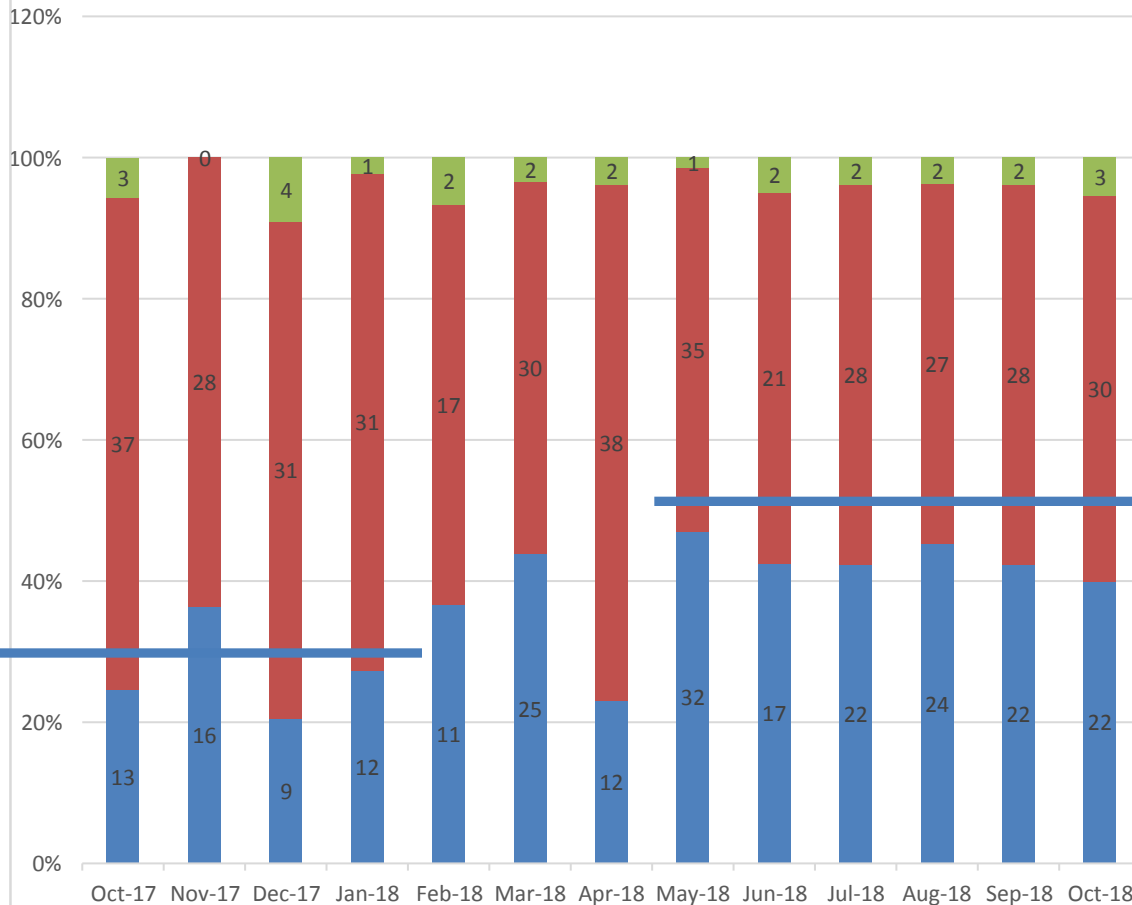


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**Project Licence applications:  
The current situation – progress  
towards one high quality draft**

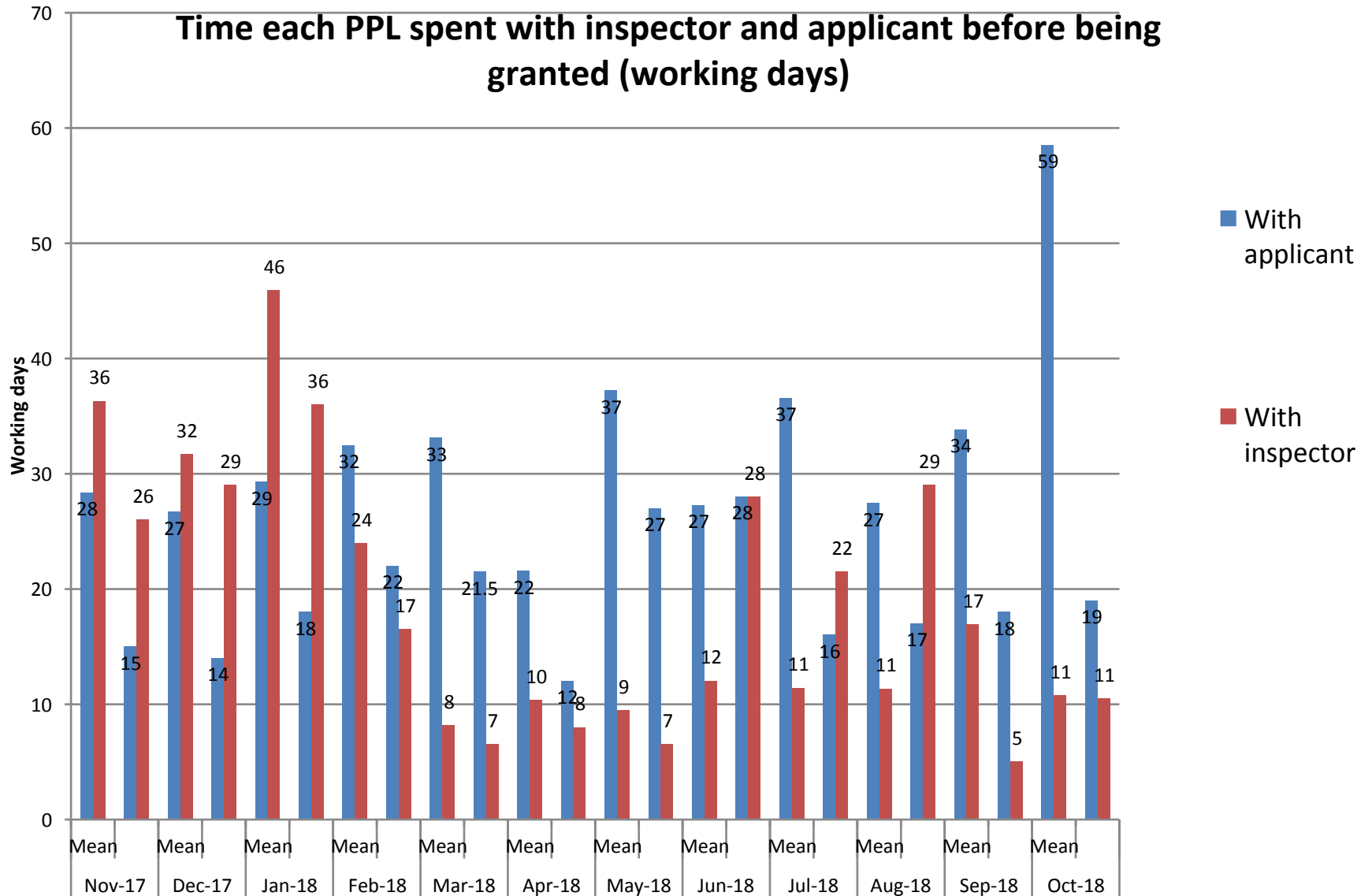
# One good draft

Number of drafts before correct & complete version was received



- 1 draft or direct submission
- 2-4 redrafts required
- 5-9 redrafts required

# PPL timings





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# **‘Service licences’**

# PPLs to enable delivery of a service

- There are a range of different circumstances where PPL holders provide a service for other researchers:

## Type 1

Those which provide **products or data** using repeated **highly standardised** protocols e.g. GAA production, antibody production, surgically prepared animal production, regulatory toxicology/ADME

- These are **multiple generic projects** (ASPA Guidance 5.14)  
“...Generic is best understood by reference to the breeding of GA mice, the production of antibodies or the conduct of a safety evaluation test – within each of which the particular production process, experiment or study is the same irrespective of the actual genotype, specific antibody or substance concerned.”

# When is a 'Service' licence Not a Multiple Generic licence

## Type 2

- Projects which generate **data** using **variable protocols** usually as part of pre-regulatory drug development e.g. projects offering a range of **disease models** for use in compound screening for efficacy or safety.

# Aim of our work

- Produce specific criteria for applications for multiple generic projects (Type 1) which will then be ‘added’ into new ASPEL
- Ensure **clarity and consistency** for community
- Set **limits** for work that can be done through generic project license
- **Simplify** processes for projects which are highly standardised



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# ASRU and NC3Rs

# NC3Rs & ASRU: Memorandum of Understanding

- ASRU and NC3Rs have agreed a MoU.
- Strategies will be developed over the coming months.
- A copy of the MoU can be found here:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/734630/establishment-licence-holder-newsletter-august-2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/734630/establishment-licence-holder-newsletter-august-2018.pdf)



The screenshot shows the NC3Rs website header with the logo and navigation menu. The main content area features a news article titled "The NC3Rs signs an MOU with the UK's Animals in Science Regulatory Unit" dated Wednesday 05 September 2018. The article text discusses the NC3Rs remit, the need for collaboration, and the signing of a Memorandum of Understanding (MOU) with the ASRU. A small image of a hand signing a document is visible. To the right of the article is a blue "Subscribe to our newsletter" button with a preview of the newsletter content.



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# Themed inspections

# Themed Inspections

Finn Lonsdale on mouse handling.



Home > News & Blog > Re-use of needles: is this an indicator of a culture of care?

## Re-use of needles: is this an indicator of a culture of care?

Wednesday 06 December 2017

Our recent guest blog is from Dr Lucy Whitfield, Royal Veterinary College and Dr Sally Robinson, AstraZeneca, who cover the topic of re-using hypodermic needles in day-to-day practice.



Directive EU2010/63 requires, throughout associated guidance documents, that we work within a 'culture of care' in our institutes: demonstrating excellent commitment to and

Subscribe to our newsletter

Get the latest articles, events and funding opportunities from the NC3Rs in your email inbox every month.

Charlotte Inman single use needles.



John Marshall on food & water.

# To come.....

End of first ASRU session

After coffee

Kate Chandler – Head of Policy

Giles Paiba – Inspector Lead on Returns of Procedures

This afternoon.....ASRU Q&A session

# Questions?



"I don't understand your question.  
Could you restate it as an answer?"



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# Updates from the ASRU Team

## Take Two

Presented by: Kate Chandler, Giles Paiba

Date: November 2018



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# Updates from the Policy Team

# ASRU policy: headlines





- Withdrawal Agreement and Political Declaration endorsed by EU leaders
- UK parliament expected to vote on deal on 12<sup>th</sup> December
- Animals in science regulation will continue as usual
- Only minor changes to Animals (Scientific Procedures) Act
- Other issues: animal transport, imports/exports – animals and animal tissues

# Brexit and animals in science



- NO change to animals in science regulatory requirements
- NO change to high standards of animal welfare

If you have any concerns or questions about animals in science and EU exit, please email [Kate.Chandler@homeoffice.gov.uk](mailto:Kate.Chandler@homeoffice.gov.uk)

# EU Commission projects

- Non Technical Summary and Retrospective Assessment workshops
- Genetically Altered Animals
- Project evaluation
- Outputs
  - New NTS template and central database
  - RA template
  - More guidance on project evaluation



# Non Technical Summaries

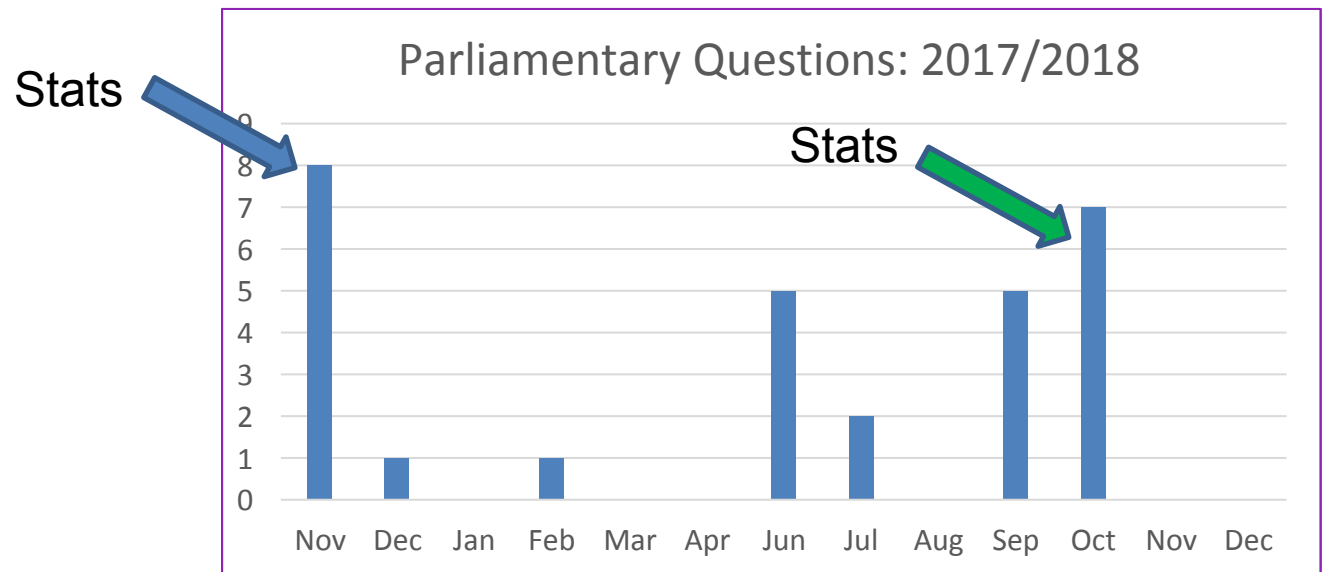
- Guidance has been published in our annotated form
- Improving quality whilst minimising burden
- E-licensing system
  - Embedded guidance notes
  - Easier to fill in
  - Avoiding repetition, especially the 3Rs



# Parliamentary Questions (PQs)

PQs allow MPs to hold the Government to account:

- used by MPs to **seek information** or to **press for action**
- They oblige Ministers to explain and defend work, policy decisions and actions of their Departments



# Recent PQ Topics

- ROPs – increase in numbers of horses used, use of NMBA without GA
- 2<sup>nd</sup> species in medicines safety testing
- Non-animal alternatives
- Severe severity
- Questions and answers are published:
- <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-questions-answers/>

## **Question:**

To ask the Secretary of State for the Home Department, if he will take steps to end severe suffering as a research category for all research animals after the UK leaves the EU. 170766

## **Answering Minister:**

There are no plans to remove the category “severe” for procedures authorised under the Animals (Scientific Procedures) Act 1986, as amended in 2012 (ASPA). The regulatory system ensures that animal research and testing is carried out under controls which keep suffering to the minimum. Following EU exit, the principles of the 3Rs (Replacement, Reduction and Refinement) will be fully retained in ASPA.





# Requests under the Freedom of Information Act

- **The Freedom of Information Act (FOIA) provides the public with two rights:**
  - (1) To be informed whether information is **held**
  - (2) To have information **communicated** to them
- **What info is within scope?**
  - All information **held** by public bodies (or on their behalf)  
Covers **all recorded** information, in any form
- **Who can request under FOIA?**
  - Anyone, anywhere – the FOIA is ‘applicant blind’
  - No reason needs to be given



# Examples of exemptions under FOIA

- We refuse if we do not “hold” the information
- ‘cost limit’ (s.12)
  - >24h to identify/locate/retrieve/do we hold it?
- the request is ‘vexatious or repeated’ (s.14)
- the ‘information is already accessible’ (s.21)
- ‘intended for future publication’ (s.22)
- ‘personal data’ to withhold all of the information (s.40)



# Example of FOIA requests

- How many animals have been experimented on in the UK in the last 12 months for Household products?
- How many animals have been experimented on in the UK in the last 12 months for the pharmaceutical industry?



# Example of FOIA requests

- Could you let us have the PPLs corresponding to the following NTSs [in volume xx] with the Primary Purpose of xx in 2016, including any conditions applied
- We do release entire PPLs
  - Suitably redacted
  - Checked with establishment for identifiers



# Imminent publications

- Annual Report
- Genetically altered animal framework
- Education and training advice note
- Zebrafish protocols for project licence applicants



# Annual Report: compliance

	2014	2015	2016	2017
Cases reported by the establishment	49	43	40	37
Cases discovered by an Inspector	12	12	5	3
Cases reported by others independent of the establishment	2	0	0	0
<b>Total cases</b>	<b>63</b>	<b>55</b>	<b>45</b>	<b>40</b>

- Unauthorised procedures
  - Administrative lapses and error
  - Inadequate record keeping
  - Communication lapses
- Failure to provide food and water
  - Themed inspection



# Annual Statistics on Scientific Procedures on Living Animals

## Great Britain, 2017

Dr Giles Paiba, ASRU Inspector


# Introduction

- 2017 Annual Statistical Report  
on the Returns of Procedures
- Additional returns for 2017
- Cumulative total of animals used  
for regulated science in GB
- Genotyping
  - Species
  - Refinements

# Annual Statistical publication New Style

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## Annual Statistics of Scientific Procedures on Living Animals Great Britain 2017



HC 1309

### Purpose

Experimental procedures accounted for half (50%) of the 3.79 million procedures in 2017. They were carried out for a variety of purposes.

Figure 9. Experimental procedures by purpose, 2017



Over half (55%) of experimental procedures in 2017 were carried out for regulatory purposes. A further 27% were carried out for basic research.

The data collected on primates can be divided into two species categories: Old World monkeys and New World monkeys. Throughout the period, New World monkeys used in procedures were mainly used for neurotoxicology, immunology and rheumatology research. Old World monkeys account for 4% of primates used in experimental procedures. In 2017, the number of monkeys used fell by 17% from the previous year. Figure 6 shows there has been an overall reduction in the use of primates in the last decade, mostly driven by a 34% decrease (1,400) in procedures involving Old World monkeys.

Old World monkeys are considered more relevant models for some human conditions than New World monkeys, and are predominantly used for the testing of pharmaceuticals.

Old World monkeys are considered more relevant models for some human conditions than New World monkeys, and are predominantly used for the testing of pharmaceuticals.

### Species not used in procedures

In 2017, no procedures were carried out on:

- various primate species (the use of great apes has not been permitted since 2013, although great apes have not been used since the 1960 Act was implemented)
- Chinese hamsters (*Cricetus griseus*)
- cephalopods

Species have been presented in previous publications but full breakdowns are available in the [data tables](#). For the first time, further information has been included on [Table 12](#) (online only) and [Table 2.1.2.2](#) and [2.3](#) provide further information on place of birth for all species and location for primates.

### Nic status

3.80 million experimental procedures in 2017, the majority (82%) used animals that were not genetically altered.

Percentage change from last year



Figure 16. Procedures and project licences by establishment, 2017



As shown by Figure 16, universities accounted for the majority of project licences (73%), and the largest proportion of procedures (62%). In contrast, commercial organisations accounted for 14% of the project licences, but 25% of procedures. This is due to commercial organisations conducting a greater number of work involving repeated procedures and lots of other types of work.

Of these, 100 were registered as other establishments, 106 as health establishments and 75 as business establishments. There are also 10 more than the number of establishments established in 2016. This is because some establishments were registered as both a business and other.

### Appendix A: Revisions

It is standard practice across all Home Office statistical releases to incorporate revisions to previous years' data in the latest release. Corrections and revisions follow the Home Office's statement of compliance with the Code of Practice for Official Statistics.

Quality assurance checks revealed a small number of misclassifications within the 2014, 2015 and 2016 datasets. The headline figures for 2014 remain unchanged (3.87 million), while there were small changes to the total number of procedures for 2015 (a decrease of 420 procedures, from a total of 4.14 million) and 2016 (a decrease of 210 procedures, from a total of 3.94 million). The revision table below details all revisions to the 2014, 2015 and 2016 data made since the 2016 release.

#### Revisions to 2014

The sub-purpose of 32,310 experimental procedures involving sheep, originally reported under as 'Routine production - other' (Regulatory), was revised to 'Routine production - blood products' (Regulatory).

The sub-purpose of 6,051 experimental procedures involving horses, originally reported under as 'Routine production - other' (Regulatory), was revised to 'Routine production - blood products' (Regulatory).

The purpose of 129 experimental procedures involving mice, originally reported under 'Multisystemic' (Basic research), was revised to 'Higher education or training'.

The purpose of 87 experimental procedures involving rats, originally reported under 'Cardiovascular blood and lymphatic system' (Basic research), was revised to 'Higher education or training'.

The purpose of 35 experimental procedures involving mice, originally reported under 'Nervous system' (Basic research), was revised to 'Higher education or training'.

The purpose of 22 experimental procedures involving mice, originally reported under 'Respiratory system' (Basic research), was revised to 'Higher education or training'.

The purpose of 11 experimental procedures involving guinea pigs, originally reported under 'Respiratory system' (Basic research), was revised to 'Higher education or training'.

#### Revisions to 2015

The sub-purpose of 38,520 experimental procedures in 'Routine production - other' (Regulatory), was revised to 'Routine production - blood products' (Regulatory).

The sub-purpose of 1,000 experimental procedures in 'Routine production - other' (Regulatory), was revised to 'Routine production - blood products' (Regulatory).

#### Revisions to 2016

The sub-purpose of 38,520 experimental procedures in 'Routine production - other' (Regulatory), was revised to 'Routine production - blood products' (Regulatory).

The sub-purpose of 1,000 experimental procedures in 'Routine production - other' (Regulatory), was revised to 'Routine production - blood products' (Regulatory).

### Figure 15. Reporting of animals used for scientific purposes under ASPA

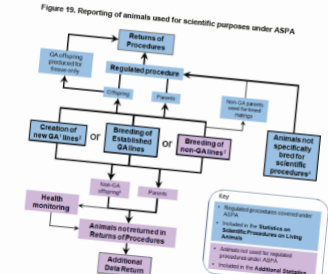


Chart notes:

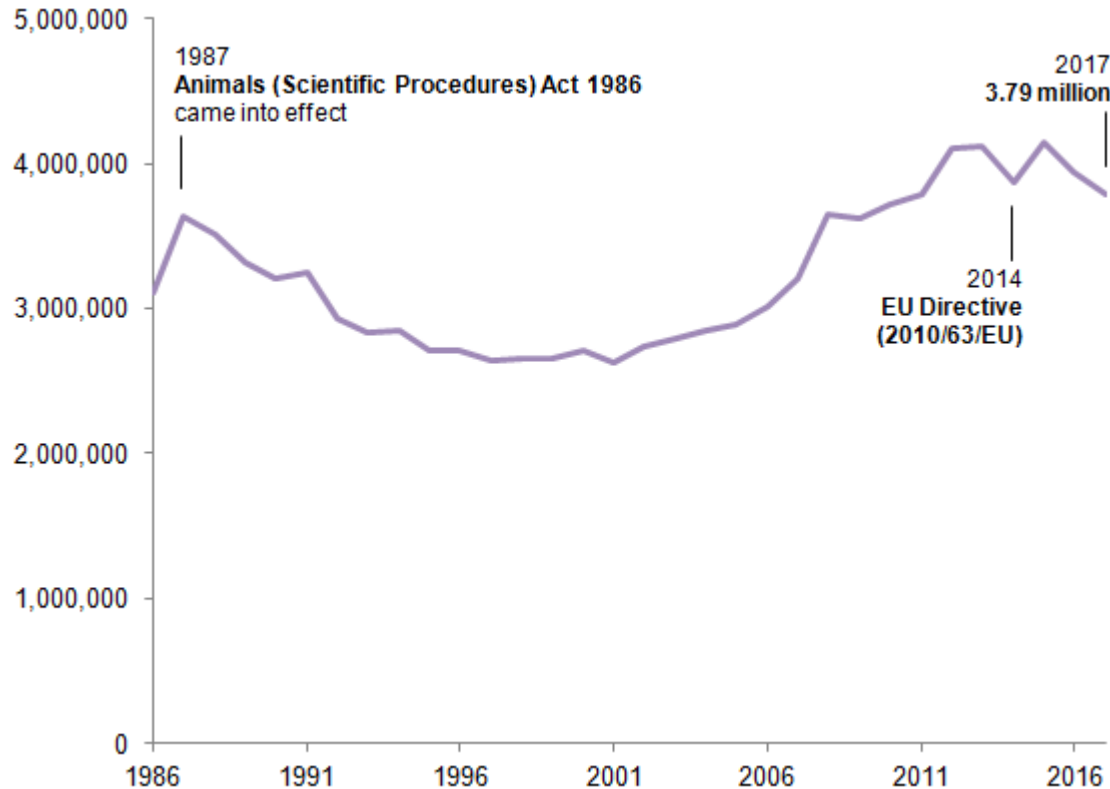
- For the purposes of statistical reporting, 'GA' animals include genetically modified or induced mutant animals (including knock-out and other forms of genetic alteration) and naturally occurring transgenerations of genetic alteration is stable for at least two generations and a welfare assessment showing no adverse effects from the alteration has been completed. At this point, breeding animals move from the 'Creation of new GA lines' category into the 'Breeding of non-GA lines' category.
- Spontaneous mutant animals that are to be kept alive are moved into the 'Creation of new GA lines' category.
- Animals not specifically bred for scientific purposes include, for example, animals sourced from the wild or from commercial livestock farms.
- Offspring not used for regulated procedures and that are genotyped by methods other than those requiring genotyping (e.g. where ear notching is not used for identification) are returned in the 'Additional Data Return'.

# Total number of procedures 2017

**3.79 million**

# Total procedures – long term

## 1986 - 2017

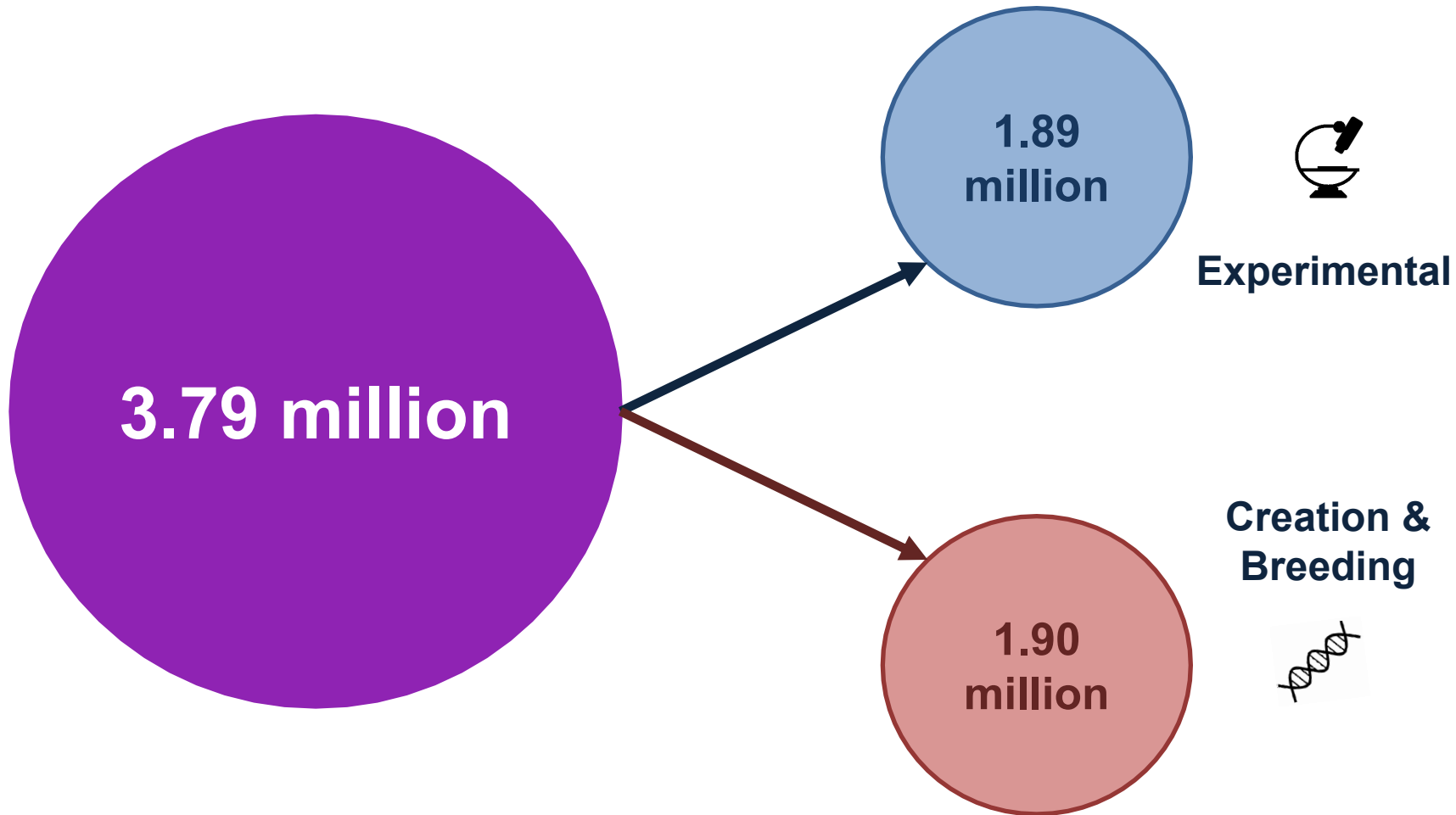


- **3.79 million** procedures in 2017
- **-4%** compared to 2016
- Procedures **remain around 4 million** in recent years
- Variation due to **changes in licences** and the **2014 EU Directive**

# Total number of procedures 2017

**3.79 million**

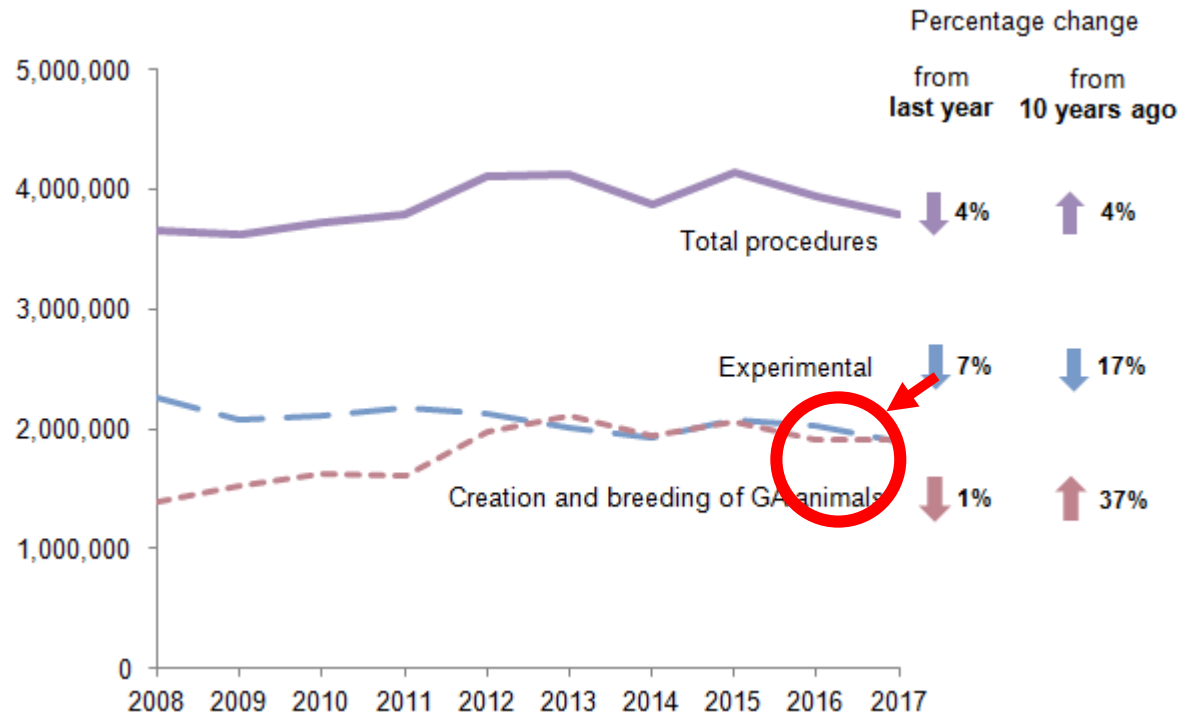
# Total number of procedures 2017



# Total procedures – the last decade

## 2008 - 2017

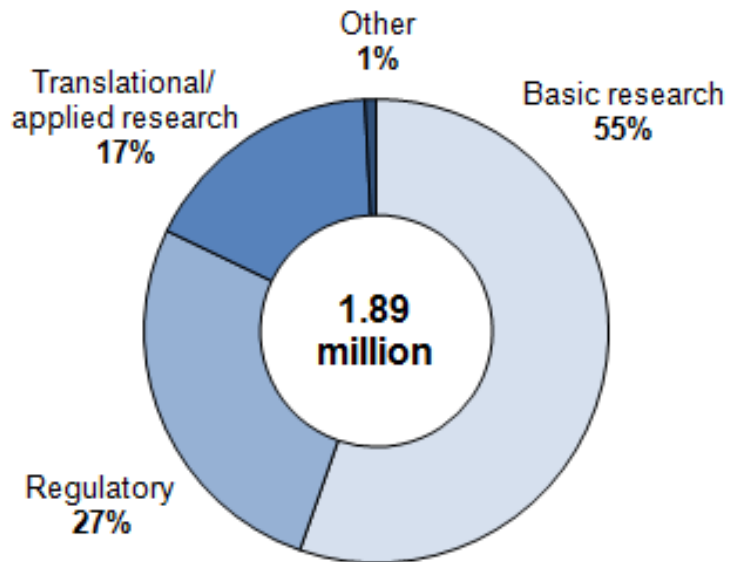
- Total procedures is split into **experimental** and **creation/breeding of GA animals**



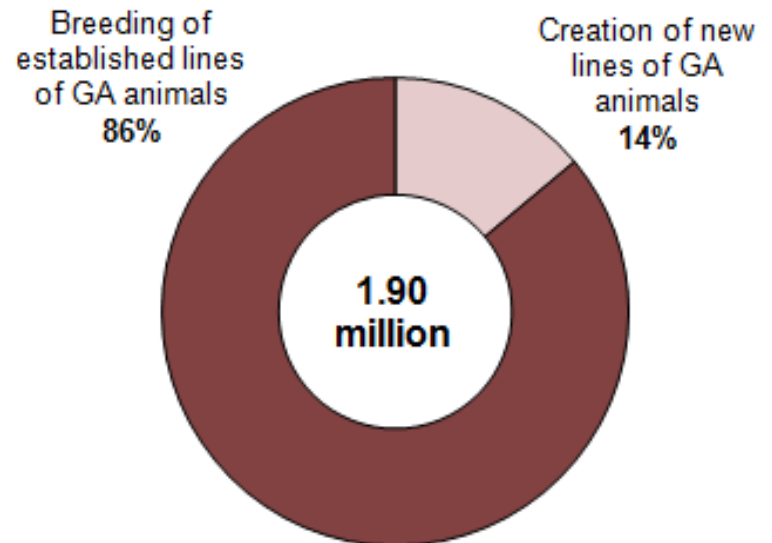
# Purpose of procedures

2017

## Experimental



## Creation/breeding of GA animals

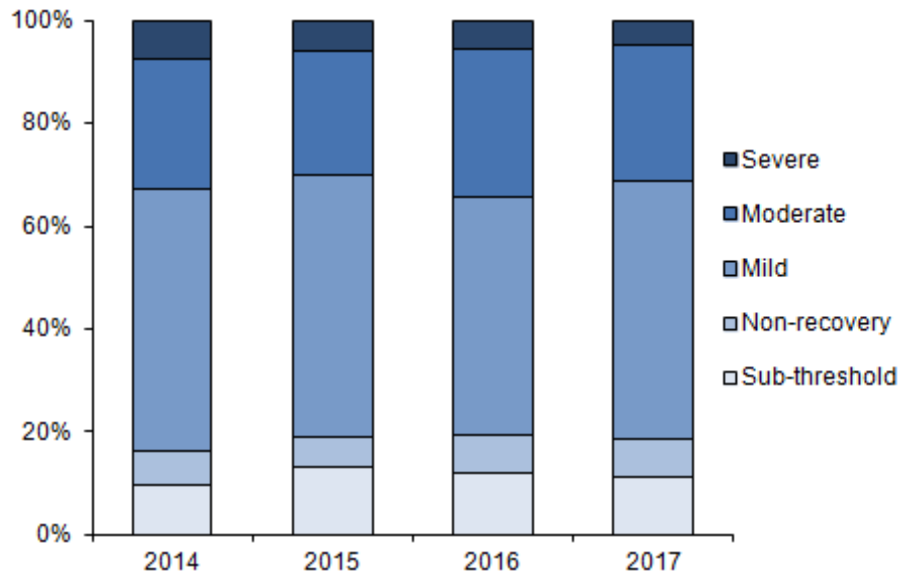


- Equal split between experimental and creation/breeding – similar to recent years

# Severity of procedures

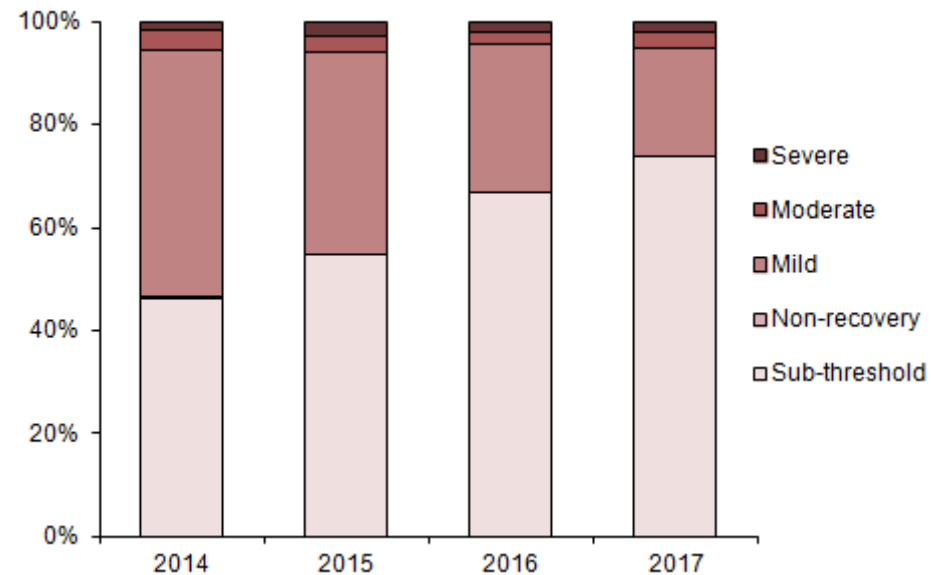
2014 - 2017

## Experimental



- 50% of procedures 'Mild'
- Trends stable

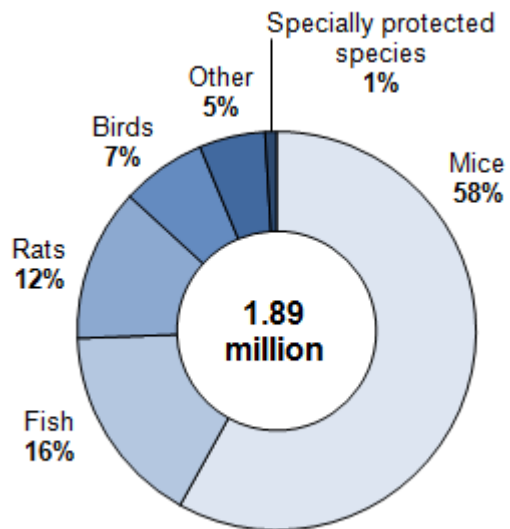
## Creation/breeding of GA animals



- 74% of procedures 'Sub-threshold'
- Severities above threshold decreasing

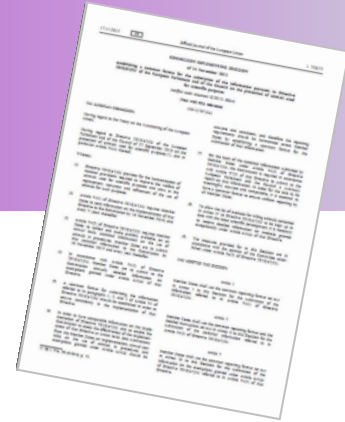
# Species in experimental procedures 2017

- **Mice, fish and rats** were the most used species
- Stable trend over time



# Additional statistics

2017

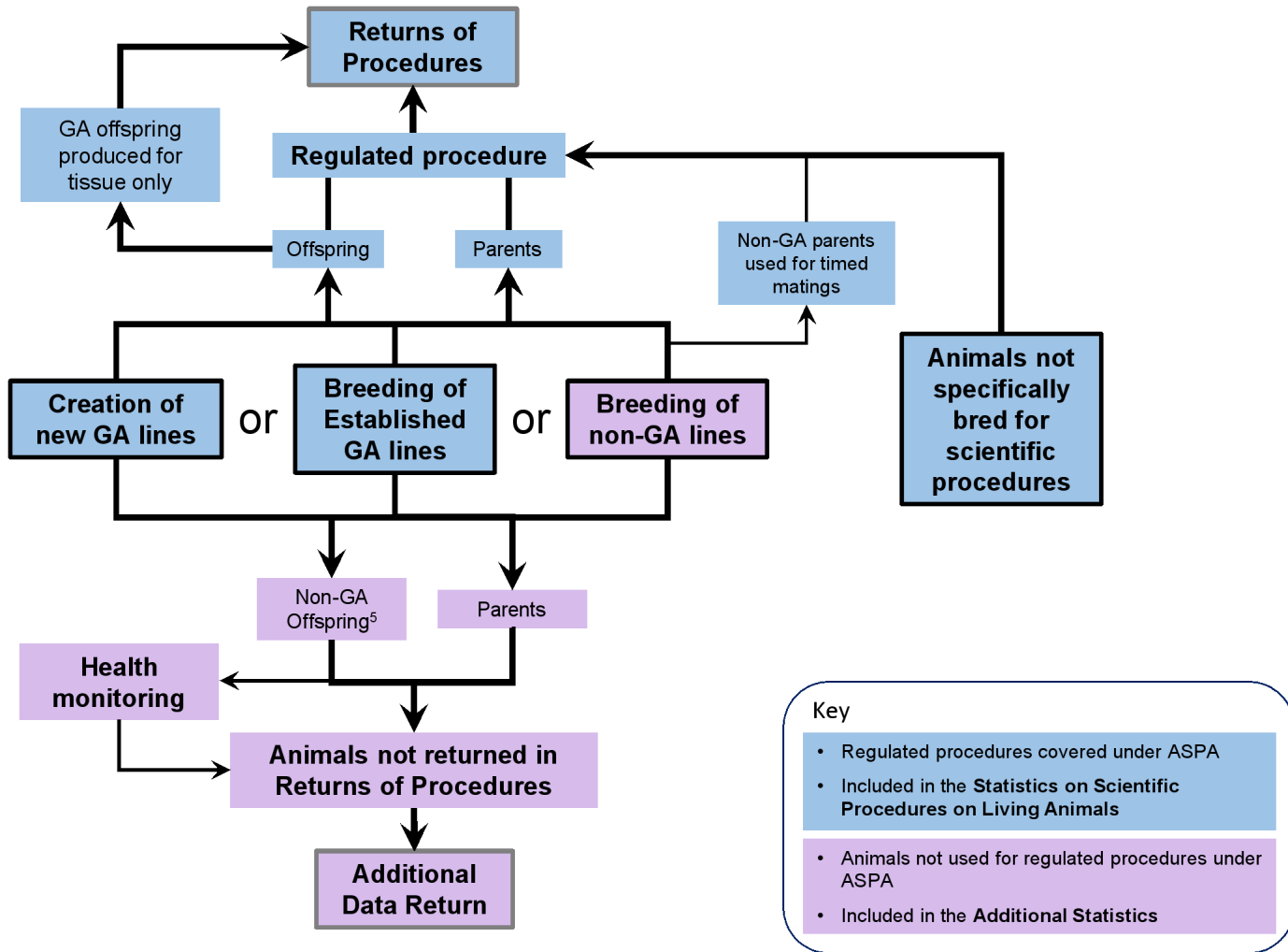


- Implementing Decision 2012/707/EU
  - implements Article 54(1) of EU Directive (2010/63/EU)
  - requires Member States to collect additional information every 5 years
- First collection covers 2017; published 8<sup>th</sup> November 2018
- Statistics on the number of non-GA animals that were bred for scientific procedures but were killed or died without being used
- Genotyping methods and refinements
  - collected over 6 months – 1<sup>st</sup> July to 31<sup>st</sup> December 2017



# Additional 5 year return – 2017

## Non-genetically altered animals bred for scientific procedures but not used in procedures



# Additional data

## Caveats

- First time collected
- Published as 'Experimental Statistics'
- Quality limitations include:
  - No previous data against which to compare
  - Assumption that instructions were correct and correctly followed
  - Genotyping data covers 6-month period, so assumption that there is no seasonality in genotyping
- Great Britain – England, Scotland and Wales

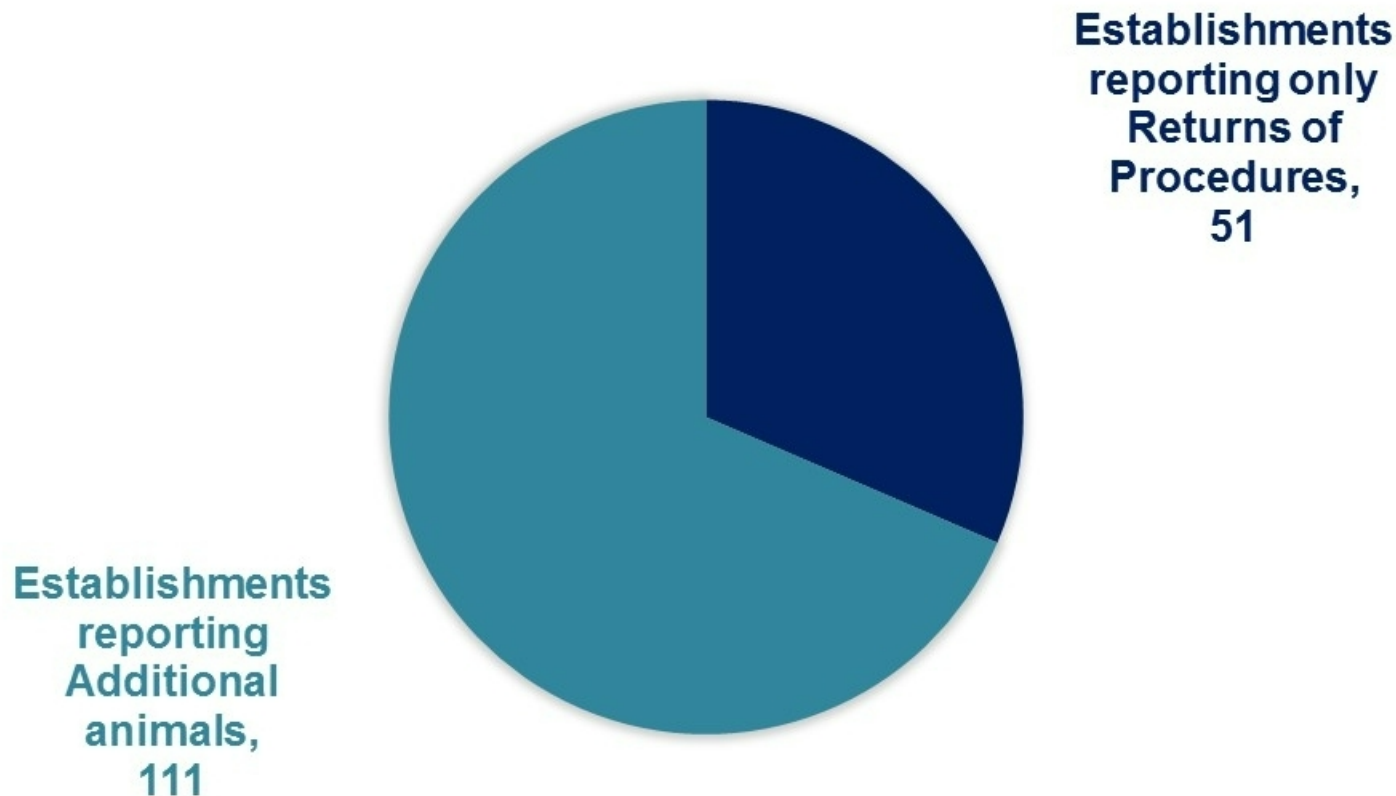
# Additional data

## What animals?

- Animals bred for scientific purposes but were killed or died without being used in procedures
  - breeding animals (i.e. wildtypes) that underwent no procedures themselves
  - not subjected to procedures themselves but were used to provide tissue only
  - wrong gender for desired purpose
  - a necessary surplus resulting from the breeding of animals to ensure an adequate supply for scientific purposes

# Establishment reporting

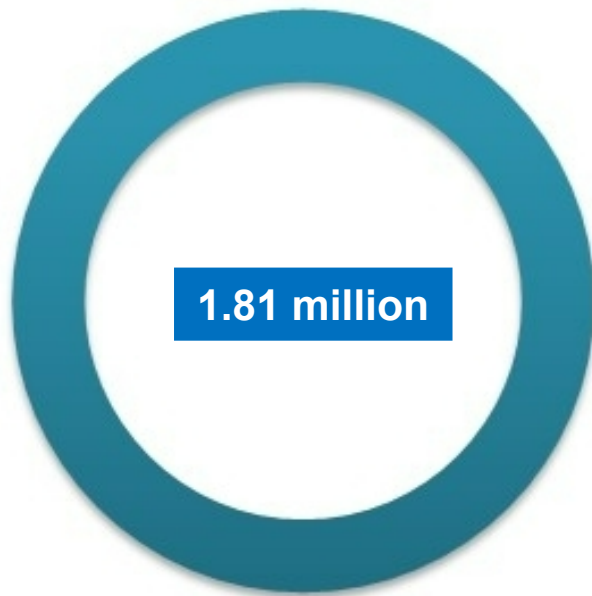
*N* = 162



# Total additional animals reported

2017

## Non-RoP animals



# Total number of animals used towards ASPA regulated research in 2017

Non-GA animals bred but not used in Regulated Procedures

1.81 million

GA animals created or bred but not used in Regulated Procedures

1.90 million

Animals used in Regulated Procedures for the first time in 2017

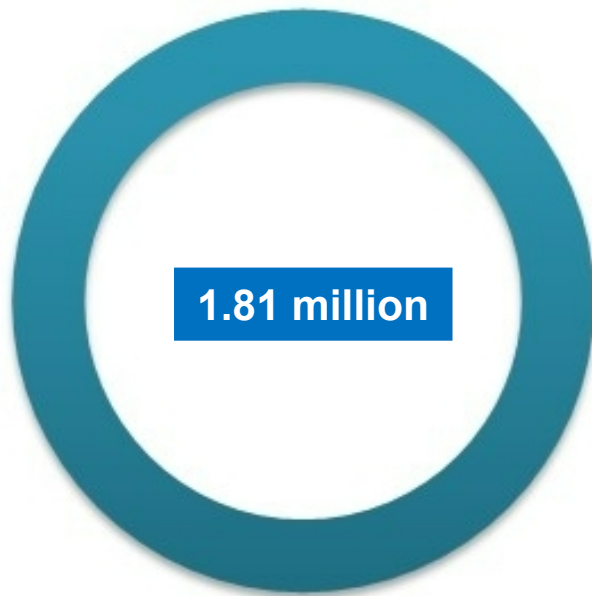
1.82 million

**5.53 million**

# Total additional animals reported

2017

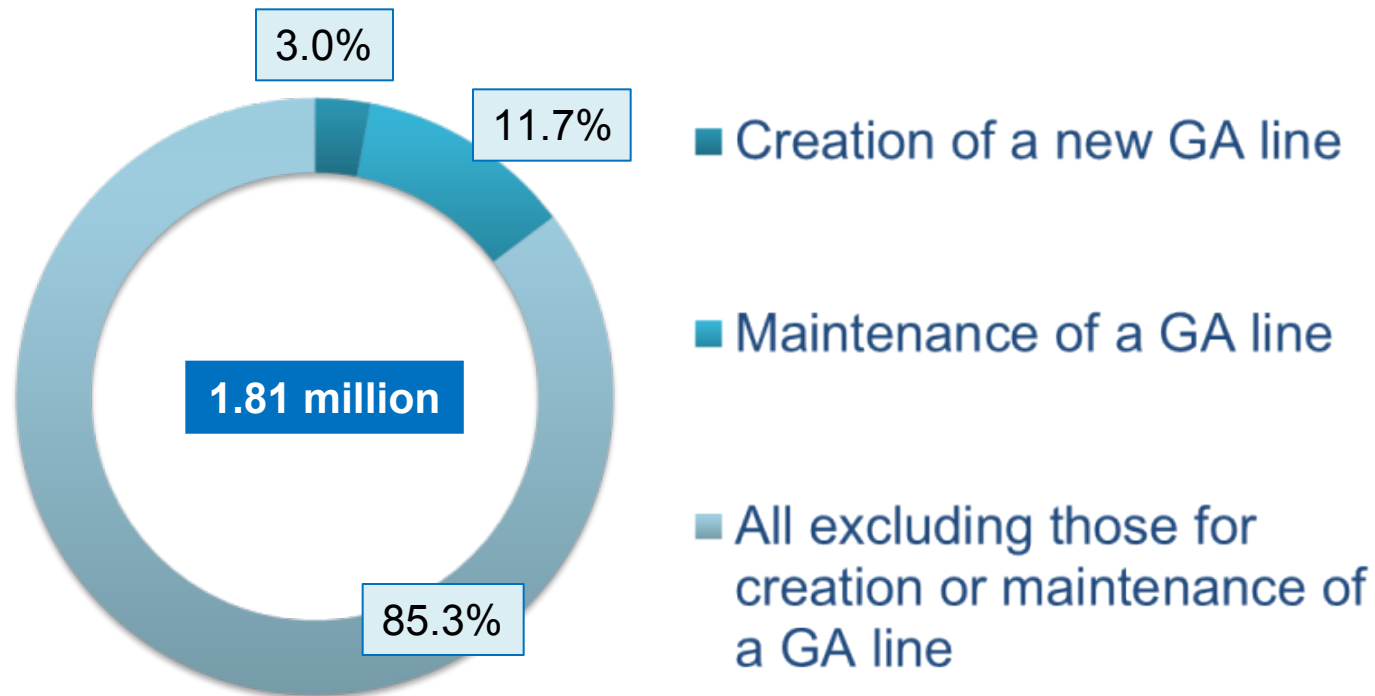
## Non-RoP animals



# Total additional animals reported

2017

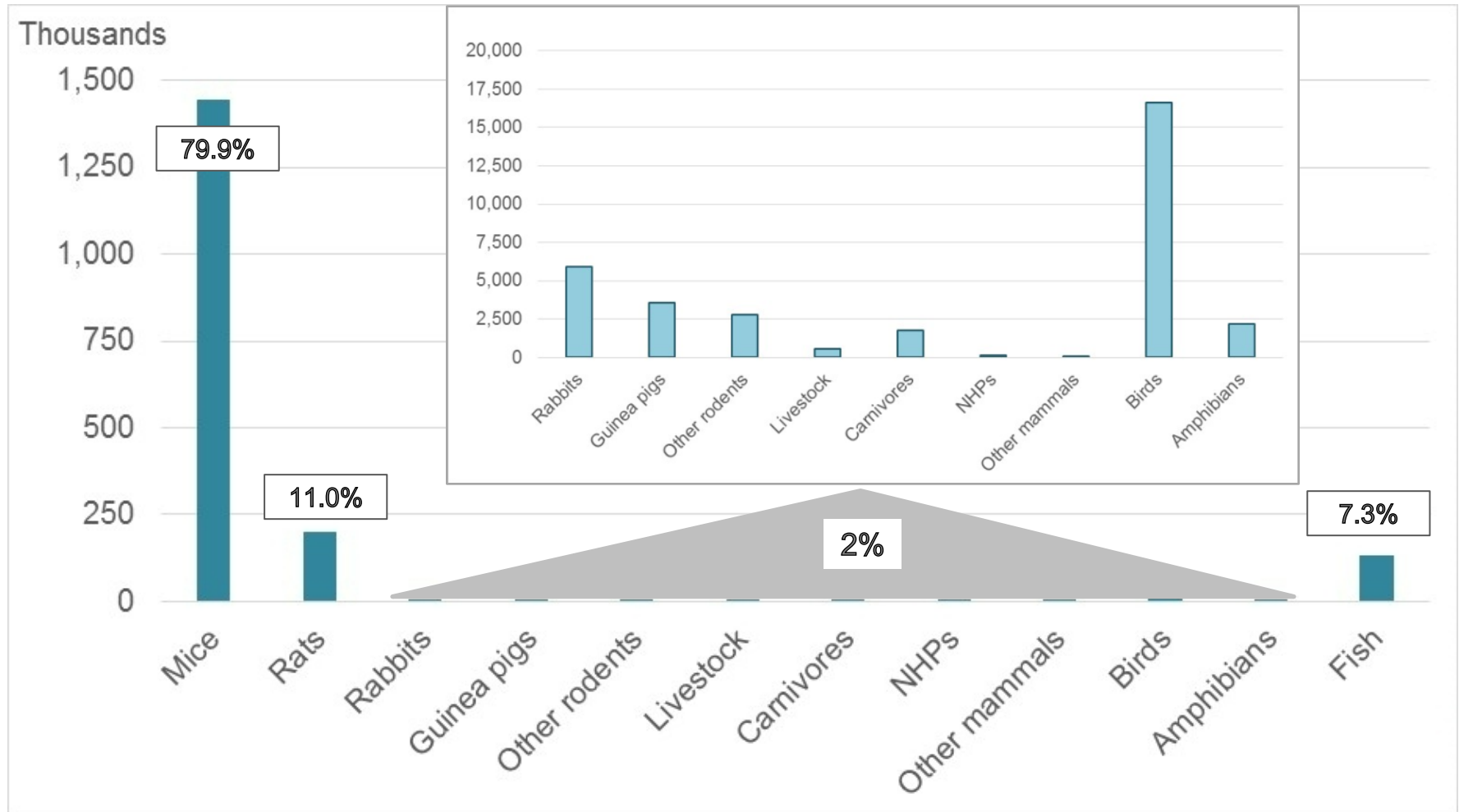
## Non-RoP animals



# Total additional animals by species

2017

*N=1.81million*

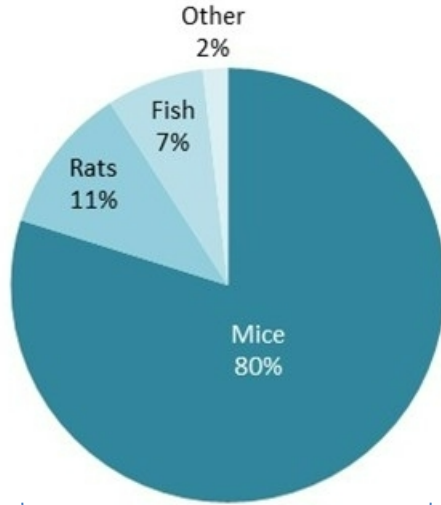


# Total animals by species

2017

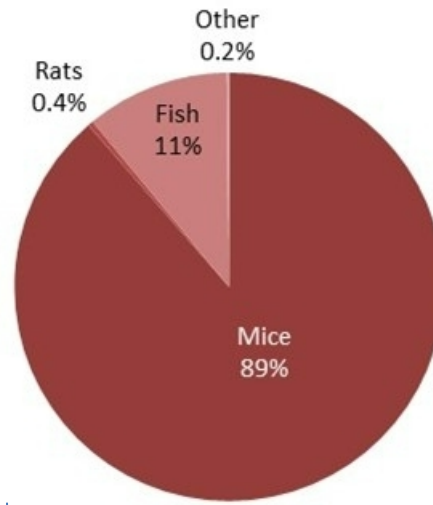
*N = 5.53 million*

Non-GA animals bred but not used in Regulated Procedures



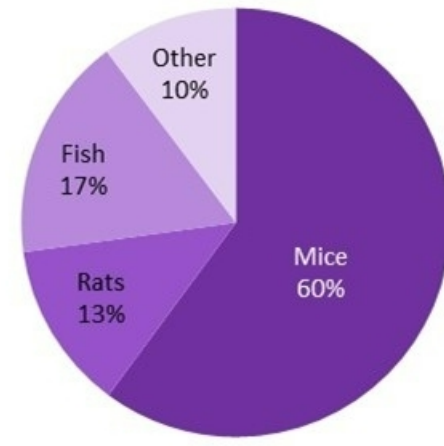
2017 Additional Return

GA animals created or bred but not used in Regulated Procedures



2017 Annual statistics (RoP)

Animals used in Regulated Procedures for the first time in 2017

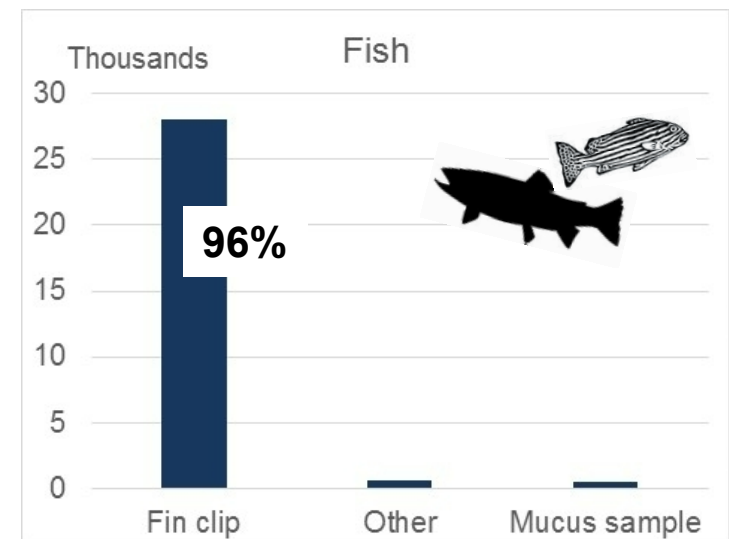
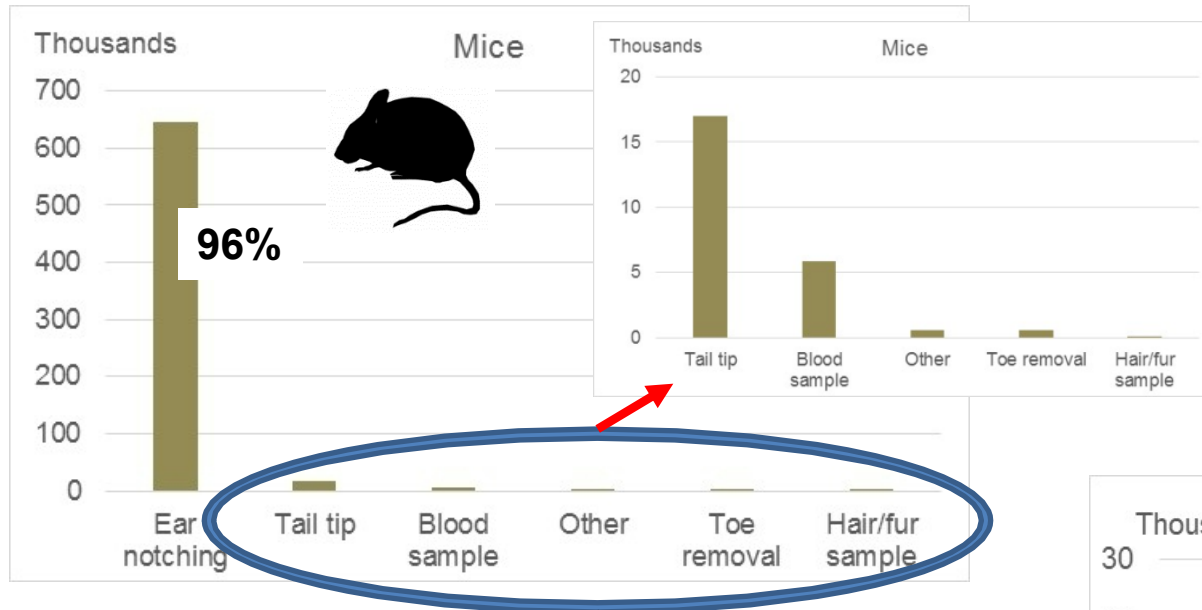


# Genotyping methods

July – Dec 2017

## Methods employed

*N* = 704,594



# Genotyping methods

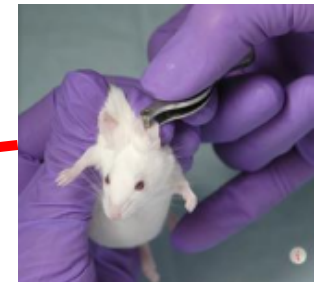
July – Dec 2017

## Surplus to identification

*N* = 704,594

Sample type	Surplus from identification		Grand Total
	No	Yes	
Ear notching	106,169	542,083	648,252
Tail tip	16,035	1,541	17,576
Blood sample	6,567		6,567
Toe removal	105	465	570
Hair/fur sample	69		69
Saliva	30		30
Fin clip	28,021		28,021
Mucus sample	528		528
Other	2,981		2,981
<b>TOTAL</b>	<b>160,505</b>	<b>544,089</b>	<b>704,594</b>

84%



9%



82%



- All methods classified as Mild or Sub-threshold
- Multiple tissue samples were collected from
  - 3.0% (15,000) mice
  - 0.8% (180) fish

[82% (581,000) animals where a record was available]

# Genotyping methods

## Refinements

*N = 68 PELs*

### What refinements for genotyping have been made?

- Main themes

- Reduced number of samples being taken
  - Supported by centralising or use of commercial genotyping
- Moved to lower severity methods for genotyping
  - Principally from tail tipping to ear notching
  - Genotyping post-mortem where possible
- Continuing attempts to improve
  - Swabbing
  - Fluorescence marking



**~2/3 PELs**

# Future

- Deadline for 2018 Annual Returns submissions is **31<sup>st</sup> January 2019**
- Please suggest changes to improve, make more relevant or more informative the Annual Returns publication
- No additional data collection planned for 2018



Home Office

## **Acknowledgements**

Licence Holders – Establishment and Project  
HOLCs

Home Office Analysis and Insight Team  
ASRU staff

