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Application of the 3Rs through policy, inspection, and project licence assessment

Examples from the UK



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Date: 5/6th November 2018

Animals in Science Regulation Unit (ASRU)

- GB regulator for ASPA - The Animals (Scientific Procedures) Act 1986 (as amended)
- ***“We regulate the use of animals in scientific research for the benefit of people, animals and the environment through the provision of impartial licensing procedures and evidence-based advice, and by encouraging the development and use of the 3Rs (replacement, reduction and refinement)”***



Britain's exit from the EU

- Seamless transition
- 3Rs will remain central to UK
- Harm-benefit analysis will remain cornerstone



Why the 3Rs?

- Benefit to Animals – Science - Innovation
- Public expectation and trust
- Support life sciences
- Embedded in:
 - ASPA
 - Guidance
 - Published advice notes
 - Newsletters
 - Culture



Government – influence as a funder

- UK Government bodies are a major funder of research
- Funders can have large influence on the 3Rs
- UK public funded bodies seeks NC3Rs advice on grant proposals

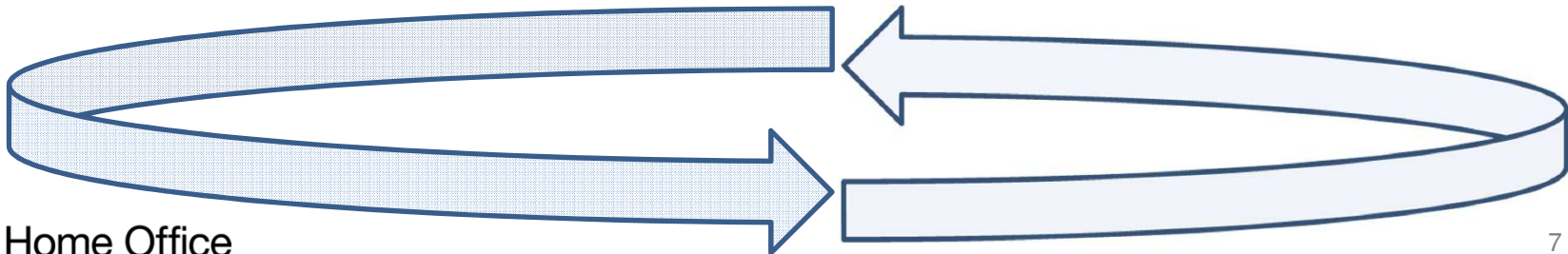
- PUSH – Setting standards e.g. Source of NHP
- PULL – Funding proposals that assess & build on the 3RS e.g. Remote monitoring kit

Government - influence on 3rs through regulations / rules

- Sets / agrees legislation – (Parliament vs. regulator) AND “cultural tone”
- Animals Directive – but also: e.g. MAD in REACH implementation, Pharma approvals, labelling, transport rules etc
- e.g. Shellfish paralytic toxin – ASRU working with Industry, Food regulator, government research agency, chemists, NORECOPA - to implement in-vitro assay
- Wins - ↓ animals / suffering, ↑ innovation

National expert body & NC3Rs

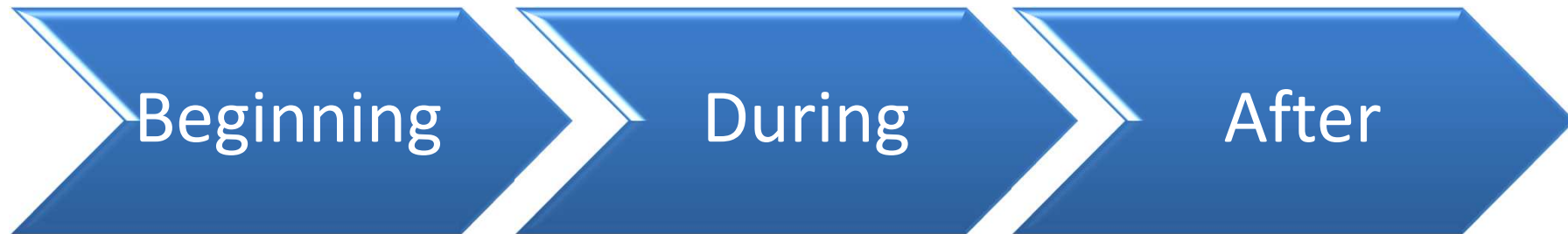
- NC3Rs partnership & Gov sponsorship
- Different ways of working – MOU with ASRU
- NC3Rs funds research & promotes the results
- Through MOU, ASRU advise, promote, implement and monitor the outcomes



Who and what - Support structures - PG

- Responsibility for the regulator
 - Advisory Section 3 of Code of Practice
 - GAA framework tool
 - ASC (national committee) and knowledge hub
- NC3Rs – Memorandum of understanding
- Establishments
 - PELh (also committee across establishments)
AWERBs, Named persons / information officers
- NGOs and industry groups
 - LASA, LAVA, Industry groups

Project licences



- Project evaluation
- Inspector advice
- AWERBs
- Named persons
- NTS

- Inspection
- Emerging evidence - monitor
- Named persons

- Retrospective assessment
- Publication
- New licence application?
- New review

Inspection – promotion of the 3RS

- Leadership areas
- ASRU conferences and virtual organisation – CPD
- Thematic inspections & initiatives
 - Mouse handling
 - Asepsis
 - Needle re-use
 - Basic care / food & water
 - GAA breeding framework



Policy contribution

- UK standards : Code of Practice on care & accommodation
- Mostly “Directive” minimum standards
- Some “retained” higher standards
- Included a “higher” minimum cage height for older rats (20cm)
- Dated from time grid floors stopped

Higher cage heights by policy

Pros

- Clear standard
- Monitor / Enforceable
- Selling point?
- Can be built upon
- Sets the direction
- Feels good?

Cons

- Reduces competitiveness?
- Minimum becomes the standard
- Inflexible?
- Legal aspects - Directive

Updating standards based on evidence

- If evidence suggests a standard may be inadequate, should it be changed?



Cite this article: Makowska IJ, Weary DM.

2016 The importance of burrowing, climbing and standing upright for laboratory rats.

R. Soc. open sci. **3**: 160136.

<http://dx.doi.org/10.1098/rsos.160136>

Received: 25 February 2016

Accepted: 26 May 2016

Subject Category:

Biology (whole organism)

Subject Areas:

behaviour

Keywords:

housing, environmental enrichment,
natural behaviours

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The importance of burrowing, climbing and standing upright for laboratory rats

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Standard laboratory cages prevent rats (*Rattus norvegicus*) from performing many behaviours that they perform in the wild, but little is known about how this may affect their welfare. The aims of this study were (i) to record the propensity to burrow, climb and stand upright in 3-, 8- and 13-month old laboratory rats housed in semi-naturalistic environments and (ii) to compare the frequency of lateral stretching in semi-naturalistic versus standard-housed rats; we predicted standard-housed rats would perform more lateral stretches to compensate for the inability to stretch upright. Rats' propensity to burrow remained constant as they aged (approx. 30 bouts per day totalling 20–30 min), suggesting burrowing is important to rats. Climbing decreased from 76 to 7 bouts per day at 3 versus 13 months, probably because of declining physical ability. Upright standing decreased from 178 to 73 bouts per day, but continued to be frequently expressed even in older rats. Standard-housed rats stretched much more frequently than semi-naturalistic-housed rats (53 versus 6 bouts per day at 13 months), perhaps in compensation for inability to stretch upright and to relieve stiffness caused by low mobility associated with standard housing. These findings suggest that standard laboratory cages interfere with important natural behaviours, which is likely to compromise rat welfare.

Consideration

- Evidence & opinion – from all stakeholders
- Understanding the current position – Industry & inspectors
 - Inspection evidence
 - Establishment information – different sectors
 - Numbers (ROPs), ages, specific situations
 - Impact of changes
 - “Witness” evidence
 - Links to named persons / representative groups

Considerations

- Everyone thinks a good idea to increase if possible ?
- Many places – (especially academia) have bought larger cages
- Refurbishments being planned use double height cages
- Some sectors have difficulty

Local effects can work

- Excellent examples of named persons promoting / pushing higher / more complex cages
- Support to revalidate
- Different strains being used
- Funders requesting better cages
- Staff pressure
- “Playtime”
- Strain size
- Situation specific

Rat cage height – influence of inspectors

- Collation of info across the UK
- Respected source of advice & best practice
- Experienced in persuasion / nudge
- Advice at design stage of new / refurbished facilities – (PREPARE)
- Good contacts in stakeholder groups
- Direct contact and constructive challenge to project licence holders – key