ASRU – 2013/2014

Society of Biology

Will Reynolds

Head of Policy and Administration, ASRU
Presentation

- ASRU
- Transposition of the Directive
  - Operational Guidance
  - CoP
  - Statistics and reporting
  - ACHM
  - [Severity]
- Section 24
- Coalition Commitment
- ASPeL – licensing for the future
There are currently

-~15,500 active personal licences;
-~2,700 project licences; and,
-~175 designated establishments
The Act and Guidance


- Guidance: a reference document that explains how the Act is administered and enforced.
  - i) the scope and main provisions of the amended Act;
  - ii) the responsibilities of those with roles under the Act;
  - iii) licences granted under the Act, including the terms and conditions of their issue;
  - iv) severity classification, humane killing and the accommodation and care of animals; and,
  - v) how non-compliance is investigated and the range of sanctions available.

[The Guidance does not set any additional compliance requirements beyond those of the Act and the conditions included in licences.]
Transposition of the Directive

- Transposition points…
  - Absolute ban on use of great apes and stray animals of domestic species.
  - Simplified PIL system.
  - Publish of statistical information (21A – actual severity reporting).
  - ASC.

What we did - Guidance:
- Published ‘Quick start guide’ to the revised legislation.
CoP

- Draft published.
- Retained UK standards where applicable.
- CoP to be finalised and published in the New Year.
2013 collection:

- Electronic collection form to be compiled to send to users instead of paper form.
- Expectation that all returns will use the electronic format, although alternatives will be available if required.
- Forms to be sent out late December to early January as usual.
2014 Collection:

- Note to Stakeholders to go out in next ASRU Newsletter clarifying:
  - When we will make the form for 2014 available,
  - Advice notes,
  - ...particularly relating to the assessment of actual severity.
Animals Containing Human Material

Academy of Medical Sciences report in July 2011.

Purpose

● While most research of this sort will only require licence authority from a single regulator, some may require submission to more than one and/or referral to the national expert body before licence authorities can be granted.

● Guidance for investigators to make early contact with the appropriate regulator for advice on the authorities they will require.
Animals Containing Human Material

- Background information on relevant legislation (3 Acts).
- Classification of experiments included in the Academy of Medical Sciences report on Animals Containing Human Material published in July 2011.
- Examples of work in the relevant categories that is currently feasible and licensed – ASC referral category 3 (2 possibly).
- Guidance on the regulatory pathways applicable to different types of research involving the use of human material in animals.
- To be issued as further advice in the New Year.
Coalition Commitments

● Two commitments relating to ASPA
  i) Work to reduce the use of animals in scientific research
  ii) To end the testing of household products on animals.
Working to reduce the use of animals in scientific research.

- Brings together the UKs long tradition of support for animal welfare alongside its strength in, and our position at the forefront of, science and innovation. Builds on the UKs word leading status in adoption of 3Rs.
- Contribution to achieving wider openness, transparency and understanding about this area of work.
- A continuing need for regulated and ethically conducted research.
- Support for development and adoption of 3Rs techniques.
The Delivery Plan

● The Delivery Plan - a narrative of rationale for the use of animals in scientific research and a framework of measurable actions.

● Delivery of the Commitment is through 3 strategic priorities:
  1. A domestic programme – advancing the use of the 3Rs in the UK
  2. An international programme – influencing uptake and adoption of 3Rs
  3. Promoting understanding and awareness about the use of animals where no alternatives exist.

● Publication – envisaged mid-December.
Household Products

- The testing of household products is currently authorised in project licences granted under ASPA.
- Public consultation - general acceptance of the policy objective to end the testing of household products on animals.
- Concerns about detail of the implementation, particularly regarding the inclusion of ingredients.
- Ministerial consideration on the issue – plans for a way forward in the New Year.
Views of the public – openness and transparency.....Section 24.

- Over four-fifths (85%) are ‘conditional acceptors’ of the use of animals in scientific research.

- Over half (54%) trust the Government’s inspectorate and a similar proportion (53%) believe that Britain probably has tough rules in place to govern animal experimentation.

- Three-quarters (76%) agree there needs to be more research into alternatives to animal research.
Section 24

Issue

● A statutory bar that provides for the protection of confidential information provided. A breach of Section 24 can result in criminal sanctions.

● Section 24 – out of step with the Government’s drive for openness and transparency

Aim

● To design a new, more flexible framework, providing clarity while matching with the protection of information that would not be in the public interest to be released.
Section 24

Scope

● Maintain the position of the UK at the forefront of science and innovation, while ensuring the public fully understand the rationale behind the use of animals.

● A demonstrable commitment to foster a culture of openness and understanding and provide for informed public dialogue.

● Not in scope to provide information for others to conduct their own harm / benefit analysis as to whether a particular project should be initiated.
Stakeholder engagement

Wide-ranging engagement reaffirmed the need to design a more flexible framework:
- Design Council (x2 workshops)
- Focus groups
- ASRU Stakeholder meetings

Information to be protected
- People / Place
- Commercial information
- Intellectual Property

Next steps
- Public consultation will be early 2014. An open process to develop the options.
Accountability for Regulatory Impact

- Part of a range of Government measures.
- To incentivise regulators to make improvements to the business experience of regulation and foster a regulatory environment that is conducive to compliant growth.
- Minimisation of burden.
- Voluntary measure.
- The Accountability for Regulator Impact approach picks up what is not in scope of Impact Assessments.
- Early engagement and continued dialogue is key.
Growth duty

- Promotion of economic growth.

- A legal duty to require regulators to have regard to the impact of their actions on economic growth.

- Duty to be applied as part of the draft Deregulation Bill (final form will likely be guidance on how to meet the duty in execution of functions).

- Inappropriate to apply the growth duty to that which is concerned with the harm/benefit assessment of Project licence applications.

- Would fetter the intent of the Act and would be counter Government policy of reducing the harm and suffering to animals under scientific procedures.
ASPeL

- ASPeL is the new e-licensing system developed for the Home Office by the Web Technology Group.
- It is a web based solution designed to work on a variety of browsers.
- It is designed to be intuitive and easy to use.
- It was developed in parallel with the legislative changes so the forms and processes should be familiar.
ASPeL (the good bits)

● Can log in from anywhere with web access
● All licences are held on the system
● The system is quick
● The system is secure
● Works with the main web browsers
● Is flexible for the future
ASPeL (the not so good bits?)

- You need to monitor your work trays in the system
- The process flows are quite rigid
- It uses web forms
- It has a high level of security giving some issues with process
Issues and solutions

- ASRU helpdesk and technical support for resolution of problems
- Planned maintenance during the year
- Data security - off-site vaulting will be done to protect data.
What next?

- UAT completed
- Released to ASRU this week
- ASRU to put on establishments
- Phased roll out to the community PEL/PIL then PPL.
  - Early adopters
- Lessons learned
- Planned upgrades annually
2014 – policy and administration

Delivering
• The Coalition Commitment
• Advice under the Guidance
• ASPeL
• Section 24
• CoP
• Growth Duty

Embedding and consolidating
• The transposed Directive
• The guidance
• Accountability for regulatory impact