



Home Office

## Operational Newsletter

### Animals in Science Regulation Unit (ASRU)

**You should have received an invitation to register for SMART to enable you to continue to receive communications from us. This newsletter is being sent both via Notify and SMART but subsequent newsletters will be sent via SMART only.**

August 16, 2021

# 1. Update on Bridging Ways of Working

We have now completed and reviewed the first month of the new operating model.

We would like to thank all of you for your commitment to and patience in making this new model a success.

We have already in the first month:

- Identified **compliance assurance** issues which may not have been identified previously
- Started to manage **resourcing and priorities** in a more dynamic manner
- Started to identify **trends and themes** in areas of practice and of risk
- Identified **variation in practice** within ASRU and within the regulated community

We are highly encouraged by the delivery of these early benefits which will enable us to deliver better quality regulatory services.

In terms of delivery metrics these are still developing and being refined but we can share the following information with you:

## Regulatory Advice

- There have been formal central answers provided to **59 requests for regulatory advice**.
- **39(66%) of these were answered on the same day**.
- The median response time for answering queries was 2 days with a range of 1 - 10 days.
- These 59 requests for advice were received from 38 different establishments.
- Most queries have been requested by a licence holder.
- 60% of queries are about project licence authorities.

## Compliance Assurance

- The primary focus this month is on ensuring a standardised thorough review and response to PPL SC 18 reports.
- We have already received feedback that receiving these thorough responses in a timely way has been beneficial to the recipients.
- **Responses were provided to 107 PPL SC 18 reports between July 5 - 31.**

- There has been one remote audit conducted during the month and work is well underway to communicate pilot audit processes and standards as planned in September.
- **There are 37 ongoing cases of potential non-compliance being progressed.**

## Licensing

- There was a decline in the rate of processing project licensing tasks during the first two weeks of July. This was expected due to the time required to establish new processes in the compliance assurance and regulatory advice teams. This trend has now reversed.
- Also, during the first two weeks of July a quality control process returned amendments of licenses granted in `old format` to applicants as not complete due to vacant fields which occur in the new format application. Please note all vacant fields should be reviewed by applicants as some are relevant to complete even if not completed previously. However, the quality control process which returns applications with such identified vacant fields has been suspended.
- The number of licencing tasks processed during July 2021 is shown below together with corresponding data for April-June 2021:

	April	May	June	July
PPL applications	34	39	61	<b>59</b>
PPL amendments	104	93	109	<b>77</b>
PEL tasks	288	248	372	<b>520</b>
PIL applications	358	191	222	<b>180</b>
PIL amendments	65	50	61	<b>48</b>

- This data demonstrates some of the variability in demand which occur from month to month (for example, all PIL applications received are processed within the same month) but also demonstrates that the **number of licensing tasks processed in July 2021 was not significantly different to previous months with the possible exception of number of PPL amendments processed.**
- We continue to manually triage amendments within ASPeL to ensure they are processed more rapidly than new PPL applications. We are working with the ASPeL development team to see if this process can occur electronically in the future.

- We do not have accurate baseline data for project licensing task processing times as previous metrics were based on processing times for licences agreed as `complete and correct` only.
- We have agreed **typical timelines for licensing tasks** as shown below and will commence reporting on metrics against these timelines for licenses processed from August 2021 onwards. Please note these can vary based on the complexity of the task and overall workload. All days referenced are working days.
  - Initial project application review requiring ASC referral: 55 days
  - Initial project application review: 40 days
  - Second/subsequent project application reviews: 20 days
  - Initial project amendment applications: 20 days
  - Second/subsequent project amendment applications: 14 days
  - Urgent project amendment applications: 10 days
- During July we received **39 requests to expedite first review of applications which were less than 3 months prior to their expiry date**, and which required transfer of animals. In future we will not be expediting any such requests unless there are exceptional circumstances.
- At the start of the bridging ways of working on July 5 we identified there were 12 project licence applications submitted between February and April allocated to individual inspectors prior to the bridging ways of working which had not been yet been processed. **We prioritised processing these applications and that backlog is now resolved.**
- We are engaging with the ASPeL development team to prioritise and focus their upcoming activities to focus on **improvements to the project licence application process**. Our intentions are to reduce the amount of duplications and thus the length of project licence applications; to improve review processes for AWERBs and ASRU; and to remove from the issued licence any content that is not legally required. We will update you on details as they are available.
- The development of ASPeL processes for submission of **Returns of Procedures (ROPs)** is close to finalised and we will update you ahead of this functionality going live and provide updated guidance to you.

## Policy Development

- We are currently finalising two strategic policies:
  - Policy on Openness and Transparency
  - Regulatory Policy on use of animals for regulatory testing
- Once these are approved, they will be published, and we will communicate with you accordingly.
- As you will be aware there has been increased activity calling for a review of the government policy on the use of animals, particularly dogs, in science. The overall responsibility for the policy on the use of animals in science belongs to the Department for Business, Energy and Industrial Strategy (BEIS). We have been collaborating with our colleagues in BEIS to answer correspondence related to this activity.

## Relationship Management

- We are commencing the quarterly meetings between HOLCs and our operational relationship management lead in August and we will share trends and themes arising from these meetings in due course.
- We have undertaken the following activities in July:
  - Meeting with three members of the **Animals in Science Committee** on 9 July to obtain feedback into proposed priorities for ASRU objectives
  - **Steering Team Meeting** on the 27 July which focused on leading regulatory practice related to project licence assessment
  - **Regulated Community Change Team Meeting** on 9 July where we received feedback on the commencement of the bridging ways of working
  - 15 separate meetings with different stakeholders to answer questions on the Change Programme
  - Answering 45 emails to answer questions or receive feedback on the Change Programme
- The next **PEL holder meeting** is scheduled for **October 18 from 12.00-13.30** with a **follow up meeting** to address questions and feedback on **November 1 from 12-13.30**.
- The next **stakeholder meeting** is scheduled for **October 19 from 12-13.30** with a **follow up meeting** to address questions and feedback on **November 2 from 11.30-13.00**.

- Invites to these meetings will be sent in due course.

## 2. Sessions on Project Licence Standard Condition 18

- We will be running a sequence of three Teams sessions (each covering the same material) to outline the purpose and requirement for PPL Standard Condition 18 reports and to run through scenarios which commonly arise.
- Each establishment has been allocated up to three places on these sessions.
- **The PEL holder or their delegate should nominate the most appropriate individuals to attend (up to 3) from their establishment who can then cascade the information and training within the establishment.**
- These individuals can attend the same or different sessions as the material covered will be the same in all sessions.
- Each session will consist of a 90-minute communication, a 30-minute break and then 90 minutes reviewing scenarios.
- These sessions are scheduled as follows:
  - Tuesday September 21: 12.30-16.00
  - Wednesday September 29: 12.00-15.30
  - Thursday October 14: 13.30-17.00
- Please can one central contact per establishment (ideally the HOLC) notify Farai Dangarembizi at [Farai.Dangarembizi@homeoffice.gov.uk](mailto:Farai.Dangarembizi@homeoffice.gov.uk) of the names and contact details of the nominated individuals as soon as possible and no later than 10 September 2021. These individuals will then receive joining instructions for their chosen session.
- After all sessions are complete updated regulatory guidance in the form of frequently asked questions will be published on the ASRU website.