

Minutes of Meeting held on 12th September 2012 2 Marsham Street London SW1P 4DF

Present

Ms Sara Nathan (Chair)

Mr Mike Dennis

Dr Simon Glendinning

Dr Penny Hawkins

Dr Peter Hunt

Ms Hilary Newiss

Dr Ian Peers

Professor John Pickard

Dr Ken Simpson

Dr David Smith

Mrs Sarah Wolfensohn

Home Office (ASRU)

Dr Judy MacArthurClark (Head of ASRU) Mrs Sue Houlton (Chief Inspector ASRU) Dr Norman Flynn (ASRU Item 4 only) Mr Paul Vallender (ASRU Item 4 only)

Science Secretariat

Ms Rachel Humphreys (Head of Science Secretariat) Mr Philip Brenner (APC Secretariat) Mr Soheel Joosab (APC Secretariat)

Item 1: Welcome and apologies for absence

1.1 The Chair welcomed members to the meeting. Apologies had been received from Professor Hannah Buchanan-Smith, Dr John Doe and, Dr Mark Prescott.

Item 2: Minutes of the meeting held on 13 June 2012 APC (12)10

2.1 The minutes were subject to a number of amendments and were then approved.

Item 3: Matters arising

- 3.1 The Chair informed members that, following the Government reshuffle, Lord Taylor of Holbeach has been appointed as the new Minister responsible for the Committee. The Chair said she would be having a meeting with the new Minister shortly.
- 3.2 The Chair introduced the new Head of the Science Secretariat to members.

3.3 The Chair confirmed that a representative of the Office of Life Sciences at the Department for Business, Innovation and Skills had been invited to attend the October meeting to discuss the Non-human primates strategy recommended by the Weatherall report..

Item 4: Infringements paper APC(12)10

- 4.1 A paper was circulated to members summarising all the infringements which had action completed on them in 2011. Members were updated on the categories of infringements and the numbers of infringements in each category and actions taken. Members were asked what additional information they would like to see included in the summary as the Home Office was currently reviewing the data taking account of the new EU Directive requirements.
- 4.2 Members were advised that infringements were referred to senior management within days of being discovered by the Inspector or reported by establishments in order to promote national consistency in the handling of infringements. The Chief Inspector confirmed that the most serious class of infringements in Category D were referred to the Crown Prosecution Service. Concerns were raised that the Crown Prosecution Service rarely prosecuted regulatory matters but members agreed it was important to refer them to the Crown Prosecution Service for consideration to assure the public the Home Office was taking a proper approach to its regulatory functions. The Chief Inspector confirmed that every case was examined on its own merits. The establishments with more infringements were often academic ones and the number of infringements was often a reflection on differing managerial control systems.
- 4.3 Members asked about the policy on sanctions as there were concerns these had minimal effect. The Chief Inspector said that the main purpose of sanctions was to avoid future similar problems. Consequently, retraining of licensees was often required. A member noted this could delay a research programme but it was important for licensees to be appropriately retrained. The Head of ASRU said the Inspectorate wanted to encourage a culture of self reporting of infringements in the hope that more people would be inclined to raise any concerns.
- 4.4 One member suggested that changing the language to refer to non compliance rather than infringements might encourage more self reporting as sounding less punitive. The Inspectorate confirmed that they used the term "irregularity" until such time as an incident was confirmed as an infringement. This had the effect of encouraging more people to raise their concerns with the Inspectorate..
- 4.5 Another member asked about the relationship between the Inspectorate and establishments and whether a risk based approach to inspection was having an effect. It was confirmed that high risk establishments did have more visits. The Committee agreed they would like to see more information about long term trends and details of penalties.

Item 5: Philosophy and Neuroscience – reflections on a dialogue at the February meeting APC(12)11

5.1 A paper had been circulated summarising the dialogue that had taken place at the February meeting. The ensuing discussion raised several important points such as the balance of harms against benefits, the issue of medical benefit and the importance of research. It was agreed that this had been a useful discussion and it was up to the new Committee to consider whether and how to take this further.

Item 6: Developments on Recommendations on Education and Training to meet 2010/63/EU

- 6.1 A presentation on Developments on Recommendations on Education & Training to meet the new Directive had been circulated to members. This summarised the first Commission Expert Working Group on Education & Training (February 2012) and the progress of the FELASA/EFAT working group. Members were advised that the Expert Working Group was meeting later in September to make further progress.
- 6.2 The Expert Working Group meeting in February had discussed the development of EU non-binding education and training requirements for the four roles in Article 23. It was agreed to establish a modular system of training, together with requirements for supervision, competence assessment and continuing training needs. Learning outcomes were developed for some modules but this work was still ongoing. The criteria for passing and failing was discussed and there was a general call for papers with ideas about supervision, competence assessment and accreditation for the next meeting.
- 6.3 For the September meeting a `thought starter` paper was put forward by the Commission which included ideas for mechanisms for supervision and assessment of competence and a common framework to deliver consistency and quality assurance of the training. The UK was very well placed and represented through the Institute of Biology, UK accrediting bodies and UK training group.
- 6.4 A training package was envisaged that could avoid difficulties in retraining in different European countries. Currently there were problems in standardisation as in for instance Germany an applicant had to have a degree in a biological subject before being granted a project licence. However, the Commission was favourable to the more flexible approach currently in use in the UK.
- 6.5 Members were informed that there had been some concerns at the slow progress with implementation of the Directive needed by the end of the year. Existing UK training will satisfy the requirements apart from a module on the new legislation. What the Commission is deciding are minimum standards and some learning outcomes may be in excess of UK requirements. It has to be considered whether this is proportionate. It was suggested that there was an opportunity for the Committee to put forward a UK perspective. Another member advised that affordability would be an important factor and that e-learning was very far forward in several European countries compared to the UK.

Item 7: Statutory position of new Committee, APC actions for rest of year and successor body

- 7.1 Members were advised that discussions have been taking place with the Cabinet Office with a view to the new Committee remaining a non-departmental public body. The Home Office would be considering the process of recruiting a new chair and members. A working protocol and a memorandum of Understanding would be drafted on how the new Committee will engage with Government.
- 7.2 Members considered the outstanding actions for the remainder of the year. It was agreed that the most important action was to complete and publish the Committee's work on Cumulative Severity.
- 7.2 Members were informed that a farewell reception for the Committee was being arranged for the beginning of November.

Item 8: Home Office updates

8.1 Work was progressing on a coalition agreement to reduce and ban the use of laboratory animals in the testing of household products. A write around concerning the transposition of the new legislation was due to take place at the end of September. It was expected to be sent to the Joint Committee on Statutory Instruments on the 8th October and laid before Parliament on the 15th October.

Item 9: Cumulative Severity working group update

10.1 Members were advised that the analysis of the database by the Cumulative Severity working group was progressing. It was noted that this report might provide useful information to input into any EU discussions on severity. It was noted that there were disagreements between member states about the definitions of different levels of severity.

Item 10: Any other business

11.1 The Committee were informed that ASRU had developed excellent links with the Medicines and Healthcare Regulatory Agency following the Wickham expose.

Item 11: Date of next meeting

12.1 10 October 2012

APC Secretariat

September 2012