



The Sub-Committee for Biological Safety meeting on Monday, 19 January 2021 at 14:00 hrs took place virtually due to England entering a third National lockdown. University staff are instructed to work from home, where possible, during the Covid-19 pandemic lockdown.

This meeting took place on the online platform MS-TEAMS.

Present: Dr M Wills (Chairman), Dr A Gilliland (Secretary), Dr H Bertrand, Professor I Brierley, Dr G Christie, Mr M Elsdon, Mr T Fitzmaurice, Mrs C Gewert, Dr A Grant, Mr S Jameson, Dr T O'Connell, Professor S Ozanne, Dr K Tibbles and Dr M Vinnell.

In attendance: Mrs D Grover

**1. Apologies for absence**

Mr R Borthwick, Mr A Dahal, Ms A Gilderdale, Mr T Jones, Dr G Martell and Ms L Smith

**2. Minutes of the Sub-Committee meeting held on 19 October 2020**

The minutes were circulated to the Sub-Committee on 28 October 2020 with an invitation to provide comments via email. None were received and the Chairman signalled that he was content to sign these off.

**3. Matters arising from the Minutes**

There were no matters arising, all actions were completed or in the process of being completed and to be discussed under the relevant agenda item in the meeting.

**4. Biological Compliance**

**4.1 SAPO**

Dr Christie reported that the overhead water pipe work in the CL3 laboratory has been completed. However, there is a danger of being locked in, as the laboratory doors are not fully functional, even though the external contractors have signed off on this work. The external contractors are unable to come back on site for several months. Due to the lack of secure lab doors and the other maintenance work that needs to be undertaken, the department took the decision to destroy the lab stocks of the SAPO and Schedule 5 agent (*B.anthraxis* Sterne strain).

**4.2 Human Tissue Act**

The Secretary reported that there were a number of changes in Persons Designated, which had been approved by the Human Tissue Authority. The MRC-Toxicology Unit relocated from Leicester to Cambridge in November 2020 and has joined the University HTA Research Licence.

**4.3 Consultation on Gene Editing by Defra (Paper BS/2021/16)**

The Secretary outlined the Defra consultation on Gene Editing which focuses on research and marketing of gene edited organisms (GEOs) and GMOs that take place outside of the laboratory (ie activities under the 'Contained Use' (CU) regulations are not in scope).

Post- Brexit, retained EU law, together with domestic legislation, will continue to regulate the use of all GMOs as currently defined, including plants, animals and microbes in a range of applications including agriculture, food, medicine and environmental sensors.

The Defra consultation argues that the underlying EU legislation was written more than thirty years ago in response to the development of new genetic technologies that enabled scientists to transfer sections of genetic material from one species to another. Whilst this can occur in nature, it is not typical in traditional breeding. Therefore, as a precautionary measure, the current law requires that every GMO must be assessed and authorised before it can be released into the environment for research and development purposes or placed on the market.

Defra is consulting on the implications of ending the regulation of organisms developed by GE and other genetic technologies as GMOs, in cases where their genetic changes could have been produced by traditional breeding.

Defra is seeking comments on regulatory aspects as well as safety aspects; the Sub-Committee for Biological Safety's remit is to focus on human health and the impact on the environment. The Secretary stated that deliberate releases were not only restricted to plants and animals, but also occurred in other areas such as in medicine eg gene therapy.

The Secretary brought this consultation to the attention of the Sub-Committee as it relates to relevant legislation and to highlight that the future legal definition of GMOs may change for deliberate releases (DR) of marketing and trials in England.

The Secretary informed the Sub-Committee members that Dr Tibbles, Mr Elsdon, Mrs Gewert and herself (known as 'T+1' group) met to discuss this Consultation and their initial thoughts were:

- It would be preferable to have a single definition of what does/does not constitute a GMO to cover both DR and CU activities, most, if not all DR's are synthesised under CU prior to DR.
- Any new definition should apply to the UK and not only England.
- The scope and definition of 'Traditional breeding methods' will need to be defined.
- Will and if so, how, will GEOs be regulated? There are likely to be off-target effects - who/how will these be risk assessed before being released into the environment?

Some other academics will be consulted and a response put in to Defra.

A discussion of the Consultation then ensued:

Mr Fitzmaurice would like to know what Defra means by 'produced by traditional breeding' as these changes will affect different genetic structures, which might result in off-target effects. Those terms will need to be defined quite precisely and the consultation seemed very vague.

Dr O'Connell asked if the response would come from the Sub-Committee, from the University or as individuals as there most likely would be different views across the University and the T+1 group are the ones that deal with the regulation, which is a key point. Dr O'Connell would like to see that many people across the University are encouraged to respond with their views. The Secretary confirmed that there would likely be a range of views across the University of Cambridge and it was unlikely to reach a consensus opinion.

The Secretary offered to act as a point of contact for the collection of responses and would send the Consultation to other Academics within the University, she will also collate the responses into a summary.

The Secretary informed the Sub-Committee that the Consultation would be sent to a few departments who might not be aware that this was launched on 7 January 2021. Mr Fitzmaurice would like to know whether the Law Department should be included in the Consultation. Mr Elsdon thought that the Consultation should be sent out to the wider community at the University. Professor Ozanne also would like a couple of departments within the Clinical School to be consulted. The Secretary commented that the Science departments would be the most qualified to understand the scientific / technical aspects of GE and the proposed definition change.

Dr O'Connell pointed out that there is the University of Cambridge Centre for Law, Medicine and Life Sciences who might have an interest and a view on this issue as amending the definition of the technology may raise ethical questions. In the past, the Centre has produced papers on reproductive technology and gathered a University wide response. Dr Grant stated that parts of the consultation asks about wider GMO reform which would be relevant to other departments.

Dr Vinnell confirmed that it would be better to pursue a limited number of Academic responses to begin with, instead of sending it out to a vast number of Academics.

**Action: The Secretary will consult a limited set of departments as discussed by the sub-committee and noted in the minutes above.**

**Action: Dr O'Connell to send the Centre for Law, Medicine and Life Sciences contact to the Secretary.**

**Action: Members of the biological safety sub-committee to submit their responses to the consultation to the Secretary by the end of February 2021.**

#### 4.4 **Reports on Visits and Inspections (CTSA/HSE/Defra/APHA)**

The Secretary reported that there had been an Annual 'virtual' routine visit from APHA on 14 January 2021 to the Department of Plant Sciences. Some import/export issues had been highlighted. The APHA will carry out an onsite visit later this year. The Department of Zoology's APHA visit scheduled for 23 November 2020 had been postponed by APHA.

The CTSA visited the Department of Medicine to inspect one of the CL3 labs in the JCBC building on 15 January 2021. It has carried out inspections throughout the building process and there were no actions arising.

The HSE visited Wren Therapeutics on 8 December 2020, it is situated within the Department of Chemistry. The inspectors focused on large GMOs (in this case, *C.elegans*) and also inspected the premises in terms of Covid-secure measures. There were no issues raised.

#### 4.5 **Biological Safety Officers**

The Chair reported that BSO appointment letters were still outstanding for Professor Brierley and Mr Elsdon. Dr O'Connell informed the Sub-Committee that Ms Osborn is the BSO for the Department of Archaeology.

Post meeting note – The Safety Office has now received Mr Elsdon's BSO confirmation appointment letter.

**Action: The Secretariat to amend the BSO list to update Ms Osborn as BSO for the Department of Archaeology.**

#### 4.6 Leaflets/Policies and Codes of Practice

Mrs Gewert went through the draft outline of the new 'Safe Use of Blood and Tissue' leaflet (*Paper BS/2021/18*). Any comments on this leaflet should be sent to Mrs Gewert before the next Sub-Committee meeting as it is intended to launch the document at the BSO Training Event in May 2021.

Dr O'Connell gave congratulations on getting this information into a leaflet and asked if it would it be simpler to have a leaflet that provided information on 'The Safe Use of Blood in Laboratories' and another leaflet on 'Working with Human/Animal Tissue'? If not, then all Import/Export legislations should be included in this leaflet. Mr Elsdon was opposed to creating two leaflets and informed the Sub-Committee that there were signposts to other documents for more information on the Safety Office's website.

Dr Vinnell left the meeting at 14:50 hrs.

**Action: Sub-Committee members to provide Mrs Gewert with any comments before the next meeting as the new 'Safe Use of Blood and Tissue' document will be launched at the BSO Training Event in May 2021.**

#### 4.7 Containment Level 3

The Chairman summarised the CL3 Working Group's activities since October 2020 (*Paper BS/2021/19*). The Chairman reported that the cross-departmental inspections had started with a visit to the Anne McLaren building in November and a visit to the Department of Medicine in December. Selected members of the CL3 Working Group will be carrying out these visits. On each of the visits, different inspectors will participate to enable an exchange of opinions and ideas in a drive to continuously improve safe practice amongst all departments. Findings from those inspections will be shared amongst all stakeholders.

The Chairman reported that the CL3 Laboratory Policy (*Paper BS/2021/ 20*) had been approved at the CCFS in November 2020 and was now on the Safety Office's Intranet pages.

### 5. Training

#### 5.1 Biological Safety Officers Training Event (Tuesday, 18 May 2021)

Due to the COVID-19 pandemic restrictions that were in place last year, the Biological Safety Officers training event was cancelled. It has been decided that this year's BSOs training event will go ahead and that it will be held via TEAMS.

The Secretary went through the suggested topics for the programme:

- New Blood & Tissue leaflet / Sharps incidents statistics
- New Biological Risk Assessment template – to be sent to departments for beta-testing comment and then to finalise at the Sub-Committee meeting in April.
- Gene editing definition- update, if any from Defra
- BSO talk - either 'What to do in an emergency' or 'I have recently become a BSO, what do I do?'
- Autoclaves - validation and compliance with PSSR regulations

**Action: The Secretariat to send the new Biological Risk Assessment Template to departments for comment before it is finalised, this includes members of the Sub-Committee.**

**Action: Other suggestions or comments for the BSO Training Event are welcome from members of the Sub-Committee.**

## **5.2 Training Courses 2020-2021, biological and others**

The Secretary reported that there is a GM training course online on Tuesday, 9 March. The training course is due for a review and the aim is for it to be revamped and be placed on Moodle. Other training courses available this term include radiation, water safety training for responsible persons and fire manager training.

## **6. Accidents/Incidents**

The Chairman drew members' attention to the report (*Paper BS/2021/21*). He reported that the majority of the incidents were injuries from sharps, needle sticks and animal bites. Queries had been raised by Sub-Committee members regarding the following two incidents:

- ACCB236/A8 – this incident was originally reported to the Sub-Committee last year but it was logged incorrectly as a 'Dangerous Occurrence' (ACCB346/A5). Under the HSE, this is not a 'Dangerous Occurrence', but a 'Near Miss' event. A new incident record (ACCB236/A8) with all the information was created in November last year and has been included in this Accidents/Incidents report.
- ACCB397/A19 – concerns had been raised of a possible allergy risk due to a carcass having been taken out from the Anne McLaren building. Mark Elsdon informed the Sub-Committee that in principle it is acceptable to remove carcasses if the experimental set-up requires this, however this must be properly risk assessed. He pointed out that the UBS is not responsible for individual department's Risk Assessment. Appropriate LEV, good COSHH management and disposal are essential.

## **7. Reports**

### **7.1 Report from Estate Division (*Paper BS/2021/22*)**

No issues were raised relating to this report.

### **7.2 Report from the Safety Officer, School of the Biological Sciences**

Mr Elsdon informed the Sub-Committee that he is continuing to work with UBS/AMB to get various procedures and validation tests for the animal CL3 lab facility completed including the writing of SOPs. From a biological science training point of view, the 'Using Containment Facilities and Microbiological Safety Cabinets' training course will be run 'live' at the beginning of February 2021. This training course is due for a review and may result in parts of it needing to be rewritten.

### **7.3 Report from the Safety Officer, School of Clinical Medicine**

Dr Tibbles had nothing to report.

### **7.4 Report from Occupational Health**

The Secretary reported that Occupational Health were unable to attend the meeting, however they had provided the following update by email:

- Since Oct 2020 – three Containment Level 3 assessments have been completed.
- Appointments continue for occupational vaccinations/blood tests as part of any 'health clearance' that are required for work.
- Initial and follow up allergy screening continues to be undertaken via telephone contact.

### **7.5 Stevenage Bioscience Catalyst (SBC)**

The HSE was notified that the GM3190 centre for the Stevenage Bioscience Catalyst (SBC) is now closed. SBC will now be removed from the Sub-Committee's Terms of

Reference for the next Academic year and will no longer be a standing item on the Agenda.

**Action: The Secretariat to amend the Terms of Reference for the next Academic year and remove SBC as a standing item on the Agenda.**

**7.6 Report from Consultative Committee for Safety (CCFS)**

The Secretary drew members' attention to this report (*Paper BS/2021/23*), for noting only.

The meeting closed at 15:20 hrs.

**ACTION TABLE**

| ACTION NUMBER | ACTION                                                                                                                                                                                            | BY WHOM     | DATE COMPLETED |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------|
| 4.3 (i)       | Regarding the Defra GE consultation, the Secretary will consult a limited set of departments as discussed by the sub-committee and noted in the minutes.                                          | Secretary   |                |
| 4.3 (ii)      | Dr O'Connell to send the Centre for Law, Medicine and Life Sciences contact to the Secretary.                                                                                                     | TO'C        |                |
| 4.3 (iii)     | Members of the biological safety sub-committee to submit their responses to the consultation to the Secretary by the end of February 2021                                                         | All         |                |
| 4.5           | The Secretariat to amend the BSO list to update Ms Osborn as BSO for the Department of Archaeology.                                                                                               | Secretariat | Done           |
| 4.6           | Sub-Committee members to provide Mrs Gewert with any comments before the next meeting as this new 'Safe Use of Blood and Tissue' document will be launched at the BSO Training Event in May 2021. | All         |                |
| 5.1 (i)       | The Secretariat to send the new Biological Risk Assessment Template to selected departments for beta testing before it is finalised, this includes members of the Sub-Committee.                  | Secretariat |                |
| 5.1 (ii)      | Other suggestions or comments for the BSO Training Event are welcome from members of the Sub-Committee.                                                                                           | All         |                |