

**Guidelines of minimum requirements and criteria for
training provision and competency assessment for
operating high containment farmed animal facilities**

VetBioNet Deliverable 3.4 (ANNEX 2)

Version 01 (June 2021)



INTRODUCTION

VetBioNet's overall objective is to enhance the preparedness of the European Research Area to respond to and to control highly pathogenic (re-)emerging epizootic and zoonotic diseases through the rapid development of diagnostic tests, the generation of experimental data feeding European regulations, and the conception of preventive solutions. One key aspect for this preparedness is to connect a network of veterinary infectious disease research infrastructures being able to undertake experiments with farm or wildlife animals in high containment facilities. For this to be effective, there is a clear need for competent and well-trained staff to run and maintain HCFAFs.

As part of the VetBioNet Networking Activities, and to help with the (advanced) training of highly qualified staff, this Deliverable seeks to stipulate the minimum requirements and criteria for training provision and competency assessment to run and maintain these facilities.

The only standard available for the management of high containment facilities is the CEN CWA 15793:2011 agreement relating to "Laboratory biorisk management". Filling the gaps of the CWA 15793:2011, VetBioNet/WP3 strives to advise the project partners and other HCFAFs operators on how to meet the CWA 15793: 2011 standard.

The CWA 15793:2011 standard states that "The organization shall ensure that personnel that have responsibilities and /or perform tasks that may impact biorisk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience. The organization shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency" (item 4.4.2.).

This statement implies that all personnel working in a high or maximum containment facility must be properly trained, from animal caretakers to biosafety officers or technical personnel, as all of them "have responsibilities and/or perform tasks that may impact in biorisk management".



The CWA 15793:2011 lists specific roles, responsibilities and authorities that can be assigned to staff in biocontained facilities including: top management (item 4.4.1.1.), senior management (item 4.4.1.2), biorisk management committee (item 4.4.1.3), biorisk management advisor or biosafety officer (item 4.4.1.4), scientific management (item 4.4.1.5), occupational health responsible (item 4.4.1.6), facility management (item 4.4.1.7), security management (item 4.4.1.8) and animal handling (item 4.4.1.9).

The CWA 15793:2011 further stipulates that to be recruited or operational, staff fulfilling the roles listed above should have provable qualifications, experience and skills related to biosafety and biosecurity; otherwise the staff activities within the biocontained facility must be conducted under close supervision until competence has been demonstrated. All staff must be provided with (continuously updated) procedure documents (SOPs), training materials, practical courses and teaching offers related to biosafety and biosecurity and/or their specific operational roles.

OBJECTIVE

The present Guidelines aim to define:

- The minimum standards for biosafety and biosecurity training required by VetBioNet HCFAFs or biocontained laboratories
- The academic requirements for critical staff roles and positions and the associated biosafety training requirements and how they are fulfilled
- The evolving biosafety training needs identified by VetBioNet
- The minimum standards for health monitoring and vaccination in VetBioNet HCFAFs or biocontained laboratories

MATERIAL AND METHODS

An Excel questionnaire was sent to all partners (n=17) involved in Task 3.5 “Competence, training and health monitoring of staff”. This questionnaire looked at the staff roles indicated in the CWA 15793:2011 and the training and competence requirements that were considered critical by the VetBioNet partners for running HCFAFs: “Safe entry/exit”; “Use of critical barrier equipment”; “Donning and doffing PPE”; “Lab Disinfection & decontamination”; “Lab waste management”; “Facility Disinfection & decontamination”, “Fumigation”; “Facility waste management”; “Emergency/Contingency Plan”; “Animal care and welfare”; “Commissioning/Decommissioning”; “Maintenance”, “Calibration”, “Validation of devices”; “Security”; and “Transport of biological agents”.

The questionnaire was filled free-style, as the Excel sheets were not locked. Each partner/facility could provide the information they deemed suitable, and additional information regarding specific staff roles or training activities were readily accepted.

After receiving the collective feedback, follow-up requests were sent to some partners to ask for clarifications.

RESULTS

The questionnaire was sent to 17 network partners. Thirteen replies were obtained; 12 out of these came from partner organisations running HCFAFs for terrestrial animals; one reply came from a partner organisation working on aquatic animal diseases, and it became evident that additional work must be dedicated to define specific competence and training requirements for running aquatic animal/fish facilities (“Addendum Fish facilities”).

The Excel questionnaire, with a compilation of all partner indications for each queried item, is available on the VetBioNet collaborative workspace and can be shared upon request.

From the partner responses the following conclusions could be drawn:



Trained and competent staff are considered crucial for maintaining biosafety in high containment facilities that undertake research with exotic or zoonotic pathogens. The questionnaire pointed to two main instruments for acquiring the required qualification:

- Teaching using several tools such as e-learning, videos, (virtual) lectures and printed materials or manuals
- Hands-on training (on-site) with instructions or demonstrations

Being complementary, both training instruments were considered vital to warrant sufficient staff qualification and biosafety.

Training

Standard Operation Procedures (SOPs) are a standard element in biosafety training and Quality Assurance management, and all VetBioNet partner organisations use SOPs as training tools.

Preparatory classes prior to specialised training courses are put in place in 7 to 10 out of 12 partner sites depending on the activities concerned.

A clear conclusion from the questionnaire was that some specialised activities such as “Commissioning/decommissioning”, “Maintenance”, “Calibration”, “Validation of devices” and “Security” are not sufficiently covered by the partners’ standard training materials or courses.

The specific content of the training programme varies between facilities and also between containment areas within the same facility. Hence, a case-by-case assessment is needed to identify specific training and competence requirements (considering the pathogen risk group and a biosecurity risk analysis).

The questionnaire revealed some common trends regarding position vs qualification. At most of the VetBioNet partner sites, the key positions, that is “Head of Biocontainment Unit”, “Biosafety Officer”, “Senior Researcher” and “Researcher”, require a minimum academic qualification at a Master or PhD level, preferably in biological sciences. This does also apply to the “Building Officer” position, although in this case an engineer training or qualification is generally preferred.



Regarding the years of experience required in relevant tasks, major differences emerged for the same position among the partners/facilities. Extremes are the “Building Officer”, with requirements ranging from 15 years of experience to no requirements, and the “Biosafety Officer”, “Senior Researcher” or “Animal Caretaker Manager” positions, with requirements ranging from 10 years of experience to no requirements. The most common reply was “no reply”, pointing to no specific requirement as explicitly stated by some partners. When years of experience are required the present range is from 2 to 5 years.

A frequent reply to exclusion criteria for applicants is “no special requirements”. In other words, many facilities do not consider exclusion criteria ex ante. The only response that was given more often concerned the keeping of susceptible animals in private households. Surprisingly, the security profile or penal record of workers was not denoted as an exclusion criterion considering that some of the pathogens handled can be misused as biological weapons. Still, it should be stated that a criminal background check is a regulatory standard for recruiting staff for high containment facilities in most European countries.

Regarding the main SOPs for running high containment facilities and their observance by the different listed positions, the following picture emerged:

“Safe entry/exit” SOPs are, by far, the most common SOP required. For most of the partner facilities, all positions with the exceptions of the “Security Manager” and “Security Staff” must observe these SOPs. Second are SOPs delineating the facilities’ “Emergency/Contingency Plan”.

Three positions, “Head of the facility”, “Building officer” and “Biosafety officer” should sign and observe most of the SOPs at >50% of the surveyed facilities. These SOPs concern “Safe entry/exit”, “Critical barrier equipment”, “Donning and doffing PPE”, “Facility Disinfection & decontamination”, “Fumigation”, “Facility waste management”, “Emergency/Contingency Plan”, “Maintenance”, “Calibration”, “Validation of devices”



and “Security”. From this information, more general conclusions can be drawn about the competence requirements for different staff roles in biocontained facilities.

Close to the highest level of required competencies is the “Animal Caretaker Manager” role; only observance of “Validation of devices” and “Security” SOPs is not required for this position at most partner facilities.

The positions necessitating the least diverse competencies, based on the required observance of SOPs, are the “Security Manager” and “Security staff”; only specific “Security” SOPs do apply for these positions.

“Animal care” and “Animal welfare” SOPs do mainly apply to the “Animal caretaker manager” and associated staff (“Animal caretaker”). Only the “Head of the Biocontainment Unit” and “Biosafety Officer” (in this case only on “Animal care” SOPs) are also required to have knowledge of these SOPs.

The SOPs least required to be observed are those relating to “Commissioning/Decommissioning”.

For external visitors, and temporary workers, knowledge is required regarding “Safe entry/exit” procedures and to a lesser extent regarding “Critical barrier equipment”. For the remaining SOPs roughly $\frac{3}{4}$ of the surveyed facilities do not request or did not indicate requirements. It is assumed that visitors or temporary workers are either not performing critical “risky” tasks or that they are supervised and controlled during their stay.

In summary, the questionnaire results indicated that the “Head of Biocontainment Unit”, “Building Officer”, “Biosafety Officer” and the “Animal caretaker manager” and associated staff are crucial staff positions in terms of competence requirements.

Educational Technology

An additional trend emerging from the questionnaire was that activities related to “Commissioning/Decommissioning”, “Maintenance”, “Calibration”, “Validation of devices” and “Security” are not sufficiently covered by the standard training materials or courses. This is somewhat surprising, given the increased availability of e-learning



VetBioNet – H2020 n°731014

tools and recorded or live-streamed videos as useful tools for training programmes. Only 1 or 2 of the queried partner organisations have training videos available, and only for some specific activities such as “Safe entry/exit”, “Use of critical barrier equipment”, “Donning and doffing PPE”, “Lab disinfection & decontamination” and “Emergency/Contingency Plan”. A similar trend was observed when considering the use of institutional/own or external on-line platforms; strikingly, the latter has received no affirmative replies at all. The use of institutional/own on-line platforms was confirmed by 1 to 4 out of 12 partner organisations, but mainly centred on specific activities such as “Safe entry/exit”, “Donning and doffing PPE”, “Lab waste management”, “Facility waste management”, “Emergency/Contingency Plan” and “Security”.

Most trainings in the VetBioNet partner facilities are practical trainings involving supervision and/or mentoring. Five to 8 out of 12 answers indicated in-person supervision of the training. In other words, the role of the supervisor is critical in the VetBioNet facilities, notably when it comes to competence assessment. Activities for which trainings are rarely based on in-person supervision or hand-on experience are “Commissioning/Decommissioning”, “Security” and “Transport of biological agents”.

Obviously, all newly recruited staff must be enrolled in the facilities’ training programmes. In all facilities, the training programmes put in place consist of a combination of SOP-based theoretical training, hands-on training and in-person supervision or monitoring during the initial period of employment. Variations were seen regarding the supervision period.

Existing, experienced staff must be also re-trained as training is a continuous process. Procedures/SOPs are constantly amended and new biological risks may be introduced over time. Refresher trainings are thus common in the surveyed facilities; depending the respective activity, refresher trainings received 5 to 10 out of 12 affirmative replies. Based on the VetBioNet partner replies, the most and least frequently organised refresher trainings concern “Transport of biological agents” and “Commissioning/Decommissioning”, respectively. Refresher trainings are clearly considered mandatory by the facilities. Yet, the frequency of refresher trainings shows



net differences between facilities and staff positions. Nevertheless, an organisation of annual refresher trainings is common and received the majority of affirmative replies irrespective of the concerned activity.

External personnel (visitors, contractors, and maintenance staff) need also to be trained and/or to be under strict supervision by authorised personnel while conducting activities in the containment zone. Many facilities, however, schedule a technical stop each year of such personnel under less stringent rules and/or training to review their need and the conditions of access.

The questionnaire revealed that most of the facilities use diverse teaching methods and tools. This is in line with the general assumption that training is most effective when a variety of methods are used as people are differing in their learning techniques and capacities.

Regarding internal training evaluation, its main objective must be to evaluate the knowledge and skills obtained and if this knowledge/skill transfer is good enough to warrant staff qualification. The questionnaire indicated that in all VetBioNet facilities training evaluation rests on various pillars including written tests, quizzes, hands-on evaluation and auditing by supervisors and/or colleagues.

Competence assessment sheets are used by all facilities. The most common competence assessment system was “Direct supervision by training provider” (from 8 to 10 out of 12 replies), followed by “Direct supervision by different person” which received 5 to 9 out of 12 replies. This implies that both systems are put in place in the same facility in most of the cases. In contrast, oral or written examinations are scarcely used in the facilities and account for the highest number of explicit “No” replies, notably with regard to the following activities requiring solid practical experience: “Safe entry/exit”; “Critical barrier equipment”; “Donning and doffing PPE”; “Animal care”; “Animal welfare”; and “Transport of biological agents”.

Training records

Reviewing the partner replies concerning record keeping, it can be said that the preferred option to keep and survey training records is to keep and update a personal



checklist (hardcopy format), probably as part of the personal file for each employee (6 out of 12 replies). Personal electronic checklists and general facility electronic checklists are clearly less common (2 to 4 out of 12 replies). General facility checklists (hardcopy format) are kept by 5 out of the 12 facilities.

No common approach was seen regarding how and by whom these records are kept in the VetBioNet facilities. The most frequent replies indicated “Facility manager” or “Head of Biocontainment Unit” and “Biosafety Officer” or the “Biorisk Management” as contact points. “Quality Assurance” was indicated by 3 out of 9 replies as a general means for keeping the records.

Occupational Health

Regarding Occupational Health there is no standard approach adopted by all surveyed VetBioNet facilities. Half of the facilities/partner organisations have institutional Occupational Health services. However, most of the facilities rely on external or subcontracted Occupational Health services including those with dedicated institutional offices (for specific issues or services).

Most of the facilities have specific SOPs on Occupational Health (in some cases included in the biosafety manual); only 2-3 of the surveyed facilities answered in the negative.

Vaccine programmes are implemented in all facilities, but important differences exist regarding the pathogens targeted by vaccination. This is largely due to the diverse research activities at the VetBioNet facilities. However, the most quoted, by far, was anti-influenza vaccination. Compulsory influenza vaccination was quoted by 8 out of 12 surveyed facilities; anti-rabies ranked second among the compulsory vaccine programmes.

As to the collection and testing of baseline serum samples from staff, the questionnaire replies comprised “never” or “abandoned” in some cases, but most facilities affirmed that serum sampling is currently done. Still, differences exist in the sampling frequency and storage duration, ranging from “never” to >25 years.

Only 2 out of 12 facilities have an allergen surveillance program and another facility practices regular lung function tests for selected staff. However, most of the surveyed facilities replied “no” this question.

DISCUSSION

There have been various approaches to review biosafety training and competence requirements in recent years. Homer et al. 2013 listed ten main elements requiring managerial oversight to ensure biosafety: 1) fundamental principles of biosafety and biocontainment; 2) hazardous characteristics of each agents and toxin; 3) proper care and use of personal protective equipment (PPE); 4) proper care and use of laboratory safety equipment; 5) medical surveillance; 6) animal biosafety; 7) relevant federal, state and local regulations; 8) institutional and facility policies; 9) Standard Operating Procedures; and 10) biosecurity.

Another review by Canadian colleagues assigned equal importance to the training on containment systems and equipment: primary containment devices such as biological safety cabinets (BSC), how they work and are properly maintained; heating, ventilation and air conditioning (HVAC) systems; and decontamination systems (autoclaves, chemical airlocks, effluent decontamination systems, dunk tanks; and primary containment caging systems in animal facilities). The Canadian review further specified biosecurity issues: awareness on behaviours of concern; policies concerning access to dual use research pathogens; escort procedures; inventory documentation and record management and countermeasure responding.

Both reviews have been fed into the CWA 15793:2011 standard which provided the framework for the VetBioNet facilities questionnaire. The standard looks at the various roles required to achieve biosafety in biocontained laboratories (or HCFAFs for most of the VetBioNet facilities) and what training programmes and oversight they should have. The following are considered as critical in the standard: “Safe entry/exit”; “Use of critical barrier equipment”; “Donning and doffing PPE”; “Lab disinfection & decontamination”; “Lab waste management”; “Facility disinfection & decontamination”; “Fumigation”; “Facility waste management”; “Emergency/Contingency Plan”; “Animal



care and animal welfare”; “Commissioning/Decommissioning”; “Maintenance”; “Calibration”; “Validation of devices”; “Security”; and “Transport of biological agents”.

All of these training programmes share certain components and requirements as they are mainly focused on proper management of biological risks. Consequently, any specific position at a given facility should also share certain components and requirements with other positions of the same facility. As VetBioNet strives to promote harmonisation of standards among its partner facilities, these components and requirements should ideally be the same for equivalent positions in the different facilities. For instance, Biosafety Officers or equivalent positions should share core elements of their respective biosafety training and management programmes, including objectives and goals. The same applies to animal care takers or any other staff position high containment animal facilities.

Educational courses

An observed trend from the questionnaire was that certain activities such as “Commissioning/Decommissioning”, “Maintenance”, “Calibration”, “Validation devices” and “Security” are potentially underrepresented in the existing training materials or courses. This is somewhat surprising, given the increased availability of e-learning tools and recorded or live-streamed videos as useful tools for training programmes. Only 1 or 2 of the queried partner organisations have training videos available, and only for some specific activities such as “Safe entry/exit”, “Use of critical barrier equipment”, “Donning and doffing PPE”, “Lab disinfection & decontamination” and “Emergency/Contingency Plan”. A similar trend was observed when considering the use of institutional/own or external on-line platforms; strikingly, the latter has received no affirmative replies at all. The use of institutional/own on-line platforms was confirmed by 1 to 4 out of 12 partner organisations, but mainly centred on specific activities such as “Safe entry/exit”, “Donning and doffing PPE”, “Lab waste management”, “Facility waste management”, “Emergency/Contingency Plan” and “Security”.

Competence assessment



The standard is the direct supervision by someone with a proven level of competence, who is independent of the training provider. Though difficult to put into execution at small-medium size facilities, the preferred solution would be to opt for a direct supervision by a different person than the training provider as this would condition a higher degree of standardisation and normalisation within the facility.

Evaluation of Training

Although not explicitly mentioned by the surveyed facilities, the policy to hand out training evaluation forms at the end of the training course or session to obtain feedback from the trainees should be a common practice.

Recording of Training

There is not a common clear-cut standard regarding record keeping in the VetBioNet partner facilities. The ideal would probably be an electronic checklist that can be consulted anytime and anywhere. Whether this should be a personal or institutional checklist is a matter of debate. However, if we consider the subtext of the CWA 15793:2011, with biorisk management as the main objective, and the biocontained facility being at the centre of all biorisk elements, a general facility checklist should be the preferred option. Regarding archival storage, in the end, it must be a matter of Quality Assurance or any institutional officer taking care of this subject by delegation. Hence, we could distinguish a final archive managed by a QA programme/officer and an operational file which could be run by executive staff of the facility.

Conclusions

Can we define the minimum standards for biosafety and biocontainment training among facilities?

- Minimum training standards are achieved by instructing staff on SOPs, with additional educational courses being held prior to and/or accompanying the training
- Supervision until final qualification by competence assessment is mandatory

- Training by video and institutional on-line platforms or external on-line platforms are not often used

Can we define the minimum standards for health monitoring and vaccination?

- It seems impossible to determine minimum standards for health monitoring beyond specific vaccination programmes relating to the handled pathogens. Allergen surveillance is scarcely done, but this will likely change in the future.

What are the critical staff positions in HCFAFs and the necessary qualifications?

- Academic degree and work experience requirements as well as biosafety training requirements and how they are fulfilled, must be established for each position and each facility. Considering staff-specific training requirements, critical positions in HCFAFs are the “Head of Biocontainment”, “Biosafety Officer” and “Animal Caretaker Manager” and to some extent also the “Building Officer” and “Animal Caretaker staff”. To determine training requirements, it is necessary to define the biological risks linked to specific activities. All positions should be trained according to a proper risk management plan. From the survey it became evident that certain positions require more training than others. The questionnaire revealed that researchers (at all career levels) and technicians have particular training requirements regarding “Critical barrier equipment”, “Donning and doffing PPE”, “Lab disinfection & Decontamination”, “Lab waste management”, “Emergency/Contingency Plan” and “Transport of biological substances”. However, half or more than half of the surveyed facilities do not provide training programmes that are fully adapted to these requirements.

Future work

VetBioNet can help facilities with the design and/or implementation of training programmes on different aspects of biosafety and biocontainment and also promotes the exchange of knowledge and experiences. This is mainly accomplished by uploading regularly updated information and training materials on the VetBioNet website hosted by the WP5 (“Dissemination, training, data management and technology transfer”) lead.



Additional training material is required for specific activities including “Commissioning/Decommissioning”, “Maintenance”, “Calibration”, “Validation of devices” and “Security” which are rarely included in the existing training programmes. Task 3.4 “Facility design including commissioning and decommissioning” is dedicated to design such training materials.

REFERENCES

- Abad, Xavier (2013) Biosafety and quality issues must go hand in hand. *Biosafety* 2(3): e142; DOI: 10.4172/2167-0331.1000e142
- Abad, Xavier. (2014). CWA 15793: When the Biorisk Management is the Core of a Facility. *Biosafety* 3:2. DOI: 10.4172/2167-0331.1000119
- CWA 15793:2011 Laboratory Biorisk Assessment. A CEN Workshop agreement.
- Homer, I.C., Alderman, T.S., Blair, H.A., Brocard, A-S., Broussard, E.E et al. (2013). Guidelines for Biosafety Training Programs for Workers Assigned to BSL-3 Research Laboratories. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*. Volume 11 (1):10-19. DOI: 10.1089/bsp.2012.0038