RECHERCHE EXPERIMENTALE ET
PROTECTION DE L'ANIMAL DE LABORATOIRE

Bref'OPAL n°4 - Mai 2015

Chers Amis de l'OPAL,

Nous avons le grand plaisir de vous proposer ce quatrième numéro de notre lettre électronique, Bref'OPAL. Ce numéro est entièrement consacré à la Plateforme ETP-LAS : Education and Training Platform for Laboratory Animal Science. Cette plateforme a été créée le 5 juillet 2013 à Bruxelles, sous l'impulsion de la Commission, lors d'un meeting sur ce thème dans les locaux de la DG-ENV. La Commission a souhaité montrer sa volonté de faciliter et encourager la reconnaissance mutuelle des formations dans le domaine de l'expérimentation animale (LAS en anglais (Laboratory Animal Science)). Nous utiliserons ce Bref'OPAL pour vous diffuser le plus largement possible les dernières informations concernant le travail effectué par cette plateforme, qui après un début assez lent, a maintenant pris une importance qu'on ne peut pas négliger. Rappelons aussi que le domaine des formations en expérimentation animale est strictement de la compétence des Etats Membres.

A la dernière réunion des 'National Contact Points' (NCP) à Bruxelles les 10 et 11 mars 2015, la plateforme a été présentée. Le document a été présenté à la fois durant la séance à huis clos et à celle des observateurs de la réunion des NCP le 11 Mars.

Au cours de la séance à huis clos, il y eu une présentation conjointe de la DG ENV et la DG GROW sur l'impact de la proposition de reconnaissance mutuelle ETP-LAS sur la révision de la directive sur les qualifications professionnelles (2013/55 / UE). Les deux DG ont convenu que l'initiative ETPLAS était utile que les formations LAS <u>deviennent des professions réglementées</u> ou pas dans le cadre de la directive 2013/55. Des membres du 'Steering Committee' de la plateforme ETP-LAS sont en faveur du passage des formations 'LAS' au rang de formations réglementées, avec reconnaissance mutuelle.

Certaines inquiétudes ont été exprimées par le NCP de la Suède concernant le statut du document ETPLAS et son impact sur les processus nationaux.

*Pour vos commentaires, avis et réflexion, nous reproduisons ci-dessous l'intégralité de la version actuelle non définitive du document produit par la plateforme et qui concerne la reconnaissance mutuelle des formations dans le domaine de l'expérimentation animale, à l'échelle européenne. Nous vous recommandons particulièrement la lecture attentive du paragraphe '**The need for Mutual Recognition and Acceptance'**, et l'usage pas anodin du mot 'discretion'. Nous référons aussi au Bref'OPAL 2 pour un résumé rapide de la situation actuelle (très disparate) en Europe.*

Le CA de l'OPAL vous souhaite une excellente continuation dans vos travaux et vous donne rendez-vous pour notre prochaine lettre électronique.

Education & Training in Laboratory Animal Science – Minimal Requirements for Mutual Recognition of Courses

A Proposal from the Education & Training Platform for Laboratory Animal Science (ETPLAS) to Competent Authorities of the Member States (Draft 3)

Background

A laboratory animal science (LAS) education and training (E&T) framework has been developed by the EU to respond to the need for harmonisation and a common approach to ensure competence and to facilitate free movement of personnel. The details are contained in a working document [1] that was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes at their meeting of 19-20 February 2014. Within this document, one topic covered is that of approval and accreditation of training courses. However, the EU working document does not differentiate between processes of approval and accreditation and sets out requirements that could be applicable to both. Whilst this might be a desirable solution in the long-term, there is a need to address the current situation and develop a set of principles and information requirements that would allow mutual recognition of training courses between Member States. Currently, there are many different approaches employed within the EU to provide LAS training.

There is agreement by Member States (MS) that there needs to be a common approach to assure confidence in the quality of training and assessments being provided.

The need for Mutual Recognition and Acceptance

Lack of mutual recognition of training courses within the EU could lead to animals being used unnecessarily for training purposes if training has to be repeated. Free movement of personnel could also be hindered. Since arrangements for LAS education and training is at the discretion of the Member States, there is the risk that different requirements for assuring the quality of E & T courses may arise. This could also lead to a variable quality of animal welfare and the science using live animals. There is the need, therefore, to develop **common principles** and **information requirements** for E & T programmes on which MS could agree in order to achieve confidence in the quality of E & T and its assessment process and hence mutual recognition. Such principles could also be beneficial to aid programme providers in setting up courses of agreed quality and content.

This document sets out guidance for stakeholders involved in establishing education and training programmes which aim to achieve mutual recognition within the EU. The document is developed using the EU E&T Guidance document as the basis.

Further work is required to establish a common evaluation framework to permit mutual acceptance of a person's practical training and competence achieved in the work place.

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[1] National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. A working document on the development of a common education and training framework to fulfil the requirements under the Directive.
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf

Principles of Mutual Recognition and Acceptance

To meet obligations under Article 23 of the Directive, Member States have to ensure that all staff is appropriately trained and competent – there is therefore a need between Member States to indicate satisfaction over training provisions and competence assessment– whether delivered locally, regionally, nationally or internationally. This is a two-stage process with initial training during a prescribed course followed by development of competence at the work place. Training alone does not deliver competence.

Any course recognition is achieved in a number of ways including Member State's (or delegated) authority, through educational management and quality control or through independent bodies providing relevant expertise and objectivity.

Therefore we need:

- Confidence in training standards

- Agreement on the principles for competence assessment and confidence in adherence to these principles

- Good communications to deliver mutual recognition between Member States

- A recognition process based on similar information and assessment in order to ensure quality and greater consistency

- A common evaluation framework as the basis for mutual acceptance of training carried out elsewhere

Adherence to these principles should result in mutual recognition of a training program *per se*. MS could agree to accept courses that have undergone an approval or accreditation process meeting the information requirements set out below.

Information Requirements for Mutual Recognition of Training Courses

Any process to ensure mutual recognition should specify clearly to course providers which information on course content, delivery and assessment should be provided to approval or accrediting bodies. The information should cover *inter alia*

1. Applicant and institution. When applicable include appropriate quality reference (legal, regulatory or any relevant training reference)

2. Information on qualifications/experience of educators, trainers and assessors

3. Syllabus for the Module(s) including practical elements, if applicable, and the associated Learning Outcomes (LO)

4. If existing, full reference to course programme and other relevant information as to how LOs are assessed. All relevant information to readily assess course programme and LOs achievement

5. Certification (in course language and English) to promote free movement

6. Certificate to include module details for information (or link to relevant information)

7. Module provider to maintain records of participants and course assessment results in accordance with requirements of the Member State

8. Comprehensive detailed course listing of topics covered regarding regulatory and legal modules (European framework, national, local legislation)

The above information requirements are considered the minimum to allow for mutual recognition and are extracted from the list in the EU Working document (page 17) that details those requirements for approval/accreditation. The information requirements listed in the EU document and not considered essential for achieving mutual recognition are presented in Appendix B.

The Role of the ETPLAS in aiding Mutual Recognition

The Education & Training Platform for Laboratory Animal Science (ETPLAS), formerly the EU Platform, has been established to enable information sharing and communication between course providers, approval/accrediting bodies and Member State authorities. Mutual recognition is a continuing process which is reliant on good communication between all interested parties. ETPLAS can facilitate this process and can:

- **offer advice and information** to new and existing accreditation/approval bodies [2]

- **offer advice and information** to prospective course providers

- **facilitate the process to develop and agree quality criteria**

- **maintain a list of courses** which respond to the agreed quality criteria

- **encourage consistency of content and outcomes** across modules and between training providers

- **encourage compliance with declared objectives** and procedures in relation to the delivery of training and assessment of the LOs

- **review and update the mechanisms for monitori**ng the successful outcome of training and assessment when deemed useful

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[2] See Appendix A, Glossary of Terms

Glossary of terms

Accreditation

Process in which certification of competency, or credibility is presented. In this context, an accredited course meets all the required criteria for a course approval but in addition has some additional criteria.

Approval

Process by which the quality of a course and its ability to deliver competence to the trainee is recognized

(Education and) Training

Training may cover one or more modules as outlined in the endorsed consensus document and may consist of just theoretical or both theoretical and practical training

Mutual recognition

Agreement between stakeholders to recognise each other's processes or programmes (if they are in line with the recommendations of the endorsed consensus document).

Mutual acceptance

Agreement between stakeholders to accept a person's training/competency records

Quality assurance

The maintenance of a desired level of quality in a service or product, which might form part of an accreditation process.

Additional elements required for a course accreditation

The following list of information requirements that are usually required for a course accreditation, extracted from the EU endorsed consensus document, are not considered essential in order for a course to meet minimum quality criteria for the purposes of mutual recognition:

- Minimum of two courses to be held prior to approval/accreditation

- Visit to course

- Course material and the way it will be taught including hand-outs, pre-course reading, teaching aids

- Information on use (and justification for use) of live animals

- Description of facilities where course is taking place

- Timetable and information about type of teaching in each session

- Communication with students

- Ration of trainees to lecturers in both theory and practical elements

- If distance learning, what methods will be used and how to ensure independent assessments

- Attendance requirements

- Information on attendance and pass/fail frequency of course