Key points in new legislation and revised project license

KEKS Seminar
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New legislation

- EU directive 2010/63/EU on the protection of animals used for scientific purposes
  - Full harmonization directive which means that it must be implemented in the legislation in member countries
- National legislation in Finland
  - Act on the protection of animals used for scientific or educational purposes 497/2013
  - Government Decree on the protection of animals used for scientific or educational purposes 564/2013
- Unofficial translations in ELLA-pages
  - [http://www.laaninhallitus.fi/lh%5Cetc%5Cetela%5Chanka%5Ckоеet%5Cellapro%5Chome.nsf/pages/indexeng](http://www.laaninhallitus.fi/lh%5Cetc%5Cetela%5Chanka%5Ckоеet%5Cellapro%5Chome.nsf/pages/indexeng)
  - In English, also other information and links, regularly updated, now under revision
New legislation – anything new?

● Yes

● Especial emphasis on the 3R’s principle

● The definitions have changed
  ● An animal experiment is a project
  ● An experimental animal is an animal used for scientific or educational purposes
  ● Fetuses (the last third of their normal development) are regulated by this law

● National committee for the protection of animals used for scientific purposes

● Union Reference Laboratory for replacement methods
  ● In Finland in Tampere
New legislation – anything new?

- Yes in facilities (so called operator)
  - More responsibilities to control, follow and organize
    - Person responsible for the activity
    - Person(s) responsible for the establishment
    - Designated veterinarian
  - More record keeping and statistics
  - Records on the medication of animals (Sakari)
  - Animal welfare body (Sakari)
  - Animals can be rehomed after experiment under certain circumstances
  - More education and training
    - Responsibility to take care that the staff is competent and the competence is maintained
New legislation – anything new?

- Yes in license applications and projects
  - A non-technical summary
  - Severity classification (Sakari, Veikko) and actual severity
  - Retrospective assessment with severe projects (Sakari)

- The definition of procedure is still the same:
  - A procedure which may cause the animal the level of pain, suffering, distress or lasting harm equivalent to, or higher than that caused by introduction of a needle in accordance with good veterinary practice
License application – some hints

- License can still be applied only in Finnish
  - There will be updated application form in English, just to help the group in preparation of application
- Use always the newest form in ELLA-pages
- Different types of forms – different prices
  - Short (?) license 600 €
  - Normal license 1000 €
  - Long (?) license 2500 €
  - Change of the license
    - ELLA decision 300 €
    - ESAVI decision 100 €
- Announcement only, no decision 0 €
License application – some hints

● 3 R’s must be considered in each step

● The persons involved
  ● The applicant
  ● The person responsible for the project is responsible that everything under the project is done according to legislation and license
  ● Designer of the project and procedures
    ● Needs to have the designer competence
    ● At least one in each project

● The competence of those doing procedures
  ● No names, but a statement
License application – some hints

- Explanations how the severity classification will be done for statistics and retrospective assessment
  - The statistics in Provet – but someone needs to do it!
- The statement from the animal facility
  - Animal welfare body, veterinarian or other responsible person – in KEKS Hanna-Marja or Sakari
- License is usually given for 3 years, in some special cases for 5 years
- Non-technical summary
  - Guidance in English
License application – some hints

- Often the project has one or more subprojects
  - The aim of all those must be the same
- First the overall project will be described and all 3R’s must be considered
  - Each subproject will described separately
- All the procedures must be explained in details
  - That will anyway be asked by ELLA
- Use tables or other way which may help the reader to understand what will be done and when
- Especially important is to understand what will be done to an individual animal
License application – some hints

- Animal care is asked in point 5.6. – especial attention if the social animals are planned to be kept alone. Why? Any refinement?
- The harm to animals in point 5.9. – what kind of harm, what is the risk, how do you make sure that the harm is minimized, humane end points
- Severity assessment separately to each subprojects
- ELLA makes the harm-benefit analysis
- Actual severity or retrospective analysis after the project has been finished
Some special details—changes in the license

- **No change or announcement** is needed to ELLA when
  - The change does not increase the pain and distress of the animal
  - The change improves animal welfare, according to 3R’s

- **Announcement** to ELLA is enough when
  - The license holder or the responsible person are changed
  - No decision is given, no charge

- **Some minor changes**, like minor increasing of the number of animals or extended time for the project
  - Use the license change form
  - License can be given directly by ELLA officers (ESAVI decision, 100 €)

- Contact Hanna-Marja or Sakari, or ELLA (Eila Kaliste or Seppo Peuranen) – sometimes the question may be new and needs some consideration
Some special details—changes in the license

- Change in the license is not needed if you want to change the animal strain/line during the experiment and the new line has no welfare problems
  - BUT if there are welfare problems, you need to apply for the change in the license
Some special details – gm-animals

- DNA-sample without ELLA-license only as an ear sample
  - For tail biopsy, the license is needed
- Gm-line with any welfare issue must be under ELLA-license – even if the animals are killed before the welfare problem starts
- Crosses of two gm-lines need ELLA-license if this new line will be continued to be a real line
  - No ELLA-license is needed if only F1-hybrids are done

- Anything else?
How to get competence – laboratory animal courses
New requirements for competences

- All persons working with laboratory animals must have an appropriate competence
- Competence must be maintained – continued professional development – continuous training
New requirements for competences

- New function groups
  - Directive art. 23 and legislation §8
- The staff shall be adequately educated and trained before they perform any of the following functions:
  a. Carrying out procedures on animals
  b. Designing procedures and projects An academic degree in an appropriate scientific discipline
  c. Taking care of animals
  d. Killing animals
- Staff carrying out functions a, c and d shall be supervised before they have demonstrated the competence
New education

- For all working with laboratory animals
  - Also for designated veterinarians, project evaluators, inspectors
- Detailed and accepted document on education and training
- Based on modular structure, with the aim that different modules can be taken in different institutes
- Emphasize on species specific education and training
- Many steps before the competence is reached
  - The course is not enough
- In Finland, we have harmonized the course programmes at the beginning of 2013
# New requirements - modules

## Core Modules - Functions A, B, C & D

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<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>National legislation</td>
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<tr>
<td>2</td>
<td>Ethics, animal welfare and the Three Rs (level 1)</td>
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<tr>
<td>3.1</td>
<td>Basic and appropriate biology – species specific (theory)</td>
</tr>
<tr>
<td>4</td>
<td>Animal care, health and management – species specific (theory)</td>
</tr>
<tr>
<td>5</td>
<td>Recognition of pain, suffering and distress – species specific</td>
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<td>6.1</td>
<td>Humane methods of killing (theory)</td>
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## Function Specific (Prerequisite) Modules - Function A

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<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>3.2</td>
<td>Basic and appropriate biology – species specific (practical)</td>
</tr>
<tr>
<td>7</td>
<td>Minimally invasive procedures without anaesthesia – species specific (theory)</td>
</tr>
<tr>
<td>8</td>
<td>Minimally invasive procedures without anaesthesia – species specific (skills)</td>
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## Function Specific (Prerequisite) Modules - Function B

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<tbody>
<tr>
<td>7</td>
<td>Minimally invasive procedures without anaesthesia – species specific (theory)</td>
</tr>
<tr>
<td>9</td>
<td>Ethics, animal welfare and the Three Rs (level 2)</td>
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<tr>
<td>10</td>
<td>Design of procedures and projects (level 1)</td>
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<tr>
<td>11</td>
<td>Design of procedures and projects (level 2)</td>
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New requirements - modules

### Additional Task Specific Modules

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<tr>
<td>20</td>
<td>Anaesthesia for minor procedures</td>
</tr>
<tr>
<td>21</td>
<td>Advanced anaesthesia for surgical or prolonged procedures</td>
</tr>
<tr>
<td>22</td>
<td>Principles of surgery</td>
</tr>
<tr>
<td>23</td>
<td>Advanced animal husbandry, care and enrichment practices</td>
</tr>
<tr>
<td>24</td>
<td>Designated Veterinarian</td>
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<td>25</td>
<td>Project Evaluator</td>
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### Other Additional Modules

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<tbody>
<tr>
<td>30</td>
<td>Introduction to the local environment (establishment) for persons taking specific roles under the Directive</td>
</tr>
<tr>
<td>31</td>
<td>Information provision and retrieval</td>
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Example of a module

Module 5: Recognition of pain, suffering and distress – species specific [Core]

This module prepares individuals to be able to identify normal condition and behaviour of experimental animals and enable them to differentiate between a normal animal and one which is showing signs of pain, suffering or distress which could be a result of factors including environment, husbandry or the effect of experimental protocols. It will also provide information regarding severity classifications, cumulative severity and the use of humane endpoints.

Learning Outcomes

Trainees should be able to:

5.1. Recognise normal or desirable behaviour and appearance of the individuals in the context of species, environment and physiological status.

5.2. Recognise abnormal behaviour and signs of discomfort, pain, suffering, or distress, as well as signs of positive well-being and principles of how pain, suffering and distress can be managed.

5.3. Discuss factors to be considered and methods available for assessing and recording the welfare of animals e.g. score sheets.

5.4. Describe what a humane end point is. Identify criteria to be used to set humane endpoints. Define action to be taken when a humane endpoint is reached and consider possible options for refining methods to finish at an earlier endpoint.

5.5. Describe the severity classifications included in the Directive and give examples of each category, explain cumulative severity and the effect this may have on the severity classification.

5.6. Describe the circumstances when anaesthesia or analgesia may be necessary to minimise pain, suffering, distress or lasting harm.
EDUCATIONAL LEARNING PROCESS
UNDER DIRECTIVE 2010/63/EU
New courses – what is different?

- Main difference is that the old researcher course (80 hours course which gave competence to do procedures and design the experiments) is divided in two courses
- The contents is based on the recommendations
  - No real changes compared to old contents, more hands-on
- Species specific training – in KEKS: mice, rats and on request pigs and sheep
  - The training is documented in species specific certificates
- **Before any education and competence**, it is possible to work under supervision of competent persons – but not in a project where pain or harm is expected (figure in slide 21)
Course for carrying out procedures

- Aimed at researchers, students and other personnel doing experimental procedures
- Around 30 hours theory + 10 hours hands-on /species
  - Mouse and rat; pig, sheep and other species if needed
- KEKS organizes this course annually
  - Every second year in Finnish, every second in English
  - A video course was organized with Kuopio 2014
- After the course, a person is allowed to do the procedures under supervision
  - The skills must be documented
- The competence will be accomplished when
  - Course has been passed
  - More training, and skills shown in specific procedures
Course for designing projects

- In each project there must be at least one person who has the competence for designing procedures and projects
  - Academic degree and a course for designers
  - Equivalent to the competence which was given in the old C-category course – some universities still organize the long courses

- In Oulu (harmonized system) the person needs to pass first the procedure course and have 180 ECTS credits
  - In the course, a project will be planned
  - Mainly working in pairs, a few hours of theory
  - The first design-course will be organized in spring 2015, in English
The role of EU

- The purpose of EU is that education and competences are harmonized in the way that the competence given in one country is valid in another EU-country.
- The accreditation/recognition system is under preparation.
- A register of people having competences must be created.

- EU Education & Training Platform has been established to work on those questions.
  - Hanna-Marja represents Finland and is a treasurer of this (still poor) platform.
Questions – ideas ?