# Directive 2010/63/EU

## Working together towards a successful transposition

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# Working together towards a successful transposition

- Legal background
- Tools to promote uniform transposition
- Topics of priority
  - *Objectives*
  - *Outcomes*
- Future work

# Legal background

- Directive 2010/63/EU entered into force in 2010
- Member States have 24 months for transposition
- Maintenance of stricter measures
- Adoption of national measures by 10 Nov 2012
- Directive fully applicable from 1 Jan 2013

➢ No interference with MS legislative process

# Tools to promote uniform transposition

The Commission facilitates the process through

- Twice yearly National Contact Point meetings
- **Expert Working Group discussions**
- Legal and technical questions

- Information portal at the Commission web-site

# Composition of Expert Working Groups

## Experts requested to be nominated by

- Member States
- Other countries (candidate/acceding, NO, CH)
- Main stakeholder organisations representing
  - *Science/Academia*
  - *Industry*
  - *NGOs for Animal Welfare*
  - *Other relevant organisations such as FELASA, ESLAV, EFAT, AAALAC*

# Topics of priority for discussion at Expert Working Groups

- Statistical reporting
- Genetically Altered (GA) animals
- Severity Assessment
- Education and Training

# Statistical reporting - legal framework and status

- Legal requirement under Article 54
- From voluntary agreement to binding rules
- Draft Implementing Act proposed for adoption
- Vote by 11 Sep 2012

➢ Current reporting system needs to be aligned to respond to the new requirements

# Statistical reporting – legal background

Art 54 requires that

*" 2. Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures,* ***including information*** *on* ***the actual severity*** *of the procedures and on the* ***origin and species of non-human primates*** *used in procedures…"*

# Statistical reporting – legal background

Article 2 provides that

*"..2. This Directive shall apply where animals are used or intended to be used in procedures, or **bred specifically so that their organs or tissues may be used** for scientific purposes.*

*3. This Directive shall apply to the following animals: ….. (ii) **foetal forms of mammals** as from the last third of their normal development;*

*… (b) **live cephalopods.."***

# Statistical reporting – legal background

Art 3 provides that

*"..This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the **creation and maintenance of a genetically modified animal line** in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;.."*

# Statistical reporting - requirements

- Total number of *naïve animals*
- *Use of animals* in *procedures* with details
- Related actual severity for animal for procedure
- Genetically altered animals are reported either
  - *when used for the creation of a new line;*
  - *when used for the maintenance of an "established" line with an intended and exhibited "harmful phenotype"; or*
  - *when used in other (scientific) procedures (i.e. not for creation or for the maintenance of a line).*

# Topics of priority

- Statistical reporting
- GA animals
- Severity Assessment
- Education and Training

# Genetically altered animals – objectives

To develop and agree general principles as to

- Terminology
- How GA animals are to be considered under project authorisation and statistical reporting
- The severity assessment of GA animals to determine what is considered a harmful phenotype

# Genetically altered animals – results

- ***GA animals*** *= include genetically modified (transgenic, knock-out and other forms of genetic alteration) and naturally occurring or induced mutant animals as per the definition in Article 3(1).*
- ***Defining factor :*** *intended non-harmful or harmful phenotype*

# Genetically altered animals – results

- *A new **strain or line** of genetically altered animals is considered to be "**established**"*
  - ✓ *when transmission of the **genetic alteration is stable,** which will be a minimum of two generations, and*
  - ✓ *an **initial welfare assessment** has been **completed**.*

# Genetically altered animals – results

- ***Welfare Assessment***

  *Should include an assessment of general health, welfare and behaviour together with a review of production parameters such as breeding and growth performance which will ideally be compared with an appropriate non-GA background strain.*

# Topics of priority

- Statistical reporting
- GA animals
- Severity Assessment
- Education and Training

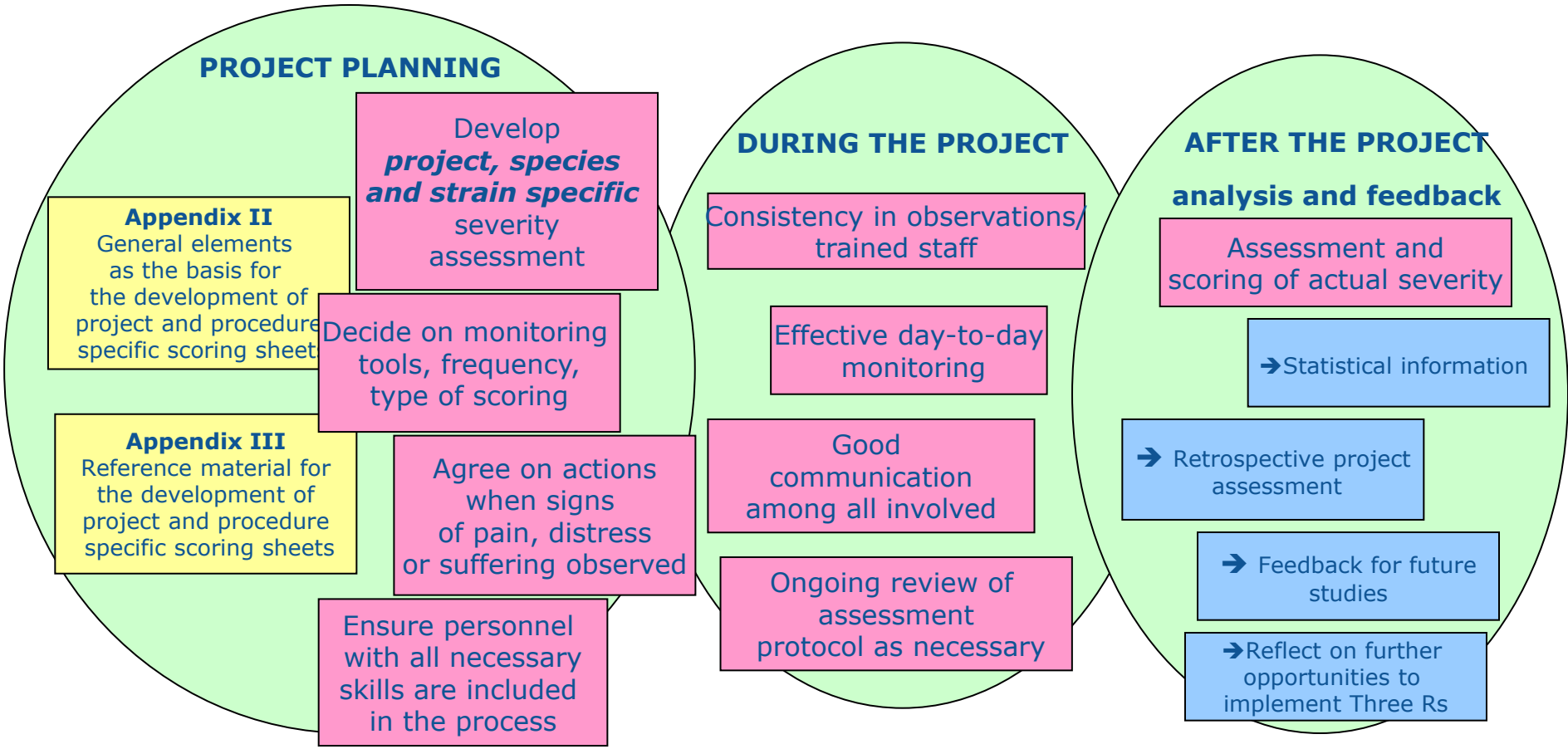
# Severity assessment – legal requirements

- Article 4(3) *"MS shall ensure refinement of breeding, accommodation and care, and of methods used in procedures,* ***eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm*** *to the animals."*
- Article 54(2) *"…statistical information on the use of animals in procedures, including* ***information on the actual severity*** *of the procedures…"*

# Severity assessment – objectives

- Define and develop a retrospective severity assessment framework
- Develop some worked examples to illustrate the severity assessment process

# SEVERITY ASSESSMENT – A CONTINUOUS PROCESS




**Appendix IV**
Example(s) of project/procedure specific severity assessment including the day-to-day assessment sheets, scoring tools, choices of monitoring methods and final assessment.

# Topics of priority

- Statistical reporting
- GA animals
- Severity Assessment
- Education and Training

# Education and training – legal requirements

Art 23(2) requires that

*"..The staff shall be **adequately educated** and **trained** before they perform any of the following functions" …*

*"…Staff carrying out functions referred to in points (a), (c) or (d) shall be **supervised** in the performance of their tasks until they have **demonstrated the requisite competence**"…*

# Education and training – legal requirements

Art 23(3) requires that

> *"Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for **obtaining**, **maintaining** and **demonstrating** requisite **competence** for the functions set out in paragraph 2."*

# Education and training – legal requirements

Art 23(4) requires that

> *"Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2)."*

# Education and training – objectives

- A common understanding of a flexible, need-driven quality training
- Reliance on the modules provided in the EU to meet the agreed quality criteria
- Confidence in competence assessment

➢ Ensure competence of staff

➢ Facilitate free movement of personnel

# Education and training – objectives

## Key criteria

- Flexible
- Available and accessible
- Affordable
- Of agreed quality

# Education and training

Spring 2012 – Focus on ***WHAT***

- Agree on *principles*
- Set the *common framework*
- Agree on output driven *quality standards* for contents

Autumn 2012 – Focus on ***HOW***

- 'Accreditation' of modules
- Assessment of competence
- Delivery of training
- Additional training needs

# Education and training – outcome/work in progress

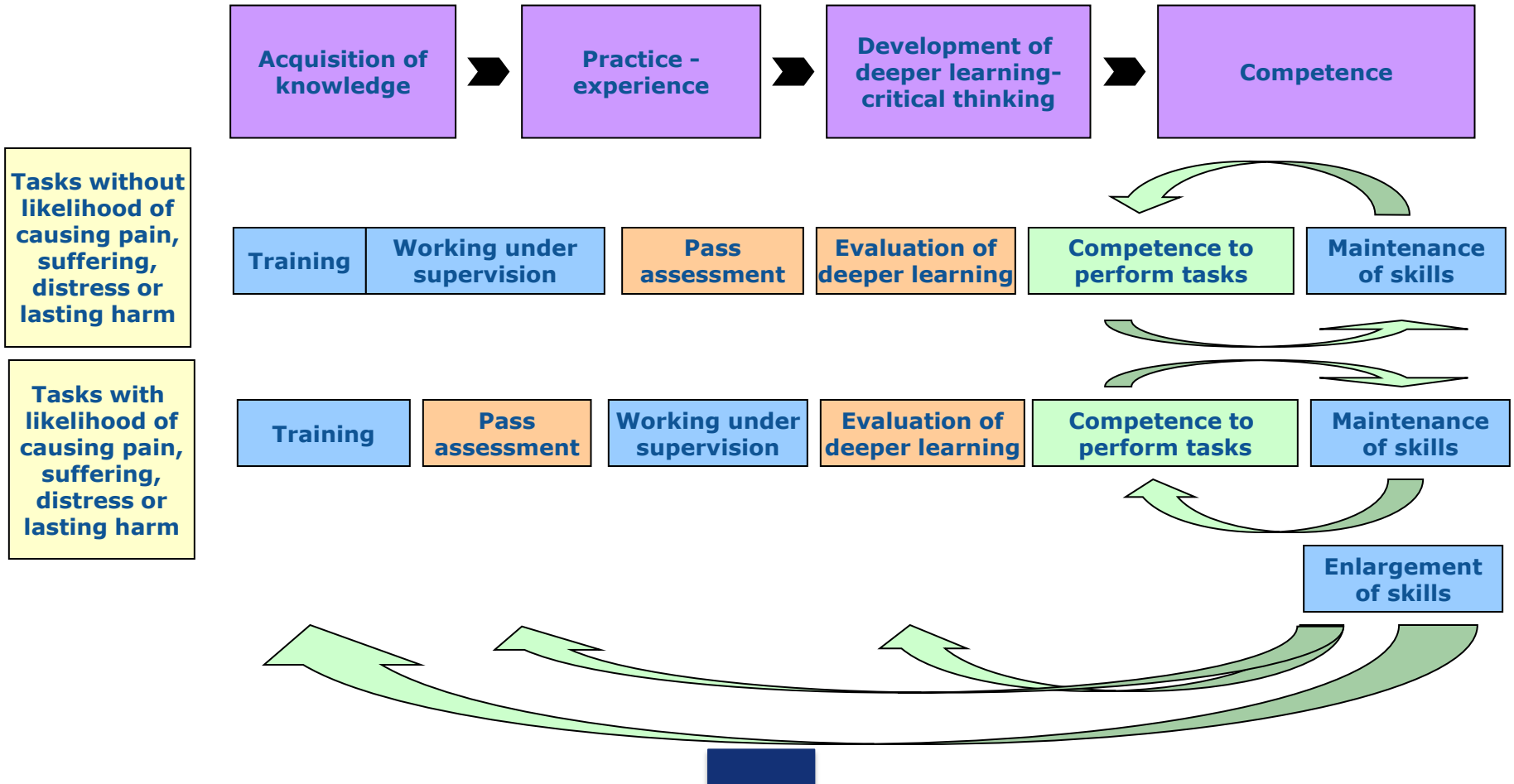
- ***Core module*** *= a compulsory module for* ***all functions*** *and with the* ***same learning outcomes***
- ***Prerequisite module*** *= a compulsory module for (a) specific function(s)*
- ***National module*** *= includes national/regional transposing legislation and any other legislation relevant to the use of animals for scientific purposes (e.g. transport, CITES, waste, GM)*

# Education and training – outcome/work in progress

## Quality criteria for a training module:

- Sufficiently detailed learning outcomes
  - *Theoretical knowledge to be gained*
  - *Practical skills to be obtained*
- Defined assessment of competence

# Education and training – outcome/work in progress



# Future work for discussion at Expert Working Groups

- Education and Training III
- Information on Three R alternatives
- Project evaluation/Retrospective assessment
- Inspections

Laboratory Animals

- Legislation
  - Legislation for the protection of animals used for scientific purposes
  - Implementation of Directive 2010/63/EU
    - Interpretation and terminology
    - Transposition scoreboard
    - Stricter national measures
    - Member States National contact points
    - PARERE Network
  - Revision of Directive 86/609/EEC
- Statistics
- Opinions of European Commission Expert Committees
- Alternative methods
- Related topics
- Events
- Links
- Contact Us

# Interpretation and terminology of Directive 2010/63/EU

The following documents are intended as guidance to assist Member States and others affected by this Directive to arrive at a common understanding of the provisions contained in the Directive. All comments should be considered only within the context of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority.

## legal understanding

ing the legal understanding of specific provisions of the ument for the benefit of all those affected by the

The National Contact Points (NCP) sible for the implementation of Directive 2010/63/EU on the protection of animals used for mmission agreed to discuss a number of articles contained in the Directive with a vi ach throughout the EU.

Some elements of the Directive have been/are subject to specific Expert Working Group (EWG) meetings to which all Member States and main stakeholder organisations are invited to nominate experts. The outcome of the EWG meetings is then presented to NCP for endorsement.

The consensus on the understanding of the elements discussed at the NCP meetings are presented below to promote uniform implementation and application of the Directive. It is important to note that some of these documents may present "work in progress" (indicated as such). However, it was felt important to inform all those affected by the Directive as soon as progress is made.

The consensus document II of 22-23 March 2012 covers the principles of creation, establishment and maintenance of **genetically altered animal** lines and how these are considered within project authorisation and statistical reporting.

# *Thank you for your attention!*

***http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm***