# Directive 2010/63/EU

## Focus on implementation – the key to success

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# Focus on implementation – the key to success

- Legal background and transposition
- Tools to promote uniform implementation
- Topics of priority
  - *Objectives*
  - *Examples*
- Future work

# Legal background

- Directive 2010/63/EU entered into force in 2010
- Possibility for the maintenance of existing stricter measures
- Adoption of national measures by 10 Nov 2012
- Directive fully applicable from 1 Jan 2013
- The Commission examines the ***completeness*** as well as the ***correctness*** of transposition

# Transposition

- Enforcement is a key priority for the Commission
- The advancement of transposition is followed up closely
- The first letters of formal notice have already been sent to those MS that have not yet transposed
- Follow-up through initiation of a formal infringement where appropriate, including a possibility of fines

ENVIRONMENT

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# Laboratory Animals

## Transposition Scoreboard

According to Article 61 of the Directive "*Member States shall adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.*"

…ys for a quick overview as to whether the Member States have notified partially or …cluding re-notification of already existing measures if these are intended to be relied …

…itative overview as to whether or not a Member State …udgement on the completeness and accuracy of the national transposition.

| MEMBER STATE | AWAITING NOTIFICATION | FULL NOTIFICATION |
|---|---|---|
| AUSTRIA | |  |
| BELGIUM |  | |
| BULGARIA | |  |

# Back to the basics - the Three Rs in the Directive

- *Explicitly spells out the Three Rs: e.g. Recitals 10-13; Articles 1, 4, 13*
- *Ensuring that Refinement is not limited to scientific procedures but also relevant in relation to care, accommodation and breeding of animals*
- *The development, validation and use of alternative approaches more firmly anchored – as a clear legal requirement*

# Tools to promote uniform transposition

The Commission facilitates the process through

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

➢ Information portal at the Commission web-site

# Topics of priority

- ***Statistical reporting***
- Genetically Altered animals
- ***Severity Assessment***
- ***Education and Training***
- Non-technical project summaries
- Information on the Three Rs

# The objectives and the work of the Expert Working Groups

- Reach common **understanding** of the issues
- Agree on a **common framework** and **approach**
- Agree on **criteria** and **principles**
- Recommend **good practice** and **optimum processes**
- Provide practical, demonstrative examples to facilitate understanding

# Statistical reporting – legal background – Article 54

*" 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…"*

- **The current reporting needs to be aligned to respond to the new requirements**

# Statistical reporting - requirements

- Total number of *naïve animals*
- *Use of animals* in *procedures* with details
- Related ***actual severity*** for animal for procedure
- Genetic status of the animals

➢ ***Commission Implementing Decision 2012/707/EU of 14 November 2012***

# Severity assessment – legal requirements

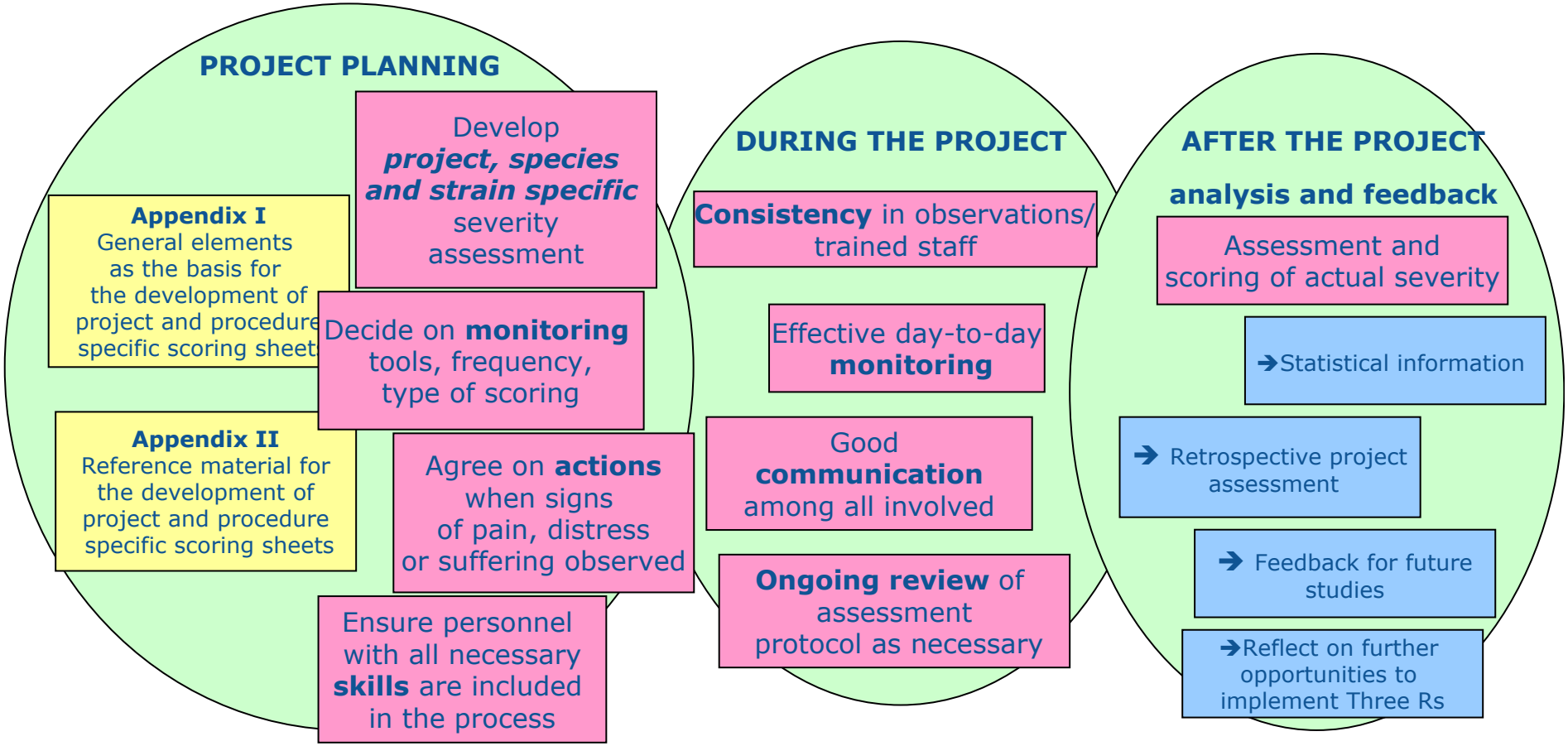
- Article 4(3) *"[MS] shall ensure … **eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm** …."*
- Article 15(1) *"[MS] shall ensure that **all procedures are classified** as 'non-recovery', 'mild', 'moderate', or 'severe' …"*
- Article 54(2) *"…statistical information…, including **information on the actual severity** of the procedures…"*

# Severity assessment – objectives

- Define and develop a severity assessment framework covering the entire process from the project conception to a final assessment

- Develop some worked examples to illustrate the severity assessment process

# SEVERITY ASSESSMENT – A CONTINUOUS PROCESS




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

# 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 – objectives

## Key criteria

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

➢ Ensure ***competence*** of staff

➢ Facilitate free movement of personnel

# Education and training framework

- *Agree on principles for a modular training*
- *Define output driven quality standards (LOs)*
- *Define principles for module accreditation/approval*
- *Set criteria for the assessment of competence, supervision and CPD*
- *Create a common Training Record Template*
- *Possibility of establishing an EU platform for E&T*

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# 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.

# Future work for discussion at Expert Working Groups

- Project evaluation/Retrospective assessment
  - **19-20 March 2012**
- Education and Training III
  - **3-4 July 2013**
- Inspections
  - **Nov/Dec 2013**

# Three Rs beyond the Directive

*Working together to facilitate the implementation of the Three Rs by focusing on*

- Individual attitudes
- Culture of the environment/community

➢ ***through development of tools of implementation and promotion of improved practises***

# Conclusions

- The Directive sets the **legal requirement to apply the Three Rs**
- There is a true opportunity to **bring the Three Rs *alive*** beyond 'just transposition'
- The results are a demonstration of the willingness of all involved to bring together the state of the art knowledge for a successful implementation
- ***ultimately for the benefit of animals and science***


The work continues –
let's keep the
momentum going!

# *Thank you for your attention!*

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