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Moving forwards with effective regulation, the 3Rs and alternative methods

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Directive 2010/63/EU

- Adopted 2010. Applicable from January 2013. Required to be reviewed by November 2017.
- Represents **improved framework** for regulation in many Member States.
- Includes requirements which could help **replace, reduce** and **refine** animal use (3Rs), and **improve animal welfare**.
- A **compromise** text. Contains many 'exemptions'; no real restriction on use of non-human primates or strategy for phasing out; permits 'severe' suffering etc.
- **Requires effective implementation and enforcement**.

Harmonisation

- A main aim of the Directive - but concerns persist about **poor** and **inconsistent implementation** and **enforcement**.

Differences between MS:

- How some requirements have been **transposed**.
- How some requirements are being **interpreted**.
- **Understanding** of what is actually required.
- Level of priority and resourcing given to competent authorities.

Member State endorsed EC guidance documents NOT widely disseminated/utilised

- Inspections and enforcement
- Project evaluation and retrospective assessment
- Animal Welfare Bodies and National Committees
- Education and training
- Severity assessment

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Areas of concern

Authorisation and enforcement	
Obligations	**Concerns arising**
Effective enforcement of legislation.	Some MS's still **lack experience and expertise** of regulating this area.
Competent authorities require **expertise** in science and animal welfare, and proper **resourcing** (personnel, infrastructure).	Some have **minimal number of government inspectors**.
Includes '**regular**' **inspections of all breeders, suppliers and users** to verify compliance.	Establishments could go several years without being inspected.

Areas of concern

Project evaluation	
Obligations	**Concerns arising**
Must evaluate **scientific objectives, predicted benefits, compliance with 3Rs, impacts on animals, justification (science, ethics) etc**.	**Lack of transparency.** Unclear how 3Rs are considered, what expertise is being utilised, and priority given to animal welfare.
Process must be **impartial** and **transparent.** 	Lack of critical challenge - concerns it can be a **'tick-box' exercise**.
	Badly designed, carried out and reported animal research is still being funded, authorised and carried out.
	Animal use remains **high**, inc. hundreds of thousands of animals experiencing '**severe**' suffering.

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Areas of concern

Animal Welfare Bodies (AWB)	
Obligations	**Concerns**
An internal body at each breeder, supplier or user institution **to advise on and promote application of 3Rs,** and **animal welfare** at local level.	Unclear whether in some Member States AWBs have even been **set up**, or EC guidance followed.
	Minimum requirements in Directive for AWB **tasks** and **membership** (inc. skills and expertise) are insufficient - can just involve two people.
	Little training available for AWB members in most Member States.

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Areas of concern

National Committees for the Protection of Animals Used for Scientific Purposes	
Obligations	**Concerns**
Advise competent authority & AWBs on matters including care and use of animals, '**ensure sharing of best practice**', and exchange info at EU level.	While majority of MS have now established a Committee, many are **inactive** or have only a **narrow membership**, or very **limited resourcing**.
Important to have a **balanced membership** and involve a wide range of expertise and perspectives.	**Lack of liaison** with AWBs, or involvement of stakeholders.
Require sufficient funding and **resources**.	

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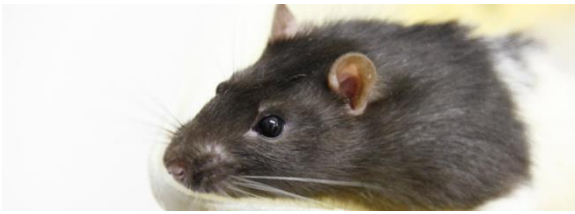
Areas of concern

Stricter national measures - Article 2	
Obligation	**Concern arising**
Member States must have regard for Article 114 of the Treaty on the Functioning of the European Union.	MS's may consider that this prevents them from adopting any improved welfare standards. We believe that this is **unacceptable** given significant public morality and societal concerns on this issue, and our increasing understanding of animals' behavioural needs and capacity to suffer.



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Areas of concern

Openness and transparency	
Obligations	**Concerns**
Directive contains some **useful tools.** Essential for **public accountability** and for **helping focus 3Rs efforts** (e.g. where animal suffering is currently greatest): • Non-technical summaries of projects. • Statistical reporting (including of 'actual severity'). • Implementation reports from MS. • A transparent project evaluation process.	NTS **often poorly written**, weighted towards the 'benefits', lacking discussion of harms, giving only minimal insight. **Lack of information** on how **AWBs** operate, or how **project evaluation** is being done Concerns on **accuracy of statistical reports** on animal use from some Member States.

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Areas of concern

Alternative approaches	
Obligations	**Concerns**
Requirement to follow **3Rs** principles and mandates the **use of alternative methods** wherever possible.	Unacceptable **delays to regulatory uptake** of alternatives once developed. **Insufficient training** for scientists on alternatives.
Member States and Commission shall **contribute to the development and validation of alternative methods.**	**Insufficient contributions and activities.**
Union Reference Laboratory (**EURL ECVAM**) and a network of laboratories shall be set up with aim of speeding up development, validation and uptake of alternatives (Art 47, 48 and Annex VII).	**Little evidence that EURL ECVAM is** much better **funded**, **impactful** or **effective** now than pre-Directive.
Commission shall conduct periodic **thematic reviews** of 3Rs uptake.	Need more work targeting the 90% (approx.) of animal use (e.g. **basic, applied research**) that doesn't relate to 'regulatory testing'.

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EURL ECVAM - is it functioning properly?

ECVAM
Established 1994
Art 7.2 and 23 of Dir 86/609/EEC

Primary focus:
VALIDATION of alternative methods

EURL ECVAM
Established 2011
Art 48 of Dir 2010/63/EU

Participate in the validation of alternative approaches.
Be responsible, in particular, for:

(a) **Coordinating** and promoting the **development** and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing;

(b) **Coordinating** the **validation** of alternative approaches at Union level;

(c) Acting as a **focal point for the exchange of information**

(d) Setting up, maintaining and **managing public databases and information systems**

(e) **Promoting dialogue** with a view to the development, validation, regulatory acceptance, international recognition, and application of alternative approaches.

EURL ECVAM	
Achievements	**Concerns**
Helping lead a number of significant projects on the **OECD Test Guidelines Programme** (human health and environment effects).	Only a **small number** of replacement methods have been **validated** in recent years.
Work (along with EPAA) led to **regulatory acceptance under REACH** of non-animal approaches for assessing **skin sensitisation**.	The Network of Laboratories for the Validation of Alternative Methods Laboratories (**EU NETVAL**) are **not being used to their full potential/capacity**.
Established a **database**, a **search guide**, and a **tracking system** on alternative methods.	There is insufficient transparency and interaction with members within EURL ECVAM's **Stakeholder Forum** (ESTAF). It does not operate as a proper forum for exchange.
Has brought range of '**3R centres**' together for meetings.	Requires increased **funding and resources**.

Review process of Directive 2010/63/EU

Nov 2010	Jan 2013	2015	May 2016	June 2016	Sept 2016
Adoption of Directive 2010/63/EU.	Directive due to apply in all Member States.	Final Member State adopts Directive into their law.	**Commission review process started** Questionnaires to stakeholders	SCHEER opinion concerning the need for the use of non-human primates in biomedical research, safety and efficacy testing: Call for information (8 June - 3 July)	**Commission started analysis of questionnaires** **Member States:** 28 **Stakeholders:** 52 **Users:** 889

Time

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Review process of Directive 2010/63/EU

February/March 2017	Nov 2017	Nov 2018	2019
Draft Review report produced by Commission. Public consultation on draft SCHEER opinion.	**Final Review report published by EC** Commission to propose amendments? *Not obliged to be sent to Council or Parliament for scrutiny.*	Member States to submit **implementation reports** to Commission (Article 54)	Commission report on **implementation** of Directive *(to be sent to Council and Parliament).* First **statistical report** under Directive 2010/63/EU for all 28 Member States published. Commission to carry out an **evaluation report**.

Time

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Summary of problems

- **Inconsistent implementation** of Directive requirements.
- **Insufficient training, understanding** and **resources**.
- Potential '**rubber-stamp' regulation** and only lip service paid to 3Rs.
- More could be done in practice to **reduce animal use and suffering**.
- Alternatives efforts need **more investment**, and are currently **too focused on regulatory toxicology**.

Positive actions

- **European Parliament** adoption of pilot project in 2017 budget - €1 million towards promotion of alternatives etc.
- Training provided by the **European Commission** to help people better report data on ‘actual severity’ of animal suffering.
- **Member States** activities e.g. Swedish government to provide funding for a new 3Rs centre.
- **Animal welfare NGO** initiatives e.g. RSPCA’s work to end ‘severe’ suffering.

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What is now needed?

- Every MS needs appropriate **mechanisms** and **action plans** to deliver and monitor the new measures.
- More **critical challenge** of the validity of animal models and the standards to which science is being undertaken.
- Increased focus on **basic** and **applied research** for the development and use of alternative methods.
- More opportunities for **training**, **dialogue** between stakeholders and **sharing good practice** (e.g. National Committees, Animal Welfare Bodies, scientists)
- **Amendments** to be taken up as part of the Review and the Evaluation process, to improve effectiveness of **Directive**.

Thank you

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