Introduction

This paper is designed to help those who are perhaps unfamiliar with European Union Law with some basic starting points, and to pose some questions about the implementation of the Directive in Member States' domestic Law that will help in analysing how effective the harmonisation has been. It is separated into three parts: A) general points about EU Law; B) general comments on the Directive, and C) comments on specific Articles.

A. **General points about European Union Law**

1. "Directive"

There are three types of primary legislation that the EU institutions can produce: "Regulation", "Directive", and "Guideline".

Regulations have "direct effect" in Member States' law, and in the law of countries in the European Economic Area - from the day that they come into effect as described in the Regulation, a Regulation is, as it stands, part of the law of the MS or EEA jurisdiction without further implementation. They used to reflect specific areas with a high level of political and practical agreement, and high harmonisation goals.

Directives have "indirect effect". MS and EEA are bound to implement the Directive, but they must translate it into their own law (by primary or secondary legislation, etc.) to give effect to the Directive. The European Commission is charged with ensuring that the Directive is implemented (which it largely does by responding to complaints first at a political level - letters to the national government - or through a case at the European Court of Justice. Directives traditionally cover a wider area than Regulations, and tend to have more areas of discretion for the MS; there will be issues, perhaps reflecting political disagreement in the legislative process, where there is no general agreement about, for example, how far a measure should go in relation to particular aspects of the issue, and in that case the MS is given space to accommodate its own view. However, this is only discretion within the strict limits set by the Directive. The Directive should not be considered 'optional'; a Directive is binding on the MS and EEA.

Guidelines are optional, reflecting a political wish in the Union, but insufficient consensus to produce harmonising, binding legislation.

2. Article 114

Directive 2010/63/EU, as with the vast majority of EU legislation, concerns harmonisation of domestic law to create a single market. MS of the European Union surrender parts of their sovereignty to the EU, under the two treaties of the Union ("the Treaty of European Union" and the "Treaty on the Functioning of the European Union" - "The Treaties"). These are analogous to the 'operating software' in a computer system. They give the legal 'code' within which 'apps' (legislation on specific issues) can work. Therefore, each 'app', in our case legislation on using animals for scientific purposes, needs to be based in the ceded authority given to the Union by the MS - and the major authority to legislate is to create measures to harmonise domestic legislation to create a single market across Europe.

So, we are not primarily concerned with animal welfare here - we are concerned to harmonise the rules concerning animal welfare to create a single market across Europe. (See Recital 1, "These disparities [in MS law since the implementation of the 1986 Directive] are liable to constitute barriers to trade in products and substances the development of which involves experiments on animals.") We are dealing with legislation that creates an acceptable compromise between the MS about animal welfare in science such that 1) there is one (relatively) harmonised approach to ease the operation of the free flow of people, goods and services, and 2) no individual MS is advantaged over the others by applying different (i.e. lower, cheaper) standards.

Recital 2 indicates a second justification, although not legal basis upon which to legislate: Article 13 of the Treaty on the Functioning of the European Union on the importance of animal welfare. The Union has an emerging underpinning formulation of fundamental rights and freedoms - a more value-driven agenda - arguably this is most clearly defined in its human rights agenda, but even then it finds its purchase in legislation through Article 114 (and the argument about unfair economic advantage).

3. From the proposal of the European Commission and the 'ordinary legislative process'

Under the Treaties, particularly as they are strengthened by the Treaty of Lisbon amendments, legislation is now mainly conducted through 'Ordinary Legislative Process' or the 'co-decision' process. The European Commission is the institution that has the right to propose (draft) legislation for the Union (this can be of its own volition or at the suggestion of the European Parliament or European Council or Council of Ministers). Once presented, both Parliament and Council have to agree the legislation - through a process of, normally, two 'readings' in each place, but essentially through a process of lobbying and political negotiation (that may be more or less to do with the specific issues

in the proposed legislation). It differs from legislation that is created by Council with only the opinion of Parliament - which was the norm at the beginning of the European project, but with increased arguments for democracy through the Parliament, has diminished largely to matters that require new money from MS or where the competence (the ceded authority) of the Union is in question or where the Union does not have competence.

The further part of the process is taking the opinion of two committees - the European Economic and Social Committee and the Committee of the Regions.

4. "Recitals" and "Articles"

Directives and Regulations have a standard form - first a series of propositions "recitals", starting "whereas" and individually numbered from 1-n, and then a set of rules "Articles", separately numbered from 1-n.

Recitals start with the legal authority and something of the legal context of the Directive or Regulation, they then relate to the Articles, giving an indication of the reasoning for each Article. They are not specifically tied to the relevant Article - certainly not on a 'Recital 1 relates to Article 1' basis; there could be two or three Recitals per Article - Articles tend to follow a pattern - authority and context, broad purpose, definitions of terms as they are used in the particular Directive or Regulation, major law, other aspects included in the legislative opportunity, implementation, and knock-on effects for other legislation.

Whilst Articles are clearly binding, there is an interesting debate about the effect of the Recitals in Law. They clearly have a different purpose in the creation of the legislation and cannot be used directly in hue he same way as Articles, and they do not receive the same level of detailed attention in the process, they cannot be dismissed as legislative 'junk'. They have an interpretative purpose and give insight about the intention behind Articles.

B. General comments on the Directive

5. Specific justifications for 2010/63/EU

Recitals 1 to 5 indicate a general concern that the former EU Directive in this area from 1986 (86/609/EEC) had not harmonised the area sufficiently at the practical level. Recitals 6, 8 and 9 indicate that the definition of welfare has changed in its substance - science and the understanding of animal welfare has also moved on from the understanding in 1986.

Recital 7 and Article 2 is particularly interesting. It shows the underlying tension. Some MS wish to see strong animal welfare, others do not share the same understanding or desire. The Directive has to accommodate this balance: finding a level of welfare that accommodates better the spectrum between trade and human health arguments, and animal welfare arguments, always balancing the politics of unfair trade advantages. So Recital 7 also shows at there is also a top ceiling on animal welfare, as well as a bottom level.

Recital 12 is also very interesting; it moves far too fast from simple assertion of a controversial premise that "animals have an intrinsic value which must be respected" and the fact that the public have "ethical concerns" to the conclusion that "animals should always be treated as sentient creatures and their use in procedures should be restricted to areas which may ultimately benefit human or animal health, or the environment." It's far from obvious that animals (which ones? Why?) Have intrinsic value, and if they do then it's far from clear that they should be used in procedures at all, whatever the benefits. Also, such unequivocal statements don't sit very well with the intended flexibility of the directive in terms of different MS views on the topic.

Recital 13 states that "The methods selected should use the minimum number of animals that would provide reliable results", but doesn't really go far enough in pointing out that using too few animals for reliable evidence and other common design flaws in preclinical research render all suffering in such experiments pointless and future research on humans more risky. (http://www.bmj.com/content/348/bmj.g3387) It's very surprising that the directive doesn't place more emphasis on the importance of sound scientific design, given that it goes into so much depth about design of facilities etc.

6. A shared purpose?

Recital (10) indicates: "this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. (There is a question here: does scientific also covers xenotransplantation/medical use?)

Is this the shared goal?

- Is it believed that this is possible?
- Is it believed that this is desirable?
    - Is there agreement around the statement in Recital (12) "Animals have an intrinsic value which must be respected." Or is the public's ethical perspective the more prevalent? Does this make a difference?
- Is this just fantasy/ a realistic compromise?

7. Scientific interpretation of welfare and suffering - developing a harmonised minimum standard"

Whereas there is a strong welfare line justifying the intervention of the EU in the use of animals in scientific research and education, it is a line that requires interpretation, by the individual scientists and by the regulators at the Member State level.

There are three standards that interact:

1. a level of pain not greater than 'the introduction of a needle in accordance with good veterinary practice;
2. The 3Rs (as a gold standard) "internationally established principles of replacement, reduction and refinement" (Recital (11));
3. But within these standards an acceptance of a compromise of welfare (i.e. suffering) that is scientifically necessary (i.e. where there is no accepted alternative method available, where the numbers involved produce scientifically valid results, and the animals are kept in suitable conditions). (It is worth noting here that some would say that the 3Rs are entirely a compromise and that anything other than stopping using animals completely is unethical.)

Whereas these seem to appeal to a scientific community (objective) understanding of pain and suffering, these are not defined, of course, in the Directive. The questions to be addressed from this are:

1. How far are there regional differences - different sensitivities - in the interpretation of these seemingly objective standards? (See also the "classification of severity" of suffering in Article 15.
2. What are the standards that local IRBs and regulators apply?
3. How far is there a scientific consensus to which the EC could appeal in seeking to ensure harmonisation of practice through the implementation of the Directive?

a. How far are the "internationally established principles" more than a framework within which to manage a spectrum of acceptable standards of welfare and suffering?
b. Does such a standard emerge through peer-review processes for funding and publication?
c. Where else might such a standard emerge, or could the EU be a forum for such a debate (within Art. 14)?

8. Responding to changing understanding

The EC is charged with reviewing periodically the state of the art in relation to the understanding of animal suffering and welfare and to develop the standards in the Directive in response to these reviews.

1. How far is there a strong enough mechanism within the scientific community to feed those reviews?
2. Is there a sufficiently well established debate to respond to paradigmatic turbulence and shifting?
3. How should the EC respond to differences in scientific opinion?
    a) What mechanisms can be used for the review process to achieve an adequate reflection of scientific difference and to achieve consensus?
    b) How far should the EC drive forward consensus (especially in the name of the single market)?

9. Purposes

Are these acceptable generally?

How far are the definitions interpreted differently in MSs?

Is there general agreement that the specially protected species are
1. appropriately identified and included?

2. adequately protected across the MS - is this a situation where the words to accommodate scientific necessity defeat the harmonisation of a desire to severely restrict the use of particular species?
3. Is the EC adequately policing this?

C. **Comments on the specific Articles.**

10. Discretion Issues in the Directive - distinguishing scientific and legal questions

A motivation for the Directive is an acknowledgement that science has a new understanding of animal suffering and of the proper use of animals in scientific research. However, this does not produce one translatable position on the use of animals, or the acceptable level of suffering to be balanced with potential benefits to humans or animals. Therefore throughout the Directive, there is a first set of discretion: what we might call 'scientific definition' (indicated in red).

There is a second set of discretions in the Directive that, perhaps, reflects other points of disagreement between Member States. A Directive is the product of negotiations between Member States and political parties within the European Council and European Parliament (and arguably from the starting point of the European Commission also), and compromise is found in words within the Directive that are open to different interpretations. Whilst achieving a broadly similar end, Member States can find different interpretations from these open textured terms to accommodate their political or cultural position. These we might call 'interpretational latitude' (indicated in blue).

The real harmonising effect of the Directive depends, then, on the breadth and difference of the scientific definition and interpretational leeway. In this document, these points for potential divergence are indicated; the second stage of this workpackage is to identify the actual differences that are created by the Member States' implementations of the Directive into their domestic Law.

This identification is undertaken Article-by-Article, with common threads being identified.

Article 1. This outlines the general purpose and scope of the Directive. Terms here are defined in Article 3. Note, terms used in the Directive may have other meanings or uses elsewhere - in difference disciplines. Where a term is defined in Article 3 (or elsewhere in the Directive) then only

that definition for the term applies in its use in relation to the Directive. (I know that this sounds obvious, but in practice it causes a lot of misunderstanding.)

How far are the definitions of animals clear and uncontested?

Article 2. MS may operate with stricter provisions than required under the Directive. MS must notify EC of such provisions (and EC will provide this information to other MSs).

Article 3. Definitions.

How far are the definitions clear and uncontested, and do they cover the terms of art used in the Directive sufficiently?

Article 4. The centrality of the 3Rs in the Directive.

This seems a fairly standard expression of the 3Rs. Reduce, Refine, Replace, all in balance with scientifically robust results.

Scientific definition: How far are these concepts objective? There is clearly a discussion about the proper interpretation of each of the terms, and whether they are desirable or achievable in balance with 'good science'. How far are these positions also dependent on local, cultural questions? How far does the local sensitivity towards animal welfare colour the interpretation of the science in each area - producing a more subjective interpretation of the scientific concept, or are these terms defined in a more trans-cultural, international debate?

How far are differences visible in the interpretation of the 3Rs in local ethics committee decisions?

Article 5. Purposes of procedures

Article 6. Methods of killing (early in the Directive to raise this?)

e.g. 6.1: "Member States shall ensure that animals are killed with minimum pain, suffering and distress."
Throughout the Article and Directive, the MS is given power to "ensure" particular things happen, without particular requirements as to how that is done. This gives room for difference. Here, it goes to inspection and the rigour that is used in training those charged with employing the methods outlined in Annex IV, that those people are the ones carrying out the killing, and that they are using the prescribed methods.

How far is minimum pain, suffering and distress universally understood and accepted?

Have other methods been allowed by different competent authorities (under Article 6.4)?

What is accepted in difference MSs as an "emergency" sufficient to exempt a killing under Article 6.5?

Article 7. Endangered Species

Here a technical form emerges: x is prohibited, unless there is "scientific justification".
- The question is, how is "scientific justification" used in practice?
In relation to Article 7, is there consistency in situations that are accepted as justifying the use of endangered species? [This could be a scientific or administrative discretion point.]

Article 8. Non human primates

Here a prohibition with a lifting of the prohibition in particular circumstances.
(see also Article 55.1 -
"Where a MS has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates."

How far is there scientific consensus that the lifting of the prohibition conditions are appropriate?

When, in practice, is the prohibition lifted, and how are the circumstances explored and policed in the particular MS?
For example, in some MS, using primates is theoretically possible but not possible in practice as they simply will not grant a licence.

"A debilitating clinical condition for the purposes of this Directive means a reduction in a person's normal physical or psychological ability to function." Again, this is a joint scientific and administrative question: what is the scope of the definition, is it clear, and when is it used?

Again, there is the prohibited unless clause here - same question.

Art. 8.3 - prohibition on Great Apes subject to Article 55.2
"Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life- threatening or debilitating clinical condition in human beings, it may adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in points (b)(i), (c) or (e) of Article 5; provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods. However, the reference to Article 5(b)(i) shall not be taken to include the reference to animals and plants."
Justifiable?
How is it applied?

Article 9. Use of wild animals
General prohibition (9.1), subject to possible lifting where 'scientifically justifiable' where only wild animals can be used to achieve the purpose of the procedure (not purpose bred animals).
Are scientific justifications clear"
How is the science used to justify the administrative decision?

Article 10. Animals bred for use
Are the animals listed in Annex II sufficient for foreseeable scientific purposes and procedures?

Is the provision for the breeding and supply of non-human primates ethically acceptable (and on what terms)?

How is the Commission review and oversight to be undertaken?

And again, the lifting of the prescription for scientifically justified reasons operates here - when is it used?

Is the Article 28 breeding programme requirement effective and uniform?

Article 11 Stray and Feral Animals

Is the lifting of the prohibition for scientifically justifiable purposes acceptable and consistent?

Article 12 Conduct of procedures

How do MS "ensure" that the procedures are undertaken in a user's establishment?

On what grounds do they grant exemptions - how broadly do they interpret "scientific justification"?

How broadly is "the framework of a project" interpreted?

Article 13 Choice of methods.

MS given a duty to prohibit processes where a method that does not require animal use is available - tie-in to 3Rs duty -
but how is this operationalised?

Duty to adopt the methods that "to the greatest extent" achieve the 3Rs. How far is this made a focus of the initial and on-going review process?

13.3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:
(a) result in the deaths of as few animals as possible; and
(b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.
Again, enforcement (and interpretation)?

Article (4) Anaesthetic

(4.) Member States shall ensure that, unless it is inappropriate, procedures are carried out under general or local anaesthesia, and that analgesia or another appropriate method is used to ensure that pain, suffering and distress are kept to a minimum.
Procedures that involve serious injuries that may cause severe pain shall not be carried out without anaesthesia.

Article (5) and Annex (VIII) addresses severity classification - but how far is this scientifically accepted - where are the conflict/ contested points? How far are there cultural differences in the interpretation of responses?
How is the classification applied in the cultural context?

Article (6) Reuse

What are the scientific (project-administration) limits on reuse?
How are these incorporated into the review processes?
Are the pain and suffering classifications applied consistently (and with an international standard)?

Article (7) End of procedure provisions

Animals likely to experience continued moderate or severe pain after the end of the procedure "shall' be killed.

Animals that will be allowed to live have to be provided with appropriate care.

What is the scientific expectation about postmortem evaluation of the animal, or about killing after a procedure?
Under what criteria in different MS? or are there accepted practice guidelines internationally?

What are appropriate care standards (appropriate to the animal's health)? How is the rehoming plan devised and executed (Article (29))?

Article 18 Tissue and organ sharing

How widely does this happen, how does it work, what are the problems?

Article 19 Setting free and rehoming

How often does this happen?
Under what criteria or conditions?

What is the biodiversity risk in reality?

Article 20 Breeders - registration and standards

How do MS ensure the required standards and assurances?
How far do the standards and assurances differ between areas/ committees?

Article 21 Withdrawal of authorisation

What are the criteria that operate, and how often is this provision used?
What sort of complaint mechanism is in place to make it operate?

Article 22 Equipment etc.

What constitutes an adequate design? and ?

Article 23 Staffing

23.1 "Member States shall ensure that each breeder, supplier and user has sufficient staff on site."

How are the education and training duties of the user monitored and enforced? Is Annex V sufficient? What is "adequate" and "required competence"?

Article 24 Personnel

How are the provision of necessary personnel and their (Directive-required) duties discussed (and with whom) monitored?

Is "competence" a universal, or do the standards differ significantly across the MSs?
- What training is required?
- Are common standards applied?
- Do MSs adequately monitor and apply standards for training and practice?
- Does the EC adequately enforce common standards?

Where does training occur?
- How is it delivered?
- Is there some sort of accreditation?
- Is it independently reviewed?

Articles 26 and 27 Animal Welfare Body and their functions

How uniform and how effective are these bodies? What do they, in practice, do?

Articles 31-32 Recording and identifying animals

Are the provisions for recording and identifying animals harmonised? Are there significant differences between jurisdictions?

Article 33 and Annex III.

How easy is it to achieve the care and accommodation standards? Are they acceptable (what are the arguments that form the spectrum of opinion here)?

Are there significant differences in the interpretation or observation of the standards across the EU?

Article 34 Inspections

On their face, the provisions for inspections seem rigorous. However, the way that individual MS interpret the requirements - e.g. 'at least' one third of inspections to be unannounced - will be critical. How much variation is there in practice?

Articles 36-45. Project authorisation

Here is another "MS shall ensure" clause, and again, this invites an investigation of regional difference.

Retrospective assessment (39) is particularly interesting: when is it used, and how often is authorisation withheld? How often, generally, is authorisation refused from projects?

Article 46 Data Sharing

There is an increase in the desire for data transferability in various sectors (see Clinical Trials Regulation). As this is about data from 'procedures' how realistic is this? And how widely is it happening?

Article 47-49 Alternative approaches, Union reference laboratory, National Committees

Here there are distinct duties on MS to participate in funding and finding alternatives.
How far are alternatives possible - is this a paradigm shift issue, and can a paradigm shift be forced? What level of investment are individual MS putting into this, and how enthusiastically are they accepting their duties?

Article 64 Reporting

There are duties on MS to collect and publish various statistics in relation to this Directive.
Again, what level of thoroughness and enthusiasm will be seen in making the reports; what is the depth of information that is provided under the obligation?

Article 59. Competent Authorities

Whilst the duties are clear, the level of investment is important, as is the authority given to the national body.
What is the investment?
What are the powers, compared to other similar (quasi-)judicial or administrative bodies?

Article 60. Penalties

Similarly, the effectiveness of the implementation (or the importance placed on the measures) might be indicated by the seriousness the MS places on the breach.
What are the levels of punishment that are chose by the MS?
What is the practice of enforcement that emerges for breach?
What is the culture of breach - is the Law respected?