Enhancing the Protection of Animals Used for Scientific Purposes

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> **Around 12 million animals are used every year throughout the EU for experimental and other scientific purposes**

In September 2010, closely following adoption of the first international welfare standards on the use of animals in research and education by the World Organisation for Animal Health's (OIE)[1], the European Parliament, after many years of discussion, consultation and petition, voted to revise the European Union's legislation[2] on animals used for scientific purposes. This is significant because around 12 million animals are used every year throughout the EU for experimental and other scientific purposes[3]. In the UK alone, just over 3.6 million scientific procedures were started in 2009; a third higher than in 2000[4]. This is perhaps a surprising statistical rise when set against the findings of Home Office consultation on the, then evolving, EU legislation. This consultation seemed reflect the desire, outside of the respondents involved in animal research, for broader and deeper regulation[5].

This article will set out to identify the reasons that the EU has, finally, moved to legislate and will set out the content of the new Directive.

Background

Directive 86/609[6] was adopted by the, then, European Economic Community with the aim of eliminating disparities between the Member States in respect of the protection of animals used for experimental and other scientific purposes. The Directive was never significantly amended[7]. By the start of the new millennium the legislation was out of date from both a scientific perspective, in that there had been significant improvement in experimental techniques in the last two decades; and from an ethical perspective Neither aspect was reflected in what was becoming an increasingly archaic piece of legislation. The EU itself had also 'moved on', recognising the protection of animal welfare in the 1997 Treaty of Amsterdam Protocol on the protection and welfare of animals and more recently Article 13 of the Treaty on the Functioning of the European Union.

At a fundamental level, Directive 86/609 also failed to embed the application of the 'Three R's' principle. This principle, widely recognised and hence one that should be reflected in policy, legislation and practice, is that there should be the replacement, reduction and refining of animal testing. The Directive's lack of fitness for purpose was further reflected in the fact that Member States' national legislation offered more significant protection than the standards set out in the Directive. In addition, the Directive

[1]Adopted at the 78th General Session under the OIE Terrestrial Animal Health Code Chapter 7.8 see http://www.oie.int/eng/normes/mcode/en_chapitre_1.7.8.htm

[2]Directive 86/609/EEC OJ L358/1 18.12.1986 available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0609:EN:HTML

[3]Statistics for 2008 see 6th Report from the Commission to the Council and European Parliament on the statistics on the number of animals used for experimental and other scientific purposes COM (2910) 511/ final 2; mice are the most commonly used accounting for 59% followed by rats at 17%. Larger animals though are also used with around 20,000 dogs and 10,000 non-human primates being the most significant. The total number used has remained relatively static as compared to 2007 and 2006 see 5th Report COM/2007/675 final and 4th Report COM/2005/7 final

[4]mostly accounted for by breeding to produce genetically modified and harmful mutant animals; excluding such breeding, the total was slightly higher than in 2000 (an increase of 70,000 procedures), Home Office, Statistics of Scientific Procedures on Living Animals, 2009 27 July 2010 HC 317 available at http://rds.homeoffice.gov.uk/rds/pdfs10/spanimals09.pdf

[5]Consultation available at http://tna.europarchive.org/20100413151426/http:/scienceandresearch.homeoffice.gov.uk/animal-research/legislation/summary report2835.pdf?view=Binary

[6]transposed into UK law through the Animals (Scientific Procedures) Act 1986 see http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm

[7]There was though Commission Recommendation 2007/526/EC that Member States ensured they complied with the revised guidelines from the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes adopted on 15 June 2006: see OJ L197/1 30.7.2007

was an unclear and ambiguous piece of drafting that had in turn resulted in a lack of uniformity in national implementation measures, discussed further below. So, 24 years after the adoption of the Directive there was, as well as an out of date legislative environment, a varied legal regime throughout the Union generating a "highly diversified, unequal competitive environment"[8].

Revising the Law

Work on revising the Directive began in 2002, when the European Commission's Directorate-General for Environment (DG ENV) requested an opinion on the welfare of non-human primates used in experiments from the Commission's Scientific Committee on Animal Health and Animal Welfare (SCAHAW)[9]. During the same period, the European Parliament drafted a report[10] calling for the Commission to revise the Directive.

> **significant public demand for revision of the law**

In 2003, the DG ENV convened a Technical Expert Working Group to collect scientific and technical background information for the revision of the Directive[11]. Of note was that during this time the EU was taking the final steps towards banning the use of animal testing in respect of cosmetic products[12]. In 2005[13], the Animal Health and Animal Welfare Panel gave its scientific opinion on the use of animals for scientific purposes, which was followed by the European Parliament requesting the Commission prepare a proposal to revise Directive 86/609 by the end of 2006, but the process continued, with the Commission conducting an external impact assessment[14] (the 'Prognos Study') during 2006-7.

During 2007 it also became clear that there was significant public demand for revision of the law; the public consultation received a total of 42,655 replies, then the third largest number of responses to a Commission internet consultation. A large majority of respondents supported measures at a European level to increase the welfare of animals and believed that the EU should be a world leader in promoting animal welfare and protection. The Commission also had to publish a response to the large number of petitions and letters it had received from EU citizens on revision of the law, and specifically on the use of non-human primates in experimentation[15]. Indeed, on 25 September, the European Parliament adopted a Declaration[16] urging the institutions when revising the Directive to take the opportunity to formally end the use of apes and wild-caught monkeys and to introduce a timetable for the replacement of all primates in scientific experiments with alternatives. The culmination of this increasing demand for change was a proposal from the Commission[17], published on 5 November 2008, for a new directive accompanied by an impact assessment[18] drawing on, inter alia, the Prognos Study.

The Problems

The impact assessment identified four principal 'dimensional' issues associated with Directive 86/609 namely environmental/ animal welfare, economic, scientific and public/ societal problems. Heading the list of dimensional problems according to the Commission, although not perhaps in the eyes of the public, were the economic problems generated by competitive disadvantages for countries with high animal welfare standards[19]. The welfare problems were associated, first, with differing levels of care resulting from distinctions made between animals that were and were not protected under the Directive. This was compounded by differing standards in force as a result of Member States adopting different legislative levels of protection. The scientific problems were identified as being low innovation and lack of incentives to use alternatives, and obstacles to free movement for researchers due to differing standards in education and training. Finally, the public or societal problems were

[8]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543

[9]available at: http://europa.eu.int/comm/food/fs/aw/aw_scahaw_en.html

[10]http://ec.europa.eu/environment/chemicals/lab_animals/pdf/evans_report.pdf

[11]For the final reports see http://ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm

[12]Directive 2003/15/EC OJ L66/26 11.3.2003 amending Directive 76/768/EEC OJ L262/169 27.9.1976 – a testing ban on finished cosmetic products became effective on 11 September 2004 and on ingredients and combinations of ingredients on 1 March 2009. A marketing ban also came into effect on 1 March 2009 except for repeated dose toxicity, reproductive toxicity and toxicokinetics, in which case marketing bans will be introduced as alternative methods are adopted but with a maximum cut-off date of 11 March 2013

[13]Available at: http://ec.europa.eu/environment/chemicals/lab_animals/scientific_en.htm

[14]See the Prognos Report 2007 http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

[15]Brussels, 28.9.2007 available at http://ec.europa.eu/environment/chemicals/lab_animals/pdf/petitions_dir86_609.pdf

[16]DCL 0040/2007/ P6_TA-PROV (2007) 00407 available at:http://ec.europa.eu/environment/chemicals/lab_animals/pdf/fische_suite_en.pdf

[17]SEC (2008) 2410, COM (2008) 543 final Brussels 5.11.2008 see IP/08/1632, Brussels, 5 November 2008

[18]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543

[19]According to the Commission this resulted from price differences; divergent regulatory and authorisation procedures resulting in variable durations and costs of projects; unsatisfactory working conditions and "increasing activist criminality" – Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 11

stated by the Commission to be an 'increasing dissociation between weak legislation and strong public concern, evolving from changed ethical and societal values and increased public interest about the acceptability of animal testing'[20]. In light of these dimensional problems, the impact assessment pin-pointed thirteen specific policy issues.

First, Directive 86/609 did not cover animals used in basic research, education and training, animals bred and killed for tissue and organs, or any invertebrate species or embryonic and foetal forms. This was most surely a reflection of the time in which the Directive was drafted – since the late 1980's there has been a shift from in-viro to in-vitro experimentation and a corresponding increase in the number of animals specifically bred for such purposes. This development had though been reflected in the legislation and practice adopted by Member States: 80% had extended their regulatory protection to animals used in basic research; 60% of them had extended protection to animals bred and killed for tissue and organs; however in contrast only 30% offered protection to invertebrate species or embryonic and foetal forms.

Another fundamental flaw was that the Directive did not require compulsory authorisation of projects. The impact assessment discovered that 21 Member States had forms of project authorisation and processes that were significantly different, often with non-transparent criteria. Stakeholders estimated that authorisation could account for 3-4% of the overall costs of a project involving animals[21] and take between 70 and 100 days. In addition, whilst every Member State had adopted ethical evaluation as part of its authorisation process, there were significant differences in practice so, for example, the Three R's principle was used as part of the evaluation in only 15 Member States. The Prognos Study ascertained that in 2005 whilst 7.3 million animal experiments were covered by mandatory ethical evaluation, a further 4.9 million were not[22].

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Additionally, in analysing the embedding of the Three Rs principle in the Directive it was found that whilst the Commission had set up the European Centre for the Validation of Alternative Methods (ECVAM) in 1991 to generate validation procedures and criteria, which it had been relatively successful at doing, only a small handful of States such as the UK, Germany, Austria and the Netherlands were prepared to establish national centres to pursue the goal of exploring alternative methods.

In terms of the important issue of animal welfare, Annex II of Directive 86/609 contained non-binding guidelines on accommodation and care. As such, their adoption by Member States had been erratic, with only some considering them compulsory standards. In addition, the Prognos Study revealed that whilst all the Member States had minimum legal requirements for the competence of personnel working with experimental animals once again practice differed, with only 35% of Member States requiring personnel to demonstrate the maintenance of competence[23].

In terms of the thorny issue of the use of non-human primates, the impact assessment found that the total use of them in the EU-25 is around 10,000 per year[24]. The use of Great Apes[25] was though extremely limited with only 6 used in 1999 and none in 2002 and 2005[26]. Inconsistency between Member States was evidenced in the fact that three had in fact outlawed the use of Great Apes and one had a partial ban[27]. As for the UK, in 1997 the Government stated that Great Apes had never been used under the Animals (Scientific Procedures) Act 1986 and whilst this had not previously constituted an actual ban,

[20]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 13

[21]See the Prognos Report 2007 Chapter 7 at 61 http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

[22]See the Prognos Report 2007 Chapter 7 at 20 http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

[23]See the Prognos Report 2007 Chapter 7 at 27 http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

[24]75-80% being Old World monkeys (primarily cynomolgus and rhesus monkeys) and 20-25% New World monkeys (primarily marmosets and tamarins) Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 20-21

[25]Chimpanzees, gorillas, pygmy gorillas and orang-utans

[26]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 21

[27]UK, Austria and the Netherlands; partial ban in Sweden.

the Government would not permit their use as a 'matter of morality' since it was 'unethical to treat them as expendable'[28].
Those research areas using non-human primates were found to be primarily the testing of pharmaceuticals; the quality control of vaccines; and applied research and regulatory testing. Interestingly, evidence failed to show that there had been any consistent decrease in the use of non-human primates, as would be expected if the Three Rs principle was being effectively pursued[29].

The aspect of the Directive pinpointed as being significantly flawed was that whilst it did provide for the need for the State to impose 'periodic' inspections, the frequency with which they were to take place was not specifically stated. Consequently, Member States' practice differed significantly. The impact assessment also concluded that there was no systematic method or instrument employed to ensure that Member States avoided duplication of testing[30]; meaning around 160,000 animals per year could be subject to unnecessary testing[31].

Finally, in terms of the information available on animal testing, Directive 86/609 provided that States had to report every three years to the Commission. However, there was inconsistency on the reporting criteria and analytical categories, which had undermined confidence in the data[32]. There were additional problems with a lack of data at an institutional level, making it particularly difficult to ascertain trends. Evidence also indicated inconsistency at a national level, with most Member States making public information about animal testing through yearly reports but only some providing information in respect of the authorisation process and only a handful providing access to ethical evaluation reports.

The New Directive
On the 9 September, with the claim that the EU 'will soon have the highest standards of experimental animal welfare in the world'[33] the Commission announced the adoption of Directive 2010/63/EU34. The Directive applies to all situations 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, and continues to apply until the animals are killed, re-homed or returned to a suitable habitat or husbandry system.

the EU 'will soon have the highest standards of experimental animal welfare in the world'

The Preamble to Directive 2010/63 states that one reason for its introduction is to bring the law into line with new scientific knowledge in respect of 'animal welfare as well as the capacity for animals to sense and express pain, suffering, distress and lasting harm[35]'. Hence a primary aim of the Directive is to raise minimum standards and 'tighten the loopholes, remove ambiguities' and 'make the provisions coherent[36]'. The primary aim is therefore to offer uniformity but the Preamble does refer to a limited ability of the Member States to retain 'more extensive animal-welfare rules' in order to reflect 'national perceptions[37]'.

Main Themes
The 'theme' of the new Directive is one that attempts to strike the delicate balancing act between recognising the continued need to permit the use of live animals, whilst treating such animals as 'sentient creatures' with an 'intrinsic value'[38] that must be respected. Consequently, the Directive restricts their use to areas that 'may ultimately benefit human or animal health or the environment'[39]. The new Directive also emphasises the need to ensure that the 'final goal'[40] of removing the need to rely on such types of experimentation is one that is firmly embedded in the legislative framework.

To this purpose, the Directive specifically iterates that the Three R's principle must operate 'through a strict hierarchy of the requirement to use alternative methods'[41]; Article 4 of the Directive requires Member States to 'wherever possible' use a method that does not involve the use of live animals; to reduce the number

[28]HC, EU bibliographies: animal experiments directive, SN/IA/5081, 17 September 2010 available at http://www.parliament.uk/briefingpapers/commons/lib/research/briefings/SNIA-05081.pdf

[29]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 21 for example: the assessment identified that whilst the Netherlands had seen a small decrease in the use of NHPs between 2000 and 2004, the UK had seen a corresponding increase.

[30]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 25

[31]See the Prognos Report 2007 Chapter 7 at 29 http://ec.europa.eu/environment/chemicals/lab_animals/ia_en.htm

[32]Commission Staff Working Paper, Impact Assessment, SEC (2008) 2410/2, COM (2008) 543 at 27

[33]European Environment Commissioner, Press Release IP/10/1105

[34]OJ L276/33 22.9.2010

[35]OJ L276/33 22.9.2010 at para. 6

[36]Proposal for a directive on the protection of animals used for scientific purposes, COM (2008) 543 final, Brussels, 5.11.2008 at 4

[37]OJ L276/33 22.9.2010 at para. 7 This is set out in Article 2 of the Directive, which permits Member States to continue any provisions in force as of 9 November 2010 with the aim of ensuring more extensive protection than that contained in the Directive. Such provisions must be notified to the Commission by 1 January 2013: Article 2(1)

[38]OJ L276/33 22.9.2010 at para. 12

[39]OJ L276/33 22.9.2010 at para. 12

[40]OJ L276/33 22.9.2010 at para. 10

[41]OJ L276/33 22.9.2010 at para. 11

of animals used to a minimum; and refine breeding, accommodation and care and methods so as to eliminate or reduce to a minimum 'any possible pain, suffering, distress or lasting harm'.

Chapter V of the Directive focuses on the avoidance of duplication of procedures using live animals, through an obligation set out in Article 47, to accept data from other Member States, and the promotion of alternative approaches. The latter is an obligation that rests on both the Commission and the Member States, who are required under Article 49 to establish national committees for the protection of animals used for scientific purposes. It is expected that these bodies will both advise national competent authorities and animal-welfare bodies, as well as disseminate best practice. Further reflections of the Three Rs principle in the Directive include that it perceives the use of endangered species as a threat to biodiversity that means only a strict minimum may be used[42] ; that the 'ultimate goal[43]' of moving towards sourcing non-human primates from only self-sustaining colonies should be explored[44] (discussed further below); and that programmes to share the organs and tissue of killed animals should be promoted[45].

In order to boost the development of alternative methods the new Directive will require the establishment of an EU Reference Laboratory[46] , which will be responsible for coordinating and promoting the development and use of alternatives to animal procedures, and continue the work carried out by ECVAM. Member States are required to contribute in this activity by identifying and nominating suitable specialised and qualified laboratories, as well as ensuring the promotion of alternative methods at national level[47].

The Selection of Methods and Species

The new Directive requires the drawing of distinctions between both the choice of method and of the species used, on the basis that both factors can have a direct impact on the numbers of animals used and their welfare. The overriding factor in selecting the method according to Article 13 is that it must produce the 'most satisfactory results', using the least number of animals, whilst causing the 'minimum pain, suffering or distress[48]' and avoiding death as an 'end-point[49]'. The selection of species should in turn be based on that which displays the 'lowest capacity to experience pain, suffering, distress or lasting harm that are optimal for extrapolation into target species[50]'.

Animals with additional protection

The Directive offers an interesting development in that certain animals seem to be offered a higher level of protection– justified it appears from the language of the Preamble as a reflection of public concern, something already witnessed in State practice. Firstly, the use of Great Apes is generally banned: Article 8(3). Non-human primates can only be used for 'biomedical areas essential for the benefit of human beings for which no other alternative methods are yet available'[51]. The use of non-human primates will therefore require the Commission's authorisation, presumably to ensure uniformity in decision-making, and will only be permitted for basic research; the preservation of the species; or when the work is carried out in relation to potentially life-threatening or debilitating conditions[52]. There must be no other alternative method available. The burden of proof will rest on the State to establish such a claim.

Other categories of animal that the Directive provides added protection for include animals taken from the wild and stray and feral animals of domestic species. In terms of the former, Article 9 provides that the use of animals taken from the wild should be limited to cases where the purpose of the procedure cannot be achieved using specifically bred animals[53]. In addition, the Directive has the aim of requiring that in the future the only non-human primates used are those that are either the offspring of an animal bred in captivity or sourced from self-sustaining colonies: Article 10[54]. To achieve this, the Commission will conduct a feasibility study, to be published by 10 November 2017, five years after which the requirement will come into force[55]. Feral and stray animals should not, as a general rule, be used at all under Article 11(1)[56]. The reason according to the Directive being that their background is not known and that capture and placement 'increases distress[57]'.

[42]OJ L276/33 22.9.2010 at para. 16; see Article 7

[43]OJ L276/33 22.9.2010 at para.19

[44]Article 10

[45]OJ L276/33 22.9.2010 at para. 27; Article 18

[46]Article 48

[47]Article 47

[48]OJ L276/33 22.9.2010 at para. 13

[49]OJ L276/33 22.9.2010 at para. 14

[50]OJ L276/33 22.9.2010 at para. 15; Article 13(2)(b)

[51]OJ L276/33 22.9.2010 at para. 17

[52]Article 8

[53]OJ L276/33 22.9.2010 at para. 20

[54]To which, see Kite, S. BUAV call on the UK Government to stop supporting the trade in wild-caught monkeys for research, Journal of Animal Welfare Law, December 2010, pp 6-7.

[55]Although this requirement will apply to marmosets from 1 January 2013: Annex II

[56]Although exemption to this can be granted in limited situations where there is an essential need and justification that it is necessary: Article 11 (2)

[57]OJ L276/33 22.9.2010 at para. 21

The Procedures
One of the most interesting innovations of the new Directive, following an amendment approved by the European Parliament at its first reading[58] , is the creation of a sliding scale of 'severity' for procedures: Article 15. This means that a test may inflict pain that will be categorised as being either 'non-recovery', 'mild', 'moderate' or 'severe'. Under Article 15(2) a procedure should not be performed if it will cause 'severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated'. The Preamble to the Directive justifies this step as being a reflection of 'an ethical standpoint'.

As in Directive 89/609, the new Directive provides that procedures may be repeated on animals, since permitting such re-use may reduce the overall numbers used. However, the new Directive requires that this be permitted only after taking into account the 'lifetime experience[59]' of the animal and cannot adversely affect their welfare, so whether such repetition is warranted will have to be explored on a case-by-case basis. A proposal from the Commission[60] to only permit repeated procedures on animals that had been subject to 'mild' pain was rejected as being too strict and potentially liable to increase the number of animals required, thereby defeating the purpose of the new legislation. The compromise is that repeated procedures can be on animals that have experienced 'moderate' pain, as long as any subsequent procedure inflicts nothing more than 'moderate' pain: Article 16.

The Directive also deals with post-procedure welfare, where the most appropriate decision as to what to do with the animal is defined as one based on the animal's welfare and any potential risks to the environment. Those whose welfare has been compromised should be killed[61] , but those which are kept alive must receive care and accommodation appropriate to their state of health: Article 17. The Directive provides under Article 19 that animals may be set free or re-homed[62] if the animal's state of health permits it; there is no danger to the public, animal health or the environment and 'appropriate measures are taken to safeguard the well-being of the animal'. Apparently this is justified on the basis of the public's 'high level of concern[63]' about the fate of animals, particularly domestic ones such as cats and dogs. The Directive also lays down in Article 29 that if re-homing is permitted the breeder, supplier or user is under an obligation to adequately socialise the animal to ensure success and avoid unnecessary distress and any potential threat to the public and if the animal is wild, to provide a rehabilitation programme if necessary before they are returned to their natural habitat.[64]

Animal Welfare
There is emphasis within the Directive on aspects designed to ensure better protection of welfare standards. These are more comprehensive than those contained in the old Directive and in part codify developments in State practice, and

> **"animals may be set free or re-homed if the animal's state of health permits it"**

evolution of welfare standards referred to above. Indeed, the Preamble refers to the differences that had developed between Member States and that standards adopted 'no longer reflect the most recent knowledge on the impacts of accommodation and care conditions on both animal welfare and the scientific results of procedures[65]'. The Directive consequently provides for harmonized accommodation and care requirements, and sets out the obligation that these will be 'updated on the basis of scientific and technical development[66]' presumably so that Directive 2010/63 does not become effectively redundant in the same way that its predecessor did. A reporting requirement on the operation of the Directive is inbuilt, with Article 54 providing that the first report is due in 2018. The Commission may then make use of powers to amend the key annexes in line with developments in knowledge. There are a range of measures introduced in the Directive to enhance animal welfare including:

- A requirement that staff be authorised as being adequately educated and trained and that they be supervised until they have demonstrated the necessary competence[67];
- The need for breeders, suppliers and users to be authorised and have adequate installations and

[58]5 May 2009 available at http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0343

[59]Article 16(d)

[60]Commission Communication on the Common Position COM(2010) 324 final 15 June 2010 page 5 available at http://www.parliament.uk/briefingpapers/commons/lib/research/briefings/SNIA-05081.pdf

[61]Article 17(2) – where it is likely to remain in moderate or severe pain, suffering, distress or lasting harm

[62]In contrast, Article 11 of Directive 86/609 stated that "... where it is necessary for the legitimate purposes of the experiment, the authority may allow the animal concerned to be set free, provided that it is satisfied that the maximum possible care has been taken to safeguard the animal's well-being, as long as its state of health allows this to be done and there is no danger for public health and the environment" (emphasis added). See Case C-205/01 Commission v Netherlands [2003] ECR I-661 for an example of failure to implement this provision correctly

[63]OJ L276/33 22.9.2010 at para. 26

[64]No further guidance as to minimum requirements, in relation to health, safety or socialising is provided in the Directive or its annexes however.

[65]OJ L276/33 22.9.2010 at para. 35

[66]Article 50

[67]OJ L276/33 22.9.2010 at para. 28; Article 23

equipment to meet the accommodation requirements of the particular species, for the procedures to be performed efficiently and for the least distress to be inflicted[68];

- That appropriate veterinary care be available at all times and a staff member of each establishment made responsible for animal welfare[69];
- That breeder/ supplier/ users create animal-welfare bodies with the primary task of advising on welfare matters. They should also follow the development and outcomes of projects at an establishment level; foster a climate of care; and provide tools for the practical application and timely implementation of scientific developments. This advice must be documented and open to scrutiny during inspections;
- That breeders, suppliers and users be required to maintain records of the numbers, origins and fate of all animals[71] and that dogs, cats and NHPs have a 'personal history file[72]'

A basic principle underpinning the Directive's approach is that both accommodation and care be tailored[73] in that they must be based on the needs and characteristics of each species[74], indeed Annex III establishes minimum enclosure size, floor area and height for a range of different species[75]. It also specifically provides that all animals, except those that are naturally solitary, be housed 'socially' in 'stable groups of compatible individuals[76]'. Where in single housing, the animal must be able to maintain visual, auditory, olfactory and/ tactile contact with its species; be kept alone for the minimum period necessary; and be re-introduced in a careful manner to avoid 'disrupted social relationships'. All animals must also be provided with enrichment in that they must be provided with 'space of sufficient complexity to allow expression of a wide range of normal behaviour'; enrichment must be species-specific and tailored for the individual. Enrichment strategies are also targeted as being subject to regular review and to requiring updating.

Inspections

Section 2 of Directive 2010/63 deals specifically with the issue of inspections something considered seriously flawed under the old legislation. Article 34(1) provides that competent authorities must now carry out inspections on a 'regular basis'. The Directive introduces a new concept in that the frequency will be specifically tailored to the institution being inspected, based on a risk analysis taking into account four factors, namely, the number and species of animals housed; the record of the breeder, supplier or user in complying with the Directive; the number and type of projects being carried out; and any information that may indicate non-compliance: Article 34(2).

This is subject to the new requirement that at least one third of users be inspected yearly and the exception that all breeders, suppliers and users of NHPs be subject to at least annual inspections. According to Article 34(4) an 'appropriate proportion' of inspections will have to be carried out without prior warning. A final safeguard is that if the Commission has reason for concern, such as the number of inspections without notification, it can take over the operation of a Member State's inspection infrastructure: Article 35(1).

Project authorisation

For the first time authorisation for all projects will be compulsory; all facilities wishing to breed, supply or use animals will be obliged to seek authorisation for their activities. An application[77] for project authorisation[78] will have to include a proposal; a non-technical summary[79]; and information on various elements as set out in Annex VI[80]. The

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[68]OJ L276/33 22.9.2010 at para. 29; Articles 20-22

[69]OJ L276/33 22.9.2010 at para. 30; Articles 25 and 24(1)(a) respectively

[70]OJ L276/33 22.9.2010 at para. 31; Articles 26-27

[71]OJ L276/33 22.9.2010 at para. 32; Article 30

[72]OJ L276/33 22.9.2010 at para. 33; Article 32

[73]Annex III sets out provisions in terms of, for example, holding rooms, service rooms, enclosure design, ventilation and temperature, lighting, noise, feeding/diet, watering, rest and sleep areas and general care, such as that all animals must be checked daily.

[74]OJ L276/33 22.9.2010 at para. 34. It is to be noted that the success or otherwise of such approaches is heavily dependent upon the effectiveness of member states' practical compliance with the law, including proper inspection regimes by suitably qualified individuals, and timely enforcement of issues of malpractice.

[75]Including for mice, rats etc, rabbits, dogs, ferrets, marmosets, squirrel monkeys, macaques and vervets, baboons, cattle, sheep and goats, pigs, equines, domestic fowl and turkeys, quails, ducks and geese, pigeons, zebra finches, aquatic and semi-aquatic and semi-terrestrial anurans, aquatic urodeles, arboreal anurans, aquatic chelanians and terrestrial snakes

[76]OJ L276/33 22.9.2010 Annex III at 3.3(a)

[77]Decisions on authorisation must be communicated within 40 working days from receipt, extended by a further 15 days for complex or multi-disciplinary applications: Article 41

[78]Valid for a maximum period of 5 years: Article 40(3)

[79]Except for projects with procedures that are classified as non-recovery, moderate or mild and not using NHPs that are necessary to satisfy regulatory requirements or which use animals for production or diagnostic purposes with established methods: Article 42(1)

[80]These factors include the origin, numbers, species and life stages of animals to be used; the procedures; methods to replace refine and reduce the use of animals; the planned use of anaesthesia, analgesia and other pain relieving methods; reduction, alleviation and avoidance of any form of suffering; use of humane end-points; the experimental/ observational strategy; animal reuse and any accumulative effect; avoidance of unjustified duplication of procedures; housing, husbandry and care conditions; methods of killing; and the competence of the persons involved in the project.

evaluation of an application must be 'transparent[81]' and consider that the project is justified from a scientific or educational point, or is required under law; that its purposes justify the use of animals; and that it is designed to enable any procedures to be carried out 'in the most humane and environmentally sensitive manner possible': Article 38(1). Article 38(2) also requires that there be specific reference to the compliance of the project with the Three Rs principle; an assignment of the classification of the procedures to be used; and a harm-benefit analysis conducted. The Directive also specifically provides for the carrying out of additional, retrospective inspections to determine whether the objectives were met and the type and severity of harm inflicted. These will be compulsory for all projects using non-human primates and those where procedures are classified as 'severe'.

Reporting

Every 5 years from 10 November 2018, Member States will be required to send information on the implementation of the Directive to the Commission, which will in turn present a report to the European Parliament and Council: Articles 54(1) and 57. In addition, from 10 November 2015 Member States will be required under Article 54(2) to make publicly available annual information on the use of animals in procedures, including information on procedure severity and on the origin and species of non-human primates used.

Conclusion

The new Directive has to be welcome but certainly not only from the perspective of bringing a level playing field to the area in terms of reducing the 'unequal competitive environment'. Of far more significance is that Directive 2010/63 brings with it contemporary measures recognising the importance of animal welfare, the overt significance of which had previously been absent for too many years, and the obligation stated in the Preamble[82] to regularly review the new Directive should hopefully mean that the law will never again be so out of step with scientific and societal developments. It will certainly place the EU on a footing that means it as a whole has the greatest protection for animals used for scientific purposes in the world, and the hope may well be that this in turn generates a cascade effect of changes to the legislation of other countries.

Of greatest significance in the new Directive are probably the general ban on the use of Great Apes; the requirement for authorisation under ethical criteria and a better inspection system; and the improved provisions on animal welfare and care. The embedding of the Three Rs principle is also beneficial in that there will hopefully be increased action at EU and Member State level to develop and promote non-animal methods.

Additionally, the new legislation will significantly raise standards in some Member States, most notably the newly acceded countries:

"Currently in many of these countries, the bare minimum of regulation is in place with only voluntary guidance on animal housing, no meaningful ethical assessment of proposed experiments and virtually no national-level effort to develop non-animal alternative techniques[83]."

However, in other Member States, such as the UK, Germany and Austria, there will probably be little difference at a practical level. Some may therefore see the Directive as a 'missed opportunity[84]' to not only raise standards at the lower end, but to stretch the principles, and protection offered under those principles, to the next level. Of note in this context is that the Directive does not set out any clear, targeted schedule for the reduction of animal testing per se over any defined period of time[85].

In addition there are 'safeguard clauses' within the Directive, introduced at the first reading of the proposed legislation[86]. These offer three potentially worrying 'exceptions'. Firstly, whilst Article 15(2) provides that a procedure not be performed if it involves 'severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated', Article 55(3) permits such pain to be inflicted where it is

"The vote in Strasbourg on 'new' rules with regard to scientific experiments on animals is a huge disappointment..."

[81]Article 38(4)

[82]OJ L276/33 22.9.2010 at para. 49

[83]http://www.makeanimaltestinghistory.org/directive.php?lang=gb

[84]See for example comments of the Humane Society International at http://www.makeanimaltestinghistory.org/resources/news/86_609%20Press%20Release%20Sept%202010%20for%20MATH%20site.pdf

[85]See for example comments of Four Paws 20 May 2010 available at http://www.makeanimaltestinghistory.org/resources/news/MATH%20press%20release%20May%202010%20website%20version.pdf

[86]Commission Communication on the Common Position COM(2010) 324 final 15 June 2010 available at http://www.parliament.uk/briefingpapers/commons/lib/research/briefings/SNIA-05081.pdf

'exceptional and scientifically justifiable'. In addition, there is no prohibition on this being applied to non-human primates, only that the State 'may decide not to' allow their use in such circumstances.

The 'ban' on Great Apes is perhaps more symbolic than anything else, since in practice no Member States was using them anyway. However, Article 55(2) does in fact permit the use of Great Apes, provided no other animal or alternative method can be used, where the State can justify believing such use 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'.

Finally, non-human primates can indeed still be used for purposes that are not for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, where the State has scientifically justifiable grounds for believing it is essential to use them and provided the purpose cannot be achieved by the use of any other species: Article 55(1). Any State wishing to proceed under one of the above safeguard clauses must seek the authorisation of the Commission, which can be granted only for a defined period of time. It can only be hoped that requests for such authorisation will be few in number, closely scrutinised by the Commission, and permitted only for the shortest of periods[87].

The new Directive represents a degree of progress, although some would argue the correct balance remains to be struck. David Martin MEP, Scotland's senior European MP and Vice-President of the European Parliament's Intergroup on Animal Welfare has said:

'The vote in Strasbourg on 'new' rules with regard to scientific experiments on animals is a huge disappointment...what we must move towards is clear restrictions on the use of non-human primates, a ban on the use of wild-caught animals, an unequivocal obligation to use non-animal alternative methods when scientifically available, and a ban on experiments which involve severe and prolonged suffering – today's ruling fell woefully below this'[88].

This sense of missed opportunity is also reflected in the view of the Pan-European ECEAE, which has stated that the Directive's more rigorous basis remains out of step with its own research into public opinion[89]. Ultimately, what interested parties must hope for is a more systematic approach to a law applied across a significantly larger European Union than when the original measure was introduced some 25 years ago.

Ultimately, therefore, to be truly meaningful, the new Directive will have to be far more rigorously enforced than its predecessor ever was. To begin, the Member States have two years from the publication of the Directive to adopt and publish national legislation transposing its provisions (the new Directive will not come into full force until 1 January 2013)[90]. The fact that many had imposed stricter measures under its predecessor may mean that this will not prove unduly problematic.

Nevertheless it is to be hoped that the Commission will demonstrate its genuine and significant commitment by ensuring this two year deadline is complied with.

[87]Provoking wildly different opinions in the Home Office Consultation referenced at footnote 5, above (see para 58 of that report)

[88]The full is available at http://www.martinmep.com/senior-scottish-mep-condemns-new-eu-laboratory-rules-as-inadequa

[89]The European Coalition to End Animal Experiments: for more information on their research, see http://www.eceae.org/en/what-we-do/campaigns/12-million-reasons/public-opinion.

[90]Article 61