



Good Regulatory Practice: Directive 2010/63/EU – a Missed Opportunity?

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Summary

Directive 2010/63/EU will provide the European regulatory framework for the protection of sentient animals bred, kept, and used for experimental and other scientific purposes for the foreseeable future. Although public policy strives for perfection, few regulatory regimens are “right first time.” Regulation must also adapt to trends and technical progress in science and animal welfare, taking account of evolving informed societal and political thinking. Good contemporary regulatory regimens adopt a transparent and flexible approach, focusing on the clearly articulated policy objectives that must be delivered rather than mandating fixed frameworks for their delivery. Whilst a consideration of Directive 2010/63/EU reveals worthy policy objectives with the detail of how these are delivered entrusted to individual European Member States, a more rigorous analysis identifies areas where ideology, a focus on frameworks and inputs rather than outcomes, ambiguities, compromise, and a need for long-term commitment and resources to better define and develop elements of the Directive may compromise delivery of the intended policy objectives – unless the Commission and Member States use the time available before the main provisions “go live” on 1 January 2013 to better define how key components of the new Directive will be interpreted and will operate.

Keywords: Europe, public policy, legislation, animals

1 Introduction

Consideration at the 6th World Congress on Alternatives and Animal Use in the Life Sciences of whether regulation drives, manages, or merely monitors change concluded that regulatory frameworks for the use of animals for experimental and other scientific purposes should adopt a flexible approach – not only because the measures taken to address many real-life public policy problems are seldom “right first time” (Hartford, 2011), but also to anticipate, promote, and make provision for innovation and technical progress in science and animal welfare, and reflect the evolution of informed societal and political thinking. Good regulation focuses on the policy objectives that must be delivered, rather than mandating the frameworks by which they are to be delivered (Richmond, 2007).

European Directive 2010/63/EU (EC, 2010), which will provide the European regulatory framework for the protection of sentient animals bred, kept, and used for experimental and other scientific purposes throughout Europe for the foreseeable future, was an opportunity to put the principles of good contemporary regulation into practice.

Whilst a preliminary review of the Directive confirms a desire to provide for the delivery of worthy policy objectives through a sound contemporary regulatory framework, a more detailed analysis identifies a number of shortcomings that may, both from the outset and over time, make it difficult for the positive policy objectives to be fully realised unless the Commission and

the Member States use the time before the main provisions of the new Directive take effect (1 January 2013) to better explain and define how the prescribed frameworks can best be used to deliver the underlying policy objectives.

2 Background

Regulation is the term used for systematic measures intended to deliver public policy objectives by promoting desired behaviours and outcomes, and discouraging unwanted behaviours and outcomes. Regulation generally involves balancing different and often incommensurate interests, bringing benefits for some and imposing costs on others (Baldwin and Black, 2008).

The frameworks by which the policy objectives are delivered are always of secondary importance to the policy objectives themselves.

Although some mistakenly assume regulation is synonymous with legislation, in many cases non-legislative measures will be more appropriate and effective (Tab. 1): and even when legislation is the preferred means, it is almost always combined with non-legislative measures.

The regulation of the use of animals for experimental and other scientific purposes typically combines legislation with other administrative controls. In this context the main elements tend to be means of registration or authorisation of places, programmes of work, and people; standards, codes of practice,

**Tab. 1: Regulatory tools**

▶ Do nothing	▶ Societal norms	▶ Self-regulation
▶ Codes of practice	▶ Quality marks	▶ Service charters
▶ Co-regulation	▶ Quasi-regulation	▶ Professional bodies
▶ Trade associations	▶ Information	▶ Education
▶ Incentives	▶ Sanctions	▶ Market forces
▶ Market-based tools	▶ Marketable rights	▶ Standards
▶ Peer pressure	▶ Reputation risk	▶ Legislation

and guidance specifying the desired or required performance and outcomes; and processes to monitor compliance and remedy non-compliance, including the ability to sanction or disenfranchise those who cannot or do not operate safely or to the required standard.

Directive 2010/63/EU is the product of the European Commission's resolve to revise Directive 86/609/EEC (EC, 1986). The principal drivers of change, in the Commission's view, were distortions of the internal market and barriers to trade caused by some Member States applying only the minimum requirements, the Commission having strengthened its commitment to animal welfare, scientific developments, and an improved understanding of animal welfare issues, and a desire for greater transparency relating to animals in science (EUROPA, 2010a,b). The revised Directive, 2010/63/EU, was concluded in September, 2010 and its main provisions take effect in Member States from 1 January 2013.

The European Commission's proposal to remedy these issues took the form of a revised Directive. Directives are binding on Member States as to the results to be achieved, but it is left to the individual Member States to choose the necessary form and methods to transpose them into national legislation and implement the requirements. However, it is not unknown for Directives to stray into specifying the precise means by which some elements of compliance must be achieved: and that is the case with Directive 2010/63/EU.

A European Directive can be considered to consist of three main components: 1) Recitals, setting out the background, rationale, and policy objectives (but containing no requirements); 2) Articles, which define the requirements; and 3) more detailed technical requirements, not affecting the scope of the Directive, set out in normative Annexes which may be amended to better meet the policy objectives in the light of experience and progress without invoking the full European legislative procedures that would otherwise be required to formally revise Articles of the Directive.

It is the responsibility of the individual Member States both to transpose the requirements into national legislation, and to develop the associated legal, administrative, and other controls to implement the requirements. In doing so, each Member State will have to weigh a number of legislative and regulatory options in order to develop the national system that both delivers

compliance and is best suited to national needs. It is likely that no two Member States will implement the revised Directive in precisely the same way.

In most Member States, this process will be informed by regulatory impact assessments, public and stakeholder consultations, and consideration of measures planned by other Member States before final decisions are taken as to how best to implement a proportionate and flexible approach to legislation and regulation that delivers the animal welfare outcomes but does not compromise the success, sustainability, or competitiveness of the national biomedical research sector. The European Commission will also work with the Member States during this time, individually and collectively, in order to clarify the requirements and promote the consistent delivery of the underlying policy objectives.

Member States must implement the main requirements of the revised Directive on or before 1 January 2013. They may decide to amend or replace existing systems of control. They may simply copy out the minimum requirements, or justify, finance, implement, or retain more stringent measures (providing they do not distort the European internal market). They may seek to fund the regulatory system through general taxation or fees (again, providing this is not deemed to distort the internal market). Bearing in mind the increased scope of, and detail contained within, the revised Directive, transposition and implementation are likely to challenge the Member States' and European Union's aspirations and pledges (EC, 2008) to reduce regulatory burdens.

Looking in detail at Directive 2010/63/EU, it is important to consider whether the intentions, policy objectives, and required outcomes are clear (the Recitals); whether the requirements (the Articles and normative Annexes) are unambiguous and will deliver the policy objectives; whether the requirements are flexible and proportionate; and, where the individual Member States have discretion, whether the requirements are framed in terms of what must be achieved (outcomes), or what must be done (inputs, frameworks and outputs); what constitutes compliance; and where updates will be required and when and how this will be done.

Directive 2010/63/EU has been described by the European Commission (EUROPA, 2010a,b) and others as introducing a number of significant new measures including not only that live

animals may only be used for experimental and other scientific purposes when no other means are available, and that when animals are used any resulting pain, suffering, distress, or lasting harm is minimised, but also that the 3Rs must be reflected in all aspects of animal production and care; that ethical evaluation of projects prior to their authorisation ensures the expected benefits are both fully justified and outweigh the harm to be caused to the animals used; that high, minimum standards of animal accommodation and care are required; that restrictions are placed on the use of non-human primates; that a “ban” is placed on the use of Great Apes; that those working with and caring for animals are educated, trained, and competent; and that the Commission and the Member States must work together to develop and promote alternative methods.

This paper considers whether Directive 2010/63/EU is likely to provide a long-term remedy to the drivers which prompted the European Commission to revise Directive 86/609/EEC; to what extent some of the perceived significant new provisions are really new; whether Directive 2010/63/EU reflects the principles of good contemporary regulation set out at the 6th World Congress; and where the Commission may need to provide additional advice and support to Member States to ensure consistent delivery of the underlying policy objectives when the main provisions take effect in Member States on 1 January 2013.

3 Analysis

3.1 Drivers for change

In bringing forward its proposal for the revision of Directive 86/609/EEC (EC, 1986) the European Commission identified the principle drivers of change as being distortions to the internal market and barriers to trade caused by some Member States applying only the minimum requirements (although the real, but generally unstated or understated, problem was arguably distortions caused by Member States exceeding the minimum requirements); the Commission having strengthened its commitment to animal welfare; scientific developments and an improved understanding of animal welfare issues; and a desire for greater transparency relating to animals in science (EUROPA, 2010a,b).

That different Member States adopted different approaches to implementing Directive 86/609/EEC, with some only implementing the minimum requirements while others introduced more stringent requirements, is undoubtedly true. The key concern for the Commission was that in some cases these disparities distorted the European internal market by creating barriers to trade – a problem the Commission had the power to deal with by other means.

However, Member States will nevertheless still have discretion and flexibility with respect to how many elements of Directive 2010/63/EU are implemented at national level. While it is perhaps inevitable that this will result in diversity of practice between individual Member States, there has been little publicly accessible guidance to date from the Commission as to what existing “*more stringent measures*” (for example, an absolute ban on the use of Great Apes (see below); funding the regula-

tory system through fees charged to the persons and places using animals; and requiring higher standards of animal care and accommodation than are set out in Annex III of the Directive) might be deemed to be non-compliant, in the sense they will – in the view of the European Commission – distort the internal market by retaining existing, or introducing new, barriers to trade by either imposing inappropriate costs on the national science-base or acting as a barrier to entry into the market for goods and services from other Member States. This uncertainty, and the Commission’s reluctance to tackle competition issues during the currency of Directive 86/609/EEC, may set the scene for the perpetuation of such problems.

There is no doubt the European Union recognises and increasingly values the importance of animal welfare (EC, 2006), and that this is reflected in Directive 2010/63/EU. However, there is one very significant shortcoming that may frustrate attempts to objectively demonstrate any resulting animal welfare benefits. This is the absence, in any Commission publication, including the impact assessments for its Proposal, of any objective measure of the nature or consequences of animal welfare issues arising from the implementation of Directive 86/609/EEC that will be remedied by the revised Directive. That is, no baseline has been provided against which progress can be objectively measured.

There is no doubt that during the time Directive 86/609/EEC has been in force there have been developments in science (for example, the production and use of cloned and genetically modified animals) and in our understanding of animal care and animal welfare that have impacted the production, care, and use of animals for experimental and other scientific purposes.

Nevertheless, some Member States, such as the United Kingdom, considered that the general and specific requirements of Directive 86/609/EEC, with respect to the protection of animals, were sufficiently flexible to incorporate these new technologies and higher standards of animal care and accommodation in real-time. Directive 2010/63/EU, in some cases, supplements the requisite general requirements previously contained in Directive 86/609/EEC with delivery frameworks and detailed technical annexes which, because of their prescriptive nature and content, are likely to date rapidly and require constant maintenance as science and our understanding of animal welfare evolve.

There is a case to be made that the policy objectives would have been better served by retaining flexibility in the framework and technical requirements and relying on the Commission to ensure that Member States adapted their practices in the light of progress, rather than substituting defined frameworks and processes (some of which do not represent best current practice and may not be able to incorporate progress and change) for judgement, guidance, and enforcement. It remains to be seen whether the European Commission can or will provide the leadership and resources required to make sure that the European requirements and practice evolve to keep pace with technical progress, and that non-compliance will be recognised and remedied.

Directive 2010/63/EU does reflect the European Commission’s desire for greater transparency with respect to the use of



Tab. 2: Directive 86/609/EEC – Replacement, Reduction, Refinement

Article 7

2. An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.
3. ...In a choice between experiments, those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected...
4. All experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animals...

Article 8

1. All experiments shall be carried out under general or local anaesthesia.
2. Paragraph 1 above does not apply when:
 - (a) anaesthesia is judged to be more traumatic to the animal than the experiment itself;
 - (b) anaesthesia is incompatible with the object of the experiment. In such cases appropriate legislative and/or administrative measures shall be taken to ensure that no such experiment is carried out unnecessarily.

Anaesthesia should be used in the case of serious injuries which may cause severe pain.
3. If anaesthesia is not possible, analgesics or other appropriate methods should be used in order to ensure as far as possible that pain, suffering, distress or harm are limited and that in any event the animal is not subject to severe pain, distress or suffering.
4. Provided such action is compatible with the object of the experiment, an anaesthetized animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.

animals for experimental and other scientific purposes, although it is not clear if the public's demand for greater transparency has increased, or if it is merely the political will to provide more transparency that has increased. Significant new requirements are the publication of summaries of authorised projects, retrospective reviews of selected projects, and information on actual animal welfare costs incorporated into statistical reports. Potential benefits of these and other publications are that they will, if accurate and balanced, better inform the general public and others of the reasons why animals are used and provide insights into both the potential benefits of the animal use and of the animal welfare costs.

However, the new Directive does have some shortcomings in this area. For example, Member States have the option of adopting streamlined administrative procedures for project evaluation and authorisation for some classes of animal use that may dispense with the publication of project summary information about large areas of animal use. The resulting selective, partial disclosure will give undue prominence to more contentious classes of animal use; and by requiring the publication of information on animal welfare costs in statistical reports relatively shortly after animal use has been completed, this "cost" information will be divorced from the resulting "benefits" which are both difficult to capture in a statistical report and may only be realised some years after the animal use was completed.

3.2 "New" provisions

Press coverage, and press releases, of new events are intended to inform – even though in some cases they lack balance. However, in the interest of brevity, they inevitably oversimplify complex proposals and their operational implications, and in some

cases this can mislead readers. Some of the media coverage of the revised Directive to date has not given the full picture.

3.3 The 3Rs

Directive 2010/63/EU was described by the European Commission (EC, 2010) as introducing, as a new measure, a requirement that live animals may only be used for experimental and other scientific purposes when no other means is available, and when animals are used, any resulting pain, suffering, distress, or lasting harm is minimised. While the new Directive does provide more detail on how this is to be achieved, the same policy objective was clearly set out as a requirement of Directive 86/609/EEC (see Tab. 2). On closer inspection, the new requirement was the extension of the 3Rs to other elements of laboratory animal production and care.

As we shall see (see *Accommodation and care* below), much of that could also have been delivered through enforcement of other elements of Directive 86/609/EEC.

3.4 Ethical evaluation

The ethical evaluation of projects is required under the terms of Directive 2010/63/EU prior to authorisation to ensure the expected benefits are both fully justified and outweigh the harm likely to be caused to the animals used.

This involves two types of consideration: verification that the proposed project satisfies certain objective requirements (for example that it meets one or more of the permissible purposes set out in the Directive), and other more subjective considerations in the form of a cost/benefit analysis (premised on prospective assumptions about the potential benefits of the specified programme of work and the likely animal welfare costs).

Although cost/benefit considerations form one of the most basic forms of ethical evaluation, practised for some time in a number of Member States including the United Kingdom (Home Office, 1998), as you move from extreme cases (where there are very clear, indisputable differences in the values of the implied costs and benefits) towards the centre ground occupied by most project proposals, where the cost and benefits are more closely balanced, different experts and groups of experts may reach different conclusions about the same proposal based on the same information. It is also possible that different processes and cultural considerations in different Member States may lead to divergent regulatory decisions and outcomes across the European Union that will require the European Commission to produce supplementary guidance for Member States with respect to the required outcomes.

3.5 Animal accommodation and care

The introduction of minimum standards of animal accommodation and care in Annex III of the Directive is an attempt to make more robust provisions for animal welfare.

However, the Commission has not explicitly criticised existing standards in any Member State, or itemised or determined costs of any contingent welfare issues arising resulting from current practices. Instead, the European Commission presented disparities in animal accommodation and care standards as problems distorting the internal market, even though it had not sought to remedy these problems under its existing powers.

Three points may be worth further consideration in trying to determine the significance and likely impact of some of the new animal care and accommodation requirements.

First, it is not clear from the Commission's publications that there are significant animal welfare problems arising from current practices, and if there are, why (as under the terms of Article 5 of Directive 86/609/EEC Member States must already ensure animals are housed and cared for in ways which make appropriate provision for their health and well-being) these have not been previously tackled and remedied by the Commission, and what resources and leadership will be made available by the Commission to update the Appendix to take account of future technical progress and problems in practice.

Second, the Annex III provisions were not developed as optimal, mandatory, minimum standards. They were developed within the Council of Europe as guidance only, and were accompanied by detailed information and other reference material to allow them to be interpreted to best meet local needs. Much of this detailed, informative, explanatory material has not been incorporated or referenced in the new Directive.

Third, it is not clear whether individual Member States can retain and mandate higher standards of animal care and accommodation (which already exist in some Member States) without being deemed to have distorted the internal market. There is a considerable difference between Member States being empowered to require higher standards, rather than simply being able to encourage them.

Unless Annex III of Directive 2010/63/EU is updated regularly to take account of new evidence, there is the possibility that

simply complying with the minimum requirements may both deter innovation and require that changes to national minimum requirements must be preceded by changes to the Annex at European Union level.

3.6 Training and competence

Directive 2010/63/EU has been lauded for including provisions that require that staff working with and caring for animals are educated, trained, and competent. There are two underlying policy objectives: first, ensuring high standards of science and animal welfare, and second, promoting the movement of skilled labour within the European Union.

In fact, Article 7 of Directive 86/609/EEC already required that "...experiments shall only be performed by competent... persons, or under the direction of such a person...." The new Directive (Annex V) adds headings for the minimum elements of training – though not the syllabus or pass/fail criteria. Although the European Commission may develop and publish non-binding guidance on such training, it seems not to have the legal competence to require that such guidance is adopted and followed by Member States.

Again in this case the European Commission seemed already to have the powers required to ensure Member States ensure the competence of key persons and, in the absence of an agreed Europe-wide training scheme, with an agreed means of establishing and documenting competence, it is difficult to see how the free movement of skilled labour will be facilitated.

3.7 Non-human primates

The European Commission and others have drawn attention to new restrictions in Directive 2010/63/EU on the use of non-human primates for experimental and other scientific purposes – in particular, although allowing their use for basic research, restricting their use for translational and applied research and testing to uses related to the avoidance, prevention, diagnosis, or treatment of debilitating or potentially life-threatening clinical conditions.

While this has been understood by some as setting the scene for elimination of some current classes of non-human primate use in Europe, there are two points to bear in mind.

First, it is conceptually difficult to explain or understand why basic research (which is, by its nature, speculative) is permissible, yet applied research and testing (where the benefits are nearer to realisation) seem to be subject to more restrictions.

Second, there is no indication that the Commission seriously believes that the use of non-human primates for the development or testing of new or improved healthcare technologies (where the unmet clinical needs often relate to conditions which are not life-threatening or debilitating) within the European Union will either have to cease or be done elsewhere, or that the Commission would consider it necessary to authorise such use as exceptional under Article 55 of the new Directive.

I suspect this is an example of political "cheap talk" – something which costs nothing, is populist, and sounds good, but will change nothing in practice. Indeed, I predict that any future changes to the patterns, nature, or scale of non-human primate



use in Europe for translational or applied research will be the result of technical progress, or of such work being displaced outside or imported into Europe, rather than as a consequence of this requirement of the revised Directive.

3.8 Great apes

The widely reported “ban” on the use of Great Apes for experimental and other scientific purposes proves, on examination, not to be an absolute prohibition. Although elements of the decision-making mechanism are unclear, the Commission may, under the terms of Article 55, authorise their use. Their use is strictly regulated, not banned.

4 Discussion

The above analysis with respect to the drivers which led to the revision of Directive 86/609/EEC and its replacement with Directive 2010/63/EU suggests that the European Commission’s primary publicly stated concerns will only be partly resolved.

With respect to the “new” provisions, some address problems with compliance and distortions of the internal market which the Commission could and should have remedied by other means; some would appear only to add process detail to existing general provisions capable of delivering, if enforced, the same policy objectives, behaviours, and outputs through requirements already set out in Directive 86/609/EEC; others would appear to contain framework requirements, where simply complying with the framework requirements (which deal largely with inputs) may, by substituting process for judgement and enforcement, frustrate the delivery of the underlying policy objective outputs; and some may have raised unrealistic expectations (and, in some cases, fears) of how the new Directive will impact animal care and use.

4.1 Good contemporary regulatory practice

Next it should be considered to what extent Directive 2010/63/EU satisfies the principles of good regulation being flexible; allowing future developments in science and animal welfare to be anticipated; reflecting and adapting to informed societal and political thinking; and focusing on the policy objectives to be achieved, rather than the means by which they are to be achieved.

It is necessary to consider whether the revised Directive’s policy objectives are clear and the requirements, whether specified as frameworks or outputs, are precisely aligned to those objectives; where Member States have discretion, whether it is clear what constitutes compliance; whether provision is made for flexible and proportionate approaches; and whether and how key provisions and requirements can and will be updated to take account of progress.

For the purposes of this paper four provisions will be considered in more detail: methods of killing; classification of severity of procedures; animal welfare bodies; and inspections by Member States and their oversight by the European Commission.

4.2 Methods of killing

The policy objectives (Recital 15) are to ensure that animals bred, kept, or used for scientific and other scientific purposes are killed by competent persons, using methods which minimise any resulting animal pain, suffering, or distress.

Article 6(1) requires animals are killed by competent persons with the minimum of pain, suffering, and distress – implementing the stated policy objective.

Article 6(3) requires, for animals covered by Annex IV, that only the methods set out in Annex IV are used, unless Competent Authorities permit the use of other methods for these animals when there is scientific evidence that the alternative method is at least as humane, or when the purpose of scientific procedure cannot be achieved by an Annex IV method. Under the terms of Article 3(1) the “*killing of animals solely for the use of their organs and tissues*” is not a procedure – procedures being component parts of projects.

The Annex IV methods are the product, in part, of analysis done on behalf of the European Commission, but not published in the peer-reviewed scientific literature. The Annex has been criticised for not including some common humane methods endorsed by the Commission in other contexts, yet including methods which are seldom undertaken in this context, or for which both the evidence-base and experience to date are insufficient to endorse them as good practice.

This sets the scene for both short-term and long-term problems.

In the short-term, evidence relating the humaneness of some of the methods included in the Annex has not been consolidated and is not robust or authoritative, making it difficult for Member States to judge or demonstrate that other methods are more or less humane than they are. It is not clear whether it is the Member State or the European Commission that must be satisfied before another method is deemed to be at least as humane. This sets the scene for an early divergence of practices between Member States, and could leave the European Commission with the problem of exercising expert judgement and ruling on a case-by-case basis.

Also, as killing an animal solely for its organs and tissues is not a procedure and therefore cannot be authorised as part of a project, it is not clear what means Member States may use to authorise the use of non-Annex IV methods solely for tissue harvest for experimental and other scientific purposes.

In the longer-term, this is an area where evidence and practice are rapidly evolving and considerable resources will be required to properly maintain Annex IV.

4.3 Classification of severity of procedures

Directive 2010/63/EU makes provision for authorised procedures to be prospectively assigned a severity classification, and for details of the actual welfare costs subsequently incurred in practice to be incorporated retrospectively into statistical reports.

The policy objectives (Recitals 22, 23, 24) are to enhance transparency, facilitate project evaluation and authorisation, and monitor compliance; set an upper limit for permissible pain, suf-

fering, and distress; prohibit procedures resulting in severe pain, suffering, or distress, that is likely to be long-lasting and cannot be ameliorated; and to develop a common format for reporting purposes of the severity of pain, suffering, distress, and lasting harm actually experienced by protected animals used for scientific purposes.

The requirements of the Directive (Article 15) introduce four classes of severity (non-recovery, mild, moderate, and severe), and provide a technical Annex (Annex VIII) produced in consultation with experts providing insights into how the system is intended to operate in practice.

The intended policy ban prohibiting procedures resulting in severe pain, suffering, or distress that is likely to be long-lasting and cannot be ameliorated is not reproduced as an absolute prohibition: rather, Member States may provisionally authorise such use, and the Commission can then confirm or require the Member State to revoke the provisional authority. It is highly regulated, but not prohibited.

The severity classification system is an important constituent part of the new Directive, but ensuring that it is consistently applied both within individual Member States and across the Member States, and providing supplementary guidance for a broader range of procedure and in the light of experience, will not be simple undertakings. Unless the Commission can quality-assure Member States' application of the severity classification system (something which requires access to detailed information and expert judgement), statistical reports incorporating such data should be treated with caution.

European Commission powers of oversight of national inspection programmes do not extend to oversight of operation of the severity classification system – as for the purposes of the Directive project evaluation, authorisation, and inspection are considered to be three separate and discrete activities.

4.4 Animal welfare bodies

The policy objective (Recital 31) is to ensure that consideration of animal welfare “...should be given the highest priority in the context of animal keeping, breeding and use ... should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal issues ... follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the timely implementation ... in relation to the principles of replacement, reduction and refinement...”.

The requirements are set out in Articles 26 and 27. The bodies shall involve at least the persons responsible for the welfare and care of animals, and at user establishments, a scientific member. Input from the designated veterinarian is required, but this person is not a required member of the animal-welfare body. The Article 26 general requirement that each breeder, supplier, and user establishment should have such a body is waived or varied with respect to small establishments (though “small” is not defined), which may make other arrangements for discharging the tasks set out in Article 27.

Article 27 sets out the tasks to be undertaken by animal welfare bodies. At user establishments, they are not required to be

involved in the drafting or refinement of project applications prior to their being evaluated and authorised by a national competent authority.

Experience in the United Kingdom (Home Office, 2001) has been that such bodies can and do produce significant benefits. They make corporate resources available to those caring for and using animals, and ensure those with key roles and responsibilities are well-resourced, well-informed and well-advised.

It is regrettable that the designated veterinary need not be a member of the animal-welfare body, and that the body has no statutory role in advising on the preparation and refinement of project proposals – both of which are undoubted strengths of the current UK system.

4.5 Inspections by Member States and the European Commission

Inspection is one regulatory tool for verifying compliance with the Directive and national regulatory requirements, and detecting non-compliance.

Directive 2010/63/EU makes provision for both regular risk-based inspections of breeders, suppliers and users, an “*appropriate proportion*” of which should be without prior warning and by competent authorities appointed by each Member State to monitor compliance with the Directive; and oversight of national inspection programmes by the European Commission to assist Member States enforce the Directive.

In the case of inspections by individual Member State competent authorities, the Directive specifies four factors to be taken into account when undertaking risk analysis to determine the nature and number of inspections – the number and species of animals held, compliance record, the number and types of projects, and any information that might indicate non-compliance. On the basis of risk assessments, at least one-third of user establishments must be inspected each year, with breeders, suppliers, and users of non-human primates being inspected at least once per year. An “*appropriate proportion*” of inspections shall be without prior warning.

Where the European Commission has “*due reason for concern*,” taking account of the proportion of national level inspections undertaken without notice, it may undertake “*controls*” of the infrastructure and operation of national inspection programmes.

Although some factors relevant to risk analysis are specified, the precise nature of the risks to be managed is not specified, nor is the “*risk appetite*” – that is, bearing in mind that performance can always be expected to be substandard in some cases, what resulting incidence and degree of non-compliance might be deemed tolerable or acceptable when designing, implementing, and evaluating a national inspection programme. The low specified potential minimum frequency of inspection suggests the European Commission has a relatively high “*risk appetite*” – and Member States, and the public, would benefit from further information and guidance and transparency on this point.

No guidance is given as to what will constitute an appropriate proportion of inspections without notice, although this is something the European Commission must take into account



when evaluating national inspection programmes. Again guidance would be welcomed by Member States hoping to adopt a proportionate approach, mindful that the European Commission oversight requires that the Commission has a transparent and objective means of determining what constitutes an appropriate proportion.

It is not clear exactly what constitutes an inspection of a breeder, user, or supplier – bearing in mind that any one of these may operate multiple animal facilities at several sites. For accounting purposes, is a one-hour visit by a single inspector to a single facility an “inspection”? An individual inspector spending several days on site touring multiple facilities? Or a team of inspectors spending several days on several sites? As Member States will have to disclose the numbers of visits of inspection undertaken to the European Commission, some form of accounting rule will have to be published to ensure consistency of reporting.

The UK has a well-established risk-based programme of inspecting breeders, suppliers, and users of laboratory animals, and it currently operates well above the new European notional minimum requirements, even though compliance levels and standards are generally high. In 2010, when there were approximately 190 “designated” establishments (breeders, suppliers, users) a total of 1,984 inspections, representing 5,690 man-hours on site, were performed; 45% of the total were without notice – with 75% of the inspections of animal facilities being without notice (Home Office, 2011). It remains to be seen whether such a resource intensive system – with its additional cost and resource implications for those who are inspected – will be considered compliant with the new requirements and not deemed to be distorting the internal market (particularly if the cost of the system is to be recouped through fees), and whether, in line with pressure to minimise regulatory burdens, this scale of operation can be justified and maintained in view of the less demanding, new European requirements.

Who will undertake the European Commission oversight of national programmes, and what training and competences they will have, are not specified in the Directive. It is likely to be an existing European Union institution. It must be remembered that project evaluation and authorisation are undertaken outside the inspection programme, and, therefore, will not be subject to scrutiny by the European Commission as part of its oversight of national inspection programmes.

5 Conclusions

I played an active part in discussions leading up to the revision of Directive 86/609/EEC and the production of Directive 2010/67/EU, and believe that the new Directive potentially contains many new and improved features.

The underlying policy objectives, as set out in the Recitals, are to be welcomed as exemplifying current informed European political and societal thinking about animals in science.

While I have been critical of the new Directive, my concerns are largely to do with how the policy objectives have been translated into requirements, and with the need for the European

Commission and Member States to use the time between now and 1 January 2013 to work together to clarify key framework requirements, and with what will constitute compliance to best ensure both compliance and consistency.

Although in many instances a flexible approach to implementation is permitted at Member State level, there are instances where the precise requirement of and what will be deemed to constitute compliance are insufficiently clear, and guidance on interpretation and how compliance will be judged would be welcomed.

There are also instances where the requirement seems to focus more on the framework to be used at the expense of the underlying policy objective to be achieved.

By providing technical requirements in a series of Annexes that can be updated without re-opening the whole Directive, a mechanism has been provided for these to be adapted to take account of technical progress in science and animal welfare. However, some of the Annexes are already arguably imperfect and in need of revision, and it is not clear how the European Commission will provide the leadership and resources required to maintain and develop these Annexes. More importantly, better provision for delivery of some of the policy objectives might have been made by more general and less prescriptive requirements.

Also, mindful of the Commission’s previous reluctance to address inconsistencies in Member States’ implementation of the Directive 86/609/EU, it remains to be seen how active and effective a part the Commission will play in ensuring compliance and a level playing field under Directive 2010/63/EU.

In closing, it is only right to reflect briefly on how, although aware of the principles of good regulatory practice, they are not all plainly visible in the resulting new European legislation. Indeed, the same is true of many public policy initiatives where, although we aim at perfection, we generally do not attain it.

In my opinion this is due, in part, to how public policy is developed – balancing different interests and political priorities at national level, combined with a tendency at times at the international level (where there are also different national cultures and existing values and frameworks to consider) to work within processes where some judge it more important to be consensual, and to stick to timetables, than to be right.

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