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International regulatory definitions of animal distress in animal research and animal production – an overview.

*Jon Richmond**

*The views expressed are those of the author, and do not necessarily represent those of his employer.

Introduction

There is abundant evidence that animals experience pain and display behavioural and other behaviours and clinical signs indicative of pain and other forms of impaired welfare - and that if recognised, appropriately diagnosed and remedied, these findings can be reversed (National Research Council 1992).

Legislative provision for the care and use of animals for experimental and other scientific purposes varies from region to region and country to country. However, regardless of the precise details of the individual regulatory frameworks, one feature which they generally have in common is that they make provision for the protection of animals by seeking to minimise the animal welfare impact of animal care and use and of the procedures applied.

To a regulator, and arguably to any practitioner, it is essential that the operational definitions are meaningful, reasonable, evidence-based, practical and proportionate.

In the United States of America, for example, the welfare costs are generally couched in terms of "*pain and distress*" (Public Health Service 1986), whilst within the European Union the imperative is to minimise "*pain, suffering, distress and lasting harm*" (European Commission 1986). No matter what the regulatory and administrative systems, it seems best to take a holistic approach to protect animals from all avoidable harms - rather than to consider making separate provision for each of the harms.

Unfortunately, these terms are not precisely defined in any of the relevant legislation. There seems to be a dearth of case-law as to how the terms have been interpreted by the courts, and it is generally necessary to look to the formal policies, regulations and official guidance for further enlightenment on what these individual terms might be deemed to mean. Even then it is generally necessary to settle for examples and principles rather than definitions (Home Office 2000).

Various systems already exist to judge animal welfare - of which distress can be one component - in the laboratory setting (see Hendriksen and Morton 1998). Many rely on non-specific measures; that is they may be manifestations of a number of states, not all of them necessarily indicative of poor welfare. Certainly, there is already good provision for methods to recognise some of the commoner manifestations of distress, arguably they are sufficiently meaningful to categorise various distress states, though to my mind they are for the present still not suited for use as means of strictly quantifying the negative impact/suffering on animal welfare that they represent. Generally they will allow the condition of individual animals to be described and assigned to broad categories, rather than allowing fine distinctions to be made. There is a need to continue to look carefully for means of properly discriminating distress and suffering produced by pain, from suffering and distress caused by other factors - as both the diagnosis of the cause and the provision of effective relief require a proper understanding of the cause of these negative states.

An enlightened interpretation of the available official documents suggest that the U.S. and European systems should have much in common when dealing with animal welfare in this context. However, it is probably more the interpretation and implementation of the

provisions, and the prevailing attitudes and culture of care, that determine whether this is the case in practice.

To examine this proposal, the remainder of this short paper considers the significance of “*distress*” in the regulatory practices of the United States of America, the European Community and the United Kingdom.

The United States of America

In making provision for the protection of animals used for scientific purposes, The Animal Welfare Act and the related Principles and Policies deal with welfare primarily in the context of “*pain and distress*”.

On first reading, particularly of some of the older documents, these two terms appear almost to deal with the latter only in the context of the former. Closer scrutiny of these documents, the background to and deliberations of a formal consultation by the regulator on “*distress*” during 2000, and the tone and content of the more recent provisions, make it clear that this is not now the case. It is clear from examples to found in the related Policies (for example Policy #11’s mention of food and water deprivation, and paralysis and immobility) that distress is not simply to be deemed only as manifestation of unrelieved pain.

In responding to the 2000 USDA/APHIS consultation I was conscious that the welfare costs were understood to extend beyond pain and death, and that distress was not to be taken simply as a manifestation of pain requiring treatment with analgesia.

The European Union

Directive 86/609/EEC (European Commission 1986) makes provision for the protection of animals used for experimental and other scientific purposes in the 27 member states. Although Directives dictate what has to be achieved, it is for the individual member states to interpret and implement its provisions in national legislation. Furthermore, it is for the member states, rather than the Commission, to enforce the provisions.

The Directive sets out the key welfare considerations as “*pain, suffering, distress and lasting harm*”. These terms, alone or on combination, appear in numerous Articles of the Directive. However, they are not defined in the Directive itself; nor in any official guidance produced by the Commission; nor in case-law handed down by the European courts to date.

Nevertheless the Directive places the onus on national regulators and, through the authorities issued by the regulators, on those involved in the care and use of animals to be able to recognise, prevent, and alleviate or minimise these welfare costs.

In practice, the European national ‘competent authorities’ have taken a practical and holistic approach, interpreting the legislative imperative as being to minimise all identifiable animal welfare costs, rather than seeking to separate them into their component parts.

The Directive will shortly be revised and, although the term ‘distress’ is expected to be retained, it is not currently expected that a definition will be provided in the revised legislation.

The United Kingdom

Animal research in the United Kingdom has been regulated since 1876.

The original legislation, the *Cruelty to Animals Act (1876)*, regulated “...experiments...calculated to cause pain...”. Despite the narrow and precise wording of the legislation itself, it was made clear during a formal review of the operation of the legislation thirty years after its introduction that in practice pain was already being interpreted as “...including disease, discomfort or disturbance of normal health...” (Royal Commission on Vivisection 1906). Although the legislation remained essentially unchanged until it was repealed in 1986, its provisions were re-interpreted over time to keep abreast of scientific progress and welfare issues.

The legislative framework was critically reviewed in the Littlewood Report published in 1965. Many of the scientific experts who gave evidence argued that the essential animal welfare considerations extended beyond pain and should include, for example, “...any interference with or departure from the animal’s normal state of health or well-being, and that this larger concept should be termed ‘discomfort’ or ‘distress’...”. Two other quotes from the report seem to be relevant to the current debate; “...some were of the opinion that ‘distress’, e.g. malaise, fear and frustration, are more easy to detect than physical pain whilst others took the opposite view...”; “...it would be assumed that any procedure that would cause pain or distress in man would do so also in the animal...”

These considerations were relevant to the drafting of the Animals (Scientific Procedures) Act 1986 (Home Office 2000), which implemented the requirements of European Directive 86/609/EEC in UK legislation, and its underlying policies and administrative arrangements. The 1986 Act identified the welfare issues as “*pain, suffering, distress and lasting harm*”.

Although the term “distress” is used throughout the text of the 1986 Act, it is not defined in the legislation itself.

The Home Office Guidance on the operation of the 1986 Act, the Government’s interpretation of the legislation, offers a broad holistic definition of pain, suffering, distress and lasting harm rather than dissecting them into their component parts. Paragraph 2.14 makes it clear that “Pain, suffering, distress and lasting harm” are deemed to encompass any material disturbance to normal health (defined as the physical, mental and social well-being of the animal). These include disease, injury and physiological and psychological discomfort.

Operationally distress is deemed to be a negative psychological state indicative of poor welfare, and that further degrades the animal’s welfare and quality of life. It is not necessarily either a consequence of, or even associated with, pain.

UK regulators, animal care staff and scientists pragmatically acknowledge that such states exist and should be avoided, treated and minimized. When it comes to the question of how the state is detected and graded, distress is perhaps best considered to be inseparable from the other welfare costs.

Attempts to unpack what such ‘negative states’ actually constitute generally result in comparison with human experiences such as anxiety, agitation, frustration, depression, fear. Furthermore, such considerations also prompt the realisation that it is to be expected that the manifestations of chronic distress are likely to be more subtle and insidious than those caused by acute distress.

Operationally, and in practical terms, the problem of identifying and dealing with distress has not been recognising and addressing florid examples. Rather the challenge has proved to be acknowledging that not all departures from the ideal (for example with respect to care and accommodation systems that prevent animals being fully able to express and satisfy their

natural motivations) necessarily cause negative welfare states of a nature, intensity or quality that merit being classified as distress.

Analysis and Conclusions

It is clear that debate and consideration of the animal welfare costs of using animals for experimental and other scientific purposes has progressed beyond a simple discussion of those states which are directly related to pain and its manifestations.

The broader US considerations of “*pain and distress*”, and European considerations of “*pain, suffering, distress and lasting harm*” acknowledge this – albeit without precisely defining the terms used.

If it is accepted that the key consideration is, as argued by Russell and Burch (1959), “what the animal experiences”, then there is a good case to be made for the use of such composite determinants of welfare considerations, coupled with general, broad definitions of what they represent; and with systems to detect and measure their presence that not only allow quantitative assessment, but also provide insights into the nature of the negative experience, its significance, and thus the likely means to relieve it.

Arguably, if it is acknowledged that distress is one possible important manifestation of impaired welfare and suffering, the true imperative should be to integrate it into any holistic welfare assessment, rather than seek to separate it from the other negative impacts on welfare.

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