ABSTRACT

UK law obliges the government to undertake a cost-benefit assessment before licensing any scientific procedure on an animal. The rodent carcinogenicity bioassay has long been identified as a highly problematic animal test, producing data of doubtful reliability and relevance in assessing the cancer risk posed by chemicals. People for the Ethical Treatment of Animals (PETA) conducted a literature search and investigated the utility of the test by analyzing data from more than 502 rodent carcinogenicity studies available on a public database. The available data indicated poor concordance between rat and mouse data, a high number of inadequate studies, and little correlation between test results and final classifications of carcinogenic risk assigned to chemicals by regulatory bodies. PETA also analyzed the welfare implications of this bioassay, demonstrating aspects of the test that could be classified as causing moderate or severe suffering. On the basis that the scientific failings of the test may mean that the cost to the animals involved exceeds any benefits, PETA identified the assay as a possible candidate to challenge the UK government’s application of the law. However, meeting the requirements for bringing forward a legal challenge requires the substantial evidence of related aspects of the use of the assay by the UK, and, while the welfare of animals experimentation from the UK’s Freedom of Information legislation. The value of animal protection legislation is compromised where there is no concurrent legal right to the information that would allow proper evaluation of its implementation and enforcement.

BACKGROUND

UK Law
Animal experimentation in the UK is regulated by the Animals (Scientific Procedures) Act 1986 (ASPA). No scientific procedure may be undertaken unless an licence is issued by the Secretary of State (or his representative in the Home Office). Section 5.4 of the Act contains the following provision:

"In determining whether or not a licensing authority shall grant a licence, the Secretary of State shall have regard to the following factors:...

According to Home Office guidance, in the case of regulatory toxicology, the principal benefit derived from any test is defined as ‘the facilitation of sound regulatory decisions’ (Home Office, 2005). However, the UK’s Animal Procedures Committee (the body charged with advising the Home Office on the licensing of experiments) has stated: ‘A regulatory requirement is not in itself, sufficient to justify particular animal tests’ (APC, 2003).

REODENT CARCINOGENICITY TEST AND COST-BENEFIT

Concern has been expressed about the usefulness of the rodent carcinogenicity (RBC) assay for decades (Brinkley, 1993; Contrera et al, 1997; Schmidt 2002). If the bioassay does not provide relevant and reliable data and cannot facilitate sound regulatory decisions it should not pass the cost-benefit test required by ASPA. PETA therefore undertook research into the bioassay to assess its cost and benefit.

FINDINGS

1. Low-reliability and Repetitvity

The literature review demonstrated that the RBC test fails to identify human carcinogens false negatives) (contrary to the claims of regulatory agencies) in 20% of the cases (APC, 2003). Studies have found that the RBC test results are unreliable because:

a. False negatives

b. False positives

c. Tumour classification errors

2. Continuing Controversy

The literature search identified that the presence of tumours might be a factor in the failure of the test when compared to the test results. This is due to:

a. High levels of tumour occurrence specifically, for instance in animals of the same sex, strain and age

b. Continued tumour development over the course of a study (Masen et al, 1998)

c. Continued tumour development over the course of a study (Masen et al, 1998)

3. Inaccuracy in Identifying Human Carcinogens and Non-Carcinogens

The literature search demonstrated that the RBC test could not identify human carcinogenic false negatives) or relevant cost-benefit ratios. The fact that the test cannot be used to estimate the cost of the procedure.

4. Infeasibility in Identifying Human Carcinogens and Non-Carcinogens

The literature search demonstrated that the RBC test could not identify human carcinogenic (false negatives) or relevant cost-benefit ratios. The fact that the test cannot be used to estimate the cost of the procedure.

5. Infeasibility in Identifying Human Carcinogens and Non-Carcinogens

The literature search demonstrated that the RBC test could not identify human carcinogenic (false negatives) or relevant cost-benefit ratios. The fact that the test cannot be used to estimate the cost of the procedure.

6. Cost to Animals

Evaluating cost is a complex and subjective process. The Home Office offers guidance to researchers making applications for licences and does not reflect in the harm caused to the animals. In the case of RBC, the cost could be calculated as the total cost of the test divided by the number of animals used.

7. Challenging the RBC assay under the law

The UK’s Home Office rejected these conclusions, arguing that the test is required for licensing purposes. In the case of RBC, the cost could be calculated as the total cost of the test divided by the number of animals used.

The Legal Hardwood

Several factors made it difficult to meet the high legal threshold:

Existing data analyzed for the report was compiled from a US database. No equivalent centralized study of carcinogenicity bioassays in the UK was available. Most such studies are carried out by commercial bodies and therefore may not be published in full in the open literature or, if published, identify where they were conducted. Information relevant to assessing the potential of the RBC bioassay to cause moderate or severe suffering is largely unavailable.

The only source of comprehensive information about the conduct and utility of the rodent carcinogenicity bioassay in the UK is the Home Office itself, which licenses the tests and processes project licence applications, involving repeated consultation with the Home Office. In order to access a judicial review, the applicant must show that the relevant individual in the public body is not simply mistaken but has behaved ‘maliciously’ in reaching their conclusion. For a successful judicial review the applicant must demonstrate that:

a. Carcinogenic tests conducted within the UK had broadly the same problems of reliability, relevance, accuracy and utility as those analyzed by PETA’s literature review and study.

b. The suffering of animals in carcinogenicity tests conducted in the UK was higher than that characterized by the Home Office.

Conclusion

On the basis of the research conducted by PETA, there is a strong case that the rodent carcinogenicity bioassay cannot meet the cost-benefit standard outlined in Section 1. The Home Office, however, requires additional information. However, the necessary information to meet the high legal threshold of demonstrating that the government has behaved ‘maliciously’ is not available - indeed, UK law places a significant legal obstacle in the way of obtaining it. Without a right to information about the administration of the law, it is extremely difficult to establish whether the law is being implemented fairly or appropriately.

As the case of the rodent carcinogenicity bioassay demonstrates, the theoretical legal protection offered by the presence of the cost-benefit standard in ASPA is undermined by the lack of transparency required for the UK’s implementation of the law.

A more detailed examination of the Home Office’s case, however, indicates that the section of ASPA should be repealed and Freedom of Information extended to allow access to information. In the case of the forthcoming European Union directive on animal research, mechanisms to ensure full transparency must be embedded within the legislation.

References