

## Animals in research

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### The 'animals for experimentation' issue remains deadlocked

In spite of some high-level interventions on the 'animals for experimentation' issue, animal activists and scientists continue to lock horns. The issue needs to be addressed sensibly and quickly, with the greatest political will for the good of biomedical research in India. This would prevent the whole confrontation getting murkier, with cases being filed in courts of law to resolve disputes. Saionton Basu<sup>1</sup> states, 'courts may well be the last bastion which the scientists would have to storm'. There is need for an objective and careful look at the possible *raison d'être* beneath all the fiery exchanges and war of words. This article hopes to do just that. Turning a deaf ear to the pleas and appeals from every section of biomedical science in this country would inevitably sound the death knell for an important field of scientific research.

### Musings frequently heard among those directly concerned

Why are we so impervious to the issue? Where is funding for 'animal activism' sabotaging Indian science and industry originating from? Is there a pattern seen in the protests of 'animal lovers'? Why is there apathy at the 'top' for resolving the issue?

Scientists do not oppose regulation that is in place. They know and agree that rules are needed for the use of animals for experimentation. They also agree that rules are necessary for the ethical and proper treatment of animals while conducting any research with animals. The regulatory body is the Committee for the Prevention of Cruelty in Scientific Experiments on Animals, in short CPCSEA, set up by the Government of India 'for the purpose of controlling and supervising experiments on animals'. Then, why do scientists face a dilemma? The problem, say scientists, lies in the 'intent of implementation of the regulation'. They claim, and there is evidence to

show, that the regulators are often sadly lacking in a scientific background and therefore the ability to judge fairly is impaired.

Quite a different tenor can be heard from the 'opposing' perspective, this being, 'bringing sanity into the business' (referring to biomedical research), 'animals have souls too', 'biomedical research in India has very little to show for the large numbers of animals sacrificed', etc.

### Two sides of the same coin: On animal experimentation

Apart from animal activists and animal lovers, there are also several scientists and clinicians who seek to challenge the use of animals in experimentation on ethical, medical and scientific grounds. In laboratories all over the world, including India, animals, mostly mice, are used to 'model' and investigate various diseases that affect people. Arguments have been raised as to the validity of animal experimentation and scientific limitations thereof as an aid to understanding human disease, in contrast to human clinical investigation. Then, there is the question of the value of extrapolation of data between species rather than from the same species, problem of cross-contamination during experiments, etc. This set of people feel quite strongly about the 'controlled' experiments, which they claim are for increasing the number of research papers through changes in variables, subjecting the laboratory animals to painful procedures and protocols, and the unnatural confinement that the animals face, affecting them both psychologically and physically. They call for tighter regulation and for using non-animal methodologies to address the same problem. Some possibilities recommended are for the greater use of autopsies and biopsies, use of human tissues, human clinical trials, epidemiological methods, mathematical modelling and use of modern medical instrumentation to investigate human diseases and to find solutions.

Notwithstanding this point of view held by some, there still remains a definite need for use of animals in research especially biomedical research, such as in vaccines, etc. One needs a balanced approach based on scientific principles and proper understanding of scientific research and modalities along with good ethical guidelines.

### Indian scientists seek transparent regulation

Regulation is agreed on by both sides, so where is the hitch? Researchers seek 'transparent regulation' and 'intent of implementation'. Both these factors are central to the animal issue problem. Nothing is being done to sort out these core issues. Scientists appeal for streamlining the functioning, induction of competent regulators, easing approval procedures presently burdened by lengthy timescales, all of which in their opinion require due and immediate attention. Or else, they feel Indian science would be jeopardized in this competitive environment.

### Animal issue saga: Fact and fiction

The main players in this controversy are the scientists and the regulatory agency (CPCSEA) of the Government of India. CPCSEA is enabled in its duties by 'The Prevention of Cruelty to Animals Act, 1960 (59 of 1960) as amended up to 30 July 1982'. Chapter IV dealing with experimentation of animals (item 14) states thus, 'Nothing contained in this Act renders unlawful the performance of experiments (including experiments involving operations) on animals for the purpose of advancement by new discovery of physiological knowledge or of knowledge which will be useful for saving or for prolonging life or alleviating suffering or for combating any disease, whether of human beings, animals or plants'. The role of CPCSEA is to monitor animal experiments through ethics committees set up in institutions.

So if there is a law to regulate animal experimentation, wherein laboratory animals play a crucial role in drug develop-

ment, production of antisera, vaccines and the like, and if scientists believe that regulation is necessary, then why is the issue reaching a boiling point?

In 1998, according to the requirement of the sub-section (1) of Section 17 of the Act of 1960, an Official Gazette notification was published laying down the ground rules for the purpose of the regulatory authority. The sub-section 17 (1) reads, 'It shall be the duty of the committee to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performances of experiments on them, and for that purpose it may, by notification in the Gazette of India and subject to the condition of previous publication, make such rules as it may think fit in relation to the conduct of such experiments'. The draft rules were circulated to concerned people in September 1998 and became official on 15 December 1998. There was no public debate on this important matter and the time period for suggestions, if any, was too short.

CPCSEA amended the Breeding and Experiments on Animals (Control and Supervision) Rules, 1998 that became the Breeding and Experiments (Control and Supervision) Amendment Rules, 2000. These, among other changes include the following:

1. In rule 6 (a), 'of particulars about the animals actually used from day-to-day for conducting experiments, with the number of animals, the species, the age and gender and other relevant particulars'.
2. In rule 10(b), 'a breeder/establishment should not acquire any animal by sale or otherwise, except from a registered breeder/establishment, except in the case of acquisition of laboratory-bred experimental animals of genetically defined strains from non-Indian sources for which registered breeders/establishments shall apply for permission to the Committee or Institutional Animal Ethics Committee recognized by the CPCSEA'.
3. In rule 10(e), 'No animal, except genetically defined ones shall be imported by a breeder . . . '.

The CPCSEA has the power to suspend or revoke registration based on an authorized report of an inspection or information received otherwise of non-compliance by any establishment, breeder or an Institutional Animal Ethics Commit-

tee after a suitable time is given for being heard on the matter.

Scientists mostly acquiesce to 'the 1998 rules, but caution that the rules are being implemented in a biased and motivated fashion'. The Institutional Animal Ethics Committee is said to function more as an institutional 'animal care' and not as an Animal Ethics Committee.

### Who are the members of the CPCSEA?

The website of CPCSEA ([www.cpcsea.org](http://www.cpcsea.org)) provides a list of members. There is more than a sprinkling of NGO (such as the People for Animals)-associated persons in the committee, directly or indirectly. Some others have little or no experience whatsoever in experimental work involving the use of animals. This is important to note when any future reforms are considered in the composition of the committee. The latest news is that Maneka Gandhi has been removed from the post of Chairperson of CPCSEA. The Environment Ministry asked the parliament secretariat and found out that an MP cannot hold an 'office of profit'. V. K. Duggal, Special Secretary in the Union Ministry for Environment and Forests has since taken over as Chairperson with temporary charge in the middle of December 2002.

Various sub-committees have been constituted under CPCSEA for the following:

- The purpose of examining the alternatives for experiments on animals in pure and applied research.
- To define the term 'genetically defined animals'.
- For the purpose of prescribing detailed guidelines for animal housing facilities based on 'good laboratory practices'. The standard guidelines so established would be applicable to all establishments in India.
- For the purpose of scrutinizing and approving research projects conducted using animals.

Besides the rules and procedures laid down by the CPCSEA, the Indian National Science Academy, New Delhi has brought out 'guidelines for care and use of animals in scientific research', under an expert committee with P. N. Tandon as Chairman. Published in the form of a handy booklet, the guidelines follow international norms and detail the fol-

lowing: sources of experimental animals, laboratory animal husbandry and management, transport of laboratory animals, anaesthesia and euthanasia, disposal of animal carcasses, laboratory animal ethics and legal provisions. These guidelines are widely read and followed by Indian researchers who use animals for experiments.

The following are some of the reforms needed that may be worth considering:

1. The backgrounds and affiliations of the CPCSEA members have to be scrutinized and changes made in the composition of the committee, with a larger representation for scientists who have expertise both in experience and modalities involved in the use of animals for experimental research.
2. Rule 18, Chapter IV, The Prevention of Cruelty to Animals Act, 1960 (59 of 1960) as amended up to 30 July 1982 states, 'For the purpose of ensuring that the rules made by it are being complied with, the committee may authorize any of its officers or any other person in writing to inspect any institution or place where experiments are being carried on and report to it as a result of such inspection, and any officer or person so authorized may: (a) enter at any time considered reasonable by him and inspect any institution or place in which experiments on animals are being carried on, and (b) require any person to produce any record kept by him with respect to experiments on animals'.

It is here that reform is most required. For reasons that would be detailed subsequently, it is imperative that the 'inspection teams' are constituted differently than at present, i.e. composed of people in a larger percentage who have the necessary scientific background to conduct a scientific inspection. In addition, the affiliations of all members need to be scrutinized as their interests could lead to prejudices and hidden agendas detrimental to the interests of the country. It is the composition of the visiting team, its procedures, timing and lack of transparency that worries scientists immensely as well as the demeanour of the team members towards them. 'To whomsoever it may concern' letters from the CPCSEA informing institutions about possible checks are signed under 'Expert Consultant', but surprisingly do not carry the name of the signatory. Several drawbacks in the stru-

cture and functioning of these teams have been coming to light ever so often, and most recently a report by the Delhi Science Forum (DSF), posted on its website, raises deep concerns. DSF has found during its own investigation following some recent press reports about a premier institute based in New Delhi, that 'CPCSEA Inspection Team Report had not provided a copy of the report either to the Institute concerned or to the media'. Even the attempts of DSF, they claim, to obtain a copy of the report from the CPCSEA proved futile. This signifies a complete breach of transparency in operation, that even keeps the inspected institution in the dark on findings and also leads to lack of objective reporting by the media, adding fuel to the fire. Surely, transparency in regulation should not be hard to achieve, provided there is the necessary will to do so. The inspection team, say scientists, should constitute at least one member who has knowledge of animal-house technicalities. In a few cases, the team had difficulty identifying rat and mice. The DSF Study Group report on 'Primates in scientific experiments in the National Institute of Immunology, New Delhi', gives a detailed understanding on how an inspection team performs its duties.

3. The physical location of the CPCSEA office in Chennai as well as the frequent shifting of the Animal Welfare Division (AWD) under different ministries need to be reconsidered. In recent years, the AWD has roller-coasted within ministries starting from Food and Agriculture, then to Environment and Forests, Social Justice and Empowerment, Culture, Statistics and Programme Implementation. This was followed by a brief sojourn again in Food and Agriculture and presently with the Environment and Forests.

The CPCSEA, unlike most other bodies under the umbrella of ministries, is physically located outside the buildings that usually house the ministry, and its website also lacks the logo of a government-appointed body. This raises questions about its mode of working. Scientists are highly skeptic about the latter. Why? The secretariat of the CPCSEA in Chennai is run, say scientists, by 'ad hoc appointees' leading to a 'great deal of confusion and lack of proper responsibility' necessary from a statutory and regulatory body. These ad hoc appointees or alternatively named 'expert consultants' hold stipendiary positions with no *locus*

*standi*, said one bench scientist. The CPCSEA, through internal memorandum, authorizes these so-called experts for inspection teams. This needs to be given a closer look.

4. Another essential change that must be considered while reforming the CPCSEA is of nominees with 'de facto' veto powers, especially with regard to Institutional Animal Ethics Committees. On the surface all appears well with constituted committees and their working. The veto power vested on the CPCSEA member negates all democratic consensus on any issue taken up in committees, leaving even distinguished scientists on such committees at a loss to intervene. The nominee should be divested of such overriding powers and the requisite backgrounds for the job on hand, looked into more closely. Further, the committee is unable to hold the meeting if the CPCSEA nominee is absent. Also, the mechanism of approval requires sanctions for use of large animals to be obtained from Chennai, while the Institutional Animal Ethics Committee can do so for small animals. The composition of CPCSEA sub-committees constituted needs to be carefully analysed in a reform package, with members having some working knowledge of animal experiments. Another suggestion is that persons from the Department of Biotechnology or the Department of Science and Technology could be deputed for periods of one year to assist the CPCSEA.

While the format of the Institutional Ethics Committee has been generally agreed to by scientists, the CPCSEA nominee usually asks for proven justification saying that 'one experiment is not good enough'. This puts the scientists in a quandary, in support of the number of animals needed for experiments during presentations, with heavy bargaining in terms of number of monkeys or mice that have to be sanctioned.

5. Procedural delays in sanctioning projects and the huge amount of paperwork involved need to be considered. Although scientists feel that the paperwork is the lesser of the evils at this point in time, a report that appeared in *The Times* in 2000 by Nigel Hawkes titled 'Scientists seek more animal test freedom' with an inset showing the 'maze of red tape' involved, indicates this is an issue faced by scientists all over the world. In the United Kingdom, says Hawkes, the whole procedure could take

as little as two months, or as long as 20 months. Typical delay is nine months as against a few days or weeks in USA or Germany, he added. According to him the 'maze of red tape' involved in the UK is the following: Three licences are required by the Home Office, the laboratory has to have its own licence, a certificate of designation, showing it is a proper place to do research involving animals, the researcher has to have a personal licence to carry out the research, and each programme of research has to be separately licensed.

This indicates that all is not well as is the case in our country too. Recently, Sandip Basu, in his talk titled 'Health-care disparities: conundrums and quandaries' delivered at the WHO-ICMR interactive session on ELSI of Genomics said, 'there is far too much paperwork demanded than is needed. For instance, even to import laboratory-bred mice, the chain starts-off with the institutional committee, followed by the national committee secretariat, the national committee sub-committee, the wildlife department, and finally the commerce ministry'. He also spoke on the activities of CPCSEA that 'have led to either a withdrawal of the Indian biotech and pharma sector industry from animal-based trials, or an exodus of such centres to overseas sites, auguring ill for India's industrial strength'. Basu added, 'humane use of experimental animals and good cutting-edge science are both essential societal commitments. Animal liberation activism flies in the face of both. It is imperative to bring the derailed process of animal experimentation regulation back on a balanced track so that both aims can be fulfilled harmoniously'.

6. Reforms are sought also in import licenses for exchange of mice strains. The procedure is presently long winding, involving the Director-General, Foreign Trade Office, Krishi Bhavan and Customs and the prior approval of the CPCSEA. Scientists put the time taken for getting an import license at an average of eleven months, with the necessity for interventions at the highest level.

With several cases pending in court and after incidents involving the CPCSEA in National Institute of Immunology, All India Institute of Medical Sciences, Jawaharlal Nehru University (all in New Delhi), National Institute of Nutrition, Hyderabad and a host of other institutions in the country, the Indian

Council of Medical Research sought the opinion of the Solicitor General's office. It is said that the Solicitor General's office has given an opinion that Sec. 14 of the rule takes precedence over Sec. 17. Therefore, the rules under Sec. 17 cannot be used to hamper animal experimentation. This means that the role of CPCSEA

becomes recommendatory and not regulatory.

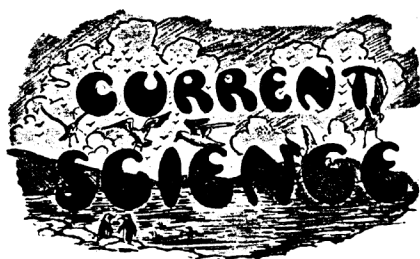
Considering the urgency and importance of the whole issue of animal experimentation, the least policy-makers could do is consider some of the reforms so that there is no further derailment of scientific research.

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1. Basu, Saionton, *Curr. Sci.*, 2002, **83**, 800–802.
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## FROM THE ARCHIVES



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### Europa Angustia

... The evolution of modern Europe is virtually the evolution of war technology, and it is not therefore surprising that nations regret that their genius has not been sufficiently harnessed for the invention of more formidable and more destructive engines, than are those employed in the present conflict. When in 1919 the statesmen of the victorious countries sat at the table in the Court of Versailles to draw up the instruments for implementing their war-born political faith of making the world safe for democracy, one could have almost heard the hoarse laughter of that spirit, whose name is unmentionable in polite society, at their un-

consciously sowing seeds for a second European conflagration. . . .

The present conflict differs fundamentally from its classical predecessors. The reproach that wars generally place a premium on the uneugenic propagation of the race is now practically removed. We can hardly recollect any period in the history of mankind, when even the most savage enemy selected old men, women, children, schools, churches, hospitals, and art treasures as special targets for destruction, with the object either of creating confusion among the civil population or of breaking the spirit of Government's resistance. In the previous wars the flower of manhood and the excellent traits of national military character may have perished on the battle field, but they reappeared in the succeeding generation, because they are qualities more or less inherent in the national chromosomes. In the wholly indefensible and absurd slaughter of children, we might lose potential Newtons and Darwins; the favourable genes for producing them do not occur with the periodic frequency of planets in the Heavens. Nothing is more senseless than wars, and nothing is more easily or more carelessly provoked. Our religion is

war-minded. Our culture is war-based. Our civilization is a war-product. Our mentality is war-tinged. We talk the language of peace, but tread the path of war.

... Modern technological civilization and its by-product, Imperialism, have become sociophagous. It is no wonder therefore that, in the circumstances in which the international relations subsist to-day, wars are the inevitable arbiters of disputes provoked by economic rivalries and political jealousies, which are inseparable from the maladjustment of social organisations. The world must develop the spirit of the Eskimo or of the Mahatma, before it can even dream of universal and perpetual peace, love, goodwill and contentment. Dr Nansen wrote of the Eskimo that "his peacefulness even goes so far that when anything is stolen from him, which seldom happens, he does not as a rule reclaim it, even if he knows who has taken it". . . .

... Our labours of successive civilizations have been like those of Sisyphus, and the history of political progress has been a circuitous folly. We have to place the wheels of human advancement on a new track, before we can hope to have peace for a reasonable term of our existence.