

genus *Decalepis* and is, therefore, of higher conservation concern.

iii) *Myristica malabarica* – a tree species endemic to Western Ghats (India). Fruits and arils being traded mixed with *Myristica fragrans* (cultivated). It has been assigned threat status 'vulnerable'. (Ref. CAMP Workshop I, 1995).

iv) *Nilgirianthus ciliatus* – a shrubby species of Western Ghats, which is used in large quantities by the traditional medicine industry. It has been assigned the threat status 'endangered' (Ref. CAMP Workshop II, 1996). The genus is endemic to Western Ghats.

MoEF in 1997, set up an expert committee to review the 1994 ban notice. This committee has suggested a more rational and comprehensive framework for drawing up negative lists of plants for regulating their trade. The committee has recommended the preparation of negative lists at four levels – the first level is to enlist plants for immediate ban, while, the listings for levels 2, 3 and 4 will involve staggering the ban on other threatened plant species over different periods of time, depending on various criteria discussed mentioned above, in order to allow the industry sufficient time to initiate cultivation/plantation of these plants and

thus develop alternative sources of supply for their use. These four levels of negative lists may operate in a 7–8 years time frame. The committee further recommended that such negative lists need to be made applicable not only for exports but also for regulating domestic trade because the volume of domestic trade in respect of most of these threatened plant species is higher than their export trade and it makes little sense to ban export of a critically-endangered species while permitting its unregulated consumption through domestic trade.

Conclusion

Government regulation on wild collections of endangered species is necessary and inevitable given the loss and degradation of natural habitats and overharvesting of some of these species. A reasonable degree of scientific rigour is needed to assess the threat status of species to be banned and evaluation must be done on several parameters. If government has to perform its governance role effectively, it has to take the task of scientific evaluation more seriously and not merely take populist decisions to show its concern. Regulating

trade in natural products harvested from the wild, is a serious business. Government needs to immediately take steps to collect from licensed Industry and Trade (by threatening to revoke licenses if necessary) reliable information on current and projected consumption of medicinal plants. The conservation status of all species in trade and the conservation biology of threatened species should also be studied.

Banning trade needs transparent guidelines and scientific inputs in order to take balanced administrative decisions. Where species are not on the verge of extinction and consumption level is high and plant parts used do not involve destruction, i.e. leaf, flower, fruit, etc., a reasonable time can be given to industry to develop cultivation strategies. In the absence of a rigorous and balanced approach to regulations, the conservation movement will earn a bad name and be accused of merely crying 'wolf' and industry will continue to make merry with its irresponsible plundering of nature.

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Animal experiments and biomedical advance

V. Ramalingaswami

The reported move of the 17-member Committee, the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), to bring about wide-ranging rules and regulations on the use of animals for research as reported in *Express Pharma Pulse*, 2 July 1998 is fraught with serious consequences to the progress of biomedical research in India. I am appalled that the heads of research agencies concerned with biomedical research are shown as members of the Committee. Are they also signatories to the proposed rules? Apparently, the CPCSEA draws its authority from Section 15 of

the Prevention of Cruelty to Animals Act, 1960. If the rules proposed by the CPCSEA are brought to Gazettee notification, research into new vaccines and new drugs, leave alone research into a better understanding of physiological processes in the human body, cannot advance in Indian laboratories. As I had written elsewhere, India is now well poised for major advances in new drug development and new vaccine discovery, on account of the high level of relevant scientific capabilities and the growing interest in this regard in Indian industry. It will be a great pity if new drug and vaccine development is im-

peded at this juncture on account of the proposed rules.

Research is the only way to win the fight against diseases still on the ascendancy, viz. the emerging and the re-emerging infectious diseases, heart diseases, strokes and cancer. Just now, as I write this note, a report has appeared in the *New Scientist*, 20 June 1998 that most recent animal experiments demonstrated that a new protein may speed the recovery of patients with strokes. According to this report, all the rats that received the protein recovered 'far faster' than those in the control group. The report goes on to say 'it may be

possible to begin clinical trials in a year's time, once safety and toxicological tests on animals have been completed.' Discovery of a new phenomenon in the laboratory, its conversion into a usable product, its testing for safety and efficacy in a suitable animal model and, finally, studying the effect of the product in humans from the point of view of safety, benefit and cost are well-known steps in the voyage of scientific discovery to the endpoint of public health benefit.

India's Prevention of Cruelty to Animals Act of 1960 is an act of faith on the part of civil society and at the same time, it tacitly recognizes the principle that animals may have to be used in experiments if the much-needed information for advancing human health cannot be obtained in any other way. Industrial nations have gone through the agonies of public debates on animal experiments for the benefit of both men and animals and have adopted legislation and procedures. What India is doing today is broadly similar. Under the rubric of the Act of 1960, India has developed progressively a system that seems to address the concerns in this field. Broadly, the system that obtains in India consists of the Act and a Committee authorized under the Act which is empowered to carry out inspections and grant registration to institutions or persons planning to do animal experiments after satisfying itself that optimal conditions for the welfare of animals exist and that all experiments would be carried out under the most humane conditions. Such a Committee may also conduct surprise inspections. The institutions and laboratories doing research on their part develop their research plans which may require animal experimentation and each project would then be submitted to the equivalent of an ethics committee for clearance. The Indian National Science Academy, on the basis of recommendations of an Expert Committee, prescribed certain 'guidelines for care and use of animals in scientific research' in 1992. *Inter alia*, the guidelines state: 'At the same time, it is an obligation of the scientist to ensure that the experiments conducted on animals are rational and no unnecessary pain or injury is inflicted on them and they are maintained in best possible environmental conditions. It is,

therefore, necessary to have well-defined guidelines which will safeguard the interest of the scientist, the animals and the society without hampering useful biomedical research.' These guidelines are being followed by our research institutes. While this is the broad scene, I must admit there are lacunae in implementation at the institutional level which need to be addressed. But this cannot be a reason for scrapping what actually exists altogether and introducing in its place a set of unworkable and impractical rules that are certain to hamper progress in medical and health sciences. Wisdom requires that the existing system which has been functioning reasonably well should be scrutinized and further strengthened.

As I said earlier, the proposed rules are unworkable despite their good intent. Here is a sample of the proposed rules:

- (1) Rule No. 4: 'Registration of establishments: a. No establishment shall perform any experiment without the written permission of the Committee.'

If each experiment has to be cleared by the Committee and these run into hundreds if not thousands of experiments at any one time, the impracticability of such a step is obvious. It may be remembered that the Committee in question consists of all very busy people.

- (2) Rule No. 6: 'Permission for conducting the experiments. a. Every registered establishment before acquiring an animal for conducting any experiment on an animal shall apply for permission of the Committee in the forms annexed as Annexure-II to these Rules.'

Once again the impossibility of implementing such a rule is obvious, even if the Chairperson and other members of the Committee have nothing else to do. Is it necessary once the Committee is satisfied that optimal conditions exist for the humane use of animals in experiments in any registered establishment?

- (3) Rule 6 (b): 'The Committee after scrutiny of the said application, if satisfied, shall grant permission to the applicant's establishment stat-

ing the name of the species and the number of animals that can be acquired for carrying out the experiment.'

It is obvious that the rules have now reached a stage of impossibility. And so it goes on. The whole tenor of the proposed rules works against facilitating science and scientific research and against encouraging industry to engage in R&D seriously, at a time when all the world over it is realized that industrial R&D holds the key to competitiveness and economic growth. I am not sure they contribute any more to experimental animal care and caring in the country, other than steeping the whole process in more paper work and more bureaucratic control. We in India are moving in the direction of collaborative efforts between academia and industry for fostering competitiveness and economic growth. A challenge for the 21st century is how to balance the goals of our research establishments and industrial units in the promotion of human welfare.

An elaborate exercise of this nature as proposed by the CPCSEA does not contribute to national development. Under the circumstances, may I suggest that a Working Group be convened:

- (1) To review the existing arrangements for humane and caring use of animals for scientific experimental purposes;
- (2) To identify deficiencies in the existing arrangements and suggest improvements in the rules, regulations and other arrangements as needed. The Committee would, in the process, develop a framework of guidelines to facilitate essential animal experiments that may be needed for the advancement of animal and human health in India. The composition of the Committee should be broadly representative not only of policy-makers, government scientific institutions, industrial R&D but also scientists and representatives of the public.

The recommendations of the Group may be considered in framing the Rules under the Act.

Apart from the practical utilities of animal experimentation in the form of product development, there is another

side of the coin, viz. the need for scientific experiments to advance the understanding of the functioning of the human body which is different from the application of science and technology. Reliable scientific knowledge is value free and ethical issues arise in relation to how its technology is used. So much of today's knowledge of the functioning of the human body and mind is derived from animal experiments. I must pay

tribute to the original framers of the Act of 1960 for their wisdom and foresight as they say in 'Section 14. 'Experiments on animals – Nothing contained in this Act shall render 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 alleviat-

ing suffering or for combating any disease, whether of human beings, animals or plants'. What a vision! and in the process of translating that vision into action, what a fall!

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Appendix

The newly formulated rules for regulating animal use in experimentation may have a far-reaching effect on biomedical research in India. We are therefore reproducing the draft rules to facilitate a wider discussion on this important issue.

–Editors

Experiments on Animals by Establishments and Breeding (Control and Supervision) Rules, 1998

In exercise of the powers conferred by Section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), the Committee for the Purpose of Controlling and Supervising Experiments on Animals*, hereby makes the following rules:

1. Short title

These rules may be called the Experiments on Animals by Establishments and Breeding (Control and Supervision) Rules, 1998.

2. Definitions

In these Rules, unless the context otherwise required:

- a) 'Act' means the Prevention of Cruelty to Animals Act, 1960 (59 of 1960).
- b) 'Committee' means the Committee constituted under Section 15 of

the Act, for controlling and supervising experiments on animals.

- c) 'Establishment' means any company, firm, corporation, institution other than an educational institution and includes a person, which performs experiments on animals.
- d) for saving or for prolonging life or alleviating suffering or for combating any disease whether on human being, animals or plants.
- e) 'Breeder' means any person including institution which breed animals for the purpose of transfer to other authorized institutions for performing experiments.
- f) 'Person' includes firms, companies, institutions, trusts, etc.

3. Breeding of animals

- a) Every person who carries on the business of breeding or trade of such bred animals for the purpose of experiment, shall get itself registered within three months of the commencement of these Rules and apply for registration in the form prescribed in Annexure I(A).
- b) After the expiry of the said three months, no person shall carry on such business or trade unless it is duly registered.
- c) The breeder so registered for the purpose of carrying on the said trade or business, shall comply with all such directions as may be issued by the Committee for the said purpose.

4. Registration of establishments

- a) No establishment shall perform any experiment without the written permission of the Committee.
- b) Every establishment which performs experiments on animals shall get itself registered within 30 days from the date of the commencement of these Rules.
- c) No establishment after the expiry of the said period shall perform an experiment unless it is registered.

5. Application for registration

- a) Application for registration shall be made in the form prescribed in Annexure 1 [not reproduced here]. The Committee would be empowered to get the premises inspected where the experiments are to be conducted, animal housing facilities and other infrastructure for verification of facts mentioned in the application and for deciding the issue of registration.
- b) The establishment so registered for the purpose of performing experiments on animals shall comply with all such directions as may be issued by the Committee for the said purpose.
- c) All laboratories whether commercial or government shall register the exact number/species of animals with the Committee.
- d) Institutions which are being funded by Government shall for-

*The Committee, chaired by Maneka Gandhi, had 17 members of whom 12 were *ex-officio*. These include the Secretaries of the Departments of Biotechnology and Education, the Special Secretary of the National Informatics Centre, the Directors General of Health Services and Medical Research, the Drug Controller of India, the Directors of the Indian Veterinary Research Institute, the Central Drug Research Institute and the All India Institute of Medical Sciences, the Chair of the Animal Welfare Board of India, the Additional Inspector General of Forests (Wildlife) and the Director (Animal welfare) in the Ministry of Environment and Forests.

ward the application for permission to perform an experiment in the form annexed or Annexure-II [not reproduced here] to their respective funding agency for necessary permission. The said funding agency shall submit a monthly statement of such permission granted for approval of the Committee.

6. Permission for conducting the experiments

- a) Every registered establishment before acquiring an animal for conducting any experiment on an animal shall apply for permission of the Committee in the forms annexed as Annexure-II to these Rules. The establishment shall truthfully disclose all the particulars about the kind of animal to be used, the health of the animal, the nature of experiment to be performed, and the reasons necessitating the performance of such an experiment on a particular species.
- b) The Committee after scrutiny of the said application, if satisfied, shall grant permission to the applicant's establishment stating the name of the species and the number of animals that can be acquired for carrying out the experiment.
- c) The establishments (and persons) carrying on experiments on animals shall forward to the Committee the reports and such other information on completion of experiments for which permission has been granted.

7. Stocking of animals

- i. The animals shall be stocked by the breeders and establishments in the following manner;
 - a) Animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises kept tidy, and hygienic and the animals protected from drought and extremes of weather;
 - b) Animal cages for small animals and stables for larger animals shall be such that animals can live in comfort and overcrowding is avoided;
 - c) Where standards have been laid down by the Indian Standards Institution, the cages, the stable, as the case may be, shall conform to these standards;

- d) Animals attendants shall be suitably trained and sufficiently experienced in the duties allotted to them;
- e) Animals shall be looked after, before and after the experiments by a trained and experienced attendant;
- f) There shall be satisfactory arrangements for looking after the animals during off hours and on holidays.

8. Performance of experiments

In conducting experiments on animals, regard shall be had to the following conditions, namely:

- a) Experiments shall be performed in every case by or under the supervision of persons duly qualified in that behalf, viz. Degree or Diploma holders in Medicine and Veterinary Science or Pharmacy or Natural Science or other sciences of a University or an Institution recognized by Government for the purpose and under the responsibility of the person performing the experiment;
- b) Experiments shall be performed with due care and humanity;
- c) Animals intended for the performance of the experiments are properly looked after both before and after experiments.
- d) Experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthetic of sufficient power to prevent the animal feeling pain and it shall remain so throughout the experiment. Anaesthesia shall be administered by a Veterinary Surgeon adequately trained in methods of anaesthesia and who shall remain present near the animal till the completion of the experiment;
- e) Animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anaesthesia;
- f) When there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment;

- g) The experiment shall not be performed for the purpose of attaining or retaining manual skill;
- h) Experiments shall not be performed by way of an illustration;
- i) Experiments shall not be performed as a public demonstration;
- j) The substance known as Urari or Curari or any such paralytic shall not be used or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness;
- k) No experiment, the result of which is already conclusively known, shall be repeated.
- l) These shall not be applied to the eye of an animal by way of experiment, any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to give pain;
- m) Dogs held for experimental purposes shall not be debarked;
- n) Where experiments are performed in any institution, the responsibility thereof is placed on the person in charge of the institution and that, in cases where experiments are performed outside an institution by individuals, the individuals are qualified in that behalf and the experiments are performed on their full responsibility.
- o) Experiments on animals are avoided wherever it is possible to do so;
- p) Experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea pigs, rabbits, frogs and rats.

9. Transfer and acquisition of animals for experiment

A breeder shall not transfer any animal by sale or otherwise to any establishment other than to an establishment registered under these rules.

An establishment shall not acquire any animal by sale or otherwise except from a registered breeder under these rules.

Every establishment after acquisition of an animal or animals shall not transfer such animal or animals by sale or otherwise to any

other establishment or person except to a registered breeder.

10. Records

- a) Every establishment shall maintain a record of the animals which are in its control and custody, in the form as prescribed in Annexure-III [not reproduced here]; to these Rules. Similarly, every establishment shall maintain record in manner as prescribed in Annexure-IV [not reproduced here].
- b) Every establishment shall provide such other information as the Committee may from time to time requirement.

11. Contract animal experiments

No establishment shall contract or undertake to perform or perform experiments on contract basis on behalf of any other establishment or any other research, educational or charitable institution which is not registered within the country.

12. Power or inspection

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 place where animals are being kept or bred for the purpose of transfer to other establishments and report to it as a result of such inspection, and any officer so authorized may:

- a) Enter and inspect at any time considered reasonable by him such premises.
- b) Require any person to produce any record kept by him with respect to such animals.

13. Power to suspend/ revoke registration

- a) If the Committee is satisfied, on the report of any officer or other person made to it as a result of any inspection under Section 18

of the Act or Rule of Experiment on Animals by Establishment and Breeding (Control and Supervision) Rules or otherwise that the Rules made by it under Section 17 are not being complied with by any establishment or breeder, the Committee may after giving a reasonable opportunity to the establishment or breeder of being heard in the matter, by order, revoke the registration of such establishment or breeder either for a specified period or indefinitely, or may allow the establishment or breeder to carry on subject to such special conditions as the Committee may think fit to impose.

- b) Without prejudice to the provisions contained above in Rule 11, the Committee may, pending the final determination, if it is of the opinion that such establishment or breeder has prima facie failed to comply with the provisions of the Act, Rules or such directions issued by the Committee, it may suspend the registration of such establishment or breeder.
- c) The Committee may in the event of revocation or suspension of registration of an establishment or breeder issue such directions as it deems fit for the care and protection of the animals which are under the custody or control of such establishment or breeder.
- d) That in the event of suspension or revocation of a license, such establishment or breeder shall forthwith on the communication of the order cease to perform any experiment on any animal or acquire or transfer any animal.

- e) In addition to the provisions of the Act, if any establishment or breeder fails to comply with the revocation or suspension or any other direction issued by the Committee or otherwise in respect of animals under their custody or control, it shall be deemed to be treating animals cruelly.

14. Offences by companies

- a) It is made clear that where an offence against these Rules or the Act has been committed by a company, every person who, at the time the offence was committed, was in charge of and was responsible to, the company for the conduct of the business of the company as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

- b) Notwithstanding anything contained in sub-section (1), where an offence against this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of any director, manager, secretary, veterinarian, or other officer of the company, such director, manager, secretary, veterinarian or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.