

MINUTES OF THE XIX MEETING OF COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA) HELD ON 21.5.2007 AT 11.00 A.M. UNDER THE CHAIRMANSHIP OF SHRI B.S. PARSHEERA, CHAIRMAN, CPCSEA AND ADDITIONAL SECRETARY, MINISTRY OF ENVIRONMENT & FORESTS

A List of Members who attended the meeting and list of Members granted leave of absence is enclosed.

Chairman, CPCSEA, welcomed the members and agenda items were taken up as follows:

19.1 CONFIRMATION OF THE MINUTES OF THE XVIII MEETING OF CPCSEA HELD ON 20TH MARCH 2007.

The Committee confirmed the Minutes of the XVIII Meeting held on 20th March 2007.

19.2 TO REVIEW THE ACTION TAKEN ON THE MINUTES OF THE XVIII MEETING AND PENDING POINTS OF PREVIOUS MEETINGS OF CPCSEA.

9.2-3.1.2 Review of experiments using animals in case of traditional medicine

9.2-3.2.5 Funding of projects on traditional on system of medicine and proper scientific review with regard to the scope and purpose of research.

The Committee was informed that a letter from Chairman, CPCSEA to Secretary, AYUSH had already been issued on 19.3.07 and reminders had been sent on 23.4.07 and 10.5.07 but no response has been received. Chairman, CPCSEA, stated that he had discussed this issue with representatives of AYUSH and it was expected that Department of AYUSH would make a presentation in the next meeting of the CPCSEA. Confirmation of Department of AYUSH would be obtained in this regard.

13.6 Deposit of the amount collected as registration/renewal fee

The Committee was informed that the matter had been referred to the Department of Expenditure, Ministry of Finance for their comments on 18.3.2007 and response was awaited. Since reminders dated 23.4.2007 and 10.5.2007 had already been issued, it was decided that Under Secretary (Animal Welfare) would personally follow up the matter with the Ministry of Finance.

13.7 Meeting of the Sub-Committee on Rehabilitation on Animals after their Experimentation

The Committee was informed that recommendations had been placed on the website of the Ministry on 7.5.2007 and it was decided that further follow up would be

done by writing to about 20 prominent institutions registered with CPCSEA, including Veterinary Universities and organizations such as CSIR, ICMR etc., with the approval of Chairman, CPCSEA. The institutions would be requested to provide their response within a period of 8 weeks, after which the proposals of the Sub-Committee would be considered for implementation. Request for comments would also be placed on the ticker of the website of the Ministry.

16.6.2 Action to be taken on the basis of Report of Consultative Group on Review of the Norms and practices for Regulation of Animal Experimentation

The Committee accepted Dr. P. Balakrishnamurthy's request for four weeks time to complete his report.

16.8 Approval of Animal House Facility by CPCSEA

The Committee accepted the suggestion made by Vice-Chairman, CPCSEA that any items relating to previous meetings, which were placed for approval of CPCSEA, should also be included as distinct agenda items in the agenda of future meetings.

The Committee approved the proposal for Animal House Facility in respect of M/s. VELS College of Pharmacy, Chennai for the purpose of breeding and experimentation of Rats, Mice, Guinea Pigs and Rabbit

17.5 (a) In respect of Medical Education Department, Stanley Medical College, Chennai, Tamil Nadu, the Committee noted that the compliance report was awaited.

(b) In respect of Southern Regional Research Centre, Central Sheep and Wool Research Institute, Tamil Nadu, the Committee recommended that Expert Consultant CPCSEA inspect all the Centres under the Institute and the proposal for approval of animal house facilities be submitted to CPCSEA thereafter.

(c) In respect of the Institute of Veterinary Biology Products, Department of Animal Husbandry, Pune, the Committee noted that the compliance report had not yet been received.

17.6 Proposal of Forest Department, Govt. of NCT of Delhi for use of commensal monkeys being rehabilitated at their monkey shelter at Rajokari for research purposes.

The Committee was informed that no response had been received to letters dated 20th February, 2007, 18th April, 2007 and 10th May, 2007. It was agreed that Vice-Chairman CPCSEA would write to Secretary, Environment, N.C.T. of Delhi.

17.7 Sub-Committee for Selection of CPCSEA Nominees on Institutional Animal Ethics Committees.

Prof. A.J. Rao informed that he had forwarded draft guidelines to Dr. Vasantha Muthuswamy, Sr DDG, ICMR. Dr. Muthuswamy confirmed she concurred with the guidelines proposed. It was agreed that Dr. Rao would email the draft guidelines to all the Members of the CPCSEA for further consideration.

18.4 Consideration of New Proposals

Dr. Balakrishnamurthy indicated that the revised formats for submission of new proposals to CPCSEA would be submitted shortly.

18.5 Approval of Animal House Facility by CPCSEA

The CPCSEA noted the status that compliance reports were awaited from the Veterinary College, University Agricultural science, Hebbal, Bangalore and PGIMER, Chandigarh .

18.6 Financial Assistance for Conduct of International Conference on Alternatives to Animal Studies and In Vitro Studies

The Committee noted that letters had been issued to various organizations in this regard.

19.3 REGISTRATION OF INSTITUTES WITH CPCSEA

The Committee noted that 1059 institutions have been registered with CPCSEA.

19.4 CONSIDERATION OF PROPOSALS RELATING TO ANIMAL EXPERIMENTATION.

19.4.1 Update regarding proposals submitted earlier.

In the meeting of CPCSEA held on 20.3.2007, the following project proposal was deferred for want of details regarding the project and was resubmitted for consideration on receipt of clarifications.

S.No.	Name of the Institute / Name of the Investigator	AGENDA	Decision of XIX CPCSEA
1.	M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. /Mr. V. D. Pawar, M. Pharm.	The Institute has submitted the details of Code Numbers of NCE's, bearing code numbers ZYH7 and ZYD1	Approved.

19.4.2 CONSIDERATION OF NEW PROPOSALS:

The project proposals placed before the Committee were examined as under:

S. No	Name of the institute/Name of the Investigator	Project Title	Decision of XIX CPCSEA
1.	M/s. Sun Pharma Advanced Research Center (SPARC), Tandalji Vadodara – 390 020 (Gujarat). / Dr. M. R. Marathe Received on 23.3.2007	DRF and one month Oral toxicity of NCE in Beagle Dogs (Project code: 10712408)	<p>The Committee noted that no details had been provided regarding frequency of bleeding of the animals and the size of the blood sample to be drawn.</p> <p>The Committee expressed dissatisfaction as the complete details had not been provided in the proposal and stated that the IAEC should have scrutinized the proposal carefully.</p> <p>In particular, the IAEC nominee should be advised to take due care in this regard.</p>
2.	M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. /Mr. Harilal Patel Received on 3.5.2007	Pharmacokinetic study of new molecules and In-vivo release study of novel formulation in dogs.	<p>The Committee noted that the proposal indicated that the pharmacokinetic profile had been observed to be inconsistent in case of rodents.</p> <p>Accordingly, the rationale for further testing in beagle dogs should be clarified in detail before the proposal could be considered by CPCSEA.</p> <p>In particular the code numbers of the 5 NCEs and the purpose for use of the particular NCEs had not been provided.</p> <p>NCEs used in the earlier rodent studies and details of the pharmacokinetic data were also required for further consideration of the proposal by CPCSEA.</p>
3	Tamil Nadu Veterinary and Animal Sciences University (TANUVAS), Madhavaram Milk Colony, Chennai – 600 051/ Dr. N. Daniel Joy Chandran Received on 4.5.2007	Efficacy of TSU (Ayurvedic product) against Peste des petits ruminants	<p>CPCSEA noted that neither details/specification of the Ayurvedic Drug nor the rationale for its use had been given. The IAEC report was not enclosed with the proposal and the parameters for evaluation were not clear. The Committee pointed out the virus-infected animals could not be rehabilitated and should be euthanised. The proposal was not approved by CPCSEA.</p>

General Observations of CPCSEA regarding proposals received from NDRI, Karnal:

(i) It was noted that the proposals received from NDRI in many cases did not contain the relevant particulars as per prescribed formats.

(ii) The detailed rationale for the studies or justification for research had not been provided.

(iii) The IAEC approvals were not accompanied by the requisite tables and it appeared that the IAEC was not examining the proposals carefully.

The Committee decided that a letter be addressed to Director, NDRI, Karnal recommending that the Chairman of the IAEC should be at least of the level of Joint Director.

(iv) The Committee also recommended that the CPCSEA nominees on the IAEC of the Institution be changed.

(v) It was noted that the Consultative Group on Review of the Norms and Practices for Regulation of Animal Experimentation had stated in its Report that the conventional regulatory framework could not be made applicable in the case of Agriculture Production & Research. In case of research activities, which did not involve causing any pain and injury to Animals or injection of any toxic substances, what was required was that norms be laid down to address requirements of housing and proper animal husbandry. Operational Guidelines were to be framed by CPCSEA to provide for self-regulation by practitioners. CPCSEA thereafter proceeded to examine the proposals received from NDRI Karnal, in light of the above directions.

4	N. D. R. I, Karnal, Haryana-132 001. / Dr. S.S. Thakur Received on 4.5.2007	Nutrient utilization for growth in calves fed rations supplemented with bypass fat	The Committee directed that the proposal be re-submitted after providing the IAEC table and detailed justification for the study.
5	N. D. R. I, Karnal, Haryana-132 001. / Dr. R.C. Chopra	Effect of sun drying of aflatoxin contaminated feed on growth and certain blood parameters in calves	Approved.
6	N. D. R. I, Karnal, Haryana-132 001. / Dr. Aruna Chhabra Received on 4.5.2007	Status of certain contaminants in animal feeds and measures to minimize their carry over to milk in goats	CPCSEA did not approve the proposal as no background information had been provided regarding the use of the specific drug in the study.

7	National Dairy Research Institute, Karnal, Haryana-132 001. / Dr. K.K. Singhal Received on 4.5.2007	Effect of feeding cottonseed produced from Bt cotton cultivar on feed intake, production and composition on milk in dairy cows	The proposal was not approved by CPCSEA as it involved use of transgenic material requiring appropriate clearances.
8	National Dairy Research Institute, Karnal, Haryana-132 001./ Head, DCN Division	Drawing the rumen liquor from the rumen fistulated animals for practical classes of M.V.Sc., and Ph.D., Students	Approved.
9	National Dairy Research Institute, Karnal, Haryana-132 001./ Dr. S.K. Sirohi Received on 4.5.2007	Impact of fibrolytic enzymes on nutrient digestibility and growth in buffalo and cattle calves	Approved.
10	National Dairy Research Institute, Karnal, Haryana-132 001./ Dr. S.K. Sirohi Received on 4.5.2007	Effects of rumensin on methanogenesis, nutrient utilization and milk production in lactating cows.	Approved.
11	N. D. R. I, Karnal, Haryana-132 001./ Dr. Amit Kumar Srivastava	Studies on Symbiotic supplementation on growth and health status of crossbred calves	Approved.
12	N. D. R. I, Karnal, Haryana-132 001./ Mr. Hilal Musadiq Khan Received on 4.5.2007	Prepartum and postpartum management intervention for improving reproductive performance in Murrah buffaloes	Approved.

13	N. D. R. I, Karnal, Haryana-132 001./ Mr. Raj Kumar Meena Received on 4.5.2007	Managerial intervention for reducing age at sexual maturity in Sahiwal heifers	Approved.
14	N. D. R. I, Karnal, Haryana-132 001./ Dr. P.K. Nagpaul Received on 4.5.2007	Studies on Growth and Production Performance of Kids and Crossbred Goats under Different Shelter Systems	CPCSEA did not approve the proposal as no details regarding justification of such a study had been provided.
15	National Dairy Research Institute, Karnal, Haryana-132 001. / Dr. Shiv Prasad	Studies on soya-maize based milk replacer and ruminal fluid inoculation on productive performance of crossbred calves	Approved.
16	N. D. R. I, Karnal, Haryana-132 001. / Mr. Riaz Ahmad Shah Received on 4.5.2007	Establishment of electrofusion procedure and culture conditions for production of handmade cloned embryos in Buffalo (<i>Bubalus bubalis</i>)	Approved.
17	N. D. R. I, Karnal, Haryana-132 001. / Dr. Prava Mayengbam Received on 4.5.2007	Heat Shock Protein 70 Expression in Relation to Thermotolerance of Sahiwal and Sahiwal x Holstein- Friesian Crossbred Cattle	Approved.
18	N. D. R. I, Karnal, Haryana-132 001. / Dr. S.N. Rai Received on 4.5.2007	Studies on <i>Acacia nilotica</i> pods replacing energy sources in ration of dairy cows on production performance and nutraceutical value of milk and milk products	CPCSEA directed that the proposal should be re-submitted after the testing on rats has been completed. Results of the study on rats should also be provided at the time of resubmission of the proposal.

19	National Dairy Research Institute, Karnal, Haryana-132 001. / Dr. Veena Mani and Dr. Neelam Kewalrmani Received on 4.5.2007	Evaluation of certain binding agents/nutrients to counteract heavy metal toxicity in cross-bred calves/kids	Approved.
20	N. D. R. I, Karnal, Haryana-132 001. / Dr. Rajesh Kanna Received on 4.5.2007	Effects of Body Condition Score on metabolic and oxidative status in Periparturient cows	Approved.
21	N. D. R. I, Karnal, Haryana-132 001. / Dr. Sanjay Kumar Received on 4.5.2007	Development and evaluation of complete feed block on low grade roughage fortified with potential anerobic fungi in buffaloes	Approved.
22	N. D. R. I, Karnal, Haryana-132 001. / Santosh Kumar Guide, Dr. K.K. Mehla Received on 4.5.2007	Effect of herbal feed supplement Jivanti (<i>Leptadeni reticulata</i>) on milk production in crossbred cattle	Approved.
23	National Dairy Research Institute, Karnal, Haryana-132 001. / Dr. K.K. Singhal Received on 4.5.2007	Optimization of energy and nitrogen availability for microbial protein synthesis in the rumen	Approved.
24	Ranbaxy Laboratories Limited R & D-II, Sarhaul, Sector-18, Gurgoan-122 001/ Dr. N. Parthiban Received on 7.5.2007	Import of Beagle dogs to conduct experiments against approved protocols	CPCSEA directed that clarification regarding the import requirements of beagle dogs be obtained personally by Expert Consultant, CPCSEA along with another official to be nominated by Sr DDG, ICMR. Based on the report the Committee authorized Chairman, CPCSEA to take decision in this regard.
25	Ranbaxy Laboratories Limited R & D-II, Sarhaul, Sector-18, Gurgoan-122 001/ Dr. Srinivasan M. Rajaram, Received on 7.5.2007	A sub-acute oral toxicity study of a new chemical entity, NCE (Ketolide class) in Beagle dogs	As above at S. No 24

26	Ranbaxy Laboratories Limited R & D-II, Sarhaul, Sector-18, Gurgoan-122 001/ Dr. Srinivasan M. Rajaram, Received on 7.5.2007	Dose range finding study of a new chemical entity, NCE (Ketolide class) in Beagle dogs	As above at S. No 24
27	National Institute of Nutrition Jamai Osmania P.O. Hyderabad – 500 007 (A.P.)/Dr. P. Suresh Received on 8.5.2007	Pharmacokinetic study of Radiation Protection Drug EX-RADTM ON 1210Na in Monkeys, Macaca mulatta	CPCSEA directed that details of earlier testing on animals below the level of sentience of monkeys should be provided. It may also be confirmed as to whether the proposal was in the nature of contract research.

19.5: PERMISSION SOUGHT BY DEFENCE INSTITUTE OF PHYSIOLOGY & ALLIED SCIENCES, LUCKNOW ROAD, TIMARPUR, DELHI-110054 FOR PROCUREMENT OF CATS

The Committee approved that the institution may obtain locally available domestic cats for the purpose of experimentation.

19.6: APPROVAL OF ANIMAL HOUSE FACILITY BY CPCSEA

(a) Bharat Serum & vaccines Limited, Road No. 27, Wagle Industrial Estate, Thane-400604, Maharashtra.

The Committee decided that the institution be given six months time for compliance with the suggestions for improvement of the Animal House Facilities.

(b) Muljibhai Patel Urological Hospital, Dr. Virendra Desai Road, Nadiad – 387001, Gujarat.

The Animal House Facilities were approved for the purpose of experimentation on rats, mice, Guinea Pig, Rabbit, Pigs, dog and Sheep.

(c) Vetcare Group of Companies, IS-40, KHB Industrial Area, Yelahanka New Town, Bangalore-560064, Karnataka.

The Committee decided that the institution be given six months time to comply with recommendations for improvement of the Animal House Facilities. Advice of Dr K.Venkaiiah, Head and Asst Dir. Bio Statistics Deptt, NIN should be obtained regarding statistical analysis.

19.7: ANY OTHER ITEM WITH PERMISSION OF CHAIRMAN: NIL

Annexure**The following Members were present for the meeting on 21.5.2007**

1. Shri. B.S. Parsheera, Chairman
Additional Secretary,
Ministry of Environment & Forests,
Paryavaran Bhawan, CGO Complex,
Lodhi Road, New Delhi – 110 003.
2. Shri. G. Balachandhran Vice Chairman
Joint Secretary (Animal Welfare),
Ministry of Environment & Forests,
Paryavaran Bhawan, CGO Complex,
Lodhi Road, New Delhi – 110 003.
3. Ms. Somya T. Dave,
Director & Member-Secretary, CPCSEA
Ministry of Environment & Forests
8th Floor, Jeevan Prakash Bldg.,
25, Kasturba Gandhi marg,
New Delhi – 110001.
4. Dr. V.K. Vinayak,
(Retd.) Senior Advisor,
Department of Biotechnology,
B-1, E-12, Mohan Co-Operative Industrial
Estate, Mathura Road, New Delhi-110 044.
5. Dr. Vasantha Muthuswamy,
Sr. Dy. Director General &
Chief, Division of BMS, Traditional Medicines & Bioethics,
Indian Council of Medical Research,
Ansari Nagar, New Delhi-110 029.
6. Prof. A. J. Rao (Retd),
Department of Biochemistry,
Indian Institute of Science,
Bangalore – 560012.
7. Dr. P. Balakrishnamurthy,
Director,
International Institute of Biotechnology & toxicology (IIBAT),
12, Harleys Road, Kilpauk,
Chennai – 600 010.

8. Dr. D. Swaroop
Head, Division of Medicine,
IVRI, Izatnagar – 243122
Uttar Pradesh
9. Dr. Kondavalla Venkaiah,
Head & Addl. Director,
Bio-Statistics Department,
National Institute of Nutrition,
Hyderabad-500 007.
10. Dr. K. Nachimuthu,
Director of Research,
Tamilnadu Veterinary and Animal Sciences University (TANUVAS),
No.4, Dhamodara Street, Panchvadi, Chetpet,
Chennai-600 031.

Leave of absence was granted to following:

1. Dr. Shashi Motilal,
Professor (Philosophy),
University of Delhi,
7, Vaishali Apartments, IIT/Delhi, Hauz Khas,
New Delhi-110 016.
2. Dr. T.P.R. Bhardwaj,
Senior Consultant, Haematologist,
Apollo Hospitals, 21, Greams Lane,
Off. Greams Road, Chennai-600 006.
3. Prof. Anup Kumar Nayak,
Wildlife Institute of India,
Post Bag #18, Chandrabani,
Dehradun – 248 001, Uttaranchal.
