

**AGENDA NOTES FOR THE MEETING OF
COMMITTEE FOR
THE PURPOSE OF CONTROL AND SUPERVISION
OF
EXPERIMENTS ON ANIMALS (CPCSEA)**

DATE : 20th December, 2004

TIME : 11.30 A.M.

VENUE : COMMITTEE ROOM NO. 403

**PARYAVARAN BHAWAN
C.G.O. COMPLEX,
NEW DELHI-110 003.**



**Ministry of Environment & Forests
Government of India
New Delhi-110 003.**

Agenda for the meeting of Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) to be held on 20th December, 2004 in the Committee Room No.403, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi-110 003

Agenda Item No. 1 : Confirmation of the Minutes of the Meeting held on 24th September, 2004. A copy of the minutes is at **Annexure-I**.

Agenda Item No. 2 : Follow up action on the meeting of CPCSEA held on 24th September, 2004 is at **Annexure- II**.

Agenda Item No. 3 : Registration of Institutes with CPCSEA:

Since 25th September,2004, 37 Institutes have been registered with CPCSEA, bringing the total number of registered institutes to 862. Applications have been received from another 4 institutes and are being processed.

Agenda Item No. 4 : Approval of Animal House Facilities:

Subsequent to the last meeting of CPCSEA, Inspection of another three institutes have been conducted. The Inspection Reports are enclosed. The CPCSEA may consider approval of Animal House Facilities of these institutes. The brief details of the Inspection Reports of the Animal House Facilities are as follows:

S.No	Name of Institute	Brief Recommendation / suggestions of inspection team
1.	Russel Kennels, Ajmer	No proper facility available for proper breeding and housing. No adequate Veterinary attention available. Different types of breeds are housed in the residential premises. No exercise available. All dogs kept in a single room. Owner mentioned that he supplied pups to his friends and he does not breed animals for commercial purposes. The animals may be shifted to the Russel Kennel Farm situated about 40 Kms from the existing residential facility where the dogs are currently housed. Until then the facility should not be recommended for breeding for commercial purposes.

		<p>Proper housing & hygiene should be provided for all exotic birds, which are bred in this facility. Subject to the above, the facility should not be recommended for breeding for commercial purposes</p>
2.	Ranbaxy Laboratory, Satbadi and Gurgaon	<p>In the IX meeting of SCLA held on 25th June 2003, the project of import of beagle dogs for conducting sub-chronic toxicity studies was rejected on the ground that it was not supported with the recommendation of IAEC & the animal house facility was not approved. In its X meeting held on 25.08.2003 SCLA observed that the drainage/sewage system should be in conformity with the CPCSEA's guidelines. Further in the XIV meeting of SCLA held on 10.08.2004, it was decided that the institute be re-inspected and accordingly a team was constituted to conduct the inspection. The comments/recommendations of the re-inspection team are as follows: "The small animal facility was found to be generally good. The old dog facility was satisfactory and no further breeding should be permitted in this facility. The old Beagle facility, because of modification in sewage facility as recommended by the previous zonal inspection team may be given temporary permission to conduct pharmacokinetic studies with prior approval of CPCSEA along with IAEC recommendations. No toxicological studies should be conducted with the existing old Beagle dogs. The new facility is under construction. On completion of this new facility at Gurgaon this facility has to be inspected before the fresh stock of Beagles are imported. No Beagle dog from the old facility should be transferred to the new dog facility. Once the new facility is completed and its approval is accorded, the old facility should be closed down and all the</p>

		existing Beagles should be rehabilitated immediately. Subject to the above, the facility may be considered for approval.”
3.	Haffkin Institute, Pune	De-worming is to be done every 3 months, flooring of some sheds needs improvement, cleaning can be improved, facilities are satisfactory (improved since last inspection by other teams), Records are OK, developing Elisa test for antibody detection instead of mouse neutralization test.

Agenda Item No. 5: Delegation of power to SCLA for approval of animal house facilities:

The Animal House facilities of the establishments are approved by CPCSEA, while the Sub-Committee on Large Animals (SCLA) which meets alternate month, examines the protocols of establishments with regard to experimentation on large animals and directs to conduct the inspection of animal house facility depending upon the protocols. In view of the fact that the process of approval of animal house facilities of institutes is a long haul and time consuming and it consequently causes delay in consideration of protocols, the SCLA in its meeting held on 10th August, 2004 expressed a view that to speed up this process, the power to approve the animal house facility may be given to SCLA (Sub Committee on Large Animals) or only those proposals will be considered by SCLA where animal house facility has been approved by CPCSEA. Therefore a decision needs to be taken whether the existing arrangement wherein the CPCSEA approves the AHF first and then only SCLA considers the related project proposals of such approved institutes should continue or the power of approval of AHF will also be delegated to SCLA.

The issue was discussed in the last meeting. The members however unanimously decided that the issue of the need for delegation of the powers to approve large animal house facilities to the SCLA could be considered separately later. A decision in this regard may be taken by CPCSEA.

Agenda Item No. 6 : Review of CPCSEA norms - Report of the consultative group on streamlining of the norms of CPCSEA.

A need was felt to review CPCSEA norms as there have been complaints of CPCSEA regulations proving to be a hurdle in smooth conduct of medical research. The existing CPCSEA norms and the issue regarding promulgation of new ones were considered in six brainstorming meeting of a consultative group set up under the Chairpersonship of the Secretary (E&F). In these meetings the principles for utilization and care of animals used in testing, research and training were finalized along with some related issues. A copy of the report of

the consultative group is enclosed herewith. The report calls for some amendments in PCA, Act and Breeding Rules. It also stipulates for formation of guidelines by the CPCSEA. The action for amendment in PCA, Act and Breeding Rules are being taken by the Ministry taking into account all relevant factors.

Section 17 (3) of PCA, Act, 1960 lays down that in making any rules under this section the committee shall be guided by such directions as the Central Government (consistently with the object for which the Committee is set up) may give to it, and the Central Government is hereby authorized to give such direction.

The recommendations of the Groups have been considered in the Ministry and approved with order of the MEF. These approved norms have been communicated as 'direction' under Section 17 (3) of the PCA Act for needful by the CPCSEA.

The Report has already been circulated to all the members of CPCSEA for adoption. After its adoption, the guidelines as finalized in the report will be communicated to all concerned. A decision in this regard may be taken by CPCSEA.

Agenda Item No.7 : Adoption of Good Regulatory Practices issued by the Ministry - Authorization to Chairperson, CPCSEA to issue guidelines in this regard.

Ministry of Environment & Forests has issued Operational Guidelines for Observance of Good Practices in Environmental Regulation. In accordance to this, the Operational Guidelines specific to CPCSEA, being one of the regulatory authority, have also been formulated. A copy of these Guidelines has been sent to all members of CPCSEA. These guide lines may be adopted and then may be communicated to all concerned.

Agenda Item No. 8 : Hiring of vehicle by Member Secretary ,CPCSEA:

The Member Secretary, CPCSEA is frequently required to visit the office of the Chairperson CPCSEA/ Ministry at CGO complex for various official works apart from attending to the regular meetings with regards to works related to CPCSEA and its sub-committees. Accordingly, the Chairperson, CPCSEA has approved hiring of vehicle by Member Secretary up to a maximum of 15 days per month with a ceiling of Rs.9000/- per month. The same is put up for ratification. It is also requested that in view of the multifaceted activities in CPCSEA (regular discussion & coordination with ministries like M/o Agriculture, M/o Health & Family Welfare, their subordinate organizations, MCI, VCI, PCI, DGFT, DCGI etc) the limit of hiring of vehicle may be extended from existing 15 days (Rs.9000/-) per month to 20 days (Rs.12000/-) per month. This is put up for approval of the committee.

